表 2.7.3.6-66. ベースラインで副腎皮質ステロイドを投与しており，投与 8 週時に Mayo スコアにより改善例となり，かつ投与 52 週時に副腎皮質ステロイドを 90 日間以上離脱できた被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Week 8 Responders with Steroid Usage at Baseline and Steroid Free at Least 90 Days at Week 52 (Week 44 of Maintenance Study)	(N=11)	(N=13)	(N=103)	(N=109)
Yes, n (%)	7 (63.6)	9 (69.2)	56 (54.4)	81 (74.3)
No, n (%)	4 (36.4)	4 (30.8)	47 (45.6)	28 (25.7)
Risk Difference[A]		5.6		19.9
Adjusted Risk Difference[A,B]		0.9		19.9
95% Confidence Interval[B]		(-39.8, 41.6)		(6.8, 32.9)
P-Value[B]		0.966		0.003**
Induction Treatment Regimen (Higher Dosing Regimen) & Week 8 Remission Status (Yes)	(N=4)	(N=5)	(N=22)	(N=21)
Yes, n (%)	2 (50.0)	3 (60.0)	10 (45.5)	17 (81.0)
No, n (%)	2 (50.0)	2 (40.0)	12 (54.5)	4 (19.0)
Risk Difference[A]		10.0		35.5
95% Confidence Interval[C]		(-55.2, 75.2)		(8.8, 62.2)
P-Value[D]		1.000		0.016*
Induction Treatment Regimen (Higher Dosing Regimen) & Week 8 Remission Status (No)	(N=3)	(N=5)	(N=44)	(N=45)
Yes, n (%)	2 (66.7)	5 (100)	24 (54.5)	35 (77.8)
No, n (%)	1 (33.3)	0	20 (45.5)	10 (22.2)
Risk Difference[A]		33.3		23.2
95% Confidence Interval[C]		(-20.0, 86.7)		(4.2, 42.3)
P-Value[D]		0.375		0.020*

表 2.7.3.6-66. ベースラインで副腎皮質ステロイドを投与しており，投与 8 週時に Mayo スコアにより改善例となり，かつ投与 52 週時に副腎皮質ステロイドを 90 日間以上離脱できた被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Induction Treatment Regimen (Standard Dosing Regimen) & Week 8 Remission Status (Yes)	(N=2)	(N=3)	(N=10)	(N=15)
Yes, n (%)	2 (100)	1 (33.3)	8 (80.0)	9 (60.0)
No, n (%)	0	2 (66.7)	2 (20.0)	6 (40.0)
Risk Difference[A]		-66.7		-20.0
95% Confidence Interval[C]		(-100.0,-13.3)		(-55.1, 15.1)
P-Value[D]		0.400		0.402
Induction Treatment Regimen (Standard Dosing Regimen) & Week 8 Remission Status (No)	(N=2)	(N=0)	(N=27)	(N=28)
Yes, n (%)	1 (50.0)	0	14 (51.9)	20 (71.4)
No, n (%)	1 (50.0)	0	13 (48.1)	8 (28.6)
Risk Difference[A]		0		19.6
95% Confidence Interval[C]		NA		(-5.6, 44.8)
P-Value[D]		NA		0.135

[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen and week 8 remission status.
[C]: 95% confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[D]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count < 5).
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__2.2_J

表 2.7.3.6-67. ベースラインで副腎皮質ステロイドを投与しており，投与 8 週時に Mayo スコアにより改善例となり，かつ投与 52 週時に副腎皮質ステロイドを 90 日間以上離脱でき，更に Mayo スコアにより寛解を達成した被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Week 8 Responders with Steroid Usage at Baseline and Steroid Free at Least 90 Days and in Clinical Remission at Week 52 (Week 44 of Maintenance Study)	(N=11)	(N=13)	(N=103)	(N=109)
Yes, n (%)	4 (36.4)	6 (46.2)	29 (28.2)	44 (40.4)
No, n (%)	7 (63.6)	7 (53.8)	74 (71.8)	65 (59.6)
Risk Difference[A]		9.8		12.2
Adjusted Risk Difference[A,B]		12.4		11.4
95% Confidence Interval[B]		(-31.6, 56.5)		(-1.3, 24.1)
P-Value[B]		0.580		0.079+
Induction Treatment Regimen (Higher Dosing Regimen) & Week 8 Remission Status (Yes)	(N=4)	(N=5)	(N=22)	(N=21)
Yes, n (%)	1 (25.0)	2 (40.0)	5 (22.7)	12 (57.1)
No, n (%)	3 (75.0)	3 (60.0)	17 (77.3)	9 (42.9)
Risk Difference[A]		15.0		34.4
95% Confidence Interval[C]		(-45.4, 75.4)		(6.9, 61.9)
P-Value[D]		1.000		0.021*
Induction Treatment Regimen (Higher Dosing Regimen) & Week 8 Remission Status (No)	(N=3)	(N=5)	(N=44)	(N=45)
Yes, n (%)	0	3 (60.0)	13 (29.5)	14 (31.1)
No, n (%)	3 (100)	2 (40.0)	31 (70.5)	31 (68.9)
Risk Difference[A]		60.0		1.6
95% Confidence Interval[C]		(17.1,100.0)		(-17.5, 20.7)
P-Value[D]		0.196		0.872

表 2.7.3.6-67. ベースラインで副腎皮質ステロイドを投与しており，投与 8 週時に Mayo スコアにより改善例となり，かつ投与 52 週時に副腎皮質ステロイドを 90 日間以上離脱でき，更に Mayo スコアにより寛解を達成した被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Induction Treatment Regimen (Standard Dosing Regimen) & Week 8 Remission Status (Yes)	(N=2)	(N=3)	(N=10)	(N=15)
Yes, n (%)	2 (100)	1 (33.3)	7 (70.0)	7 (46.7)
No, n (%)	0	2 (66.7)	3 (30.0)	8 (53.3)
Risk Difference[A]		-66.7		-23.3
95% Confidence Interval[C]		(-100.0,-13.3)		(-61.3, 14.7)
P-Value[D]		0.400		0.414
Induction Treatment Regimen (Standard Dosing Regimen) & Week 8 Remission Status (No)	(N=2)	(N=0)	(N=27)	(N=28)
Yes, n (%)	1 (50.0)	0	4 (14.8)	11 (39.3)
No, n (%)	1 (50.0)	0	23 (85.2)	17 (60.7)
Risk Difference[A]		0		24.5
95% Confidence Interval[C]		NA		(2.0, 47.0)
P-Value[D]		NA		0.042*

表 2.7.3.6-67. ベースラインで副腎皮質ステロイドを投与しており，投与 8 週時に Mayo スコアにより改善例となり，かつ投与 52 週時に副腎皮質ステロイドを 90 日間以上離脱でき，更に Mayo スコアにより寛解を達成した被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising endoscopy subscore provided by the central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen and week 8 remission status.
[C]: 95% confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[D]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count < 5).
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__2.3_J

表 2.7.3.6-68. 投与 8 週時，投与 52 週時にいずれも Mayo スコアにより寛解例となった被験者の割合（NRI）（維持療法試験，ITT-RM 集団，M14-033 日本サブ試験）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Week 8 Remitters with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=8)	(N=10)	(N=45)	(N=52)
Yes, n (%)	5 (62.5)	5 (50.0)	20 (44.4)	29 (55.8)
No, n (%)	3 (37.5)	5 (50.0)	25 (55.6)	23 (44.2)
Risk Difference[A]		-12.5		11.3
Adjusted Risk Difference[A,B]		-14.1		10.4
95% Confidence Interval[B]		(-64.7, 36.6)		(-9.8, 30.6)
P-Value[B]		0.586		0.312
Induction Treatment Regimen (Higher Dosing Regimen)	(N=6)	(N=5)	(N=32)	(N=32)
Yes, n (%)	3 (50.0)	3 (60.0)	11 (34.4)	19 (59.4)
No, n (%)	3 (50.0)	2 (40.0)	21 (65.6)	13 (40.6)
Risk Difference[A]		10.0		25.0
95% Confidence Interval[C]		(-48.7, 68.7)		(1.3, 48.7)
P-Value[D]		1.000		0.045*
Induction Treatment Regimen (Standard Dosing Regimen)	(N=2)	(N=5)	(N=13)	(N=20)
Yes, n (%)	2 (100)	2 (40.0)	9 (69.2)	10 (50.0)
No, n (%)	0	3 (60.0)	4 (30.8)	10 (50.0)
Risk Difference[A]		-60.0		-19.2
95% Confidence Interval[C]		(-100.0,-17.1)		(-52.5, 14.1)
P-Value[D]		0.429		0.275

表 2.7.3.6-68. 投与 8 週時，投与 52 週時にいずれも Mayo スコアにより寛解例となった被験者の割合（NRI）（維持療法試験，ITT-RM 集団，M14-033 日本サブ試験）（続き）

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Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising endoscopy subscore provided by the
      central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and
     P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen.
[C]: 95% confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[D]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count < 5).
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.
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Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__2.4_J

表 2.7.3.6-69. 投与 8 週時に Mayo スコアにより寛解例となり，かつ投与 52 週時に内視鏡検査により改善（内視鏡所見サブスコアが 0 又は 1）が認められた被験者の割合（NRI）（維持療法試験，ITT-RM 集団，M14-033 日本サブ試験）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Week 8 Remitters with Endoscopic Improvement at Week 52 (Week 44 of Maintenance Study)	(N=8)	(N=10)	(N=45)	(N=52)
Yes, n (%)	6 (75.0)	5 (50.0)	25 (55.6)	32 (61.5)
No, n (%)	2 (25.0)	5 (50.0)	20 (44.4)	20 (38.5)
Risk Difference[A]		-25.0		6.0
Adjusted Risk Difference[A,B]		-25.0		5.3
95% Confidence Interval[B]		(-74.5, 24.5)		(-14.6, 25.2)
P-Value[B]		0.322		0.600
Induction Treatment Regimen (Higher Dosing Regimen)	(N=6)	(N=5)	(N=32)	(N=32)
Yes, n (%)	4 (66.7)	3 (60.0)	15 (46.9)	21 (65.6)
No, n (%)	2 (33.3)	2 (40.0)	17 (53.1)	11 (34.4)
Risk Difference[A]		-6.7		18.8
95% Confidence Interval[C]		(-63.8, 50.5)		(-5.1, 42.6)
P-Value[D]		1.000		0.131
Induction Treatment Regimen (Standard Dosing Regimen)	(N=2)	(N=5)	(N=13)	(N=20)
Yes, n (%)	2 (100)	2 (40.0)	10 (76.9)	11 (55.0)
No, n (%)	0	3 (60.0)	3 (23.1)	9 (45.0)
Risk Difference[A]		-60.0		-21.9
95% Confidence Interval[C]		(-100.0,-17.1)		(-53.5, 9.7)
P-Value[D]		0.429		0.278

表 2.7.3.6-69.　投与 8 週時に Mayo スコアにより寛解例となり，かつ投与 52 週時に内視鏡検査により改善（内視鏡所見サブスコアが 0 又は 1）が認められた被験者の割合（NRI）（維持療法試験，ITT-RM 集団，M14-033 日本サブ試験）（続き）

Note: Endoscopic improvement is defined as endoscopy subscore of 0 or 1.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen.
[C]: 95% confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[D]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count < 5).

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__2.5_J

表 2.7.3.6-70. ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 8 週時に Mayo スコアにより寛解例となり，かつ投与 52 週時に副腎皮質ステロイドを 90 日間以上離脱できた被験者の割合（NRI）（維持療法試験，ITT-RM 集団，M14-033 日本サブ試験）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Week 8 Remitters with Steroid Usage at Baseline and Steroid Free at Least 90 Days at Week 52 (Week 44 of Maintenance Study)	(N=6)	(N=8)	(N=32)	(N=36)
Yes, n (%)	4 (66.7)	4 (50.0)	18 (56.3)	26 (72.2)
No, n (%)	2 (33.3)	4 (50.0)	14 (43.8)	10 (27.8)
Risk Difference[A]		-16.7		16.0
Adjusted Risk Difference[A,B]		-16.9		15.6
95% Confidence Interval[B]		(-73.5, 39.7)		(-7.6, 38.8)
P-Value[B]		0.559		0.187
Induction Treatment Regimen (Higher Dosing Regimen)	(N=4)	(N=5)	(N=22)	(N=21)
Yes, n (%)	2 (50.0)	3 (60.0)	10 (45.5)	17 (81.0)
No, n (%)	2 (50.0)	2 (40.0)	12 (54.5)	4 (19.0)
Risk Difference[A]		10.0		35.5
95% Confidence Interval[C]		(-55.2, 75.2)		(8.8, 62.2)
P-Value[D]		1.000		0.016*
Induction Treatment Regimen (Standard Dosing Regimen)	(N=2)	(N=3)	(N=10)	(N=15)
Yes, n (%)	2 (100)	1 (33.3)	8 (80.0)	9 (60.0)
No, n (%)	0	2 (66.7)	2 (20.0)	6 (40.0)
Risk Difference[A]		-66.7		-20.0
95% Confidence Interval[C]		(-100.0,-13.3)		(-55.1, 15.1)
P-Value[D]		0.400		0.402

表 2.7.3.6-70.　ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 8 週時に Mayo スコアにより寛解例となり，かつ投与 52 週時に副腎皮質ステロイドを 90 日間以上離脱できた被験者の割合（NRI）（維持療法試験，ITT-RM 集団，M14-033 日本サブ試験）（続き）

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[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and
     P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen.
[C]: 95% confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[D]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count < 5).
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.
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Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__2.6_J

表 2.7.3.6-71. ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 8 週時に Mayo スコアにより寛解例となり，かつ投与 52 週時に副腎皮質ステロイドを 90 日間以上離脱でき，更に Mayo スコアにより寛解を達成した被験者の割合（NRI）（維持療法試験，ITT-RM 集団，M14-033 日本サブ試験）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Week 8 Remitters with Steroid Usage at Baseline and Steroid Free at Least 90 Days and in Clinical Remission at Week 52 (Week 44 of Maintenance Study)	(N=6)	(N=8)	(N=32)	(N=36)
Yes, n (%)	3 (50.0)	3 (37.5)	12 (37.5)	19 (52.8)
No, n (%)	3 (50.0)	5 (62.5)	20 (62.5)	17 (47.2)
Risk Difference[A]		-12.5		15.3
Adjusted Risk Difference[A,B]		-13.6		13.7
95% Confidence Interval[B]		(-68.4, 41.2)		(-10.2, 37.6)
P-Value[B]		0.626		0.260
Induction Treatment Regimen (Higher Dosing Regimen)	(N=4)	(N=5)	(N=22)	(N=21)
Yes, n (%)	1 (25.0)	2 (40.0)	5 (22.7)	12 (57.1)
No, n (%)	3 (75.0)	3 (60.0)	17 (77.3)	9 (42.9)
Risk Difference[A]		15.0		34.4
95% Confidence Interval[C]		(-45.4, 75.4)		(6.9, 61.9)
P-Value[D]		1.000		0.021*
Induction Treatment Regimen (Standard Dosing Regimen)	(N=2)	(N=3)	(N=10)	(N=15)
Yes, n (%)	2 (100)	1 (33.3)	7 (70.0)	7 (46.7)
No, n (%)	0	2 (66.7)	3 (30.0)	8 (53.3)
Risk Difference[A]		-66.7		-23.3
95% Confidence Interval[C]		(-100.0,-13.3)		(-61.3, 14.7)
P-Value[D]		0.400		0.414

表 2.7.3.6-71. ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 8 週時に Mayo スコアにより寛解例となり，かつ投与 52 週時に副腎皮質ステロイドを 90 日間以上離脱でき，更に Mayo スコアにより寛解を達成した被験者の割合（NRI）（維持療法試験，ITT-RM 集団，M14-033 日本サブ試験）（続き）

Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising endoscopy subscore provided by the central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen.
[C]: 95% confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[D]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count < 5).
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__2.7_J

表 2.7.3.6-72. 投与 8 週時に Mayo スコアにより改善例となり，かつ投与 52 週時に IBDQ の改善（ベースラインと比較して IBDQ スコアの 16 以上の増加）が認められた被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Week 8 Responders with IBDQ Response at Week 52 (Week 44 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	12 (66.7)	14 (60.9)	102 (62.6)	115 (65.7)
No, n (%)	6 (33.3)	9 (39.1)	61 (37.4)	60 (34.3)
Risk Difference[A]		-5.8		3.1
Adjusted Risk Difference[A,B]		-4.8		3.4
95% Confidence Interval[B]		(-37.1, 27.4)		(-6.8, 13.6)
P-Value[B]		0.769		0.513
Induction Treatment Regimen (Higher Dosing Regimen) & Week 8 Remission Status (Yes)	(N=6)	(N=5)	(N=32)	(N=32)
Yes, n (%)	4 (66.7)	3 (60.0)	17 (53.1)	24 (75.0)
No, n (%)	2 (33.3)	2 (40.0)	15 (46.9)	8 (25.0)
Risk Difference[A]		-6.7		21.9
95% Confidence Interval[C]		(-63.8, 50.5)		(-1.0, 44.8)
P-Value[D]		1.000		0.068+
Induction Treatment Regimen (Higher Dosing Regimen) & Week 8 Remission Status (No)	(N=7)	(N=12)	(N=74)	(N=82)
Yes, n (%)	4 (57.1)	7 (58.3)	40 (54.1)	50 (61.0)
No, n (%)	3 (42.9)	5 (41.7)	34 (45.9)	32 (39.0)
Risk Difference[A]		1.2		6.9
95% Confidence Interval[C]		(-44.9, 47.3)		(-8.6, 22.4)
P-Value[D]		1.000		0.382

表 2.7.3.6-72. 投与 8 週時に Mayo スコアにより改善例となり，かつ投与 52 週時に IBDQ の改善（ベースラインと比較して IBDQ スコアの 16 以上の増加）が認められた被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Induction Treatment Regimen (Standard Dosing Regimen) & Week 8 Remission Status (Yes)	(N=2)	(N=5)	(N=13)	(N=20)
Yes, n (%)	2 (100)	3 (60.0)	12 (92.3)	11 (55.0)
No, n (%)	0	2 (40.0)	1 (7.7)	9 (45.0)
Risk Difference[A]		-40.0		-37.3
95% Confidence Interval[C]		(-82.9, 2.9)		(-63.5,-11.1)
P-Value[D]		1.000		0.050*
Induction Treatment Regimen (Standard Dosing Regimen) & Week 8 Remission Status (No)	(N=3)	(N=1)	(N=44)	(N=41)
Yes, n (%)	2 (66.7)	1 (100)	33 (75.0)	30 (73.2)
No, n (%)	1 (33.3)	0	11 (25.0)	11 (26.8)
Risk Difference[A]		33.3		-1.8
95% Confidence Interval[C]		(-20.0, 86.7)		(-20.5, 16.8)
P-Value[D]		1.000		0.847

Note: IBDQ response is defined as increase of IBDQ >= 16 from baseline.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen and week 8 remission status.
[C]: 95% confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[D]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count < 5).
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__2.8_J

表 2.7.3.6-73. 投与 8 週時に Mayo スコアにより非改善例であった被験者のうち，投与 52 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（維持療法試験，ITT-NRP 集団，M14-033 日本サブ試験）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Week 8 Non-Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=25)	(N=23)	(N=182)	(N=175)
Yes, n (%)	3 (12.0)	4 (17.4)	22 (12.1)	28 (16.0)
No, n (%)	22 (88.0)	19 (82.6)	160 (87.9)	147 (84.0)
Risk Difference[A]		5.4		3.9
Adjusted Risk Difference[A,B]		4.8		3.9
95% Confidence Interval[B]		(-15.6, 25.2)		(-3.3, 11.1)
P-Value[B]		0.644		0.292
Induction Treatment Regimen (Higher Dosing Regimen)	(N=15)	(N=12)	(N=105)	(N=98)
Yes, n (%)	1 (6.7)	2 (16.7)	11 (10.5)	16 (16.3)
No, n (%)	14 (93.3)	10 (83.3)	94 (89.5)	82 (83.7)
Risk Difference[A]		10.0		5.9
95% Confidence Interval[C]		(-14.6, 34.6)		(-3.5, 15.2)
P-Value[D]		0.569		0.220
Induction Treatment Regimen (Standard Dosing Regimen)	(N=10)	(N=11)	(N=77)	(N=77)
Yes, n (%)	2 (20.0)	2 (18.2)	11 (14.3)	12 (15.6)
No, n (%)	8 (80.0)	9 (81.8)	66 (85.7)	65 (84.4)
Risk Difference[A]		-1.8		1.3
95% Confidence Interval[C]		(-35.5, 31.9)		(-10.0, 12.6)
P-Value[D]		1.000		0.821

表 2.7.3.6-73. 投与 8 週時に Mayo スコアにより非改善例であった被験者のうち，投与 52 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（維持療法試験，ITT-NRP 集団，M14-033 日本サブ試験）（続き）

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Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising endoscopy subscore provided by the
      central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and
     P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen.
[C]: 95% confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[D]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count < 5).
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Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__2.9_J

表 2.7.3.6-74. 投与 8 週時に Mayo スコアにより非寛解例であった被験者のうち，投与 52 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（維持療法試験，ITT-NRM*集団，M14-033 日本サブ試験）* ITT 集団のうち 8 週時非寛解 Non-Remitters

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Week 8 Non-Remitters with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=35)	(N=36)	(N=300)	(N=298)
Yes, n (%)	5 (14.3)	11 (30.6)	51 (17.0)	71 (23.8)
No, n (%)	30 (85.7)	25 (69.4)	249 (83.0)	227 (76.2)
Risk Difference[A]		16.3		6.8
Adjusted Risk Difference[A,B]		13.3		6.5
95% Confidence Interval[B]		(-6.1, 32.7)		(0.1, 12.8)
P-Value[B]		0.180		0.046*
Induction Treatment Regimen (Higher Dosing Regimen) & Week 8 Response Status (Yes)	(N=7)	(N=12)	(N=74)	(N=82)
Yes, n (%)	1 (14.3)	7 (58.3)	21 (28.4)	27 (32.9)
No, n (%)	6 (85.7)	5 (41.7)	53 (71.6)	55 (67.1)
Risk Difference[A]		44.0		4.5
95% Confidence Interval[C]		(6.0, 82.1)		(-9.9, 19.0)
P-Value[D]		0.147		0.539
Induction Treatment Regimen (Higher Dosing Regimen) & Week 8 Response Status (No)	(N=15)	(N=12)	(N=105)	(N=98)
Yes, n (%)	1 (6.7)	2 (16.7)	11 (10.5)	16 (16.3)
No, n (%)	14 (93.3)	10 (83.3)	94 (89.5)	82 (83.7)
Risk Difference[A]		10.0		5.9
95% Confidence Interval[C]		(-14.6, 34.6)		(-3.5, 15.2)
P-Value[D]		0.569		0.220

表 2.7.3.6-74. 投与 8 週時に Mayo スコアにより非寛解例であった被験者のうち，投与 52 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（維持療法試験，ITT-NRM*集団，M14-033 日本サブ試験）* ITT 集団のうち 8 週時非寛解 Non-Remitters（続き）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Induction Treatment Regimen (Standard Dosing Regimen) & Week 8 Response Status (Yes)	(N=3)	(N=1)	(N=44)	(N=41)
Yes, n (%)	1 (33.3)	0	8 (18.2)	16 (39.0)
No, n (%)	2 (66.7)	1 (100)	36 (81.8)	25 (61.0)
Risk Difference[A]		-33.3		20.8
95% Confidence Interval[C]		(-86.7, 20.0)		(2.1, 39.6)
P-Value[D]		1.000		0.033*
Induction Treatment Regimen (Standard Dosing Regimen) & Week 8 Response Status (No)	(N=10)	(N=11)	(N=77)	(N=77)
Yes, n (%)	2 (20.0)	2 (18.2)	11 (14.3)	12 (15.6)
No, n (%)	8 (80.0)	9 (81.8)	66 (85.7)	65 (84.4)
Risk Difference[A]		-1.8		1.3
95% Confidence Interval[C]		(-35.5, 31.9)		(-10.0, 12.6)
P-Value[D]		1.000		0.821

Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising endoscopy subscore provided by the central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen and week 8 response status.
[C]: 95% confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[D]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count < 5).
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__2.10_J

表 2.7.3.6-75. 投与 8 週時に Mayo スコアにより改善例となり，かつ投与 52 週時に内視鏡所見サブスコアが 0 ポイントになった被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Week 8 Responders with Endoscopic Subscore of 0 at Week 52 (Week 44 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	4 (22.2)	8 (34.8)	44 (27.0)	62 (35.4)
No, n (%)	14 (77.8)	15 (65.2)	119 (73.0)	113 (64.6)
Risk Difference[A]		12.6		8.4
Adjusted Risk Difference[A,B]		9.7		8.0
95% Confidence Interval[B]		(-20.3, 39.8)		(-1.8, 17.9)
P-Value[B]		0.526		0.109
Induction Treatment Regimen (Higher Dosing Regimen) & Week 8 Remission Status (Yes)	(N=6)	(N=5)	(N=32)	(N=32)
Yes, n (%)	1 (16.7)	1 (20.0)	11 (34.4)	15 (46.9)
No, n (%)	5 (83.3)	4 (80.0)	21 (65.6)	17 (53.1)
Risk Difference[A]		3.3		12.5
95% Confidence Interval[C]		(-42.7, 49.4)		(-11.4, 36.4)
P-Value[D]		1.000		0.309
Induction Treatment Regimen (Higher Dosing Regimen) & Week 8 Remission Status (No)	(N=7)	(N=12)	(N=74)	(N=82)
Yes, n (%)	1 (14.3)	5 (41.7)	15 (20.3)	24 (29.3)
No, n (%)	6 (85.7)	7 (58.3)	59 (79.7)	58 (70.7)
Risk Difference[A]		27.4		9.0
95% Confidence Interval[C]		(-10.7, 65.5)		(-4.5, 22.4)
P-Value[D]		0.333		0.195

表 2.7.3.6-75. 投与 8 週時に Mayo スコアにより改善例となり，かつ投与 52 週時に内視鏡所見サブスコアが 0 ポイントになった被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Induction Treatment Regimen (Standard Dosing Regimen) & Week 8 Remission Status (Yes)	(N=2)	(N=5)	(N=13)	(N=20)
Yes, n (%)	1 (50.0)	2 (40.0)	8 (61.5)	8 (40.0)
No, n (%)	1 (50.0)	3 (60.0)	5 (38.5)	12 (60.0)
Risk Difference[A]		-10.0		-21.5
95% Confidence Interval[C]		(-91.5, 71.5)		(-55.6, 12.5)
P-Value[D]		1.000		0.226
Induction Treatment Regimen (Standard Dosing Regimen) & Week 8 Remission Status (No)	(N=3)	(N=1)	(N=44)	(N=41)
Yes, n (%)	1 (33.3)	0	10 (22.7)	15 (36.6)
No, n (%)	2 (66.7)	1 (100)	34 (77.3)	26 (63.4)
Risk Difference[A]		-33.3		13.9
95% Confidence Interval[C]		(-86.7, 20.0)		(-5.4, 33.1)
P-Value[D]		1.000		0.161

[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen and week 8 remission status.
[C]: 95% confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[D]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count < 5).

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__2.11_J

表 2.7.3.6-76. 投与 8 週時に Mayo スコアにより寛解例となり，かつ投与 52 週時に内視鏡所見サブスコアが 0 ポイントになった被験者の割合（NRI）（維持療法試験，ITT-RM 集団，M14-033 日本サブ試験）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Week 8 Remitters with Endoscopic Subscore of 0 at Week 52 (Week 44 of Maintenance Study)	(N=8)	(N=10)	(N=45)	(N=52)
Yes, n (%)	2 (25.0)	3 (30.0)	19 (42.2)	23 (44.2)
No, n (%)	6 (75.0)	7 (70.0)	26 (57.8)	29 (55.8)
Risk Difference[A]		5.0		2.0
Adjusted Risk Difference[A,B]		-1.3		1.3
95% Confidence Interval[B]		(-44.8, 42.3)		(-18.8, 21.3)
P-Value[B]		0.955		0.901
Induction Treatment Regimen (Higher Dosing Regimen)	(N=6)	(N=5)	(N=32)	(N=32)
Yes, n (%)	1 (16.7)	1 (20.0)	11 (34.4)	15 (46.9)
No, n (%)	5 (83.3)	4 (80.0)	21 (65.6)	17 (53.1)
Risk Difference[A]		3.3		12.5
95% Confidence Interval[C]		(-42.7, 49.4)		(-11.4, 36.4)
P-Value[D]		1.000		0.309
Induction Treatment Regimen (Standard Dosing Regimen)	(N=2)	(N=5)	(N=13)	(N=20)
Yes, n (%)	1 (50.0)	2 (40.0)	8 (61.5)	8 (40.0)
No, n (%)	1 (50.0)	3 (60.0)	5 (38.5)	12 (60.0)
Risk Difference[A]		-10.0		-21.5
95% Confidence Interval[C]		(-91.5, 71.5)		(-55.6, 12.5)
P-Value[D]		1.000		0.226

表 2.7.3.6-76. 投与 8 週時に Mayo スコアにより寛解例となり，かつ投与 52 週時に内視鏡所見サブスコアが 0 ポイントになった被験者の割合（NRI）（維持療法試験，ITT-RM 集団，M14-033 日本サブ試験）（続き）

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[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and
     P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen.
[C]: 95% confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[D]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count < 5).
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Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__2.12_J

表 2.7.3.6-77. 投与 8 週時に Mayo スコアにより改善例となり，かつ投与 52 週時に IBDQ 腸症状ドメインの改善（ベースラインと比較して IBDQ 腸症状ドメインスコアの 6 以上の増加）が認められた被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Week 8 Responders Achieving Response in IBDQ Bowel Symptom Domain at Week 52 (Week 44 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	12 (66.7)	19 (82.6)	102 (62.6)	125 (71.4)
No, n (%)	6 (33.3)	4 (17.4)	61 (37.4)	50 (28.6)
Risk Difference[A]		15.9		8.9
Adjusted Risk Difference[A,B]		16.8		9.1
95% Confidence Interval[B]		(-12.1, 45.8)		(-0.9, 19.1)
P-Value[B]		0.255		0.076+
Induction Treatment Regimen (Higher Dosing Regimen) & Week 8 Remission Status (Yes)	(N=6)	(N=5)	(N=32)	(N=32)
Yes, n (%)	4 (66.7)	4 (80.0)	17 (53.1)	26 (81.3)
No, n (%)	2 (33.3)	1 (20.0)	15 (46.9)	6 (18.8)
Risk Difference[A]		13.3		28.1
95% Confidence Interval[C]		(-38.2, 64.8)		(6.2, 50.1)
P-Value[D]		1.000		0.017*
Induction Treatment Regimen (Higher Dosing Regimen) & Week 8 Remission Status (No)	(N=7)	(N=12)	(N=74)	(N=82)
Yes, n (%)	4 (57.1)	11 (91.7)	41 (55.4)	55 (67.1)
No, n (%)	3 (42.9)	1 (8.3)	33 (44.6)	27 (32.9)
Risk Difference[A]		34.5		11.7
95% Confidence Interval[C]		(-5.3, 74.4)		(-3.6, 26.9)
P-Value[D]		0.117		0.135

表 2.7.3.6-77. 投与 8 週時に Mayo スコアにより改善例となり，かつ投与 52 週時に IBDQ 腸症状ドメインの改善（ベースラインと比較して IBDQ 腸症状ドメインスコアの 6 以上の増加）が認められた被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Induction Treatment Regimen (Standard Dosing Regimen) & Week 8 Remission Status (Yes)	(N=2)	(N=5)	(N=13)	(N=20)
Yes, n (%)	2 (100)	3 (60.0)	12 (92.3)	12 (60.0)
No, n (%)	0	2 (40.0)	1 (7.7)	8 (40.0)
Risk Difference[A]		-40.0		-32.3
95% Confidence Interval[C]		(-82.9, 2.9)		(-58.2, -6.4)
P-Value[D]		1.000		0.056+
Induction Treatment Regimen (Standard Dosing Regimen) & Week 8 Remission Status (No)	(N=3)	(N=1)	(N=44)	(N=41)
Yes, n (%)	2 (66.7)	1 (100)	32 (72.7)	32 (78.0)
No, n (%)	1 (33.3)	0	12 (27.3)	9 (22.0)
Risk Difference[A]		33.3		5.3
95% Confidence Interval[C]		(-20.0, 86.7)		(-12.9, 23.6)
P-Value[D]		1.000		0.570

表 2.7.3.6-77. 投与 8 週時に Mayo スコアにより改善例となり，かつ投与 52 週時に IBDQ 腸症状ドメインの改善（ベースラインと比較して IBDQ 腸症状ドメインスコアの 6 以上の増加）が認められた被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Note: Response in IBDQ bowel symptom domain is defined as increase of IBDQ bowel symptom domain score >= 6 from baseline.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen and week 8 remission status.
[C]: 95% confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[D]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count < 5).
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__2.13_J

表 2.7.3.6-78. 投与 8 週時に Mayo スコアにより改善例となり，かつ投与 52 週時に IBDQ 疲労尺度の改善（ベースラインと比較して IBDQ 疲労尺度スコアの 1 以上の増加）が認められた被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Week 8 Responders Achieving Response in IBDQ Fatigue Item at Week 52 (Week 44 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	12 (66.7)	11 (47.8)	90 (55.2)	104 (59.4)
No, n (%)	6 (33.3)	12 (52.2)	73 (44.8)	71 (40.6)
Risk Difference[A]		-18.8		4.2
Adjusted Risk Difference[A,B]		-17.7		4.2
95% Confidence Interval[B]		(-50.9, 15.6)		(-6.4, 14.8)
P-Value[B]		0.297		0.440
Induction Treatment Regimen (Higher Dosing Regimen) & Week 8 Remission Status (Yes)	(N=6)	(N=5)	(N=32)	(N=32)
Yes, n (%)	4 (66.7)	2 (40.0)	15 (46.9)	21 (65.6)
No, n (%)	2 (33.3)	3 (60.0)	17 (53.1)	11 (34.4)
Risk Difference[A]		-26.7		18.8
95% Confidence Interval[C]		(-83.8, 30.5)		(-5.1, 42.6)
P-Value[D]		0.567		0.131
Induction Treatment Regimen (Higher Dosing Regimen) & Week 8 Remission Status (No)	(N=7)	(N=12)	(N=74)	(N=82)
Yes, n (%)	4 (57.1)	6 (50.0)	38 (51.4)	47 (57.3)
No, n (%)	3 (42.9)	6 (50.0)	36 (48.6)	35 (42.7)
Risk Difference[A]		-7.1		6.0
95% Confidence Interval[C]		(-53.4, 39.2)		(-9.7, 21.6)
P-Value[D]		1.000		0.455

表 2.7.3.6-78. 投与 8 週時に Mayo スコアにより改善例となり，かつ投与 52 週時に IBDQ 疲労尺度の改善（ベースラインと比較して IBDQ 疲労尺度スコアの 1 以上の増加）が認められた被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Induction Treatment Regimen (Standard Dosing Regimen) & Week 8 Remission Status (Yes)	(N=2)	(N=5)	(N=13)	(N=20)
Yes, n (%)	2 (100)	2 (40.0)	10 (76.9)	11 (55.0)
No, n (%)	0	3 (60.0)	3 (23.1)	9 (45.0)
Risk Difference[A]		-60.0		-21.9
95% Confidence Interval[C]		(-100.0,-17.1)		(-53.5, 9.7)
P-Value[D]		0.429		0.278
Induction Treatment Regimen (Standard Dosing Regimen) & Week 8 Remission Status (No)	(N=3)	(N=1)	(N=44)	(N=41)
Yes, n (%)	2 (66.7)	1 (100)	27 (61.4)	25 (61.0)
No, n (%)	1 (33.3)	0	17 (38.6)	16 (39.0)
Risk Difference[A]		33.3		-0.4
95% Confidence Interval[C]		(-20.0, 86.7)		(-21.1, 20.3)
P-Value[D]		1.000		0.971

Note: Response in IBDQ fatigue item is defined as increase of IBDQ fatigue item score >= 1 from baseline.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen and week 8 remission status.
[C]: 95% confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[D]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count < 5).

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__2.14_J

表 2.7.3.6-79. 投与 0 週時から投与 8 週時までの原因を問わない入院及び手術，又は UC に関連する入院及び手術の頻度（導入療法試験，ITT 集団，M14-033 主試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=340) n (%)	HIGHER INDUCTION DOSE (N=512) n (%)
HOSPITALIZATIONS		
ALL-CAUSE		
YES	16 (4.7)	18 (3.5)
NO	324 (95.3)	494 (96.5)
P-VALUE		0.385
UC-RELATED		
YES	13 (3.8)	15 (2.9)
NO	327 (96.2)	497 (97.1)
P-VALUE		0.474
SURGERIES		
ALL-CAUSE		
YES	3 (0.9)	3 (0.6)
NO	337 (99.1)	509 (99.4)
P-VALUE		0.612
UC-RELATED		
YES	1 (0.3)	3 (0.6)
NO	339 (99.7)	509 (99.4)
P-VALUE		0.542

表 2.7.3.6-79.　投与 0 週時から投与 8 週時までの原因を問わない入院及び手術，又は UC に関連する入院及び手術の頻度（導入療法試験，ITT 集団，M14-033 主試験）（続き）

NOTE: P-VALUE FOR COMPARISONS BETWEEN ADALIMUMAB HIGHER INDUCTION DOSE AND ADALIMUMAB STANDARD INDUCTION DOSE USING CHI-SQUARE TEST.

Cross reference: M14-033 Induction_Main study Final CSR Table 14.2__3.1

表 2.7.3.6-80. 投与 8 週時の Adapted Mayo スコア及び Mayo スコアのベースラインからの変化（OC）（導入療法試験，ITT 集団，M14-033 主試験）

PARAMETER / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP — CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON — (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
ADAPTED MAYO SCORE											
ADALIMUMAB STANDARD INDUCTION DOSE	297	6.42	4.24	-2.18	2.237	-8.0	-2.00	3.0			
ADALIMUMAB HIGHER INDUCTION DOSE	452	6.55	3.94	-2.61	2.202	-8.8	-2.40	4.8	-0.40	(-0.71, -0.09)	0.012*
MAYO SCORE											
ADALIMUMAB STANDARD INDUCTION DOSE	297	8.65	5.78	-2.87	2.784	-10.0	-2.80	3.0			
ADALIMUMAB HIGHER INDUCTION DOSE	452	8.82	5.33	-3.49	2.833	-11.8	-3.20	5.8	-0.59	(-1.00, -0.19)	0.004**

@ P-VALUE FOR TEST OF DIFFERENCE BETWEEN ADALIMUMAB HIGHER INDUCTION DOSE AND ADALIMUMAB STANDARD INDUCTION DOSE FOR CHANGE FROM BASELINE USING ANALYSIS OF COVARIANCE WITH TREATMENT, PREVIOUS INFLIXIMAB USE, BASELINE CORTICOSTEROID USE, AND BASELINE VALUE AS COVARIATE.
***, **, *, + STATISTICALLY SIGNIFICANT AT 0.001, 0.01, 0.05 AND 0.1 LEVEL, RESPECTIVELY.

Cross reference: M14-033 Induction_Main study Final CSR Table 14.2__3.2.1

表 2.7.3.6-81. 投与 8 週時に Adapted Mayo スコアにより寛解を達成した被験者の割合（NRI）（導入療法試験，ITT 集団，M14-033 主試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE	HIGHER INDUCTION DOSE
CLINICAL REMISSION PER ADAPTED MAYO SCORE AT WEEK 8	(N=340)	(N=512)
YES, n (%)	53 (15.6)	93 (18.2)
NO, n (%)	287 (84.4)	419 (81.8)
RISK DIFFERENCE[A]		2.6
ADJUSTED RISK DIFFERENCE[A,B]		2.8
95% CONFIDENCE INTERVAL[B]		(-2.4, 8.0)
P-VALUE[B]		0.286

CLINICAL REMISSION PER ADAPTED MAYO SCORE IS DEFINED AS AN ADAPTED MAYO SCORE <= 2, WITH STOOL FREQUENCY SUBSCORE <= 1, RBS OF 0, AND ENDOSCOPIC SUBSCORE <= 1.
[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: ADJUSTED RISK DIFFERENCE, 95% CONFIDENCE INTERVAL FOR THE DIFFERENCE IN THE PROPORTIONS BETWEEN THE TREATMENT GROUPS AND P-VALUE WERE CALCULATED USING COCHRAN-MANTEL-HAENSZEL (CMH) TEST ADJUSTED FOR PREVIOUS INFLIXIMAB USE AND BASELINE CORTICOSTEROID USE.

Cross reference: M14-033 Induction_Main study Final CSR Table 14.2__3.3.1

表 2.7.3.6-82. 投与 8 週時に Adapted Mayo スコアにより寛解（Mayo スコアが 2 以下で，かついずれのサブスコアも 1 を超えない）を達成した被験者の割合（NRI）（導入療法試験，ITT 集団，M14-033 主試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE	HIGHER INDUCTION DOSE
CLINICAL REMISSION DEFINED AS ADAPTED MAYO SCORE <= 2 WITH NO SUBSCORE > 1 AT WEEK 8	(N=340)	(N=512)
YES, n (%)	62 (18.2)	107 (20.9)
NO, n (%)	278 (81.8)	405 (79.1)
RISK DIFFERENCE[A]		2.7
ADJUSTED RISK DIFFERENCE[A,B]		2.9
95% CONFIDENCE INTERVAL[B]		(-2.5, 8.4)
P-VALUE[B]		0.294

[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: ADJUSTED RISK DIFFERENCE, 95% CONFIDENCE INTERVAL FOR THE DIFFERENCE IN THE PROPORTIONS BETWEEN THE TREATMENT GROUPS AND P-VALUE WERE CALCULATED USING COCHRAN-MANTEL-HAENSZEL (CMH) TEST ADJUSTED FOR PREVIOUS INFLIXIMAB USE AND BASELINE CORTICOSTEROID USE.

Cross reference: M14-033 Induction_Main study Final CSR Table 14.2__3.4.1

表 2.7.3.6-83. 評価時点ごとの PMS により寛解を達成した被験者の割合（NRI）（導入療法試験，ITT 集団，M14-033 主試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE	HIGHER INDUCTION DOSE
CLINICAL REMISSION PER PARTIAL MAYO SCORE AT WEEK 1	(N=340)	(N=512)
YES, n (%)	20 (5.9)	32 (6.3)
NO, n (%)	320 (94.1)	480 (93.8)
RISK DIFFERENCE[A]		0.4
ADJUSTED RISK DIFFERENCE[A,B]		0.4
95% CONFIDENCE INTERVAL[B]		(-2.9, 3.7)
P-VALUE[B]		0.821
CLINICAL REMISSION PER PARTIAL MAYO SCORE AT WEEK 2	(N=340)	(N=512)
YES, n (%)	50 (14.7)	73 (14.3)
NO, n (%)	290 (85.3)	439 (85.7)
RISK DIFFERENCE[A]		-0.4
ADJUSTED RISK DIFFERENCE[A,B]		-0.3
95% CONFIDENCE INTERVAL[B]		(-5.2, 4.5)
P-VALUE[B]		0.889

表 2.7.3.6-83. 評価時点ごとの PMS により寛解を達成した被験者の割合（NRI）（導入療法試験，ITT 集団，M14-033 主試験）（続き）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE	HIGHER INDUCTION DOSE
CLINICAL REMISSION PER PARTIAL MAYO SCORE AT WEEK 4	(N=340)	(N=512)
YES, n (%)	63 (18.5)	130 (25.4)
NO, n (%)	277 (81.5)	382 (74.6)
RISK DIFFERENCE[A]		6.9
ADJUSTED RISK DIFFERENCE[A,B]		6.9
95% CONFIDENCE INTERVAL[B]		(1.2, 12.7)
P-VALUE[B]		0.018*
CLINICAL REMISSION PER PARTIAL MAYO SCORE AT WEEK 8	(N=340)	(N=512)
YES, n (%)	85 (25.0)	148 (28.9)
NO, n (%)	255 (75.0)	364 (71.1)
RISK DIFFERENCE[A]		3.9
ADJUSTED RISK DIFFERENCE[A,B]		4.2
95% CONFIDENCE INTERVAL[B]		(-1.9, 10.3)
P-VALUE[B]		0.181

CLINICAL REMISSION PER PARTIAL MAYO SCORE IS DEFINED AS PARTIAL MAYO SCORE <= 2, WITH NO SUBSCORE > 1.
[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: ADJUSTED RISK DIFFERENCE, 95% CONFIDENCE INTERVAL FOR THE DIFFERENCE IN THE PROPORTIONS BETWEEN THE TREATMENT GROUPS AND P-VALUE WERE CALCULATED USING COCHRAN-MANTEL-HAENSZEL (CMH) TEST ADJUSTED FOR PREVIOUS INFLIXIMAB USE AND BASELINE CORTICOSTEROID USE.
***, **, *, + STATISTICALLY SIGNIFICANT AT 0.001, 0.01, 0.05 AND 0.1 LEVEL, RESPECTIVELY.

Cross reference: M14-033 Induction_Main study Final CSR Table 14.2__3.5.1

表 2.7.3.6-84. 評価時点ごとの PMS により改善を達成した被験者の割合（NRI）（導入療法試験，ITT 集団，M14-033 主試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE	HIGHER INDUCTION DOSE
CLINICAL RESPONSE PER PARTIAL MAYO SCORE AT WEEK 1	(N=340)	(N=512)
YES, n (%)	81 (23.8)	142 (27.7)
NO, n (%)	259 (76.2)	370 (72.3)
RISK DIFFERENCE[A]		3.9
ADJUSTED RISK DIFFERENCE[A,B]		3.8
95% CONFIDENCE INTERVAL[B]		(-2.3, 9.8)
P-VALUE[B]		0.222
CLINICAL RESPONSE PER PARTIAL MAYO SCORE AT WEEK 2	(N=340)	(N=512)
YES, n (%)	132 (38.8)	211 (41.2)
NO, n (%)	208 (61.2)	301 (58.8)
RISK DIFFERENCE[A]		2.4
ADJUSTED RISK DIFFERENCE[A,B]		2.4
95% CONFIDENCE INTERVAL[B]		(-4.3, 9.2)
P-VALUE[B]		0.476

表 2.7.3.6-84. 評価時点ごとの PMS により改善を達成した被験者の割合（NRI）（導入療法試験，ITT 集団，M14-033 主試験）（続き）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE	HIGHER INDUCTION DOSE
CLINICAL RESPONSE PER PARTIAL MAYO SCORE AT WEEK 4	(N=340)	(N=512)
YES, n (%)	158 (46.5)	275 (53.7)
NO, n (%)	182 (53.5)	237 (46.3)
RISK DIFFERENCE[A]		7.2
ADJUSTED RISK DIFFERENCE[A,B]		7.4
95% CONFIDENCE INTERVAL[B]		(0.6, 14.3)
P-VALUE[B]		0.034*
CLINICAL RESPONSE PER PARTIAL MAYO SCORE AT WEEK 8	(N=340)	(N=512)
YES, n (%)	162 (47.6)	275 (53.7)
NO, n (%)	178 (52.4)	237 (46.3)
RISK DIFFERENCE[A]		6.1
ADJUSTED RISK DIFFERENCE[A,B]		6.4
95% CONFIDENCE INTERVAL[B]		(-0.4, 13.2)
P-VALUE[B]		0.067+

表 2.7.3.6-84.　評価時点ごとの PMS により改善を達成した被験者の割合（NRI）（導入療法試験，ITT 集団，M14-033 主試験）（続き）

CLINICAL RESPONSE PER PARTIAL MAYO SCORE IS DEFINED AS A DECREASE IN PARTIAL MAYO SCORE >= 2 POINTS AND >= 30% FROM BASELINE, PLUS A DECREASE IN RBS >= 1 OR AN ABSOLUTE RBS <=1.
[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: ADJUSTED RISK DIFFERENCE, 95% CONFIDENCE INTERVAL FOR THE DIFFERENCE IN THE PROPORTIONS BETWEEN THE TREATMENT GROUPS AND P-VALUE WERE CALCULATED USING COCHRAN-MANTEL-HAENSZEL (CMH) TEST ADJUSTED FOR PREVIOUS INFLIXIMAB USE AND BASELINE CORTICOSTEROID USE.
***, **, *, + STATISTICALLY SIGNIFICANT AT 0.001, 0.01, 0.05 AND 0.1 LEVEL, RESPECTIVELY.

Cross reference: M14-033 Induction_Main study Final CSR Table 14.2__3.6.1

表 2.7.3.6-85. 投与 8 週時に排便回数サブスコア，直腸出血サブスコア，及び内視鏡的サブスコアが 0 であった被験者の割合（NRI）（導入療法試験，ITT 集団，M14-033 主試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE	HIGHER INDUCTION DOSE
SFS = 0, RBS = 0 AND ENDOSCOPIC SUBSCORE = 0 AT WEEK 8	(N=340)	(N=512)
YES, n (%)	3 (0.9)	12 (2.3)
NO, n (%)	337 (99.1)	500 (97.7)
RISK DIFFERENCE[A]		1.5
ADJUSTED RISK DIFFERENCE[A,B]		1.5
95% CONFIDENCE INTERVAL[B]		(-0.3, 3.3)
P-VALUE[B]		0.101

[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: ADJUSTED RISK DIFFERENCE, 95% CONFIDENCE INTERVAL FOR THE DIFFERENCE IN THE PROPORTIONS BETWEEN THE TREATMENT GROUPS AND P-VALUE WERE CALCULATED USING COCHRAN-MANTEL-HAENSZEL (CMH) TEST ADJUSTED FOR PREVIOUS INFLIXIMAB USE AND BASELINE CORTICOSTEROID USE.

Cross reference: M14-033 Induction_Main study Final CSR Table 14.2__3.7.1

表 2.7.3.6-86. 評価時点ごとの排便回数サブスコアが 1 以下であった被験者の割合（NRI）（導入療法試験，ITT 集団，M14-033 主試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE	HIGHER INDUCTION DOSE
SFS <= 1 AT WEEK 1	(N=340)	(N=512)
YES, n (%)	69 (20.3)	99 (19.3)
NO, n (%)	271 (79.7)	413 (80.7)
RISK DIFFERENCE[A]		-1.0
ADJUSTED RISK DIFFERENCE[A,B]		-1.1
95% CONFIDENCE INTERVAL[B]		(-6.5, 4.4)
P-VALUE[B]		0.698
SFS <= 1 AT WEEK 2	(N=340)	(N=512)
YES, n (%)	97 (28.5)	143 (27.9)
NO, n (%)	243 (71.5)	369 (72.1)
RISK DIFFERENCE[A]		-0.6
ADJUSTED RISK DIFFERENCE[A,B]		-0.6
95% CONFIDENCE INTERVAL[B]		(-6.8, 5.6)
P-VALUE[B]		0.849

表 2.7.3.6-86. 評価時点ごとの排便回数サブスコアが 1 以下であった被験者の割合（NRI）（導入療法試験，ITT 集団，M14-033 主試験）（続き）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE	HIGHER INDUCTION DOSE
SFS <= 1 AT WEEK 4	(N=340)	(N=512)
YES, n (%)	108 (31.8)	203 (39.6)
NO, n (%)	232 (68.2)	309 (60.4)
RISK DIFFERENCE[A]		7.9
ADJUSTED RISK DIFFERENCE[A,B]		7.9
95% CONFIDENCE INTERVAL[B]		(1.3, 14.5)
P-VALUE[B]		0.019*
SFS <= 1 AT WEEK 8	(N=340)	(N=512)
YES, n (%)	114 (33.5)	199 (38.9)
NO, n (%)	226 (66.5)	313 (61.1)
RISK DIFFERENCE[A]		5.3
ADJUSTED RISK DIFFERENCE[A,B]		5.5
95% CONFIDENCE INTERVAL[B]		(-1.1, 12.1)
P-VALUE[B]		0.103

[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: ADJUSTED RISK DIFFERENCE, 95% CONFIDENCE INTERVAL FOR THE DIFFERENCE IN THE PROPORTIONS BETWEEN THE TREATMENT GROUPS AND P-VALUE WERE CALCULATED USING COCHRAN-MANTEL-HAENSZEL (CMH) TEST ADJUSTED FOR PREVIOUS INFLIXIMAB USE AND BASELINE CORTICOSTEROID USE.
***, **, *, + STATISTICALLY SIGNIFICANT AT 0.001, 0.01, 0.05 AND 0.1 LEVEL, RESPECTIVELY.

Cross reference: M14-033 Induction_Main study Final CSR Table 14.2__3.8.1

表 2.7.3.6-87. 評価時点ごとの直腸出血サブスコアが 0 以下であった被験者の割合（NRI）（導入療法試験，ITT 集団，M14-033 主試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE	HIGHER INDUCTION DOSE
RBS = 0 AT WEEK 1	(N=340)	(N=512)
YES, n (%)	38 (11.2)	63 (12.3)
NO, n (%)	302 (88.8)	449 (87.7)
RISK DIFFERENCE[A]		1.1
ADJUSTED RISK DIFFERENCE[A,B]		1.1
95% CONFIDENCE INTERVAL[B]		(-3.3, 5.6)
P-VALUE[B]		0.615
RBS = 0 AT WEEK 2	(N=340)	(N=512)
YES, n (%)	82 (24.1)	129 (25.2)
NO, n (%)	258 (75.9)	383 (74.8)
RISK DIFFERENCE[A]		1.1
ADJUSTED RISK DIFFERENCE[A,B]		1.2
95% CONFIDENCE INTERVAL[B]		(-4.7, 7.2)
P-VALUE[B]		0.684

表 2.7.3.6-87. 評価時点ごとの直腸出血サブスコアが 0 以下であった被験者の割合（NRI）（導入療法試験，ITT 集団，M14-033 主試験）（続き）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE	HIGHER INDUCTION DOSE
RBS = 0 AT WEEK 4	(N=340)	(N=512)
YES, n (%)	108 (31.8)	191 (37.3)
NO, n (%)	232 (68.2)	321 (62.7)
RISK DIFFERENCE[A]		5.5
ADJUSTED RISK DIFFERENCE[A,B]		5.8
95% CONFIDENCE INTERVAL[B]		(-0.7, 12.3)
P-VALUE[B]		0.083+
RBS = 0 AT WEEK 8	(N=340)	(N=512)
YES, n (%)	121 (35.6)	209 (40.8)
NO, n (%)	219 (64.4)	303 (59.2)
RISK DIFFERENCE[A]		5.2
ADJUSTED RISK DIFFERENCE[A,B]		5.5
95% CONFIDENCE INTERVAL[B]		(-1.1, 12.2)
P-VALUE[B]		0.102

[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: ADJUSTED RISK DIFFERENCE, 95% CONFIDENCE INTERVAL FOR THE DIFFERENCE IN THE PROPORTIONS BETWEEN THE TREATMENT GROUPS AND P-VALUE WERE CALCULATED USING COCHRAN-MANTEL-HAENSZEL (CMH) TEST ADJUSTED FOR PREVIOUS INFLIXIMAB USE AND BASELINE CORTICOSTEROID USE.
***, **, *, + STATISTICALLY SIGNIFICANT AT 0.001, 0.01, 0.05 AND 0.1 LEVEL, RESPECTIVELY.

Cross reference: M14-033 Induction_Main study Final CSR Table 14.2__3.9.1

表 2.7.3.6-88. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，ITT 集団，M14-033 主試験）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
AVERAGE RECTAL BLEEDING SUBSCORE											
WEEK 1											
ADALIMUMAB STANDARD INDUCTION DOSE	335	1.70	1.25	-0.46	0.679	-3.0	-0.40	2.0			
ADALIMUMAB HIGHER INDUCTION DOSE	504	1.78	1.19	-0.59	0.767	-3.0	-0.40	1.2	-0.10	(-0.20, -0.01)	0.032*
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	326	1.70	1.00	-0.70	0.900	-3.0	-0.40	2.2			
ADALIMUMAB HIGHER INDUCTION DOSE	490	1.76	0.96	-0.79	0.926	-3.0	-0.60	2.4	-0.08	(-0.19, 0.03)	0.178
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	331	1.69	0.87	-0.82	0.930	-3.0	-0.80	2.4			
ADALIMUMAB HIGHER INDUCTION DOSE	498	1.77	0.79	-0.98	1.028	-3.0	-1.00	2.8	-0.14	(-0.25, -0.02)	0.021*
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	315	1.68	0.81	-0.87	1.055	-3.0	-0.80	2.0			
ADALIMUMAB HIGHER INDUCTION DOSE	481	1.75	0.71	-1.04	1.073	-3.0	-1.00	2.4	-0.17	(-0.30, -0.05)	0.008**

表 2.7.3.6-88. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，ITT 集団，M14-033 主試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
AVERAGE STOOL FREQUENCY SUBSCORE											
WEEK 1											
ADALIMUMAB STANDARD INDUCTION DOSE	335	2.40	1.98	-0.42	0.630	-2.8	-0.20	1.4			
ADALIMUMAB HIGHER INDUCTION DOSE	504	2.47	2.01	-0.46	0.615	-3.0	-0.20	1.2	-0.03	(-0.12, 0.05)	0.458
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	326	2.41	1.84	-0.57	0.777	-3.0	-0.40	1.8			
ADALIMUMAB HIGHER INDUCTION DOSE	490	2.47	1.80	-0.67	0.742	-3.0	-0.60	1.2	-0.09	(-0.20, 0.01)	0.074+
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	331	2.41	1.71	-0.70	0.827	-3.0	-0.60	1.4			
ADALIMUMAB HIGHER INDUCTION DOSE	498	2.47	1.58	-0.89	0.893	-3.0	-0.80	1.8	-0.17	(-0.29, -0.06)	0.004**
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	315	2.41	1.64	-0.77	0.944	-3.0	-0.60	1.6			
ADALIMUMAB HIGHER INDUCTION DOSE	481	2.46	1.53	-0.93	0.960	-3.0	-1.00	1.8	-0.16	(-0.29, -0.03)	0.014*

表 2.7.3.6-88. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，ITT 集団，M14-033 主試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
ENDOSCOPY SUBSCORE											
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	299	2.3	1.8	-0.5	0.88	-3	0.0	1			
ADALIMUMAB HIGHER INDUCTION DOSE	461	2.4	1.8	-0.6	0.93	-3	0.0	1	-0.1	(-0.2, 0.1)	0.230

表 2.7.3.6-88. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，ITT 集団，M14-033 主試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
PHYSICIAN'S GLOBAL ASSESSMENT SUBSCORE											
WEEK 1											
ADALIMUMAB STANDARD INDUCTION DOSE	335	2.3	1.9	-0.4	0.59	-2	0.0	1			
ADALIMUMAB HIGHER INDUCTION DOSE	507	2.3	1.9	-0.4	0.65	-3	0.0	1	-0.1	(-0.1, 0.0)	0.145
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	326	2.2	1.7	-0.5	0.66	-3	0.0	1			
ADALIMUMAB HIGHER INDUCTION DOSE	494	2.3	1.7	-0.6	0.74	-3	-1.0	1	-0.1	(-0.2, 0.0)	0.200
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	331	2.3	1.6	-0.7	0.76	-3	-1.0	1			
ADALIMUMAB HIGHER INDUCTION DOSE	501	2.3	1.5	-0.8	0.83	-3	-1.0	1	-0.1	(-0.2, -0.0)	0.009**
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	315	2.2	1.5	-0.7	0.84	-3	-1.0	1			
ADALIMUMAB HIGHER INDUCTION DOSE	485	2.3	1.4	-0.9	0.90	-3	-1.0	1	-0.1	(-0.2, -0.0)	0.029*

表 2.7.3.6-88. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，ITT 集団，M14-033 主試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
PARTIAL MAYO SCORE											
WEEK 1											
ADALIMUMAB STANDARD INDUCTION DOSE	335	6.37	5.13	-1.24	1.397	-6.0	-1.00	3.4			
ADALIMUMAB HIGHER INDUCTION DOSE	504	6.55	5.05	-1.50	1.533	-8.0	-1.20	2.2	-0.21	(-0.42, -0.01)	0.037*
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	326	6.36	4.55	-1.81	1.788	-7.4	-1.70	3.4			
ADALIMUMAB HIGHER INDUCTION DOSE	490	6.51	4.42	-2.09	1.844	-9.0	-2.00	2.4	-0.24	(-0.49, 0.00)	0.054+
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	331	6.35	4.16	-2.19	1.918	-7.4	-2.20	4.4			
ADALIMUMAB HIGHER INDUCTION DOSE	498	6.53	3.83	-2.70	2.158	-9.0	-2.60	3.4	-0.47	(-0.75, -0.19)	<0.001***
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	315	6.34	3.97	-2.36	2.243	-8.6	-2.20	2.8			
ADALIMUMAB HIGHER INDUCTION DOSE	481	6.49	3.65	-2.84	2.373	-9.0	-2.80	4.8	-0.49	(-0.81, -0.17)	0.002**

表 2.7.3.6-88. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，ITT 集団，M14-033 主試験）（続き）

@ P-VALUE FOR TEST OF DIFFERENCE BETWEEN ADALIMUMAB HIGHER INDUCTION DOSE AND ADALIMUMAB STANDARD INDUCTION DOSE FOR CHANGE FROM BASELINE USING THE REPEATED MEASURE MODEL INCLUDING TREATMENT, PREVIOUS INFLIXIMAB USE, BASELINE CORTICOSTERIOD USE, VISIT, BASELINE VALUE, INTERACTION OF TREATMENT AND VISIT.
***, **, *, + STATISTICALLY SIGNIFICANT AT 0.001, 0.01, 0.05 AND 0.1 LEVEL, RESPECTIVELY.

Cross reference: M14-033 Induction_Main study Final CSR Table 14.2__3.10.1

表 2.7.3.6-89.　投与 8 週時の高感度 CRP のベースラインからの変化量（OC）（導入療法試験，ITT 集団，M14-033 主試験）

PARAMETER / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP – CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON – (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
HIGH-SENSITIVITY C-REACTIVE PROTEIN (MG/L)											
ADALIMUMAB STANDARD INDUCTION DOSE	312	10.807	9.351	-1.456	15.8808	-80.95	-0.458	152.91			
ADALIMUMAB HIGHER INDUCTION DOSE	481	11.292	7.616	-3.676	18.8227	-126.62	-0.950	144.05	-2.007	(-4.169, 0.155)	0.069+

@ P-VALUE FOR TEST OF DIFFERENCE BETWEEN ADALIMUMAB HIGHER INDUCTION DOSE AND ADALIMUMAB STANDARD INDUCTION DOSE FOR CHANGE FROM BASELINE USING ANALYSIS OF COVARIANCE WITH TREATMENT, PREVIOUS INFLIXIMAB USE, BASELINE CORTICOSTEROID USE, AND BASELINE VALUE AS COVARIATE.
***, **, *, + STATISTICALLY SIGNIFICANT AT 0.001, 0.01, 0.05 AND 0.1 LEVEL, RESPECTIVELY.

Cross reference: M14-033 Induction_Main study Final CSR Table 14.2__3.11.1

表 2.7.3.6-90.　投与 8 週時の便中カルプロテクチン値のベースラインからの変化量（OC）（導入療法試験，ITT 集団，M14-033 主試験）

PARAMETER / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP — CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON — (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
FECAL CALPROTECTIN (MCG/G)											
ADALIMUMAB STANDARD INDUCTION DOSE	261	2256.3	1404.3	-852.0	2419.89	-9590	-259.0	8726			
ADALIMUMAB HIGHER INDUCTION DOSE	401	2441.8	1346.6	-1095.2	2848.10	-9587	-631.0	8687	-125.0	(-416.1, 166.0)	0.399

@ P-VALUE FOR TEST OF DIFFERENCE BETWEEN ADALIMUMAB HIGHER INDUCTION DOSE AND ADALIMUMAB STANDARD INDUCTION DOSE FOR CHANGE FROM BASELINE USING ANALYSIS OF COVARIANCE WITH TREATMENT, PREVIOUS INFLIXIMAB USE, BASELINE CORTICOSTEROID USE, AND BASELINE VALUE AS COVARIATE.

Cross reference: M14-033 Induction_Main study Final CSR Table 14.2__3.12.1

表 2.7.3.6-91. 評価時点ごとの IBDQ スコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，ITT 集団，M14-033 主試験）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
IBDQ - BOWEL											
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	337	35.790	46.533	10.743	9.2802	-12.00	10.000	43.00			
ADALIMUMAB HIGHER INDUCTION DOSE	505	35.533	47.648	12.115	10.4082	-15.00	10.000	54.00	1.239	(-0.053, 2.530)	0.060+
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	328	35.815	48.508	12.693	10.8599	-15.00	12.500	46.00			
ADALIMUMAB HIGHER INDUCTION DOSE	500	35.505	50.221	14.716	12.1118	-32.00	14.000	51.00	1.963	(0.486, 3.439)	0.009**
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	314	36.074	49.030	12.955	12.2838	-19.00	12.000	52.00			
ADALIMUMAB HIGHER INDUCTION DOSE	486	35.731	50.719	14.988	13.1535	-27.00	14.000	51.00	2.111	(0.457, 3.765)	0.012*

表 2.7.3.6-91. 評価時点ごとの IBDQ スコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，ITT 集団，M14-033 主試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
IBDQ - EMOTIONAL											
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	337	46.094	55.931	9.838	10.6026	-13.00	9.000	51.00			
ADALIMUMAB HIGHER INDUCTION DOSE	506	44.240	55.500	11.260	12.6623	-23.00	9.000	63.00	0.766	(-0.760, 2.292)	0.325
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	329	46.227	57.482	11.256	11.9907	-20.00	11.000	52.00			
ADALIMUMAB HIGHER INDUCTION DOSE	502	44.349	58.551	14.201	14.7524	-30.00	13.000	64.00	2.179	(0.445, 3.913)	0.014*
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	314	46.381	57.828	11.447	13.5531	-21.00	11.000	60.00			
ADALIMUMAB HIGHER INDUCTION DOSE	487	44.469	58.980	14.511	15.5967	-26.00	13.000	63.00	2.522	(0.612, 4.433)	0.010**

表 2.7.3.6-91. 評価時点ごとの IBDQ スコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，ITT 集団，M14-033 主試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
IBDQ - FATIGUE											
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	336	2.8	3.8	1.0	1.44	-3	1.0	6			
ADALIMUMAB HIGHER INDUCTION DOSE	506	2.9	3.9	1.1	1.55	-3	1.0	6	0.1	(-0.1, 0.3)	0.167
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	329	2.8	4.0	1.1	1.65	-4	1.0	6			
ADALIMUMAB HIGHER INDUCTION DOSE	502	2.9	4.3	1.4	1.78	-4	1.0	6	0.3	(0.1, 0.5)	0.003**
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	314	2.9	4.1	1.3	1.70	-3	1.0	6			
ADALIMUMAB HIGHER INDUCTION DOSE	485	2.9	4.3	1.4	1.86	-4	1.0	6	0.2	(-0.0, 0.4)	0.052+

表 2.7.3.6-91. 評価時点ごとの IBDQ スコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，ITT 集団，M14-033 主試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
IBDQ - SOCIAL											
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	330	19.3	24.2	4.9	5.83	-10	4.0	29			
ADALIMUMAB HIGHER INDUCTION DOSE	495	18.2	24.0	5.8	6.46	-14	5.0	29	0.6	(-0.3, 1.4)	0.179
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	321	19.3	25.3	6.1	6.51	-14	5.0	29			
ADALIMUMAB HIGHER INDUCTION DOSE	493	18.3	25.9	7.7	7.72	-19	7.0	29	1.3	(0.4, 2.2)	0.006**
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	308	19.4	25.9	6.4	6.94	-14	6.0	29			
ADALIMUMAB HIGHER INDUCTION DOSE	478	18.3	26.2	7.9	8.16	-19	7.0	30	1.3	(0.3, 2.2)	0.011*

表 2.7.3.6-91. 評価時点ごとの IBDQ スコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，ITT 集団，M14-033 主試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
IBDQ - SYSTEMIC											
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	334	16.4	21.0	4.6	5.05	-11	4.0	24			
ADALIMUMAB HIGHER INDUCTION DOSE	501	16.2	21.3	5.1	5.57	-10	4.0	24	0.5	(-0.2, 1.1)	0.182
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	327	16.4	21.7	5.3	5.77	-12	5.0	23			
ADALIMUMAB HIGHER INDUCTION DOSE	500	16.2	22.8	6.6	6.56	-15	6.0	27	1.2	(0.4, 2.0)	0.002**
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	313	16.5	22.4	5.9	6.28	-12	6.0	24			
ADALIMUMAB HIGHER INDUCTION DOSE	484	16.3	23.2	6.9	6.93	-15	7.0	26	1.1	(0.2, 1.9)	0.013*

表 2.7.3.6-91. 評価時点ごとの IBDQ スコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，ITT 集団，M14-033 主試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
IBDQ - TOTAL											
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	329	118.026	147.857	29.831	26.9420	-39.00	25.000	134.00			
ADALIMUMAB HIGHER INDUCTION DOSE	492	114.345	148.539	34.194	31.7762	-49.00	29.000	158.00	3.073	(-0.842, 6.988)	0.124
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	320	117.989	153.157	35.167	31.5582	-46.00	32.000	140.00			
ADALIMUMAB HIGHER INDUCTION DOSE	490	114.463	157.643	43.180	37.8149	-90.00	39.000	164.00	6.489	(1.934, 11.045)	0.005**
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	307	118.826	155.577	36.750	35.7025	-44.00	33.000	153.00			
ADALIMUMAB HIGHER INDUCTION DOSE	474	114.818	159.069	44.251	40.4220	-80.00	41.000	167.00	6.895	(1.844, 11.945)	0.008**

表 2.7.3.6-91. 評価時点ごとの IBDQ スコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，ITT 集団，M14-033 主試験）（続き）

@ P-VALUE FOR TEST OF DIFFERENCE BETWEEN ADALIMUMAB HIGHER INDUCTION DOSE AND ADALIMUMAB STANDARD INDUCTION DOSE FOR CHANGE FROM BASELINE USING THE REPEATED MEASURE MODEL INCLUDING TREATMENT, PREVIOUS INFLIXIMAB USE, BASELINE CORTICOSTERIOD USE, VISIT, BASELINE VALUE, INTERACTION OF TREATMENT AND VISIT.
***, **, *, + STATISTICALLY SIGNIFICANT AT 0.001, 0.01, 0.05 AND 0.1 LEVEL, RESPECTIVELY.

Cross reference: M14-033 Induction_Main study Final CSR Table 14.2__3.13.1

表 2.7.3.6-92. 評価時点ごとの IBDQ スコアが 170 以上となった被験者の割合（NRI）（導入療法試験，ITT 集団，M14-033 主試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE	HIGHER INDUCTION DOSE
IBDQ TOTAL SCORE >= 170 AT WEEK 0	(N=335)	(N=504)
YES, n (%)	20 (6.0)	30 (6.0)
NO, n (%)	315 (94.0)	474 (94.0)
RISK DIFFERENCE[A]		-0.0
ADJUSTED RISK DIFFERENCE[A,B]		-0.1
95% CONFIDENCE INTERVAL[B]		(-3.4, 3.1)
P-VALUE[B]		0.938
IBDQ TOTAL SCORE >= 170 AT WEEK 2	(N=340)	(N=512)
YES, n (%)	108 (31.8)	155 (30.3)
NO, n (%)	232 (68.2)	357 (69.7)
RISK DIFFERENCE[A]		-1.5
ADJUSTED RISK DIFFERENCE[A,B]		-1.6
95% CONFIDENCE INTERVAL[B]		(-7.9, 4.8)
P-VALUE[B]		0.624

表 2.7.3.6-92. 評価時点ごとの IBDQ スコアが 170 以上となった被験者の割合（NRI）（導入療法試験，ITT 集団，M14-033 主試験）（続き）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE	HIGHER INDUCTION DOSE
IBDQ TOTAL SCORE >= 170 AT WEEK 4	(N=340)	(N=512)
YES, n (%)	127 (37.4)	217 (42.4)
NO, n (%)	213 (62.6)	295 (57.6)
RISK DIFFERENCE[A]		5.0
ADJUSTED RISK DIFFERENCE[A,B]		5.0
95% CONFIDENCE INTERVAL[B]		(-1.7, 11.7)
P-VALUE[B]		0.144
IBDQ TOTAL SCORE >= 170 AT WEEK 8	(N=340)	(N=512)
YES, n (%)	129 (37.9)	217 (42.4)
NO, n (%)	211 (62.1)	295 (57.6)
RISK DIFFERENCE[A]		4.4
ADJUSTED RISK DIFFERENCE[A,B]		4.4
95% CONFIDENCE INTERVAL[B]		(-2.4, 11.1)
P-VALUE[B]		0.202

[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: ADJUSTED RISK DIFFERENCE, 95% CONFIDENCE INTERVAL FOR THE DIFFERENCE IN THE PROPORTIONS BETWEEN THE TREATMENT GROUPS AND P-VALUE WERE CALCULATED USING COCHRAN-MANTEL-HAENSZEL (CMH) TEST ADJUSTED FOR PREVIOUS INFLIXIMAB USE AND BASELINE CORTICOSTEROID USE.

Cross reference: M14-033 Induction_Main study Final CSR Table 14.2__3.13.3

表 2.7.3.6-93. 投与 8 週時の WPAI のベースラインからの変化量（OC）（導入療法試験，ITT 集団，M14-033 主試験）

PARAMETER / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP — CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON — (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
WPAI - ACTIVITY IMPAIRMENT (%)											
ADALIMUMAB STANDARD INDUCTION DOSE	307	57.2	40.5	-16.7	26.67	-100	-10.0	50			
ADALIMUMAB HIGHER INDUCTION DOSE	472	59.0	36.0	-23.0	28.74	-100	-20.0	60	-5.6	(-9.2, -2.0)	0.002**
WPAI - IMPAIRMENT WHILE WORKING (%)											
ADALIMUMAB STANDARD INDUCTION DOSE	178	51.0	33.2	-17.8	28.01	-100	-15.0	40			
ADALIMUMAB HIGHER INDUCTION DOSE	263	52.4	32.9	-19.5	30.60	-100	-10.0	100	-0.9	(-5.7, 3.9)	0.709

表 2.7.3.6-93. 投与 8 週時の WPAI のベースラインからの変化量（OC）（導入療法試験，ITT 集団，M14-033 主試験）（続き）

PARAMETER / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP — CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON — (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
WPAI - OVERALL WORK IMPAIRMENT (%)											
ADALIMUMAB STANDARD INDUCTION DOSE	172	57.297	39.701	-17.595	29.2332	-96.19	-11.238	54.36			
ADALIMUMAB HIGHER INDUCTION DOSE	265	59.227	37.712	-21.515	33.5608	-100.00	-15.526	65.00	-3.087	(-8.505, 2.331)	0.263
WPAI - WORK TIME MISSED (%)											
ADALIMUMAB STANDARD INDUCTION DOSE	173	21.131	13.443	-7.688	25.0675	-100.00	0.000	100.00			
ADALIMUMAB HIGHER INDUCTION DOSE	265	20.951	11.546	-9.406	33.5963	-100.00	0.000	100.00	-1.967	(-6.602, 2.669)	0.405

@ P-VALUE FOR TEST OF DIFFERENCE BETWEEN ADALIMUMAB HIGHER INDUCTION DOSE AND ADALIMUMAB STANDARD INDUCTION DOSE FOR CHANGE FROM BASELINE USING ANALYSIS OF COVARIANCE WITH TREATMENT, PREVIOUS INFLIXIMAB USE, BASELINE CORTICOSTEROID USE, AND BASELINE VALUE AS COVARIATE.
***, **, *, + STATISTICALLY SIGNIFICANT AT 0.001, 0.01, 0.05 AND 0.1 LEVEL, RESPECTIVELY.

Cross reference: M14-033 Induction_Main study Final CSR Table 14.2__3.14.1

表 2.7.3.6-94. 投与 8 週時の SF-36 スコアのベースラインからの変化量（OC）（導入療法試験，ITT 集団，M14-033 主試験）

PARAMETER / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
SF-36 V2 BODILY PAIN SCALE											
ADALIMUMAB STANDARD INDUCTION DOSE	312	38.719	45.789	7.071	9.8051	-24.93	5.071	32.96			
ADALIMUMAB HIGHER INDUCTION DOSE	488	38.372	46.584	8.212	11.0710	-26.20	6.762	42.26	1.019	(-0.273, 2.312)	0.122
SF-36 V2 GENERAL HEALTH SCALE											
ADALIMUMAB STANDARD INDUCTION DOSE	311	33.830	37.775	3.945	8.0735	-14.30	2.383	34.32			
ADALIMUMAB HIGHER INDUCTION DOSE	486	34.295	38.535	4.240	7.6868	-24.79	3.337	29.55	0.515	(-0.528, 1.558)	0.332
SF-36 V2 MENTAL COMPONENT SUMMARY											
ADALIMUMAB STANDARD INDUCTION DOSE	311	36.113	42.137	6.024	10.5843	-17.67	4.421	39.78			
ADALIMUMAB HIGHER INDUCTION DOSE	483	33.887	41.955	8.068	11.7173	-19.48	6.070	52.29	1.120	(-0.301, 2.541)	0.122

表 2.7.3.6-94. 投与 8 週時の SF-36 スコアのベースラインからの変化量（OC）（導入療法試験，ITT 集団，M14-033 主試験）（続き）

PARAMETER / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP – CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON – (HIGHER DOSE - STANDARD DOSE) - LSMEAN	95% CI	P-VALUE@
SF-36 V2 MENTAL HEALTH SCALE											
ADALIMUMAB STANDARD INDUCTION DOSE	312	38.247	43.572	5.325	9.5410	-14.08	2.816	42.24			
ADALIMUMAB HIGHER INDUCTION DOSE	487	36.026	42.924	6.898	11.2133	-19.71	5.632	47.87	0.683	(-0.664, 2.029)	0.320
SF-36 V2 PHYSICAL COMPONENT SUMMARY											
ADALIMUMAB STANDARD INDUCTION DOSE	311	39.324	44.713	5.389	7.4676	-12.69	4.659	39.28			
ADALIMUMAB HIGHER INDUCTION DOSE	483	39.890	45.599	5.709	7.8794	-16.04	4.651	38.97	0.626	(-0.355, 1.608)	0.211
SF-36 V2 PHYSICAL FUNCTIONING SCALE											
ADALIMUMAB STANDARD INDUCTION DOSE	311	43.750	48.058	4.308	7.5378	-21.04	2.104	33.67			
ADALIMUMAB HIGHER INDUCTION DOSE	487	43.777	48.399	4.622	8.3944	-23.15	4.209	37.88	0.372	(-0.628, 1.372)	0.465

表 2.7.3.6-94. 投与 8 週時の SF-36 スコアのベースラインからの変化量（OC）（導入療法試験，ITT 集団，M14-033 主試験）（続き）

PARAMETER / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
SF-36 V2 ROLE-EMOTIONAL SCALE											
ADALIMUMAB STANDARD INDUCTION DOSE	312	36.816	42.572	5.756	12.3750	-31.10	3.887	46.65			
ADALIMUMAB HIGHER INDUCTION DOSE	486	35.699	42.937	7.239	13.2438	-34.98	3.887	46.65	0.974	(-0.559, 2.506)	0.213
SF-36 V2 ROLE-PHYSICAL SCALE											
ADALIMUMAB STANDARD INDUCTION DOSE	312	34.961	41.963	7.002	9.6147	-26.94	4.898	39.18			
ADALIMUMAB HIGHER INDUCTION DOSE	487	34.601	42.577	7.976	11.2025	-24.49	4.898	39.18	0.856	(-0.492, 2.204)	0.213
SF-36 V2 SOCIAL FUNCTIONING SCALE											
ADALIMUMAB STANDARD INDUCTION DOSE	311	34.297	41.715	7.418	11.0550	-21.82	5.454	43.63			
ADALIMUMAB HIGHER INDUCTION DOSE	487	32.480	41.719	9.239	11.9198	-21.82	5.454	43.63	1.023	(-0.438, 2.483)	0.170

表 2.7.3.6-94. 投与 8 週時の SF-36 スコアのベースラインからの変化量（OC）（導入療法試験，ITT 集団，M14-033 主試験）（続き）

PARAMETER / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP — CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON — (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
SF-36 V2 VITALITY SCALE											
ADALIMUMAB STANDARD INDUCTION DOSE	312	37.782	44.286	6.504	10.0423	-18.73	6.244	37.46			
ADALIMUMAB HIGHER INDUCTION DOSE	487	36.750	45.187	8.436	11.1544	-18.73	6.244	49.95	1.555	(0.178, 2.932)	0.027*

@ P-VALUE FOR TEST OF DIFFERENCE BETWEEN ADALIMUMAB HIGHER INDUCTION DOSE AND ADALIMUMAB STANDARD INDUCTION DOSE FOR CHANGE FROM BASELINE USING ANALYSIS OF COVARIANCE WITH TREATMENT, PREVIOUS INFLIXIMAB USE, BASELINE CORTICOSTEROID USE, AND BASELINE VALUE AS COVARIATE.
***, **, *, + STATISTICALLY SIGNIFICANT AT 0.001, 0.01, 0.05 AND 0.1 LEVEL, RESPECTIVELY.

Cross reference: M14-033 Induction_Main study Final CSR Table 14.2__3.15.1

表 2.7.3.6-95. 評価時点ごとの被験者から報告された排便回数のベースラインからの変化量（OC）（導入療法試験，ITT 集団，M14-033 主試験）

PARAMETER VISIT TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
AVERAGE STOOL FREQUENCY ABSOLUTE VALUE											
WEEK 1											
ADALIMUMAB STANDARD INDUCTION DOSE	332	7.12	5.79	-1.33	1.914	-11.8	-1.20	4.2			
ADALIMUMAB HIGHER INDUCTION DOSE	502	7.50	5.75	-1.75	2.150	-19.0	-1.40	3.6	-0.33	(-0.58, -0.07)	0.013*
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	323	7.10	5.29	-1.80	2.379	-11.4	-1.40	10.2			
ADALIMUMAB HIGHER INDUCTION DOSE	489	7.51	5.17	-2.35	2.610	-17.2	-2.00	5.4	-0.40	(-0.70, -0.09)	0.010**
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	328	7.13	5.03	-2.10	2.869	-14.8	-1.80	10.2			
ADALIMUMAB HIGHER INDUCTION DOSE	498	7.50	4.68	-2.82	3.267	-18.8	-2.40	15.6	-0.57	(-0.95, -0.20)	0.003**
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	311	7.08	4.85	-2.23	3.092	-17.6	-2.20	10.2			
ADALIMUMAB HIGHER INDUCTION DOSE	480	7.43	4.52	-2.90	3.451	-19.5	-2.60	15.6	-0.53	(-0.93, -0.13)	0.010**

表 2.7.3.6-95. 評価時点ごとの被験者から報告された排便回数のベースラインからの変化量（OC）（導入療法試験，ITT 集団，M14-033 主試験）（続き）

@ P-VALUE FOR TEST OF DIFFERENCE BETWEEN ADALIMUMAB HIGHER INDUCTION DOSE AND ADALIMUMAB STANDARD INDUCTION DOSE FOR CHANGE FROM BASELINE USING ANALYSIS OF COVARIANCE WITH TREATMENT, PREVIOUS INFLIXIMAB USE, BASELINE CORTICOSTEROID USE, AND BASELINE VALUE AS COVARIATE.
***, **, *, + STATISTICALLY SIGNIFICANT AT 0.001, 0.01, 0.05 AND 0.1 LEVEL, RESPECTIVELY.

Cross reference: M14-033 Induction_Main study Final CSR Table 14.2__3.16

表 2.7.3.6-96. PMS による寛解達成までの期間（OC）（導入療法試験，ITT 集団，M14-033 主試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=339) n (%)	HIGHER INDUCTION DOSE (N=510) n (%)
NUMBER OF EVENTS PER PARTIAL MAYO SCORE	104 (30.7)	191 (37.5)
KAPLAN-MEIER METHOD:		
PERCENTILES (WEEKS)		
25TH	8.0	4.0
MEDIAN	NE[A]	NE[A]
75TH	NE[A]	NE[A]
COX PROPORTIONAL HAZARDS MODEL$:		
HAZARDS RATIO HIGHER DOSE VERSUS STANDARD DOSE		1.234
(%95 CI)		(0.972, 1.568)
P-VALUE		0.084

NOTE: CLINICAL REMISSION PER PARTIAL MAYO SCORE IS DEFINED AS PARTIAL MAYO SCORE <= 2, WITH NO SUBSCORE > 1.
$ THE COVARIATES TREATMENT, PREVIOUS INFLIXIMAB USE AND BASELINE CORTICOSTEROID USE ARE INCLUDED IN THE COX PROPORTIONAL HAZARDS MODEL.
SUBJECTS WHO DID NOT RESPOND BY WEEK 8 WERE CENSORED AT LAST OC VISIT.
[A] NOT ESTIMABLE.

Cross reference: M14-033 Induction_Main study Final CSR Table 14.2__3.17

表 2.7.3.6-97. PMS による改善達成までの時間（OC）（導入療法試験，ITT 集団，M14-033 主試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=339) n (%)	HIGHER INDUCTION DOSE (N=510) n (%)
NUMBER OF EVENTS PER PARTIAL MAYO SCORE	225 (66.4)	359 (70.4)
KAPLAN-MEIER METHOD:		
PERCENTILES (WEEKS)		
25TH	2.0	1.0
MEDIAN	4.0	4.0
75TH	NE[A]	9.0
COX PROPORTIONAL HAZARDS MODEL$:		
HAZARDS RATIO HIGHER DOSE VERSUS STANDARD DOSE		1.092
(%95 CI)		(0.924, 1.290)
P-VALUE		0.302

表 2.7.3.6-97.　　PMS による改善達成までの時間（OC）（導入療法試験，ITT 集団，M14-033 主試験）（続き）

NOTE: CLINICAL RESPONSE PER PARTIAL MAYO SCORE IS DEFINED AS A DECREASE IN PARTIAL MAYO SCORE >= 2 POINTS AND >= 30% FROM BASELINE, PLUS A DECREASE IN RBS >= 1 OR AN ABSOLUTE RBS <= 1.
$ THE COVARIATES TREATMENT, PREVIOUS INFLIXIMAB USE AND BASELINE CORTICOSTEROID USE ARE INCLUDED IN THE COX PROPORTIONAL HAZARDS MODEL.
SUBJECTS WHO DID NOT RESPOND BY WEEK 8 WERE CENSORED AT LAST OC VISIT.
[A] NOT ESTIMABLE.

Cross reference: M14-033 Induction_Main study Final CSR Table 14.2__3.18

表 2.7.3.6-98.　治験期間中の腸管外合併症の有無の変化（導入療法試験，ITT 集団，M14-033 主試験）

VARIABLE/ TREATMENT/ BASELINE VALUE	WEEK 8 YES N (%)	WEEK 8 NO N (%)	WEEK 8 MISSING N (%)
ANEMIA			
ADALIMUMAB STANDARD INDUCTION DOSE (N=333)			
YES (N=76)	50 (65.8)	24 (31.6)	2 (2.6)
NO (N=257)	9 (3.5)	240 (93.4)	8 (3.1)
ADALIMUMAB HIGHER INDUCTION DOSE (N=502)			
YES (N=95)	53 (55.8)	38 (40.0)	4 (4.2)
NO (N=407)	18 (4.4)	379 (93.1)	10 (2.5)
AUTOIMMUNE HEPATITIS			
ADALIMUMAB STANDARD INDUCTION DOSE (N=333)			
YES (N=0)	0	0	0
NO (N=333)	1 (0.3)	322 (96.7)	10 (3.0)
ADALIMUMAB HIGHER INDUCTION DOSE (N=502)			
YES (N=1)	1 (100)	0	0
NO (N=501)	0	486 (97.0)	15 (3.0)

表 2.7.3.6-98. 治験期間中の腸管外合併症の有無の変化（導入療法試験，ITT 集団，M14-033 主試験）（続き）

VARIABLE/ TREATMENT/ BASELINE VALUE	WEEK 8 YES N (%)	WEEK 8 NO N (%)	WEEK 8 MISSING N (%)
AXIAL ARTHROPATHY			
ADALIMUMAB STANDARD INDUCTION DOSE (N=333)			
YES (N=13)	6 (46.2)	7 (53.8)	0
NO (N=320)	2 (0.6)	308 (96.3)	10 (3.1)
ADALIMUMAB HIGHER INDUCTION DOSE (N=502)			
YES (N=9)	2 (22.2)	7 (77.8)	0
NO (N=493)	1 (0.2)	478 (97.0)	14 (2.8)
BRONCHIECTASIS			
ADALIMUMAB STANDARD INDUCTION DOSE (N=333)			
YES (N=0)	0	0	0
NO (N=333)	0	323 (97.0)	10 (3.0)
ADALIMUMAB HIGHER INDUCTION DOSE (N=502)			
YES (N=0)	0	0	0
NO (N=502)	0	487 (97.0)	15 (3.0)

表 2.7.3.6-98. 治験期間中の腸管外合併症の有無の変化（導入療法試験，ITT 集団，M14-033 主試験）（続き）

VARIABLE/ TREATMENT/ BASELINE VALUE	WEEK 8 YES N (%)	WEEK 8 NO N (%)	WEEK 8 MISSING N (%)
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
ADALIMUMAB STANDARD INDUCTION DOSE (N=333)			
YES (N=2)	2 (100)	0	0
NO (N=331)	0	321 (97.0)	10 (3.0)
ADALIMUMAB HIGHER INDUCTION DOSE (N=502)			
YES (N=2)	2 (100)	0	0
NO (N=500)	0	486 (97.2)	14 (2.8)
EPISCLERITIS			
ADALIMUMAB STANDARD INDUCTION DOSE (N=333)			
YES (N=0)	0	0	0
NO (N=333)	0	323 (97.0)	10 (3.0)
ADALIMUMAB HIGHER INDUCTION DOSE (N=502)			
YES (N=1)	0	1 (100)	0
NO (N=501)	0	487 (97.2)	14 (2.8)

表 2.7.3.6-98. 治験期間中の腸管外合併症の有無の変化（導入療法試験，ITT 集団，M14-033 主試験）（続き）

VARIABLE/ TREATMENT/ BASELINE VALUE	WEEK 8 YES N (%)	WEEK 8 NO N (%)	WEEK 8 MISSING N (%)
ERYTHEMA NODOSUM			
ADALIMUMAB STANDARD INDUCTION DOSE (N=333)			
YES (N=1)	0	1 (100)	0
NO (N=332)	1 (0.3)	321 (96.7)	10 (3.0)
ADALIMUMAB HIGHER INDUCTION DOSE (N=502)			
YES (N=2)	0	2 (100)	0
NO (N=500)	1 (0.2)	485 (97.0)	14 (2.8)
IRITIS			
ADALIMUMAB STANDARD INDUCTION DOSE (N=333)			
YES (N=1)	1 (100)	0	0
NO (N=332)	0	322 (97.0)	10 (3.0)
ADALIMUMAB HIGHER INDUCTION DOSE (N=502)			
YES (N=2)	1 (50.0)	1 (50.0)	0
NO (N=500)	0	486 (97.2)	14 (2.8)

表 2.7.3.6-98. 治験期間中の腸管外合併症の有無の変化（導入療法試験，ITT 集団，M14-033 主試験）（続き）

VARIABLE/ TREATMENT/ BASELINE VALUE	WEEK 8 YES N (%)	WEEK 8 NO N (%)	WEEK 8 MISSING N (%)
NEPHROLITHIASIS			
ADALIMUMAB STANDARD INDUCTION DOSE (N=333)			
YES (N=1)	0	1 (100)	0
NO (N=332)	1 (0.3)	321 (96.7)	10 (3.0)
ADALIMUMAB HIGHER INDUCTION DOSE (N=502)			
YES (N=5)	4 (80.0)	1 (20.0)	0
NO (N=497)	2 (0.4)	480 (96.6)	15 (3.0)
ORAL APHTHOUS ULCERS			
ADALIMUMAB STANDARD INDUCTION DOSE (N=333)			
YES (N=4)	1 (25.0)	3 (75.0)	0
NO (N=329)	3 (0.9)	316 (96.0)	10 (3.0)
ADALIMUMAB HIGHER INDUCTION DOSE (N=502)			
YES (N=4)	0	4 (100)	0
NO (N=498)	1 (0.2)	483 (97.0)	14 (2.8)

表 2.7.3.6-98. 治験期間中の腸管外合併症の有無の変化（導入療法試験，ITT 集団，M14-033 主試験）（続き）

VARIABLE/ TREATMENT/ BASELINE VALUE	WEEK 8 YES N (%)	WEEK 8 NO N (%)	WEEK 8 MISSING N (%)
PERIPHERAL ARTHROPATHY			
ADALIMUMAB STANDARD INDUCTION DOSE (N=333)			
YES (N=36)	15 (41.7)	21 (58.3)	0
NO (N=297)	9 (3.0)	278 (93.6)	10 (3.4)
ADALIMUMAB HIGHER INDUCTION DOSE (N=502)			
YES (N=64)	23 (35.9)	40 (62.5)	1 (1.6)
NO (N=438)	10 (2.3)	415 (94.7)	13 (3.0)
PRIMARY SCLEROSING CHOLANGITIS			
ADALIMUMAB STANDARD INDUCTION DOSE (N=333)			
YES (N=4)	2 (50.0)	2 (50.0)	0
NO (N=329)	0	319 (97.0)	10 (3.0)
ADALIMUMAB HIGHER INDUCTION DOSE (N=502)			
YES (N=2)	2 (100)	0	0
NO (N=500)	0	486 (97.2)	14 (2.8)

表 2.7.3.6-98. 治験期間中の腸管外合併症の有無の変化（導入療法試験，ITT 集団，M14-033 主試験）（続き）

VARIABLE/ TREATMENT/ BASELINE VALUE	WEEK 8 YES N (%)	WEEK 8 NO N (%)	WEEK 8 MISSING N (%)
PYODERMA GANGRENOSUM			
ADALIMUMAB STANDARD INDUCTION DOSE (N=333)			
YES (N=2)	1 (50.0)	1 (50.0)	0
NO (N=331)	0	321 (97.0)	10 (3.0)
ADALIMUMAB HIGHER INDUCTION DOSE (N=502)			
YES (N=1)	0	1 (100)	0
NO (N=501)	1 (0.2)	486 (97.0)	14 (2.8)
SWEET'S SYNDROME			
ADALIMUMAB STANDARD INDUCTION DOSE (N=333)			
YES (N=0)	0	0	0
NO (N=333)	0	323 (97.0)	10 (3.0)
ADALIMUMAB HIGHER INDUCTION DOSE (N=502)			
YES (N=0)	0	0	0
NO (N=502)	0	488 (97.2)	14 (2.8)

表 2.7.3.6-98. 治験期間中の腸管外合併症の有無の変化（導入療法試験，ITT 集団，M14-033 主試験）（続き）

VARIABLE/ TREATMENT/ BASELINE VALUE	WEEK 8 YES N (%)	WEEK 8 NO N (%)	WEEK 8 MISSING N (%)
UVEITIS			
ADALIMUMAB STANDARD INDUCTION DOSE (N=333)			
YES (N=2)	2 (100)	0	0
NO (N=331)	0	321 (97.0)	10 (3.0)
ADALIMUMAB HIGHER INDUCTION DOSE (N=502)			
YES (N=0)	0	0	0
NO (N=502)	0	488 (97.2)	14 (2.8)
VENOUS THROMBOEMBOLISM			
ADALIMUMAB STANDARD INDUCTION DOSE (N=333)			
YES (N=1)	1 (100)	0	0
NO (N=332)	0	322 (97.0)	10 (3.0)
ADALIMUMAB HIGHER INDUCTION DOSE (N=502)			
YES (N=1)	1 (100)	0	0
NO (N=501)	1 (0.2)	486 (97.0)	14 (2.8)

Cross reference: M14-033 Induction_Main study Final CSR Table 14.2__3.19

表 2.7.3.6-99. 投与 0 週時から投与 8 週時までの原因を問わない入院及び手術，又は UC に関連する入院及び手術の頻度（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）

	JAPAN ITT SET / ADALIMUMAB		INTEGRATED ITT SET / ADALIMUMAB		ITT SET / ADALIMUMAB	
	STANDARD DOSE (N=39) n (%)	HIGHER DOSE (N=61) n (%)	STANDARD DOSE (N=379) n (%)	HIGHER DOSE (N=573) n (%)	STANDARD DOSE (N=340) n (%)	HIGHER DOSE (N=512) n (%)
HOSPITALIZATIONS						
ALL-CAUSE						
YES	2 (5.1)	3 (4.9)	18 (4.7)	21 (3.7)	16 (4.7)	18 (3.5)
NO	37 (94.9)	58 (95.1)	361 (95.3)	552 (96.3)	324 (95.3)	494 (96.5)
P-VALUE		0.962		0.409		0.385
UC-RELATED						
YES	2 (5.1)	3 (4.9)	15 (4.0)	18 (3.1)	13 (3.8)	15 (2.9)
NO	37 (94.9)	58 (95.1)	364 (96.0)	555 (96.9)	327 (96.2)	497 (97.1)
P-VALUE		0.962		0.500		0.474

表 2.7.3.6-99. 投与 0 週時から投与 8 週時までの原因を問わない入院及び手術，又は UC に関連する入院及び手術の頻度（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	JAPAN ITT SET		INTEGRATED ITT SET		ITT SET	
	ADALIMUMAB		ADALIMUMAB		ADALIMUMAB	
	STANDARD DOSE (N=39) n (%)	HIGHER DOSE (N=61) n (%)	STANDARD DOSE (N=379) n (%)	HIGHER DOSE (N=573) n (%)	STANDARD DOSE (N=340) n (%)	HIGHER DOSE (N=512) n (%)
SURGERIES						
ALL-CAUSE						
YES	1 (2.6)	1 (1.6)	4 (1.1)	4 (0.7)	3 (0.9)	3 (0.6)
NO	38 (97.4)	60 (98.4)	375 (98.9)	569 (99.3)	337 (99.1)	509 (99.4)
P-VALUE		0.747		0.554		0.612
UC-RELATED						
YES	1 (2.6)	1 (1.6)	2 (0.5)	4 (0.7)	1 (0.3)	3 (0.6)
NO	38 (97.4)	60 (98.4)	377 (99.5)	569 (99.3)	339 (99.7)	509 (99.4)
P-VALUE		0.747		0.745		0.542

NOTE: P-VALUE FOR COMPARISONS BETWEEN ADALIMUMAB HIGHER INDUCTION DOSE AND ADALIMUMAB STANDARD INDUCTION DOSE USING CHI-SQUARE TEST.

Cross reference: M14-033 Induction_Japan Sub-study Final CSR Table 14.2__3.1_J

表 2.7.3.6-100. 投与 8 週時の Adapted Mayo スコア及び Mayo スコアのベースラインからの変化（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）

PARAMETER		BASELINE	VISIT	WITHIN GROUP / CHANGE FROM BASELINE					BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE)		
TREATMENT	N	MEAN	MEAN	MEAN	STD	MIN	MEDIAN	MAX	LSMEAN	95% CI	P-VALUE@
JAPAN ITT SET											
ADAPTED MAYO SCORE											
ADALIMUMAB STANDARD INDUCTION DOSE	32	6.41	4.36	-2.06	2.661	-8.2	-1.50	1.0			
ADALIMUMAB HIGHER INDUCTION DOSE	57	6.33	4.22	-2.10	2.062	-8.0	-2.00	1.2	-0.03	(-1.00, 0.94)	0.951
MAYO SCORE											
ADALIMUMAB STANDARD INDUCTION DOSE	32	8.60	5.67	-2.93	3.571	-11.2	-1.80	1.6			
ADALIMUMAB HIGHER INDUCTION DOSE	57	8.57	5.63	-2.94	2.837	-10.0	-3.00	1.4	0.05	(-1.23, 1.33)	0.940

表 2.7.3.6-100. 投与 8 週時の Adapted Mayo スコア及び Mayo スコアのベースラインからの変化（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER		BASELINE	VISIT	WITHIN GROUP / CHANGE FROM BASELINE					BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE)		
TREATMENT	N	MEAN	MEAN	MEAN	STD	MIN	MEDIAN	MAX	LSMEAN	95% CI	P-VALUE@
INTEGRATED ITT SET											
ADAPTED MAYO SCORE											
ADALIMUMAB STANDARD INDUCTION DOSE	329	6.42	4.25	-2.17	2.278	-8.2	-2.00	3.0			
ADALIMUMAB HIGHER INDUCTION DOSE	509	6.52	3.97	-2.55	2.191	-8.8	-2.20	4.8	-0.37	(-0.66, -0.07)	0.016*
MAYO SCORE											
ADALIMUMAB STANDARD INDUCTION DOSE	329	8.65	5.77	-2.88	2.863	-11.2	-2.60	3.0			
ADALIMUMAB HIGHER INDUCTION DOSE	509	8.80	5.36	-3.43	2.836	-11.8	-3.20	5.8	-0.53	(-0.92, -0.15)	0.007**

表 2.7.3.6-100. 投与 8 週時の Adapted Mayo スコア及び Mayo スコアのベースラインからの変化（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP — CHANGE FROM BASELINE — MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON — (HIGHER DOSE - STANDARD DOSE) — LSMEAN	95% CI	P-VALUE@
ITT SET											
ADAPTED MAYO SCORE											
ADALIMUMAB STANDARD INDUCTION DOSE	297	6.42	4.24	-2.18	2.237	-8.0	-2.00	3.0			
ADALIMUMAB HIGHER INDUCTION DOSE	452	6.55	3.94	-2.61	2.202	-8.8	-2.40	4.8	-0.40	(-0.71, -0.09)	0.012*
MAYO SCORE											
ADALIMUMAB STANDARD INDUCTION DOSE	297	8.65	5.78	-2.87	2.784	-10.0	-2.80	3.0			
ADALIMUMAB HIGHER INDUCTION DOSE	452	8.82	5.33	-3.49	2.833	-11.8	-3.20	5.8	-0.59	(-1.00, -0.19)	0.004**

@ P-VALUE FOR TEST OF DIFFERENCE BETWEEN ADALIMUMAB HIGHER INDUCTION DOSE AND ADALIMUMAB STANDARD INDUCTION DOSE FOR CHANGE FROM BASELINE USING ANALYSIS OF COVARIANCE WITH TREATMENT, PREVIOUS INFLIXIMAB USE, BASELINE CORTICOSTEROID USE, AND BASELINE VALUE AS COVARIATE.
***, **, *, + STATISTICALLY SIGNIFICANT AT 0.001, 0.01, 0.05 AND 0.1 LEVEL, RESPECTIVELY.

Cross reference: M14-033 Induction_Japan Sub-study Final CSR Table 14.2__3.2_J

表 2.7.3.6-101. 投与 8 週時に Adapted Mayo スコアにより寛解を達成した被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
JAPAN ITT SET		
CLINICAL REMISSION PER ADAPTED MAYO SCORE AT WEEK 8	(N=39)	(N=61)
YES, n (%)	9 (23.1)	13 (21.3)
NO, n (%)	30 (76.9)	48 (78.7)
RISK DIFFERENCE[A]		-1.8
ADJUSTED RISK DIFFERENCE[A,B]		-3.3
95% CONFIDENCE INTERVAL[B]		(-19.2, 12.5)
P-VALUE[B]		0.679

表 2.7.3.6-101. 投与 8 週時に Adapted Mayo スコアにより寛解を達成した被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
INTEGRATED ITT SET		
CLINICAL REMISSION PER ADAPTED MAYO SCORE AT WEEK 8	(N=379)	(N=573)
YES, n (%)	62 (16.4)	106 (18.5)
NO, n (%)	317 (83.6)	467 (81.5)
RISK DIFFERENCE[A]		2.1
ADJUSTED RISK DIFFERENCE[A,B]		2.3
95% CONFIDENCE INTERVAL[B]		(-2.6, 7.2)
P-VALUE[B]		0.355

表 2.7.3.6-101. 投与 8 週時に Adapted Mayo スコアにより寛解を達成した被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
ITT SET		
CLINICAL REMISSION PER ADAPTED MAYO SCORE AT WEEK 8	(N=340)	(N=512)
YES, n (%)	53 (15.6)	93 (18.2)
NO, n (%)	287 (84.4)	419 (81.8)
RISK DIFFERENCE[A]		2.6
ADJUSTED RISK DIFFERENCE[A,B]		2.8
95% CONFIDENCE INTERVAL[B]		(-2.4, 8.0)
P-VALUE[B]		0.286

CLINICAL REMISSION PER PARTIAL MAYO SCORE IS DEFINED AS PARTIAL MAYO SCORE <= 2, WITH NO SUBSCORE > 1.
[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER DOSE - ADALIMUMAB STANDARD DOSE).
[B]: ADJUSTED RISK DIFFERENCE, 95% CONFIDENCE INTERVAL FOR THE DIFFERENCE IN THE PROPORTIONS BETWEEN THE TREATMENT GROUPS AND P-VALUE WERE CALCULATED USING COCHRAN-MANTEL-HAENSZEL (CMH) TEST ADJUSTED FOR PREVIOUS INFLIXIMAB USE AND BASELINE CORTICOSTEROID USE.

Cross reference: M14-033 Induction_Japan Sub-study Final CSR Table 14.2__3.3_J

表 2.7.3.6-102. 投与 8 週時に Adapted Mayo スコアにより寛解（Mayo スコアが 2 以下で，かついずれのサブスコアも 1 を超えない）を達成した被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
JAPAN ITT SET		
CLINICAL REMISSION DEFINED AS ADAPTED MAYO SCORE <= 2 WITH NO SUBSCORE > 1 AT WEEK 8	(N=39)	(N=61)
YES, n (%)	10 (25.6)	14 (23.0)
NO, n (%)	29 (74.4)	47 (77.0)
RISK DIFFERENCE[A]		-2.7
ADJUSTED RISK DIFFERENCE[A,B]		-4.3
95% CONFIDENCE INTERVAL[B]		(-20.7, 12.1)
P-VALUE[B]		0.608

表 2.7.3.6-102. 投与 8 週時に Adapted Mayo スコアにより寛解（Mayo スコアが 2 以下で，かついずれのサブスコアも 1 を超えない）を達成した被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
INTEGRATED ITT SET		
CLINICAL REMISSION DEFINED AS ADAPTED MAYO SCORE <= 2 WITH NO SUBSCORE > 1 AT WEEK 8	(N=379)	(N=573)
YES, n (%)	72 (19.0)	121 (21.1)
NO, n (%)	307 (81.0)	452 (78.9)
RISK DIFFERENCE[A]		2.1
ADJUSTED RISK DIFFERENCE[A,B]		2.3
95% CONFIDENCE INTERVAL[B]		(-2.9, 7.5)
P-VALUE[B]		0.380

表 2.7.3.6-102. 投与 8 週時に Adapted Mayo スコアにより寛解（Mayo スコアが 2 以下で，かついずれのサブスコアも 1 を超えない）を達成した被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
ITT SET		
CLINICAL REMISSION DEFINED AS ADAPTED MAYO SCORE <= 2 WITH NO SUBSCORE > 1 AT WEEK 8	(N=340)	(N=512)
YES, n (%)	62 (18.2)	107 (20.9)
NO, n (%)	278 (81.8)	405 (79.1)
RISK DIFFERENCE[A]		2.7
ADJUSTED RISK DIFFERENCE[A,B]		2.9
95% CONFIDENCE INTERVAL[B]		(-2.5, 8.4)
P-VALUE[B]		0.294

CLINICAL REMISSION PER PARTIAL MAYO SCORE IS DEFINED AS PARTIAL MAYO SCORE <= 2, WITH NO SUBSCORE > 1.
[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER DOSE - ADALIMUMAB STANDARD DOSE).
[B]: ADJUSTED RISK DIFFERENCE, 95% CONFIDENCE INTERVAL FOR THE DIFFERENCE IN THE PROPORTIONS BETWEEN THE TREATMENT GROUPS AND P-VALUE WERE CALCULATED USING COCHRAN-MANTEL-HAENSZEL (CMH) TEST ADJUSTED FOR PREVIOUS INFLIXIMAB USE AND BASELINE CORTICOSTEROID USE.

Cross reference: M14-033 Induction_Japan Sub-study Final CSR Table 14.2__3.4_J

表 2.7.3.6-103. 評価時点ごとの PMS により寛解を達成した被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
JAPAN ITT SET		
CLINICAL REMISSION PER PARTIAL MAYO SCORE AT WEEK 1	(N=39)	(N=61)
YES, n (%)	4 (10.3)	3 (4.9)
NO, n (%)	35 (89.7)	58 (95.1)
RISK DIFFERENCE[A]		-5.3
ADJUSTED RISK DIFFERENCE[A,B]		-5.4
95% CONFIDENCE INTERVAL[B]		(-15.5, 4.7)
P-VALUE[B]		0.295
CLINICAL REMISSION PER PARTIAL MAYO SCORE AT WEEK 2	(N=39)	(N=61)
YES, n (%)	6 (15.4)	7 (11.5)
NO, n (%)	33 (84.6)	54 (88.5)
RISK DIFFERENCE[A]		-3.9
ADJUSTED RISK DIFFERENCE[A,B]		-4.2
95% CONFIDENCE INTERVAL[B]		(-17.9, 9.4)
P-VALUE[B]		0.543

表 2.7.3.6-103. 評価時点ごとの PMS により寛解を達成した被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
CLINICAL REMISSION PER PARTIAL MAYO SCORE AT WEEK 4	(N=39)	(N=61)
YES, n (%)	10 (25.6)	13 (21.3)
NO, n (%)	29 (74.4)	48 (78.7)
RISK DIFFERENCE[A]		-4.3
ADJUSTED RISK DIFFERENCE[A,B]		-5.4
95% CONFIDENCE INTERVAL[B]		(-21.6, 10.7)
P-VALUE[B]		0.509
CLINICAL REMISSION PER PARTIAL MAYO SCORE AT WEEK 8	(N=39)	(N=61)
YES, n (%)	11 (28.2)	19 (31.1)
NO, n (%)	28 (71.8)	42 (68.9)
RISK DIFFERENCE[A]		2.9
ADJUSTED RISK DIFFERENCE[A,B]		1.7
95% CONFIDENCE INTERVAL[B]		(-16.5, 19.9)
P-VALUE[B]		0.853

表 2.7.3.6-103. 評価時点ごとの PMS により寛解を達成した被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
INTEGRATED ITT SET		
CLINICAL REMISSION PER PARTIAL MAYO SCORE AT WEEK 1	(N=379)	(N=573)
YES, n (%)	24 (6.3)	35 (6.1)
NO, n (%)	355 (93.7)	538 (93.9)
RISK DIFFERENCE[A]		-0.2
ADJUSTED RISK DIFFERENCE[A,B]		-0.2
95% CONFIDENCE INTERVAL[B]		(-3.3, 2.9)
P-VALUE[B]		0.904
CLINICAL REMISSION PER PARTIAL MAYO SCORE AT WEEK 2	(N=379)	(N=573)
YES, n (%)	56 (14.8)	80 (14.0)
NO, n (%)	323 (85.2)	493 (86.0)
RISK DIFFERENCE[A]		-0.8
ADJUSTED RISK DIFFERENCE[A,B]		-0.7
95% CONFIDENCE INTERVAL[B]		(-5.3, 3.8)
P-VALUE[B]		0.754

表 2.7.3.6-103. 評価時点ごとの PMS により寛解を達成した被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
CLINICAL REMISSION PER PARTIAL MAYO SCORE AT WEEK 4	(N=379)	(N=573)
YES, n (%)	73 (19.3)	143 (25.0)
NO, n (%)	306 (80.7)	430 (75.0)
RISK DIFFERENCE[A]		5.7
ADJUSTED RISK DIFFERENCE[A,B]		5.8
95% CONFIDENCE INTERVAL[B]		(0.4, 11.3)
P-VALUE[B]		0.036*
CLINICAL REMISSION PER PARTIAL MAYO SCORE AT WEEK 8	(N=379)	(N=573)
YES, n (%)	96 (25.3)	167 (29.1)
NO, n (%)	283 (74.7)	406 (70.9)
RISK DIFFERENCE[A]		3.8
ADJUSTED RISK DIFFERENCE[A,B]		4.0
95% CONFIDENCE INTERVAL[B]		(-1.7, 9.8)
P-VALUE[B]		0.171

表 2.7.3.6-103. 評価時点ごとの PMS により寛解を達成した被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
ITT SET		
CLINICAL REMISSION PER PARTIAL MAYO SCORE AT WEEK 1	(N=340)	(N=512)
YES, n (%)	20 (5.9)	32 (6.3)
NO, n (%)	320 (94.1)	480 (93.8)
RISK DIFFERENCE[A]		0.4
ADJUSTED RISK DIFFERENCE[A,B]		0.4
95% CONFIDENCE INTERVAL[B]		(-2.9, 3.7)
P-VALUE[B]		0.821
CLINICAL REMISSION PER PARTIAL MAYO SCORE AT WEEK 2	(N=340)	(N=512)
YES, n (%)	50 (14.7)	73 (14.3)
NO, n (%)	290 (85.3)	439 (85.7)
RISK DIFFERENCE[A]		-0.4
ADJUSTED RISK DIFFERENCE[A,B]		-0.3
95% CONFIDENCE INTERVAL[B]		(-5.2, 4.5)
P-VALUE[B]		0.889

表 2.7.3.6-103. 評価時点ごとの PMS により寛解を達成した被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
CLINICAL REMISSION PER PARTIAL MAYO SCORE AT WEEK 4	(N=340)	(N=512)
YES, n (%)	63 (18.5)	130 (25.4)
NO, n (%)	277 (81.5)	382 (74.6)
RISK DIFFERENCE[A]		6.9
ADJUSTED RISK DIFFERENCE[A,B]		6.9
95% CONFIDENCE INTERVAL[B]		(1.2, 12.7)
P-VALUE[B]		0.018*
CLINICAL REMISSION PER PARTIAL MAYO SCORE AT WEEK 8	(N=340)	(N=512)
YES, n (%)	85 (25.0)	148 (28.9)
NO, n (%)	255 (75.0)	364 (71.1)
RISK DIFFERENCE[A]		3.9
ADJUSTED RISK DIFFERENCE[A,B]		4.2
95% CONFIDENCE INTERVAL[B]		(-1.9, 10.3)
P-VALUE[B]		0.181

CLINICAL REMISSION PER PARTIAL MAYO SCORE IS DEFINED AS PARTIAL MAYO SCORE <= 2, WITH NO SUBSCORE > 1.
[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER DOSE - ADALIMUMAB STANDARD DOSE).
[B]: ADJUSTED RISK DIFFERENCE, 95% CONFIDENCE INTERVAL FOR THE DIFFERENCE IN THE PROPORTIONS BETWEEN THE TREATMENT GROUPS AND P-VALUE WERE CALCULATED USING COCHRAN-MANTEL-HAENSZEL (CMH) TEST ADJUSTED FOR PREVIOUS INFLIXIMAB USE AND BASELINE CORTICOSTEROID USE.
***, **, *, + STATISTICALLY SIGNIFICANT AT 0.001, 0.01, 0.05 AND 0.1 LEVEL, RESPECTIVELY.

Cross reference: M14-033 Induction_Japan Sub-study Final CSR Table 14.2__3.5_J

表 2.7.3.6-104. 評価時点ごとの PMS により改善を達成した被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
JAPAN ITT SET		
CLINICAL RESPONSE PER PARTIAL MAYO SCORE AT WEEK 1	(N=39)	(N=61)
YES, n (%)	9 (23.1)	9 (14.8)
NO, n (%)	30 (76.9)	52 (85.2)
RISK DIFFERENCE[A]		-8.3
ADJUSTED RISK DIFFERENCE[A,B]		-8.7
95% CONFIDENCE INTERVAL[B]		(-24.1, 6.7)
P-VALUE[B]		0.267
CLINICAL RESPONSE PER PARTIAL MAYO SCORE AT WEEK 2	(N=39)	(N=61)
YES, n (%)	10 (25.6)	24 (39.3)
NO, n (%)	29 (74.4)	37 (60.7)
RISK DIFFERENCE[A]		13.7
ADJUSTED RISK DIFFERENCE[A,B]		13.4
95% CONFIDENCE INTERVAL[B]		(-5.8, 32.6)
P-VALUE[B]		0.173

表 2.7.3.6-104. 評価時点ごとの PMS により改善を達成した被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
CLINICAL RESPONSE PER PARTIAL MAYO SCORE AT WEEK 4	(N=39)	(N=61)
YES, n (%)	16 (41.0)	29 (47.5)
NO, n (%)	23 (59.0)	32 (52.5)
RISK DIFFERENCE[A]		6.5
ADJUSTED RISK DIFFERENCE[A,B]		5.8
95% CONFIDENCE INTERVAL[B]		(-14.4, 25.9)
P-VALUE[B]		0.576
CLINICAL RESPONSE PER PARTIAL MAYO SCORE AT WEEK 8	(N=39)	(N=61)
YES, n (%)	14 (35.9)	30 (49.2)
NO, n (%)	25 (64.1)	31 (50.8)
RISK DIFFERENCE[A]		13.3
ADJUSTED RISK DIFFERENCE[A,B]		12.0
95% CONFIDENCE INTERVAL[B]		(-7.6, 31.6)
P-VALUE[B]		0.229

表 2.7.3.6-104. 評価時点ごとの PMS により改善を達成した被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
INTEGRATED ITT SET		
CLINICAL RESPONSE PER PARTIAL MAYO SCORE AT WEEK 1	(N=379)	(N=573)
YES, n (%)	90 (23.7)	151 (26.4)
NO, n (%)	289 (76.3)	422 (73.6)
RISK DIFFERENCE[A]		2.6
ADJUSTED RISK DIFFERENCE[A,B]		2.5
95% CONFIDENCE INTERVAL[B]		(-3.1, 8.2)
P-VALUE[B]		0.383
CLINICAL RESPONSE PER PARTIAL MAYO SCORE AT WEEK 2	(N=379)	(N=573)
YES, n (%)	142 (37.5)	235 (41.0)
NO, n (%)	237 (62.5)	338 (59.0)
RISK DIFFERENCE[A]		3.5
ADJUSTED RISK DIFFERENCE[A,B]		3.6
95% CONFIDENCE INTERVAL[B]		(-2.8, 10.0)
P-VALUE[B]		0.267

表 2.7.3.6-104. 評価時点ごとの PMS により改善を達成した被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
CLINICAL RESPONSE PER PARTIAL MAYO SCORE AT WEEK 4	(N=379)	(N=573)
YES, n (%)	174 (45.9)	304 (53.1)
NO, n (%)	205 (54.1)	269 (46.9)
RISK DIFFERENCE[A]		7.1
ADJUSTED RISK DIFFERENCE[A,B]		7.3
95% CONFIDENCE INTERVAL[B]		(0.8, 13.8)
P-VALUE[B]		0.027*
CLINICAL RESPONSE PER PARTIAL MAYO SCORE AT WEEK 8	(N=379)	(N=573)
YES, n (%)	176 (46.4)	305 (53.2)
NO, n (%)	203 (53.6)	268 (46.8)
RISK DIFFERENCE[A]		6.8
ADJUSTED RISK DIFFERENCE[A,B]		7.1
95% CONFIDENCE INTERVAL[B]		(0.6, 13.5)
P-VALUE[B]		0.031*

表 2.7.3.6-104. 評価時点ごとの PMS により改善を達成した被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
ITT SET		
CLINICAL RESPONSE PER PARTIAL MAYO SCORE AT WEEK 1	(N=340)	(N=512)
YES, n (%)	81 (23.8)	142 (27.7)
NO, n (%)	259 (76.2)	370 (72.3)
RISK DIFFERENCE[A]		3.9
ADJUSTED RISK DIFFERENCE[A,B]		3.8
95% CONFIDENCE INTERVAL[B]		(-2.3, 9.8)
P-VALUE[B]		0.222
CLINICAL RESPONSE PER PARTIAL MAYO SCORE AT WEEK 2	(N=340)	(N=512)
YES, n (%)	132 (38.8)	211 (41.2)
NO, n (%)	208 (61.2)	301 (58.8)
RISK DIFFERENCE[A]		2.4
ADJUSTED RISK DIFFERENCE[A,B]		2.4
95% CONFIDENCE INTERVAL[B]		(-4.3, 9.2)
P-VALUE[B]		0.476

表 2.7.3.6-104. 評価時点ごとの PMS により改善を達成した被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
CLINICAL RESPONSE PER PARTIAL MAYO SCORE AT WEEK 4	(N=340)	(N=512)
YES, n (%)	158 (46.5)	275 (53.7)
NO, n (%)	182 (53.5)	237 (46.3)
RISK DIFFERENCE[A]		7.2
ADJUSTED RISK DIFFERENCE[A,B]		7.4
95% CONFIDENCE INTERVAL[B]		(0.6, 14.3)
P-VALUE[B]		0.034*
CLINICAL RESPONSE PER PARTIAL MAYO SCORE AT WEEK 8	(N=340)	(N=512)
YES, n (%)	162 (47.6)	275 (53.7)
NO, n (%)	178 (52.4)	237 (46.3)
RISK DIFFERENCE[A]		6.1
ADJUSTED RISK DIFFERENCE[A,B]		6.4
95% CONFIDENCE INTERVAL[B]		(-0. 4, 13.2)
P-VALUE[B]		0.07+

CLINICAL REMISSION PER PARTIAL MAYO SCORE IS DEFINED AS PARTIAL MAYO SCORE <= 2, WITH NO SUBSCORE > 1.
[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER DOSE - ADALIMUMAB STANDARD DOSE).
[B]: ADJUSTED RISK DIFFERENCE, 95% CONFIDENCE INTERVAL FOR THE DIFFERENCE IN THE PROPORTIONS BETWEEN THE TREATMENT GROUPS AND P-VALUE WERE CALCULATED USING COCHRAN-MANTEL-HAENSZEL (CMH) TEST ADJUSTED FOR PREVIOUS INFLIXIMAB USE AND BASELINE CORTICOSTEROID USE.
***, **, *, + STATISTICALLY SIGNIFICANT AT 0.001, 0.01, 0.05 AND 0.1 LEVEL, RESPECTIVELY.

Cross reference: M14-033 Induction_Japan Sub-study Final CSR Table 14.2__3.6_J

表 2.7.3.6-105. 投与 8 週時の排便回数サブスコア，直腸出血サブスコア，及び内視鏡的サブスコアが 0 であった被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
JAPAN ITT SET		
SFS = 0, RBS = 0 AND ENDOSCOPIC SUBSCORE = 0 AT WEEK 8	(N=39)	(N=61)
YES, n (%)	1 (2.6)	1 (1.6)
NO, n (%)	38 (97.4)	60 (98.4)
RISK DIFFERENCE[A]		-0.9
ADJUSTED RISK DIFFERENCE[A,B]		-1.2
95% CONFIDENCE INTERVAL[B]		(-6.8, 4.4)
P-VALUE[B]		0.673

表 2.7.3.6-105. 投与 8 週時の排便回数サブスコア，直腸出血サブスコア，及び内視鏡的サブスコアが 0 であった被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
INTEGRATED ITT SET		
SFS = 0, RBS = 0 AND ENDOSCOPIC SUBSCORE = 0 AT WEEK 8	(N=379)	(N=573)
YES, n (%)	4 (1.1)	13 (2.3)
NO, n (%)	375 (98.9)	560 (97.7)
RISK DIFFERENCE[A]		1.2
ADJUSTED RISK DIFFERENCE[A,B]		1.3
95% CONFIDENCE INTERVAL[B]		(-0.5, 3.0)
P-VALUE[B]		0.152

表 2.7.3.6-105. 投与 8 週時の排便回数サブスコア，直腸出血サブスコア，及び内視鏡的サブスコアが 0 であった被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
ITT SET		
SFS = 0, RBS = 0 AND ENDOSCOPIC SUBSCORE = 0 AT WEEK 8	(N=340)	(N=512)
YES, n (%)	3 (0.9)	12 (2.3)
NO, n (%)	337 (99.1)	500 (97.7)
RISK DIFFERENCE[A]		1.5
ADJUSTED RISK DIFFERENCE[A,B]		1.5
95% CONFIDENCE INTERVAL[B]		(-0.3, 3.3)
P-VALUE[B]		0.101

CLINICAL REMISSION PER PARTIAL MAYO SCORE IS DEFINED AS PARTIAL MAYO SCORE <= 2, WITH NO SUBSCORE > 1.
[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER DOSE - ADALIMUMAB STANDARD DOSE).
[B]: ADJUSTED RISK DIFFERENCE, 95% CONFIDENCE INTERVAL FOR THE DIFFERENCE IN THE PROPORTIONS BETWEEN THE TREATMENT GROUPS AND P-VALUE WERE CALCULATED USING COCHRAN-MANTEL-HAENSZEL (CMH) TEST ADJUSTED FOR PREVIOUS INFLIXIMAB USE AND BASELINE CORTICOSTEROID USE.

Cross reference: M14-033 Induction_Japan Sub-study Final CSR Table 14.2__3.7_J

表 2.7.3.6-106. 評価時点ごとの排便回数サブスコアが 1 以下であった被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
JAPAN ITT SET		
SFS <= 1 AT WEEK 1	(N=39)	(N=61)
YES, n (%)	10 (25.6)	8 (13.1)
NO, n (%)	29 (74.4)	53 (86.9)
RISK DIFFERENCE[A]		-12.5
ADJUSTED RISK DIFFERENCE[A,B]		-12.8
95% CONFIDENCE INTERVAL[B]		(-28.1, 2.5)
P-VALUE[B]		0.101
SFS <= 1 AT WEEK 2	(N=39)	(N=61)
YES, n (%)	7 (17.9)	15 (24.6)
NO, n (%)	32 (82.1)	46 (75.4)
RISK DIFFERENCE[A]		6.6
ADJUSTED RISK DIFFERENCE[A,B]		6.2
95% CONFIDENCE INTERVAL[B]		(-10.5, 22.8)
P-VALUE[B]		0.470

表 2.7.3.6-106. 評価時点ごとの排便回数サブスコアが 1 以下であった被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
SFS <= 1 AT WEEK 4	(N=39)	(N=61)
YES, n (%)	13 (33.3)	19 (31.1)
NO, n (%)	26 (66.7)	42 (68.9)
RISK DIFFERENCE[A]		-2.2
ADJUSTED RISK DIFFERENCE[A,B]		-2.8
95% CONFIDENCE INTERVAL[B]		(-21.7, 16.1)
P-VALUE[B]		0.770
SFS <= 1 AT WEEK 8	(N=39)	(N=61)
YES, n (%)	14 (35.9)	24 (39.3)
NO, n (%)	25 (64.1)	37 (60.7)
RISK DIFFERENCE[A]		3.4
ADJUSTED RISK DIFFERENCE[A,B]		2.6
95% CONFIDENCE INTERVAL[B]		(-17.1, 22.2)
P-VALUE[B]		0.798

表 2.7.3.6-106. 評価時点ごとの排便回数サブスコアが 1 以下であった被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
INTEGRATED ITT SET		
SFS <= 1 AT WEEK 1	(N=379)	(N=573)
YES, n (%)	79 (20.8)	107 (18.7)
NO, n (%)	300 (79.2)	466 (81.3)
RISK DIFFERENCE[A]		-2.2
ADJUSTED RISK DIFFERENCE[A,B]		-2.2
95% CONFIDENCE INTERVAL[B]		(-7.4, 2.9)
P-VALUE[B]		0.395
SFS <= 1 AT WEEK 2	(N=379)	(N=573)
YES, n (%)	104 (27.4)	158 (27.6)
NO, n (%)	275 (72.6)	415 (72.4)
RISK DIFFERENCE[A]		0.1
ADJUSTED RISK DIFFERENCE[A,B]		0.2
95% CONFIDENCE INTERVAL[B]		(-5.6, 6.0)
P-VALUE[B]		0.957

表 2.7.3.6-106. 評価時点ごとの排便回数サブスコアが 1 以下であった被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
SFS <= 1 AT WEEK 4	(N=379)	(N=573)
YES, n (%)	121 (31.9)	222 (38.7)
NO, n (%)	258 (68.1)	351 (61.3)
RISK DIFFERENCE[A]		6.8
ADJUSTED RISK DIFFERENCE[A,B]		6.9
95% CONFIDENCE INTERVAL[B]		(0.6, 13.1)
P-VALUE[B]		0.031*
SFS <= 1 AT WEEK 8	(N=379)	(N=573)
YES, n (%)	128 (33.8)	223 (38.9)
NO, n (%)	251 (66.2)	350 (61.1)
RISK DIFFERENCE[A]		5.1
ADJUSTED RISK DIFFERENCE[A,B]		5.3
95% CONFIDENCE INTERVAL[B]		(-1.0, 11.5)
P-VALUE[B]		0.098+

表 2.7.3.6-106. 評価時点ごとの排便回数サブスコアが 1 以下であった被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
ITT SET		
SFS <= 1 AT WEEK 1	(N=340)	(N=512)
YES, n (%)	69 (20.3)	99 (19.3)
NO, n (%)	271 (79.7)	413 (80.7)
RISK DIFFERENCE[A]		-1.0
ADJUSTED RISK DIFFERENCE[A,B]		-1.1
95% CONFIDENCE INTERVAL[B]		(-6.5, 4.4)
P-VALUE[B]		0.698
SFS <= 1 AT WEEK 2	(N=340)	(N=512)
YES, n (%)	97 (28.5)	143 (27.9)
NO, n (%)	243 (71.5)	369 (72.1)
RISK DIFFERENCE[A]		-0.6
ADJUSTED RISK DIFFERENCE[A,B]		-0.6
95% CONFIDENCE INTERVAL[B]		(-6.8, 5.6)
P-VALUE[B]		0.849

表 2.7.3.6-106. 評価時点ごとの排便回数サブスコアが 1 以下であった被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
SFS <= 1 AT WEEK 4	(N=340)	(N=512)
YES, n (%)	108 (31.8)	203 (39.6)
NO, n (%)	232 (68.2)	309 (60.4)
RISK DIFFERENCE[A]		7.9
ADJUSTED RISK DIFFERENCE[A,B]		7.9
95% CONFIDENCE INTERVAL[B]		(1.3, 14.5)
P-VALUE[B]		0.019*
SFS <= 1 AT WEEK 8	(N=340)	(N=512)
YES, n (%)	114 (33.5)	199 (38.9)
NO, n (%)	226 (66.5)	313 (61.1)
RISK DIFFERENCE[A]		5.3
ADJUSTED RISK DIFFERENCE[A,B]		5.5
95% CONFIDENCE INTERVAL[B]		(-1.1, 12.1)
P-VALUE[B]		0.103

CLINICAL REMISSION PER PARTIAL MAYO SCORE IS DEFINED AS PARTIAL MAYO SCORE <= 2, WITH NO SUBSCORE > 1.
[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER DOSE - ADALIMUMAB STANDARD DOSE).
[B]: ADJUSTED RISK DIFFERENCE, 95% CONFIDENCE INTERVAL FOR THE DIFFERENCE IN THE PROPORTIONS BETWEEN THE TREATMENT GROUPS AND P-VALUE WERE CALCULATED USING COCHRAN-MANTEL-HAENSZEL (CMH) TEST ADJUSTED FOR PREVIOUS INFLIXIMAB USE AND BASELINE CORTICOSTEROID USE.
***, **, *, + STATISTICALLY SIGNIFICANT AT 0.001, 0.01, 0.05 AND 0.1 LEVEL, RESPECTIVELY.

Cross reference: M14-033 Induction_Japan Sub-study Final CSR Table 14.2__3.8_J

表 2.7.3.6-107. 評価時点ごとの直腸出血サブスコアが 0 以下であった被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
JAPAN ITT SET		
RBS = 0 AT WEEK 1	(N=39)	(N=61)
YES, n (%)	6 (15.4)	10 (16.4)
NO, n (%)	33 (84.6)	51 (83.6)
RISK DIFFERENCE[A]		1.0
ADJUSTED RISK DIFFERENCE[A,B]		1.3
95% CONFIDENCE INTERVAL[B]		(-13.6, 16.2)
P-VALUE[B]		0.866
RBS = 0 AT WEEK 2	(N=39)	(N=61)
YES, n (%)	8 (20.5)	18 (29.5)
NO, n (%)	31 (79.5)	43 (70.5)
RISK DIFFERENCE[A]		9.0
ADJUSTED RISK DIFFERENCE[A,B]		9.1
95% CONFIDENCE INTERVAL[B]		(-8.9, 27.0)
P-VALUE[B]		0.323

表 2.7.3.6-107. 評価時点ごとの直腸出血サブスコアが 0 以下であった被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
RBS = 0 AT WEEK 4	(N=39)	(N=61)
YES, n (%)	12 (30.8)	24 (39.3)
NO, n (%)	27 (69.2)	37 (60.7)
RISK DIFFERENCE[A]		8.6
ADJUSTED RISK DIFFERENCE[A,B]		7.3
95% CONFIDENCE INTERVAL[B]		(-11.7, 26.3)
P-VALUE[B]		0.453
RBS = 0 AT WEEK 8	(N=39)	(N=61)
YES, n (%)	11 (28.2)	28 (45.9)
NO, n (%)	28 (71.8)	33 (54.1)
RISK DIFFERENCE[A]		17.7
ADJUSTED RISK DIFFERENCE[A,B]		16.1
95% CONFIDENCE INTERVAL[B]		(-2.7, 34.9)
P-VALUE[B]		0.094+

表 2.7.3.6-107. 評価時点ごとの直腸出血サブスコアが 0 以下であった被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
INTEGRATED ITT SET		
RBS = 0 AT WEEK 1	(N=379)	(N=573)
YES, n (%)	44 (11.6)	73 (12.7)
NO, n (%)	335 (88.4)	500 (87.3)
RISK DIFFERENCE[A]		1.1
ADJUSTED RISK DIFFERENCE[A,B]		1.1
95% CONFIDENCE INTERVAL[B]		(-3.2, 5.4)
P-VALUE[B]		0.616
RBS = 0 AT WEEK 2	(N=379)	(N=573)
YES, n (%)	90 (23.7)	147 (25.7)
NO, n (%)	289 (76.3)	426 (74.3)
RISK DIFFERENCE[A]		1.9
ADJUSTED RISK DIFFERENCE[A,B]		2.0
95% CONFIDENCE INTERVAL[B]		(-3.6, 7.6)
P-VALUE[B]		0.484

表 2.7.3.6-107. 評価時点ごとの直腸出血サブスコアが 0 以下であった被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
RBS = 0 AT WEEK 4	(N=379)	(N=573)
YES, n (%)	120 (31.7)	215 (37.5)
NO, n (%)	259 (68.3)	358 (62.5)
RISK DIFFERENCE[A]		5.9
ADJUSTED RISK DIFFERENCE[A,B]		6.1
95% CONFIDENCE INTERVAL[B]		(-0.1, 12.3)
P-VALUE[B]		0.054+
RBS = 0 AT WEEK 8	(N=379)	(N=573)
YES, n (%)	132 (34.8)	237 (41.4)
NO, n (%)	247 (65.2)	336 (58.6)
RISK DIFFERENCE[A]		6.5
ADJUSTED RISK DIFFERENCE[A,B]		6.8
95% CONFIDENCE INTERVAL[B]		(0.5, 13.1)
P-VALUE[B]		0.034*

表 2.7.3.6-107. 評価時点ごとの直腸出血サブスコアが 0 以下であった被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
ITT SET		
RBS = 0 AT WEEK 1	(N=340)	(N=512)
YES, n (%)	38 (11.2)	63 (12.3)
NO, n (%)	302 (88.8)	449 (87.7)
RISK DIFFERENCE[A]		1.1
ADJUSTED RISK DIFFERENCE[A,B]		1.1
95% CONFIDENCE INTERVAL[B]		(-3.3, 5.6)
P-VALUE[B]		0.615
RBS = 0 AT WEEK 2	(N=340)	(N=512)
YES, n (%)	82 (24.1)	129 (25.2)
NO, n (%)	258 (75.9)	383 (74.8)
RISK DIFFERENCE[A]		1.1
ADJUSTED RISK DIFFERENCE[A,B]		1.2
95% CONFIDENCE INTERVAL[B]		(-4.7, 7.2)
P-VALUE[B]		0.684

表 2.7.3.6-107. 評価時点ごとの直腸出血サブスコアが 0 以下であった被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
RBS = 0 AT WEEK 4	(N=340)	(N=512)
YES, n (%)	108 (31.8)	191 (37.3)
NO, n (%)	232 (68.2)	321 (62.7)
RISK DIFFERENCE[A]		5.5
ADJUSTED RISK DIFFERENCE[A,B]		5.8
95% CONFIDENCE INTERVAL[B]		(-0.7, 12.3)
P-VALUE[B]		0.083+
RBS = 0 AT WEEK 8	(N=340)	(N=512)
YES, n (%)	121 (35.6)	209 (40.8)
NO, n (%)	219 (64.4)	303 (59.2)
RISK DIFFERENCE[A]		5.2
ADJUSTED RISK DIFFERENCE[A,B]		5.5
95% CONFIDENCE INTERVAL[B]		(-1.1, 12.2)
P-VALUE[B]		0.102

[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER DOSE - ADALIMUMAB STANDARD DOSE).
[B]: ADJUSTED RISK DIFFERENCE, 95% CONFIDENCE INTERVAL FOR THE DIFFERENCE IN THE PROPORTIONS BETWEEN THE TREATMENT GROUPS AND P-VALUE WERE CALCULATED USING COCHRAN-MANTEL-HAENSZEL (CMH) TEST ADJUSTED FOR PREVIOUS INFLIXIMAB USE AND BASELINE CORTICOSTEROID USE.
***, **, *, + STATISTICALLY SIGNIFICANT AT 0.001, 0.01, 0.05 AND 0.1 LEVEL, RESPECTIVELY.

Cross reference: M14-033 Induction_Japan Sub-study Final CSR Table 14.2__3.9_J

表 2.7.3.6-108. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP / CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
JAPAN ITT SET											
AVERAGE RECTAL BLEEDING SUBSCORE											
WEEK 1											
ADALIMUMAB STANDARD INDUCTION DOSE	39	1.62	1.28	-0.34	0.721	-2.8	-0.20	0.8			
ADALIMUMAB HIGHER INDUCTION DOSE	59	1.52	1.15	-0.36	0.581	-2.2	-0.20	1.0	-0.05	(-0.29, 0.19)	0.698
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	33	1.61	1.09	-0.52	0.959	-3.0	-0.20	1.0			
ADALIMUMAB HIGHER INDUCTION DOSE	61	1.53	0.99	-0.54	0.758	-3.0	-0.60	1.8	-0.06	(-0.37, 0.26)	0.711
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	37	1.60	1.02	-0.58	1.094	-3.0	-0.20	1.2			
ADALIMUMAB HIGHER INDUCTION DOSE	60	1.55	0.83	-0.73	0.971	-3.0	-0.80	1.6	-0.18	(-0.54, 0.17)	0.309
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	35	1.54	0.80	-0.74	1.095	-3.0	-0.60	1.4			
ADALIMUMAB HIGHER INDUCTION DOSE	57	1.54	0.70	-0.84	0.978	-3.0	-0.60	1.2	-0.11	(-0.46, 0.23)	0.520

表 2.7.3.6-108. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
AVERAGE STOOL FREQUENCY SUBSCORE											
WEEK 1											
ADALIMUMAB STANDARD INDUCTION DOSE	39	2.52	2.03	-0.49	0.599	-2.2	-0.40	0.3			
ADALIMUMAB HIGHER INDUCTION DOSE	59	2.39	2.08	-0.31	0.520	-2.4	-0.20	0.4	0.19	(-0.04, 0.41)	0.099+
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	33	2.48	1.99	-0.49	0.795	-2.4	-0.20	1.2			
ADALIMUMAB HIGHER INDUCTION DOSE	61	2.38	1.94	-0.44	0.589	-2.2	-0.20	0.6	0.02	(-0.26, 0.30)	0.897
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	37	2.57	1.83	-0.74	0.873	-2.8	-0.40	0.2			
ADALIMUMAB HIGHER INDUCTION DOSE	60	2.37	1.76	-0.61	0.760	-2.2	-0.60	1.4	0.07	(-0.27, 0.41)	0.676
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	35	2.54	1.85	-0.70	0.900	-2.8	-0.20	0.2			
ADALIMUMAB HIGHER INDUCTION DOSE	57	2.37	1.58	-0.79	0.893	-3.0	-0.80	1.4	-0.11	(-0.49, 0.27)	0.561

表 2.7.3.6-108. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER				WITHIN GROUP					BETWEEN GROUP COMPARISON		
VISIT		BASELINE	VISIT	CHANGE FROM BASELINE					(HIGHER DOSE - STANDARD DOSE)		
TREATMENT	N	MEAN	MEAN	MEAN	STD	MIN	MEDIAN	MAX	LSMEAN	95% CI	P-VALUE@
ENDOSCOPY SUBSCORE											
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	33	2.3	1.8	-0.5	0.97	-3	0.0	1			
ADALIMUMAB HIGHER INDUCTION DOSE	57	2.4	1.9	-0.5	1.05	-3	0.0	1	0.1	(-0.3, 0.5)	0.657

表 2.7.3.6-108. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
PHYSICIAN'S GLOBAL ASSESSMENT SUBSCORE											
WEEK 1											
ADALIMUMAB STANDARD INDUCTION DOSE	39	2.2	1.8	-0.5	0.76	-3	0.0	1			
ADALIMUMAB HIGHER INDUCTION DOSE	61	2.2	1.8	-0.5	0.70	-3	0.0	0	0.0	(-0.3, 0.3)	0.960
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	35	2.2	1.7	-0.5	0.89	-3	0.0	1			
ADALIMUMAB HIGHER INDUCTION DOSE	61	2.2	1.6	-0.7	0.83	-3	-1.0	1	-0.1	(-0.4, 0.2)	0.439
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	37	2.2	1.4	-0.9	0.92	-3	-1.0	1			
ADALIMUMAB HIGHER INDUCTION DOSE	60	2.3	1.5	-0.8	0.94	-3	-1.0	1	0.1	(-0.3, 0.4)	0.674
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	35	2.2	1.4	-0.8	1.03	-3	-1.0	1			
ADALIMUMAB HIGHER INDUCTION DOSE	57	2.2	1.4	-0.8	0.94	-3	-1.0	1	0.0	(-0.4, 0.4)	0.972

表 2.7.3.6-108. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
PARTIAL MAYO SCORE											
WEEK 1											
ADALIMUMAB STANDARD INDUCTION DOSE	39	6.37	5.07	-1.30	1.660	-8.0	-0.80	1.1			
ADALIMUMAB HIGHER INDUCTION DOSE	59	6.14	5.00	-1.14	1.395	-6.6	-0.80	1.2	0.11	(-0.48, 0.70)	0.713
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	33	6.33	4.75	-1.58	2.343	-8.2	-1.20	1.8			
ADALIMUMAB HIGHER INDUCTION DOSE	61	6.16	4.49	-1.67	1.627	-6.2	-1.80	2.2	-0.19	(-0.95, 0.57)	0.622
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	37	6.41	4.22	-2.19	2.489	-8.8	-1.60	1.4			
ADALIMUMAB HIGHER INDUCTION DOSE	60	6.18	4.04	-2.14	2.243	-8.2	-1.90	2.4	-0.08	(-0.99, 0.82)	0.855
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	35	6.29	4.07	-2.21	2.722	-8.8	-1.20	1.6			
ADALIMUMAB HIGHER INDUCTION DOSE	57	6.15	3.68	-2.47	2.348	-8.0	-2.20	1.4	-0.24	(-1.23, 0.74)	0.621

表 2.7.3.6-108. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
INTEGRATED ITT SET											
AVERAGE RECTAL BLEEDING SUBSCORE											
WEEK 1											
ADALIMUMAB STANDARD INDUCTION DOSE	374	1.70	1.25	-0.45	0.683	-3.0	-0.40	2.0			
ADALIMUMAB HIGHER INDUCTION DOSE	563	1.75	1.19	-0.57	0.752	-3.0	-0.40	1.2	-0.10	(-0.19, -0.01)	0.027*
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	359	1.69	1.01	-0.68	0.906	-3.0	-0.40	2.2			
ADALIMUMAB HIGHER INDUCTION DOSE	551	1.73	0.96	-0.77	0.912	-3.0	-0.60	2.4	-0.08	(-0.18, 0.03)	0.157
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	368	1.68	0.88	-0.79	0.948	-3.0	-0.80	2.4			
ADALIMUMAB HIGHER INDUCTION DOSE	558	1.75	0.79	-0.96	1.024	-3.0	-1.00	2.8	-0.14	(-0.25, -0.03)	0.012*
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	350	1.67	0.81	-0.86	1.058	-3.0	-0.80	2.0			
ADALIMUMAB HIGHER INDUCTION DOSE	538	1.73	0.71	-1.02	1.064	-3.0	-1.00	2.4	-0. 17	(-0.28, -0.05)	0.006**

表 2.7.3.6-108. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
AVERAGE STOOL FREQUENCY SUBSCORE											
WEEK 1											
ADALIMUMAB STANDARD INDUCTION DOSE	374	2.42	1.99	-0.43	0.627	-2.8	-0.30	1.4			
ADALIMUMAB HIGHER INDUCTION DOSE	563	2.46	2.02	-0.45	0.608	-3.0	-0.20	1.2	-0.01	(-0.09, 0.07)	0.771
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	359	2.41	1.85	-0.56	0.778	-3.0	-0.40	1.8			
ADALIMUMAB HIGHER INDUCTION DOSE	551	2.46	1.82	-0.64	0.730	-3.0	-0.60	1.2	-0.08	(-0.18, 0.01)	0.094+
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	368	2.43	1.72	-0.71	0.830	-3.0	-0.60	1.4			
ADALIMUMAB HIGHER INDUCTION DOSE	558	2.46	1.60	-0.86	0.883	-3.0	-0.80	1.8	-0.15	(-0.26, -0.04)	0.008**
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	350	2.43	1.66	-0.77	0.939	-3.0	-0.60	1.6			
ADALIMUMAB HIGHER INDUCTION DOSE	538	2.45	1.53	-0.92	0.953	-3.0	-1.00	1.8	-0.16	(-0.28, -0.04)	0.011*

表 2.7.3.6-108. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER VISIT TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
ENDOSCOPY SUBSCORE											
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	332	2.3	1.8	-0.5	0.89	-3	0.0	1			
ADALIMUMAB HIGHER INDUCTION DOSE	518	2.4	1.8	-0.6	0.95	-3	0.0	1	-0.1	(-0.2, 0.1)	0.290

表 2.7.3.6-108. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
PHYSICIAN'S GLOBAL ASSESSMENT SUBSCORE											
WEEK 1											
ADALIMUMAB STANDARD INDUCTION DOSE	374	2.3	1.9	-0.4	0.61	-3	0.0	1			
ADALIMUMAB HIGHER INDUCTION DOSE	568	2.3	1.8	-0.4	0.66	-3	0.0	1	-0.1	(-0.1, 0.0)	0.166
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	361	2.2	1.7	-0.5	0.68	-3	0.0	1			
ADALIMUMAB HIGHER INDUCTION DOSE	555	2.3	1.6	-0.6	0.75	-3	-1.0	1	-0.1	(-0.2, 0.0)	0.136
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	368	2.3	1.6	-0.7	0.78	-3	-1.0	1			
ADALIMUMAB HIGHER INDUCTION DOSE	561	2.3	1.5	-0.8	0.84	-3	-1.0	1	-0.1	(-0.2, -0.0)	0.019*
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	350	2.2	1.5	-0.7	0.86	-3	-1.0	1			
ADALIMUMAB HIGHER INDUCTION DOSE	542	2.3	1.4	-0.9	0.90	-3	-1.0	1	-0.1	(-0.2, -0.0)	0.036*

表 2.7.3.6-108. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
PARTIAL MAYO SCORE											
WEEK 1											
ADALIMUMAB STANDARD INDUCTION DOSE	374	6.37	5.12	-1.24	1.425	-8.0	-1.00	3.4			
ADALIMUMAB HIGHER INDUCTION DOSE	563	6.50	5.04	-1.46	1.521	-8.0	-1.20	2.2	-0.18	(-0.37, 0.01)	0.062+
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	359	6.35	4.57	-1.79	1.843	-8.2	-1.60	3.4			
ADALIMUMAB HIGHER INDUCTION DOSE	551	6.47	4.43	-2.05	1.824	-9.0	-2.00	2.4	-0.23	(-0.47, 0.00)	0.051+
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	368	6.36	4.17	-2.19	1.979	-8.8	-2.10	4.4			
ADALIMUMAB HIGHER INDUCTION DOSE	558	6.49	3.85	-2.64	2.172	-9.0	-2.60	3.4	-0.43	(-0.69, -0.16)	0.002**
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	350	6.33	3.98	-2.35	2.291	-8.8	-2.20	2.8			
ADALIMUMAB HIGHER INDUCTION DOSE	538	6.46	3.66	-2.80	2.371	-9.0	-2.80	4.8	-0.47	(-0.77, -0.16)	0.002**

表 2.7.3.6-108. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
ITT SET											
AVERAGE RECTAL BLEEDING SUBSCORE											
WEEK 1											
ADALIMUMAB STANDARD INDUCTION DOSE	335	1.70	1.25	-0.46	0.679	-3.0	-0.40	2.0			
ADALIMUMAB HIGHER INDUCTION DOSE	504	1.78	1.19	-0.59	0.767	-3.0	-0.40	1.2	-0.10	(-0.20, -0.01)	0.032*
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	326	1.70	1.00	-0.70	0.900	-3.0	-0.40	2.2			
ADALIMUMAB HIGHER INDUCTION DOSE	490	1.76	0.96	-0.79	0.926	-3.0	-0.60	2.4	-0.08	(-0.19, 0.03)	0.178
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	331	1.69	0.87	-0.82	0.930	-3.0	-0.80	2.4			
ADALIMUMAB HIGHER INDUCTION DOSE	498	1.77	0.79	-0.98	1.028	-3.0	-1.00	2.8	-0.14	(-0.25, -0.02)	0.021*
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	315	1.68	0.81	-0.87	1.055	-3.0	-0.80	2.0			
ADALIMUMAB HIGHER INDUCTION DOSE	481	1.75	0.71	-1.04	1.073	-3.0	-1.00	2.4	-0.17	(-0.30, -0.05)	0.008**

表 2.7.3.6-108. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
AVERAGE STOOL FREQUENCY SUBSCORE											
WEEK 1											
ADALIMUMAB STANDARD INDUCTION DOSE	335	2.40	1.98	-0.42	0.630	-2.8	-0.20	1.4			
ADALIMUMAB HIGHER INDUCTION DOSE	504	2.47	2.01	-0.46	0.615	-3.0	-0.20	1.2	-0.03	(-0.12, 0.05)	0.458
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	326	2.41	1.84	-0.57	0.777	-3.0	-0.40	1.8			
ADALIMUMAB HIGHER INDUCTION DOSE	490	2.47	1.80	-0.67	0.742	-3.0	-0.60	1.2	-0.09	(-0.20, 0.01)	0.074+
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	331	2.41	1.71	-0.70	0.827	-3.0	-0.60	1.4			
ADALIMUMAB HIGHER INDUCTION DOSE	498	2.47	1.58	-0.89	0.893	-3.0	-0.80	1.8	-0.17	(-0.29, -0.06)	0.004**
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	315	2.41	1.64	-0.77	0.944	-3.0	-0.60	1.6			
ADALIMUMAB HIGHER INDUCTION DOSE	481	2.46	1.53	-0.93	0.960	-3.0	-1.00	1.8	-0.16	(-0.29, -0.03)	0.014*

表 2.7.3.6-108. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
ENDOSCOPY SUBSCORE											
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	299	2.3	1.8	-0.5	0.88	-3	0.0	1			
ADALIMUMAB HIGHER INDUCTION DOSE	461	2.4	1.8	-0.6	0.93	-3	0.0	1	-0.1	(-0.2, 0.1)	0.230

表 2.7.3.6-108. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
PHYSICIAN'S GLOBAL ASSESSMENT SUBSCORE											
WEEK 1											
ADALIMUMAB STANDARD INDUCTION DOSE	335	2.3	1.9	-0.4	0.59	-2	0.0	1			
ADALIMUMAB HIGHER INDUCTION DOSE	507	2.3	1.9	-0.4	0.65	-3	0.0	1	-0.1	(-0.1, 0.0)	0.145
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	326	2.2	1.7	-0.5	0.66	-3	0.0	1			
ADALIMUMAB HIGHER INDUCTION DOSE	494	2.3	1.7	-0.6	0.74	-3	-1.0	1	-0.1	(-0.2, 0.0)	0.200
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	331	2.3	1.6	-0.7	0.76	-3	-1.0	1			
ADALIMUMAB HIGHER INDUCTION DOSE	501	2.3	1.5	-0.8	0.83	-3	-1.0	1	-0.1	(-0.2, -0.0)	0.009**
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	315	2.2	1.5	-0.7	0.84	-3	-1.0	1			
ADALIMUMAB HIGHER INDUCTION DOSE	485	2.3	1.4	-0.9	0.90	-3	-1.0	1	-0.1	(-0.2, -0.0)	0.029*

表 2.7.3.6-108. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
PARTIAL MAYO SCORE											
WEEK 1											
ADALIMUMAB STANDARD INDUCTION DOSE	335	6.37	5.13	-1.24	1.397	-6.0	-1.00	3.4			
ADALIMUMAB HIGHER INDUCTION DOSE	504	6.55	5.05	-1.50	1.533	-8.0	-1.20	2.2	-0.21	(-0.42, -0.01)	0.037*
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	326	6.36	4.55	-1.81	1.788	-7.4	-1.70	3.4			
ADALIMUMAB HIGHER INDUCTION DOSE	490	6.51	4.42	-2.09	1.844	-9.0	-2.00	2.4	-0.24	(-0.49, 0.00)	0.054+
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	331	6.35	4.16	-2.19	1.918	-7.4	-2.20	4.4			
ADALIMUMAB HIGHER INDUCTION DOSE	498	6.53	3.83	-2.70	2.158	-9.0	-2.60	3.4	-0.47	(-0.75, -0.19)	<0.001***
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	315	6.34	3.97	-2.36	2.243	-8.6	-2.20	2.8			
ADALIMUMAB HIGHER INDUCTION DOSE	481	6.49	3.65	-2.84	2.373	-9.0	-2.80	4.8	-0.49	(-0.81, -0.17)	0.002**

表 2.7.3.6-108. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

@ P-VALUE FOR TEST OF DIFFERENCE BETWEEN ADALIMUMAB HIGHER INDUCTION DOSE AND ADALIMUMAB STANDARD INDUCTION DOSE FOR CHANGE FROM BASELINE USING THE REPEATED MEASURE MODEL INCLUDING TREATMENT, PREVIOUS INFLIXIMAB USE, BASELINE CORTICOSTERIOD USE, VISIT, BASELINE VALUE, INTERACTION OF TREATMENT AND VISIT.
***, **, *, + STATISTICALLY SIGNIFICANT AT 0.001, 0.01, 0.05 AND 0.1 LEVEL, RESPECTIVELY.

Cross reference: M14-033 Induction_Japan Sub-study Final CSR Table 14.2__3.10_J

表 2.7.3.6-109. 投与 8 週時の高感度 CRP のベースラインからの変化量（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）

JAPAN ITT SET

PARAMETER / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
HIGH-SENSITIVITY C-REACTIVE PROTEIN (MG/L)											
ADALIMUMAB STANDARD INDUCTION DOSE	35	12.091	3.500	-8.591	30.3938	-159.72	-0.430	6.03			
ADALIMUMAB HIGHER INDUCTION DOSE	57	8.414	3.454	-4.959	16.4491	-86.15	-0.470	17.82	0.162	(-1.766, 2.090)	0.868

表 2.7.3.6-109. 投与 8 週時の高感度 CRP のベースラインからの変化量（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

INTEGRATED ITT SET

PARAMETER / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
HIGH-SENSITIVITY C-REACTIVE PROTEIN (MG/L)											
ADALIMUMAB STANDARD INDUCTION DOSE	347	10.937	8.761	-2.176	17.9470	-159.72	-0.450	152.91			
ADALIMUMAB HIGHER INDUCTION DOSE	538	10.987	7.175	-3.812	18.5758	-126.62	-0.910	144.05	-1.635	(-3.632, 0.363)	0.109

表 2.7.3.6-109. 投与 8 週時の高感度 CRP のベースラインからの変化量（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

ITT SET

PARAMETER / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP — CHANGE FROM BASELINE — MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON — (HIGHER DOSE - STANDARD DOSE) — LSMEAN	95% CI	P-VALUE@
HIGH-SENSITIVITY C-REACTIVE PROTEIN (MG/L)											
ADALIMUMAB STANDARD INDUCTION DOSE	312	10.807	9.351	-1.456	15.8808	-80.95	-0.458	152.91			
ADALIMUMAB HIGHER INDUCTION DOSE	481	11.292	7.616	-3.676	18.8227	-126.62	-0.950	144.05	-2.007	(-4.169, 0.155)	0.069+

@ P-VALUE FOR TEST OF DIFFERENCE BETWEEN ADALIMUMAB HIGHER INDUCTION DOSE AND ADALIMUMAB STANDARD INDUCTION DOSE FOR CHANGE FROM BASELINE USING ANALYSIS OF COVARIANCE WITH TREATMENT, PREVIOUS INFLIXIMAB USE, BASELINE CORTICOSTEROID USE, AND BASELINE VALUE AS COVARIATE.
***, **, *, + STATISTICALLY SIGNIFICANT AT 0.001, 0.01, 0.05 AND 0.1 LEVEL, RESPECTIVELY.

Cross reference: M14-033 Induction_Japan Sub-study Final CSR Table 14.2__3.11_J

表 2.7.3.6-110. 投与 8 週時の便中カルプロテクチン値のベースラインからの変化量（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）

JAPAN ITT SET

PARAMETER / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
FECAL CALPROTECTIN (MCG/G)											
ADALIMUMAB STANDARD INDUCTION DOSE	35	2546.1	1474.7	-1071.4	3004.63	-8388	-45.0	3757			
ADALIMUMAB HIGHER INDUCTION DOSE	54	2940.1	1487.7	-1452.4	3164.94	-9326	-682.0	6670	-34.7	(-882.9, 813.4)	0.935

表 2.7.3.6-110. 投与 8 週時の便中カルプロテクチン値のベースラインからの変化量（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

INTEGRATED ITT SET

PARAMETER / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
FECAL CALPROTECTIN (MCG/G)											
ADALIMUMAB STANDARD INDUCTION DOSE	296	2290.6	1412.6	-878.0	2491.32	-9590	-258.0	8726			
ADALIMUMAB HIGHER INDUCTION DOSE	455	2500.9	1363.3	-1137.6	2886.10	-9587	-639.0	8687	-110.6	(-385.1, 163.9)	0.429

表 2.7.3.6-110. 投与 8 週時の便中カルプロテクチン値のベースラインからの変化量（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

ITT SET

PARAMETER / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP – CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON – (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
FECAL CALPROTECTIN (MCG/G)											
ADALIMUMAB STANDARD INDUCTION DOSE	261	2256.3	1404.3	-852.0	2419.89	-9590	-259.0	8726			
ADALIMUMAB HIGHER INDUCTION DOSE	401	2441.8	1346.6	-1095.2	2848.10	-9587	-631.0	8687	-125.0	(-416.1, 166.0)	0.399

@ P-VALUE FOR TEST OF DIFFERENCE BETWEEN ADALIMUMAB HIGHER INDUCTION DOSE AND ADALIMUMAB STANDARD INDUCTION DOSE FOR CHANGE FROM BASELINE USING ANALYSIS OF COVARIANCE WITH TREATMENT, PREVIOUS INFLIXIMAB USE, BASELINE CORTICOSTEROID USE, AND BASELINE VALUE AS COVARIATE.

Cross reference: M14-033 Induction_Japan Sub-study Final CSR Table 14.2__3.12_J

表 2.7.3.6-111. 評価時点ごとの IBDQ スコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
JAPAN ITT SET											
IBDQ - BOWEL											
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	39	39.718	47.462	7.744	6.6717	-5.00	8.000	29.00			
ADALIMUMAB HIGHER INDUCTION DOSE	61	41.672	49.574	7.902	7.8543	-6.00	6.000	34.00	0.727	(-2.155, 3.608)	0.618
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	37	38.919	48.649	9.730	8.7199	-3.00	8.000	30.00			
ADALIMUMAB HIGHER INDUCTION DOSE	60	41.550	51.533	9.983	10.0617	-11.00	10.000	33.00	1.270	(-2.345, 4.885)	0.487
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	35	39.171	48.800	9.629	11.4945	-18.00	11.000	36.00			
ADALIMUMAB HIGHER INDUCTION DOSE	57	41.737	52.035	10.298	12.0564	-18.00	10.000	42.00	1.439	(-3.304, 6.183)	0.548

表 2.7.3.6-111. 評価時点ごとの IBDQ スコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
IBDQ - EMOTIONAL											
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	39	55.077	59.487	4.410	8.3279	-8.00	4.000	33.00			
ADALIMUMAB HIGHER INDUCTION DOSE	61	55.672	60.426	4.754	9.6689	-24.00	5.000	30.00	0.423	(-3.192, 4.037)	0.817
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	37	54.162	59.027	4.865	8.1519	-8.00	4.000	29.00			
ADALIMUMAB HIGHER INDUCTION DOSE	60	55.450	61.750	6.300	9.1546	-16.00	5.500	26.00	1.708	(-1.733, 5.149)	0.327
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	35	54.029	57.857	3.829	8.8267	-18.00	5.000	18.00			
ADALIMUMAB HIGHER INDUCTION DOSE	57	55.421	61.614	6.193	11.7495	-19.00	5.000	37.00	2.857	(-1.561, 7.276)	0.202

表 2.7.3.6-111. 評価時点ごとの IBDQ スコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER VISIT TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
IBDQ - FATIGUE											
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	39	3.3	4.4	1.0	1.27	-1	1.0	4			
ADALIMUMAB HIGHER INDUCTION DOSE	61	3.7	4.3	0.6	1.58	-2	1.0	6	-0.3	(-0.8, 0.3)	0.342
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	37	3.2	4.0	0.8	1.32	-2	1.0	4			
ADALIMUMAB HIGHER INDUCTION DOSE	60	3.7	4.3	0.7	1.47	-2	0.0	4	0.1	(-0.4, 0.6)	0.768
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	35	3.3	4.3	1.1	1.45	-2	1.0	5			
ADALIMUMAB HIGHER INDUCTION DOSE	57	3.7	4.4	0.7	1.67	-3	1.0	4	-0.1	(-0.7, 0.5)	0.714

表 2.7.3.6-111. 評価時点ごとの IBDQ スコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
IBDQ - SOCIAL											
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	39	21.9	24.1	2.1	5.79	-13	1.0	20			
ADALIMUMAB HIGHER INDUCTION DOSE	60	22.6	25.2	2.6	4.89	-9	2.0	15	0.5	(-1.6, 2.7)	0.617
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	37	21.6	25.4	3.7	6.96	-16	3.0	20			
ADALIMUMAB HIGHER INDUCTION DOSE	59	22.5	26.2	3.7	5.47	-7	3.0	16	0.1	(-2.3, 2.5)	0.912
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	35	22.2	25.7	3.5	7.10	-12	3.0	21			
ADALIMUMAB HIGHER INDUCTION DOSE	56	22.6	26.8	4.2	6.64	-12	3.0	22	1.0	(-1.7, 3.7)	0.458

表 2.7.3.6-111. 評価時点ごとの IBDQ スコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
IBDQ - SYSTEMIC											
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	39	17.1	20.8	3.7	3.82	-4	3.0	12			
ADALIMUMAB HIGHER INDUCTION DOSE	61	19.1	22.0	2.9	4.53	-3	2.0	19	-0.3	(-2.0, 1.3)	0.681
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	37	16.5	20.5	3.9	4.78	-4	3.0	13			
ADALIMUMAB HIGHER INDUCTION DOSE	60	19.0	22.7	3.7	4.53	-7	4.0	16	0.4	(-1.4, 2.2)	0.672
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	35	16.7	21.2	4.6	5.30	-9	4.0	14			
ADALIMUMAB HIGHER INDUCTION DOSE	57	19.0	23.0	4.0	6.55	-15	4.0	23	0.2	(-2.2, 2.6)	0.891

表 2.7.3.6-111. 評価時点ごとの IBDQ スコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
IBDQ - TOTAL											
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	39	133.821	151.821	18.000	20.4038	-16.00	16.000	77.00			
ADALIMUMAB HIGHER INDUCTION DOSE	60	138.683	156.900	18.217	23.6163	-34.00	16.500	97.00	1.121	(-7.908, 10.151)	0.806
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	37	131.243	153.486	22.243	24.9459	-20.00	18.000	77.00			
ADALIMUMAB HIGHER INDUCTION DOSE	59	138.068	162.220	24.153	25.5011	-37.00	21.000	87.00	3.615	(-6.393, 13.623)	0.475
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	35	132.086	153.571	21.486	28.8621	-52.00	24.000	76.00			
ADALIMUMAB HIGHER INDUCTION DOSE	56	138.339	163.571	25.232	34.1403	-64.00	24.000	124.00	5.770	(-7.446, 18.986)	0.388

表 2.7.3.6-111. 評価時点ごとの IBDQ スコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
INTEGRATED ITT SET											
IBDQ - BOWEL											
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	376	36.198	46.630	10.432	9.0838	-12.00	9.000	43.00			
ADALIMUMAB HIGHER INDUCTION DOSE	566	36.195	47.856	11.661	10.2418	-15.00	10.000	54.00	1.203	(0.009, 2.397)	0.048*
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	365	36.130	48.522	12.393	10.6897	-15.00	12.000	46.00			
ADALIMUMAB HIGHER INDUCTION DOSE	560	36.152	50.362	14.209	11.9909	-32.00	13.000	51.00	1.906	(0.534, 3.279)	0.007**
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	349	36.385	49.007	12.622	12.2322	-19.00	12.000	52.00			
ADALIMUMAB HIGHER INDUCTION DOSE	543	36.362	50.857	14.496	13.1114	-27.00	14.000	51.00	2.057	(0.497, 3.616)	0.010**

表 2.7.3.6-111. 評価時点ごとの IBDQ スコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
IBDQ - EMOTIONAL											
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	376	47.025	56.300	9.275	10.5118	-13.00	8.000	51.00			
ADALIMUMAB HIGHER INDUCTION DOSE	567	45.470	56.030	10.560	12.5314	-24.00	8.000	63.00	0.743	(-0.676, 2.161)	0.305
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	366	47.029	57.638	10.609	11.8101	-20.00	10.000	52.00			
ADALIMUMAB HIGHER INDUCTION DOSE	562	45.534	58.892	13.358	14.4615	-30.00	11.000	64.00	2.138	(0.537, 3.738)	0.009**
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	349	47.148	57.831	10.683	13.3445	-21.00	10.000	60.00			
ADALIMUMAB HIGHER INDUCTION DOSE	544	45.617	59.256	13.640	15.4422	-26.00	12.000	63.00	2.561	(0.778, 4.344)	0.005**

表 2.7.3.6-111. 評価時点ごとの IBDQ スコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER VISIT TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
IBDQ - FATIGUE											
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	375	2.9	3.8	1.0	1.42	-3	1.0	6			
ADALIMUMAB HIGHER INDUCTION DOSE	567	3.0	4.0	1.0	1.56	-3	1.0	6	0.1	(-0.1, 0.3)	0.296
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	366	2.9	4.0	1.1	1.62	-4	1.0	6			
ADALIMUMAB HIGHER INDUCTION DOSE	562	3.0	4.3	1.4	1.77	-4	1.0	6	0.3	(0.1, 0.5)	0.003**
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	349	2.9	4.1	1.3	1.67	-3	1.0	6			
ADALIMUMAB HIGHER INDUCTION DOSE	542	3.0	4.3	1.4	1.85	-4	1.0	6	0.2	(-0.0, 0.4)	0.081+

表 2.7.3.6-111. 評価時点ごとの IBDQ スコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER VISIT TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
IBDQ - SOCIAL											
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	369	19.6	24.2	4.6	5.88	-13	4.0	29			
ADALIMUMAB HIGHER INDUCTION DOSE	555	18.7	24.1	5.5	6.38	-14	4.0	29	0.6	(-0.2, 1.3)	0.141
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	358	19.5	25.3	5.8	6.59	-16	5.0	29			
ADALIMUMAB HIGHER INDUCTION DOSE	552	18.7	26.0	7.2	7.60	-19	7.0	29	1.2	(0.3, 2.0)	0.007**
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	343	19.7	25.8	6.1	7.00	-14	5.0	29			
ADALIMUMAB HIGHER INDUCTION DOSE	534	18.8	26.3	7.5	8.09	-19	6.0	30	1.3	(0.3, 2.2)	0.008**

表 2.7.3.6-111. 評価時点ごとの IBDQ スコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
IBDQ - SYSTEMIC											
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	373	16.4	20.9	4.5	4.94	-11	4.0	24			
ADALIMUMAB HIGHER INDUCTION DOSE	562	16.5	21.4	4.9	5.51	-10	4.0	24	0.4	(-0.2, 1.0)	0.202
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	364	16.4	21.5	5.1	5.69	-12	5.0	23			
ADALIMUMAB HIGHER INDUCTION DOSE	560	16.5	22.8	6.3	6.44	-15	6.0	27	1.2	(0.4, 1.9)	0.002**
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	348	16.5	22.3	5.8	6.19	-12	5.0	24			
ADALIMUMAB HIGHER INDUCTION DOSE	541	16.6	23.2	6.6	6.94	-15	6.0	26	1.0	(0.2, 1.8)	0.013*

表 2.7.3.6-111. 評価時点ごとの IBDQ スコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
IBDQ - TOTAL											
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	368	119.700	148.277	28.577	26.5545	-39.00	24.000	134.00			
ADALIMUMAB HIGHER INDUCTION DOSE	552	116.990	149.447	32.457	31.3731	-49.00	27.000	158.00	2.949	(-0.683, 6.581)	0.111
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	357	119.363	153.191	33.828	31.1592	-46.00	31.000	140.00			
ADALIMUMAB HIGHER INDUCTION DOSE	549	116.999	158.135	41.135	37.1434	-90.00	36.000	164.00	6.265	(2.048, 10.482)	0.004**
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	342	120.183	155.371	35.188	35.3322	-52.00	32.500	153.00			
ADALIMUMAB HIGHER INDUCTION DOSE	530	117.303	159.544	42.241	40.2044	-80.00	39.000	167.00	6.845	(2.105, 11.585)	0.005**

表 2.7.3.6-111. 評価時点ごとの IBDQ スコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
ITT SET											
IBDQ - BOWEL											
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	337	35.790	46.533	10.743	9.2802	-12.00	10.000	43.00			
ADALIMUMAB HIGHER INDUCTION DOSE	505	35.533	47.648	12.115	10.4082	-15.00	10.000	54.00	1.239	(-0.053, 2.530)	0.060+
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	328	35.815	48.508	12.693	10.8599	-15.00	12.500	46.00			
ADALIMUMAB HIGHER INDUCTION DOSE	500	35.505	50.221	14.716	12.1118	-32.00	14.000	51.00	1.963	(0.486, 3.439)	0.009**
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	314	36.074	49.030	12.955	12.2838	-19.00	12.000	52.00			
ADALIMUMAB HIGHER INDUCTION DOSE	486	35.731	50.719	14.988	13.1535	-27.00	14.000	51.00	2.111	(0.457, 3.765)	0.012*

表 2.7.3.6-111. 評価時点ごとの IBDQ スコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
IBDQ - EMOTIONAL											
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	337	46.094	55.931	9.838	10.6026	-13.00	9.000	51.00			
ADALIMUMAB HIGHER INDUCTION DOSE	506	44.240	55.500	11.260	12.6623	-23.00	9.000	63.00	0.766	(-0.760, 2.292)	0.325
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	329	46.227	57.482	11.256	11.9907	-20.00	11.000	52.00			
ADALIMUMAB HIGHER INDUCTION DOSE	502	44.349	58.551	14.201	14.7524	-30.00	13.000	64.00	2.179	(0.445, 3.913)	0.014*
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	314	46.381	57.828	11.447	13.5531	-21.00	11.000	60.00			
ADALIMUMAB HIGHER INDUCTION DOSE	487	44.469	58.980	14.511	15.5967	-26.00	13.000	63.00	2.522	(0.612, 4.433)	0.010**

表 2.7.3.6-111. 評価時点ごとの IBDQ スコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER VISIT TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
IBDQ - FATIGUE											
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	336	2.8	3.8	1.0	1.44	-3	1.0	6			
ADALIMUMAB HIGHER INDUCTION DOSE	506	2.9	3.9	1.1	1.55	-3	1.0	6	0.1	(-0.1, 0.3)	0.167
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	329	2.8	4.0	1.1	1.65	-4	1.0	6			
ADALIMUMAB HIGHER INDUCTION DOSE	502	2.9	4.3	1.4	1.78	-4	1.0	6	0.3	(0.1, 0.5)	0.003**
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	314	2.9	4.1	1.3	1.70	-3	1.0	6			
ADALIMUMAB HIGHER INDUCTION DOSE	485	2.9	4.3	1.4	1.86	-4	1.0	6	0.2	(-0.0, 0.4)	0.052+

表 2.7.3.6-111. 評価時点ごとの IBDQ スコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
IBDQ - SOCIAL											
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	330	19.3	24.2	4.9	5.83	-10	4.0	29			
ADALIMUMAB HIGHER INDUCTION DOSE	495	18.2	24.0	5.8	6.46	-14	5.0	29	0.6	(-0.3, 1.4)	0.179
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	321	19.3	25.3	6.1	6.51	-14	5.0	29			
ADALIMUMAB HIGHER INDUCTION DOSE	493	18.3	25.9	7.7	7.72	-19	7.0	29	1.3	(0.4, 2.2)	0.006**
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	308	19.4	25.9	6.4	6.94	-14	6.0	29			
ADALIMUMAB HIGHER INDUCTION DOSE	478	18.3	26.2	7.9	8.16	-19	7.0	30	1.3	(0.3, 2.2)	0.011*

表 2.7.3.6-111. 評価時点ごとの IBDQ スコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER VISIT TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
IBDQ - SYSTEMIC											
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	334	16.4	21.0	4.6	5.05	-11	4.0	24			
ADALIMUMAB HIGHER INDUCTION DOSE	501	16.2	21.3	5.1	5.57	-10	4.0	24	0.5	(-0.2, 1.1)	0.182
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	327	16.4	21.7	5.3	5.77	-12	5.0	23			
ADALIMUMAB HIGHER INDUCTION DOSE	500	16.2	22.8	6.6	6.56	-15	6.0	27	1.2	(0.4, 2.0)	0.002**
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	313	16.5	22.4	5.9	6.28	-12	6.0	24			
ADALIMUMAB HIGHER INDUCTION DOSE	484	16.3	23.2	6.9	6.93	-15	7.0	26	1.1	(0.2, 1.9)	0.013*

表 2.7.3.6-111. 評価時点ごとの IBDQ スコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER VISIT TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
IBDQ - TOTAL											
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	329	118.026	147.857	29.831	26.9420	-39.00	25.000	134.00			
ADALIMUMAB HIGHER INDUCTION DOSE	492	114.345	148.539	34.194	31.7762	-49.00	29.000	158.00	3.073	(-0.842, 6.988)	0.124
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	320	117.989	153.157	35.167	31.5582	-46.00	32.000	140.00			
ADALIMUMAB HIGHER INDUCTION DOSE	490	114.463	157.643	43.180	37.8149	-90.00	39.000	164.00	6.489	(1.934, 11.045)	0.005**
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	307	118.826	155.577	36.750	35.7025	-44.00	33.000	153.00			
ADALIMUMAB HIGHER INDUCTION DOSE	474	114.818	159.069	44.251	40.4220	-80.00	41.000	167.00	6.895	(1.844, 11.945)	0.008**

表 2.7.3.6-111. 評価時点ごとの IBDQ スコアのベースラインからの変化量の Mixed Effect Model Repeated Measurement（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

@ P-VALUE FOR TEST OF DIFFERENCE BETWEEN ADALIMUMAB HIGHER INDUCTION DOSE AND ADALIMUMAB STANDARD INDUCTION DOSE FOR CHANGE FROM BASELINE USING THE REPEATED MEASURE MODEL INCLUDING TREATMENT, PREVIOUS INFLIXIMAB USE, BASELINE CORTICOSTERIOD USE, VISIT, BASELINE VALUE, INTERACTION OF TREATMENT AND VISIT.
***, **, *, + STATISTICALLY SIGNIFICANT AT 0.001, 0.01, 0.05 AND 0.1 LEVEL, RESPECTIVELY.

Cross reference: M14-033 Induction_Japan Sub-study Final CSR Table 14.2__3.13.1_J

表 2.7.3.6-112. 評価時点ごとの IBDQ スコアが 170 以上となった被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
JAPAN ITT SET		
IBDQ TOTAL SCORE >= 170 AT WEEK 0	(N=39)	(N=60)
YES, n (%)	6 (15.4)	13 (21.7)
NO, n (%)	33 (84.6)	47 (78.3)
RISK DIFFERENCE[A]		6.3
ADJUSTED RISK DIFFERENCE[A,B]		6.1
95% CONFIDENCE INTERVAL[B]		(-9.9, 22.1)
P-VALUE[B]		0.457
IBDQ TOTAL SCORE >= 170 AT WEEK 2	(N=39)	(N=61)
YES, n (%)	13 (33.3)	23 (37.7)
NO, n (%)	26 (66.7)	38 (62.3)
RISK DIFFERENCE[A]		4.4
ADJUSTED RISK DIFFERENCE[A,B]		3.9
95% CONFIDENCE INTERVAL[B]		(-15.6, 23.5)
P-VALUE[B]		0.693

表 2.7.3.6-112. 評価時点ごとの IBDQ スコアが 170 以上となった被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
IBDQ TOTAL SCORE >= 170 AT WEEK 4	(N=39)	(N=61)
YES, n (%)	15 (38.5)	31 (50.8)
NO, n (%)	24 (61.5)	30 (49.2)
RISK DIFFERENCE[A]		12.4
ADJUSTED RISK DIFFERENCE[A,B]		11.7
95% CONFIDENCE INTERVAL[B]		(-8.2, 31.5)
P-VALUE[B]		0.250
IBDQ TOTAL SCORE >= 170 AT WEEK 8	(N=39)	(N=61)
YES, n (%)	16 (41.0)	30 (49.2)
NO, n (%)	23 (59.0)	31 (50.8)
RISK DIFFERENCE[A]		8.2
ADJUSTED RISK DIFFERENCE[A,B]		7.2
95% CONFIDENCE INTERVAL[B]		(-12.5, 26.9)
P-VALUE[B]		0.474

表 2.7.3.6-112. 評価時点ごとの IBDQ スコアが 170 以上となった被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
INTEGRATED ITT SET		
IBDQ TOTAL SCORE >= 170 AT WEEK 0	(N=374)	(N=564)
YES, n (%)	26 (7.0)	43 (7.6)
NO, n (%)	348 (93.0)	521 (92.4)
RISK DIFFERENCE[A]		0.7
ADJUSTED RISK DIFFERENCE[A,B]		0.6
95% CONFIDENCE INTERVAL[B]		(-2.8, 4.0)
P-VALUE[B]		0.722
IBDQ TOTAL SCORE >= 170 AT WEEK 2	(N=379)	(N=573)
YES, n (%)	121 (31.9)	178 (31.1)
NO, n (%)	258 (68.1)	395 (68.9)
RISK DIFFERENCE[A]		-0.9
ADJUSTED RISK DIFFERENCE[A,B]		-0.9
95% CONFIDENCE INTERVAL[B]		(-6.9, 5.2)
P-VALUE[B]		0.774

表 2.7.3.6-112. 評価時点ごとの IBDQ スコアが 170 以上となった被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
IBDQ TOTAL SCORE >= 170 AT WEEK 4	(N=379)	(N=573)
YES, n (%)	142 (37.5)	248 (43.3)
NO, n (%)	237 (62.5)	325 (56.7)
RISK DIFFERENCE[A]		5.8
ADJUSTED RISK DIFFERENCE[A,B]		5.9
95% CONFIDENCE INTERVAL[B]		(-0.5, 12.3)
P-VALUE[B]		0.071+
IBDQ TOTAL SCORE >= 170 AT WEEK 8	(N=379)	(N=573)
YES, n (%)	145 (38.3)	247 (43.1)
NO, n (%)	234 (61.7)	326 (56.9)
RISK DIFFERENCE[A]		4.8
ADJUSTED RISK DIFFERENCE[A,B]		4.9
95% CONFIDENCE INTERVAL[B]		(-1.5, 11.3)
P-VALUE[B]		0.135

表 2.7.3.6-112. 評価時点ごとの IBDQ スコアが 170 以上となった被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
ITT SET		
IBDQ TOTAL SCORE >= 170 AT WEEK 0	(N=335)	(N=504)
YES, n (%)	20 (6.0)	30 (6.0)
NO, n (%)	315 (94.0)	474 (94.0)
RISK DIFFERENCE[A]		-0.0
ADJUSTED RISK DIFFERENCE[A,B]		-0.1
95% CONFIDENCE INTERVAL[B]		(-3.4, 3.1)
P-VALUE[B]		0.938
IBDQ TOTAL SCORE >= 170 AT WEEK 2	(N=340)	(N=512)
YES, n (%)	108 (31.8)	155 (30.3)
NO, n (%)	232 (68.2)	357 (69.7)
RISK DIFFERENCE[A]		-1.5
ADJUSTED RISK DIFFERENCE[A,B]		-1.6
95% CONFIDENCE INTERVAL[B]		(-7.9, 4.8)
P-VALUE[B]		0.624

表 2.7.3.6-112. 評価時点ごとの IBDQ スコアが 170 以上となった被験者の割合（NRI）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD DOSE	HIGHER DOSE
IBDQ TOTAL SCORE >= 170 AT WEEK 4	(N=340)	(N=512)
YES, n (%)	127 (37.4)	217 (42.4)
NO, n (%)	213 (62.6)	295 (57.6)
RISK DIFFERENCE[A]		5.0
ADJUSTED RISK DIFFERENCE[A,B]		5.0
95% CONFIDENCE INTERVAL[B]		(-1.7, 11.7)
P-VALUE[B]		0.144
IBDQ TOTAL SCORE >= 170 AT WEEK 8	(N=340)	(N=512)
YES, n (%)	129 (37.9)	217 (42.4)
NO, n (%)	211 (62.1)	295 (57.6)
RISK DIFFERENCE[A]		4.4
ADJUSTED RISK DIFFERENCE[A,B]		4.4
95% CONFIDENCE INTERVAL[B]		(-2.4, 11.1)
P-VALUE[B]		0.202

[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER DOSE - ADALIMUMAB STANDARD DOSE).
[B]: ADJUSTED RISK DIFFERENCE, 95% CONFIDENCE INTERVAL FOR THE DIFFERENCE IN THE PROPORTIONS BETWEEN THE TREATMENT GROUPS AND P-VALUE WERE CALCULATED USING COCHRAN-MANTEL-HAENSZEL (CMH) TEST ADJUSTED FOR PREVIOUS INFLIXIMAB USE AND BASELINE CORTICOSTEROID USE.
***, **, *, + STATISTICALLY SIGNIFICANT AT 0.001, 0.01, 0.05 AND 0.1 LEVEL, RESPECTIVELY.

Cross reference: M14-033 Induction_Japan Sub-study Final CSR Table 14.2__3.13.2_J

表 2.7.3.6-113. 投与 8 週時の WPAI スコアのベースラインからの変化量（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）

PARAMETER		BASELINE	VISIT	WITHIN GROUP CHANGE FROM BASELINE					BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE)		
TREATMENT	N	MEAN	MEAN	MEAN	STD	MIN	MEDIAN	MAX	LSMEAN	95% CI	P-VALUE@
JAPAN ITT SET											
WPAI - ACTIVITY IMPAIRMENT (%)											
ADALIMUMAB STANDARD INDUCTION DOSE	35	61.4	43.4	-18.0	39.69	-100	-20.0	80			
ADALIMUMAB HIGHER INDUCTION DOSE	57	54.0	36.5	-17.5	30.43	-90	-10.0	40	-4.1	(-16.6, 8.3)	0.512
WPAI - IMPAIRMENT WHILE WORKING (%)											
ADALIMUMAB STANDARD INDUCTION DOSE	23	43.5	24.8	-18.7	38.88	-90	-20.0	80			
ADALIMUMAB HIGHER INDUCTION DOSE	47	47.4	30.0	-17.4	33.91	-100	-20.0	80	5.2	(-8.2, 18.6)	0.439

表 2.7.3.6-113. 投与 8 週時の WPAI スコアのベースラインからの変化量（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP — CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON — (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
WPAI - OVERALL WORK IMPAIRMENT (%)											
ADALIMUMAB STANDARD INDUCTION DOSE	26	54.141	34.722	-19.419	39.1362	-90.00	-15.000	80.00			
ADALIMUMAB HIGHER INDUCTION DOSE	46	51.010	34.145	-16.864	35.6972	-92.29	-11.221	80.00	1.311	(-13.301, 15.923)	0.858
WPAI - WORK TIME MISSED (%)											
ADALIMUMAB STANDARD INDUCTION DOSE	26	24.086	11.190	-12.896	33.6303	-100.00	0.000	50.00			
ADALIMUMAB HIGHER INDUCTION DOSE	46	19.825	7.990	-11.835	31.2767	-100.00	0.000	15.03	-0.975	(-10.912, 8.962)	0.845

表 2.7.3.6-113. 投与 8 週時の WPAI スコアのベースラインからの変化量（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER		BASELINE	VISIT	WITHIN GROUP CHANGE FROM BASELINE					BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE)		
TREATMENT	N	MEAN	MEAN	MEAN	STD	MIN	MEDIAN	MAX	LSMEAN	95% CI	P-VALUE@
INTEGRATED ITT SET											
WPAI - ACTIVITY IMPAIRMENT (%)											
ADALIMUMAB STANDARD INDUCTION DOSE	342	57.6	40.8	-16.8	28.20	-100	-10.0	80			
ADALIMUMAB HIGHER INDUCTION DOSE	529	58.5	36.1	-22.4	28.95	-100	-20.0	60	-5.3	(-8.8, -1.9)	0.003**
WPAI - IMPAIRMENT WHILE WORKING (%)											
ADALIMUMAB STANDARD INDUCTION DOSE	201	50.1	32.2	-17.9	29.34	-100	-20.0	80			
ADALIMUMAB HIGHER INDUCTION DOSE	310	51.7	32.5	-19.2	31.08	-100	-10.0	100	-0.3	(-4.8, 4.2)	0.901

表 2.7.3.6-113. 投与 8 週時の WPAI スコアのベースラインからの変化量（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP — CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON — (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
WPAI - OVERALL WORK IMPAIRMENT (%)											
ADALIMUMAB STANDARD INDUCTION DOSE	198	56.882	39.048	-17.835	30.6030	-96.19	-11.238	80.00			
ADALIMUMAB HIGHER INDUCTION DOSE	311	58.012	37.184	-20.827	33.8660	-100.00	-14.478	80.00	-2.506	(-7.555, 2.543)	0.330
WPAI - WORK TIME MISSED (%)											
ADALIMUMAB STANDARD INDUCTION DOSE	199	21.517	13.149	-8.368	26.3014	-100.00	0.000	100.00			
ADALIMUMAB HIGHER INDUCTION DOSE	311	20.785	11.020	-9.765	33.2261	-100.00	0.000	100.00	-2.000	(-6.207, 2.207)	0.351

表 2.7.3.6-113. 投与 8 週時の WPAI スコアのベースラインからの変化量（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER		BASELINE	VISIT	WITHIN GROUP CHANGE FROM BASELINE					BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE)		
TREATMENT	N	MEAN	MEAN	MEAN	STD	MIN	MEDIAN	MAX	LSMEAN	95% CI	P-VALUE@
ITT SET											
WPAI - ACTIVITY IMPAIRMENT (%)											
ADALIMUMAB STANDARD INDUCTION DOSE	307	57.2	40.5	-16.7	26.67	-100	-10.0	50			
ADALIMUMAB HIGHER INDUCTION DOSE	472	59.0	36.0	-23.0	28.74	-100	-20.0	60	-5.6	(-9.2, -2.0)	0.002**
WPAI - IMPAIRMENT WHILE WORKING (%)											
ADALIMUMAB STANDARD INDUCTION DOSE	178	51.0	33.2	-17.8	28.01	-100	-15.0	40			
ADALIMUMAB HIGHER INDUCTION DOSE	263	52.4	32.9	-19.5	30.60	-100	-10.0	100	-0.9	(-5.7, 3.9)	0.709

表 2.7.3.6-113. 投与 8 週時の WPAI スコアのベースラインからの変化量（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP — CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON — (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
WPAI - OVERALL WORK IMPAIRMENT (%)											
ADALIMUMAB STANDARD INDUCTION DOSE	172	57.297	39.701	-17.595	29.2332	-96.19	-11.238	54.36			
ADALIMUMAB HIGHER INDUCTION DOSE	265	59.227	37.712	-21.515	33.5608	-100.00	-15.526	65.00	-3.087	(-8.505, 2.331)	0.263
WPAI - WORK TIME MISSED (%)											
ADALIMUMAB STANDARD INDUCTION DOSE	173	21.131	13.443	-7.688	25.0675	-100.00	0.000	100.00			
ADALIMUMAB HIGHER INDUCTION DOSE	265	20.951	11.546	-9.406	33.5963	-100.00	0.000	100.00	-1.967	(-6.602, 2.669)	0.405

@ P-VALUE FOR TEST OF DIFFERENCE BETWEEN ADALIMUMAB HIGHER INDUCTION DOSE AND ADALIMUMAB STANDARD INDUCTION DOSE FOR CHANGE FROM BASELINE USING ANALYSIS OF COVARIANCE WITH TREATMENT, PREVIOUS INFLIXIMAB USE, BASELINE CORTICOSTEROID USE, AND BASELINE VALUE AS COVARIATE.
***, **, *, + STATISTICALLY SIGNIFICANT AT 0.001, 0.01, 0.05 AND 0.1 LEVEL, RESPECTIVELY.

Cross reference: M14-033 Induction_Japan Sub-study Final CSR Table 14.2__3.14_J

表 2.7.3.6-114. 投与 8 週時の SF-36 スコアのベースラインからの変化量（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）

PARAMETER / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
JAPAN ITT SET											
SF-36 V2 BODILY PAIN SCALE											
ADALIMUMAB STANDARD INDUCTION DOSE	35	40.662	47.822	7.160	9.8671	-13.52	8.452	37.19			
ADALIMUMAB HIGHER INDUCTION DOSE	57	42.129	49.618	7.488	10.1737	-13.52	8.452	32.96	0.937	(-2.498, 4.372)	0.589
SF-36 V2 GENERAL HEALTH SCALE											
ADALIMUMAB STANDARD INDUCTION DOSE	35	34.084	37.407	3.323	6.0875	-4.77	0.953	19.07			
ADALIMUMAB HIGHER INDUCTION DOSE	57	34.034	37.512	3.479	6.6486	-8.10	2.383	30.98	0.079	(-2.628, 2.786)	0.954
SF-36 V2 MENTAL COMPONENT SUMMARY											
ADALIMUMAB STANDARD INDUCTION DOSE	35	37.709	40.160	2.450	7.8056	-15.56	1.097	22.40			
ADALIMUMAB HIGHER INDUCTION DOSE	57	38.097	43.086	4.989	10.0431	-12.36	3.086	42.77	2.624	(-0.977, 6.224)	0.151

表 2.7.3.6-114. 投与 8 週時の SF-36 スコアのベースラインからの変化量（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
SF-36 V2 MENTAL HEALTH SCALE											
ADALIMUMAB STANDARD INDUCTION DOSE	35	40.835	42.927	2.092	6.2350	-11.26	0.000	16.90			
ADALIMUMAB HIGHER INDUCTION DOSE	57	40.226	44.771	4.545	9.7801	-16.90	2.816	36.61	2.194	(-1.135, 5.522)	0.194
SF-36 V2 PHYSICAL COMPONENT SUMMARY											
ADALIMUMAB STANDARD INDUCTION DOSE	35	43.220	47.339	4.119	6.3282	-10.52	4.099	22.11			
ADALIMUMAB HIGHER INDUCTION DOSE	57	44.041	47.677	3.637	5.8532	-10.73	3.773	16.01	-0.211	(-2.509, 2.088)	0.856
SF-36 V2 PHYSICAL FUNCTIONING SCALE											
ADALIMUMAB STANDARD INDUCTION DOSE	35	48.915	50.298	1.383	5.4722	-6.31	0.000	23.15			
ADALIMUMAB HIGHER INDUCTION DOSE	57	49.722	50.756	1.034	4.9053	-14.73	2.104	18.94	-0.048	(-1.993, 1.897)	0.961

表 2.7.3.6-114. 投与 8 週時の SF-36 スコアのベースラインからの変化量（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
SF-36 V2 ROLE-EMOTIONAL SCALE											
ADALIMUMAB STANDARD INDUCTION DOSE	35	38.775	40.552	1.777	9.9482	-23.32	0.000	27.21			
ADALIMUMAB HIGHER INDUCTION DOSE	57	40.875	44.558	3.683	12.2137	-15.55	0.000	46.65	2.814	(-1.455, 7.082)	0.194
SF-36 V2 ROLE-PHYSICAL SCALE											
ADALIMUMAB STANDARD INDUCTION DOSE	35	40.480	43.629	3.149	8.6397	-19.59	2.449	19.59			
ADALIMUMAB HIGHER INDUCTION DOSE	57	41.171	45.640	4.468	10.6160	-17.14	2.449	39.18	1.641	(-2.051, 5.332)	0.379
SF-36 V2 SOCIAL FUNCTIONING SCALE											
ADALIMUMAB STANDARD INDUCTION DOSE	35	38.617	41.890	3.272	12.5629	-27.27	5.454	32.72			
ADALIMUMAB HIGHER INDUCTION DOSE	57	37.904	43.932	6.028	11.6009	-21.82	5.454	43.63	2.357	(-2.401, 7.115)	0.328

表 2.7.3.6-114. 投与 8 週時の SF-36 スコアのベースラインからの変化量（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER		BASELINE	VISIT	WITHIN GROUP CHANGE FROM BASELINE					BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE)		
TREATMENT	N	MEAN	MEAN	MEAN	STD	MIN	MEDIAN	MAX	LSMEAN	95% CI	P-VALUE@
SF-36 V2 VITALITY SCALE											
ADALIMUMAB STANDARD INDUCTION DOSE	35	39.425	44.687	5.263	6.8889	-9.37	6.244	21.85			
ADALIMUMAB HIGHER INDUCTION DOSE	57	41.027	45.847	4.820	9.7139	-12.49	3.122	40.59	-0.151	(-3.646, 3.344)	0.932

表 2.7.3.6-114. 投与 8 週時の SF-36 スコアのベースラインからの変化量（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP — CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON — (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
INTEGRATED ITT SET											
SF-36 V2 BODILY PAIN SCALE											
ADALIMUMAB STANDARD INDUCTION DOSE	347	38.915	45.994	7.080	9.7971	-24.93	5.071	37.19			
ADALIMUMAB HIGHER INDUCTION DOSE	545	38.765	46.901	8.136	10.9740	-26.20	6.762	42.26	1.040	(-0.174, 2.254)	0.093+
SF-36 V2 GENERAL HEALTH SCALE											
ADALIMUMAB STANDARD INDUCTION DOSE	346	33.856	37.738	3.882	7.8902	-14.30	2.383	34.32			
ADALIMUMAB HIGHER INDUCTION DOSE	543	34.268	38.428	4.160	7.5826	-24.79	2.383	30.98	0.470	(-0.503, 1.444)	0.344
SF-36 V2 MENTAL COMPONENT SUMMARY											
ADALIMUMAB STANDARD INDUCTION DOSE	346	36.274	41.937	5.663	10.3842	-17.67	4.244	39.78			
ADALIMUMAB HIGHER INDUCTION DOSE	540	34.332	42.074	7.743	11.5824	-19.48	5.724	52.29	1.292	(-0.035, 2.620)	0.056+

表 2.7.3.6-114. 投与 8 週時の SF-36 スコアのベースラインからの変化量（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
SF-36 V2 MENTAL HEALTH SCALE											
ADALIMUMAB STANDARD INDUCTION DOSE	347	38.508	43.507	4.999	9.3056	-14.08	2.816	42.24			
ADALIMUMAB HIGHER INDUCTION DOSE	544	36.466	43.118	6.652	11.0871	-19.71	5.632	47.87	0.850	(-0.404, 2.103)	0.184
SF-36 V2 PHYSICAL COMPONENT SUMMARY											
ADALIMUMAB STANDARD INDUCTION DOSE	346	39.718	44.979	5.261	7.3621	-12.69	4.478	39.28			
ADALIMUMAB HIGHER INDUCTION DOSE	540	40.328	45.818	5.491	7.7127	-16.04	4.349	38.97	0.543	(-0.368, 1.453)	0.242
SF-36 V2 PHYSICAL FUNCTIONING SCALE											
ADALIMUMAB STANDARD INDUCTION DOSE	346	44.272	48.284	4.012	7.4018	-21.04	2.104	33.67			
ADALIMUMAB HIGHER INDUCTION DOSE	544	44.400	48.646	4.246	8.1707	-23.15	2.104	37.88	0.315	(-0.605, 1.236)	0.501

表 2.7.3.6-114. 投与 8 週時の SF-36 スコアのベースラインからの変化量（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP — CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON — (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
SF-36 V2 ROLE-EMOTIONAL SCALE											
ADALIMUMAB STANDARD INDUCTION DOSE	347	37.014	42.369	5.355	12.1989	-31.10	3.887	46.65			
ADALIMUMAB HIGHER INDUCTION DOSE	543	36.242	43.107	6.865	13.1741	-34.98	3.887	46.65	1.160	(-0.284, 2.605)	0.115
SF-36 V2 ROLE-PHYSICAL SCALE											
ADALIMUMAB STANDARD INDUCTION DOSE	347	35.518	42.131	6.613	9.5800	-26.94	4.898	39.18			
ADALIMUMAB HIGHER INDUCTION DOSE	544	35.289	42.898	7.608	11.1848	-24.49	4.898	39.18	0.919	(-0.348, 2.186)	0.155
SF-36 V2 SOCIAL FUNCTIONING SCALE											
ADALIMUMAB STANDARD INDUCTION DOSE	346	34.734	41.733	6.999	11.2665	-27.27	5.454	43.63			
ADALIMUMAB HIGHER INDUCTION DOSE	544	33.048	41.951	8.903	11.9170	-21.82	5.454	43.63	1.176	(-0.220, 2.571)	0.099+

表 2.7.3.6-114. 投与 8 週時の SF-36 スコアのベースラインからの変化量（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP — CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON — (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
SF-36 V2 VITALITY SCALE											
ADALIMUMAB STANDARD INDUCTION DOSE	347	37.947	44.326	6.379	9.7699	-18.73	6.244	37.46			
ADALIMUMAB HIGHER INDUCTION DOSE	544	37.198	45.256	8.058	11.0598	-18.73	6.244	49.95	1.437	(0.148, 2.725)	0.029*

表 2.7.3.6-114. 投与 8 週時の SF-36 スコアのベースラインからの変化量（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP — CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON — (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
ITT SET											
SF-36 V2 BODILY PAIN SCALE											
ADALIMUMAB STANDARD INDUCTION DOSE	312	38.719	45.789	7.071	9.8051	-24.93	5.071	32.96			
ADALIMUMAB HIGHER INDUCTION DOSE	488	38.372	46.584	8.212	11.0710	-26.20	6.762	42.26	1.019	(-0.273, 2.312)	0.122
SF-36 V2 GENERAL HEALTH SCALE											
ADALIMUMAB STANDARD INDUCTION DOSE	311	33.830	37.775	3.945	8.0735	-14.30	2.383	34.32			
ADALIMUMAB HIGHER INDUCTION DOSE	486	34.295	38.535	4.240	7.6868	-24.79	3.337	29.55	0.515	(-0.528, 1.558)	0.332
SF-36 V2 MENTAL COMPONENT SUMMARY											
ADALIMUMAB STANDARD INDUCTION DOSE	311	36.113	42.137	6.024	10.5843	-17.67	4.421	39.78			
ADALIMUMAB HIGHER INDUCTION DOSE	483	33.887	41.955	8.068	11.7173	-19.48	6.070	52.29	1.120	(-0.301, 2.541)	0.122

表 2.7.3.6-114. 投与 8 週時の SF-36 スコアのベースラインからの変化量（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP — CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON — (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
SF-36 V2 MENTAL HEALTH SCALE											
ADALIMUMAB STANDARD INDUCTION DOSE	312	38.247	43.572	5.325	9.5410	-14.08	2.816	42.24			
ADALIMUMAB HIGHER INDUCTION DOSE	487	36.026	42.924	6.898	11.2133	-19.71	5.632	47.87	0.683	(-0.664, 2.029)	0.320
SF-36 V2 PHYSICAL COMPONENT SUMMARY											
ADALIMUMAB STANDARD INDUCTION DOSE	311	39.324	44.713	5.389	7.4676	-12.69	4.659	39.28			
ADALIMUMAB HIGHER INDUCTION DOSE	483	39.890	45.599	5.709	7.8794	-16.04	4.651	38.97	0.626	(-0.355, 1.608)	0.211
SF-36 V2 PHYSICAL FUNCTIONING SCALE											
ADALIMUMAB STANDARD INDUCTION DOSE	311	43.750	48.058	4.308	7.5378	-21.04	2.104	33.67			
ADALIMUMAB HIGHER INDUCTION DOSE	487	43.777	48.399	4.622	8.3944	-23.15	4.209	37.88	0.372	(-0.628, 1.372)	0.465

表 2.7.3.6-114. 投与 8 週時の SF-36 スコアのベースラインからの変化量（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP — CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON — (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
SF-36 V2 ROLE-EMOTIONAL SCALE											
ADALIMUMAB STANDARD INDUCTION DOSE	312	36.816	42.572	5.756	12.3750	-31.10	3.887	46.65			
ADALIMUMAB HIGHER INDUCTION DOSE	486	35.699	42.937	7.239	13.2438	-34.98	3.887	46.65	0.974	(-0.559, 2.506)	0.213
SF-36 V2 ROLE-PHYSICAL SCALE											
ADALIMUMAB STANDARD INDUCTION DOSE	312	34.961	41.963	7.002	9.6147	-26.94	4.898	39.18			
ADALIMUMAB HIGHER INDUCTION DOSE	487	34.601	42.577	7.976	11.2025	-24.49	4.898	39.18	0.856	(-0.492, 2.204)	0.213
SF-36 V2 SOCIAL FUNCTIONING SCALE											
ADALIMUMAB STANDARD INDUCTION DOSE	311	34.297	41.715	7.418	11.0550	-21.82	5.454	43.63			
ADALIMUMAB HIGHER INDUCTION DOSE	487	32.480	41.719	9.239	11.9198	-21.82	5.454	43.63	1.023	(-0.438, 2.483)	0.170

表 2.7.3.6-114. 投与 8 週時の SF-36 スコアのベースラインからの変化量（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP — CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON — (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
SF-36 V2 VITALITY SCALE											
ADALIMUMAB STANDARD INDUCTION DOSE	312	37.782	44.286	6.504	10.0423	-18.73	6.244	37.46			
ADALIMUMAB HIGHER INDUCTION DOSE	487	36.750	45.187	8.436	11.1544	-18.73	6.244	49.95	1.555	(0.178, 2.932)	0.027*

@ P-VALUE FOR TEST OF DIFFERENCE BETWEEN ADALIMUMAB HIGHER INDUCTION DOSE AND ADALIMUMAB STANDARD INDUCTION DOSE FOR CHANGE FROM BASELINE USING ANALYSIS OF COVARIANCE WITH TREATMENT, PREVIOUS INFLIXIMAB USE, BASELINE CORTICOSTEROID USE, AND BASELINE VALUE AS COVARIATE.
***, **, *, + STATISTICALLY SIGNIFICANT AT 0.001, 0.01, 0.05 AND 0.1 LEVEL, RESPECTIVELY.

Cross reference: M14-033 Induction_Japan Sub-study Final CSR Table 14.2__3.15_J

表 2.7.3.6-115. 評価時点ごとの被験者から報告された排便回数のベースラインからの変化量（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
JAPAN ITT SET											
AVERAGE STOOL FREQUENCY ABSOLUTE VALUE											
WEEK 1											
ADALIMUMAB STANDARD INDUCTION DOSE	39	7.50	5.97	-1.53	1.392	-5.8	-1.20	0.7			
ADALIMUMAB HIGHER INDUCTION DOSE	59	7.59	6.15	-1.44	2.233	-8.4	-0.80	2.2	0.13	(-0.59, 0.85)	0.723
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	33	7.21	5.83	-1.38	1.987	-6.0	-1.10	1.8			
ADALIMUMAB HIGHER INDUCTION DOSE	61	7.50	5.50	-2.00	2.467	-9.2	-1.20	1.6	-0.51	(-1.36, 0.33)	0.231

表 2.7.3.6-115. 評価時点ごとの被験者から報告された排便回数のベースラインからの変化量（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	37	7.70	5.70	-1.99	2.434	-7.8	-1.80	3.2			
ADALIMUMAB HIGHER INDUCTION DOSE	60	7.44	4.86	-2.58	3.075	-11.6	-1.80	3.6	-0.69	(-1.69, 0.32)	0.177
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	35	7.58	5.73	-1.85	2.649	-8.2	-1.40	3.8			
ADALIMUMAB HIGHER INDUCTION DOSE	57	7.42	4.50	-2.92	3.481	-13.2	-2.00	2.8	-1.14	(-2.33, 0.05)	0.061+

表 2.7.3.6-115. 評価時点ごとの被験者から報告された排便回数のベースラインからの変化量（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP / CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
INTEGRATED ITT SET											
AVERAGE STOOL FREQUENCY ABSOLUTE VALUE											
WEEK 1											
ADALIMUMAB STANDARD INDUCTION DOSE	371	7.16	5.81	-1.35	1.865	-11.8	-1.20	4.2			
ADALIMUMAB HIGHER INDUCTION DOSE	561	7.51	5.79	-1.72	2.159	-19.0	-1.20	3.6	-0.28	(-0.52, -0.04)	0.023*
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	356	7.11	5.34	-1.76	2.346	-11.4	-1.40	10.2			
ADALIMUMAB HIGHER INDUCTION DOSE	550	7.51	5.20	-2.31	2.595	-17.2	-2.00	5.4	-0.40	(-0.69, -0.12)	0.006**

表 2.7.3.6-115. 評価時点ごとの被験者から報告された排便回数のベースラインからの変化量（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	365	7.19	5.10	-2.09	2.825	-14.8	-1.80	10.2			
ADALIMUMAB HIGHER INDUCTION DOSE	558	7.50	4.70	-2.80	3.245	-18.8	-2.40	15.6	-0.58	(-0.94, -0.23)	0.001**
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	346	7.13	4.94	-2.19	3.049	-17.6	-2.00	10.2			
ADALIMUMAB HIGHER INDUCTION DOSE	537	7.43	4.52	-2.90	3.451	-19.5	-2.60	15.6	-0.59	(-0.97, -0.21)	0.002**

表 2.7.3.6-115. 評価時点ごとの被験者から報告された排便回数のベースラインからの変化量（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP / CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
ITT SET											
AVERAGE STOOL FREQUENCY ABSOLUTE VALUE											
WEEK 1											
ADALIMUMAB STANDARD INDUCTION DOSE	332	7.12	5.79	-1.33	1.914	-11.8	-1.20	4.2			
ADALIMUMAB HIGHER INDUCTION DOSE	502	7.50	5.75	-1.75	2.150	-19.0	-1.40	3.6	-0.33	(-0.58, -0.07)	0.013*
WEEK 2											
ADALIMUMAB STANDARD INDUCTION DOSE	323	7.10	5.29	-1.80	2.379	-11.4	-1.40	10.2			
ADALIMUMAB HIGHER INDUCTION DOSE	489	7.51	5.17	-2.35	2.610	-17.2	-2.00	5.4	-0.40	(-0.70, -0.09)	0.010**

表 2.7.3.6-115. 評価時点ごとの被験者から報告された排便回数のベースラインからの変化量（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

PARAMETER / VISIT / TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP CHANGE FROM BASELINE MEAN	STD	MIN	MEDIAN	MAX	BETWEEN GROUP COMPARISON (HIGHER DOSE - STANDARD DOSE) LSMEAN	95% CI	P-VALUE@
WEEK 4											
ADALIMUMAB STANDARD INDUCTION DOSE	328	7.13	5.03	-2.10	2.869	-14.8	-1.80	10.2			
ADALIMUMAB HIGHER INDUCTION DOSE	498	7.50	4.68	-2.82	3.267	-18.8	-2.40	15.6	-0.57	(-0.95, -0.20)	0.003**
WEEK 8											
ADALIMUMAB STANDARD INDUCTION DOSE	311	7.08	4.85	-2.23	3.092	-17.6	-2.20	10.2			
ADALIMUMAB HIGHER INDUCTION DOSE	480	7.43	4.52	-2.90	3.451	-19.5	-2.60	15.6	-0.53	(-0.93, -0.13)	0.010**

@ P-VALUE FOR TEST OF DIFFERENCE BETWEEN ADALIMUMAB HIGHER INDUCTION DOSE AND ADALIMUMAB STANDARD INDUCTION DOSE FOR CHANGE FROM BASELINE USING ANALYSIS OF COVARIANCE WITH TREATMENT, PREVIOUS INFLIXIMAB USE, BASELINE CORTICOSTEROID USE, AND BASELINE VALUE AS COVARIATE.
***, **, *, + STATISTICALLY SIGNIFICANT AT 0.001, 0.01, 0.05 AND 0.1 LEVEL, RESPECTIVELY.

Cross reference: M14-033 Induction_Japan Sub-study Final CSR Table 14.2__3.16_J

表 2.7.3.6-116.　PMS による寛解達成までの期間（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）

	JAPAN ITT SET		INTEGRATED ITT SET		ITT SET	
	ADALIMUMAB		ADALIMUMAB		ADALIMUMAB	
	STANDARD DOSE (N=39) n (%)	HIGHER DOSE (N=61) n (%)	STANDARD DOSE (N=378) n (%)	HIGHER DOSE (N=571) n (%)	STANDARD DOSE (N=339) n (%)	HIGHER DOSE (N=510) n (%)
NUMBER OF EVENTS PER PARTIAL MAYO SCORE	15 (38.5)	20 (32.8)	119 (31.5)	211 (37.0)	104 (30.7)	191 (37.5)
KAPLAN-MEIER METHOD:						
PERCENTILES (WEEKS)						
25TH	4.0	8.0	8.0	4.0	8.0	4.0
MEDIAN	NE[A]	NE[A]	NE[A]	NE[A]	NE[A]	NE[A]
75TH	NE[A]	NE[A]	NE[A]	NE[A]	NE[A]	NE[A]
COX PROPORTIONAL HAZARDS MODEL$:						
HAZARDS RATIO HIGHER DOSE VERSUS STANDARD DOSE		0.718		1.173		1.234
(%95 CI)		(0.367, 1.405)		(0.937, 1.469)		(0.972, 1.568)
P-VALUE		0.333		0.164		0.084

表 2.7.3.6-116.　PMS による寛解達成までの期間（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

NOTE: CLINICAL REMISSION PER PARTIAL MAYO SCORE IS DEFINED AS PARTIAL MAYO SCORE <= 2, WITH NO SUBSCORE > 1.
$ THE COVARIATES TRT01PN CORBLN PRIFMN ARE INCLUDED IN THE COX PROPORTIONAL HAZARDS MODEL.
SUBJECTS WHO DID NOT RESPOND BY WEEK 8 WERE CENSORED AT LAST OC VISIT.
[A] NOT ESTIMABLE.

Cross reference: M14-033 Induction_Japan Sub-study Final CSR Table 14.2__3.17_J

表 2.7.3.6-117.　PMS による改善達成までの時間（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）

	JAPAN ITT SET		INTEGRATED ITT SET		ITT SET	
	ADALIMUMAB		ADALIMUMAB		ADALIMUMAB	
	STANDARD DOSE (N=39) n (%)	HIGHER DOSE (N=61) n (%)	STANDARD DOSE (N=378) n (%)	HIGHER DOSE (N=571) n (%)	STANDARD DOSE (N=339) n (%)	HIGHER DOSE (N=510) n (%)
NUMBER OF EVENTS PER PARTIAL MAYO SCORE	21 (53.8)	36 (59.0)	246 (65.1)	395 (69.2)	225 (66.4)	359 (70.4)
KAPLAN-MEIER METHOD:						
PERCENTILES (WEEKS)						
25TH	2.0	2.0	2.0	1.0	2.0	1.0
MEDIAN	4.0	4.0	4.0	4.0	4.0	4.0
75TH	NE[A]	NE[A]	NE[A]	9.0	NE[A]	9.0
COX PROPORTIONAL HAZARDS MODEL$:						
HAZARDS RATIO HIGHER DOSE VERSUS STANDARD DOSE		1.066		1.089		1.092
(%95 CI)		(0.621, 1.829)		(0.929, 1.278)		(0.924, 1.290)
P-VALUE		0.816		0.292		0.302

表 2.7.3.6-117.　PMS による改善達成までの時間（OC）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

NOTE: CLINICAL RESPONSE PER PARTIAL MAYO SCORE IS DEFINED AS A DECREASE IN PARTIAL MAYO SCORE >= 2 POINTS AND >= 30% FROM BASELINE, PLUS A DECREASE IN RBS >= 1 OR AN ABSOLUTE RBS <= 1.
$ THE COVARIATES TRT01PN CORBLN PRIFMN ARE INCLUDED IN THE COX PROPORTIONAL HAZARDS MODEL.
SUBJECTS WHO DID NOT RESPOND BY WEEK 8 WERE CENSORED AT LAST OC VISIT.
[A] NOT ESTIMABLE.

Cross reference: M14-033 Induction_Japan Sub-study Final CSR Table 14.2__3.18_J

表 2.7.3.6-118.　治験期間中の腸管外合併症の有無の変化（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）

VARIABLE/ TREATMENT/ BASELINE VALUE	WEEK 8 YES N (%)	WEEK 8 NO N (%)	WEEK 8 MISSING N (%)
JAPAN ITT SET			
ANEMIA			
ADALIMUMAB STANDARD INDUCTION DOSE (N=39)			
YES (N=9)	7 (77.8)	2 (22.2)	0
NO (N=30)	3 (10.0)	27 (90.0)	0
ADALIMUMAB HIGHER INDUCTION DOSE (N=61)			
YES (N=17)	16 (94.1)	1 (5.9)	0
NO (N=44)	1 (2.3)	43 (97.7)	0
AUTOIMMUNE HEPATITIS			
ADALIMUMAB STANDARD INDUCTION DOSE (N=39)			
YES (N=0)	0	0	0
NO (N=39)	0	39 (100)	0
ADALIMUMAB HIGHER INDUCTION DOSE (N=61)			
YES (N=0)	0	0	0
NO (N=61)	0	61 (100)	0

表 2.7.3.6-118. 治験期間中の腸管外合併症の有無の変化（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

VARIABLE/ TREATMENT/ BASELINE VALUE	WEEK 8 YES N (%)	WEEK 8 NO N (%)	WEEK 8 MISSING N (%)
AXIAL ARTHROPATHY			
ADALIMUMAB STANDARD INDUCTION DOSE (N=39)			
YES (N=1)	1 (100)	0	0
NO (N=38)	0	38 (100)	0
ADALIMUMAB HIGHER INDUCTION DOSE (N=61)			
YES (N=0)	0	0	0
NO (N=61)	0	61 (100)	0
BRONCHIECTASIS			
ADALIMUMAB STANDARD INDUCTION DOSE (N=39)			
YES (N=0)	0	0	0
NO (N=39)	0	39 (100)	0
ADALIMUMAB HIGHER INDUCTION DOSE (N=61)			
YES (N=0)	0	0	0
NO (N=61)	0	61 (100)	0

表 2.7.3.6-118. 治験期間中の腸管外合併症の有無の変化（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

VARIABLE/ TREATMENT/ BASELINE VALUE	WEEK 8 YES N (%)	WEEK 8 NO N (%)	WEEK 8 MISSING N (%)
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
ADALIMUMAB STANDARD INDUCTION DOSE (N=39)			
YES (N=0)	0	0	0
NO (N=39)	0	39 (100)	0
ADALIMUMAB HIGHER INDUCTION DOSE (N=61)			
YES (N=1)	0	1 (100)	0
NO (N=60)	0	60 (100)	0
EPISCLERITIS			
ADALIMUMAB STANDARD INDUCTION DOSE (N=39)			
YES (N=0)	0	0	0
NO (N=39)	0	39 (100)	0
ADALIMUMAB HIGHER INDUCTION DOSE (N=61)			
YES (N=1)	0	1 (100)	0
NO (N=60)	0	60 (100)	0

表 2.7.3.6-118. 治験期間中の腸管外合併症の有無の変化（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

VARIABLE/ TREATMENT/ BASELINE VALUE	WEEK 8 YES N (%)	WEEK 8 NO N (%)	WEEK 8 MISSING N (%)
ERYTHEMA NODOSUM			
ADALIMUMAB STANDARD INDUCTION DOSE (N=39)			
YES (N=0)	0	0	0
NO (N=39)	0	39 (100)	0
ADALIMUMAB HIGHER INDUCTION DOSE (N=61)			
YES (N=2)	0	2 (100)	0
NO (N=59)	0	59 (100)	0
IRITIS			
ADALIMUMAB STANDARD INDUCTION DOSE (N=39)			
YES (N=0)	0	0	0
NO (N=39)	0	39 (100)	0
ADALIMUMAB HIGHER INDUCTION DOSE (N=61)			
YES (N=0)	0	0	0
NO (N=61)	0	61 (100)	0

表 2.7.3.6-118. 治験期間中の腸管外合併症の有無の変化（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

VARIABLE/ TREATMENT/ BASELINE VALUE	WEEK 8 YES N (%)	WEEK 8 NO N (%)	WEEK 8 MISSING N (%)
NEPHROLITHIASIS			
ADALIMUMAB STANDARD INDUCTION DOSE (N=39)			
YES (N=0)	0	0	0
NO (N=39)	0	39 (100)	0
ADALIMUMAB HIGHER INDUCTION DOSE (N=61)			
YES (N=0)	0	0	0
NO (N=61)	0	61 (100)	0
ORAL APHTHOUS ULCERS			
ADALIMUMAB STANDARD INDUCTION DOSE (N=39)			
YES (N=0)	0	0	0
NO (N=39)	0	39 (100)	0
ADALIMUMAB HIGHER INDUCTION DOSE (N=61)			
YES (N=1)	0	1 (100)	0
NO (N=60)	0	60 (100)	0

表 2.7.3.6-118. 治験期間中の腸管外合併症の有無の変化（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

VARIABLE/ TREATMENT/ BASELINE VALUE	WEEK 8 YES N (%)	WEEK 8 NO N (%)	WEEK 8 MISSING N (%)
PERIPHERAL ARTHROPATHY			
ADALIMUMAB STANDARD INDUCTION DOSE (N=39)			
YES (N=4)	2 (50.0)	2 (50.0)	0
NO (N=35)	0	35 (100)	0
ADALIMUMAB HIGHER INDUCTION DOSE (N=61)			
YES (N=1)	0	1 (100)	0
NO (N=60)	0	60 (100)	0
PRIMARY SCLEROSING CHOLANGITIS			
ADALIMUMAB STANDARD INDUCTION DOSE (N=39)			
YES (N=1)	1 (100)	0	0
NO (N=38)	0	38 (100)	0
ADALIMUMAB HIGHER INDUCTION DOSE (N=61)			
YES (N=0)	0	0	0
NO (N=61)	0	61 (100)	0

表 2.7.3.6-118. 治験期間中の腸管外合併症の有無の変化（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

VARIABLE/ TREATMENT/ BASELINE VALUE	WEEK 8 YES N (%)	WEEK 8 NO N (%)	WEEK 8 MISSING N (%)
PYODERMA GANGRENOSUM			
ADALIMUMAB STANDARD INDUCTION DOSE (N=39)			
YES (N=1)	0	1 (100)	0
NO (N=38)	0	38 (100)	0
ADALIMUMAB HIGHER INDUCTION DOSE (N=61)			
YES (N=0)	0	0	0
NO (N=61)	0	61 (100)	0
SWEET'S SYNDROME			
ADALIMUMAB STANDARD INDUCTION DOSE (N=39)			
YES (N=0)	0	0	0
NO (N=39)	0	39 (100)	0
ADALIMUMAB HIGHER INDUCTION DOSE (N=61)			
YES (N=0)	0	0	0
NO (N=61)	0	61 (100)	0

表 2.7.3.6-118. 治験期間中の腸管外合併症の有無の変化（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

VARIABLE/ TREATMENT/ BASELINE VALUE	WEEK 8 YES N (%)	WEEK 8 NO N (%)	WEEK 8 MISSING N (%)
UVEITIS			
ADALIMUMAB STANDARD INDUCTION DOSE (N=39)			
YES (N=0)	0	0	0
NO (N=39)	0	39 (100)	0
ADALIMUMAB HIGHER INDUCTION DOSE (N=61)			
YES (N=0)	0	0	0
NO (N=61)	0	61 (100)	0
VENOUS THROMBOEMBOLISM			
ADALIMUMAB STANDARD INDUCTION DOSE (N=39)			
YES (N=0)	0	0	0
NO (N=39)	0	39 (100)	0
ADALIMUMAB HIGHER INDUCTION DOSE (N=61)			
YES (N=0)	0	0	0
NO (N=61)	0	61 (100)	0

表 2.7.3.6-118. 治験期間中の腸管外合併症の有無の変化（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

VARIABLE/ TREATMENT/ BASELINE VALUE	WEEK 8 YES N (%)	WEEK 8 NO N (%)	WEEK 8 MISSING N (%)
INTEGRATED ITT SET			
ANEMIA			
ADALIMUMAB STANDARD INDUCTION DOSE (N=372)			
YES (N=85)	57 (67.1)	26 (30.6)	2 (2.4)
NO (N=287)	12 (4.2)	267 (93.0)	8 (2.8)
ADALIMUMAB HIGHER INDUCTION DOSE (N=563)			
YES (N=112)	69 (61.6)	39 (34.8)	4 (3.6)
NO (N=451)	19 (4.2)	422 (93.6)	10 (2.2)
AUTOIMMUNE HEPATITIS			
ADALIMUMAB STANDARD INDUCTION DOSE (N=372)			
YES (N=0)	0	0	0
NO (N=372)	1 (0.3)	361 (97.0)	10 (2.7)
ADALIMUMAB HIGHER INDUCTION DOSE (N=563)			
YES (N=1)	1 (100)	0	0
NO (N=562)	0	547 (97.3)	15 (2.7)

表 2.7.3.6-118. 治験期間中の腸管外合併症の有無の変化（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

VARIABLE/ TREATMENT/ BASELINE VALUE	WEEK 8 YES N (%)	WEEK 8 NO N (%)	WEEK 8 MISSING N (%)
AXIAL ARTHROPATHY			
ADALIMUMAB STANDARD INDUCTION DOSE (N=372)			
YES (N=14)	7 (50.0)	7 (50.0)	0
NO (N=358)	2 (0.6)	346 (96.6)	10 (2.8)
ADALIMUMAB HIGHER INDUCTION DOSE (N=563)			
YES (N=9)	2 (22.2)	7 (77.8)	0
NO (N=554)	1 (0.2)	539 (97.3)	14 (2.5)
BRONCHIECTASIS			
ADALIMUMAB STANDARD INDUCTION DOSE (N=372)			
YES (N=0)	0	0	0
NO (N=372)	0	362 (97.3)	10 (2.7)
ADALIMUMAB HIGHER INDUCTION DOSE (N=563)			
YES (N=0)	0	0	0
NO (N=563)	0	548 (97.3)	15 (2.7)

表 2.7.3.6-118. 治験期間中の腸管外合併症の有無の変化（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

VARIABLE/ TREATMENT/ BASELINE VALUE	WEEK 8 YES N (%)	WEEK 8 NO N (%)	WEEK 8 MISSING N (%)
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
ADALIMUMAB STANDARD INDUCTION DOSE (N=372)			
YES (N=2)	2 (100)	0	0
NO (N=370)	0	360 (97.3)	10 (2.7)
ADALIMUMAB HIGHER INDUCTION DOSE (N=563)			
YES (N=3)	2 (66.7)	1 (33.3)	0
NO (N=560)	0	546 (97.5)	14 (2.5)
EPISCLERITIS			
ADALIMUMAB STANDARD INDUCTION DOSE (N=372)			
YES (N=0)	0	0	0
NO (N=372)	0	362 (97.3)	10 (2.7)
ADALIMUMAB HIGHER INDUCTION DOSE (N=563)			
YES (N=2)	0	2 (100)	0
NO (N=561)	0	547 (97.5)	14 (2.5)

表 2.7.3.6-118. 治験期間中の腸管外合併症の有無の変化（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

VARIABLE/ TREATMENT/ BASELINE VALUE	WEEK 8 YES N (%)	WEEK 8 NO N (%)	WEEK 8 MISSING N (%)
ERYTHEMA NODOSUM			
ADALIMUMAB STANDARD INDUCTION DOSE (N=372)			
YES (N=1)	0	1 (100)	0
NO (N=371)	1 (0.3)	360 (97.0)	10 (2.7)
ADALIMUMAB HIGHER INDUCTION DOSE (N=563)			
YES (N=4)	0	4 (100)	0
NO (N=559)	1 (0.2)	544 (97.3)	14 (2.5)
IRITIS			
ADALIMUMAB STANDARD INDUCTION DOSE (N=372)			
YES (N=1)	1 (100)	0	0
NO (N=371)	0	361 (97.3)	10 (2.7)
ADALIMUMAB HIGHER INDUCTION DOSE (N=563)			
YES (N=2)	1 (50.0)	1 (50.0)	0
NO (N=561)	0	547 (97.5)	14 (2.5)

表 2.7.3.6-118. 治験期間中の腸管外合併症の有無の変化（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

VARIABLE/ TREATMENT/ BASELINE VALUE	WEEK 8 YES N (%)	WEEK 8 NO N (%)	WEEK 8 MISSING N (%)
NEPHROLITHIASIS			
ADALIMUMAB STANDARD INDUCTION DOSE (N=372)			
YES (N=1)	0	1 (100)	0
NO (N=371)	1 (0.3)	360 (97.0)	10 (2.7)
ADALIMUMAB HIGHER INDUCTION DOSE (N=563)			
YES (N=5)	4 (80.0)	1 (20.0)	0
NO (N=558)	2 (0.4)	541 (97.0)	15 (2.7)
ORAL APHTHOUS ULCERS			
ADALIMUMAB STANDARD INDUCTION DOSE (N=372)			
YES (N=4)	1 (25.0)	3 (75.0)	0
NO (N=368)	3 (0.8)	355 (96.5)	10 (2.7)
ADALIMUMAB HIGHER INDUCTION DOSE (N=563)			
YES (N=5)	0	5 (100)	0
NO (N=558)	1 (0.2)	543 (97.3)	14 (2.5)

表 2.7.3.6-118. 治験期間中の腸管外合併症の有無の変化（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

VARIABLE/ TREATMENT/ BASELINE VALUE	WEEK 8 YES N (%)	WEEK 8 NO N (%)	WEEK 8 MISSING N (%)
PERIPHERAL ARTHROPATHY			
ADALIMUMAB STANDARD INDUCTION DOSE (N=372)			
YES (N=40)	17 (42.5)	23 (57.5)	0
NO (N=332)	9 (2.7)	313 (94.3)	10 (3.0)
ADALIMUMAB HIGHER INDUCTION DOSE (N=563)			
YES (N=65)	23 (35.4)	41 (63.1)	1 (1.5)
NO (N=498)	10 (2.0)	475 (95.4)	13 (2.6)
PRIMARY SCLEROSING CHOLANGITIS			
ADALIMUMAB STANDARD INDUCTION DOSE (N=372)			
YES (N=5)	3 (60.0)	2 (40.0)	0
NO (N=367)	0	357 (97.3)	10 (2.7)
ADALIMUMAB HIGHER INDUCTION DOSE (N=563)			
YES (N=2)	2 (100)	0	0
NO (N=561)	0	547 (97.5)	14 (2.5)

表 2.7.3.6-118. 治験期間中の腸管外合併症の有無の変化（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

VARIABLE/ TREATMENT/ BASELINE VALUE	WEEK 8 YES N (%)	WEEK 8 NO N (%)	WEEK 8 MISSING N (%)
PYODERMA GANGRENOSUM			
ADALIMUMAB STANDARD INDUCTION DOSE (N=372)			
YES (N=3)	1 (33.3)	2 (66.7)	0
NO (N=369)	0	359 (97.3)	10 (2.7)
ADALIMUMAB HIGHER INDUCTION DOSE (N=563)			
YES (N=1)	0	1 (100)	0
NO (N=562)	1 (0.2)	547 (97.3)	14 (2.5)
SWEET'S SYNDROME			
ADALIMUMAB STANDARD INDUCTION DOSE (N=372)			
YES (N=0)	0	0	0
NO (N=372)	0	362 (97.3)	10 (2.7)
ADALIMUMAB HIGHER INDUCTION DOSE (N=563)			
YES (N=0)	0	0	0
NO (N=563)	0	549 (97.5)	14 (2.5)

表 2.7.3.6-118. 治験期間中の腸管外合併症の有無の変化（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

VARIABLE/ TREATMENT/ BASELINE VALUE	WEEK 8 YES N (%)	WEEK 8 NO N (%)	WEEK 8 MISSING N (%)
UVEITIS			
ADALIMUMAB STANDARD INDUCTION DOSE (N=372)			
YES (N=2)	2 (100)	0	0
NO (N=370)	0	360 (97.3)	10 (2.7)
ADALIMUMAB HIGHER INDUCTION DOSE (N=563)			
YES (N=0)	0	0	0
NO (N=563)	0	549 (97.5)	14 (2.5)
VENOUS THROMBOEMBOLISM			
ADALIMUMAB STANDARD INDUCTION DOSE (N=372)			
YES (N=1)	1 (100)	0	0
NO (N=371)	0	361 (97.3)	10 (2.7)
ADALIMUMAB HIGHER INDUCTION DOSE (N=563)			
YES (N=1)	1 (100)	0	0
NO (N=562)	1 (0.2)	547 (97.3)	14 (2.5)

表 2.7.3.6-118. 治験期間中の腸管外合併症の有無の変化（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

VARIABLE/ TREATMENT/ BASELINE VALUE	WEEK 8 YES N (%)	WEEK 8 NO N (%)	WEEK 8 MISSING N (%)
ITT SET			
ANEMIA			
ADALIMUMAB STANDARD INDUCTION DOSE (N=333)			
YES (N=76)	50 (65.8)	24 (31.6)	2 (2.6)
NO (N=257)	9 (3.5)	240 (93.4)	8 (3.1)
ADALIMUMAB HIGHER INDUCTION DOSE (N=502)			
YES (N=95)	53 (55.8)	38 (40.0)	4 (4.2)
NO (N=407)	18 (4.4)	379 (93.1)	10 (2.5)
AUTOIMMUNE HEPATITIS			
ADALIMUMAB STANDARD INDUCTION DOSE (N=333)			
YES (N=0)	0	0	0
NO (N=333)	1 (0.3)	322 (96.7)	10 (3.0)
ADALIMUMAB HIGHER INDUCTION DOSE (N=502)			
YES (N=1)	1 (100)	0	0
NO (N=501)	0	486 (97.0)	15 (3.0)

表 2.7.3.6-118. 治験期間中の腸管外合併症の有無の変化（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

VARIABLE/ TREATMENT/ BASELINE VALUE	WEEK 8 YES N (%)	WEEK 8 NO N (%)	WEEK 8 MISSING N (%)
AXIAL ARTHROPATHY			
ADALIMUMAB STANDARD INDUCTION DOSE (N=333)			
YES (N=13)	6 (46.2)	7 (53.8)	0
NO (N=320)	2 (0.6)	308 (96.3)	10 (3.1)
ADALIMUMAB HIGHER INDUCTION DOSE (N=502)			
YES (N=9)	2 (22.2)	7 (77.8)	0
NO (N=493)	1 (0.2)	478 (97.0)	14 (2.8)
BRONCHIECTASIS			
ADALIMUMAB STANDARD INDUCTION DOSE (N=333)			
YES (N=0)	0	0	0
NO (N=333)	0	323 (97.0)	10 (3.0)
ADALIMUMAB HIGHER INDUCTION DOSE (N=502)			
YES (N=0)	0	0	0
NO (N=502)	0	487 (97.0)	15 (3.0)

表 2.7.3.6-118. 治験期間中の腸管外合併症の有無の変化（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

VARIABLE/ TREATMENT/ BASELINE VALUE	WEEK 8 YES N (%)	WEEK 8 NO N (%)	WEEK 8 MISSING N (%)
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
ADALIMUMAB STANDARD INDUCTION DOSE (N=333)			
YES (N=2)	2 (100)	0	0
NO (N=331)	0	321 (97.0)	10 (3.0)
ADALIMUMAB HIGHER INDUCTION DOSE (N=502)			
YES (N=2)	2 (100)	0	0
NO (N=500)	0	486 (97.2)	14 (2.8)
EPISCLERITIS			
ADALIMUMAB STANDARD INDUCTION DOSE (N=333)			
YES (N=0)	0	0	0
NO (N=333)	0	323 (97.0)	10 (3.0)
ADALIMUMAB HIGHER INDUCTION DOSE (N=502)			
YES (N=1)	0	1 (100)	0
NO (N=501)	0	487 (97.2)	14 (2.8)

表 2.7.3.6-118. 治験期間中の腸管外合併症の有無の変化（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

VARIABLE/ TREATMENT/ BASELINE VALUE	WEEK 8 YES N (%)	WEEK 8 NO N (%)	WEEK 8 MISSING N (%)
ERYTHEMA NODOSUM			
ADALIMUMAB STANDARD INDUCTION DOSE (N=333)			
YES (N=1)	0	1 (100)	0
NO (N=332)	1 (0.3)	321 (96.7)	10 (3.0)
ADALIMUMAB HIGHER INDUCTION DOSE (N=502)			
YES (N=2)	0	2 (100)	0
NO (N=500)	1 (0.2)	485 (97.0)	14 (2.8)
IRITIS			
ADALIMUMAB STANDARD INDUCTION DOSE (N=333)			
YES (N=1)	1 (100)	0	0
NO (N=332)	0	322 (97.0)	10 (3.0)
ADALIMUMAB HIGHER INDUCTION DOSE (N=502)			
YES (N=2)	1 (50.0)	1 (50.0)	0
NO (N=500)	0	486 (97.2)	14 (2.8)

表 2.7.3.6-118. 治験期間中の腸管外合併症の有無の変化（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

VARIABLE/ TREATMENT/ BASELINE VALUE	WEEK 8 YES N (%)	WEEK 8 NO N (%)	WEEK 8 MISSING N (%)
NEPHROLITHIASIS			
ADALIMUMAB STANDARD INDUCTION DOSE (N=333)			
YES (N=1)	0	1 (100)	0
NO (N=332)	1 (0.3)	321 (96.7)	10 (3.0)
ADALIMUMAB HIGHER INDUCTION DOSE (N=502)			
YES (N=5)	4 (80.0)	1 (20.0)	0
NO (N=497)	2 (0.4)	480 (96.6)	15 (3.0)
ORAL APHTHOUS ULCERS			
ADALIMUMAB STANDARD INDUCTION DOSE (N=333)			
YES (N=4)	1 (25.0)	3 (75.0)	0
NO (N=329)	3 (0.9)	316 (96.0)	10 (3.0)
ADALIMUMAB HIGHER INDUCTION DOSE (N=502)			
YES (N=4)	0	4 (100)	0
NO (N=498)	1 (0.2)	483 (97.0)	14 (2.8)

表 2.7.3.6-118. 治験期間中の腸管外合併症の有無の変化（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

VARIABLE/ TREATMENT/ BASELINE VALUE	WEEK 8 YES N (%)	WEEK 8 NO N (%)	WEEK 8 MISSING N (%)
PERIPHERAL ARTHROPATHY			
ADALIMUMAB STANDARD INDUCTION DOSE (N=333)			
YES (N=36)	15 (41.7)	21 (58.3)	0
NO (N=297)	9 (3.0)	278 (93.6)	10 (3.4)
ADALIMUMAB HIGHER INDUCTION DOSE (N=502)			
YES (N=64)	23 (35.9)	40 (62.5)	1 (1.6)
NO (N=438)	10 (2.3)	415 (94.7)	13 (3.0)
PRIMARY SCLEROSING CHOLANGITIS			
ADALIMUMAB STANDARD INDUCTION DOSE (N=333)			
YES (N=4)	2 (50.0)	2 (50.0)	0
NO (N=329)	0	319 (97.0)	10 (3.0)
ADALIMUMAB HIGHER INDUCTION DOSE (N=502)			
YES (N=2)	2 (100)	0	0
NO (N=500)	0	486 (97.2)	14 (2.8)

表 2.7.3.6-118. 治験期間中の腸管外合併症の有無の変化（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

VARIABLE/ TREATMENT/ BASELINE VALUE	WEEK 8 YES N (%)	WEEK 8 NO N (%)	WEEK 8 MISSING N (%)
PYODERMA GANGRENOSUM			
ADALIMUMAB STANDARD INDUCTION DOSE (N=333)			
YES (N=2)	1 (50.0)	1 (50.0)	0
NO (N=331)	0	321 (97.0)	10 (3.0)
ADALIMUMAB HIGHER INDUCTION DOSE (N=502)			
YES (N=1)	0	1 (100)	0
NO (N=501)	1 (0.2)	486 (97.0)	14 (2.8)
SWEET'S SYNDROME			
ADALIMUMAB STANDARD INDUCTION DOSE (N=333)			
YES (N=0)	0	0	0
NO (N=333)	0	323 (97.0)	10 (3.0)
ADALIMUMAB HIGHER INDUCTION DOSE (N=502)			
YES (N=0)	0	0	0
NO (N=502)	0	488 (97.2)	14 (2.8)

表 2.7.3.6-118. 治験期間中の腸管外合併症の有無の変化（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

VARIABLE/ TREATMENT/ BASELINE VALUE	WEEK 8 YES N (%)	WEEK 8 NO N (%)	WEEK 8 MISSING N (%)
UVEITIS			
ADALIMUMAB STANDARD INDUCTION DOSE (N=333)			
YES (N=2)	2 (100)	0	0
NO (N=331)	0	321 (97.0)	10 (3.0)
ADALIMUMAB HIGHER INDUCTION DOSE (N=502)			
YES (N=0)	0	0	0
NO (N=502)	0	488 (97.2)	14 (2.8)
VENOUS THROMBOEMBOLISM			
ADALIMUMAB STANDARD INDUCTION DOSE (N=333)			
YES (N=1)	1 (100)	0	0
NO (N=332)	0	322 (97.0)	10 (3.0)
ADALIMUMAB HIGHER INDUCTION DOSE (N=502)			
YES (N=1)	1 (100)	0	0
NO (N=501)	1 (0.2)	486 (97.0)	14 (2.8)

Cross reference: M14-033 Induction_Japan Sub-study Final CSR Table 14.2__3.19_J

表 2.7.3.6-119. 投与 8 週時から投与 52 週時までの原因を問わない入院及び手術，又は UC に関連する入院及び手術を行った被験者の割合（維持療法試験，ITT-RP 集団，M14-033 主試験）

Variable Treatment	Number of Subjects with Event	Time at Risk in Patient-Year$	Incidence Rate	Relative Risk of EW/EOW (95% CI)	P-value&	Total Subjects
ALL-CAUSE HOSPITALIZATIONS						
Adalimumab 40mg EOW	16	126.4	0.13	1.1 (2.1, 0.5)	0.858	145
Adalimumab 40mg EW	18	133.7	0.13			152
UC-RELATED HOSPITALIZATIONS						
Adalimumab 40mg EOW	9	129.0	0.07	0.4 (0.1, 1.3)	0.119	145
Adalimumab 40mg EW	4	141.9	0.03			152
ALL-CAUSE SURGERIES						
Adalimumab 40mg EOW	4	129.7	0.03	2.1 (6.7, 0.7)	0.205	145
Adalimumab 40mg EW	9	138.6	0.06			152
UC-RELATED SURGERIES						
Adalimumab 40mg EOW	1	130.4	0.01	0.9 (0.1,14.5)	0.947	145
Adalimumab 40mg EW	1	143.3	0.01			152

$ Censored to first event (hospitalization or surgery). All subjects without event will be censored to last dose date of the study drug + 70 days.
& Based on z-score.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.1.1

表 2.7.3.6-120. 投与 8 週時から投与 52 週時までの原因を問わない入院及び手術，又は UC に関連する入院及び手術の頻度（維持療法試験，ITT-RP 集団，M14-033 主試験）

	Adalimumab 40mg EOW (N=145) (PYS=126.4) Events (E/100PY)	Adalimumab 40mg EW (N=152) (PYS=133.4) Events (E/100PY)	P-Value&
ALL-CAUSE HOSPITALIZATIONS	19 (15.0)	24 (18.0)	0.570
UC-RELATED HOSPITALIZATIONS	9 (7.1)	5 (3.7)	0.249
ALL-CAUSE SURGERIES	4 (3.2)	10 (7.5)	0.146
UC-RELATED SURGERIES	1 (0.8)	1 (0.7)	0.969

Note: All subjects without event will be censored to last dose date of the study drug + 70 days.
E/100PY = Events per 100 patient-years.
& Based on Poisson Regression.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.1.2

表 2.7.3.6-121. 投与 8 週時に Mayo スコアにより改善例となり，かつ投与 52 週時に改善を達成した被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 主試験）

	Adalimumab	
	40mg EOW	40mg EW
Week 8 Responders with Clinical Response at Week 52 (Week 44 of Maintenance Study)	(N=145)	(N=152)
Yes, n (%)	74 (51.0)	98 (64.5)
No, n (%)	71 (49.0)	54 (35.5)
Risk Difference[A]		13.4
Adjusted Risk Difference[A,B]		13.4
95% Confidence Interval[B]		(2.1, 24.6)
P-Value[B]		0.020*

Note: Clinical response is defined as a decrease in Full Mayo Score of >= 3 points and >= 30% from baseline, plus a decrease in the rectal bleeding subscore [RBS] >= 1 or an absolute RBS <= 1.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen and week 8 remission status.
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.2.1

表 2.7.3.6-122. 投与 8 週時に Mayo スコアにより非改善例となり，かつ投与 52 週時に改善を達成した被験者の割合（NRI）（維持療法試験，ITT-NRP 集団，M14-033 主試験）

	Adalimumab 40mg EOW	Adalimumab 40mg EW
Week 8 Non-Responders with Clinical Response at Week 52 (Week 44 of Maintenance Study)	(N=157)	(N=152)
Yes, n (%)	37 (23.6)	43 (28.3)
No, n (%)	120 (76.4)	109 (71.7)
Risk Difference[A]		4.7
Adjusted Risk Difference[A,B]		4.7
95% Confidence Interval[B]		(-5.1, 14.5)
P-Value[B]		0.348

Note: Clinical response is defined as a decrease in Full Mayo Score of >= 3 points and >= 30% from baseline, plus a decrease in the rectal bleeding subscore [RBS] >= 1 or an absolute RBS <= 1.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.3.1

表 2.7.3.6-123. 投与 8 週時に Mayo スコアにより非改善例となり，かつ投与 52 週時に内視鏡検査により改善が認められた被験者の割合（NRI）（維持療法試験，ITT-NRP 集団，M14-033 主試験）

	Adalimumab 40mg EOW	Adalimumab 40mg EW
Week 8 Non-Responders with Endoscopic Improvement at Week 52 (Week 44 of Maintenance Study)	(N=157)	(N=152)
Yes, n (%)	28 (17.8)	38 (25.0)
No, n (%)	129 (82.2)	114 (75.0)
Risk Difference[A]		7.2
Adjusted Risk Difference[A,B]		7.2
95% Confidence Interval[B]		(-2.0, 16.3)
P-Value[B]		0.126

Note: Endoscopic improvement is defined as endoscopy subscore of 0 or 1.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.4.1

表 2.7.3.6-124. 投与 8 週時に Adapted Mayo スコアにより改善例となり，かつ投与 52 週時に Adapted Mayo スコアにより寛解を達成した被験者の割合（NRI）（維持療法試験，ITT 集団，M14-033 主試験）

	Adalimumab 40mg EOW	Adalimumab 40mg EW
Week 8 Responders per Adapted Mayo Score Achieving Clinical Remission per Adapted Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=147)	(N=158)
Yes, n (%)	48 (32.7)	60 (38.0)
No, n (%)	99 (67.3)	98 (62.0)
Risk Difference[A]		5.3
Adjusted Risk Difference[A,B]		6.9
95% Confidence Interval[B]		(-3.7, 17.4)
P-Value[B]		0.205

Note: Clinical remission per Adapted Mayo Score is defined as an Adapted Mayo Score <= 2, with stool frequency subscore <= 1, RBS of 0, and endoscopic subscore <= 1.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen and week 8 remission per Adapted Mayo Score status.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.5.1

表 2.7.3.6-125. 投与 8 週時に改善例となり，かつ投与 52 週時に Adapted Mayo スコアにより寛解を達成した被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 主試験）

	Adalimumab 40mg EOW	Adalimumab 40mg EW
Week 8 Responders Achieving Clinical Remission per Adapted Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=145)	(N=152)
Yes, n (%)	45 (31.0)	61 (40.1)
No, n (%)	100 (69.0)	91 (59.9)
Risk Difference[A]		9.1
Adjusted Risk Difference[A,B]		8.5
95% Confidence Interval[B]		(-2.3, 19.3)
P-Value[B]		0.121

Note: Clinical remission per Adapted Mayo Score is defined as an Adapted Mayo Score <= 2, with stool frequency subscore <= 1, RBS of 0, and endoscopic subscore <= 1.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen and week 8 remission status.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.6.1

表 2.7.3.6-126. ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 8 週時に Mayo スコアにより改善例となった被験者のうち，投与 52 週時に副腎皮質ステロイドを 180 日間以上離脱し，かつ FMS により寛解できた被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 主試験）

	Adalimumab	
	40mg EOW	40mg EW
Week 8 Responders with Steroid Usage at Baseline and Steroid Free at Least 180 Days and in Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=92)	(N=96)
Yes, n (%)	25 (27.2)	37 (38.5)
No, n (%)	67 (72.8)	59 (61.5)
Risk Difference[A]		11.4
Adjusted Risk Difference[A,B]		10.8
95% Confidence Interval[B]		(-2.5, 24.2)
P-Value[B]		0.112

Note: Clinical remission per Full Mayo Score is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided by the central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen and week 8 remission status.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.7.1

表 2.7.3.6-127. ベースラインで副腎皮質ステロイドを投与していた被験者で，各評価時点で副腎皮質ステロイドを離脱できた被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 主試験）

	Adalimumab	
	40mg EOW	40mg EW
Subjects with Steroid Usage at Baseline and Are Steroid Free at Maintenance Baseline	(N=92)	(N=96)
Yes, n (%)	40 (43.5)	34 (35.4)
No, n (%)	52 (56.5)	62 (64.6)
Risk Difference[A]		-8.1
Adjusted Risk Difference[A,B]		-7.7
95% Confidence Interval[B]		(-21.7, 6.3)
P-Value[B]		0.282
Subjects with Steroid Usage at Baseline and Are Steroid Free at Week 10 (Week 2 of Maintenance Study)	(N=92)	(N=96)
Yes, n (%)	60 (65.2)	66 (68.8)
No, n (%)	32 (34.8)	30 (31.3)
Risk Difference[A]		3.5
Adjusted Risk Difference[A,B]		4.8
95% Confidence Interval[B]		(-8.6, 18.1)
P-Value[B]		0.484
Subjects with Steroid Usage at Baseline and Are Steroid Free at Week 12 (Week 4 of Maintenance Study)	(N=92)	(N=96)
Yes, n (%)	65 (70.7)	77 (80.2)
No, n (%)	27 (29.3)	19 (19.8)
Risk Difference[A]		9.6
Adjusted Risk Difference[A,B]		10.6
95% Confidence Interval[B]		(-1.7, 22.9)
P-Value[B]		0.091+

表 2.7.3.6-127. ベースラインで副腎皮質ステロイドを投与していた被験者で，各評価時点で副腎皮質ステロイドを離脱できた被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

	Adalimumab	
	40mg EOW	40mg EW
Subjects with Steroid Usage at Baseline and Are Steroid Free at Week 16 (Week 8 of Maintenance Study)	(N=92)	(N=96)
Yes, n (%)	73 (79.3)	80 (83.3)
No, n (%)	19 (20.7)	16 (16.7)
Risk Difference[A]		4.0
Adjusted Risk Difference[A,B]		4.5
95% Confidence Interval[B]		(-6.7, 15.7)
P-Value[B]		0.433
Subjects with Steroid Usage at Baseline and Are Steroid Free at Week 22 (Week 14 of Maintenance Study)	(N=92)	(N=96)
Yes, n (%)	68 (73.9)	80 (83.3)
No, n (%)	24 (26.1)	16 (16.7)
Risk Difference[A]		9.4
Adjusted Risk Difference[A,B]		9.6
95% Confidence Interval[B]		(-2.2, 21.4)
P-Value[B]		0.112
Subjects with Steroid Usage at Baseline and Are Steroid Free at Week 24 (Week 16 of Maintenance Study)	(N=92)	(N=96)
Yes, n (%)	64 (69.6)	81 (84.4)
No, n (%)	28 (30.4)	15 (15.6)
Risk Difference[A]		14.8
Adjusted Risk Difference[A,B]		14.9
95% Confidence Interval[B]		(2.7, 27.0)
P-Value[B]		0.017*

表 2.7.3.6-127. ベースラインで副腎皮質ステロイドを投与していた被験者で，各評価時点で副腎皮質ステロイドを離脱できた被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

	Adalimumab	
	40mg EOW	40mg EW
Subjects with Steroid Usage at Baseline and Are Steroid Free at Week 29 (Week 21 of Maintenance Study)	(N=92)	(N=96)
Yes, n (%)	65 (70.7)	79 (82.3)
No, n (%)	27 (29.3)	17 (17.7)
Risk Difference[A]		11.6
Adjusted Risk Difference[A,B]		11.6
95% Confidence Interval[B]		(-0.6, 23.9)
P-Value[B]		0.063+
Subjects with Steroid Usage at Baseline and Are Steroid Free at Week 35 (Week 27 of Maintenance Study)	(N=92)	(N=96)
Yes, n (%)	59 (64.1)	76 (79.2)
No, n (%)	33 (35.9)	20 (20.8)
Risk Difference[A]		15.0
Adjusted Risk Difference[A,B]		14.7
95% Confidence Interval[B]		(1.7, 27.7)
P-Value[B]		0.027*
Subjects with Steroid Usage at Baseline and Are Steroid Free at Week 37 (Week 29 of Maintenance Study)	(N=92)	(N=96)
Yes, n (%)	57 (62.0)	77 (80.2)
No, n (%)	35 (38.0)	19 (19.8)
Risk Difference[A]		18.3
Adjusted Risk Difference[A,B]		18.0
95% Confidence Interval[B]		(5.0, 31.1)
P-Value[B]		0.007**

表 2.7.3.6-127. ベースラインで副腎皮質ステロイドを投与していた被験者で，各評価時点で副腎皮質ステロイドを離脱できた被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

	Adalimumab	
	40mg EOW	40mg EW
Subjects with Steroid Usage at Baseline and Are Steroid Free at Week 42 (Week 34 of Maintenance Study)	(N=92)	(N=96)
Yes, n (%)	54 (58.7)	75 (78.1)
No, n (%)	38 (41.3)	21 (21.9)
Risk Difference[A]		19.4
Adjusted Risk Difference[A,B]		19.4
95% Confidence Interval[B]		(6.0, 32.8)
P-Value[B]		0.005**
Subjects with Steroid Usage at Baseline and Are Steroid Free at Week 48 (Week 40 of Maintenance Study)	(N=92)	(N=96)
Yes, n (%)	52 (56.5)	72 (75.0)
No, n (%)	40 (43.5)	24 (25.0)
Risk Difference[A]		18.5
Adjusted Risk Difference[A,B]		18.4
95% Confidence Interval[B]		(4.7, 32.1)
P-Value[B]		0.009**
Subjects with Steroid Usage at Baseline and Are Steroid Free at Week 52 (Week 44 of Maintenance Study)	(N=92)	(N=96)
Yes, n (%)	50 (54.3)	73 (76.0)
No, n (%)	42 (45.7)	23 (24.0)
Risk Difference[A]		21.7
Adjusted Risk Difference[A,B]		21.6
95% Confidence Interval[B]		(7.9, 35.4)
P-Value[B]		0.002**

表 2.7.3.6-127.　ベースラインで副腎皮質ステロイドを投与していた被験者で，各評価時点で副腎皮質ステロイドを離脱できた被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

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[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and
     P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen and week 8
     remission status.
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.
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Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.8

表 2.7.3.6-128.　評価時点ごとの PMS により寛解を達成した被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 主試験）

	Adalimumab	
	40mg EOW	40mg EW
Subjects with Clinical Remission per Partial Mayo Score at Maintenance Baseline	(N=145)	(N=152)
Yes, n (%)	81 (55.9)	83 (54.6)
No, n (%)	64 (44.1)	69 (45.4)
Risk Difference[A]		-1.3
Adjusted Risk Difference[A,B]		-2.5
95% Confidence Interval[B]		(-12.1, 7.1)
P-Value[B]		0.609
Subjects with Clinical Remission per Partial Mayo Score at Week 10 (Week 2 of Maintenance Study)	(N=145)	(N=152)
Yes, n (%)	75 (51.7)	84 (55.3)
No, n (%)	70 (48.3)	68 (44.7)
Risk Difference[A]		3.5
Adjusted Risk Difference[A,B]		2.7
95% Confidence Interval[B]		(-7.7, 13.1)
P-Value[B]		0.608
Subjects with Clinical Remission per Partial Mayo Score at Week 12 (Week 4 of Maintenance Study)	(N=145)	(N=152)
Yes, n (%)	89 (61.4)	82 (53.9)
No, n (%)	56 (38.6)	70 (46.1)
Risk Difference[A]		-7.4
Adjusted Risk Difference[A,B]		-8.1
95% Confidence Interval[B]		(-18.6, 2.3)
P-Value[B]		0.128

表 2.7.3.6-128.　評価時点ごとの PMS により寛解を達成した被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

	Adalimumab	
	40mg EOW	40mg EW
Subjects with Clinical Remission per Partial Mayo Score at Week 16 (Week 8 of Maintenance Study)	(N=145)	(N=152)
Yes, n (%)	81 (55.9)	88 (57.9)
No, n (%)	64 (44.1)	64 (42.1)
Risk Difference[A]		2.0
Adjusted Risk Difference[A,B]		1.6
95% Confidence Interval[B]		(-9.1, 12.4)
P-Value[B]		0.764
Subjects with Clinical Remission per Partial Mayo Score at Week 22 (Week 14 of Maintenance Study)	(N=145)	(N=152)
Yes, n (%)	80 (55.2)	94 (61.8)
No, n (%)	65 (44.8)	58 (38.2)
Risk Difference[A]		6.7
Adjusted Risk Difference[A,B]		5.9
95% Confidence Interval[B]		(-4.9, 16.8)
P-Value[B]		0.284
Subjects with Clinical Remission per Partial Mayo Score at Week 24 (Week 16 of Maintenance Study)	(N=145)	(N=152)
Yes, n (%)	70 (48.3)	88 (57.9)
No, n (%)	75 (51.7)	64 (42.1)
Risk Difference[A]		9.6
Adjusted Risk Difference[A,B]		9.0
95% Confidence Interval[B]		(-2.2, 20.3)
P-Value[B]		0.115

表 2.7.3.6-128. 評価時点ごとの PMS により寛解を達成した被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

	Adalimumab	
	40mg EOW	40mg EW
Subjects with Clinical Remission per Partial Mayo Score at Week 29 (Week 21 of Maintenance Study)	(N=145)	(N=152)
Yes, n (%)	71 (49.0)	89 (58.6)
No, n (%)	74 (51.0)	63 (41.4)
Risk Difference[A]		9.6
Adjusted Risk Difference[A,B]		9.0
95% Confidence Interval[B]		(-2.2, 20.2)
P-Value[B]		0.116
Subjects with Clinical Remission per Partial Mayo Score at Week 35 (Week 27 of Maintenance Study)	(N=145)	(N=152)
Yes, n (%)	69 (47.6)	86 (56.6)
No, n (%)	76 (52.4)	66 (43.4)
Risk Difference[A]		9.0
Adjusted Risk Difference[A,B]		8.4
95% Confidence Interval[B]		(-2.8, 19.6)
P-Value[B]		0.143
Subjects with Clinical Remission per Partial Mayo Score at Week 37 (Week 29 of Maintenance Study)	(N=145)	(N=152)
Yes, n (%)	70 (48.3)	83 (54.6)
No, n (%)	75 (51.7)	69 (45.4)
Risk Difference[A]		6.3
Adjusted Risk Difference[A,B]		5.7
95% Confidence Interval[B]		(-5.5, 16.9)
P-Value[B]		0.317

表 2.7.3.6-128. 評価時点ごとの PMS により寛解を達成した被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

	Adalimumab	
	40mg EOW	40mg EW
Subjects with Clinical Remission per Partial Mayo Score at Week 42 (Week 34 of Maintenance Study)	(N=145)	(N=152)
Yes, n (%)	73 (50.3)	79 (52.0)
No, n (%)	72 (49.7)	73 (48.0)
Risk Difference[A]		1.6
Adjusted Risk Difference[A,B]		0.9
95% Confidence Interval[B]		(-10.3, 12.1)
P-Value[B]		0.875
Subjects with Clinical Remission per Partial Mayo Score at Week 48 (Week 40 of Maintenance Study)	(N=145)	(N=152)
Yes, n (%)	69 (47.6)	84 (55.3)
No, n (%)	76 (52.4)	68 (44.7)
Risk Difference[A]		7.7
Adjusted Risk Difference[A,B]		7.4
95% Confidence Interval[B]		(-4.0, 18.7)
P-Value[B]		0.204
Subjects with Clinical Remission per Partial Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=145)	(N=152)
Yes, n (%)	59 (40.7)	82 (53.9)
No, n (%)	86 (59.3)	70 (46.1)
Risk Difference[A]		13.3
Adjusted Risk Difference[A,B]		12.6
95% Confidence Interval[B]		(1.3, 23.8)
P-Value[B]		0.029*

表 2.7.3.6-128.　評価時点ごとの PMS により寛解を達成した被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

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Note: Clinical remission per Partial Mayo Score is defined as Partial Mayo Score <= 2, with no subscore > 1.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and
     P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen and week 8
     remission status.
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.
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Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.9.1

表 2.7.3.6-129.　評価時点ごとの PMS により改善を達成した被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 主試験）

	Adalimumab	
	40mg EOW	40mg EW
Subjects with Clinical Response per Partial Mayo Score at Maintenance Baseline	(N=145)	(N=152)
Yes, n (%)	143 (98.6)	148 (97.4)
No, n (%)	2 (1.4)	4 (2.6)
Risk Difference[A]		-1.3
Adjusted Risk Difference[A,B]		-1.3
95% Confidence Interval[B]		(-4.5, 1.9)
P-Value[B]		0.431
Subjects with Clinical Response per Partial Mayo Score at Week 10 (Week 2 of Maintenance Study)	(N=145)	(N=152)
Yes, n (%)	127 (87.6)	136 (89.5)
No, n (%)	18 (12.4)	16 (10.5)
Risk Difference[A]		1.9
Adjusted Risk Difference[A,B]		1.7
95% Confidence Interval[B]		(-5.5, 8.8)
P-Value[B]		0.650
Subjects with Clinical Response per Partial Mayo Score at Week 12 (Week 4 of Maintenance Study)	(N=145)	(N=152)
Yes, n (%)	130 (89.7)	128 (84.2)
No, n (%)	15 (10.3)	24 (15.8)
Risk Difference[A]		-5.4
Adjusted Risk Difference[A,B]		-5.6
95% Confidence Interval[B]		(-13.2, 2.1)
P-Value[B]		0.154

表 2.7.3.6-129. 評価時点ごとの PMS により改善を達成した被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

	Adalimumab	
	40mg EOW	40mg EW
Subjects with Clinical Response per Partial Mayo Score at Week 16 (Week 8 of Maintenance Study)	(N=145)	(N=152)
Yes, n (%)	124 (85.5)	129 (84.9)
No, n (%)	21 (14.5)	23 (15.1)
Risk Difference[A]		-0.6
Adjusted Risk Difference[A,B]		-0.7
95% Confidence Interval[B]		(-8.7, 7.4)
P-Value[B]		0.866
Subjects with Clinical Response per Partial Mayo Score at Week 22 (Week 14 of Maintenance Study)	(N=145)	(N=152)
Yes, n (%)	106 (73.1)	127 (83.6)
No, n (%)	39 (26.9)	25 (16.4)
Risk Difference[A]		10.4
Adjusted Risk Difference[A,B]		10.1
95% Confidence Interval[B]		(0.7, 19.4)
P-Value[B]		0.034*
Subjects with Clinical Response per Partial Mayo Score at Week 24 (Week 16 of Maintenance Study)	(N=145)	(N=152)
Yes, n (%)	99 (68.3)	121 (79.6)
No, n (%)	46 (31.7)	31 (20.4)
Risk Difference[A]		11.3
Adjusted Risk Difference[A,B]		11.1
95% Confidence Interval[B]		(1.1, 21.1)
P-Value[B]		0.030*

表 2.7.3.6-129. 評価時点ごとの PMS により改善を達成した被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

	Adalimumab	
	40mg EOW	40mg EW
Subjects with Clinical Response per Partial Mayo Score at Week 29 (Week 21 of Maintenance Study)	(N=145)	(N=152)
Yes, n (%)	100 (69.0)	124 (81.6)
No, n (%)	45 (31.0)	28 (18.4)
Risk Difference[A]		12.6
Adjusted Risk Difference[A,B]		12.3
95% Confidence Interval[B]		(2.5, 22.2)
P-Value[B]		0.014*
Subjects with Clinical Response per Partial Mayo Score at Week 35 (Week 27 of Maintenance Study)	(N=145)	(N=152)
Yes, n (%)	93 (64.1)	114 (75.0)
No, n (%)	52 (35.9)	38 (25.0)
Risk Difference[A]		10.9
Adjusted Risk Difference[A,B]		10.6
95% Confidence Interval[B]		(0.1, 21.0)
P-Value[B]		0.047*
Subjects with Clinical Response per Partial Mayo Score at Week 37 (Week 29 of Maintenance Study)	(N=145)	(N=152)
Yes, n (%)	84 (57.9)	111 (73.0)
No, n (%)	61 (42.1)	41 (27.0)
Risk Difference[A]		15.1
Adjusted Risk Difference[A,B]		14.9
95% Confidence Interval[B]		(4.1, 25.7)
P-Value[B]		0.007**

表 2.7.3.6-129. 評価時点ごとの PMS により改善を達成した被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

	Adalimumab	
	40mg EOW	40mg EW
Subjects with Clinical Response per Partial Mayo Score at Week 42 (Week 34 of Maintenance Study)	(N=145)	(N=152)
Yes, n (%)	94 (64.8)	109 (71.7)
No, n (%)	51 (35.2)	43 (28.3)
Risk Difference[A]		6.9
Adjusted Risk Difference[A,B]		6.6
95% Confidence Interval[B]		(-4.0, 17.2)
P-Value[B]		0.220
Subjects with Clinical Response per Partial Mayo Score at Week 48 (Week 40 of Maintenance Study)	(N=145)	(N=152)
Yes, n (%)	87 (60.0)	112 (73.7)
No, n (%)	58 (40.0)	40 (26.3)
Risk Difference[A]		13.7
Adjusted Risk Difference[A,B]		13.8
95% Confidence Interval[B]		(3.1, 24.5)
P-Value[B]		0.011*
Subjects with Clinical Response per Partial Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=145)	(N=152)
Yes, n (%)	84 (57.9)	108 (71.1)
No, n (%)	61 (42.1)	44 (28.9)
Risk Difference[A]		13.1
Adjusted Risk Difference[A,B]		12.9
95% Confidence Interval[B]		(2.0, 23.8)
P-Value[B]		0.020*

表 2.7.3.6-129.　評価時点ごとの PMS により改善を達成した被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

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Note: Clinical response per Partial Mayo Score is defined as a decrease in Partial Mayo Score >= 2 points and >= 30% from baseline,
      plus a decrease in RBS >= 1 or an absolute RBS <= 1.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and
     P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen and week 8
     remission status.
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.
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Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.10.1

表 2.7.3.6-130. 評価時点ごとの高感度 CRP のベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 主試験）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
HIGH-SENSITIVITY C-REACTIVE PROTEIN (MG/L)											
Week 12 (Week 4 of Maintenance Study)											
Adalimumab 40mg EOW	143	9.315	3.445	-5.870	13.2355	-61.46	-1.810	60.65			
Adalimumab 40mg EW	150	9.079	3.329	-5.750	14.2795	-83.69	-1.940	45.72	0.055	(-1.474, 1.584)	0.944
Week 16 (Week 8 of Maintenance Study)											
Adalimumab 40mg EOW	140	9.490	4.819	-4.671	18.8786	-60.14	-1.555	139.35			
Adalimumab 40mg EW	147	9.233	4.070	-5.163	15.4948	-81.29	-1.830	66.67	-0.467	(-3.459, 2.526)	0.759
Week 24 (Week 16 of Maintenance Study)											
Adalimumab 40mg EOW	132	9.609	4.656	-4.953	14.7309	-59.37	-1.695	53.21			
Adalimumab 40mg EW	143	9.386	3.483	-5.903	14.5145	-81.99	-1.410	48.02	-1.055	(-2.818, 0.707)	0.239
Week 29 (Week 21 of Maintenance Study)											
Adalimumab 40mg EOW	124	9.440	4.671	-4.769	13.6543	-60.30	-1.505	51.86			
Adalimumab 40mg EW	135	9.573	2.885	-6.688	13.7414	-81.82	-2.120	6.32	-1.668	(-3.154, -0.182)	0.028*
Week 37 (Week 29 of Maintenance Study)											
Adalimumab 40mg EOW	117	9.192	3.644	-5.548	11.5262	-46.92	-1.710	23.32			
Adalimumab 40mg EW	129	9.621	5.473	-4.147	26.1090	-82.30	-1.370	229.23	2.241	(-1.746, 6.229)	0.269
Week 42 (Week 34 of Maintenance Study)											
Adalimumab 40mg EOW	112	9.408	3.980	-5.427	13.2173	-63.14	-1.540	45.15			
Adalimumab 40mg EW	126	9.861	3.186	-6.674	14.4899	-69.33	-1.800	24.58	-0.611	(-2.569, 1.347)	0.537

表 2.7.3.6-130. 評価時点ごとの高感度 CRP のベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
Week 52 (Week 44 of Maintenance Study)											
Adalimumab 40mg EOW	104	9.213	3.306	-5.907	11.3343	-46.69	-1.465	24.37			
Adalimumab 40mg EW	123	9.839	5.979	-3.860	20.9604	-79.30	-1.310	104.36	3.240	(-0.215, 6.695)	0.066+

@ P-value for test of difference between Adalimumab 40mg EW and Adalimumab 40mg EOW for change from baseline using the repeated measure model including treatment, induction treatment regimen, week 8 remission status, visit, baseline value, interaction of treatment and visit.
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.11.1

表 2.7.3.6-131.　評価時点ごとの副腎皮質ステロイド投与量のベースラインからの変化量（維持療法試験，ITT-RP 集団，M14-033 主試験）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison: Compare to 40mg EOW LSMEAN	95% CI
CORTICOSTEROID DOSE										
Maintenance Baseline										
Adalimumab 40mg EOW	52	27.692	13.270	-14.423	11.0650	-45.00	-15.000	0.00		
Adalimumab 40mg EW	62	25.202	10.573	-14.629	8.3450	-39.50	-15.000	0.00	-0.857	(-4.268, 2.553)
Week 10 (Week 2 of Maintenance Study)										
Adalimumab 40mg EOW	32	30.469	15.977	-14.492	14.2056	-55.00	-15.000	0.00		
Adalimumab 40mg EW	29	29.828	12.500	-17.328	9.4711	-35.00	-17.500	0.00	-3.222	(-9.446, 3.001)
Week 12 (Week 4 of Maintenance Study)										
Adalimumab 40mg EOW	25	32.200	17.325	-14.875	16.7122	-55.00	-10.000	0.00		
Adalimumab 40mg EW	18	33.056	17.222	-15.833	13.4766	-35.00	-17.500	0.00	-1.482	(-11.189, 8.225)
Week 16 (Week 8 of Maintenance Study)										
Adalimumab 40mg EOW	17	29.706	25.735	-3.971	15.9359	-55.00	0.000	15.00		
Adalimumab 40mg EW	12	32.083	21.458	-10.625	16.6216	-30.00	-12.500	30.00	-5.782	(-18.282, 6.717)
Week 22 (Week 14 of Maintenance Study)										
Adalimumab 40mg EOW	15	28.000	23.833	-4.167	6.5238	-17.50	0.000	2.50		
Adalimumab 40mg EW	9	35.556	18.889	-16.667	9.9216	-35.00	-15.000	0.00	-12.510	(-20.565, -4.456)
Week 24 (Week 16 of Maintenance Study)										
Adalimumab 40mg EOW	16	27.188	27.031	-0.156	11.2720	-15.00	0.000	35.00		
Adalimumab 40mg EW	7	35.714	21.429	-14.286	7.7344	-22.50	-15.000	0.00	-13.716	(-24.868, -2.564)

表 2.7.3.6-131. 評価時点ごとの副腎皮質ステロイド投与量のベースラインからの変化量（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison: Compare to 40mg EOW LSMEAN	95% CI
Week 29 (Week 21 of Maintenance Study)										
Adalimumab 40mg EOW	13	26.154	32.538	6.385	21.5379	-12.50	0.000	65.50		
Adalimumab 40mg EW	7	35.000	19.000	-16.000	12.2100	-32.00	-17.500	0.00	-17.908	(-38.882, 3.066)
Week 35 (Week 27 of Maintenance Study)										
Adalimumab 40mg EOW	15	29.000	27.833	-1.167	9.9493	-25.00	0.000	20.00		
Adalimumab 40mg EW	7	41.429	26.143	-15.286	15.9475	-37.50	-15.000	0.00	-14.250	(-27.375, -1.125)
Week 37 (Week 29 of Maintenance Study)										
Adalimumab 40mg EOW	13	26.154	31.154	5.000	12.4164	-10.00	0.000	35.00		
Adalimumab 40mg EW	5	41.000	26.000	-15.000	15.9099	-37.50	-15.000	0.00	-17.715	(-34.496, -0.933)
Week 42 (Week 34 of Maintenance Study)										
Adalimumab 40mg EOW	11	25.909	30.909	5.000	13.0384	-10.00	0.000	35.00		
Adalimumab 40mg EW	6	35.000	30.417	-4.583	11.8761	-22.50	0.000	10.00	-6.555	(-20.592, 7.483)
Week 48 (Week 40 of Maintenance Study)										
Adalimumab 40mg EOW	7	36.429	40.000	3.571	9.4491	0.00	0.000	25.00		
Adalimumab 40mg EW	6	34.167	25.417	-8.750	9.9687	-22.50	-7.500	0.00	-14.314	(-26.745, -1.884)
Week 52 (Week 44 of Maintenance Study)										
Adalimumab 40mg EOW	8	33.125	40.625	7.500	14.1421	0.00	0.000	35.00		
Adalimumab 40mg EW	5	33.500	31.500	-2.000	19.1540	-22.50	0.000	27.50	-9.976	(-26.179, 6.228)

Note: Only include subjects who took steroid at baseline.
Treatment group differences for changes from baseline is analyzed using Analysis of Variance (ANOVA).

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.12

表 2.7.3.6-132. 評価時点ごとの IBDQ スコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 主試験）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
IBDQ - BOWEL											
Maintenance Baseline											
Adalimumab 40mg EOW	145	35.759	57.441	21.682	10.5382	-2.00	22.000	52.00			
Adalimumab 40mg EW	152	35.784	56.934	21.151	10.8434	-4.00	21.000	51.00	-0.603	(-2.583, 1.378)	0.550
Week 12 (Week 4 of Maintenance Study)											
Adalimumab 40mg EOW	143	35.769	58.445	22.676	11.1658	-13.00	23.000	48.00			
Adalimumab 40mg EW	151	35.762	56.549	20.787	12.4262	-14.00	22.000	51.00	-1.903	(-4.019, 0.213)	0.078+
Week 24 (Week 16 of Maintenance Study)											
Adalimumab 40mg EOW	130	35.500	57.571	22.071	12.8339	-7.00	22.000	52.00			
Adalimumab 40mg EW	140	35.965	58.314	22.349	12.6119	-17.00	23.500	51.00	0.554	(-1.849, 2.957)	0.650
Week 37 (Week 29 of Maintenance Study)											
Adalimumab 40mg EOW	120	35.333	57.419	22.085	13.0172	-13.00	22.000	50.00			
Adalimumab 40mg EW	133	36.129	57.677	21.548	12.6671	-14.00	22.000	50.00	-0.029	(-2.584, 2.527)	0.982
Week 52 (Week 44 of Maintenance Study)											
Adalimumab 40mg EOW	108	35.944	59.292	23.348	12.2990	-7.00	24.000	51.00			
Adalimumab 40mg EW	123	36.310	60.089	23.780	12.0944	-15.00	26.000	48.89	0.842	(-1.398, 3.081)	0.460

表 2.7.3.6-132. 評価時点ごとの IBDQ スコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
IBDQ - EMOTIONAL											
Maintenance Baseline											
Adalimumab 40mg EOW	145	46.866	65.967	19.100	14.4093	-20.00	18.000	59.00			
Adalimumab 40mg EW	152	45.796	65.346	19.550	13.6115	-15.00	18.000	63.00	-0.298	(-2.955, 2.358)	0.825
Week 12 (Week 4 of Maintenance Study)											
Adalimumab 40mg EOW	143	47.018	66.825	19.807	14.5414	-13.00	19.000	62.00			
Adalimumab 40mg EW	151	45.795	64.802	19.007	15.2295	-24.00	18.000	66.00	-1.326	(-4.099, 1.447)	0.347
Week 24 (Week 16 of Maintenance Study)											
Adalimumab 40mg EOW	131	46.631	66.478	19.847	15.7167	-13.00	18.000	60.00			
Adalimumab 40mg EW	140	46.036	66.714	20.679	15.5032	-27.00	19.000	61.00	0.439	(-2.470, 3.348)	0.767
Week 37 (Week 29 of Maintenance Study)											
Adalimumab 40mg EOW	120	46.314	67.225	20.911	15.2733	-12.00	18.500	60.00			
Adalimumab 40mg EW	133	46.090	67.286	21.195	15.1705	-17.00	21.000	61.00	0.317	(-2.502, 3.136)	0.825
Week 52 (Week 44 of Maintenance Study)											
Adalimumab 40mg EOW	108	46.969	68.184	21.215	15.5833	-11.00	18.182	60.00			
Adalimumab 40mg EW	124	46.169	68.568	22.398	15.3417	-14.00	21.500	57.00	1.441	(-1.476, 4.358)	0.332

表 2.7.3.6-132. 評価時点ごとの IBDQ スコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
IBDQ - FATIGUE											
Maintenance Baseline											
Adalimumab 40mg EOW	145	2.7	4.8	2.1	1.89	-3	2.0	6			
Adalimumab 40mg EW	152	2.8	4.7	1.9	1.69	-2	2.0	6	-0.1	(-0.4, 0.2)	0.549
Week 12 (Week 4 of Maintenance Study)											
Adalimumab 40mg EOW	143	2.7	4.7	2.0	1.92	-3	2.0	6			
Adalimumab 40mg EW	151	2.8	4.7	1.8	1.75	-2	2.0	6	-0.1	(-0.4, 0.3)	0.772
Week 24 (Week 16 of Maintenance Study)											
Adalimumab 40mg EOW	131	2.7	5.0	2.3	2.02	-5	2.0	6			
Adalimumab 40mg EW	140	2.8	5.0	2.1	1.70	-3	2.0	6	-0.0	(-0.4, 0.3)	0.899
Week 37 (Week 29 of Maintenance Study)											
Adalimumab 40mg EOW	120	2.7	5.1	2.3	1.97	-3	2.0	6			
Adalimumab 40mg EW	133	2.9	5.0	2.2	1.76	-4	2.0	6	0.0	(-0.4, 0.4)	0.974
Week 52 (Week 44 of Maintenance Study)											
Adalimumab 40mg EOW	108	2.8	5.1	2.3	1.97	-3	2.0	6			
Adalimumab 40mg EW	124	2.9	5.0	2.1	1.93	-4	2.0	6	-0.1	(-0.5, 0.3)	0.599

表 2.7.3.6-132. 評価時点ごとの IBDQ スコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
IBDQ - SOCIAL											
Maintenance Baseline											
Adalimumab 40mg EOW	143	19.3	30.1	10.8	7.40	-1	9.0	30			
Adalimumab 40mg EW	149	19.4	29.7	10.3	7.01	-5	9.0	30	-0.4	(-1.6, 0.8)	0.525
Week 12 (Week 4 of Maintenance Study)											
Adalimumab 40mg EOW	138	19.1	30.3	11.2	7.68	-5	11.0	30			
Adalimumab 40mg EW	144	19.3	29.8	10.5	7.75	-12	11.0	30	-0.5	(-1.8, 0.7)	0.408
Week 24 (Week 16 of Maintenance Study)											
Adalimumab 40mg EOW	129	19.1	30.3	11.2	8.24	-5	10.0	30			
Adalimumab 40mg EW	135	19.6	31.1	11.5	7.74	-7	12.0	29	0.5	(-0.7, 1.8)	0.404
Week 37 (Week 29 of Maintenance Study)											
Adalimumab 40mg EOW	118	19.0	30.7	11.7	7.72	-6	12.0	30			
Adalimumab 40mg EW	129	19.5	31.6	12.1	7.86	-9	12.0	30	0.6	(-0.6, 1.8)	0.345
Week 52 (Week 44 of Maintenance Study)											
Adalimumab 40mg EOW	106	19.3	31.3	12.0	7.75	-4	12.0	30			
Adalimumab 40mg EW	120	19.7	32.0	12.3	7.27	-4	13.0	30	0.6	(-0.5, 1.8)	0.273

表 2.7.3.6-132. 評価時点ごとの IBDQ スコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
IBDQ - SYSTEMIC											
Maintenance Baseline											
Adalimumab 40mg EOW	145	16.2	25.8	9.6	6.27	-7	10.0	26			
Adalimumab 40mg EW	151	16.2	25.0	8.8	6.32	-7	9.0	25	-0.8	(-2.0, 0.4)	0.177
Week 12 (Week 4 of Maintenance Study)											
Adalimumab 40mg EOW	143	16.2	25.8	9.6	6.45	-11	9.0	26			
Adalimumab 40mg EW	147	16.3	24.8	8.6	6.54	-8	9.0	25	-0.9	(-2.2, 0.3)	0.142
Week 24 (Week 16 of Maintenance Study)											
Adalimumab 40mg EOW	131	16.0	25.6	9.6	6.95	-8	9.0	24			
Adalimumab 40mg EW	139	16.3	25.6	9.3	6.55	-6	9.0	28	-0.0	(-1.4, 1.3)	0.946
Week 37 (Week 29 of Maintenance Study)											
Adalimumab 40mg EOW	120	16.0	26.1	10.0	7.21	-8	10.0	28			
Adalimumab 40mg EW	132	16.4	26.0	9.6	6.86	-11	11.0	24	-0.1	(-1.5, 1.3)	0.900
Week 52 (Week 44 of Maintenance Study)											
Adalimumab 40mg EOW	107	16.1	26.6	10.5	7.11	-5	11.0	27			
Adalimumab 40mg EW	123	16.4	26.3	9.9	7.01	-8	11.0	26	-0.2	(-1.6, 1.2)	0.768

表 2.7.3.6-132. 評価時点ごとの IBDQ スコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
IBDQ - TOTAL											
Maintenance Baseline											
Adalimumab 40mg EOW	143	118.389	179.273	60.884	34.3645	-5.00	58.000	151.00			
Adalimumab 40mg EW	149	117.295	177.165	59.870	33.6178	-18.00	55.000	167.00	-1.964	(-8.202, 4.274)	0.536
Week 12 (Week 4 of Maintenance Study)											
Adalimumab 40mg EOW	138	117.621	181.355	63.735	35.6090	-35.00	63.000	154.00			
Adalimumab 40mg EW	143	116.937	176.028	59.091	38.1529	-31.00	61.000	170.00	-4.541	(-11.376, 2.293)	0.192
Week 24 (Week 16 of Maintenance Study)											
Adalimumab 40mg EOW	128	117.380	179.994	62.614	39.6947	-29.00	60.000	152.00			
Adalimumab 40mg EW	135	117.881	181.556	63.674	38.1401	-32.00	65.000	157.00	1.427	(-5.951, 8.806)	0.704
Week 37 (Week 29 of Maintenance Study)											
Adalimumab 40mg EOW	118	116.878	181.070	64.191	38.4947	-37.00	61.500	144.00			
Adalimumab 40mg EW	129	118.248	182.783	64.535	38.2749	-48.00	68.000	156.00	1.052	(-6.140, 8.244)	0.773
Week 52 (Week 44 of Maintenance Study)											
Adalimumab 40mg EOW	106	118.166	185.128	66.962	38.0539	-22.00	68.000	152.00			
Adalimumab 40mg EW	119	119.008	187.067	68.059	37.5679	-36.00	72.000	150.00	2.446	(-4.506, 9.398)	0.489

@ P-value for test of difference between Adalimumab 40mg EW and Adalimumab 40mg EOW for change from baseline using the repeated measure model including treatment, induction treatment regimen, week 8 remission status, visit, baseline value, interaction of treatment and visit.
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.13.1

表 2.7.3.6-133.　評価時点ごとの IBDQ スコアが 170 以上となった被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 主試験）

	Adalimumab	
	40mg EOW	40mg EW
Subjects with IBDQ Total Score >= 170 at Maintenance Baseline	(N=145)	(N=152)
Yes, n (%)	96 (66.2)	102 (67.1)
No, n (%)	49 (33.8)	50 (32.9)
Risk Difference[A]		0.9
Adjusted Risk Difference[A,B]		0.8
95% Confidence Interval[B]		(-9.9, 11.5)
P-Value[B]		0.886
Subjects with IBDQ Total Score >= 170 at Week 12 (Week 4 of Maintenance Study)	(N=145)	(N=152)
Yes, n (%)	96 (66.2)	95 (62.5)
No, n (%)	49 (33.8)	57 (37.5)
Risk Difference[A]		-3.7
Adjusted Risk Difference[A,B]		-3.9
95% Confidence Interval[B]		(-14.8, 7.0)
P-Value[B]		0.481
Subjects with IBDQ Total Score >= 170 at Week 24 (Week 16 of Maintenance Study)	(N=145)	(N=152)
Yes, n (%)	87 (60.0)	96 (63.2)
No, n (%)	58 (40.0)	56 (36.8)
Risk Difference[A]		3.2
Adjusted Risk Difference[A,B]		2.9
95% Confidence Interval[B]		(-8.2, 13.9)
P-Value[B]		0.610

表 2.7.3.6-133.　評価時点ごとの IBDQ スコアが 170 以上となった被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

	Adalimumab 40mg EOW	Adalimumab 40mg EW
Subjects with IBDQ Total Score >= 170 at Week 37 (Week 29 of Maintenance Study)	(N=145)	(N=152)
Yes, n (%)	79 (54.5)	92 (60.5)
No, n (%)	66 (45.5)	60 (39.5)
Risk Difference[A]		6.0
Adjusted Risk Difference[A,B]		5.6
95% Confidence Interval[B]		(-5.6, 16.8)
P-Value[B]		0.326
Subjects with IBDQ Total Score >= 170 at Week 52 (Week 44 of Maintenance Study)	(N=145)	(N=152)
Yes, n (%)	73 (50.3)	86 (56.6)
No, n (%)	72 (49.7)	66 (43.4)
Risk Difference[A]		6.2
Adjusted Risk Difference[A,B]		5.7
95% Confidence Interval[B]		(-5.6, 16.9)
P-Value[B]		0.325

[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen and week 8 remission status.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.14.1

表 2.7.3.6-134.　投与 52 週時の Mayo スコアのベースラインからの変化量（OC）（維持療法試験，ITT-RP 集団，M14-033 主試験）

Parameter / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
MAYO SCORE											
Adalimumab 40mg EOW	96	8.77	3.13	-5.64	2.730	-11.8	-5.80	0.8			
Adalimumab 40mg EW	116	8.73	2.32	-6.41	2.568	-11.0	-6.40	1.8	-0.67	(-1.31, -0.04)	0.038*

@ P-value for test of difference between Adalimumab 40mg EW and Adalimumab 40mg EOW for change from baseline using analysis of covariance with treatment, induction treatment regimen, week 8 remission status, and baseline value as covariate.
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.15.1

表 2.7.3.6-135. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 主試験）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
AVERAGE RECTAL BLEEDING SUBSCORE											
Maintenance Baseline											
Adalimumab 40mg EOW	145	1.73	0.16	-1.57	0.862	-3.0	-1.40	0.4			
Adalimumab 40mg EW	152	1.84	0.21	-1.63	0.938	-3.0	-1.40	0.0	0.04	(-0.04, 0.12)	0.310
Week 10 (Week 2 of Maintenance Study)											
Adalimumab 40mg EOW	141	1.73	0.24	-1.49	0.924	-3.0	-1.40	0.6			
Adalimumab 40mg EW	152	1.84	0.26	-1.58	1.041	-3.0	-1.40	2.2	0.03	(-0.09, 0.14)	0.661
Week 12 (Week 4 of Maintenance Study)											
Adalimumab 40mg EOW	138	1.75	0.17	-1.58	0.896	-3.0	-1.40	0.0			
Adalimumab 40mg EW	145	1.84	0.26	-1.58	1.082	-3.0	-1.40	2.2	0.11	(-0.00, 0.21)	0.051+
Week 16 (Week 8 of Maintenance Study)											
Adalimumab 40mg EOW	140	1.74	0.27	-1.47	0.940	-3.0	-1.40	1.0			
Adalimumab 40mg EW	147	1.88	0.28	-1.60	1.020	-3.0	-1.60	1.4	0.04	(-0.09, 0.16)	0.571
Week 22 (Week 14 of Maintenance Study)											
Adalimumab 40mg EOW	127	1.75	0.30	-1.45	1.004	-3.0	-1.40	1.6			
Adalimumab 40mg EW	141	1.87	0.21	-1.66	0.984	-3.0	-1.60	0.0	-0.06	(-0.19, 0.08)	0.395
Week 24 (Week 16 of Maintenance Study)											
Adalimumab 40mg EOW	121	1.73	0.34	-1.38	0.962	-3.0	-1.40	1.6			
Adalimumab 40mg EW	135	1.87	0.22	-1.64	0.984	-3.0	-1.60	0.4	-0.08	(-0.22, 0.07)	0.289
Week 29 (Week 21 of Maintenance Study)											
Adalimumab 40mg EOW	122	1.73	0.35	-1.37	1.010	-3.0	-1.40	1.6			
Adalimumab 40mg EW	137	1.86	0.22	-1.64	1.051	-3.0	-1.60	1.6	-0.09	(-0.25, 0.06)	0.238

表 2.7.3.6-135. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
Week 35 (Week 27 of Maintenance Study)											
Adalimumab 40mg EOW	114	1.74	0.32	-1.42	1.055	-3.0	-1.40	2.0			
Adalimumab 40mg EW	129	1.82	0.24	-1.58	1.090	-3.0	-1.60	2.0	-0.09	(-0.26, 0.08)	0.275
Week 37 (Week 29 of Maintenance Study)											
Adalimumab 40mg EOW	106	1.76	0.36	-1.40	1.040	-3.0	-1.40	2.0			
Adalimumab 40mg EW	123	1.85	0.25	-1.61	1.008	-3.0	-1.60	1.2	-0.07	(-0.25, 0.10)	0.392
Week 42 (Week 34 of Maintenance Study)											
Adalimumab 40mg EOW	112	1.74	0.29	-1.45	1.009	-3.0	-1.40	2.0			
Adalimumab 40mg EW	126	1.86	0.25	-1.60	0.993	-3.0	-1.60	1.2	-0.06	(-0.22, 0.11)	0.495
Week 48 (Week 40 of Maintenance Study)											
Adalimumab 40mg EOW	105	1.76	0.29	-1.48	1.084	-3.0	-1.40	2.0			
Adalimumab 40mg EW	125	1.84	0.20	-1.64	1.013	-3.0	-1.60	1.2	-0.10	(-0.25, 0.06)	0.223
Week 52 (Week 44 of Maintenance Study)											
Adalimumab 40mg EOW	102	1.72	0.25	-1.46	1.079	-3.0	-1.40	2.0			
Adalimumab 40mg EW	122	1.85	0.20	-1.65	0.983	-3.0	-1.60	1.2	-0.05	(-0.20, 0.10)	0.507

表 2.7.3.6-135. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
AVERAGE STOOL FREQUENCY SUBSCORE											
Maintenance Baseline											
Adalimumab 40mg EOW	145	2.41	0.93	-1.48	0.837	-3.0	-1.40	1.6			
Adalimumab 40mg EW	152	2.36	0.90	-1.46	0.781	-3.0	-1.40	0.4	-0.00	(-0.15, 0.14)	0.953
Week 10 (Week 2 of Maintenance Study)											
Adalimumab 40mg EOW	141	2.41	0.95	-1.46	0.774	-3.0	-1.40	0.0			
Adalimumab 40mg EW	152	2.36	0.94	-1.42	0.896	-3.0	-1.40	2.4	0.03	(-0.13, 0.19)	0.733
Week 12 (Week 4 of Maintenance Study)											
Adalimumab 40mg EOW	138	2.43	0.84	-1.58	0.765	-3.0	-1.60	0.4			
Adalimumab 40mg EW	145	2.35	0.89	-1.46	0.872	-3.0	-1.40	0.4	0.04	(-0.12, 0.20)	0.614
Week 16 (Week 8 of Maintenance Study)											
Adalimumab 40mg EOW	140	2.41	0.97	-1.44	0.858	-3.0	-1.50	0.6			
Adalimumab 40mg EW	147	2.35	0.90	-1.45	0.868	-3.0	-1.40	0.8	-0.02	(-0.19, 0.14)	0.772
Week 22 (Week 14 of Maintenance Study)											
Adalimumab 40mg EOW	127	2.39	0.93	-1.46	0.850	-3.0	-1.40	0.6			
Adalimumab 40mg EW	141	2.32	0.80	-1.52	0.912	-3.0	-1.60	0.8	-0.09	(-0.26, 0.09)	0.327
Week 24 (Week 16 of Maintenance Study)											
Adalimumab 40mg EOW	121	2.41	1.05	-1.36	0.937	-3.0	-1.40	1.2			
Adalimumab 40mg EW	135	2.33	0.79	-1.54	0.926	-3.0	-1.60	0.8	-0.17	(-0.36, 0.02)	0.075+
Week 29 (Week 21 of Maintenance Study)											
Adalimumab 40mg EOW	122	2.41	1.04	-1.38	1.004	-3.0	-1.40	2.0			
Adalimumab 40mg EW	137	2.32	0.84	-1.48	0.916	-3.0	-1.60	0.8	-0.14	(-0.34, 0.06)	0.173

表 2.7.3.6-135. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
Week 35 (Week 27 of Maintenance Study)											
Adalimumab 40mg EOW	114	2.42	0.95	-1.47	0.918	-3.0	-1.40	1.0			
Adalimumab 40mg EW	129	2.31	0.76	-1.55	0.945	-3.0	-1.60	1.2	-0.14	(-0.33, 0.05)	0.139
Week 37 (Week 29 of Maintenance Study)											
Adalimumab 40mg EOW	106	2.42	0.89	-1.52	0.914	-3.0	-1.60	0.6			
Adalimumab 40mg EW	123	2.33	0.73	-1.60	0.899	-3.0	-1.60	0.8	-0.13	(-0.32, 0.07)	0.198
Week 42 (Week 34 of Maintenance Study)											
Adalimumab 40mg EOW	112	2.41	0.90	-1.51	0.885	-3.0	-1.60	0.8			
Adalimumab 40mg EW	126	2.34	0.77	-1.57	0.878	-3.0	-1.60	1.2	-0.12	(-0.31, 0.07)	0.215
Week 48 (Week 40 of Maintenance Study)											
Adalimumab 40mg EOW	105	2.41	0.88	-1.53	0.908	-3.0	-1.60	1.0			
Adalimumab 40mg EW	125	2.33	0.73	-1.60	0.871	-3.0	-1.60	1.0	-0.13	(-0.32, 0.06)	0.189
Week 52 (Week 44 of Maintenance Study)											
Adalimumab 40mg EOW	102	2.40	0.90	-1.50	0.951	-3.0	-1.50	1.0			
Adalimumab 40mg EW	122	2.32	0.68	-1.65	0.916	-3.0	-1.60	0.6	-0.19	(-0.38, 0.00)	0.053+

表 2.7.3.6-135. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
ENDOSCOPY SUBSCORE											
Maintenance Baseline											
Adalimumab 40mg EOW	145	2.3	1.2	-1.1	0.88	-3	-1.0	1			
Adalimumab 40mg EW	152	2.3	1.2	-1.1	0.86	-3	-1.0	0	0.0	(-0.1, 0.2)	0.718
Week 52 (Week 44 of Maintenance Study)											
Adalimumab 40mg EOW	104	2.4	1.1	-1.2	1.09	-3	-1.0	1			
Adalimumab 40mg EW	123	2.3	0.9	-1.3	1.03	-3	-2.0	1	-0.1	(-0.4, 0.2)	0.393

表 2.7.3.6-135. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
PHYSICIAN'S GLOBAL ASSESSMENT SUBSCORE											
Maintenance Baseline											
Adalimumab 40mg EOW	145	2.3	1.0	-1.3	0.71	-3	-1.0	0			
Adalimumab 40mg EW	152	2.3	0.8	-1.5	0.75	-3	-1.0	0	-0.2	(-0.3, -0.0)	0.008**
Week 10 (Week 2 of Maintenance Study)											
Adalimumab 40mg EOW	141	2.2	0.8	-1.5	0.80	-3	-1.0	0			
Adalimumab 40mg EW	152	2.3	0.7	-1.6	0.80	-3	-1.5	0	-0.0	(-0.2, 0.1)	0.687
Week 12 (Week 4 of Maintenance Study)											
Adalimumab 40mg EOW	138	2.2	0.7	-1.5	0.82	-3	-2.0	0			
Adalimumab 40mg EW	145	2.3	0.7	-1.5	0.87	-3	-2.0	1	0.0	(-0.1, 0.2)	0.692
Week 16 (Week 8 of Maintenance Study)											
Adalimumab 40mg EOW	140	2.2	0.8	-1.5	0.86	-3	-2.0	1			
Adalimumab 40mg EW	147	2.3	0.7	-1.6	0.86	-3	-2.0	0	-0.0	(-0.2, 0.2)	0.927
Week 22 (Week 14 of Maintenance Study)											
Adalimumab 40mg EOW	128	2.2	0.7	-1.5	0.87	-3	-2.0	1			
Adalimumab 40mg EW	141	2.3	0.5	-1.8	0.86	-3	-2.0	0	-0.1	(-0.3, 0.0)	0.139
Week 24 (Week 16 of Maintenance Study)											
Adalimumab 40mg EOW	122	2.2	0.8	-1.4	0.87	-3	-1.0	1			
Adalimumab 40mg EW	136	2.3	0.5	-1.8	0.86	-3	-2.0	0	-0.2	(-0.4, -0.0)	0.040*
Week 29 (Week 21 of Maintenance Study)											
Adalimumab 40mg EOW	123	2.2	0.8	-1.5	0.88	-3	-1.0	1			
Adalimumab 40mg EW	137	2.3	0.6	-1.7	0.83	-3	-2.0	0	-0.1	(-0.3, 0.1)	0.168

表 2.7.3.6-135. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
Week 35 (Week 27 of Maintenance Study)											
Adalimumab 40mg EOW	114	2.2	0.7	-1.5	0.82	-3	-2.0	1			
Adalimumab 40mg EW	129	2.3	0.5	-1.8	0.86	-3	-2.0	1	-0.2	(-0.4, -0.0)	0.043*
Week 37 (Week 29 of Maintenance Study)											
Adalimumab 40mg EOW	106	2.2	0.7	-1.6	0.88	-3	-2.0	1			
Adalimumab 40mg EW	123	2.3	0.5	-1.8	0.88	-3	-2.0	0	-0.1	(-0.3, 0.1)	0.439
Week 42 (Week 34 of Maintenance Study)											
Adalimumab 40mg EOW	112	2.2	0.6	-1.6	0.85	-3	-2.0	1			
Adalimumab 40mg EW	126	2.3	0.5	-1.8	0.91	-3	-2.0	0	-0.1	(-0.2, 0.1)	0.588
Week 48 (Week 40 of Maintenance Study)											
Adalimumab 40mg EOW	105	2.2	0.6	-1.6	0.87	-3	-2.0	1			
Adalimumab 40mg EW	125	2.3	0.5	-1.8	0.86	-3	-2.0	1	-0.1	(-0.3, 0.1)	0.282
Week 52 (Week 44 of Maintenance Study)											
Adalimumab 40mg EOW	103	2.2	0.8	-1.4	0.92	-3	-1.0	1			
Adalimumab 40mg EW	122	2.3	0.5	-1.8	0.87	-3	-2.0	0	-0.3	(-0.5, -0.1)	0.001**

表 2.7.3.6-135. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
PARTIAL MAYO SCORE											
Maintenance Baseline											
Adalimumab 40mg EOW	145	6.40	2.07	-4.33	1.446	-9.0	-4.20	-1.4			
Adalimumab 40mg EW	152	6.50	1.91	-4.58	1.711	-9.0	-4.20	-0.6	-0.14	(-0.38, 0.10)	0.241
Week 10 (Week 2 of Maintenance Study)											
Adalimumab 40mg EOW	141	6.39	1.97	-4.42	1.649	-9.0	-4.20	-1.0			
Adalimumab 40mg EW	152	6.50	1.94	-4.55	1.984	-9.0	-4.40	1.6	0.01	(-0.30, 0.31)	0.967
Week 12 (Week 4 of Maintenance Study)											
Adalimumab 40mg EOW	138	6.42	1.74	-4.68	1.639	-9.0	-4.60	-0.6			
Adalimumab 40mg EW	145	6.46	1.89	-4.58	2.120	-9.0	-4.60	3.2	0.16	(-0.17, 0.48)	0.339
Week 16 (Week 8 of Maintenance Study)											
Adalimumab 40mg EOW	140	6.38	1.98	-4.40	1.929	-9.0	-4.40	1.2			
Adalimumab 40mg EW	147	6.53	1.88	-4.65	2.110	-9.0	-4.60	1.4	-0.00	(-0.38, 0.37)	0.980
Week 22 (Week 14 of Maintenance Study)											
Adalimumab 40mg EOW	127	6.38	1.94	-4.44	2.057	-9.0	-4.40	0.6			
Adalimumab 40mg EW	141	6.48	1.54	-4.94	2.062	-9.0	-4.80	-0.2	-0.29	(-0.69, 0.11)	0.160
Week 24 (Week 16 of Maintenance Study)											
Adalimumab 40mg EOW	121	6.38	2.20	-4.18	2.093	-8.8	-4.40	0.8			
Adalimumab 40mg EW	135	6.50	1.55	-4.95	2.031	-9.0	-4.80	0.6	-0.45	(-0.88, -0.02)	0.039*
Week 29 (Week 21 of Maintenance Study)											
Adalimumab 40mg EOW	122	6.39	2.18	-4.21	2.222	-9.0	-4.40	2.2			
Adalimumab 40mg EW	137	6.48	1.64	-4.84	2.070	-8.8	-4.80	1.8	-0.38	(-0.83, 0.08)	0.102

表 2.7.3.6-135. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
Week 35 (Week 27 of Maintenance Study)											
Adalimumab 40mg EOW	114	6.41	2.00	-4.41	2.184	-9.0	-4.70	2.2			
Adalimumab 40mg EW	129	6.42	1.50	-4.92	2.187	-8.8	-4.80	4.2	-0.44	(-0.89, 0.01)	0.056+
Week 37 (Week 29 of Maintenance Study)											
Adalimumab 40mg EOW	106	6.41	1.93	-4.48	2.123	-9.0	-4.60	2.2			
Adalimumab 40mg EW	123	6.48	1.51	-4.97	2.005	-9.0	-4.80	0.6	-0.31	(-0.79, 0.17)	0.200
Week 42 (Week 34 of Maintenance Study)											
Adalimumab 40mg EOW	112	6.38	1.81	-4.57	2.039	-8.8	-4.60	2.2			
Adalimumab 40mg EW	126	6.51	1.57	-4.94	2.036	-9.0	-4.80	1.4	-0.24	(-0.70, 0.21)	0.291
Week 48 (Week 40 of Maintenance Study)											
Adalimumab 40mg EOW	105	6.42	1.77	-4.65	2.175	-9.0	-4.80	2.2			
Adalimumab 40mg EW	125	6.49	1.42	-5.07	1.996	-9.0	-4.80	1.2	-0.36	(-0.81, 0.10)	0.125
Week 52 (Week 44 of Maintenance Study)											
Adalimumab 40mg EOW	102	6.36	1.99	-4.37	2.214	-8.8	-4.60	2.2			
Adalimumab 40mg EW	122	6.49	1.37	-5.12	2.066	-9.0	-5.00	1.8	-0.61	(-1.07, -0.15)	0.009**

@ P-value for test of difference between Adalimumab 40mg EW and Adalimumab 40mg EOW for change from baseline using the repeated measure model including treatment, induction treatment regimen, week 8 remission status, visit, baseline value, interaction of treatment and visit.
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.16.1

表 2.7.3.6-136. 評価時点ごとの被験者から報告された排便回数のベースラインからの変化量の Mixed Effect Model Repeated Measurement（維持療法試験，ITT-RP 集団，M14-033 主試験）

Parameter Visit Treatment	N	Baseline Mean	Visit Mean	Within Group Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW) LSMEAN	95% CI	P-Value@
AVERAGE STOOL FREQUENCY ABSOLUTE VALUE											
Maintenance Baseline											
Adalimumab 40mg EOW	145	6.64	2.92	-3.72	2.648	-12.6	-3.20	4.2			
Adalimumab 40mg EW	152	7.10	2.79	-4.31	3.274	-19.5	-3.60	0.8	-0.19	(-0.51, 0.13)	0.239
Week 10 (Week 2 of Maintenance Study)											
Adalimumab 40mg EOW	141	6.63	2.88	-3.76	2.520	-12.2	-3.20	1.0			
Adalimumab 40mg EW	152	7.10	2.88	-4.21	3.608	-18.4	-3.40	5.8	-0.04	(-0.41, 0.32)	0.809
Week 12 (Week 4 of Maintenance Study)											
Adalimumab 40mg EOW	138	6.68	2.68	-4.00	2.687	-12.8	-3.60	3.8			
Adalimumab 40mg EW	144	7.05	2.84	-4.22	3.614	-20.2	-3.40	1.6	0.08	(-0.28, 0.45)	0.648
Week 16 (Week 8 of Maintenance Study)											
Adalimumab 40mg EOW	140	6.66	2.95	-3.71	2.863	-12.8	-3.40	3.8			
Adalimumab 40mg EW	147	7.11	2.81	-4.30	3.557	-19.4	-3.60	1.8	-0.17	(-0.57, 0.22)	0.389
Week 22 (Week 14 of Maintenance Study)											
Adalimumab 40mg EOW	127	6.57	2.85	-3.72	2.799	-12.8	-3.20	3.8			
Adalimumab 40mg EW	139	7.04	2.61	-4.42	3.650	-19.8	-3.60	4.4	-0.31	(-0.72, 0.11)	0.152
Week 24 (Week 16 of Maintenance Study)											
Adalimumab 40mg EOW	121	6.57	3.11	-3.45	3.073	-12.8	-3.00	5.6			
Adalimumab 40mg EW	133	6.88	2.55	-4.34	3.512	-19.0	-3.80	5.0	-0.52	(-0.99, -0.04)	0.032*
Week 29 (Week 21 of Maintenance Study)											
Adalimumab 40mg EOW	119	6.68	3.26	-3.42	3.502	-13.4	-3.00	10.0			
Adalimumab 40mg EW	136	6.88	2.63	-4.25	3.402	-19.8	-3.60	4.8	-0.56	(-1.08, -0.04)	0.034*

表 2.7.3.6-136. 評価時点ごとの被験者から報告された排便回数のベースラインからの変化量の Mixed Effect Model Repeated Measurement（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
Week 35 (Week 27 of Maintenance Study)											
Adalimumab 40mg EOW	113	6.62	2.93	-3.69	3.122	-14.6	-3.20	3.8			
Adalimumab 40mg EW	129	6.92	2.43	-4.49	3.717	-19.8	-4.00	5.2	-0.49	(-0.95, -0.03)	0.035*
Week 37 (Week 29 of Maintenance Study)											
Adalimumab 40mg EOW	106	6.56	2.79	-3.77	3.074	-14.6	-3.20	3.8			
Adalimumab 40mg EW	122	6.96	2.49	-4.47	3.569	-19.8	-3.80	5.2	-0.35	(-0.83, 0.14)	0.160
Week 42 (Week 34 of Maintenance Study)											
Adalimumab 40mg EOW	112	6.61	2.78	-3.83	3.165	-14.6	-3.20	3.8			
Adalimumab 40mg EW	123	6.93	2.42	-4.51	3.586	-19.6	-4.00	3.0	-0.37	(-0.82, 0.08)	0.109
Week 48 (Week 40 of Maintenance Study)											
Adalimumab 40mg EOW	104	6.68	2.88	-3.80	3.304	-14.6	-3.30	3.8			
Adalimumab 40mg EW	125	7.00	2.33	-4.67	3.659	-19.6	-4.00	1.6	-0.60	(-1.06, -0.14)	0.012*
Week 52 (Week 44 of Maintenance Study)											
Adalimumab 40mg EOW	102	6.68	2.90	-3.78	3.357	-15.6	-3.10	3.8			
Adalimumab 40mg EW	120	7.01	2.32	-4.68	3.710	-19.8	-4.10	1.8	-0.62	(-1.10, -0.14)	0.012*

@ P-value for test of difference between Adalimumab 40mg EW and Adalimumab 40mg EOW for change from baseline using the repeated measure model including treatment, induction treatment regimen, week 8 remission status, visit, baseline value, interaction of treatment and visit.
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.17.1

表 2.7.3.6-137.　投与 52 週時の WPAI スコアのベースラインからの変化量（OC）（維持療法試験，ITT-RP 集団，M14-033 主試験）

Parameter / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
WPAI - ACTIVITY IMPAIRMENT (%)											
Adalimumab 40mg EOW	121	56.4	19.5	-36.9	31.01	-100	-40.0	50			
Adalimumab 40mg EW	128	56.3	19.4	-37.0	33.55	-100	-40.0	70	0.4	(-5.6, 6.4)	0.905
WPAI - IMPAIRMENT WHILE WORKING (%)											
Adalimumab 40mg EOW	68	52.8	17.5	-35.3	31.55	-100	-40.0	40			
Adalimumab 40mg EW	74	50.5	18.2	-32.3	33.86	-100	-30.0	40	1.5	(-6.5, 9.6)	0.705
WPAI - OVERALL WORK IMPAIRMENT (%)											
Adalimumab 40mg EOW	64	58.889	19.877	-39.011	35.5271	-100.00	-40.000	36.87			
Adalimumab 40mg EW	66	54.059	19.964	-34.096	34.9969	-100.00	-30.385	50.92	1.617	(-7.789, 11.023)	0.734
WPAI - WORK TIME MISSED (%)											
Adalimumab 40mg EOW	65	21.137	8.323	-12.814	31.8631	-100.00	0.000	68.75			
Adalimumab 40mg EW	66	18.249	3.596	-14.653	29.5351	-100.00	0.000	41.00	-4.203	(-10.512, 2.107)	0.190

@ P-value for test of difference between Adalimumab 40mg EW and Adalimumab 40mg EOW for change from baseline using analysis of covariance with treatment, induction treatment regimen, week 8 remission status, and baseline value as covariate.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.18.1

表 2.7.3.6-138. 投与 52 週時の SF-36 スコアのベースラインからの変化量（OC）（維持療法試験，ITT-RP 集団，M14-033 主試験）

Parameter / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
SF-36 V2 BODILY PAIN SCALE											
Adalimumab 40mg EOW	124	37.412	51.032	13.619	11.7817	-26.20	13.946	42.26			
Adalimumab 40mg EW	134	38.972	51.730	12.757	12.8220	-32.96	13.101	42.26	0.270	(-2.084, 2.624)	0.821
SF-36 V2 GENERAL HEALTH SCALE											
Adalimumab 40mg EOW	124	33.964	41.951	7.986	8.7290	-9.53	8.104	34.32			
Adalimumab 40mg EW	134	33.679	41.966	8.287	9.2363	-17.64	7.925	29.55	0.067	(-1.947, 2.080)	0.948
SF-36 V2 MENTAL COMPONENT SUMMARY											
Adalimumab 40mg EOW	124	34.552	48.246	13.694	12.8086	-18.68	12.945	49.42			
Adalimumab 40mg EW	134	34.428	46.567	12.139	12.0744	-16.60	10.396	41.03	-1.697	(-4.114, 0.719)	0.168
SF-36 V2 MENTAL HEALTH SCALE											
Adalimumab 40mg EOW	124	37.313	49.167	11.854	11.3962	-11.26	11.264	42.24			
Adalimumab 40mg EW	134	36.075	46.981	10.907	11.8991	-19.71	11.264	42.24	-1.830	(-4.172, 0.513)	0.125
SF-36 V2 PHYSICAL COMPONENT SUMMARY											
Adalimumab 40mg EOW	124	39.917	50.000	10.083	7.9078	-8.77	8.940	38.65			
Adalimumab 40mg EW	134	40.300	50.132	9.832	9.3492	-22.70	10.589	37.30	-0.062	(-1.714, 1.591)	0.942
SF-36 V2 PHYSICAL FUNCTIONING SCALE											
Adalimumab 40mg EOW	124	44.481	53.248	8.767	8.2346	-2.10	6.313	39.99			
Adalimumab 40mg EW	134	44.092	52.068	7.976	8.6462	-14.73	6.313	33.67	-1.041	(-2.426, 0.345)	0.140

表 2.7.3.6-138. 投与 52 週時の SF-36 スコアのベースラインからの変化量（OC）（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

Parameter / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
SF-36 V2 ROLE-EMOTIONAL SCALE											
Adalimumab 40mg EOW	124	35.534	47.728	12.195	13.6859	-19.44	11.662	46.65			
Adalimumab 40mg EW	134	35.891	47.234	11.343	13.9876	-31.10	11.662	46.65	-0.613	(-2.976, 1.749)	0.610
SF-36 V2 ROLE-PHYSICAL SCALE											
Adalimumab 40mg EOW	124	35.490	48.953	13.463	11.3577	-9.80	12.245	39.18			
Adalimumab 40mg EW	134	35.354	48.647	13.293	11.7571	-24.49	14.694	39.18	-0.380	(-2.601, 1.841)	0.737
SF-36 V2 SOCIAL FUNCTIONING SCALE											
Adalimumab 40mg EOW	124	32.790	49.416	16.626	13.2294	-21.82	16.362	43.63			
Adalimumab 40mg EW	134	34.708	49.034	14.327	12.4526	-27.27	16.362	43.63	-0.866	(-3.188, 1.455)	0.463
SF-36 V2 VITALITY SCALE											
Adalimumab 40mg EOW	124	37.614	51.638	14.024	11.5963	-9.37	12.488	43.71			
Adalimumab 40mg EW	134	36.970	49.342	12.372	11.4304	-21.85	12.488	37.46	-2.108	(-4.538, 0.322)	0.089+

@ P-value for test of difference between Adalimumab 40mg EW and Adalimumab 40mg EOW for change from baseline using analysis of covariance with treatment, induction treatment regimen, week 8 remission status, and baseline value as covariate.
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.19.1

表 2.7.3.6-139. 評価時点ごとの便中カルプロテクチン値のベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 主試験）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
FECAL CALPROTECTIN (MCG/G)											
Week 12 (Week 4 of Maintenance Study)											
Adalimumab 40mg EOW	122	2529.8	983.9	-1545.9	2803.58	-9590	-770.5	6105			
Adalimumab 40mg EW	128	2246.0	815.8	-1430.2	2641.12	-9590	-964.5	8645	-105.8	(-486.1, 274.4)	0.584
Week 16 (Week 8 of Maintenance Study)											
Adalimumab 40mg EOW	118	2567.9	836.0	-1731.9	2976.12	-9587	-854.0	6934			
Adalimumab 40mg EW	123	2200.4	751.3	-1449.1	2642.43	-9586	-900.0	4821	-90.8	(-402.8, 221.2)	0.567
Week 24 (Week 16 of Maintenance Study)											
Adalimumab 40mg EOW	115	2514.6	847.1	-1667.4	2734.25	-9590	-784.0	4611			
Adalimumab 40mg EW	122	2234.5	742.9	-1491.6	2624.81	-9590	-965.5	8856	-152.3	(-530.0, 225.4)	0.427
Week 37 (Week 29 of Maintenance Study)											
Adalimumab 40mg EOW	102	2442.5	1033.0	-1409.5	2896.78	-9590	-677.0	7848			
Adalimumab 40mg EW	113	2294.9	705.4	-1589.5	2765.98	-9590	-1072.0	9536	-319.5	(-740.0, 101.0)	0.136
Week 52 (Week 44 of Maintenance Study)											
Adalimumab 40mg EOW	85	2188.2	632.3	-1555.9	2761.70	-9571	-599.0	4611			
Adalimumab 40mg EW	103	2318.5	615.7	-1702.8	2533.24	-9590	-1140.0	7581	-119.3	(-488.6, 249.9)	0.524

@ P-value for test of difference between Adalimumab 40mg EW and Adalimumab 40mg EOW for change from baseline using the repeated measure model including treatment, induction treatment regimen, week 8 remission status, visit, baseline value, interaction of treatment and visit.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.20.1

表 2.7.3.6-140. 評価時点ごとの便中カルプロテクチン値が 150 mg/kg 未満となった被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 主試験）

	Adalimumab	
	40mg EOW	40mg EW
Subjects with Fecal Calprotectin below 150 mg/kg at Week 12 (Week 4 of Maintenance Study)	(N=145)	(N=152)
Yes, n (%)	55 (37.9)	53 (34.9)
No, n (%)	90 (62.1)	99 (65.1)
Risk Difference[A]		-3.1
Adjusted Risk Difference[A,B]		-3.3
95% Confidence Interval[B]		(-14.2, 7.6)
P-Value[B]		0.555
Subjects with Fecal Calprotectin below 150 mg/kg at Week 16 (Week 8 of Maintenance Study)	(N=145)	(N=152)
Yes, n (%)	50 (34.5)	50 (32.9)
No, n (%)	95 (65.5)	102 (67.1)
Risk Difference[A]		-1.6
Adjusted Risk Difference[A,B]		-2.2
95% Confidence Interval[B]		(-12.9, 8.5)
P-Value[B]		0.687
Subjects with Fecal Calprotectin below 150 mg/kg at Week 24 (Week 16 of Maintenance Study)	(N=145)	(N=152)
Yes, n (%)	50 (34.5)	49 (32.2)
No, n (%)	95 (65.5)	103 (67.8)
Risk Difference[A]		-2.2
Adjusted Risk Difference[A,B]		-2.7
95% Confidence Interval[B]		(-13.4, 8.0)
P-Value[B]		0.624

表 2.7.3.6-140. 評価時点ごとの便中カルプロテクチン値が 150 mg/kg 未満となった被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

	Adalimumab 40mg EOW	Adalimumab 40mg EW
Subjects with Fecal Calprotectin below 150 mg/kg at Week 37 (Week 29 of Maintenance Study)	(N=145)	(N=152)
Yes, n (%)	38 (26.2)	55 (36.2)
No, n (%)	107 (73.8)	97 (63.8)
Risk Difference[A]		10.0
Adjusted Risk Difference[A,B]		9.5
95% Confidence Interval[B]		(-0.9, 19.9)
P-Value[B]		0.074+
Subjects with Fecal Calprotectin below 150 mg/kg at Week 52 (Week 44 of Maintenance Study)	(N=145)	(N=152)
Yes, n (%)	37 (25.5)	54 (35.5)
No, n (%)	108 (74.5)	98 (64.5)
Risk Difference[A]		10.0
Adjusted Risk Difference[A,B]		9.8
95% Confidence Interval[B]		(-0.7, 20.4)
P-Value[B]		0.068+

[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen and week 8 remission status.
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.21.1

表 2.7.3.6-141.　PMS による寛解達成までの期間（OC）（維持療法試験，ITT-RP 集団，M14-033 主試験）

	Adalimumab	
	40mg EOW (N=145) n (%)	40mg EW (N=152) n (%)
Number of Events		
Per Partial Mayo Score	122 (84.1)	126 (82.9)
Kaplan-Meier Method:		
Percentiles (Weeks)		
25th	2.0	2.0
Median	3.0	2.0
75th	16.0	15.0
Cox Proportional Hazards Model$:		
Hazards Ratio 40mg EW versus 40mg EOW		1.002
(%95 CI)		(0.781, 1.286)
P-Value		0.987

Note: Clinical remission per Partial Mayo Score is defined as Partial Mayo Score <= 2, with no subscore > 1.
$ The covariates treatment, induction treatment regimen and week 8 remission status are included in the cox proportional hazards model.
Subjects who did not respond by week 52 were censored at last OC visit.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.22

表 2.7.3.6-142.　PMS による改善達成までの時間（OC）（維持療法試験，ITT-RP 集団，M14-033 主試験）

	Adalimumab	
	40mg EOW (N=145) n (%)	40mg EW (N=152) n (%)
Number of Events		
Per Partial Mayo Score	144 (99.3)	146 (96.1)
Kaplan-Meier Method:		
Percentiles (Weeks)		
25th	2.0	2.0
Median	2.0	2.0
75th	2.0	2.0
Cox Proportional Hazards Model$:		
Hazards Ratio 40mg EW versus 40mg EOW		0.989
(%95 CI)		(0.785, 1.247)
P-Value		0.927

Note: Clinical response per Partial Mayo Score is defined as a decrease in Partial Mayo Score >= 2 points and >= 30% from baseline, plus a decrease in RBS >= 1 or an absolute RBS <= 1.
$ The covariates treatment, induction treatment regimen and week 8 remission status are included in the cox proportional hazards model.
Subjects who did not respond by week 52 were censored at last OC visit.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.23

表 2.7.3.6-143.　PMS による改善消失までの時間（OC）（維持療法試験，ITT-RP 集団，M14-033 主試験）

	Adalimumab	
	40mg EOW (N=145) n (%)	40mg EW (N=152) n (%)
Number of Events		
Per Partial Mayo Score	65 (44.8)	51 (33.6)
Kaplan-Meier Method:		
Percentiles (Weeks)		
25th	14.0	27.0
Median	NE[A]	NE[A]
75th	NE[A]	NE[A]
Cox Proportional Hazards Model$:		
Hazards Ratio 40mg EW versus 40mg EOW		0.694
(%95 CI)		(0.481, 1.002)
P-Value		0.051+

Note: Clinical response per Partial Mayo Score is defined as a decrease in Partial Mayo Score >= 2 points and >= 30% from baseline, plus a decrease in RBS >= 1 or an absolute RBS <= 1.
$ The covariates treatment, induction treatment regimen and week 8 remission status are included in the cox proportional hazards model.
Subjects who did not lose response by week 52 were censored at last OC visit.
[A] Not estimable.
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.24

表 2.7.3.6-144.　治験期間中の腸管外合併症の有無の変化（維持療法試験，ITT-RP 集団，M14-033 主試験）

Variable/ Treatment/ Baseline Value	Week 52 Yes N (%)	Week 52 No N (%)	Week 52 Missing N (%)
ANEMIA			
Adalimumab 40mg EOW (N=145)			
Yes (N=25)	5 (20.0)	19 (76.0)	1 (4.0)
No (N=118)	2 (1.7)	99 (83.9)	17 (14.4)
Adalimumab 40mg EW (N=152)			
Yes (N=34)	5 (14.7)	27 (79.4)	2 (5.9)
No (N=111)	3 (2.7)	96 (86.5)	12 (10.8)
AUTOIMMUNE HEPATITIS			
Adalimumab 40mg EOW (N=145)			
Yes (N=1)	1 (100)	0	0
No (N=142)	1 (0.7)	122 (85.9)	19 (13.4)
Adalimumab 40mg EW (N=152)			
Yes (N=0)	0	0	0
No (N=145)	0	131 (90.3)	14 (9.7)

表 2.7.3.6-144.　治験期間中の腸管外合併症の有無の変化（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

Variable/ Treatment/ Baseline Value	Week 52 Yes N (%)	Week 52 No N (%)	Week 52 Missing N (%)
AXIAL ARTHROPATHY			
Adalimumab 40mg EOW (N=145)			
Yes (N=6)	3 (50.0)	2 (33.3)	1 (16.7)
No (N=137)	1 (0.7)	119 (86.9)	17 (12.4)
Adalimumab 40mg EW (N=152)			
Yes (N=3)	0	1 (33.3)	2 (66.7)
No (N=142)	2 (1.4)	128 (90.1)	12 (8.5)
BRONCHIECTASIS			
Adalimumab 40mg EOW (N=145)			
Yes (N=0)	0	0	0
No (N=143)	0	124 (86.7)	19 (13.3)
Adalimumab 40mg EW (N=152)			
Yes (N=0)	0	0	0
No (N=145)	0	131 (90.3)	14 (9.7)

表 2.7.3.6-144.　治験期間中の腸管外合併症の有無の変化（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

Variable/ Treatment/ Baseline Value	Week 52 Yes N (%)	Week 52 No N (%)	Week 52 Missing N (%)
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
Adalimumab 40mg EOW (N=145)			
Yes (N=1)	1 (100)	0	0
No (N=142)	0	123 (86.6)	19 (13.4)
Adalimumab 40mg EW (N=152)			
Yes (N=1)	0	1 (100)	0
No (N=144)	0	130 (90.3)	14 (9.7)
EPISCLERITIS			
Adalimumab 40mg EOW (N=145)			
Yes (N=0)	0	0	0
No (N=143)	0	124 (86.7)	19 (13.3)
Adalimumab 40mg EW (N=152)			
Yes (N=0)	0	0	0
No (N=145)	0	131 (90.3)	14 (9.7)

表 2.7.3.6-144.　治験期間中の腸管外合併症の有無の変化（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

Variable/ Treatment/ Baseline Value	Week 52 Yes N (%)	Week 52 No N (%)	Week 52 Missing N (%)
ERYTHEMA NODOSUM			
Adalimumab 40mg EOW (N=145)			
Yes (N=0)	0	0	0
No (N=143)	0	125 (87.4)	18 (12.6)
Adalimumab 40mg EW (N=152)			
Yes (N=1)	0	1 (100)	0
No (N=144)	0	130 (90.3)	14 (9.7)
IRITIS			
Adalimumab 40mg EOW (N=145)			
Yes (N=0)	0	0	0
No (N=143)	0	124 (86.7)	19 (13.3)
Adalimumab 40mg EW (N=152)			
Yes (N=0)	0	0	0
No (N=145)	0	131 (90.3)	14 (9.7)

表 2.7.3.6-144.　治験期間中の腸管外合併症の有無の変化（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

Variable/ Treatment/ Baseline Value	Week 52 Yes N (%)	Week 52 No N (%)	Week 52 Missing N (%)
NEPHROLITHIASIS			
Adalimumab 40mg EOW (N=145)			
Yes (N=1)	0	1 (100)	0
No (N=142)	0	124 (87.3)	18 (12.7)
Adalimumab 40mg EW (N=152)			
Yes (N=2)	1 (50.0)	1 (50.0)	0
No (N=143)	0	129 (90.2)	14 (9.8)
ORAL APHTHOUS ULCERS			
Adalimumab 40mg EOW (N=145)			
Yes (N=0)	0	0	0
No (N=143)	0	125 (87.4)	18 (12.6)
Adalimumab 40mg EW (N=152)			
Yes (N=1)	0	1 (100)	0
No (N=144)	0	130 (90.3)	14 (9.7)

表 2.7.3.6-144.　治験期間中の腸管外合併症の有無の変化（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

Variable/ Treatment/ Baseline Value	Week 52 Yes N (%)	Week 52 No N (%)	Week 52 Missing N (%)
PERIPHERAL ARTHROPATHY			
Adalimumab 40mg EOW (N=145)			
Yes (N=15)	2 (13.3)	11 (73.3)	2 (13.3)
No (N=128)	5 (3.9)	107 (83.6)	16 (12.5)
Adalimumab 40mg EW (N=152)			
Yes (N=15)	2 (13.3)	10 (66.7)	3 (20.0)
No (N=130)	7 (5.4)	112 (86.2)	11 (8.5)
PRIMARY SCLEROSING CHOLANGITIS			
Adalimumab 40mg EOW (N=145)			
Yes (N=0)	0	0	0
No (N=143)	1 (0.7)	123 (86.0)	19 (13.3)
Adalimumab 40mg EW (N=152)			
Yes (N=1)	1 (100)	0	0
No (N=144)	0	130 (90.3)	14 (9.7)

表 2.7.3.6-144.　治験期間中の腸管外合併症の有無の変化（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

Variable/ Treatment/ Baseline Value	Week 52 Yes N (%)	Week 52 No N (%)	Week 52 Missing N (%)
PYODERMA GANGRENOSUM			
Adalimumab 40mg EOW (N=145)			
Yes (N=0)	0	0	0
No (N=143)	0	125 (87.4)	18 (12.6)
Adalimumab 40mg EW (N=152)			
Yes (N=1)	0	1 (100)	0
No (N=144)	0	130 (90.3)	14 (9.7)
SWEET'S SYNDROME			
Adalimumab 40mg EOW (N=145)			
Yes (N=0)	0	0	0
No (N=143)	0	125 (87.4)	18 (12.6)
Adalimumab 40mg EW (N=152)			
Yes (N=0)	0	0	0
No (N=145)	0	131 (90.3)	14 (9.7)

表 2.7.3.6-144.　治験期間中の腸管外合併症の有無の変化（維持療法試験，ITT-RP 集団，M14-033 主試験）（続き）

Variable/ Treatment/ Baseline Value	Week 52 Yes N (%)	Week 52 No N (%)	Week 52 Missing N (%)
UVEITIS			
Adalimumab 40mg EOW (N=145)			
Yes (N=0)	0	0	0
No (N=143)	0	124 (86.7)	19 (13.3)
Adalimumab 40mg EW (N=152)			
Yes (N=0)	0	0	0
No (N=145)	0	131 (90.3)	14 (9.7)
VENOUS THROMBOEMBOLISM			
Adalimumab 40mg EOW (N=145)			
Yes (N=0)	0	0	0
No (N=143)	0	124 (86.7)	19 (13.3)
Adalimumab 40mg EW (N=152)			
Yes (N=0)	0	0	0
No (N=145)	0	131 (90.3)	14 (9.7)

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.25

表 2.7.3.6-145. 投与 8 週時に Mayo スコアにより改善例となり，かつ投与 52 週時に寛解を達成した被験者の割合（NRI）（投与群間の比較）（維持療法試験，ITT-RP 集団，M14-033 主試験）

	Adalimumab		
	40mg EOW	40mg EW	TDM Regimem
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=145)	(N=152)	(N=74)
Yes, n (%)	42 (29.0)	60 (39.5)	27 (36.5)
No, n (%)	103 (71.0)	92 (60.5)	47 (63.5)
Risk Difference[A]	-7.5	3.0	
Adjusted Risk Difference[A,B]	-5.8	3.8	
95% Confidence Interval[B]	(-18.8, 7.2)	(-9.5, 17.0)	
P-Value[B]	0.382	0.580	

Note: Clinical remission per Full Mayo Score is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided by the central reader.
[A]: Risk difference = (Adalimumab 40mg EW - TDM regimen) or (Adalimumab 40mg EOW - TDM regimen).
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen and week 8 remission status.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.26.1

表 2.7.3.6-146. 投与 8 週時に Mayo スコアにより改善例となり，かつ投与 52 週時に内視鏡検査により改善が認められた被験者の割合（NRI）（投与群間の比較）（維持療法試験，ITT-RP 集団，M14-033 主試験）

	Adalimumab 40mg EOW	Adalimumab 40mg EW	TDM Regimem
Week 8 Responders with Endoscopic Improvement at Week 52 (Week 44 of Maintenance Study)	(N=145)	(N=152)	(N=74)
Yes, n (%)	60 (41.4)	78 (51.3)	34 (45.9)
No, n (%)	85 (58.6)	74 (48.7)	40 (54.1)
Risk Difference[A]	-4.6	5.4	
Adjusted Risk Difference[A,B]	-3.8	5.7	
95% Confidence Interval[B]	(-17.7, 10.2)	(-8.1, 19.4)	
P-Value[B]	0.595	0.421	

Note: Endoscopic improvement is defined as endoscopy subscore of 0 or 1.
[A]: Risk difference = (Adalimumab 40mg EW - TDM regimen) or (Adalimumab 40mg EOW - TDM regimen).
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen and week 8 remission status.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.27.1

表 2.7.3.6-147. ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 8 週時に Mayo スコアにより改善例となり，かつ投与 52 週時に副腎皮質ステロイドを 90 日間以上離脱できた被験者の割合（NRI）（投与群間の比較）（維持療法試験，ITT-RP 集団，M14-033 主試験）

	Adalimumab		
	40mg EOW	40mg EW	TDM Regimem
Week 8 Responders with Steroid Usage at Baseline and Steroid Free at Least 90 Days at Week 52 (Week 44 of Maintenance Study)	(N=92)	(N=96)	(N=47)
Yes, n (%)	49 (53.3)	72 (75.0)	34 (72.3)
No, n (%)	43 (46.7)	24 (25.0)	13 (27.7)
Risk Difference[A]	-19.1	2.7	
Adjusted Risk Difference[A,B]	-19.2	4.1	
95% Confidence Interval[B]	(-36.6, -1.7)	(-11.4, 19.6)	
P-Value[B]	0.032*	0.607	

[A]: Risk difference = (Adalimumab 40mg EW - TDM regimen) or (Adalimumab 40mg EOW - TDM regimen).
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen and week 8 remission status.
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.28

表 2.7.3.6-148. ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 8 週時に Mayo スコアにより改善例となり，かつ投与 52 週時に副腎皮質ステロイドを 90 日間以上離脱し，寛解を達成した被験者の割合（NRI）（投与群間の比較）（維持療法試験，ITT-RP 集団，M14-033 主試験）

	Adalimumab		
	40mg EOW	40mg EW	TDM Regimem
Week 8 Responders with Steroid Usage at Baseline and Steroid Free at Least 90 Days and in Clinical Remission at Week 52 (Week 44 of Maintenance Study)	(N=92)	(N=96)	(N=47)
Yes, n (%)	25 (27.2)	38 (39.6)	19 (40.4)
No, n (%)	67 (72.8)	58 (60.4)	28 (59.6)
Risk Difference[A]	-13.3	-0.8	
Adjusted Risk Difference[A,B]	-11.8	0.5	
95% Confidence Interval[B]	(-28.1, 4.5)	(-16.3, 17.2)	
P-Value[B]	0.155	0.954	

Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided by the central reader.
[A]: Risk difference = (Adalimumab 40mg EW - TDM regimen) or (Adalimumab 40mg EOW - TDM regimen).
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen and week 8 remission status.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.29.1

表 2.7.3.6-149. 投与 8 週時に Mayo スコアにより寛解例となり，かつ投与 52 週時に寛解を達成した被験者の割合（NRI）（投与群間の比較）（維持療法試験，ITT-RM 集団，M14-033 主試験）

	Adalimumab		
	40mg EOW	40mg EW	TDM Regimem
Week 8 Remitters with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=37)	(N=42)	(N=24)
Yes, n (%)	15 (40.5)	24 (57.1)	12 (50.0)
No, n (%)	22 (59.5)	18 (42.9)	12 (50.0)
Risk Difference[A]	-9.5	7.1	
Adjusted Risk Difference[A,B]	-8.9	6.9	
95% Confidence Interval[B]	(-34.8, 17.1)	(-18.2, 32.0)	
P-Value[B]	0.504	0.591	

Note: Clinical remission per Full Mayo Score is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided by the central reader.
[A]: Risk difference = (Adalimumab 40mg EW - TDM regimen) or (Adalimumab 40mg EOW - TDM regimen).
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen status.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.30.1

表 2.7.3.6-150. 投与 8 週時に Mayo スコアにより寛解例となり，かつ投与 52 週時に内視鏡検査により改善が認められた被験者の割合（NRI）（投与群間の比較）（維持療法試験，ITT-RM 集団，M14-033 主試験）

	Adalimumab 40mg EOW	Adalimumab 40mg EW	TDM Regimem
Week 8 Remitterss with Endoscopic Improvement at Week 52 (Week 44 of Maintenance Study)	(N=37)	(N=42)	(N=24)
Yes, n (%)	19 (51.4)	27 (64.3)	13 (54.2)
No, n (%)	18 (48.6)	15 (35.7)	11 (45.8)
Risk Difference[A]	-2.8	10.1	
Adjusted Risk Difference[A,B]	-2.5	9.8	
95% Confidence Interval[B]	(-28.7, 23.6)	(-14.7, 34.4)	
P-Value[B]	0.849	0.433	

Note: Endoscopic improvement is defined as endoscopy subscore of 0 or 1.
[A]: Risk difference = (Adalimumab 40mg EW - TDM regimen) or (Adalimumab 40mg EOW - TDM regimen).
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen status.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.31.1

表 2.7.3.6-151. ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 8 週時に Mayo スコアにより寛解例となり，かつ投与 52 週時に副腎皮質ステロイドを 90 日間以上離脱した被験者の割合（NRI）（投与群間の比較）（維持療法試験，ITT-RM 集団，M14-033 主試験）

	Adalimumab		
	40mg EOW	40mg EW	TDM Regimem
Week 8 Remitters with Steroid Usage at Baseline and Steroid Free at Least 90 Days at Week 52 (Week 44 of Maintenance Study)	(N=26)	(N=28)	(N=16)
Yes, n (%)	14 (53.8)	22 (78.6)	12 (75.0)
No, n (%)	12 (46.2)	6 (21.4)	4 (25.0)
Risk Difference[A]	-21.2	3.6	
Adjusted Risk Difference[A,B]	-22.3	6.2	
95% Confidence Interval[B]	(-52.9, 8.3)	(-20.0, 32.3)	
P-Value[B]	0.153	0.644	

[A]: Risk difference = (Adalimumab 40mg EW - TDM regimen) or (Adalimumab 40mg EOW - TDM regimen).
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen status.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.32

表 2.7.3.6-152. ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 8 週時に Mayo スコアにより寛解例となり，かつ投与 52 週時に副腎皮質ステロイドを 90 日間以上離脱し，寛解を達成した被験者の割合（NRI）（投与群間の比較）（維持療法試験，ITT-RM 集団，M14-033 主試験）

	Adalimumab		
	40mg EOW	40mg EW	TDM Regimem
Week 8 Remitters with Steroid Usage at Baseline and Steroid Free at Least 90 Days and in Clinical Remission at Week 52 (Week 44 of Maintenance Study)	(N=26)	(N=28)	(N=16)
Yes, n (%)	9 (34.6)	16 (57.1)	10 (62.5)
No, n (%)	17 (65.4)	12 (42.9)	6 (37.5)
Risk Difference[A]	-27.9	-5.4	
Adjusted Risk Difference[A,B]	-29.1	-2.9	
95% Confidence Interval[B]	(-60.4, 2.3)	(-33.9, 28.1)	
P-Value[B]	0.070+	0.855	

Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided by the central reader.
[A]: Risk difference = (Adalimumab 40mg EW - TDM regimen) or (Adalimumab 40mg EOW - TDM regimen).
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen status.
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.33.1

表 2.7.3.6-153. 投与 8 週時に Mayo スコアにより改善例となり，かつ投与 52 週時に IBDQ により改善を達成した被験者の割合（NRI）（投与群間の比較）（維持療法試験，ITT-RP 集団，M14-033 主試験）

	Adalimumab		
	40mg EOW	40mg EW	TDM Regimem
Week 8 Responders with IBDQ Response at Week 52 (Week 44 of Maintenance Study)	(N=145)	(N=152)	(N=74)
Yes, n (%)	90 (62.1)	101 (66.4)	51 (68.9)
No, n (%)	55 (37.9)	51 (33.6)	23 (31.1)
Risk Difference[A]	-6.8	-2.5	
Adjusted Risk Difference[A,B]	-7.2	-2.9	
95% Confidence Interval[B]	(-20.5, 6.2)	(-16.0, 10.3)	
P-Value[B]	0.292	0.669	

Note: IBDQ response is defined as increase of IBDQ >= 16 from baseline.
[A]: Risk difference = (Adalimumab 40mg EW - TDM regimen) or (Adalimumab 40mg EOW - TDM regimen).
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen and week 8 remission status.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.34.1

表 2.7.3.6-154. 投与 8 週時に Mayo スコアにより非改善例となり，かつ投与 52 週時に寛解を達成した被験者の割合（NRI）（投与群間の比較）（維持療法試験，ITT-NRP 集団，M14-033 主試験）

	Adalimumab 40mg EOW	Adalimumab 40mg EW	TDM Regimem
Week 8 Non-Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=157)	(N=152)	(N=77)
Yes, n (%)	19 (12.1)	24 (15.8)	8 (10.4)
No, n (%)	138 (87.9)	128 (84.2)	69 (89.6)
Risk Difference[A]	1.7	5.4	
Adjusted Risk Difference[A,B]	1.7	5.3	
95% Confidence Interval[B]	(-7.1, 10.4)	(-4.2, 14.9)	
P-Value[B]	0.707	0.273	

Note: Clinical remission per Full Mayo Score is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided by the central reader.
[A]: Risk difference = (Adalimumab 40mg EW - TDM regimen) or (Adalimumab 40mg EOW - TDM regimen).
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen status.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.35.1

表 2.7.3.6-155. 投与 8 週時に Mayo スコアにより非寛解例となり，かつ投与 52 週時に寛解を達成した被験者の割合（NRI）（投与群間の比較）（維持療法試験，ITT-NRM*集団，M14-033 主試験）* ITT 集団のうち 8 週時非寛解 Non-Remitters

	Adalimumab 40mg EOW	Adalimumab 40mg EW	TDM Regimem
Week 8 Non-Remitters with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=265)	(N=262)	(N=127)
Yes, n (%)	46 (17.4)	60 (22.9)	23 (18.1)
No, n (%)	219 (82.6)	202 (77.1)	104 (81.9)
Risk Difference[A]	-0.8	4.8	
Adjusted Risk Difference[A,B]	-0.8	4.1	
95% Confidence Interval[B]	(-8.7, 7.1)	(-4.3, 12.6)	
P-Value[B]	0.847	0.339	

Note: Clinical remission per Full Mayo Score is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided by the central reader.
[A]: Risk difference = (Adalimumab 40mg EW - TDM regimen) or (Adalimumab 40mg EOW - TDM regimen).
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen and week 8 response status.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.36.1

表 2.7.3.6-156. 投与 8 週時に Mayo スコアにより改善例となり，かつ投与 52 週時に内視鏡検査サブスコアが 0 であった被験者の割合（NRI）（投与群間の比較）（維持療法試験，ITT-RP 集団，M14-033 主試験）

	Adalimumab 40mg EOW	Adalimumab 40mg EW	TDM Regimem
Week 8 Responders with Endoscopic Subscore of 0 at Week 52 (Week 44 of Maintenance Study)	(N=145)	(N=152)	(N=74)
Yes, n (%)	40 (27.6)	54 (35.5)	23 (31.1)
No, n (%)	105 (72.4)	98 (64.5)	51 (68.9)
Risk Difference[A]	-3.5	4.4	
Adjusted Risk Difference[A,B]	-1.9	4.9	
95% Confidence Interval[B]	(-14.4, 10.6)	(-8.1, 18.0)	
P-Value[B]	0.768	0.458	

[A]: Risk difference = (Adalimumab 40mg EW - TDM regimen) or (Adalimumab 40mg EOW - TDM regimen).
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen and week 8 remission status.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.37.1

表 2.7.3.6-157. 投与 8 週時に Mayo スコアにより寛解例となり，かつ投与 52 週時に内視鏡検査サブスコアが 0 であった被験者の割合（NRI）（投与群間の比較）（維持療法試験，ITT-RM 集団，M14-033 主試験）

	Adalimumab 40mg EOW	Adalimumab 40mg EW	TDM Regimem
Week 8 Remitters with Endoscopic Subscore of 0 at Week 52 (Week 44 of Maintenance Study)	(N=37)	(N=42)	(N=24)
Yes, n (%)	17 (45.9)	20 (47.6)	11 (45.8)
No, n (%)	20 (54.1)	22 (52.4)	13 (54.2)
Risk Difference[A]	0.1	1.8	
Adjusted Risk Difference[A,B]	0.6	1.5	
95% Confidence Interval[B]	(-25.5, 26.7)	(-23.6, 26.7)	
P-Value[B]	0.965	0.906	

[A]: Risk difference = (Adalimumab 40mg EW - TDM regimen) or (Adalimumab 40mg EOW - TDM regimen).
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen status.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.38.1

表 2.7.3.6-158. 投与 8 週時に Mayo スコアにより改善例となり，かつ投与 52 週時に IBDQ 腸症状ドメインスコアにより改善を達成した被験者の割合（NRI）（投与群間の比較）（維持療法試験，ITT-RP 集団，M14-033 主試験）

	Adalimumab		
	40mg EOW	40mg EW	TDM Regimem
Week 8 Responders Achieving Response in IBDQ Bowel Symptom Domain at Week 52 (Week 44 of Maintenance Study)	(N=145)	(N=152)	(N=74)
Yes, n (%)	90 (62.1)	106 (69.7)	51 (68.9)
No, n (%)	55 (37.9)	46 (30.3)	23 (31.1)
Risk Difference[A]	-6.8	0.8	
Adjusted Risk Difference[A,B]	-7.1	0.4	
95% Confidence Interval[B]	(-20.4, 6.3)	(-12.4, 13.3)	
P-Value[B]	0.301	0.948	

Note: Response in IBDQ bowel symptom domain is defined as increase of IBDQ bowel symptom domain score >= 6 from baseline.
[A]: Risk difference = (Adalimumab 40mg EW - TDM regimen) or (Adalimumab 40mg EOW - TDM regimen).
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen and week 8 remission status.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.39.1

表 2.7.3.6-159. 投与 8 週時に Mayo スコアにより改善例となり，かつ投与 52 週時に IBDQ 疲労尺度により改善を達成した被験者の割合（NRI）（投与群間の比較）（維持療法試験，ITT-RP 集団，M14-033 主試験）

	Adalimumab 40mg EOW	Adalimumab 40mg EW	TDM Regimem
Week 8 Responders Achieving Response in IBDQ Fatigue Item at Week 52 (Week 44 of Maintenance Study)	(N=145)	(N=152)	(N=74)
Yes, n (%)	78 (53.8)	93 (61.2)	50 (67.6)
No, n (%)	67 (46.2)	59 (38.8)	24 (32.4)
Risk Difference[A]	-13.8	-6.4	
Adjusted Risk Difference[A,B]	-14.0	-6.4	
95% Confidence Interval[B]	(-27.9, -0.2)	(-19.9, 7.1)	
P-Value[B]	0.047*	0.355	

Note: Response in IBDQ fatigue item is defined as increase of IBDQ fatigue item score >= 1 from baseline.
[A]: Risk difference = (Adalimumab 40mg EW - TDM regimen) or (Adalimumab 40mg EOW - TDM regimen).
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen and week 8 remission status.
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__3.40.1

表 2.7.3.6-160. 投与 8 週時から投与 52 週時までの原因を問わない入院及び手術，又は UC に関連する入院及び手術を行った被験者の割合（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

Variable Treatment	Number of Subjects with Event	Time at Risk in Patient-Year$	Incidence Rate	Relative Risk of EW/EOW (95% CI)	P-value&	Total Subjects
Japan ITT-RP Set						
ALL-CAUSE HOSPITALIZATIONS						
Adalimumab 40mg EOW	1	16.4	0.06		0.243	18
Adalimumab 40mg EW	0	22.4	0.00			23
UC-RELATED HOSPITALIZATIONS						
Adalimumab 40mg EOW	0	17.2	0.00			18
Adalimumab 40mg EW	0	22.4	0.00			23
ALL-CAUSE SURGERIES						
Adalimumab 40mg EOW	0	17.2	0.00			18
Adalimumab 40mg EW	0	22.4	0.00			23
UC-RELATED SURGERIES						
Adalimumab 40mg EOW	0	17.2	0.00			18
Adalimumab 40mg EW	0	22.4	0.00			23

表 2.7.3.6-160. 投与 8 週時から投与 52 週時までの原因を問わない入院及び手術，又は UC に関連する入院及び手術を行った被験者の割合（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Variable Treatment	Number of Subjects with Event	Time at Risk in Patient-Year$	Incidence Rate	Relative Risk of EW/EOW (95% CI)	P-value&	Total Subjects
Integrated ITT-RP Set						
ALL-CAUSE HOSPITALIZATIONS						
Adalimumab 40mg EOW	17	142.8	0.12	1.0 (0.5, 1.9)	0.924	163
Adalimumab 40mg EW	18	156.1	0.12			175
UC-RELATED HOSPITALIZATIONS						
Adalimumab 40mg EOW	9	146.2	0.06	0.4 (0.1, 1.2)	0.110	163
Adalimumab 40mg EW	4	164.4	0.02			175
ALL-CAUSE SURGERIES						
Adalimumab 40mg EOW	4	146.9	0.03	2.1 (6.5, 0.6)	0.221	163
Adalimumab 40mg EW	9	161.0	0.06			175
UC-RELATED SURGERIES						
Adalimumab 40mg EOW	1	147.7	0.01	0.9 (0.1,14.2)	0.935	163
Adalimumab 40mg EW	1	165.7	0.01			175

$ Censored to first event (hospitalization or surgery). All subjects without event will be censored to last dose date of the study drug + 70 days.
& Based on z-score.

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__3.1.1_J

表 2.7.3.6-161. 投与 8 週時から投与 52 週時までの原因を問わない入院及び手術，又は UC に関連する入院及び手術の頻度（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

	Japan				Integrated			
	Adalimumab				Adalimumab			
	40mg EOW (N= 18) (PYS= 16.4)		40mg EW (N= 23) (PYS= 22.4)		40mg EOW (N=163) (PYS=142.8)		40mg EW (N=175) (PYS=155.8)	
	Events	(E/100PY)	Events	(E/100PY) P-Value&	Events	(E/100PY)	Events	(E/100PY) P-Value&
ALL-CAUSE HOSPITALIZATIONS	1	(6.1)	0		20	(14.0)	24	(15.4) 0.764
UC-RELATED HOSPITALIZATIONS	0		0	1.000	9	(6.3)	5	(3.2) 0.226
ALL-CAUSE SURGERIES	0		0	1.000	4	(2.8)	10	(6.4) 0.162
UC-RELATED SURGERIES	0		0	1.000	1	(0.7)	1	(0.6) 0.951

Note: All subjects without event will be censored to last dose date of the study drug + 70 days.
E/100PY = Events per 100 patient-years.
& Based on Poisson Regression.

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__3.1.2_J

表 2.7.3.6-162. 投与 8 週時に Mayo スコアにより改善例となり，かつ投与 52 週時に改善を達成した被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Week 8 Responders with Clinical Response at Week 52 (Week 44 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	11 (61.1)	19 (82.6)	85 (52.1)	117 (66.9)
No, n (%)	7 (38.9)	4 (17.4)	78 (47.9)	58 (33.1)
Risk Difference[A]		21.5		14.7
Adjusted Risk Difference[A,B]		19.5		14.6
95% Confidence Interval[B]		(-9.9, 48.9)		(4.1, 25.2)
P-Value[B]		0.194		0.006**

Note: Clinical response is defined as a decrease in Full Mayo Score of >= 3 points and >= 30% from baseline, plus a decrease in the rectal bleeding subscore [RBS] >= 1 or an absolute RBS <= 1.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen and week 8 remission status.
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__3.2_J

表 2.7.3.6-163. 投与 8 週時に Mayo スコアにより非改善例となり，かつ投与 52 週時に改善を達成した被験者の割合（NRI）（維持療法試験，ITT-NRP* 集団，M14-033 日本サブ試験）* ITT-RP 集団のうち 8 週時非寛解 Non-Remitters

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Week 8 Non-Responders with Clinical Response at Week 52 (Week 44 of Maintenance Study)	(N=25)	(N=23)	(N=182)	(N=175)
Yes, n (%)	7 (28.0)	8 (34.8)	44 (24.2)	51 (29.1)
No, n (%)	18 (72.0)	15 (65.2)	138 (75.8)	124 (70.9)
Risk Difference[A]		6.8		5.0
Adjusted Risk Difference[A,B]		6.5		4.9
95% Confidence Interval[B]		(-20.3, 33.4)		(-4.3, 14.1)
P-Value[B]		0.634		0.298

Note: Clinical response is defined as a decrease in Full Mayo Score of >= 3 points and >= 30% from baseline, plus a decrease in the rectal bleeding subscore [RBS] >= 1 or an absolute RBS <= 1.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen.

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__3.3_J

表 2.7.3.6-164. 投与 8 週時に Mayo スコアにより非改善例となり，かつ投与 52 週時に内視鏡検査により改善が認められた被験者の割合（NRI）（維持療法試験，ITT-NRP*集団，M14-033 日本サブ試験）* ITT-RP 集団のうち 8 週時非寛解 Non-Remitters

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Week 8 Non-Responders with Endoscopic Improvement at Week 52 (Week 44 of Maintenance Study)	(N=25)	(N=23)	(N=182)	(N=175)
Yes, n (%)	4 (16.0)	6 (26.1)	32 (17.6)	44 (25.1)
No, n (%)	21 (84.0)	17 (73.9)	150 (82.4)	131 (74.9)
Risk Difference[A]		10.1		7.6
Adjusted Risk Difference[A,B]		9.7		7.5
95% Confidence Interval[B]		(-13.8, 33.3)		(-1.0, 16.1)
P-Value[B]		0.417		0.083+

Note: Endoscopic improvement is defined as endoscopy subscore of 0 or 1.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen.
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__3.4_J

表 2.7.3.6-165. 投与 8 週時に Adapted Mayo スコアにより改善例となり，かつ投与 52 週時に Adapted Mayo スコアにより寛解を達成した被験者の割合（NRI）（維持療法試験，ITT 集団，M14-033 日本サブ試験）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Week 8 Responders per Adapted Mayo Score Achieving Clinical Remission per Adapted Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=15)	(N=22)	(N=162)	(N=180)
Yes, n (%)	6 (40.0)	12 (54.5)	54 (33.3)	72 (40.0)
No, n (%)	9 (60.0)	10 (45.5)	108 (66.7)	108 (60.0)
Risk Difference[A]		14.5		6.7
Adjusted Risk Difference[A,B]		9.3		7.9
95% Confidence Interval[B]		(-26.8, 45.4)		(-2.2, 18.0)
P-Value[B]		0.614		0.125

Note: Clinical remission per Adapted Mayo Score is defined as an Adapted Mayo Score <= 2, with stool frequency subscore <= 1, RBS of 0, and endoscopic subscore <= 1.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen and week 8 remission per Adapted Mayo Score status.

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__3.5_J

表 2.7.3.6-166. 投与 8 週時に改善例となり，かつ投与 52 週時に Adapted Mayo スコアにより寛解を達成した被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Week 8 Responders Achieving Clinical Remission per Adapted Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	7 (38.9)	12 (52.2)	52 (31.9)	73 (41.7)
No, n (%)	11 (61.1)	11 (47.8)	111 (68.1)	102 (58.3)
Risk Difference[A]		13.3		9.8
Adjusted Risk Difference[A,B]		11.9		9.2
95% Confidence Interval[B]		(-21.1, 45.0)		(-1.0, 19.4)
P-Value[B]		0.479		0.078+

Note: Clinical remission per Adapted Mayo Score is defined as an Adapted Mayo Score <= 2, with stool frequency subscore <= 1, RBS of 0, and endoscopic subscore <= 1.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen and week 8 remission status.
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__3.6_J

表 2.7.3.6-167. ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 8 週時に Mayo スコアにより改善例となった被験者のうち，投与 52 週時に副腎皮質ステロイドを 180 日間以上離脱し，かつ FMS により寛解できた被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Week 8 Responders with Steroid Usage at Baseline and Steroid Free at Least 180 Days and in Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=11)	(N=13)	(N=103)	(N=109)
Yes, n (%)	4 (36.4)	6 (46.2)	29 (28.2)	43 (39.4)
No, n (%)	7 (63.6)	7 (53.8)	74 (71.8)	66 (60.6)
Risk Difference[A]		9.8		11.3
Adjusted Risk Difference[A,B]		12.4		10.5
95% Confidence Interval[B]		(-31.6, 56.5)		(-2.2, 23.1)
P-Value[B]		0.580		0.105

Note: Clinical remission per Full Mayo Score is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided by the central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen and week 8 remission status.

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__3.7_J

表 2.7.3.6-168. ベースラインで副腎皮質ステロイドを投与していた被験者で，各評価時点で副腎皮質ステロイドを離脱できた被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Subjects with Steroid Usage at Baseline and Are Steroid Free at Maintenance Baseline	(N=11)	(N=13)	(N=103)	(N=109)
Yes, n (%)	1 (9.1)	4 (30.8)	41 (39.8)	38 (34.9)
No, n (%)	10 (90.9)	9 (69.2)	62 (60.2)	71 (65.1)
Risk Difference[A]		21.7		-4.9
Adjusted Risk Difference[A,B]		20.1		-4.9
95% Confidence Interval[B]		(-17.4, 57.6)		(-18.0, 8.2)
P-Value[B]		0.294		0.460
Subjects with Steroid Usage at Baseline and Are Steroid Free at Week 10 (Week 2 of Maintenance Study)	(N=11)	(N=13)	(N=103)	(N=109)
Yes, n (%)	2 (18.2)	6 (46.2)	62 (60.2)	72 (66.1)
No, n (%)	9 (81.8)	7 (53.8)	41 (39.8)	37 (33.9)
Risk Difference[A]		28.0		5.9
Adjusted Risk Difference[A,B]		24.7		6.3
95% Confidence Interval[B]		(-12.9, 62.2)		(-6.7, 19.4)
P-Value[B]		0.197		0.341
Subjects with Steroid Usage at Baseline and Are Steroid Free at Week 12 (Week 4 of Maintenance Study)	(N=11)	(N=13)	(N=103)	(N=109)
Yes, n (%)	5 (45.5)	6 (46.2)	70 (68.0)	83 (76.1)
No, n (%)	6 (54.5)	7 (53.8)	33 (32.0)	26 (23.9)
Risk Difference[A]		0.7		8.2
Adjusted Risk Difference[A,B]		-6.8		8.9
95% Confidence Interval[B]		(-44.3, 30.8)		(-3.3, 21.0)
P-Value[B]		0.724		0.152

表 2.7.3.6-168. ベースラインで副腎皮質ステロイドを投与していた被験者で，各評価時点で副腎皮質ステロイドを離脱できた被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Subjects with Steroid Usage at Baseline and Are Steroid Free at Week 16 (Week 8 of Maintenance Study)	(N=11)	(N=13)	(N=103)	(N=109)
Yes, n (%)	6 (54.5)	6 (46.2)	79 (76.7)	86 (78.9)
No, n (%)	5 (45.5)	7 (53.8)	24 (23.3)	23 (21.1)
Risk Difference[A]		-8.4		2.2
Adjusted Risk Difference[A,B]		-18.6		2.4
95% Confidence Interval[B]		(-59.0, 21.9)		(-8.8, 13.7)
P-Value[B]		0.369		0.675
Subjects with Steroid Usage at Baseline and Are Steroid Free at Week 22 (Week 14 of Maintenance Study)	(N=11)	(N=13)	(N=103)	(N=109)
Yes, n (%)	5 (45.5)	8 (61.5)	73 (70.9)	88 (80.7)
No, n (%)	6 (54.5)	5 (38.5)	30 (29.1)	21 (19.3)
Risk Difference[A]		16.1		9.9
Adjusted Risk Difference[A,B]		15.3		9.8
95% Confidence Interval[B]		(-26.9, 57.4)		(-1.8, 21.5)
P-Value[B]		0.478		0.097+
Subjects with Steroid Usage at Baseline and Are Steroid Free at Week 24 (Week 16 of Maintenance Study)	(N=11)	(N=13)	(N=103)	(N=109)
Yes, n (%)	5 (45.5)	10 (76.9)	69 (67.0)	91 (83.5)
No, n (%)	6 (54.5)	3 (23.1)	34 (33.0)	18 (16.5)
Risk Difference[A]		31.5		16.5
Adjusted Risk Difference[A,B]		31.2		16.1
95% Confidence Interval[B]		(-7.9, 70.3)		(4.4, 27.8)
P-Value[B]		0.118		0.007**

表 2.7.3.6-168. ベースラインで副腎皮質ステロイドを投与していた被験者で，各評価時点で副腎皮質ステロイドを離脱できた被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Subjects with Steroid Usage at Baseline and Are Steroid Free at Week 29 (Week 21 of Maintenance Study)	(N=11)	(N=13)	(N=103)	(N=109)
Yes, n (%)	6 (54.5)	10 (76.9)	71 (68.9)	89 (81.7)
No, n (%)	5 (45.5)	3 (23.1)	32 (31.1)	20 (18.3)
Risk Difference[A]		22.4		12.7
Adjusted Risk Difference[A,B]		19.4		12.3
95% Confidence Interval[B]		(-17.9, 56.8)		(0.7, 24.0)
P-Value[B]		0.309		0.038*
Subjects with Steroid Usage at Baseline and Are Steroid Free at Week 35 (Week 27 of Maintenance Study)	(N=11)	(N=13)	(N=103)	(N=109)
Yes, n (%)	7 (63.6)	11 (84.6)	66 (64.1)	87 (79.8)
No, n (%)	4 (36.4)	2 (15.4)	37 (35.9)	22 (20.2)
Risk Difference[A]		21.0		15.7
Adjusted Risk Difference[A,B]		16.0		15.2
95% Confidence Interval[B]		(-18.2, 50.1)		(3.1, 27.4)
P-Value[B]		0.359		0.014*
Subjects with Steroid Usage at Baseline and Are Steroid Free at Week 37 (Week 29 of Maintenance Study)	(N=11)	(N=13)	(N=103)	(N=109)
Yes, n (%)	7 (63.6)	10 (76.9)	64 (62.1)	87 (79.8)
No, n (%)	4 (36.4)	3 (23.1)	39 (37.9)	22 (20.2)
Risk Difference[A]		13.3		17.7
Adjusted Risk Difference[A,B]		8.4		17.3
95% Confidence Interval[B]		(-30.2, 47.1)		(5.0, 29.7)
P-Value[B]		0.669		0.006**

表 2.7.3.6-168. ベースラインで副腎皮質ステロイドを投与していた被験者で，各評価時点で副腎皮質ステロイドを離脱できた被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Subjects with Steroid Usage at Baseline and Are Steroid Free at Week 42 (Week 34 of Maintenance Study)	(N=11)	(N=13)	(N=103)	(N=109)
Yes, n (%)	7 (63.6)	10 (76.9)	61 (59.2)	85 (78.0)
No, n (%)	4 (36.4)	3 (23.1)	42 (40.8)	24 (22.0)
Risk Difference[A]		13.3		18.8
Adjusted Risk Difference[A,B]		8.4		18.5
95% Confidence Interval[B]		(-30.2, 47.1)		(5.9, 31.1)
P-Value[B]		0.669		0.004**
Subjects with Steroid Usage at Baseline and Are Steroid Free at Week 48 (Week 40 of Maintenance Study)	(N=11)	(N=13)	(N=103)	(N=109)
Yes, n (%)	7 (63.6)	9 (69.2)	59 (57.3)	81 (74.3)
No, n (%)	4 (36.4)	4 (30.8)	44 (42.7)	28 (25.7)
Risk Difference[A]		5.6		17.0
Adjusted Risk Difference[A,B]		0.9		17.0
95% Confidence Interval[B]		(-39.8, 41.6)		(4.1, 29.9)
P-Value[B]		0.966		0.010**
Subjects with Steroid Usage at Baseline and Are Steroid Free at Week 52 (Week 44 of Maintenance Study)	(N=11)	(N=13)	(N=103)	(N=109)
Yes, n (%)	8 (72.7)	9 (69.2)	58 (56.3)	82 (75.2)
No, n (%)	3 (27.3)	4 (30.8)	45 (43.7)	27 (24.8)
Risk Difference[A]		-3.5		18.9
Adjusted Risk Difference[A,B]		-9.6		18.9
95% Confidence Interval[B]		(-49.3, 30.1)		(6.0, 31.8)
P-Value[B]		0.635		0.004**

表 2.7.3.6-168.　ベースラインで副腎皮質ステロイドを投与していた被験者で，各評価時点で副腎皮質ステロイドを離脱できた被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

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[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value
     were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen and week 8 remission status.
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.
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Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__3.8_J

表 2.7.3.6-169. 評価時点ごとの PMS により寛解を達成した被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Subjects with Clinical Remission per Partial Mayo Score at Maintenance Baseline	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	12 (66.7)	17 (73.9)	93 (57.1)	100 (57.1)
No, n (%)	6 (33.3)	6 (26.1)	70 (42.9)	75 (42.9)
Risk Difference[A]		7.2		0.1
Adjusted Risk Difference[A,B]		12.8		-1.0
95% Confidence Interval[B]		(-11.4, 37.0)		(-9.9, 7.9)
P-Value[B]		0.298		0.821
Subjects with Clinical Remission per Partial Mayo Score at Week 10 (Week 2 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	12 (66.7)	13 (56.5)	87 (53.4)	97 (55.4)
No, n (%)	6 (33.3)	10 (43.5)	76 (46.6)	78 (44.6)
Risk Difference[A]		-10.1		2.1
Adjusted Risk Difference[A,B]		-11.9		1.2
95% Confidence Interval[B]		(-43.1, 19.4)		(-8.6, 11.0)
P-Value[B]		0.457		0.813
Subjects with Clinical Remission per Partial Mayo Score at Week 12 (Week 4 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	9 (50.0)	14 (60.9)	98 (60.1)	96 (54.9)
No, n (%)	9 (50.0)	9 (39.1)	65 (39.9)	79 (45.1)
Risk Difference[A]		10.9		-5.3
Adjusted Risk Difference[A,B]		9.5		-6.0
95% Confidence Interval[B]		(-23.7, 42.7)		(-16.0, 4.1)
P-Value[B]		0.575		0.243

表 2.7.3.6-169. 評価時点ごとの PMS により寛解を達成した被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Subjects with Clinical Remission per Partial Mayo Score at Week 16 (Week 8 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	8 (44.4)	17 (73.9)	89 (54.6)	105 (60.0)
No, n (%)	10 (55.6)	6 (26.1)	74 (45.4)	70 (40.0)
Risk Difference[A]		29.5		5.4
Adjusted Risk Difference[A,B]		26.3		5.0
95% Confidence Interval[B]		(-4.5, 57.2)		(-5.2, 15.1)
P-Value[B]		0.094+		0.335
Subjects with Clinical Remission per Partial Mayo Score at Week 22 (Week 14 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	7 (38.9)	17 (73.9)	87 (53.4)	111 (63.4)
No, n (%)	11 (61.1)	6 (26.1)	76 (46.6)	64 (36.6)
Risk Difference[A]		35.0		10.1
Adjusted Risk Difference[A,B]		33.4		9.1
95% Confidence Interval[B]		(3.4, 63.5)		(-1.2, 19.3)
P-Value[B]		0.029*		0.082+
Subjects with Clinical Remission per Partial Mayo Score at Week 24 (Week 16 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	10 (55.6)	18 (78.3)	80 (49.1)	106 (60.6)
No, n (%)	8 (44.4)	5 (21.7)	83 (50.9)	69 (39.4)
Risk Difference[A]		22.7		11.5
Adjusted Risk Difference[A,B]		22.7		10.6
95% Confidence Interval[B]		(-7.1, 52.6)		(0.1, 21.1)
P-Value[B]		0.136		0.047*

表 2.7.3.6-169. 評価時点ごとの PMS により寛解を達成した被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Subjects with Clinical Remission per Partial Mayo Score at Week 29 (Week 21 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	9 (50.0)	16 (69.6)	80 (49.1)	105 (60.0)
No, n (%)	9 (50.0)	7 (30.4)	83 (50.9)	70 (40.0)
Risk Difference[A]		19.6		10.9
Adjusted Risk Difference[A,B]		22.5		10.1
95% Confidence Interval[B]		(-9.0, 54.0)		(-0.4, 20.6)
P-Value[B]		0.162		0.059+
Subjects with Clinical Remission per Partial Mayo Score at Week 35 (Week 27 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	7 (38.9)	16 (69.6)	76 (46.6)	102 (58.3)
No, n (%)	11 (61.1)	7 (30.4)	87 (53.4)	73 (41.7)
Risk Difference[A]		30.7		11.7
Adjusted Risk Difference[A,B]		33.1		10.9
95% Confidence Interval[B]		(0.3, 65.9)		(0.4, 21.5)
P-Value[B]		0.048*		0.043*
Subjects with Clinical Remission per Partial Mayo Score at Week 37 (Week 29 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	6 (33.3)	15 (65.2)	76 (46.6)	98 (56.0)
No, n (%)	12 (66.7)	8 (34.8)	87 (53.4)	77 (44.0)
Risk Difference[A]		31.9		9.4
Adjusted Risk Difference[A,B]		36.0		8.7
95% Confidence Interval[B]		(3.3, 68.6)		(-1.8, 19.3)
P-Value[B]		0.031*		0.106

表 2.7.3.6-169. 評価時点ごとの PMS により寛解を達成した被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Subjects with Clinical Remission per Partial Mayo Score at Week 42 (Week 34 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	8 (44.4)	15 (65.2)	81 (49.7)	94 (53.7)
No, n (%)	10 (55.6)	8 (34.8)	82 (50.3)	81 (46.3)
Risk Difference[A]		20.8		4.0
Adjusted Risk Difference[A,B]		20.5		3.1
95% Confidence Interval[B]		(-11.8, 52.8)		(-7.4, 13.7)
P-Value[B]		0.213		0.562
Subjects with Clinical Remission per Partial Mayo Score at Week 48 (Week 40 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	5 (27.8)	14 (60.9)	74 (45.4)	98 (56.0)
No, n (%)	13 (72.2)	9 (39.1)	89 (54.6)	77 (44.0)
Risk Difference[A]		33.1		10.6
Adjusted Risk Difference[A,B]		35.6		10.4
95% Confidence Interval[B]		(2.1, 69.1)		(-0.3, 21.0)
P-Value[B]		0.037*		0.057+
Subjects with Clinical Remission per Partial Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	8 (44.4)	18 (78.3)	67 (41.1)	100 (57.1)
No, n (%)	10 (55.6)	5 (21.7)	96 (58.9)	75 (42.9)
Risk Difference[A]		33.8		16.0
Adjusted Risk Difference[A,B]		34.0		15.1
95% Confidence Interval[B]		(1.6, 66.3)		(4.5, 25.7)
P-Value[B]		0.040*		0.005**

表 2.7.3.6-169.　評価時点ごとの PMS により寛解を達成した被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Note: Clinical remission per Partial Mayo Score is defined as Partial Mayo Score <= 2, with no subscore > 1.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen and week 8 remission status.
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__3.9_J

表 2.7.3.6-170. 評価時点ごとの PMS により改善を達成した被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Subjects with Clinical Response per Partial Mayo Score at Maintenance Baseline	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	17 (94.4)	22 (95.7)	160 (98.2)	170 (97.1)
No, n (%)	1 (5.6)	1 (4.3)	3 (1.8)	5 (2.9)
Risk Difference[A]		1.2		-1.0
Adjusted Risk Difference[A,B]		2.8		-1.0
95% Confidence Interval[B]		(-11.1, 16.8)		(-4.2, 2.2)
P-Value[B]		0.691		0.546
Subjects with Clinical Response per Partial Mayo Score at Week 10 (Week 2 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	15 (83.3)	22 (95.7)	142 (87.1)	158 (90.3)
No, n (%)	3 (16.7)	1 (4.3)	21 (12.9)	17 (9.7)
Risk Difference[A]		12.3		3.2
Adjusted Risk Difference[A,B]		10.4		2.8
95% Confidence Interval[B]		(-9.3, 30.0)		(-3.9, 9.5)
P-Value[B]		0.301		0.412
Subjects with Clinical Response per Partial Mayo Score at Week 12 (Week 4 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	15 (83.3)	20 (87.0)	145 (89.0)	148 (84.6)
No, n (%)	3 (16.7)	3 (13.0)	18 (11.0)	27 (15.4)
Risk Difference[A]		3.6		-4.4
Adjusted Risk Difference[A,B]		0.6		-4.6
95% Confidence Interval[B]		(-23.0, 24.1)		(-11.8, 2.7)
P-Value[B]		0.962		0.217

表 2.7.3.6-170. 評価時点ごとの PMS により改善を達成した被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Subjects with Clinical Response per Partial Mayo Score at Week 16 (Week 8 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	13 (72.2)	21 (91.3)	137 (84.0)	150 (85.7)
No, n (%)	5 (27.8)	2 (8.7)	26 (16.0)	25 (14.3)
Risk Difference[A]		19.1		1.7
Adjusted Risk Difference[A,B]		14.0		1.6
95% Confidence Interval[B]		(-10.1, 38.1)		(-6.0, 9.3)
P-Value[B]		0.256		0.678
Subjects with Clinical Response per Partial Mayo Score at Week 22 (Week 14 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	12 (66.7)	20 (87.0)	118 (72.4)	147 (84.0)
No, n (%)	6 (33.3)	3 (13.0)	45 (27.6)	28 (16.0)
Risk Difference[A]		20.3		11.6
Adjusted Risk Difference[A,B]		17.1		11.1
95% Confidence Interval[B]		(-10.0, 44.1)		(2.3, 19.8)
P-Value[B]		0.216		0.014*
Subjects with Clinical Response per Partial Mayo Score at Week 24 (Week 16 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	14 (77.8)	20 (87.0)	113 (69.3)	141 (80.6)
No, n (%)	4 (22.2)	3 (13.0)	50 (30.7)	34 (19.4)
Risk Difference[A]		9.2		11.2
Adjusted Risk Difference[A,B]		11.4		10.8
95% Confidence Interval[B]		(-13.0, 35.9)		(1.6, 20.1)
P-Value[B]		0.359		0.022*

表 2.7.3.6-170. 評価時点ごとの PMS により改善を達成した被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Subjects with Clinical Response per Partial Mayo Score at Week 29 (Week 21 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	14 (77.8)	19 (82.6)	114 (69.9)	143 (81.7)
No, n (%)	4 (22.2)	4 (17.4)	49 (30.1)	32 (18.3)
Risk Difference[A]		4.8		11.8
Adjusted Risk Difference[A,B]		8.4		11.5
95% Confidence Interval[B]		(-17.8, 34.6)		(2.3, 20.6)
P-Value[B]		0.531		0.014*
Subjects with Clinical Response per Partial Mayo Score at Week 35 (Week 27 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	15 (83.3)	20 (87.0)	108 (66.3)	134 (76.6)
No, n (%)	3 (16.7)	3 (13.0)	55 (33.7)	41 (23.4)
Risk Difference[A]		3.6		10.3
Adjusted Risk Difference[A,B]		7.5		10.1
95% Confidence Interval[B]		(-15.8, 30.7)		(0.4, 19.7)
P-Value[B]		0.530		0.040*
Subjects with Clinical Response per Partial Mayo Score at Week 37 (Week 29 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	12 (66.7)	19 (82.6)	96 (58.9)	130 (74.3)
No, n (%)	6 (33.3)	4 (17.4)	67 (41.1)	45 (25.7)
Risk Difference[A]		15.9		15.4
Adjusted Risk Difference[A,B]		15.9		15.2
95% Confidence Interval[B]		(-13.0, 44.8)		(5.1, 25.2)
P-Value[B]		0.280		0.003**

表 2.7.3.6-170. 評価時点ごとの PMS により改善を達成した被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Subjects with Clinical Response per Partial Mayo Score at Week 42 (Week 34 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	13 (72.2)	19 (82.6)	107 (65.6)	128 (73.1)
No, n (%)	5 (27.8)	4 (17.4)	56 (34.4)	47 (26.9)
Risk Difference[A]		10.4		7.5
Adjusted Risk Difference[A,B]		13.8		7.4
95% Confidence Interval[B]		(-13.4, 41.1)		(-2.5, 17.2)
P-Value[B]		0.319		0.142
Subjects with Clinical Response per Partial Mayo Score at Week 48 (Week 40 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	11 (61.1)	19 (82.6)	98 (60.1)	131 (74.9)
No, n (%)	7 (38.9)	4 (17.4)	65 (39.9)	44 (25.1)
Risk Difference[A]		21.5		14.7
Adjusted Risk Difference[A,B]		21.7		15.1
95% Confidence Interval[B]		(-8.0, 51.4)		(5.1, 25.1)
P-Value[B]		0.152		0.003**
Subjects with Clinical Response per Partial Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	12 (66.7)	20 (87.0)	96 (58.9)	128 (73.1)
No, n (%)	6 (33.3)	3 (13.0)	67 (41.1)	47 (26.9)
Risk Difference[A]		20.3		14.2
Adjusted Risk Difference[A,B]		20.8		14.1
95% Confidence Interval[B]		(-7.0, 48.5)		(4.0, 24.3)
P-Value[B]		0.142		0.006**

表 2.7.3.6-170.　評価時点ごとの PMS により改善を達成した被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Note: Clinical response per Partial Mayo Score is defined as a decrease in Partial Mayo Score >= 2 points and >= 30% from baseline,
plus a decrease in RBS >= 1 or an absolute RBS <= 1.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value
were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen and week 8 remission status.
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__3.10_J

表 2.7.3.6-171. 評価時点ごとの高感度 CRP のベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
Japan ITT-RP Set											
HIGH-SENSITIVITY C-REACTIVE PROTEIN (MG/L)											
Week 12 (Week 4 of Maintenance Study)											
Adalimumab 40mg EOW	18	13.457	1.456	-12.001	25.9587	-85.23	-0.450	5.37			
Adalimumab 40mg EW	23	6.813	1.056	-5.757	17.2759	-82.50	-0.780	0.63	-0.451	(-1.631, 0.730)	0.444
Week 16 (Week 8 of Maintenance Study)											
Adalimumab 40mg EOW	18	13.457	3.456	-10.001	21.1934	-73.54	-0.520	5.78			
Adalimumab 40mg EW	23	6.813	1.616	-5.197	17.3945	-82.58	-0.690	5.17	-1.891	(-5.830, 2.049)	0.337
Week 24 (Week 16 of Maintenance Study)											
Adalimumab 40mg EOW	17	9.057	1.439	-7.618	18.9732	-73.41	-0.400	4.14			
Adalimumab 40mg EW	22	7.095	1.238	-5.858	17.4669	-82.58	-0.915	1.09	-1.624	(-4.686, 1.438)	0.282
Week 29 (Week 21 of Maintenance Study)											
Adalimumab 40mg EOW	17	9.057	2.172	-6.885	18.9158	-73.45	-0.070	6.94			
Adalimumab 40mg EW	22	7.095	1.215	-5.881	17.4575	-82.54	-0.905	0.03	-1.987	(-4.625, 0.650)	0.129
Week 37 (Week 29 of Maintenance Study)											
Adalimumab 40mg EOW	17	9.057	3.380	-5.677	21.1712	-72.69	-0.310	32.94			
Adalimumab 40mg EW	22	7.095	2.241	-4.854	17.7985	-82.61	-0.755	5.54	-1.888	(-6.085, 2.309)	0.360
Week 42 (Week 34 of Maintenance Study)											
Adalimumab 40mg EOW	16	9.575	1.889	-7.686	19.3294	-73.49	-0.300	5.29			
Adalimumab 40mg EW	21	7.385	2.216	-5.170	18.0748	-82.58	-0.610	5.46	-1.747	(-6.789, 3.296)	0.476

表 2.7.3.6-171. 評価時点ごとの高感度 CRP のベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
Japan ITT-RP Set											
HIGH-SENSITIVITY C-REACTIVE PROTEIN (MG/L)											
Week 52 (Week 44 of Maintenance Study)											
Adalimumab 40mg EOW	16	9.571	1.321	-8.250	19.2919	-73.63	-0.865	1.92			
Adalimumab 40mg EW	21	7.385	1.757	-5.629	18.1406	-82.57	-0.630	7.23	-0.222	(-2.214, 1.769)	0.818

表 2.7.3.6-171. 評価時点ごとの高感度 CRP のベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
Integrated ITT-RP Set											
HIGH-SENSITIVITY C-REACTIVE PROTEIN (MG/L)											
Week 12 (Week 4 of Maintenance Study)											
Adalimumab 40mg EOW	161	9.778	3.222	-6.555	15.1929	-85.23	-1.660	60.65			
Adalimumab 40mg EW	173	8.778	3.027	-5.751	14.6565	-83.69	-1.620	45.72	0.011	(-1.349, 1.371)	0.988
Week 16 (Week 8 of Maintenance Study)											
Adalimumab 40mg EOW	158	9.942	4.663	-5.279	19.1589	-73.54	-1.435	139.35			
Adalimumab 40mg EW	170	8.906	3.738	-5.167	15.7100	-82.58	-1.420	66.67	-0.624	(-3.276, 2.028)	0.644
Week 24 (Week 16 of Maintenance Study)											
Adalimumab 40mg EOW	149	9.546	4.289	-5.257	15.2222	-73.41	-1.430	53.21			
Adalimumab 40mg EW	165	9.081	3.184	-5.897	14.8821	-82.58	-1.370	48.02	-0.984	(-2.555, 0.586)	0.218
Week 29 (Week 21 of Maintenance Study)											
Adalimumab 40mg EOW	141	9.394	4.370	-5.024	14.3238	-73.45	-1.350	51.86			
Adalimumab 40mg EW	157	9.226	2.651	-6.575	14.2584	-82.54	-1.750	6.32	-1.604	(-2.926, -0.282)	0.018*
Week 37 (Week 29 of Maintenance Study)											
Adalimumab 40mg EOW	134	9.175	3.610	-5.564	13.0305	-72.69	-1.400	32.94			
Adalimumab 40mg EW	151	9.253	5.003	-4.250	25.0222	-82.61	-1.280	229.23	1.745	(-1.739, 5.228)	0.325
Week 42 (Week 34 of Maintenance Study)											
Adalimumab 40mg EOW	128	9.428	3.719	-5.710	14.0492	-73.49	-1.385	45.15			
Adalimumab 40mg EW	147	9.507	3.048	-6.459	14.9930	-82.58	-1.320	24.58	-0.577	(-2.292, 1.138)	0.506

表 2.7.3.6-171. 評価時点ごとの高感度 CRP のベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
Integrated ITT-RP Set											
HIGH-SENSITIVITY C-REACTIVE PROTEIN (MG/L)											
Week 52 (Week 44 of Maintenance Study)											
Adalimumab 40mg EOW	120	9.261	3.041	-6.220	12.5994	-73.63	-1.405	24.37			
Adalimumab 40mg EW	144	9.482	5.363	-4.118	20.5241	-82.57	-1.095	104.36	2.676	(-0.200, 5.552)	0.068+

@ P-value for test of difference between Adalimumab 40mg EW and Adalimumab 40mg EOW for change from baseline using the repeated measure model including treatment, induction treatment regimen, week 8 remission status, visit, baseline value, interaction of treatment and visit.
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__3.11_J

表 2.7.3.6-172.　評価時点ごとの副腎皮質ステロイド投与量のベースラインからの変化量（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison: Compare to 40mg EOW LSMEAN	95% CI
Japan ITT-RP Set										
CORTICOSTEROID DOSE										
Maintenance Baseline										
Adalimumab 40mg EOW	10	19.500	8.400	-11.100	10.8341	-35.00	-7.500	-1.00		
Adalimumab 40mg EW	9	17.222	10.278	-6.944	5.8333	-15.00	-5.000	0.00	2.378	(-2.554, 7.310)
Week 10 (Week 2 of Maintenance Study)										
Adalimumab 40mg EOW	9	17.222	4.889	-12.333	9.4835	-25.00	-10.000	-1.00		
Adalimumab 40mg EW	7	15.714	7.357	-8.357	4.4414	-15.00	-10.000	-1.00	2.828	(0.373, 5.284)
Week 12 (Week 4 of Maintenance Study)										
Adalimumab 40mg EOW	6	13.333	4.000	-9.333	10.0333	-27.50	-6.250	-1.00		
Adalimumab 40mg EW	7	15.714	5.786	-9.929	5.1270	-17.50	-10.000	-2.00	1.031	(-3.108, 5.171)
Week 16 (Week 8 of Maintenance Study)										
Adalimumab 40mg EOW	5	10.000	4.000	-6.000	6.6989	-14.00	-2.500	0.00		
Adalimumab 40mg EW	7	15.714	3.714	-12.000	6.2316	-17.50	-15.000	-2.50	-1.634	(-5.572, 2.304)
Week 22 (Week 14 of Maintenance Study)										
Adalimumab 40mg EOW	6	14.167	10.250	-3.917	5.7482	-15.00	-1.750	0.00		
Adalimumab 40mg EW	4	17.500	3.750	-13.750	7.5000	-17.50	-17.500	-2.50	-9.679	(-21.100, 1.741)
Week 24 (Week 16 of Maintenance Study)										
Adalimumab 40mg EOW	6	14.167	8.167	-6.000	6.6708	-17.50	-3.750	0.00		
Adalimumab 40mg EW	2	15.000	5.000	-10.000	10.6066	-17.50	-10.000	-2.50	-2.848	(-15.857, 10.161)
Week 29 (Week 21 of Maintenance Study)										
Adalimumab 40mg EOW	5	13.000	6.300	-6.700	8.4083	-20.00	-2.500	0.00		
Adalimumab 40mg EW	2	15.000	5.000	-10.000	10.6066	-17.50	-10.000	-2.50	-1.172	(-14.849, 12.505)

表 2.7.3.6-172. 評価時点ごとの副腎皮質ステロイド投与量のベースラインからの変化量（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	Within Group: Change from Baseline STD	Within Group: Change from Baseline Min	Within Group: Change from Baseline Median	Within Group: Change from Baseline Max	Between Group Comparison: Compare to 40mg EOW LSMEAN	Between Group Comparison: Compare to 40mg EOW 95% CI
Japan ITT-RP Set										
CORTICOSTEROID DOSE										
Week 35 (Week 27 of Maintenance Study)										
Adalimumab 40mg EOW	4	15.000	6.000	-9.000	11.5758	-25.00	-5.500	0.00		
Adalimumab 40mg EW	1	10.000	7.500	-2.500		-2.50	-2.500	-2.50	-7.500	
Week 37 (Week 29 of Maintenance Study)										
Adalimumab 40mg EOW	4	15.000	12.250	-2.750	4.8563	-10.00	-0.500	0.00		
Adalimumab 40mg EW	2	15.000	13.750	-1.250	1.7678	-2.50	-1.250	0.00	13.167	(-48.393, 74.726)
Week 42 (Week 34 of Maintenance Study)										
Adalimumab 40mg EOW	4	15.000	12.250	-2.750	8.5781	-15.00	-0.500	5.00		
Adalimumab 40mg EW	1	10.000	7.500	-2.500		-2.50	-2.500	-2.50	27.500	
Week 48 (Week 40 of Maintenance Study)										
Adalimumab 40mg EOW	3	10.000	6.333	-3.667	10.2632	-15.00	-1.000	5.00		
Adalimumab 40mg EW	2	17.500	11.250	-6.250	5.3033	-10.00	-6.250	-2.50	11.500	
Week 52 (Week 44 of Maintenance Study)										
Adalimumab 40mg EOW	2	5.000	7.000	2.000	4.2426	-1.00	2.000	5.00		
Adalimumab 40mg EW	2	17.500	8.750	-8.750	8.8388	-15.00	-8.750	-2.50		

表 2.7.3.6-172. 評価時点ごとの副腎皮質ステロイド投与量のベースラインからの変化量（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison: Compare to 40mg EOW LSMEAN	95% CI
Integrated ITT-RP Set										
CORTICOSTEROID DOSE										
Maintenance Baseline										
Adalimumab 40mg EOW	62	26.371	12.484	-13.887	11.0091	-45.00	-15.000	0.00		
Adalimumab 40mg EW	71	24.190	10.535	-13.655	8.4383	-39.50	-15.000	0.00	-0.493	(-3.534, 2.548)
Week 10 (Week 2 of Maintenance Study)										
Adalimumab 40mg EOW	41	27.561	13.543	-14.018	13.2364	-55.00	-15.000	0.00		
Adalimumab 40mg EW	36	27.083	11.500	-15.583	9.3865	-35.00	-15.000	0.00	-1.861	(-6.802, 3.079)
Week 12 (Week 4 of Maintenance Study)										
Adalimumab 40mg EOW	31	28.548	14.746	-13.802	15.6579	-55.00	-10.000	0.00		
Adalimumab 40mg EW	25	28.200	14.020	-14.180	11.9390	-35.00	-12.500	0.00	-0.702	(-7.817, 6.413)
Week 16 (Week 8 of Maintenance Study)										
Adalimumab 40mg EOW	22	25.227	20.795	-4.432	14.2405	-55.00	0.000	15.00		
Adalimumab 40mg EW	19	26.053	14.921	-11.132	13.4998	-30.00	-15.000	30.00	-5.675	(-14.099, 2.749)
Week 22 (Week 14 of Maintenance Study)										
Adalimumab 40mg EOW	21	24.048	19.952	-4.095	6.1697	-17.50	0.000	2.50		
Adalimumab 40mg EW	13	30.000	14.231	-15.769	9.0361	-35.00	-17.500	0.00	-11.414	(-17.009, -5.818)
Week 24 (Week 16 of Maintenance Study)										
Adalimumab 40mg EOW	22	23.636	21.886	-1.750	10.4138	-17.50	0.000	35.00		
Adalimumab 40mg EW	9	31.111	17.778	-13.333	7.9057	-22.50	-15.000	0.00	-11.119	(-19.555, -2.683)
Week 29 (Week 21 of Maintenance Study)										
Adalimumab 40mg EOW	18	22.500	25.250	2.750	19.5051	-20.00	0.000	65.50		
Adalimumab 40mg EW	9	30.556	15.889	-14.667	11.5271	-32.00	-17.500	0.00	-15.621	(-31.287, 0.045)

表 2.7.3.6-172. 評価時点ごとの副腎皮質ステロイド投与量のベースラインからの変化量（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison: Compare to 40mg EOW LSMEAN	95% CI
Integrated ITT-RP Set										
CORTICOSTEROID DOSE										
Week 35 (Week 27 of Maintenance Study)										
Adalimumab 40mg EOW	19	26.053	23.237	-2.816	10.4923	-25.00	0.000	20.00		
Adalimumab 40mg EW	8	37.500	23.813	-13.688	15.4410	-37.50	-8.750	0.00	-10.511	(-22.075, 1.054)
Week 37 (Week 29 of Maintenance Study)										
Adalimumab 40mg EOW	17	23.529	26.706	3.176	11.4686	-10.00	0.000	35.00		
Adalimumab 40mg EW	7	33.571	22.500	-11.071	14.6385	-37.50	-2.500	0.00	-13.997	(-27.216, -0.778)
Week 42 (Week 34 of Maintenance Study)										
Adalimumab 40mg EOW	15	23.000	25.933	2.933	12.2385	-15.00	0.000	35.00		
Adalimumab 40mg EW	7	31.429	27.143	-4.286	10.8699	-22.50	0.000	10.00	-4.829	(-15.992, 6.334)
Week 48 (Week 40 of Maintenance Study)										
Adalimumab 40mg EOW	10	28.500	29.900	1.400	9.7548	-15.00	0.000	25.00		
Adalimumab 40mg EW	8	30.000	21.875	-8.125	8.7372	-22.50	-6.250	0.00	-9.787	(-20.855, 1.280)
Week 52 (Week 44 of Maintenance Study)										
Adalimumab 40mg EOW	10	27.500	33.900	6.400	12.7645	-1.00	0.000	35.00		
Adalimumab 40mg EW	7	28.929	25.000	-3.929	16.3845	-22.50	-2.500	27.50	-11.756	(-28.649, 5.137)

Note: Only include subjects who took steroid at baseline.
Treatment group differences for changes from baseline is analyzed using Analysis of Variance (ANOVA).

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__3.12_J

表 2.7.3.6-173. 評価時点ごとの IBDQ スコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
Japan ITT-RP Set											
IBDQ - BOWEL											
Maintenance Baseline											
Adalimumab 40mg EOW	18	41.500	59.667	18.167	11.0254	2.00	17.000	42.00			
Adalimumab 40mg EW	23	43.739	59.000	15.261	11.3186	0.00	13.000	38.00	-0.872	(-5.869, 4.125)	0.726
Week 12 (Week 4 of Maintenance Study)											
Adalimumab 40mg EOW	18	41.500	57.056	15.556	11.2680	-9.00	17.000	35.00			
Adalimumab 40mg EW	23	43.739	59.565	15.826	11.3284	0.00	13.000	41.00	2.304	(-2.877, 7.486)	0.373
Week 24 (Week 16 of Maintenance Study)											
Adalimumab 40mg EOW	18	41.500	54.944	13.444	13.0484	-7.00	15.000	40.00			
Adalimumab 40mg EW	22	43.727	61.091	17.364	11.9584	-2.00	14.500	45.00	5.660	(-0.263, 11.584)	0.061+
Week 37 (Week 29 of Maintenance Study)											
Adalimumab 40mg EOW	17	42.000	53.471	11.471	14.9504	-17.00	15.000	38.00			
Adalimumab 40mg EW	22	43.727	60.545	16.818	13.3831	-10.00	14.500	41.00	7.764	(1.078, 14.450)	0.024*
Week 52 (Week 44 of Maintenance Study)											
Adalimumab 40mg EOW	16	42.750	57.438	14.688	11.6946	-18.00	17.000	32.00			
Adalimumab 40mg EW	21	43.381	62.000	18.619	12.5598	-1.00	15.000	44.00	5.179	(-0.217, 10.574)	0.059+

表 2.7.3.6-173. 評価時点ごとの IBDQ スコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
Japan ITT-RP Set											
IBDQ - EMOTIONAL											
Maintenance Baseline											
Adalimumab 40mg EOW	18	53.000	64.333	11.333	12.3336	-11.00	10.000	37.00			
Adalimumab 40mg EW	23	60.826	68.130	7.304	10.7087	-12.00	4.000	35.00	-1.863	(-9.197, 5.470)	0.609
Week 12 (Week 4 of Maintenance Study)											
Adalimumab 40mg EOW	18	53.000	65.111	12.111	12.0288	-11.00	12.000	33.00			
Adalimumab 40mg EW	23	60.826	69.565	8.739	9.1910	-5.00	8.000	25.00	-1.206	(-8.279, 5.867)	0.732
Week 24 (Week 16 of Maintenance Study)											
Adalimumab 40mg EOW	18	53.000	60.500	7.500	16.0962	-22.00	9.000	44.00			
Adalimumab 40mg EW	22	60.727	71.409	10.682	11.2647	-8.00	9.500	33.00	4.653	(-4.226, 13.532)	0.295
Week 37 (Week 29 of Maintenance Study)											
Adalimumab 40mg EOW	17	52.765	61.000	8.235	16.3000	-27.00	13.000	32.00			
Adalimumab 40mg EW	22	60.727	72.818	12.091	12.9942	-14.00	10.500	35.00	6.517	(-2.936, 15.970)	0.171
Week 52 (Week 44 of Maintenance Study)											
Adalimumab 40mg EOW	16	53.563	61.875	8.313	12.2023	-23.00	9.500	24.00			
Adalimumab 40mg EW	21	60.619	71.286	10.667	13.4586	-6.00	6.000	36.00	3.325	(-5.550, 12.201)	0.453

表 2.7.3.6-173. 評価時点ごとの IBDQ スコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
Japan ITT-RP Set											
IBDQ - FATIGUE											
Maintenance Baseline											
Adalimumab 40mg EOW	18	3.4	4.8	1.4	1.62	-1	1.0	5			
Adalimumab 40mg EW	23	3.8	4.8	1.0	1.86	-3	1.0	4	-0.2	(-1.2, 0.8)	0.690
Week 12 (Week 4 of Maintenance Study)											
Adalimumab 40mg EOW	18	3.4	4.3	0.9	1.35	-1	1.0	4			
Adalimumab 40mg EW	23	3.8	4.7	0.9	1.83	-1	0.0	5	0.2	(-0.7, 1.1)	0.617
Week 24 (Week 16 of Maintenance Study)											
Adalimumab 40mg EOW	18	3.4	4.3	0.9	1.88	-3	1.0	5			
Adalimumab 40mg EW	22	3.8	4.6	0.8	1.59	-1	0.0	5	0.1	(-0.8, 1.1)	0.764
Week 37 (Week 29 of Maintenance Study)											
Adalimumab 40mg EOW	17	3.4	3.9	0.6	1.73	-2	0.0	4			
Adalimumab 40mg EW	22	3.8	4.9	1.1	1.67	-1	1.0	4	0.8	(-0.1, 1.7)	0.072+
Week 52 (Week 44 of Maintenance Study)											
Adalimumab 40mg EOW	16	3.4	4.4	0.9	1.29	-2	1.0	3			
Adalimumab 40mg EW	21	3.7	4.4	0.7	1.95	-2	1.0	6	-0.0	(-1.1, 1.0)	0.938

表 2.7.3.6-173. 評価時点ごとの IBDQ スコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
Japan ITT-RP Set											
IBDQ - SOCIAL											
Maintenance Baseline											
Adalimumab 40mg EOW	18	21.1	28.2	7.2	6.81	-3	6.5	22			
Adalimumab 40mg EW	23	22.4	29.5	7.1	6.10	-1	5.0	20	0.7	(-2.6, 4.0)	0.666
Week 12 (Week 4 of Maintenance Study)											
Adalimumab 40mg EOW	18	21.1	28.5	7.4	6.32	-3	6.5	20			
Adalimumab 40mg EW	23	22.4	30.0	7.5	6.15	0	8.0	22	0.9	(-2.6, 4.3)	0.615
Week 24 (Week 16 of Maintenance Study)											
Adalimumab 40mg EOW	18	21.1	26.9	5.8	8.11	-9	5.5	24			
Adalimumab 40mg EW	22	22.5	30.0	7.5	7.20	-1	5.5	23	2.5	(-1.7, 6.8)	0.237
Week 37 (Week 29 of Maintenance Study)											
Adalimumab 40mg EOW	17	21.5	28.6	7.2	8.62	-10	8.0	24			
Adalimumab 40mg EW	22	22.5	31.0	8.5	7.87	-7	8.5	24	2.5	(-1.9, 7.0)	0.255
Week 52 (Week 44 of Maintenance Study)											
Adalimumab 40mg EOW	16	22.1	29.5	7.4	7.70	-10	7.5	23			
Adalimumab 40mg EW	21	22.4	30.9	8.5	7.65	0	6.0	25	1.5	(-2.6, 5.6)	0.464

表 2.7.3.6-173. 評価時点ごとの IBDQ スコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
Japan ITT-RP Set											
IBDQ - SYSTEMIC											
Maintenance Baseline											
Adalimumab 40mg EOW	18	18.4	25.8	7.4	5.98	-4	7.0	23			
Adalimumab 40mg EW	23	19.4	25.1	5.7	6.21	-4	5.0	20	-1.2	(-4.6, 2.2)	0.473
Week 12 (Week 4 of Maintenance Study)											
Adalimumab 40mg EOW	18	18.4	24.8	6.4	4.83	-2	6.5	17			
Adalimumab 40mg EW	23	19.4	25.3	5.9	5.59	-1	5.0	19	-0.1	(-3.0, 2.8)	0.955
Week 24 (Week 16 of Maintenance Study)											
Adalimumab 40mg EOW	18	18.4	22.8	4.4	7.06	-8	5.0	19			
Adalimumab 40mg EW	22	19.3	25.3	6.0	6.74	-4	6.0	22	1.9	(-1.8, 5.6)	0.304
Week 37 (Week 29 of Maintenance Study)											
Adalimumab 40mg EOW	17	18.7	23.1	4.4	6.73	-8	6.0	16			
Adalimumab 40mg EW	22	19.3	26.5	7.2	7.38	-5	5.5	24	3.3	(-0.5, 7.2)	0.084+
Week 52 (Week 44 of Maintenance Study)											
Adalimumab 40mg EOW	16	18.9	24.4	5.6	5.14	-3	6.0	18			
Adalimumab 40mg EW	21	19.1	25.6	6.5	7.40	-4	6.0	18	1.0	(-2.7, 4.6)	0.597

表 2.7.3.6-173. 評価時点ごとの IBDQ スコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
Japan ITT-RP Set											
IBDQ - TOTAL											
Maintenance Baseline											
Adalimumab 40mg EOW	18	133.944	178.000	44.056	33.0783	-14.00	40.000	124.00			
Adalimumab 40mg EW	23	146.435	181.783	35.348	31.1603	-8.00	30.000	95.00	-2.179	(-20.071, 15.713)	0.806
Week 12 (Week 4 of Maintenance Study)											
Adalimumab 40mg EOW	18	133.944	175.500	41.556	30.1413	-10.00	42.500	103.00			
Adalimumab 40mg EW	23	146.435	184.391	37.957	28.5155	-5.00	35.000	101.00	2.930	(-14.157, 20.016)	0.730
Week 24 (Week 16 of Maintenance Study)											
Adalimumab 40mg EOW	18	133.944	165.111	31.167	41.2956	-39.00	37.500	127.00			
Adalimumab 40mg EW	22	146.273	187.818	41.545	33.4674	-8.00	37.000	114.00	15.582	(-5.705, 36.869)	0.146
Week 37 (Week 29 of Maintenance Study)											
Adalimumab 40mg EOW	17	134.941	166.176	31.235	42.5581	-56.00	39.000	110.00			
Adalimumab 40mg EW	22	146.273	190.864	44.591	38.4703	-36.00	35.500	111.00	21.064	(-1.862, 43.990)	0.071+
Week 52 (Week 44 of Maintenance Study)											
Adalimumab 40mg EOW	16	137.313	173.250	35.938	32.6935	-50.00	41.000	93.00			
Adalimumab 40mg EW	21	145.476	189.714	44.238	37.4338	-4.00	34.000	106.00	12.511	(-7.787, 32.809)	0.220

表 2.7.3.6-173. 評価時点ごとの IBDQ スコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
Integrated ITT-RP Set											
IBDQ - BOWEL											
Maintenance Baseline											
Adalimumab 40mg EOW	163	36.393	57.686	21.294	10.6157	-2.00	21.000	52.00			
Adalimumab 40mg EW	175	36.829	57.206	20.377	11.0552	-4.00	21.000	51.00	-0.665	(-2.499, 1.170)	0.476
Week 12 (Week 4 of Maintenance Study)											
Adalimumab 40mg EOW	161	36.410	58.290	21.880	11.3669	-13.00	22.000	48.00			
Adalimumab 40mg EW	174	36.817	56.948	20.131	12.3710	-14.00	21.000	51.00	-1.443	(-3.406, 0.520)	0.149
Week 24 (Week 16 of Maintenance Study)											
Adalimumab 40mg EOW	148	36.230	57.252	21.022	13.1238	-7.00	21.000	52.00			
Adalimumab 40mg EW	162	37.019	58.691	21.672	12.6061	-17.00	21.500	51.00	1.159	(-1.069, 3.386)	0.307
Week 37 (Week 29 of Maintenance Study)											
Adalimumab 40mg EOW	137	36.161	56.929	20.768	13.6711	-17.00	21.000	50.00			
Adalimumab 40mg EW	155	37.207	58.084	20.877	12.8335	-14.00	21.000	50.00	0.856	(-1.543, 3.254)	0.483
Week 52 (Week 44 of Maintenance Study)											
Adalimumab 40mg EOW	124	36.823	59.053	22.230	12.5206	-18.00	22.000	51.00			
Adalimumab 40mg EW	144	37.341	60.368	23.027	12.2555	-15.00	24.000	48.89	1.334	(-0.714, 3.382)	0.201

表 2.7.3.6-173. 評価時点ごとの IBDQ スコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
Integrated ITT-RP Set											
IBDQ - EMOTIONAL											
Maintenance Baseline											
Adalimumab 40mg EOW	163	47.544	65.786	18.243	14.3696	-20.00	16.000	59.00			
Adalimumab 40mg EW	175	47.771	65.712	17.941	13.8744	-15.00	17.000	63.00	-0.229	(-2.701, 2.243)	0.855
Week 12 (Week 4 of Maintenance Study)											
Adalimumab 40mg EOW	161	47.687	66.634	18.946	14.4553	-13.00	17.000	62.00			
Adalimumab 40mg EW	174	47.782	65.432	17.650	14.9669	-24.00	17.500	66.00	-1.026	(-3.596, 1.543)	0.433
Week 24 (Week 16 of Maintenance Study)											
Adalimumab 40mg EOW	149	47.400	65.756	18.355	16.2183	-22.00	16.000	60.00			
Adalimumab 40mg EW	162	48.031	67.352	19.321	15.3577	-27.00	18.000	61.00	1.286	(-1.470, 4.043)	0.359
Week 37 (Week 29 of Maintenance Study)											
Adalimumab 40mg EOW	137	47.114	66.453	19.338	15.9049	-27.00	17.000	60.00			
Adalimumab 40mg EW	155	48.168	68.071	19.903	15.1806	-17.00	19.000	61.00	1.457	(-1.261, 4.174)	0.292
Week 52 (Week 44 of Maintenance Study)											
Adalimumab 40mg EOW	124	47.820	67.370	19.551	15.7566	-23.00	16.000	60.00			
Adalimumab 40mg EW	145	48.262	68.961	20.699	15.6002	-14.00	20.000	57.00	2.047	(-0.725, 4.819)	0.147

表 2.7.3.6-173. 評価時点ごとの IBDQ スコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
Integrated ITT-RP Set											
IBDQ - FATIGUE											
Maintenance Baseline											
Adalimumab 40mg EOW	163	2.8	4.8	2.0	1.87	-3	2.0	6			
Adalimumab 40mg EW	175	3.0	4.7	1.8	1.73	-3	2.0	6	-0.1	(-0.4, 0.2)	0.510
Week 12 (Week 4 of Maintenance Study)											
Adalimumab 40mg EOW	161	2.8	4.7	1.9	1.89	-3	2.0	6			
Adalimumab 40mg EW	174	3.0	4.7	1.7	1.78	-2	2.0	6	-0.0	(-0.3, 0.3)	0.920
Week 24 (Week 16 of Maintenance Study)											
Adalimumab 40mg EOW	149	2.8	4.9	2.1	2.05	-5	2.0	6			
Adalimumab 40mg EW	162	3.0	4.9	2.0	1.74	-3	2.0	6	-0.0	(-0.3, 0.3)	0.989
Week 37 (Week 29 of Maintenance Study)											
Adalimumab 40mg EOW	137	2.8	4.9	2.1	2.02	-3	2.0	6			
Adalimumab 40mg EW	155	3.0	5.0	2.0	1.78	-4	2.0	6	0.1	(-0.2, 0.5)	0.509
Week 52 (Week 44 of Maintenance Study)											
Adalimumab 40mg EOW	124	2.9	5.0	2.1	1.95	-3	2.0	6			
Adalimumab 40mg EW	145	3.0	4.9	1.9	1.98	-4	2.0	6	-0.1	(-0.5, 0.3)	0.586

表 2.7.3.6-173. 評価時点ごとの IBDQ スコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
Integrated ITT-RP Set											
IBDQ - SOCIAL											
Maintenance Baseline											
Adalimumab 40mg EOW	161	19.5	29.9	10.4	7.40	-3	9.0	30			
Adalimumab 40mg EW	172	19.8	29.7	9.9	6.96	-5	9.0	30	-0.3	(-1.4, 0.8)	0.630
Week 12 (Week 4 of Maintenance Study)											
Adalimumab 40mg EOW	156	19.3	30.1	10.8	7.62	-5	10.5	30			
Adalimumab 40mg EW	167	19.7	29.8	10.1	7.60	-12	11.0	30	-0.4	(-1.6, 0.8)	0.523
Week 24 (Week 16 of Maintenance Study)											
Adalimumab 40mg EOW	147	19.4	29.9	10.5	8.39	-9	10.0	30			
Adalimumab 40mg EW	157	20.0	31.0	11.0	7.77	-7	11.0	29	0.7	(-0.5, 2.0)	0.250
Week 37 (Week 29 of Maintenance Study)											
Adalimumab 40mg EOW	135	19.3	30.4	11.1	7.95	-10	11.0	30			
Adalimumab 40mg EW	151	19.9	31.5	11.6	7.94	-9	12.0	30	0.8	(-0.4, 2.0)	0.206
Week 52 (Week 44 of Maintenance Study)											
Adalimumab 40mg EOW	122	19.7	31.1	11.4	7.87	-10	11.0	30			
Adalimumab 40mg EW	141	20.1	31.9	11.7	7.42	-4	12.0	30	0.7	(-0.4, 1.9)	0.226

表 2.7.3.6-173. 評価時点ごとの IBDQ スコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
Integrated ITT-RP Set											
IBDQ - SYSTEMIC											
Maintenance Baseline											
Adalimumab 40mg EOW	163	16.4	25.8	9.4	6.26	-7	9.0	26			
Adalimumab 40mg EW	174	16.6	25.0	8.4	6.37	-7	9.0	25	-0.8	(-1.9, 0.2)	0.130
Week 12 (Week 4 of Maintenance Study)											
Adalimumab 40mg EOW	161	16.4	25.7	9.3	6.35	-11	9.0	26			
Adalimumab 40mg EW	170	16.7	24.9	8.2	6.47	-8	8.0	25	-0.8	(-2.0, 0.3)	0.157
Week 24 (Week 16 of Maintenance Study)											
Adalimumab 40mg EOW	149	16.3	25.2	9.0	7.15	-8	9.0	24			
Adalimumab 40mg EW	161	16.7	25.5	8.9	6.66	-6	9.0	28	0.2	(-1.1, 1.5)	0.772
Week 37 (Week 29 of Maintenance Study)											
Adalimumab 40mg EOW	137	16.4	25.7	9.3	7.37	-8	9.0	28			
Adalimumab 40mg EW	154	16.8	26.0	9.3	6.96	-11	10.0	24	0.4	(-0.9, 1.7)	0.593
Week 52 (Week 44 of Maintenance Study)											
Adalimumab 40mg EOW	123	16.5	26.4	9.9	7.07	-5	10.0	27			
Adalimumab 40mg EW	144	16.8	26.2	9.4	7.15	-8	10.5	26	-0.1	(-1.4, 1.2)	0.922

表 2.7.3.6-173. 評価時点ごとの IBDQ スコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
Integrated ITT-RP Set											
IBDQ - TOTAL											
Maintenance Baseline											
Adalimumab 40mg EOW	161	120.128	179.131	59.003	34.5343	-14.00	54.000	151.00			
Adalimumab 40mg EW	172	121.192	177.783	56.591	34.2510	-18.00	52.500	167.00	-1.871	(-7.705, 3.963)	0.529
Week 12 (Week 4 of Maintenance Study)											
Adalimumab 40mg EOW	156	119.504	180.679	61.175	35.6500	-35.00	61.000	154.00			
Adalimumab 40mg EW	166	121.024	177.187	56.163	37.6137	-31.00	58.000	170.00	-3.509	(-9.833, 2.816)	0.276
Week 24 (Week 16 of Maintenance Study)											
Adalimumab 40mg EOW	146	119.422	178.159	58.737	41.0808	-39.00	54.000	152.00			
Adalimumab 40mg EW	157	121.860	182.433	60.573	38.2058	-32.00	58.000	157.00	3.395	(-3.583, 10.374)	0.339
Week 37 (Week 29 of Maintenance Study)											
Adalimumab 40mg EOW	135	119.153	179.194	60.041	40.3800	-56.00	55.000	144.00			
Adalimumab 40mg EW	151	122.331	183.960	61.629	38.8219	-48.00	64.000	156.00	3.771	(-3.157, 10.698)	0.285
Week 52 (Week 44 of Maintenance Study)											
Adalimumab 40mg EOW	122	120.677	183.570	62.893	38.7259	-50.00	59.500	152.00			
Adalimumab 40mg EW	140	122.979	187.464	64.486	38.3746	-36.00	69.000	150.00	3.864	(-2.708, 10.437)	0.248

表 2.7.3.6-173. 評価時点ごとの IBDQ スコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

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@ P-value for test of difference between Adalimumab 40mg EW and Adalimumab 40mg EOW for change from baseline using the repeated
  measure model including treatment, induction treatment regimen, week 8 remission status, visit, baseline value, interaction of
  treatment and visit.
  ***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.
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Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__3.13_J

表 2.7.3.6-174.　評価時点ごとの IBDQ スコアが 170 以上となった被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Subjects with IBDQ Total Score >= 170 at Maintenance Baseline	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	13 (72.2)	19 (82.6)	109 (66.9)	121 (69.1)
No, n (%)	5 (27.8)	4 (17.4)	54 (33.1)	54 (30.9)
Risk Difference[A]		10.4		2.3
Adjusted Risk Difference[A,B]		11.1		2.2
95% Confidence Interval[B]		(-16.7, 38.8)		(-7.7, 12.2)
P-Value[B]		0.435		0.663
Subjects with IBDQ Total Score >= 170 at Week 12 (Week 4 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	11 (61.1)	19 (82.6)	107 (65.6)	114 (65.1)
No, n (%)	7 (38.9)	4 (17.4)	56 (34.4)	61 (34.9)
Risk Difference[A]		21.5		-0.5
Adjusted Risk Difference[A,B]		20.8		-0.8
95% Confidence Interval[B]		(-8.8, 50.5)		(-10.9, 9.4)
P-Value[B]		0.169		0.880
Subjects with IBDQ Total Score >= 170 at Week 24 (Week 16 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	8 (44.4)	18 (78.3)	95 (58.3)	114 (65.1)
No, n (%)	10 (55.6)	5 (21.7)	68 (41.7)	61 (34.9)
Risk Difference[A]		33.8		6.9
Adjusted Risk Difference[A,B]		33.4		6.5
95% Confidence Interval[B]		(2.1, 64.7)		(-3.9, 16.9)
P-Value[B]		0.037*		0.218

表 2.7.3.6-174. 評価時点ごとの IBDQ スコアが 170 以上となった被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Subjects with IBDQ Total Score >= 170 at Week 37 (Week 29 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	10 (55.6)	19 (82.6)	89 (54.6)	111 (63.4)
No, n (%)	8 (44.4)	4 (17.4)	74 (45.4)	64 (36.6)
Risk Difference[A]		27.1		8.8
Adjusted Risk Difference[A,B]		28.5		8.4
95% Confidence Interval[B]		(-2.2, 59.1)		(-2.1, 18.8)
P-Value[B]		0.069+		0.118
Subjects with IBDQ Total Score >= 170 at Week 52 (Week 44 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	9 (50.0)	17 (73.9)	82 (50.3)	103 (58.9)
No, n (%)	9 (50.0)	6 (26.1)	81 (49.7)	72 (41.1)
Risk Difference[A]		23.9		8.6
Adjusted Risk Difference[A,B]		26.3		8.0
95% Confidence Interval[B]		(-5.9, 58.5)		(-2.6, 18.6)
P-Value[B]		0.109		0.140

[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen and week 8 remission status.
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__3.14_J

表 2.7.3.6-175.　投与 52 週時の Mayo スコアのベースラインからの変化量（OC）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

Parameter / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
Japan ITT-RP Set											
MAYO SCORE											
Adalimumab 40mg EOW	16	8.08	4.04	-4.04	2.797	-8.0	-4.50	1.4			
Adalimumab 40mg EW	21	8.66	2.18	-6.48	2.780	-11.4	-6.20	-2.6	-1.94	(-3.58, -0.31)	0.021*
Integrated ITT-RP Set											
MAYO SCORE											
Adalimumab 40mg EOW	112	8.67	3.26	-5.41	2.785	-11.8	-5.70	1.4			
Adalimumab 40mg EW	137	8.72	2.30	-6.42	2.591	-11.4	-6.20	1.8	-0.88	(-1.47, -0.29)	0.004**

@ P-value for test of difference between Adalimumab 40mg EW and Adalimumab 40mg EOW for change from baseline using analysis of covariance with treatment, induction treatment regimen, week 8 remission status, and baseline value as covariate.
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__3.15_J

表 2.7.3.6-176. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison: Compare to 40mg EOW LSMEAN	95% CI
Japan ITT-RP Set										
AVERAGE RECTAL BLEEDING SUBSCORE										
Maintenance Baseline										
Adalimumab 40mg EOW	18	1.58	0.16	-1.42	0.829	-3.0	-1.50	0.0		
Adalimumab 40mg EW	23	1.60	0.15	-1.45	1.097	-3.0	-1.00	0.0	-0.02	(-0.20, 0.17)
Week 10 (Week 2 of Maintenance Study)										
Adalimumab 40mg EOW	18	1.58	0.30	-1.28	0.936	-3.0	-1.20	0.0		
Adalimumab 40mg EW	23	1.60	0.10	-1.50	1.126	-3.0	-1.00	0.0	-0.20	(-0.47, 0.07)
Week 12 (Week 4 of Maintenance Study)										
Adalimumab 40mg EOW	18	1.58	0.39	-1.19	0.944	-3.0	-1.30	0.4		
Adalimumab 40mg EW	23	1.60	0.16	-1.44	1.149	-3.0	-1.00	0.0	-0.24	(-0.54, 0.06)
Week 16 (Week 8 of Maintenance Study)										
Adalimumab 40mg EOW	18	1.58	0.48	-1.10	0.959	-2.8	-1.00	0.0		
Adalimumab 40mg EW	23	1.60	0.16	-1.44	1.209	-3.0	-1.00	0.4	-0.33	(-0.78, 0.11)
Week 22 (Week 14 of Maintenance Study)										
Adalimumab 40mg EOW	15	1.63	0.43	-1.20	0.950	-2.6	-1.40	0.2		
Adalimumab 40mg EW	22	1.55	0.04	-1.52	1.198	-3.0	-1.00	0.0	-0.40	(-0.67, -0.12)
Week 24 (Week 16 of Maintenance Study)										
Adalimumab 40mg EOW	17	1.49	0.38	-1.12	1.003	-3.0	-1.00	0.2		
Adalimumab 40mg EW	22	1.55	0.01	-1.55	1.176	-3.0	-1.00	0.0	-0.39	(-0.68, -0.10)
Week 29 (Week 21 of Maintenance Study)										
Adalimumab 40mg EOW	17	1.49	0.32	-1.18	1.072	-3.0	-1.00	1.2		
Adalimumab 40mg EW	22	1.55	0.16	-1.39	1.151	-3.0	-1.00	0.0	-0.17	(-0.59, 0.26)

表 2.7.3.6-176. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison: Compare to 40mg EOW LSMEAN	95% CI
Japan ITT-RP Set										
AVERAGE RECTAL BLEEDING SUBSCORE										
Week 35 (Week 27 of Maintenance Study)										
Adalimumab 40mg EOW	17	1.49	0.46	-1.04	1.011	-2.6	-1.00	1.6		
Adalimumab 40mg EW	22	1.55	0.18	-1.37	1.134	-3.0	-1.00	0.0	-0.30	(-0.77, 0.18)
Week 37 (Week 29 of Maintenance Study)										
Adalimumab 40mg EOW	17	1.49	0.40	-1.09	0.884	-2.6	-1.00	0.2		
Adalimumab 40mg EW	21	1.49	0.20	-1.29	1.082	-3.0	-1.00	0.0	-0.20	(-0.61, 0.21)
Week 42 (Week 34 of Maintenance Study)										
Adalimumab 40mg EOW	17	1.49	0.45	-1.05	0.901	-2.6	-0.80	0.2		
Adalimumab 40mg EW	21	1.49	0.19	-1.30	1.177	-3.0	-1.00	0.0	-0.25	(-0.69, 0.18)
Week 48 (Week 40 of Maintenance Study)										
Adalimumab 40mg EOW	15	1.43	0.43	-1.00	0.878	-2.6	-0.80	0.0		
Adalimumab 40mg EW	21	1.49	0.16	-1.32	1.150	-3.0	-1.00	0.0	-0.24	(-0.69, 0.20)
Week 52 (Week 44 of Maintenance Study)										
Adalimumab 40mg EOW	16	1.40	0.44	-0.96	0.944	-2.6	-0.90	0.8		
Adalimumab 40mg EW	21	1.49	0.14	-1.34	1.139	-3.0	-1.00	0.0	-0.29	(-0.77, 0.19)

表 2.7.3.6-176. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison: Compare to 40mg EOW LSMEAN	95% CI
Japan ITT-RP Set										
AVERAGE STOOL FREQUENCY SUBSCORE										
Maintenance Baseline										
Adalimumab 40mg EOW	18	1.99	0.82	-1.17	0.780	-3.0	-1.10	0.0		
Adalimumab 40mg EW	23	2.45	0.83	-1.62	0.733	-2.8	-1.80	0.0	-0.12	(-0.49, 0.25)
Week 10 (Week 2 of Maintenance Study)										
Adalimumab 40mg EOW	18	1.99	0.93	-1.06	0.899	-2.8	-1.20	0.6		
Adalimumab 40mg EW	23	2.45	0.80	-1.65	0.724	-2.8	-1.80	0.0	-0.29	(-0.76, 0.17)
Week 12 (Week 4 of Maintenance Study)										
Adalimumab 40mg EOW	18	1.99	1.07	-0.92	0.993	-2.7	-1.10	1.2		
Adalimumab 40mg EW	23	2.45	0.80	-1.65	0.763	-3.0	-1.80	0.0	-0.44	(-0.96, 0.09)
Week 16 (Week 8 of Maintenance Study)										
Adalimumab 40mg EOW	18	1.99	1.06	-0.93	0.982	-2.8	-1.00	1.4		
Adalimumab 40mg EW	23	2.45	0.73	-1.72	0.795	-3.0	-1.80	0.0	-0.56	(-1.11, -0.02)
Week 22 (Week 14 of Maintenance Study)										
Adalimumab 40mg EOW	15	1.97	1.11	-0.87	0.877	-2.2	-1.00	1.4		
Adalimumab 40mg EW	22	2.44	0.82	-1.62	0.884	-3.0	-2.00	0.4	-0.48	(-1.06, 0.10)
Week 24 (Week 16 of Maintenance Study)										
Adalimumab 40mg EOW	17	1.93	1.01	-0.92	1.111	-2.8	-0.80	1.4		
Adalimumab 40mg EW	22	2.44	0.81	-1.63	0.906	-3.0	-2.00	0.4	-0.32	(-0.90, 0.26)
Week 29 (Week 21 of Maintenance Study)										
Adalimumab 40mg EOW	17	1.93	1.07	-0.86	1.029	-3.0	-0.60	0.8		
Adalimumab 40mg EW	22	2.44	0.84	-1.60	0.761	-2.6	-1.80	0.0	-0.45	(-1.03, 0.12)

表 2.7.3.6-176. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison: Compare to 40mg EOW LSMEAN	95% CI
Japan ITT-RP Set										
AVERAGE STOOL FREQUENCY SUBSCORE										
Week 35 (Week 27 of Maintenance Study)										
Adalimumab 40mg EOW	17	1.93	1.42	-0.51	0.892	-2.4	-0.60	1.2		
Adalimumab 40mg EW	22	2.44	0.79	-1.65	0.879	-3.0	-2.00	0.0	-0.91	(-1.52, -0.31)
Week 37 (Week 29 of Maintenance Study)										
Adalimumab 40mg EOW	17	1.93	1.44	-0.49	0.919	-2.0	-0.80	1.2		
Adalimumab 40mg EW	21	2.49	0.80	-1.69	0.833	-2.8	-2.00	0.0	-0.89	(-1.48, -0.31)
Week 42 (Week 34 of Maintenance Study)										
Adalimumab 40mg EOW	17	1.93	1.30	-0.63	0.904	-2.0	-0.60	1.0		
Adalimumab 40mg EW	21	2.41	0.89	-1.52	0.941	-3.0	-1.60	0.8	-0.64	(-1.27, -0.01)
Week 48 (Week 40 of Maintenance Study)										
Adalimumab 40mg EOW	15	1.81	1.25	-0.56	0.945	-2.2	-0.20	1.2		
Adalimumab 40mg EW	21	2.41	0.91	-1.50	1.001	-3.0	-2.00	0.8	-0.55	(-1.28, 0.17)
Week 52 (Week 44 of Maintenance Study)										
Adalimumab 40mg EOW	16	1.86	1.29	-0.58	0.996	-2.6	-0.60	1.4		
Adalimumab 40mg EW	21	2.41	0.75	-1.66	0.759	-3.0	-1.80	0.0	-0.77	(-1.36, -0.17)

表 2.7.3.6-176. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: Mean	STD	Min	Median	Max	Between Group Comparison: Compare to 40mg EOW: LSMEAN	95% CI
Japan ITT-RP Set										
ENDOSCOPY SUBSCORE										
Maintenance Baseline										
Adalimumab 40mg EOW	18	2.3	1.3	-1.1	1.21	-3	-1.0	1		
Adalimumab 40mg EW	23	2.4	1.2	-1.2	0.89	-3	-1.0	0	-0.1	(-0.5, 0.4)
Week 52 (Week 44 of Maintenance Study)										
Adalimumab 40mg EOW	17	2.4	1.5	-0.9	1.17	-3	-1.0	1		
Adalimumab 40mg EW	22	2.4	1.0	-1.4	1.10	-3	-1.5	0	-0.5	(-1.2, 0.2)

表 2.7.3.6-176. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison: Compare to 40mg EOW LSMEAN	95% CI
Japan ITT-RP Set										
PHYSICIAN'S GLOBAL ASSESSMENT SUBSCORE										
Maintenance Baseline										
Adalimumab 40mg EOW	18	2.4	0.8	-1.6	0.50	-2	-2.0	-1		
Adalimumab 40mg EW	23	2.4	0.7	-1.7	0.78	-3	-1.0	-1	-0.1	(-0.3, 0.2)
Week 10 (Week 2 of Maintenance Study)										
Adalimumab 40mg EOW	18	2.4	0.6	-1.8	0.65	-3	-2.0	0		
Adalimumab 40mg EW	23	2.4	0.7	-1.7	0.76	-3	-2.0	-1	0.1	(-0.3, 0.5)
Week 12 (Week 4 of Maintenance Study)										
Adalimumab 40mg EOW	18	2.4	0.7	-1.7	0.67	-3	-2.0	0		
Adalimumab 40mg EW	23	2.4	0.7	-1.7	0.70	-3	-2.0	-1	0.0	(-0.4, 0.4)
Week 16 (Week 8 of Maintenance Study)										
Adalimumab 40mg EOW	18	2.4	0.8	-1.6	0.92	-3	-1.5	0		
Adalimumab 40mg EW	23	2.4	0.6	-1.8	0.74	-3	-2.0	0	-0.2	(-0.7, 0.2)
Week 22 (Week 14 of Maintenance Study)										
Adalimumab 40mg EOW	16	2.4	0.9	-1.5	0.82	-3	-2.0	0		
Adalimumab 40mg EW	22	2.4	0.5	-2.0	0.72	-3	-2.0	-1	-0.4	(-0.9, 0.0)
Week 24 (Week 16 of Maintenance Study)										
Adalimumab 40mg EOW	17	2.4	0.7	-1.7	0.92	-3	-2.0	0		
Adalimumab 40mg EW	22	2.4	0.4	-2.0	0.76	-3	-2.0	-1	-0.3	(-0.8, 0.1)
Week 29 (Week 21 of Maintenance Study)										
Adalimumab 40mg EOW	17	2.4	0.5	-1.9	0.86	-3	-2.0	0		
Adalimumab 40mg EW	22	2.4	0.4	-2.0	0.69	-3	-2.0	-1	-0.1	(-0.6, 0.3)

表 2.7.3.6-176. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison: Compare to 40mg EOW LSMEAN	95% CI
Japan ITT-RP Set										
PHYSICIAN'S GLOBAL ASSESSMENT SUBSCORE										
Week 35 (Week 27 of Maintenance Study)										
Adalimumab 40mg EOW	17	2.4	0.6	-1.8	0.88	-3	-2.0	0		
Adalimumab 40mg EW	22	2.4	0.3	-2.1	0.64	-3	-2.0	-1	-0.3	(-0.8, 0.1)
Week 37 (Week 29 of Maintenance Study)										
Adalimumab 40mg EOW	17	2.4	0.7	-1.7	0.85	-3	-2.0	0		
Adalimumab 40mg EW	22	2.4	0.3	-2.1	0.64	-3	-2.0	-1	-0.4	(-0.9, -0.0)
Week 42 (Week 34 of Maintenance Study)										
Adalimumab 40mg EOW	17	2.4	0.5	-1.9	0.78	-3	-2.0	0		
Adalimumab 40mg EW	21	2.4	0.4	-2.0	0.71	-3	-2.0	-1	-0.2	(-0.6, 0.3)
Week 48 (Week 40 of Maintenance Study)										
Adalimumab 40mg EOW	16	2.4	0.6	-1.8	0.66	-3	-2.0	-1		
Adalimumab 40mg EW	21	2.4	0.2	-2.1	0.73	-3	-2.0	-1	-0.4	(-0.8, 0.0)
Week 52 (Week 44 of Maintenance Study)										
Adalimumab 40mg EOW	16	2.4	0.8	-1.6	0.96	-3	-2.0	0		
Adalimumab 40mg EW	21	2.4	0.3	-2.0	0.74	-3	-2.0	-1	-0.5	(-1.0, 0.0)

表 2.7.3.6-176. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison: Compare to 40mg EOW LSMEAN	95% CI
Japan ITT-RP Set										
PARTIAL MAYO SCORE										
Maintenance Baseline										
Adalimumab 40mg EOW	18	5.96	1.76	-4.20	1.512	-8.0	-4.00	-2.0		
Adalimumab 40mg EW	23	6.44	1.72	-4.72	2.283	-8.8	-3.80	-1.0	-0.10	(-0.63, 0.42)
Week 10 (Week 2 of Maintenance Study)										
Adalimumab 40mg EOW	18	5.96	1.84	-4.11	1.927	-7.8	-4.40	-0.4		
Adalimumab 40mg EW	23	6.44	1.60	-4.84	2.078	-8.8	-4.60	-1.0	-0.33	(-1.18, 0.52)
Week 12 (Week 4 of Maintenance Study)										
Adalimumab 40mg EOW	18	5.96	2.13	-3.83	2.031	-7.7	-4.00	1.2		
Adalimumab 40mg EW	23	6.44	1.65	-4.79	2.214	-8.6	-4.60	-1.0	-0.58	(-1.55, 0.39)
Week 16 (Week 8 of Maintenance Study)										
Adalimumab 40mg EOW	18	5.96	2.37	-3.59	2.206	-6.6	-3.90	1.4		
Adalimumab 40mg EW	23	6.44	1.50	-4.95	2.299	-9.0	-4.60	0.4	-1.05	(-2.23, 0.14)
Week 22 (Week 14 of Maintenance Study)										
Adalimumab 40mg EOW	15	5.93	2.47	-3.47	2.092	-6.0	-4.00	1.4		
Adalimumab 40mg EW	22	6.40	1.31	-5.09	2.246	-9.0	-4.70	-1.0	-1.28	(-2.35, -0.22)
Week 24 (Week 16 of Maintenance Study)										
Adalimumab 40mg EOW	17	5.84	2.09	-3.74	2.337	-6.6	-3.60	1.4		
Adalimumab 40mg EW	22	6.40	1.23	-5.17	2.304	-9.0	-4.70	-1.0	-1.00	(-2.06, 0.06)
Week 29 (Week 21 of Maintenance Study)										
Adalimumab 40mg EOW	17	5.84	1.92	-3.92	2.280	-8.0	-4.40	2.0		
Adalimumab 40mg EW	22	6.40	1.41	-4.99	2.184	-8.2	-4.70	-1.0	-0.70	(-1.91, 0.52)

表 2.7.3.6-176. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison: Compare to 40mg EOW LSMEAN	95% CI
Japan ITT-RP Set										
PARTIAL MAYO SCORE										
Week 35 (Week 27 of Maintenance Study)										
Adalimumab 40mg EOW	17	5.84	2.47	-3.36	2.019	-6.2	-3.20	2.8		
Adalimumab 40mg EW	22	6.40	1.25	-5.15	2.250	-8.8	-5.00	-1.0	-1.49	(-2.76, -0.22)
Week 37 (Week 29 of Maintenance Study)										
Adalimumab 40mg EOW	17	5.84	2.55	-3.29	1.845	-6.0	-3.00	0.8		
Adalimumab 40mg EW	21	6.35	1.29	-5.07	2.171	-8.4	-5.00	-1.2	-1.49	(-2.67, -0.32)
Week 42 (Week 34 of Maintenance Study)										
Adalimumab 40mg EOW	17	5.84	2.28	-3.56	1.910	-6.6	-3.20	1.0		
Adalimumab 40mg EW	21	6.28	1.46	-4.82	2.313	-8.8	-4.40	-0.6	-0.99	(-2.22, 0.25)
Week 48 (Week 40 of Maintenance Study)										
Adalimumab 40mg EOW	15	5.64	2.28	-3.36	1.875	-6.4	-3.00	0.2		
Adalimumab 40mg EW	21	6.28	1.31	-4.96	2.501	-9.0	-4.60	-0.6	-1.00	(-2.26, 0.26)
Week 52 (Week 44 of Maintenance Study)										
Adalimumab 40mg EOW	16	5.70	2.54	-3.16	2.119	-7.0	-3.20	1.4		
Adalimumab 40mg EW	21	6.28	1.23	-5.05	2.279	-9.0	-4.60	-1.0	-1.41	(-2.65, -0.16)

表 2.7.3.6-176. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: Mean	STD	Min	Median	Max	Between Group Comparison: Compare to 40mg EOW: LSMEAN	95% CI
Integrated ITT-RP Set										
AVERAGE RECTAL BLEEDING SUBSCORE										
Maintenance Baseline										
Adalimumab 40mg EOW	163	1.71	0.16	-1.55	0.857	-3.0	-1.40	0.4		
Adalimumab 40mg EW	175	1.81	0.20	-1.61	0.959	-3.0	-1.40	0.0	0.03	(-0.04, 0.10)
Week 10 (Week 2 of Maintenance Study)										
Adalimumab 40mg EOW	159	1.71	0.25	-1.47	0.925	-3.0	-1.40	0.6		
Adalimumab 40mg EW	175	1.81	0.24	-1.57	1.050	-3.0	-1.40	2.2	-0.01	(-0.11, 0.10)
Week 12 (Week 4 of Maintenance Study)										
Adalimumab 40mg EOW	156	1.73	0.19	-1.53	0.908	-3.0	-1.40	0.4		
Adalimumab 40mg EW	168	1.81	0.25	-1.56	1.089	-3.0	-1.40	2.2	0.05	(-0.05, 0.15)
Week 16 (Week 8 of Maintenance Study)										
Adalimumab 40mg EOW	158	1.72	0.29	-1.43	0.947	-3.0	-1.40	1.0		
Adalimumab 40mg EW	170	1.84	0.26	-1.58	1.045	-3.0	-1.50	1.4	-0.04	(-0.16, 0.08)
Week 22 (Week 14 of Maintenance Study)										
Adalimumab 40mg EOW	142	1.74	0.31	-1.42	0.998	-3.0	-1.40	1.6		
Adalimumab 40mg EW	163	1.83	0.18	-1.64	1.012	-3.0	-1.60	0.0	-0.13	(-0.25, -0.01)
Week 24 (Week 16 of Maintenance Study)										
Adalimumab 40mg EOW	138	1.70	0.35	-1.35	0.967	-3.0	-1.40	1.6		
Adalimumab 40mg EW	157	1.82	0.19	-1.63	1.009	-3.0	-1.60	0.4	-0.16	(-0.30, -0.03)
Week 29 (Week 21 of Maintenance Study)										
Adalimumab 40mg EOW	139	1.70	0.35	-1.35	1.016	-3.0	-1.40	1.6		
Adalimumab 40mg EW	159	1.82	0.21	-1.60	1.065	-3.0	-1.60	1.6	-0.14	(-0.28, -0.00)

表 2.7.3.6-176. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison: Compare to 40mg EOW LSMEAN	95% CI
Integrated ITT-RP Set										
AVERAGE RECTAL BLEEDING SUBSCORE										
Week 35 (Week 27 of Maintenance Study)										
Adalimumab 40mg EOW	131	1.71	0.34	-1.37	1.054	-3.0	-1.40	2.0		
Adalimumab 40mg EW	151	1.78	0.23	-1.55	1.095	-3.0	-1.40	2.0	-0.11	(-0.27, 0.05)
Week 37 (Week 29 of Maintenance Study)										
Adalimumab 40mg EOW	123	1.72	0.37	-1.36	1.022	-3.0	-1.40	2.0		
Adalimumab 40mg EW	144	1.80	0.24	-1.56	1.022	-3.0	-1.40	1.2	-0.13	(-0.28, 0.03)
Week 42 (Week 34 of Maintenance Study)										
Adalimumab 40mg EOW	129	1.71	0.31	-1.40	1.001	-3.0	-1.40	2.0		
Adalimumab 40mg EW	147	1.80	0.24	-1.56	1.023	-3.0	-1.40	1.2	-0.07	(-0.22, 0.07)
Week 48 (Week 40 of Maintenance Study)										
Adalimumab 40mg EOW	120	1.72	0.30	-1.42	1.069	-3.0	-1.40	2.0		
Adalimumab 40mg EW	146	1.79	0.20	-1.59	1.036	-3.0	-1.50	1.2	-0.11	(-0.26, 0.03)
Week 52 (Week 44 of Maintenance Study)										
Adalimumab 40mg EOW	118	1.67	0.28	-1.39	1.072	-3.0	-1.40	2.0		
Adalimumab 40mg EW	143	1.80	0.20	-1.60	1.009	-3.0	-1.40	1.2	-0.09	(-0.23, 0.05)

表 2.7.3.6-176. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison: Compare to 40mg EOW LSMEAN	95% CI
Integrated ITT-RP Set										
AVERAGE STOOL FREQUENCY SUBSCORE										
Maintenance Baseline										
Adalimumab 40mg EOW	163	2.37	0.92	-1.45	0.835	-3.0	-1.40	1.6		
Adalimumab 40mg EW	175	2.37	0.89	-1.48	0.775	-3.0	-1.40	0.4	-0.02	(-0.15, 0.12)
Week 10 (Week 2 of Maintenance Study)										
Adalimumab 40mg EOW	159	2.36	0.95	-1.41	0.797	-3.0	-1.40	0.6		
Adalimumab 40mg EW	175	2.37	0.92	-1.45	0.877	-3.0	-1.40	2.4	-0.02	(-0.17, 0.13)
Week 12 (Week 4 of Maintenance Study)										
Adalimumab 40mg EOW	156	2.38	0.87	-1.51	0.819	-3.0	-1.60	1.2		
Adalimumab 40mg EW	168	2.36	0.88	-1.48	0.859	-3.0	-1.40	0.4	0.02	(-0.13, 0.17)
Week 16 (Week 8 of Maintenance Study)										
Adalimumab 40mg EOW	158	2.36	0.98	-1.39	0.885	-3.0	-1.40	1.4		
Adalimumab 40mg EW	170	2.36	0.88	-1.49	0.861	-3.0	-1.60	0.8	-0.09	(-0.25, 0.07)
Week 22 (Week 14 of Maintenance Study)										
Adalimumab 40mg EOW	142	2.35	0.95	-1.40	0.869	-3.0	-1.40	1.4		
Adalimumab 40mg EW	163	2.34	0.80	-1.53	0.906	-3.0	-1.60	0.8	-0.13	(-0.30, 0.04)
Week 24 (Week 16 of Maintenance Study)										
Adalimumab 40mg EOW	138	2.35	1.05	-1.31	0.967	-3.0	-1.40	1.4		
Adalimumab 40mg EW	157	2.35	0.80	-1.55	0.920	-3.0	-1.60	0.8	-0.23	(-0.42, -0.05)
Week 29 (Week 21 of Maintenance Study)										
Adalimumab 40mg EOW	139	2.36	1.04	-1.32	1.018	-3.0	-1.40	2.0		
Adalimumab 40mg EW	159	2.34	0.84	-1.50	0.895	-3.0	-1.60	0.8	-0.18	(-0.37, 0.00)

表 2.7.3.6-176. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison: Compare to 40mg EOW LSMEAN	95% CI
Integrated ITT-RP Set										
AVERAGE STOOL FREQUENCY SUBSCORE										
Week 35 (Week 27 of Maintenance Study)										
Adalimumab 40mg EOW	131	2.36	1.01	-1.35	0.967	-3.0	-1.40	1.2		
Adalimumab 40mg EW	151	2.32	0.76	-1.56	0.933	-3.0	-1.60	1.2	-0.23	(-0.41, -0.04)
Week 37 (Week 29 of Maintenance Study)										
Adalimumab 40mg EOW	123	2.35	0.97	-1.38	0.979	-3.0	-1.40	1.2		
Adalimumab 40mg EW	144	2.35	0.74	-1.62	0.888	-3.0	-1.60	0.8	-0.21	(-0.40, -0.03)
Week 42 (Week 34 of Maintenance Study)										
Adalimumab 40mg EOW	129	2.34	0.95	-1.39	0.933	-3.0	-1.40	1.0		
Adalimumab 40mg EW	147	2.35	0.79	-1.57	0.884	-3.0	-1.60	1.2	-0.15	(-0.33, 0.03)
Week 48 (Week 40 of Maintenance Study)										
Adalimumab 40mg EOW	120	2.33	0.93	-1.41	0.963	-3.0	-1.40	1.2		
Adalimumab 40mg EW	146	2.35	0.76	-1.59	0.888	-3.0	-1.60	1.0	-0.16	(-0.35, 0.02)
Week 52 (Week 44 of Maintenance Study)										
Adalimumab 40mg EOW	118	2.33	0.96	-1.37	1.004	-3.0	-1.40	1.4		
Adalimumab 40mg EW	143	2.34	0.69	-1.65	0.892	-3.0	-1.60	0.6	-0.25	(-0.44, -0.06)

表 2.7.3.6-176. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: Mean	STD	Min	Median	Max	Between Group Comparison: Compare to 40mg EOW: LSMEAN	95% CI
Integrated ITT-RP Set										
ENDOSCOPY SUBSCORE										
Maintenance Baseline										
Adalimumab 40mg EOW	163	2.3	1.2	-1.1	0.91	-3	-1.0	1		
Adalimumab 40mg EW	175	2.3	1.2	-1.1	0.86	-3	-1.0	0	0.0	(-0.1, 0.2)
Week 52 (Week 44 of Maintenance Study)										
Adalimumab 40mg EOW	121	2.4	1.2	-1.2	1.10	-3	-1.0	1		
Adalimumab 40mg EW	145	2.3	0.9	-1.3	1.04	-3	-2.0	1	-0.2	(-0.4, 0.1)

表 2.7.3.6-176. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison: Compare to 40mg EOW LSMEAN	95% CI
Integrated ITT-RP Set										
PHYSICIAN'S GLOBAL ASSESSMENT SUBSCORE										
Maintenance Baseline										
Adalimumab 40mg EOW	163	2.3	1.0	-1.3	0.70	-3	-1.0	0		
Adalimumab 40mg EW	175	2.3	0.8	-1.5	0.76	-3	-1.0	0	-0.1	(-0.3, -0.0)
Week 10 (Week 2 of Maintenance Study)										
Adalimumab 40mg EOW	159	2.3	0.8	-1.5	0.79	-3	-1.0	0		
Adalimumab 40mg EW	175	2.3	0.7	-1.6	0.79	-3	-2.0	0	-0.0	(-0.1, 0.1)
Week 12 (Week 4 of Maintenance Study)										
Adalimumab 40mg EOW	156	2.3	0.7	-1.5	0.81	-3	-2.0	0		
Adalimumab 40mg EW	168	2.3	0.7	-1.6	0.85	-3	-2.0	1	0.0	(-0.1, 0.2)
Week 16 (Week 8 of Maintenance Study)										
Adalimumab 40mg EOW	158	2.3	0.8	-1.5	0.87	-3	-2.0	1		
Adalimumab 40mg EW	170	2.3	0.7	-1.6	0.84	-3	-2.0	0	-0.1	(-0.2, 0.1)
Week 22 (Week 14 of Maintenance Study)										
Adalimumab 40mg EOW	144	2.3	0.7	-1.5	0.86	-3	-2.0	1		
Adalimumab 40mg EW	163	2.3	0.5	-1.8	0.84	-3	-2.0	0	-0.2	(-0.3, -0.0)
Week 24 (Week 16 of Maintenance Study)										
Adalimumab 40mg EOW	139	2.3	0.8	-1.5	0.88	-3	-1.0	1		
Adalimumab 40mg EW	158	2.3	0.5	-1.8	0.85	-3	-2.0	0	-0.2	(-0.4, -0.1)
Week 29 (Week 21 of Maintenance Study)										
Adalimumab 40mg EOW	140	2.3	0.8	-1.5	0.89	-3	-2.0	1		
Adalimumab 40mg EW	159	2.3	0.6	-1.8	0.81	-3	-2.0	0	-0.2	(-0.4, -0.0)

表 2.7.3.6-176. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison: Compare to 40mg EOW LSMEAN	95% CI
Integrated ITT-RP Set										
PHYSICIAN'S GLOBAL ASSESSMENT SUBSCORE										
Week 35 (Week 27 of Maintenance Study)										
Adalimumab 40mg EOW	131	2.3	0.7	-1.6	0.83	-3	-2.0	1		
Adalimumab 40mg EW	151	2.3	0.5	-1.8	0.84	-3	-2.0	1	-0.2	(-0.4, -0.1)
Week 37 (Week 29 of Maintenance Study)										
Adalimumab 40mg EOW	123	2.3	0.7	-1.6	0.88	-3	-2.0	1		
Adalimumab 40mg EW	145	2.3	0.5	-1.8	0.86	-3	-2.0	0	-0.2	(-0.3, 0.0)
Week 42 (Week 34 of Maintenance Study)										
Adalimumab 40mg EOW	129	2.3	0.6	-1.6	0.85	-3	-2.0	1		
Adalimumab 40mg EW	147	2.3	0.5	-1.8	0.88	-3	-2.0	0	-0.1	(-0.2, 0.1)
Week 48 (Week 40 of Maintenance Study)										
Adalimumab 40mg EOW	121	2.3	0.6	-1.7	0.84	-3	-2.0	1		
Adalimumab 40mg EW	146	2.3	0.5	-1.9	0.85	-3	-2.0	1	-0.1	(-0.3, 0.0)
Week 52 (Week 44 of Maintenance Study)										
Adalimumab 40mg EOW	119	2.3	0.8	-1.4	0.93	-3	-1.0	1		
Adalimumab 40mg EW	143	2.3	0.5	-1.9	0.85	-3	-2.0	0	-0.3	(-0.5, -0.2)

表 2.7.3.6-176. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison: Compare to 40mg EOW LSMEAN	95% CI
Integrated ITT-RP Set										
PARTIAL MAYO SCORE										
Maintenance Baseline										
Adalimumab 40mg EOW	163	6.35	2.03	-4.32	1.449	-9.0	-4.20	-1.4		
Adalimumab 40mg EW	175	6.49	1.89	-4.60	1.790	-9.0	-4.20	-0.6	-0.14	(-0.36, 0.08)
Week 10 (Week 2 of Maintenance Study)										
Adalimumab 40mg EOW	159	6.34	1.95	-4.38	1.678	-9.0	-4.40	-0.4		
Adalimumab 40mg EW	175	6.49	1.90	-4.59	1.993	-9.0	-4.40	1.6	-0.05	(-0.33, 0.23)
Week 12 (Week 4 of Maintenance Study)										
Adalimumab 40mg EOW	156	6.37	1.79	-4.58	1.703	-9.0	-4.50	1.2		
Adalimumab 40mg EW	168	6.46	1.85	-4.61	2.128	-9.0	-4.60	3.2	0.08	(-0.24, 0.39)
Week 16 (Week 8 of Maintenance Study)										
Adalimumab 40mg EOW	158	6.33	2.03	-4.31	1.972	-9.0	-4.40	1.4		
Adalimumab 40mg EW	170	6.52	1.83	-4.69	2.132	-9.0	-4.60	1.4	-0.19	(-0.53, 0.16)
Week 22 (Week 14 of Maintenance Study)										
Adalimumab 40mg EOW	142	6.33	1.99	-4.34	2.075	-9.0	-4.40	1.4		
Adalimumab 40mg EW	163	6.47	1.51	-4.96	2.081	-9.0	-4.80	-0.2	-0.47	(-0.84, -0.10)
Week 24 (Week 16 of Maintenance Study)										
Adalimumab 40mg EOW	138	6.31	2.18	-4.13	2.120	-8.8	-4.40	1.4		
Adalimumab 40mg EW	157	6.48	1.50	-4.98	2.065	-9.0	-4.80	0.6	-0.67	(-1.07, -0.27)
Week 29 (Week 21 of Maintenance Study)										
Adalimumab 40mg EOW	139	6.32	2.14	-4.18	2.223	-9.0	-4.40	2.2		
Adalimumab 40mg EW	159	6.47	1.61	-4.86	2.079	-8.8	-4.80	1.8	-0.53	(-0.94, -0.12)

表 2.7.3.6-176. 評価時点ごとの PMS 及び各サブスコアのベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison: Compare to 40mg EOW LSMEAN	95% CI
Integrated ITT-RP Set										
PARTIAL MAYO SCORE										
Week 35 (Week 27 of Maintenance Study)										
Adalimumab 40mg EOW	131	6.33	2.06	-4.27	2.185	-9.0	-4.40	2.8		
Adalimumab 40mg EW	151	6.41	1.46	-4.95	2.191	-8.8	-4.80	4.2	-0.56	(-0.97, -0.14)
Week 37 (Week 29 of Maintenance Study)										
Adalimumab 40mg EOW	123	6.33	2.02	-4.31	2.120	-9.0	-4.60	2.2		
Adalimumab 40mg EW	144	6.46	1.48	-4.98	2.022	-9.0	-4.80	0.6	-0.52	(-0.95, -0.09)
Week 42 (Week 34 of Maintenance Study)										
Adalimumab 40mg EOW	129	6.31	1.88	-4.43	2.044	-8.8	-4.40	2.2		
Adalimumab 40mg EW	147	6.48	1.56	-4.92	2.069	-9.0	-4.80	1.4	-0.31	(-0.72, 0.10)
Week 48 (Week 40 of Maintenance Study)										
Adalimumab 40mg EOW	120	6.32	1.83	-4.49	2.175	-9.0	-4.60	2.2		
Adalimumab 40mg EW	146	6.46	1.40	-5.05	2.067	-9.0	-4.80	1.2	-0.41	(-0.82, 0.00)
Week 52 (Week 44 of Maintenance Study)										
Adalimumab 40mg EOW	118	6.27	2.06	-4.21	2.232	-8.8	-4.20	2.2		
Adalimumab 40mg EW	143	6.46	1.35	-5.11	2.091	-9.0	-4.80	1.8	-0.68	(-1.10, -0.26)

Note: Treatment group differences for changes from baseline is analyzed using Analysis of Variance (ANOVA).

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__3.16_J

表 2.7.3.6-177. 評価時点ごとの被験者から報告された排便回数のベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
Japan ITT-RP Set											
AVERAGE STOOL FREQUENCY ABSOLUTE VALUE											
Maintenance Baseline											
Adalimumab 40mg EOW	18	5.63	2.34	-3.29	3.302	-13.0	-1.90	0.2			
Adalimumab 40mg EW	23	7.03	2.67	-4.37	2.953	-13.2	-3.80	-0.6	0.21	(-0.34, 0.77)	0.436
Week 10 (Week 2 of Maintenance Study)											
Adalimumab 40mg EOW	18	5.63	2.50	-3.13	3.301	-12.6	-2.00	1.0			
Adalimumab 40mg EW	23	7.03	2.83	-4.20	2.965	-14.2	-3.60	0.0	0.22	(-0.72, 1.17)	0.633
Week 12 (Week 4 of Maintenance Study)											
Adalimumab 40mg EOW	18	5.63	2.88	-2.75	3.114	-11.4	-2.20	2.2			
Adalimumab 40mg EW	23	7.03	2.75	-4.29	3.111	-15.2	-3.80	-0.6	-0.25	(-1.33, 0.84)	0.650
Week 16 (Week 8 of Maintenance Study)											
Adalimumab 40mg EOW	18	5.63	3.12	-2.52	3.559	-11.8	-2.00	3.6			
Adalimumab 40mg EW	23	7.03	2.57	-4.46	3.171	-14.4	-3.80	-0.4	-0.65	(-1.94, 0.63)	0.311
Week 22 (Week 14 of Maintenance Study)											
Adalimumab 40mg EOW	15	5.72	2.92	-2.80	3.650	-12.2	-1.80	4.0			
Adalimumab 40mg EW	22	7.04	2.35	-4.68	3.163	-14.8	-4.20	-0.4	-0.80	(-1.94, 0.35)	0.163
Week 24 (Week 16 of Maintenance Study)											
Adalimumab 40mg EOW	17	5.47	2.92	-2.55	3.938	-13.2	-1.80	5.0			
Adalimumab 40mg EW	22	7.04	2.36	-4.67	3.189	-14.6	-4.10	-0.6	-0.97	(-2.31, 0.38)	0.150

表 2.7.3.6-177. 評価時点ごとの被験者から報告された排便回数のベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
Japan ITT-RP Set											
AVERAGE STOOL FREQUENCY ABSOLUTE VALUE											
Week 29 (Week 21 of Maintenance Study)											
Adalimumab 40mg EOW	17	5.47	2.94	-2.53	2.934	-9.4	-1.80	1.8			
Adalimumab 40mg EW	22	7.04	2.60	-4.44	2.992	-14.4	-3.90	-0.6	-0.53	(-1.56, 0.49)	0.296
Week 35 (Week 27 of Maintenance Study)											
Adalimumab 40mg EOW	16	5.46	3.89	-1.58	3.402	-9.6	-1.20	6.4			
Adalimumab 40mg EW	22	7.04	2.71	-4.33	3.372	-14.8	-3.60	0.6	-1.38	(-3.02, 0.25)	0.093+
Week 37 (Week 29 of Maintenance Study)											
Adalimumab 40mg EOW	16	5.46	3.61	-1.85	3.424	-12.0	-1.40	3.0			
Adalimumab 40mg EW	21	7.21	2.63	-4.58	3.305	-14.6	-4.00	0.2	-1.22	(-2.49, 0.05)	0.059+
Week 42 (Week 34 of Maintenance Study)											
Adalimumab 40mg EOW	16	5.46	3.10	-2.36	3.457	-12.8	-1.50	2.2			
Adalimumab 40mg EW	21	7.05	2.87	-4.18	3.248	-14.8	-3.20	-0.2	-0.22	(-1.47, 1.02)	0.719
Week 48 (Week 40 of Maintenance Study)											
Adalimumab 40mg EOW	15	5.32	3.16	-2.16	3.562	-12.8	-1.00	2.0			
Adalimumab 40mg EW	21	7.05	2.92	-4.12	3.418	-14.8	-3.40	-0.4	-0.35	(-1.70, 1.01)	0.606
Week 52 (Week 44 of Maintenance Study)											
Adalimumab 40mg EOW	16	5.34	3.33	-2.01	3.362	-12.0	-1.40	3.0			
Adalimumab 40mg EW	21	7.05	2.66	-4.39	3.042	-14.2	-3.40	-1.4	-0.84	(-2.08, 0.40)	0.175

表 2.7.3.6-177. 評価時点ごとの被験者から報告された排便回数のベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
Integrated ITT-RP Set											
AVERAGE STOOL FREQUENCY ABSOLUTE VALUE											
Maintenance Baseline											
Adalimumab 40mg EOW	163	6.53	2.85	-3.68	2.720	-13.0	-3.20	4.2			
Adalimumab 40mg EW	175	7.09	2.78	-4.31	3.225	-19.5	-3.60	0.8	-0.16	(-0.45, 0.13)	0.282
Week 10 (Week 2 of Maintenance Study)											
Adalimumab 40mg EOW	159	6.52	2.83	-3.69	2.615	-12.6	-3.20	1.0			
Adalimumab 40mg EW	175	7.09	2.88	-4.21	3.523	-18.4	-3.40	5.8	-0.02	(-0.36, 0.32)	0.889
Week 12 (Week 4 of Maintenance Study)											
Adalimumab 40mg EOW	156	6.56	2.70	-3.85	2.757	-12.8	-3.50	3.8			
Adalimumab 40mg EW	167	7.05	2.83	-4.23	3.541	-20.2	-3.60	1.6	0.04	(-0.31, 0.38)	0.840
Week 16 (Week 8 of Maintenance Study)											
Adalimumab 40mg EOW	158	6.54	2.97	-3.57	2.961	-12.8	-3.20	3.8			
Adalimumab 40mg EW	170	7.10	2.78	-4.32	3.499	-19.4	-3.60	1.8	-0.25	(-0.62, 0.13)	0.202
Week 22 (Week 14 of Maintenance Study)											
Adalimumab 40mg EOW	142	6.48	2.86	-3.62	2.899	-12.8	-3.00	4.0			
Adalimumab 40mg EW	161	7.04	2.58	-4.46	3.580	-19.8	-3.60	4.4	-0.37	(-0.76, 0.02)	0.060+
Week 24 (Week 16 of Maintenance Study)											
Adalimumab 40mg EOW	138	6.43	3.09	-3.34	3.189	-13.2	-3.00	5.6			
Adalimumab 40mg EW	155	6.90	2.52	-4.38	3.460	-19.0	-3.80	5.0	-0.58	(-1.02, -0.14)	0.010**

表 2.7.3.6-177. 評価時点ごとの被験者から報告された排便回数のベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
Integrated ITT-RP Set											
AVERAGE STOOL FREQUENCY ABSOLUTE VALUE											
Week 29 (Week 21 of Maintenance Study)											
Adalimumab 40mg EOW	136	6.53	3.22	-3.31	3.439	-13.4	-2.90	10.0			
Adalimumab 40mg EW	158	6.90	2.63	-4.27	3.340	-19.8	-3.60	4.8	-0.59	(-1.06, -0.11)	0.016*
Week 35 (Week 27 of Maintenance Study)											
Adalimumab 40mg EOW	129	6.48	3.05	-3.42	3.221	-14.6	-3.00	6.4			
Adalimumab 40mg EW	151	6.94	2.47	-4.46	3.659	-19.8	-4.00	5.2	-0.60	(-1.05, -0.15)	0.009**
Week 37 (Week 29 of Maintenance Study)											
Adalimumab 40mg EOW	122	6.42	2.90	-3.52	3.174	-14.6	-3.00	3.8			
Adalimumab 40mg EW	143	7.00	2.51	-4.49	3.520	-19.8	-3.80	5.2	-0.47	(-0.93, -0.02)	0.042*
Week 42 (Week 34 of Maintenance Study)											
Adalimumab 40mg EOW	128	6.47	2.82	-3.64	3.225	-14.6	-3.00	3.8			
Adalimumab 40mg EW	144	6.94	2.48	-4.46	3.530	-19.6	-4.00	3.0	-0.37	(-0.80, 0.06)	0.089+
Week 48 (Week 40 of Maintenance Study)											
Adalimumab 40mg EOW	119	6.51	2.92	-3.60	3.367	-14.6	-3.00	3.8			
Adalimumab 40mg EW	146	7.01	2.42	-4.59	3.619	-19.6	-3.80	1.6	-0.57	(-1.01, -0.12)	0.012*
Week 52 (Week 44 of Maintenance Study)											
Adalimumab 40mg EOW	118	6.50	2.96	-3.54	3.398	-15.6	-3.00	3.8			
Adalimumab 40mg EW	141	7.01	2.37	-4.64	3.610	-19.8	-3.80	1.8	-0.67	(-1.12, -0.22)	0.004**

表 2.7.3.6-177. 評価時点ごとの被験者から報告された排便回数のベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

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@ P-value for test of difference between Adalimumab 40mg EW and Adalimumab 40mg EOW for change from baseline using the repeated
  measure model including treatment, induction treatment regimen, week 8 remission status, visit, baseline value, interaction of
  treatment and visit.
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.
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Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__3.17_J

表 2.7.3.6-178.　投与 52 週時の WPAI スコアのベースラインからの変化量（OC）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

Parameter / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline: Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
Japan ITT-RP Set											
WPAI - ACTIVITY IMPAIRMENT (%)											
Adalimumab 40mg EOW	17	57.6	27.1	-30.6	31.91	-80	-30.0	70			
Adalimumab 40mg EW	22	52.3	13.6	-38.6	29.97	-100	-30.0	0	-12.3	(-28.8, 4.2)	0.138
WPAI - IMPAIRMENT WHILE WORKING (%)											
Adalimumab 40mg EOW	12	46.7	14.2	-32.5	27.68	-80	-25.0	10			
Adalimumab 40mg EW	19	53.2	13.2	-40.0	35.75	-100	-30.0	30	-1.7	(-18.1, 14.7)	0.832
WPAI - OVERALL WORK IMPAIRMENT (%)											
Adalimumab 40mg EOW	13	52.425	16.164	-36.262	31.6913	-83.53	-30.000	18.24			
Adalimumab 40mg EW	19	57.774	13.158	-44.616	36.1974	-100.00	-33.333	20.00	-3.731	(-19.370, 11.908)	0.628
WPAI - WORK TIME MISSED (%)											
Adalimumab 40mg EOW	13	19.819	1.113	-18.706	38.1971	-100.00	0.000	11.76			
Adalimumab 40mg EW	19	26.099	0.000	-26.099	37.6894	-100.00	0.000	0.00	-1.047	(-2.595, 0.500)	0.176

表 2.7.3.6-178. 投与 52 週時の WPAI スコアのベースラインからの変化量（OC）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW) LSMEAN	95% CI	P-Value@
Integrated ITT-RP Set											
WPAI - ACTIVITY IMPAIRMENT (%)											
Adalimumab 40mg EOW	138	56.6	20.4	-36.2	31.07	-100	-40.0	70			
Adalimumab 40mg EW	150	55.7	18.5	-37.2	32.96	-100	-40.0	70	-1.4	(-7.0, 4.2)	0.622
WPAI - IMPAIRMENT WHILE WORKING (%)											
Adalimumab 40mg EOW	80	51.9	17.0	-34.9	30.85	-100	-40.0	40			
Adalimumab 40mg EW	93	51.1	17.2	-33.9	34.20	-100	-30.0	40	0.7	(-6.4, 7.8)	0.845
WPAI - OVERALL WORK IMPAIRMENT (%)											
Adalimumab 40mg EOW	77	57.798	19.250	-38.547	34.7265	-100.00	-40.000	36.87			
Adalimumab 40mg EW	85	54.890	18.442	-36.447	35.3264	-100.00	-31.373	50.92	0.130	(-7.925, 8.185)	0.975
WPAI - WORK TIME MISSED (%)											
Adalimumab 40mg EOW	78	20.918	7.122	-13.796	32.8042	-100.00	0.000	68.75			
Adalimumab 40mg EW	85	20.004	2.792	-17.211	31.6609	-100.00	0.000	41.00	-4.151	(-9.291, 0.988)	0.113

@ P-value for test of difference between Adalimumab 40mg EW and Adalimumab 40mg EOW for change from baseline using analysis of covariance with treatment, induction treatment regimen, week 8 remission status, and baseline value as covariate.

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__3.18_J

表 2.7.3.6-179. 投与 52 週時の SF-36 スコアのベースラインからの変化量（OC）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

Parameter / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
Japan ITT-RP Set											
SF-36 V2 BODILY PAIN SCALE											
Adalimumab 40mg EOW	17	40.416	54.238	13.822	10.6231	-9.30	15.214	29.16			
Adalimumab 40mg EW	22	41.871	56.355	14.484	11.8045	0.00	10.988	32.96	1.689	(-3.970, 7.347)	0.548
SF-36 V2 GENERAL HEALTH SCALE											
Adalimumab 40mg EOW	17	35.745	40.231	4.486	8.0032	-7.15	3.337	21.45			
Adalimumab 40mg EW	22	35.036	42.512	7.475	7.8429	-7.15	6.912	24.79	2.900	(-2.495, 8.295)	0.282
SF-36 V2 MENTAL COMPONENT SUMMARY											
Adalimumab 40mg EOW	17	38.933	43.218	4.285	9.8996	-15.23	1.951	30.19			
Adalimumab 40mg EW	22	40.648	49.942	9.294	11.7279	-10.41	7.027	36.74	6.146	(0.219, 12.073)	0.043*
SF-36 V2 MENTAL HEALTH SCALE											
Adalimumab 40mg EOW	17	40.566	43.713	3.147	10.2928	-14.08	2.816	22.53			
Adalimumab 40mg EW	22	43.992	48.215	4.224	10.4553	-11.26	2.816	30.98	2.958	(-3.045, 8.961)	0.324
SF-36 V2 PHYSICAL COMPONENT SUMMARY											
Adalimumab 40mg EOW	17	44.056	52.407	8.351	6.5503	-4.59	8.620	22.63			
Adalimumab 40mg EW	22	43.081	52.135	9.054	7.2793	-0.89	7.707	29.80	0.277	(-3.851, 4.404)	0.893
SF-36 V2 PHYSICAL FUNCTIONING SCALE											
Adalimumab 40mg EOW	17	49.481	53.071	3.590	6.9704	-4.21	2.104	18.94			
Adalimumab 40mg EW	22	49.571	53.398	3.826	7.0140	-2.10	2.104	29.46	0.429	(-2.743, 3.601)	0.785

表 2.7.3.6-179. 投与 52 週時の SF-36 スコアのベースラインからの変化量（OC）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	Within Group: Change from Baseline STD	Within Group: Change from Baseline Min	Within Group: Change from Baseline Median	Within Group: Change from Baseline Max	Between Group Comparison (40mg EW - 40mg EOW) LSMEAN	Between Group Comparison (40mg EW - 40mg EOW) 95% CI	Between Group Comparison (40mg EW - 40mg EOW) P-Value@
Japan ITT-RP Set											
SF-36 V2 ROLE-EMOTIONAL SCALE											
Adalimumab 40mg EOW	17	41.702	46.275	4.573	10.2142	-11.66	3.887	27.21			
Adalimumab 40mg EW	22	41.213	53.582	12.368	13.1760	-3.89	7.774	34.98	7.664	(2.268, 13.061)	0.007**
SF-36 V2 ROLE-PHYSICAL SCALE											
Adalimumab 40mg EOW	17	42.447	50.227	7.779	9.0496	-9.80	9.796	22.04			
Adalimumab 40mg EW	22	40.601	52.401	11.800	9.7563	0.00	9.796	29.39	3.241	(-1.752, 8.234)	0.196
SF-36 V2 SOCIAL FUNCTIONING SCALE											
Adalimumab 40mg EOW	17	38.241	46.262	8.021	9.4696	-16.36	5.454	21.82			
Adalimumab 40mg EW	22	38.504	52.635	14.131	13.6384	-21.82	16.362	43.63	6.491	(-0.320, 13.301)	0.061+
SF-36 V2 VITALITY SCALE											
Adalimumab 40mg EOW	17	41.807	49.520	7.713	7.9686	-9.37	6.244	21.85			
Adalimumab 40mg EW	22	42.299	50.530	8.231	11.7427	-12.49	6.244	28.10	0.725	(-5.553, 7.003)	0.816

表 2.7.3.6-179. 投与 52 週時の SF-36 スコアのベースラインからの変化量（OC）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
Integrated ITT-RP Set											
SF-36 V2 BODILY PAIN SCALE											
Adalimumab 40mg EOW	141	37.775	51.418	13.644	11.6126	-26.20	13.946	42.26			
Adalimumab 40mg EW	156	39.381	52.382	13.001	12.6614	-32.96	13.101	42.26	0.525	(-1.650, 2.700)	0.635
SF-36 V2 GENERAL HEALTH SCALE											
Adalimumab 40mg EOW	141	34.179	41.743	7.564	8.6932	-9.53	7.150	34.32			
Adalimumab 40mg EW	156	33.871	42.043	8.172	9.0341	-17.64	7.925	29.55	0.425	(-1.454, 2.303)	0.657
SF-36 V2 MENTAL COMPONENT SUMMARY											
Adalimumab 40mg EOW	141	35.080	47.640	12.559	12.8372	-18.68	9.896	49.42			
Adalimumab 40mg EW	156	35.306	47.043	11.738	12.0299	-16.60	9.762	41.03	-0.713	(-2.962, 1.535)	0.533
SF-36 V2 MENTAL HEALTH SCALE											
Adalimumab 40mg EOW	141	37.705	48.510	10.804	11.5891	-14.08	8.448	42.24			
Adalimumab 40mg EW	156	37.191	47.155	9.964	11.9058	-19.71	9.856	42.24	-1.223	(-3.415, 0.970)	0.273
SF-36 V2 PHYSICAL COMPONENT SUMMARY											
Adalimumab 40mg EOW	141	40.416	50.290	9.874	7.7565	-8.77	8.682	38.65			
Adalimumab 40mg EW	156	40.692	50.415	9.722	9.0694	-22.70	10.520	37.30	-0.026	(-1.552, 1.500)	0.973
SF-36 V2 PHYSICAL FUNCTIONING SCALE											
Adalimumab 40mg EOW	141	45.084	53.227	8.143	8.2456	-4.21	6.313	39.99			
Adalimumab 40mg EW	156	44.865	52.256	7.391	8.5389	-14.73	4.209	33.67	-0.900	(-2.174, 0.374)	0.166

表 2.7.3.6-179. 投与 52 週時の SF-36 スコアのベースラインからの変化量（OC）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW) LSMEAN	95% CI	P-Value@
Integrated ITT-RP Set											
SF-36 V2 ROLE-EMOTIONAL SCALE											
Adalimumab 40mg EOW	141	36.277	47.553	11.276	13.5162	-19.44	7.774	46.65			
Adalimumab 40mg EW	156	36.642	48.129	11.487	13.8395	-31.10	11.662	46.65	0.444	(-1.733, 2.620)	0.689
SF-36 V2 ROLE-PHYSICAL SCALE											
Adalimumab 40mg EOW	141	36.329	49.107	12.778	11.2314	-9.80	12.245	39.18			
Adalimumab 40mg EW	156	36.094	49.177	13.082	11.4795	-24.49	14.694	39.18	0.059	(-1.971, 2.090)	0.954
SF-36 V2 SOCIAL FUNCTIONING SCALE											
Adalimumab 40mg EOW	141	33.447	49.036	15.588	13.1119	-21.82	16.362	43.63			
Adalimumab 40mg EW	156	35.243	49.542	14.299	12.5802	-27.27	16.362	43.63	0.025	(-2.181, 2.231)	0.982
SF-36 V2 VITALITY SCALE											
Adalimumab 40mg EOW	141	38.119	51.382	13.263	11.3866	-9.37	12.488	43.71			
Adalimumab 40mg EW	156	37.722	49.509	11.788	11.5274	-21.85	12.488	37.46	-1.740	(-4.004, 0.523)	0.131

@ P-value for test of difference between Adalimumab 40mg EW and Adalimumab 40mg EOW for change from baseline using analysis of covariance with treatment, induction treatment regimen, week 8 remission status, and baseline value as covariate.
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__3.19_J

表 2.7.3.6-180. 評価時点ごとの便中カルプロテクチン値のベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW) LSMEAN	95% CI	P-Value@
Japan ITT-RP Set											
FECAL CALPROTECTIN (MCG/G)											
Week 12 (Week 4 of Maintenance Study)											
Adalimumab 40mg EOW	17	3659.5	689.1	-2970.4	2983.87	-9294	-2026.0	761			
Adalimumab 40mg EW	23	3107.6	1066.1	-2041.5	3815.00	-9364	-1623.0	8529	343.1	(-892.6, 1578.8)	0.577
Week 16 (Week 8 of Maintenance Study)											
Adalimumab 40mg EOW	17	3659.5	1441.9	-2217.6	3553.61	-8620	-1587.0	5854			
Adalimumab 40mg EW	22	3093.1	462.5	-2630.5	3274.46	-9477	-1481.0	807	-1038.2	(-2161.2, 84.7)	0.069+
Week 24 (Week 16 of Maintenance Study)											
Adalimumab 40mg EOW	16	3288.3	1360.4	-1927.8	3550.65	-8627	-1538.5	7544			
Adalimumab 40mg EW	22	2812.5	740.0	-2072.5	3365.87	-9586	-1146.5	5522	-675.2	(-1950.8, 600.4)	0.290
Week 37 (Week 29 of Maintenance Study)											
Adalimumab 40mg EOW	16	3288.3	1037.6	-2250.7	3431.71	-9383	-951.0	2484			
Adalimumab 40mg EW	22	2812.5	757.0	-2055.5	3122.69	-9560	-788.0	1623	-313.8	(-1081.7, 454.1)	0.412
Week 52 (Week 44 of Maintenance Study)											
Adalimumab 40mg EOW	15	3371.1	2233.9	-1137.2	4504.33	-8012	-2008.0	8789			
Adalimumab 40mg EW	21	2848.3	849.3	-1999.0	3226.29	-9540	-448.0	2246	-1385.5	(-2939.0, 168.1)	0.079+

表 2.7.3.6-180. 評価時点ごとの便中カルプロテクチン値のベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Parameter / Visit / Treatment	N	Baseline Mean	Visit Mean	Within Group: Change from Baseline Mean	STD	Min	Median	Max	Between Group Comparison (40mg EW - 40mg EOW): LSMEAN	95% CI	P-Value@
Integrated ITT-RP Set											
FECAL CALPROTECTIN (MCG/G)											
Week 12 (Week 4 of Maintenance Study)											
Adalimumab 40mg EOW	139	2668.0	947.9	-1720.1	2853.68	-9590	-866.0	6105			
Adalimumab 40mg EW	151	2377.2	853.9	-1523.3	2844.14	-9590	-1111.0	8645	-32.9	(-397.9, 332.2)	0.860
Week 16 (Week 8 of Maintenance Study)											
Adalimumab 40mg EOW	135	2705.4	912.3	-1793.1	3044.27	-9587	-882.0	6934			
Adalimumab 40mg EW	145	2335.8	707.5	-1628.3	2767.71	-9586	-946.0	4821	-212.6	(-518.8, 93.7)	0.173
Week 24 (Week 16 of Maintenance Study)											
Adalimumab 40mg EOW	131	2609.1	909.8	-1699.2	2831.60	-9590	-828.0	7544			
Adalimumab 40mg EW	144	2322.8	742.4	-1580.4	2745.43	-9590	-1027.0	8856	-204.4	(-564.2, 155.3)	0.264
Week 37 (Week 29 of Maintenance Study)											
Adalimumab 40mg EOW	118	2557.2	1033.7	-1523.5	2972.75	-9590	-708.0	7848			
Adalimumab 40mg EW	135	2379.3	713.9	-1665.4	2820.03	-9590	-1037.0	9536	-303.4	(-669.6, 62.8)	0.104
Week 52 (Week 44 of Maintenance Study)											
Adalimumab 40mg EOW	100	2365.7	872.6	-1493.1	3059.92	-9571	-702.5	8789			
Adalimumab 40mg EW	124	2408.2	655.3	-1753.0	2650.78	-9590	-1080.0	7581	-313.4	(-717.3, 90.4)	0.128

表 2.7.3.6-180. 評価時点ごとの便中カルプロテクチン値のベースラインからの変化量（Mixed Effect Model Repeated Measurement）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

@ P-value for test of difference between Adalimumab 40mg EW and Adalimumab 40mg EOW for change from baseline using the repeated measure model including treatment, induction treatment regimen, week 8 remission status, visit, baseline value, interaction of treatment and visit.
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__3.20_J

表 2.7.3.6-181. 評価時点ごとの便中カルプロテクチン値が 150 mg/kg 未満となった被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Subjects with Fecal Calprotectin below 150 mg/kg at Week 12 (Week 4 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	7 (38.9)	12 (52.2)	62 (38.0)	65 (37.1)
No, n (%)	11 (61.1)	11 (47.8)	101 (62.0)	110 (62.9)
Risk Difference[A]		13.3		-0.9
Adjusted Risk Difference[A,B]		17.0		-1.1
95% Confidence Interval[B]		(-14.1, 48.1)		(-11.4, 9.1)
P-Value[B]		0.283		0.827
Subjects with Fecal Calprotectin below 150 mg/kg at Week 16 (Week 8 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	7 (38.9)	11 (47.8)	57 (35.0)	61 (34.9)
No, n (%)	11 (61.1)	12 (52.2)	106 (65.0)	114 (65.1)
Risk Difference[A]		8.9		-0.1
Adjusted Risk Difference[A,B]		5.2		-1.0
95% Confidence Interval[B]		(-27.1, 37.5)		(-11.1, 9.0)
P-Value[B]		0.752		0.845
Subjects with Fecal Calprotectin below 150 mg/kg at Week 24 (Week 16 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	6 (33.3)	11 (47.8)	56 (34.4)	60 (34.3)
No, n (%)	12 (66.7)	12 (52.2)	107 (65.6)	115 (65.7)
Risk Difference[A]		14.5		-0.1
Adjusted Risk Difference[A,B]		12.0		-0.9
95% Confidence Interval[B]		(-19.8, 43.7)		(-10.9, 9.2)
P-Value[B]		0.460		0.867

表 2.7.3.6-181. 評価時点ごとの便中カルプロテクチン値が 150 mg/kg 未満となった被験者の割合（NRI）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW	40mg EW	40mg EOW	40mg EW
Subjects with Fecal Calprotectin below 150 mg/kg at Week 37 (Week 29 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	6 (33.3)	13 (56.5)	44 (27.0)	68 (38.9)
No, n (%)	12 (66.7)	10 (43.5)	119 (73.0)	107 (61.1)
Risk Difference[A]		23.2		11.9
Adjusted Risk Difference[A,B]		26.7		11.3
95% Confidence Interval[B]		(-6.4, 59.9)		(1.4, 21.2)
P-Value[B]		0.114		0.025*
Subjects with Fecal Calprotectin below 150 mg/kg at Week 52 (Week 44 of Maintenance Study)	(N=18)	(N=23)	(N=163)	(N=175)
Yes, n (%)	5 (27.8)	12 (52.2)	42 (25.8)	66 (37.7)
No, n (%)	13 (72.2)	11 (47.8)	121 (74.2)	109 (62.3)
Risk Difference[A]		24.4		11.9
Adjusted Risk Difference[A,B]		23.5		11.7
95% Confidence Interval[B]		(-9.0, 55.9)		(1.7, 21.8)
P-Value[B]		0.157		0.022*

[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: Adjusted risk difference, 95% confidence interval for the difference in the proportions between the treatment groups and P-value were calculated using Cochran-Mantel-Haenszel (CMH) test adjusted for induction treatment regimen and week 8 remission status.
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__3.21_J

表 2.7.3.6-182.　PMS による寛解達成までの期間（OC）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

	Japan Adalimumab 40mg EOW (N=18) n (%)	Japan Adalimumab 40mg EW (N=23) n (%)	Integrated Adalimumab 40mg EOW (N=163) n (%)	Integrated Adalimumab 40mg EW (N=175) n (%)
Number of Events				
Per Partial Mayo Score	13 (72.2)	20 (87.0)	135 (82.8)	146 (83.4)
Kaplan-Meier Method:				
Percentiles (Weeks)				
25th	2.0	2.0	2.0	2.0
Median	2.0	2.0	3.0	2.0
75th	NE[A]	8.0	16.0	14.0
Cox Proportional Hazards Model$:				
Hazards Ratio 40mg EW versus 40mg EOW		1.150		1.015
(%95 CI)		(0.564, 2.342)		(0.803, 1.284)
P-Value		0.701		0.900

Note: Clinical remission per Partial Mayo Score is defined as Partial Mayo Score <= 2, with no subscore > 1.
$ The covariates treatment, induction treatment regimen and week 8 remission status are included in the cox proportional hazards model.
Subjects who did not respond by week 52 were censored at last OC visit.

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__3.22_J

表 2.7.3.6-183.　PMS による改善達成までの時間（OC）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

	Japan		Integrated	
	Adalimumab		Adalimumab	
	40mg EOW (N=18) n (%)	40mg EW (N=23) n (%)	40mg EOW (N=163) n (%)	40mg EW (N=175) n (%)
Number of Events				
Per Partial Mayo Score	17 (94.4)	23 (100)	161 (98.8)	169 (96.6)
Kaplan-Meier Method:				
Percentiles (Weeks)				
25th	2.0	2.0	2.0	2.0
Median	2.0	2.0	2.0	2.0
75th	3.0	2.0	2.0	2.0
Cox Proportional Hazards Model$:				
Hazards Ratio 40mg EW versus 40mg EOW		1.223		1.018
(%95 CI)		(0.648, 2.310)		(0.820, 1.264)
P-Value		0.534		0.871

Note: Clinical response per Partial Mayo Score is defined as a decrease in Partial Mayo Score >= 2 points and>= 30% from baseline, plus a decrease in RBS >= 1 or an absolute RBS <= 1.
$ The covariates treatment, induction treatment regimen and week 8 remission status are included in the cox proportional hazards model.
Subjects who did not respond by week 52 were censored at last OC visit.

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__3.23_J

表 2.7.3.6-184.　PMS による改善消失までの時間（OC）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

	Japan Adalimumab 40mg EOW (N=18) n (%)	Japan Adalimumab 40mg EW (N=23) n (%)	Integrated Adalimumab 40mg EOW (N=163) n (%)	Integrated Adalimumab 40mg EW (N=175) n (%)
Number of Events				
Per Partial Mayo Score	9 (50.0)	5 (21.7)	74 (45.4)	56 (32.0)
Kaplan-Meier Method:				
Percentiles (Weeks)				
25th	8.0	NE[A]	14.0	27.0
Median	40.0	NE[A]	NE[A]	NE[A]
75th	NE[A]	NE[A]	NE[A]	NE[A]
Cox Proportional Hazards Model$:				
Hazards Ratio 40mg EW versus 40mg EOW		0.378		0.646
(%95 CI)		(0.126, 1.136)		(0.457, 0.915)
P-Value		0.083+		0.014*

Note: Clinical response per Partial Mayo Score is defined as a decrease in Partial Mayo Score >= 2 points and >= 30% from baseline, plus a decrease in RBS >= 1 or an absolute RBS <= 1.
$ The covariates treatment, induction treatment regimen and week 8 remission status are included in the cox proportional hazards model.
Subjects who did not lose response by week 52 were censored at last OC visit.
[A] Not estimable.
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__3.24_J

表 2.7.3.6-185.　治験期間中の腸管外合併症の有無の変化（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

Variable/ Treatment/ Baseline Value	Week 52 Yes N (%)	Week 52 No N (%)	Week 52 Missing N (%)
Japan			
ANEMIA			
Adalimumab 40mg EOW (N=18)			
Yes (N=5)	2 (40.0)	2 (40.0)	1 (20.0)
No (N=13)	0	13 (100)	0
Adalimumab 40mg EW (N=23)			
Yes (N=5)	1 (20.0)	4 (80.0)	0
No (N=18)	0	17 (94.4)	1 (5.6)
AUTOIMMUNE HEPATITIS			
Adalimumab 40mg EOW (N=18)			
Yes (N=0)	0	0	0
No (N=18)	0	17 (94.4)	1 (5.6)
Adalimumab 40mg EW (N=23)			
Yes (N=0)	0	0	0
No (N=23)	0	22 (95.7)	1 (4.3)

表 2.7.3.6-185.　治験期間中の腸管外合併症の有無の変化（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Variable/ Treatment/ Baseline Value	Week 52 Yes N (%)	Week 52 No N (%)	Week 52 Missing N (%)
Japan			
AXIAL ARTHROPATHY			
Adalimumab 40mg EOW (N=18)			
Yes (N=0)	0	0	0
No (N=18)	0	17 (94.4)	1 (5.6)
Adalimumab 40mg EW (N=23)			
Yes (N=0)	0	0	0
No (N=23)	0	22 (95.7)	1 (4.3)
BRONCHIECTASIS			
Adalimumab 40mg EOW (N=18)			
Yes (N=0)	0	0	0
No (N=18)	0	17 (94.4)	1 (5.6)
Adalimumab 40mg EW (N=23)			
Yes (N=0)	0	0	0
No (N=23)	0	22 (95.7)	1 (4.3)

表 2.7.3.6-185.　治験期間中の腸管外合併症の有無の変化（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Variable/ Treatment/ Baseline Value	Week 52 Yes N (%)	Week 52 No N (%)	Week 52 Missing N (%)
Japan			
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
Adalimumab 40mg EOW (N=18)			
Yes (N=0)	0	0	0
No (N=18)	0	17 (94.4)	1 (5.6)
Adalimumab 40mg EW (N=23)			
Yes (N=0)	0	0	0
No (N=23)	0	22 (95.7)	1 (4.3)
EPISCLERITIS			
Adalimumab 40mg EOW (N=18)			
Yes (N=1)	0	1 (100)	0
No (N=17)	0	16 (94.1)	1 (5.9)
Adalimumab 40mg EW (N=23)			
Yes (N=0)	0	0	0
No (N=23)	0	22 (95.7)	1 (4.3)

表 2.7.3.6-185.　治験期間中の腸管外合併症の有無の変化（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Variable/ Treatment/ Baseline Value	Week 52 Yes N (%)	Week 52 No N (%)	Week 52 Missing N (%)
Japan			
ERYTHEMA NODOSUM			
Adalimumab 40mg EOW (N=18)			
Yes (N=1)	0	1 (100)	0
No (N=17)	0	16 (94.1)	1 (5.9)
Adalimumab 40mg EW (N=23)			
Yes (N=0)	0	0	0
No (N=23)	0	22 (95.7)	1 (4.3)
IRITIS			
Adalimumab 40mg EOW (N=18)			
Yes (N=0)	0	0	0
No (N=18)	0	17 (94.4)	1 (5.6)
Adalimumab 40mg EW (N=23)			
Yes (N=0)	0	0	0
No (N=23)	0	22 (95.7)	1 (4.3)

表 2.7.3.6-185.　治験期間中の腸管外合併症の有無の変化（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Variable/ Treatment/ Baseline Value	Week 52 Yes N (%)	Week 52 No N (%)	Week 52 Missing N (%)
Japan			
NEPHROLITHIASIS			
Adalimumab 40mg EOW (N=18)			
Yes (N=0)	0	0	0
No (N=18)	0	17 (94.4)	1 (5.6)
Adalimumab 40mg EW (N=23)			
Yes (N=0)	0	0	0
No (N=23)	0	22 (95.7)	1 (4.3)
ORAL APHTHOUS ULCERS			
Adalimumab 40mg EOW (N=18)			
Yes (N=0)	0	0	0
No (N=18)	0	17 (94.4)	1 (5.6)
Adalimumab 40mg EW (N=23)			
Yes (N=1)	0	1 (100)	0
No (N=22)	0	21 (95.5)	1 (4.5)

表 2.7.3.6-185.　治験期間中の腸管外合併症の有無の変化（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Variable/ Treatment/ Baseline Value	Week 52 Yes N (%)	Week 52 No N (%)	Week 52 Missing N (%)
Japan			
PERIPHERAL ARTHROPATHY			
Adalimumab 40mg EOW (N=18)			
Yes (N=1)	0	1 (100)	0
No (N=17)	0	16 (94.1)	1 (5.9)
Adalimumab 40mg EW (N=23)			
Yes (N=0)	0	0	0
No (N=23)	0	22 (95.7)	1 (4.3)
PRIMARY SCLEROSING CHOLANGITIS			
Adalimumab 40mg EOW (N=18)			
Yes (N=0)	0	0	0
No (N=18)	0	17 (94.4)	1 (5.6)
Adalimumab 40mg EW (N=23)			
Yes (N=0)	0	0	0
No (N=23)	0	22 (95.7)	1 (4.3)

表 2.7.3.6-185.　治験期間中の腸管外合併症の有無の変化（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Variable/ Treatment/ Baseline Value	Week 52 Yes N (%)	Week 52 No N (%)	Week 52 Missing N (%)
Japan			
PYODERMA GANGRENOSUM			
Adalimumab 40mg EOW (N=18)			
Yes (N=0)	0	0	0
No (N=18)	0	17 (94.4)	1 (5.6)
Adalimumab 40mg EW (N=23)			
Yes (N=0)	0	0	0
No (N=23)	0	22 (95.7)	1 (4.3)
SWEET'S SYNDROME			
Adalimumab 40mg EOW (N=18)			
Yes (N=0)	0	0	0
No (N=18)	0	17 (94.4)	1 (5.6)
Adalimumab 40mg EW (N=23)			
Yes (N=0)	0	0	0
No (N=23)	0	22 (95.7)	1 (4.3)

表 2.7.3.6-185.　治験期間中の腸管外合併症の有無の変化（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Variable/ Treatment/ Baseline Value	Week 52 Yes N (%)	Week 52 No N (%)	Week 52 Missing N (%)
Japan			
UVEITIS			
Adalimumab 40mg EOW (N=18)			
Yes (N=0)	0	0	0
No (N=18)	0	17 (94.4)	1 (5.6)
Adalimumab 40mg EW (N=23)			
Yes (N=0)	0	0	0
No (N=23)	0	22 (95.7)	1 (4.3)
VENOUS THROMBOEMBOLISM			
Adalimumab 40mg EOW (N=18)			
Yes (N=0)	0	0	0
No (N=18)	0	17 (94.4)	1 (5.6)
Adalimumab 40mg EW (N=23)			
Yes (N=0)	0	0	0
No (N=23)	0	22 (95.7)	1 (4.3)

表 2.7.3.6-185.　治験期間中の腸管外合併症の有無の変化（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Variable/ Treatment/ Baseline Value	Week 52 Yes N (%)	Week 52 No N (%)	Week 52 Missing N (%)
Integrated			
ANEMIA			
Adalimumab 40mg EOW (N=163)			
Yes (N=30)	7 (23.3)	21 (70.0)	2 (6.7)
No (N=131)	2 (1.5)	112 (85.5)	17 (13.0)
Adalimumab 40mg EW (N=175)			
Yes (N=39)	6 (15.4)	31 (79.5)	2 (5.1)
No (N=129)	3 (2.3)	113 (87.6)	13 (10.1)
AUTOIMMUNE HEPATITIS			
Adalimumab 40mg EOW (N=163)			
Yes (N=1)	1 (100)	0	0
No (N=160)	1 (0.6)	139 (86.9)	20 (12.5)
Adalimumab 40mg EW (N=175)			
Yes (N=0)	0	0	0
No (N=168)	0	153 (91.1)	15 (8.9)

表 2.7.3.6-185.　治験期間中の腸管外合併症の有無の変化（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Variable/ Treatment/ Baseline Value	Week 52 Yes N (%)	Week 52 No N (%)	Week 52 Missing N (%)
Integrated			
AXIAL ARTHROPATHY			
Adalimumab 40mg EOW (N=163)			
Yes (N=6)	3 (50.0)	2 (33.3)	1 (16.7)
No (N=155)	1 (0.6)	136 (87.7)	18 (11.6)
Adalimumab 40mg EW (N=175)			
Yes (N=3)	0	1 (33.3)	2 (66.7)
No (N=165)	2 (1.2)	150 (90.9)	13 (7.9)
BRONCHIECTASIS			
Adalimumab 40mg EOW (N=163)			
Yes (N=0)	0	0	0
No (N=161)	0	141 (87.6)	20 (12.4)
Adalimumab 40mg EW (N=175)			
Yes (N=0)	0	0	0
No (N=168)	0	153 (91.1)	15 (8.9)

表 2.7.3.6-185.　治験期間中の腸管外合併症の有無の変化（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Variable/ Treatment/ Baseline Value	Week 52 Yes N (%)	Week 52 No N (%)	Week 52 Missing N (%)
Integrated			
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
Adalimumab 40mg EOW (N=163)			
Yes (N=1)	1 (100)	0	0
No (N=160)	0	140 (87.5)	20 (12.5)
Adalimumab 40mg EW (N=175)			
Yes (N=1)	0	1 (100)	0
No (N=167)	0	152 (91.0)	15 (9.0)
EPISCLERITIS			
Adalimumab 40mg EOW (N=163)			
Yes (N=1)	0	1 (100)	0
No (N=160)	0	140 (87.5)	20 (12.5)
Adalimumab 40mg EW (N=175)			
Yes (N=0)	0	0	0
No (N=168)	0	153 (91.1)	15 (8.9)

表 2.7.3.6-185.　治験期間中の腸管外合併症の有無の変化（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Variable/ Treatment/ Baseline Value	Week 52 Yes N (%)	Week 52 No N (%)	Week 52 Missing N (%)
Integrated			
ERYTHEMA NODOSUM			
Adalimumab 40mg EOW (N=163)			
Yes (N=1)	0	1 (100)	0
No (N=160)	0	141 (88.1)	19 (11.9)
Adalimumab 40mg EW (N=175)			
Yes (N=1)	0	1 (100)	0
No (N=167)	0	152 (91.0)	15 (9.0)
IRITIS			
Adalimumab 40mg EOW (N=163)			
Yes (N=0)	0	0	0
No (N=161)	0	141 (87.6)	20 (12.4)
Adalimumab 40mg EW (N=175)			
Yes (N=0)	0	0	0
No (N=168)	0	153 (91.1)	15 (8.9)

表 2.7.3.6-185.　治験期間中の腸管外合併症の有無の変化（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Variable/ Treatment/ Baseline Value	Week 52 Yes N (%)	Week 52 No N (%)	Week 52 Missing N (%)
Integrated			
NEPHROLITHIASIS			
Adalimumab 40mg EOW (N=163)			
Yes (N=1)	0	1 (100)	0
No (N=160)	0	141 (88.1)	19 (11.9)
Adalimumab 40mg EW (N=175)			
Yes (N=2)	1 (50.0)	1 (50.0)	0
No (N=166)	0	151 (91.0)	15 (9.0)
ORAL APHTHOUS ULCERS			
Adalimumab 40mg EOW (N=163)			
Yes (N=0)	0	0	0
No (N=161)	0	142 (88.2)	19 (11.8)
Adalimumab 40mg EW (N=175)			
Yes (N=2)	0	2 (100)	0
No (N=166)	0	151 (91.0)	15 (9.0)

表 2.7.3.6-185. 治験期間中の腸管外合併症の有無の変化（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Variable/ Treatment/ Baseline Value	Week 52 Yes N (%)	Week 52 No N (%)	Week 52 Missing N (%)
Integrated			
PERIPHERAL ARTHROPATHY			
Adalimumab 40mg EOW (N=163)			
Yes (N=16)	2 (12.5)	12 (75.0)	2 (12.5)
No (N=145)	5 (3.4)	123 (84.8)	17 (11.7)
Adalimumab 40mg EW (N=175)			
Yes (N=15)	2 (13.3)	10 (66.7)	3 (20.0)
No (N=153)	7 (4.6)	134 (87.6)	12 (7.8)
PRIMARY SCLEROSING CHOLANGITIS			
Adalimumab 40mg EOW (N=163)			
Yes (N=0)	0	0	0
No (N=161)	1 (0.6)	140 (87.0)	20 (12.4)
Adalimumab 40mg EW (N=175)			
Yes (N=1)	1 (100)	0	0
No (N=167)	0	152 (91.0)	15 (9.0)

表 2.7.3.6-185.　治験期間中の腸管外合併症の有無の変化（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Variable/ Treatment/ Baseline Value	Week 52 Yes N (%)	Week 52 No N (%)	Week 52 Missing N (%)
Integrated			
PYODERMA GANGRENOSUM			
Adalimumab 40mg EOW (N=163)			
Yes (N=0)	0	0	0
No (N=161)	0	142 (88.2)	19 (11.8)
Adalimumab 40mg EW (N=175)			
Yes (N=1)	0	1 (100)	0
No (N=167)	0	152 (91.0)	15 (9.0)
SWEET'S SYNDROME			
Adalimumab 40mg EOW (N=163)			
Yes (N=0)	0	0	0
No (N=161)	0	142 (88.2)	19 (11.8)
Adalimumab 40mg EW (N=175)			
Yes (N=0)	0	0	0
No (N=168)	0	153 (91.1)	15 (8.9)

表 2.7.3.6-185.　治験期間中の腸管外合併症の有無の変化（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Variable/ Treatment/ Baseline Value	Week 52 Yes N (%)	Week 52 No N (%)	Week 52 Missing N (%)
Integrated			
UVEITIS			
Adalimumab 40mg EOW (N=163)			
Yes (N=0)	0	0	0
No (N=161)	0	141 (87.6)	20 (12.4)
Adalimumab 40mg EW (N=175)			
Yes (N=0)	0	0	0
No (N=168)	0	153 (91.1)	15 (8.9)
VENOUS THROMBOEMBOLISM			
Adalimumab 40mg EOW (N=163)			
Yes (N=0)	0	0	0
No (N=161)	0	141 (87.6)	20 (12.4)
Adalimumab 40mg EW (N=175)			
Yes (N=0)	0	0	0
No (N=168)	0	153 (91.1)	15 (8.9)

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__3.25_J

表 2.7.3.6-186. 投与 8 週時に FMS により寛解を達成した被験者の割合（NRI）（ベースラインの免疫抑制剤の投与の有無別）（導入療法試験，ITT 集団，M14-033 主試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=340)	HIGHER INDUCTION DOSE (N=512)
BASELINE IMMUNOSUPPRESSANT USE (YES)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=81)	(N=131)
YES, n (%)	9 (11.1)	15 (11.5)
NO, n (%)	72 (88.9)	116 (88.5)
RISK DIFFERENCE[A]		0.3
95% CONFIDENCE INTERVAL[B]		(-8.4,9.1)
P-VALUE[C]		0.940
BASELINE IMMUNOSUPPRESSANT USE (NO)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=259)	(N=381)
YES, n (%)	28 (10.8)	53 (13.9)
NO, n (%)	231 (89.2)	328 (86.1)
RISK DIFFERENCE[A]		3.1
95% CONFIDENCE INTERVAL[B]		(-2.0,8.2)
P-VALUE[C]		0.247

CLINICAL REMISSION IS DEFINED AS FULL MAYO SCORE <= 2 WITH NO SUBSCORE > 1.
[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: 95% CONFIDENCE INTERVALS FOR RISK DIFFERENCE WERE CALCULATED BASED ON NORMAL APPROXIMATION USING PROC FREQ.
[C]: P-VALUE WAS CALCULATED BASED ON CHI-SQUARE TEST (OR FISHER'S EXACT TEST IF >= 20% OF THE CELLS HAVE EXPECTED CELL COUNT < 5).

Cross reference: M14-033 Induction_Main study Final CSR Table 14.2__4.5

表 2.7.3.6-187. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（ベースラインの副腎皮質ステロイドの投与の有無別）（導入療法試験，ITT 集団，M14-033 主試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=340)	HIGHER INDUCTION DOSE (N=512)
BASELINE CORTICOSTEROID USE (YES)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=208)	(N=296)
YES, n (%)	25 (12.0)	46 (15.5)
NO, n (%)	183 (88. 0)	250 (84.5)
RISK DIFFERENCE[A]		3.5
95% CONFIDENCE INTERVAL[B]		(-2.5,9.6)
P-VALUE[C]		0. 263
BASELINE CORTICOSTEROID USE (NO)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=132)	(N=216)
YES, n (%)	12 (9.1)	22 (10.2)
NO, n (%)	120 (90.9)	194 (89.8)
RISK DIFFERENCE[A]		1.1
95% CONFIDENCE INTERVAL[B]		(-5.3,7.4)
P-VALUE[C]		0.739

CLINICAL REMISSION IS DEFINED AS FULL MAYO SCORE <= 2 WITH NO SUBSCORE > 1.
[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: 95% CONFIDENCE INTERVALS FOR RISK DIFFERENCE WERE CALCULATED BASED ON NORMAL APPROXIMATION USING PROC FREQ.
[C]: P-VALUE WAS CALCULATED BASED ON CHI-SQUARE TEST (OR FISHER'S EXACT TEST IF >= 20% OF THE CELLS HAVE EXPECTED CELL COUNT < 5).

Cross reference: M14-033 Induction_Main study Final CSR Table 14.2__4.4

表 2.7.3.6-188.　投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（性別）（導入療法試験，ITT 集団，M14-033 主試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=340)	HIGHER INDUCTION DOSE (N=512)
GENDER (MALE)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=189)	(N=289)
YES, n (%)	18 (9.5)	34 (11.8)
NO, n (%)	171 (90.5)	255 (88.2)
RISK DIFFERENCE[A]		2.2
95% CONFIDENCE INTERVAL[B]		(-3.4,7.8)
P-VALUE[C]		0.442
GENDER (FEMALE)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=151)	(N=223)
YES, n (%)	19 (12.6)	34 (15.2)
NO, n (%)	132 (87.4)	189 (84.8)
RISK DIFFERENCE[A]		2.7
95% CONFIDENCE INTERVAL[B]		(-4.4,9.8)
P-VALUE[C]		0.469

CLINICAL REMISSION IS DEFINED AS FULL MAYO SCORE <= 2 WITH NO SUBSCORE > 1.
[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: 95% CONFIDENCE INTERVALS FOR RISK DIFFERENCE WERE CALCULATED BASED ON NORMAL APPROXIMATION USING PROC FREQ.
[C]: P-VALUE WAS CALCULATED BASED ON CHI-SQUARE TEST (OR FISHER'S EXACT TEST IF >= 20% OF THE CELLS HAVE EXPECTED CELL COUNT < 5).

Cross reference: M14-033 Induction_Main study Final CSR Table 14.2__4.1

表 2.7.3.6-189.　投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（年齢別）（導入療法試験，ITT 集団，M14-033 主試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=340)	HIGHER INDUCTION DOSE (N=512)
AGE <= MEDIAN (39.00 YEARS)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=176)	(N=266)
YES, n (%)	24 (13.6)	38 (14.3)
NO, n (%)	152 (86.4)	228 (85.7)
RISK DIFFERENCE[A]		0.6
95% CONFIDENCE INTERVAL[B]		(-5.9,7.2)
P-VALUE[C]		0.847
AGE > MEDIAN (39.00 YEARS)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=164)	(N=246)
YES, n (%)	13 (7.9)	30 (12.2)
NO, n (%)	151 (92.1)	216 (87.8)
RISK DIFFERENCE[A]		4.3
95% CONFIDENCE INTERVAL[B]		(-1.5,10.1)
P-VALUE[C]		0.167

CLINICAL REMISSION IS DEFINED AS FULL MAYO SCORE <= 2 WITH NO SUBSCORE > 1.
[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: 95% CONFIDENCE INTERVALS FOR RISK DIFFERENCE WERE CALCULATED BASED ON NORMAL APPROXIMATION USING PROC FREQ.
[C]: P-VALUE WAS CALCULATED BASED ON CHI-SQUARE TEST (OR FISHER'S EXACT TEST IF >= 20% OF THE CELLS HAVE EXPECTED CELL COUNT < 5).

Cross reference: M14-033 Induction_Main study Final CSR Table 14.2__4.2

表 2.7.3.6-190. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（人種別）（導入療法試験，ITT 集団，M14-033 主試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=340)	HIGHER INDUCTION DOSE (N=512)
RACE (WHITE)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=327)	(N=484)
YES, n (%)	36 (11.0)	60 (12.4)
NO, n (%)	291 (89.0)	424 (87.6)
RISK DIFFERENCE[A]		1.4
95% CONFIDENCE INTERVAL[B]		(-3.1,5.9)
P-VALUE[C]		0.549
RACE (NON-WHITE)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=13)	(N=27)
YES, n (%)	1 (7.7)	8 (29.6)
NO, n (%)	12 (92.3)	19 (70.4)
RISK DIFFERENCE[A]		21.9
95% CONFIDENCE INTERVAL[B]		(-0.6,44.4)
P-VALUE[C]		0.226
RACE (MISSING)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=0)	(N=1)
YES, n (%)	0	0
NO, n (%)	0	1 (100)

表 2.7.3.6-190. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（人種別）（導入療法試験，ITT 集団，M14-033 主試験）（続き）

CLINICAL REMISSION IS DEFINED AS FULL MAYO SCORE <= 2 WITH NO SUBSCORE > 1.
[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: 95% CONFIDENCE INTERVALS FOR RISK DIFFERENCE WERE CALCULATED BASED ON NORMAL APPROXIMATION USING PROC FREQ.
[C]: P-VALUE WAS CALCULATED BASED ON CHI-SQUARE TEST (OR FISHER'S EXACT TEST IF >= 20% OF THE CELLS HAVE EXPECTED CELL COUNT < 5).

Cross reference: M14-033 Induction_Main study Final CSR Table 14.2__4.3

表 2.7.3.6-191. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）［ベースラインの Mayo スコア（9 以下，9 を上回る）別］（導入療法試験，ITT 集団，M14-033 主試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=340)	HIGHER INDUCTION DOSE (N=512)
BASELINE FULL MAYO SCORE <= 9		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=220)	(N=283)
YES, n (%)	30 (13.6)	48 (17.0)
NO, n (%)	190 (86.4)	235 (83.0)
RISK DIFFERENCE[A]		3.3
95% CONFIDENCE INTERVAL[B]		(-3.0,9.6)
P-VALUE[C]		0.307
BASELINE FULL MAYO SCORE > 9		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=120)	(N=226)
YES, n (%)	7 (5.8)	20 (8.8)
NO, n (%)	113 (94.2)	206 (91.2)
RISK DIFFERENCE[A]		3.0
95% CONFIDENCE INTERVAL[B]		(-2.6,8.6)
P-VALUE[C]		0.319
BASELINE FULL MAYO SCORE (MISSING)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=0)	(N=3)
YES, n (%)	0	0
NO, n (%)	0	3 (100)

表 2.7.3.6-191.　投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）［ベースラインの Mayo スコア（9 以下，9 を上回る）別］（導入療法試験，ITT 集団，M14-033 主試験）（続き）

CLINICAL REMISSION IS DEFINED AS FULL MAYO SCORE <= 2 WITH NO SUBSCORE > 1.
[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: 95% CONFIDENCE INTERVALS FOR RISK DIFFERENCE WERE CALCULATED BASED ON NORMAL APPROXIMATION USING PROC FREQ.
[C]: P-VALUE WAS CALCULATED BASED ON CHI-SQUARE TEST (OR FISHER'S EXACT TEST IF >= 20% OF THE CELLS HAVE EXPECTED CELL COUNT < 5).

Cross reference: M14-033 Induction_Main study Final CSR Table 14.2__4.6

表 2.7.3.6-192. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）［ベースラインの Mayo スコア（中央値以下，中央値を上回る）］
（導入療法試験，ITT 集団，M14-033 主試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=340)	HIGHER INDUCTION DOSE (N=512)
BASELINE FULL MAYO SCORE <= MEDIAN (8.8)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=192)	(N=245)
YES, n (%)	28 (14.6)	42 (17.1)
NO, n (%)	164 (85.4)	203 (82.9)
RISK DIFFERENCE[A]		2.6
95% CONFIDENCE INTERVAL[B]		(-4.3,9.4)
P-VALUE[C]		0.469
BASELINE FULL MAYO SCORE > MEDIAN (8.8)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=148)	(N=264)
YES, n (%)	9 (6.1)	26 (9.8)
NO, n (%)	139 (93.9)	238 (90.2)
RISK DIFFERENCE[A]		3.8
95% CONFIDENCE INTERVAL[B]		(-1.5,9.0)
P-VALUE[C]		0.188
BASELINE FULL MAYO SCORE (MISSING)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=0)	(N=3)
YES, n (%)	0	0
NO, n (%)	0	3 (100)

表 2.7.3.6-192. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）［ベースラインの Mayo スコア（中央値以下，中央値を上回る）］（導入療法試験，ITT 集団，M14-033 主試験）（続き）

CLINICAL REMISSION IS DEFINED AS FULL MAYO SCORE <= 2 WITH NO SUBSCORE > 1.
[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: 95% CONFIDENCE INTERVALS FOR RISK DIFFERENCE WERE CALCULATED BASED ON NORMAL APPROXIMATION USING PROC FREQ.
[C]: P-VALUE WAS CALCULATED BASED ON CHI-SQUARE TEST (OR FISHER'S EXACT TEST IF >= 20% OF THE CELLS HAVE EXPECTED CELL COUNT < 5).

Cross reference: M14-033 Induction_Main study Final CSR Table 14.2__4.7

表 2.7.3.6-193. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（抗 TNF 製剤の治療歴の有無別）（導入療法試験，ITT 集団，M14-033 主試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=340)	HIGHER INDUCTION DOSE (N=512)
PRIOR EXPOSURE TO ANTI-TNF (YES)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=43)	(N=67)
YES, n (%)	4 (9.3)	4 (6.0)
NO, n (%)	39 (90.7)	63 (94.0)
RISK DIFFERENCE[A]		-3.3
95% CONFIDENCE INTERVAL[B]		(-13.7,7.0)
P-VALUE[C]		0.709
PRIOR EXPOSURE TO ANTI-TNF (NO)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=297)	(N=445)
YES, n (%)	33 (11.1)	64 (14.4)
NO, n (%)	264 (88.9)	381 (85.6)
RISK DIFFERENCE[A]		3.3
95% CONFIDENCE INTERVAL[B]		(-1.6,8.1)
P-VALUE[C]		0.195

CLINICAL REMISSION IS DEFINED AS FULL MAYO SCORE <= 2 WITH NO SUBSCORE > 1.
[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: 95% CONFIDENCE INTERVALS FOR RISK DIFFERENCE WERE CALCULATED BASED ON NORMAL APPROXIMATION USING PROC FREQ.
[C]: P-VALUE WAS CALCULATED BASED ON CHI-SQUARE TEST (OR FISHER'S EXACT TEST IF >= 20% OF THE CELLS HAVE EXPECTED CELL COUNT < 5).

Cross reference: M14-033 Induction_Main study Final CSR Table 14.2__4.8

表 2.7.3.6-194. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（ベースラインの体重別）（導入療法試験，ITT 集団，M14-033 主試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=340)	HIGHER INDUCTION DOSE (N=512)
BASELINE WEIGHT <= MEDIAN (74.05 KG)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=173)	(N=253)
YES, n (%)	22 (12.7)	46 (18.2)
NO, n (%)	151 (87.3)	207 (81.8)
RISK DIFFERENCE[A]		5.5
95% CONFIDENCE INTERVAL[B]		(-1.4,12.3)
P-VALUE[C]		0.130
BASELINE WEIGHT > MEDIAN (74.05 KG)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=167)	(N=259)
YES, n (%)	15 (9.0)	22 (8.5)
NO, n (%)	152 (91.0)	237 (91.5)
RISK DIFFERENCE[A]		-0.5
95% CONFIDENCE INTERVAL[B]		(-6.0,5.0)
P-VALUE[C]		0.861

CLINICAL REMISSION IS DEFINED AS FULL MAYO SCORE <= 2 WITH NO SUBSCORE > 1.
[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: 95% CONFIDENCE INTERVALS FOR RISK DIFFERENCE WERE CALCULATED BASED ON NORMAL APPROXIMATION USING PROC FREQ.
[C]: P-VALUE WAS CALCULATED BASED ON CHI-SQUARE TEST (OR FISHER'S EXACT TEST IF >= 20% OF THE CELLS HAVE EXPECTED CELL COUNT < 5).

Cross reference: M14-033 Induction_Main study Final CSR Table 14.2__4.9

表 2.7.3.6-195. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（ベースラインの全大腸炎の有無別）（導入療法試験，ITT 集団，M14-033 主試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=340)	HIGHER INDUCTION DOSE (N=512)
PRESENCE OF PANCOLITIS AT BASELINE (YES)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=151)	(N=245)
YES, n (%)	15 (9.9)	42 (17.1)
NO, n (%)	136 (90.1)	203 (82.9)
RISK DIFFERENCE[A]		7.2
95% CONFIDENCE INTERVAL[B]		(0.5,13.9)
P-VALUE[C]		0.047*
PRESENCE OF PANCOLITIS AT BASELINE (NO)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=189)	(N=267)
YES, n (%)	22 (11.6)	26 (9.7)
NO, n (%)	167 (88.4)	241 (90.3)
RISK DIFFERENCE[A]		-1.9
95% CONFIDENCE INTERVAL[B]		(-7.7,3.9)
P-VALUE[C]		0.514

表 2.7.3.6-195. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（ベースラインの全大腸炎の有無別）（導入療法試験，ITT 集団，M14-033 主試験）（続き）

CLINICAL REMISSION IS DEFINED AS FULL MAYO SCORE <= 2 WITH NO SUBSCORE > 1.
[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: 95% CONFIDENCE INTERVALS FOR RISK DIFFERENCE WERE CALCULATED BASED ON NORMAL APPROXIMATION USING PROC FREQ.
[C]: P-VALUE WAS CALCULATED BASED ON CHI-SQUARE TEST (OR FISHER'S EXACT TEST IF >= 20% OF THE CELLS HAVE EXPECTED CELL COUNT < 5).
***, **, *, + STATISTICALLY SIGNIFICANT AT 0.001, 0.01, 0.05 AND 0.1 LEVEL, RESPECTIVELY.

Cross reference: M14-033 Induction_Main study Final CSR Table 14.2__4.10

表 2.7.3.6-196. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（ベースライン時点での罹患期間別）（導入療法試験，ITT 集団，M14-033 主試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=340)	HIGHER INDUCTION DOSE (N=512)
DISEASE DURATION AT BASELINE <= MEDIAN (4.49 YEARS)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=175)	(N=251)
YES, n (%)	21 (12.0)	25 (10.0)
NO, n (%)	154 (88.0)	226 (90.0)
RISK DIFFERENCE[A]		-2.0
95% CONFIDENCE INTERVAL[B]		(-8.1,4.0)
P-VALUE[C]		0.505
DISEASE DURATION AT BASELINE > MEDIAN (4.49 YEARS)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=165)	(N=261)
YES, n (%)	16 (9.7)	43 (16.5)
NO, n (%)	149 (90.3)	218 (83.5)
RISK DIFFERENCE[A]		6.8
95% CONFIDENCE INTERVAL[B]		(0.4,13.2)
P-VALUE[C]		0.049*

表 2.7.3.6-196. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（ベースライン時点での罹患期間別）（導入療法試験，ITT 集団，M14-033 主試験）（続き）

CLINICAL REMISSION IS DEFINED AS FULL MAYO SCORE <= 2 WITH NO SUBSCORE > 1.
[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: 95% CONFIDENCE INTERVALS FOR RISK DIFFERENCE WERE CALCULATED BASED ON NORMAL APPROXIMATION USING PROC FREQ.
[C]: P-VALUE WAS CALCULATED BASED ON CHI-SQUARE TEST (OR FISHER'S EXACT TEST IF >= 20% OF THE CELLS HAVE EXPECTED CELL COUNT < 5).
***, **, *, + STATISTICALLY SIGNIFICANT AT 0.001, 0.01, 0.05 AND 0.1 LEVEL, RESPECTIVELY.

Cross reference: M14-033 Induction_Main study Final CSR Table 14.2__4.11

表 2.7.3.6-197. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）［ベースラインの高感度 CRP（5 mg/L 以下，5 mg/L を上回る）別］（導入療法試験，ITT 集団，M14-033 主試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=340)	HIGHER INDUCTION DOSE (N=512)
BASELINE HS-CRP <= 5 MG/L		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=172)	(N=259)
YES, n (%)	21 (12.2)	44 (17.0)
NO, n (%)	151 (87.8)	215 (83.0)
RISK DIFFERENCE[A]		4.8
95% CONFIDENCE INTERVAL[B]		(-1.9,11.5)
P-VALUE[C]		0.175
BASELINE HS-CRP > 5 MG/L		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=168)	(N=253)
YES, n (%)	16 (9.5)	24 (9.5)
NO, n (%)	152 (90.5)	229 (90.5)
RISK DIFFERENCE[A]		-0.0
95% CONFIDENCE INTERVAL[B]		(-5.8,5.7)
P-VALUE[C]		0.990

CLINICAL REMISSION IS DEFINED AS FULL MAYO SCORE <= 2 WITH NO SUBSCORE > 1.
[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: 95% CONFIDENCE INTERVALS FOR RISK DIFFERENCE WERE CALCULATED BASED ON NORMAL APPROXIMATION USING PROC FREQ.
[C]: P-VALUE WAS CALCULATED BASED ON CHI-SQUARE TEST (OR FISHER'S EXACT TEST IF >= 20% OF THE CELLS HAVE EXPECTED CELL COUNT < 5).

Cross reference: M14-033 Induction_Main study Final CSR Table 14.2__4.12

表 2.7.3.6-198. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）［ベースラインの高感度 CRP（中央値以下，中央値を上回る）別］
（導入療法試験，ITT 集団，M14-033 主試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=340)	HIGHER INDUCTION DOSE (N=512)
BASELINE HS-CRP <= MEDIAN (4.88 MG/L)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=171)	(N=255)
YES, n (%)	21 (12.3)	44 (17.3)
NO, n (%)	150 (87.7)	211 (82.7)
RISK DIFFERENCE[A]		5.0
95% CONFIDENCE INTERVAL[B]		(-1.8,11.7)
P-VALUE[C]		0.162
BASELINE HS-CRP > MEDIAN (4.88 MG/L)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=169)	(N=257)
YES, n (%)	16 (9.5)	24 (9.3)
NO, n (%)	153 (90.5)	233 (90.7)
RISK DIFFERENCE[A]		-0.1
95% CONFIDENCE INTERVAL[B]		(-5.8,5.5)
P-VALUE[C]		0.964

CLINICAL REMISSION IS DEFINED AS FULL MAYO SCORE <= 2 WITH NO SUBSCORE > 1.
[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: 95% CONFIDENCE INTERVALS FOR RISK DIFFERENCE WERE CALCULATED BASED ON NORMAL APPROXIMATION USING PROC FREQ.
[C]: P-VALUE WAS CALCULATED BASED ON CHI-SQUARE TEST (OR FISHER'S EXACT TEST IF >= 20% OF THE CELLS HAVE EXPECTED CELL COUNT < 5).

Cross reference: M14-033 Induction_Main study Final CSR Table 14.2__4.13

表 2.7.3.6-199. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（ベースラインのアルブミン別）（導入療法試験，ITT 集団，M14-033 主試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=340)	HIGHER INDUCTION DOSE (N=512)
BASELINE ALBUMIN <= MEDIAN (40.00 G/L)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=179)	(N=281)
YES, n (%)	13 (7.3)	33 (11.7)
NO, n (%)	166 (92.7)	248 (88.3)
RISK DIFFERENCE[A]		4.5
95% CONFIDENCE INTERVAL[B]		(-0.9,9.8)
P-VALUE[C]		0.118
BASELINE ALBUMIN > MEDIAN (40.00 G/L)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=161)	(N=231)
YES, n (%)	24 (14.9)	35 (15.2)
NO, n (%)	137 (85.1)	196 (84.8)
RISK DIFFERENCE[A]		0.2
95% CONFIDENCE INTERVAL[B]		(-6.9,7.4)
P-VALUE[C]		0.947

CLINICAL REMISSION IS DEFINED AS FULL MAYO SCORE <= 2 WITH NO SUBSCORE > 1.
[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: 95% CONFIDENCE INTERVALS FOR RISK DIFFERENCE WERE CALCULATED BASED ON NORMAL APPROXIMATION USING PROC FREQ.
[C]: P-VALUE WAS CALCULATED BASED ON CHI-SQUARE TEST (OR FISHER'S EXACT TEST IF >= 20% OF THE CELLS HAVE EXPECTED CELL COUNT < 5).

Cross reference: M14-033 Induction_Main study Final CSR Table 14.2__4.14

表 2.7.3.6-200.　投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（地域別）（導入療法試験，ITT 集団，M14-033 主試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=340)	HIGHER INDUCTION DOSE (N=512)
REGION (US)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=65)	(N=113)
YES, n (%)	6 (9.2)	12 (10.6)
NO, n (%)	59 (90.8)	101 (89.4)
RISK DIFFERENCE[A]		1.4
95% CONFIDENCE INTERVAL[B]		(-7.7,10.4)
P-VALUE[C]		0.767
REGION (NON-US)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=275)	(N=399)
YES, n (%)	31 (11.3)	56 (14.0)
NO, n (%)	244 (88.7)	343 (86.0)
RISK DIFFERENCE[A]		2.8
95% CONFIDENCE INTERVAL[B]		(-2.3,7.8)
P-VALUE[C]		0.293

CLINICAL REMISSION IS DEFINED AS FULL MAYO SCORE <= 2 WITH NO SUBSCORE > 1.
[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: 95% CONFIDENCE INTERVALS FOR RISK DIFFERENCE WERE CALCULATED BASED ON NORMAL APPROXIMATION USING PROC FREQ.
[C]: P-VALUE WAS CALCULATED BASED ON CHI-SQUARE TEST (OR FISHER'S EXACT TEST IF >= 20% OF THE CELLS HAVE EXPECTED CELL COUNT < 5).

Cross reference: M14-033 Induction_Main study Final CSR Table 14.2__4.15

表 2.7.3.6-201. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（性別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE	HIGHER INDUCTION DOSE
	(N=39)	(N=61)
JAPAN ITT SET		
GENDER (MALE)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=24)	(N=45)
YES, n (%)	5 (20.8)	8 (17.8)
NO, n (%)	19 (79.2)	37 (82.2)
RISK DIFFERENCE[A]		-3.1
95% CONFIDENCE INTERVAL[B]		(-22.8,16.7)
P-VALUE[C]		0.756
GENDER (FEMALE)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=15)	(N=16)
YES, n (%)	2 (13.3)	3 (18.8)
NO, n (%)	13 (86.7)	13 (81.3)
RISK DIFFERENCE[A]		5.4
95% CONFIDENCE INTERVAL[B]		(-20.3,31.1)
P-VALUE[C]		1.000

表 2.7.3.6-201. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（性別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=379)	HIGHER INDUCTION DOSE (N=573)
INTERGRATED ITT SET		
GENDER (MALE)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=213)	(N=334)
YES, n (%)	23 (10.8)	42 (12.6)
NO, n (%)	190 (89.2)	292 (87.4)
RISK DIFFERENCE[A]		1.8
95% CONFIDENCE INTERVAL[B]		(-3.7,7.3)
P-VALUE[C]		0.531
GENDER (FEMALE)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=166)	(N=239)
YES, n (%)	21 (12.7)	37 (15.5)
NO, n (%)	145 (87.3)	202 (84.5)
RISK DIFFERENCE[A]		2.8
95% CONFIDENCE INTERVAL[B]		(-4.0,9.7)
P-VALUE[C]		0.424

表 2.7.3.6-201. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（性別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=340)	HIGHER INDUCTION DOSE (N=512)
ITT SET		
GENDER (MALE)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=189)	(N=289)
YES, n (%)	18 (9.5)	34 (11.8)
NO, n (%)	171 (90.5)	255 (88.2)
RISK DIFFERENCE[A]		2.2
95% CONFIDENCE INTERVAL[B]		(-3.4,7.8)
P-VALUE[C]		0.442
GENDER (FEMALE)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=151)	(N=223)
YES, n (%)	19 (12.6)	34 (15.2)
NO, n (%)	132 (87.4)	189 (84.8)
RISK DIFFERENCE[A]		2.7
95% CONFIDENCE INTERVAL[B]		(-4.4,9.8)
P-VALUE[C]		0.469

表 2.7.3.6-201. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（性別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: 95% CONFIDENCE INTERVALS FOR RISK DIFFERENCE WERE CALCULATED BASED ON NORMAL APPROXIMATION USING PROC FREQ.
[C]: P-VALUE WAS CALCULATED BASED ON CHI-SQUARE TEST (OR FISHER'S EXACT TEST IF >= 20% OF THE CELLS HAVE EXPECTED CELL COUNT < 5).

Cross reference: M14-033 Induction_Japan Sub-study Final CSR Table 14.2__4.1_J

表 2.7.3.6-202. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（年齢別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE	HIGHER INDUCTION DOSE
	(N=39)	(N=61)
JAPAN ITT SET		
AGE <= MEDIAN (42.00 YEARS)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=18)	(N=34)
YES, n (%)	2 (11.1)	8 (23.5)
NO, n (%)	16 (88.9)	26 (76.5)
RISK DIFFERENCE[A]		12.4
95% CONFIDENCE INTERVAL[B]		(-7.9,32.8)
P-VALUE[C]		0.462
AGE > MEDIAN (42.00 YEARS)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=21)	(N=27)
YES, n (%)	5 (23.8)	3 (11.1)
NO, n (%)	16 (76.2)	24 (88.9)
RISK DIFFERENCE[A]		-12.7
95% CONFIDENCE INTERVAL[B]		(-34.4,9.0)
P-VALUE[C]		0.272

表 2.7.3.6-202. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（年齢別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=379)	HIGHER INDUCTION DOSE (N=573)
INTERGRATED ITT SET		
AGE <= MEDIAN (39.00 YEARS)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=191)	(N=293)
YES, n (%)	26 (13.6)	46 (15.7)
NO, n (%)	165 (86.4)	247 (84.3)
RISK DIFFERENCE[A]		2.1
95% CONFIDENCE INTERVAL[B]		(-4.3,8.5)
P-VALUE[C]		0.528
AGE > MEDIAN (39.00 YEARS)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=188)	(N=280)
YES, n (%)	18 (9.6)	33 (11.8)
NO, n (%)	170 (90.4)	247 (88.2)
RISK DIFFERENCE[A]		2.2
95% CONFIDENCE INTERVAL[B]		(-3.4,7.9)
P-VALUE[C]		0.452

表 2.7.3.6-202. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（年齢別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=340)	HIGHER INDUCTION DOSE (N=512)
ITT SET		
AGE <= MEDIAN (39.00 YEARS)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=176)	(N=266)
YES, n (%)	24 (13.6)	38 (14.3)
NO, n (%)	152 (86.4)	228 (85.7)
RISK DIFFERENCE[A]		0.6
95% CONFIDENCE INTERVAL[B]		(-5.9,7.2)
P-VALUE[C]		0.847
AGE > MEDIAN (39.00 YEARS)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=164)	(N=246)
YES, n (%)	13 (7.9)	30 (12.2)
NO, n (%)	151 (92.1)	216 (87.8)
RISK DIFFERENCE[A]		4.3
95% CONFIDENCE INTERVAL[B]		(-1.5,10.1)
P-VALUE[C]		0.167

表 2.7.3.6-202.　投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（年齢別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: 95% CONFIDENCE INTERVALS FOR RISK DIFFERENCE WERE CALCULATED BASED ON NORMAL APPROXIMATION USING PROC FREQ.
[C]: P-VALUE WAS CALCULATED BASED ON CHI-SQUARE TEST (OR FISHER'S EXACT TEST IF >= 20% OF THE CELLS HAVE EXPECTED CELL COUNT < 5).

Cross reference: M14-033 Induction_Japan Sub-study Final CSR Table 14.2__4.2_J

表 2.7.3.6-203. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（人種別）（導入療法試験，I-ITT 集団，M14-033 日本サブ試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=379)	HIGHER INDUCTION DOSE (N=573)
RACE (WHITE)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=327)	(N=484)
YES, n (%)	36 (11.0)	60 (12.4)
NO, n (%)	291 (89.0)	424 (87.6)
RISK DIFFERENCE[A]		1.4
95% CONFIDENCE INTERVAL[B]		(-3.1,5.9)
P-VALUE[C]		0.549
RACE (NON-WHITE)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=52)	(N=88)
YES, n (%)	8 (15.4)	19 (21.6)
NO, n (%)	44 (84.6)	69 (78.4)
RISK DIFFERENCE[A]		6.2
95% CONFIDENCE INTERVAL[B]		(-6.8,19.2)
P-VALUE[C]		0.368
RACE (MISSING)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=0)	(N=1)
YES, n (%)	0	0
NO, n (%)	0	1 (100)

表 2.7.3.6-203. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（人種別）（導入療法試験，I-ITT 集団，M14-033 日本サブ試験）（続き）

[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: 95% CONFIDENCE INTERVALS FOR RISK DIFFERENCE WERE CALCULATED BASED ON NORMAL APPROXIMATION USING PROC FREQ.
[C]: P-VALUE WAS CALCULATED BASED ON CHI-SQUARE TEST (OR FISHER'S EXACT TEST IF >= 20% OF THE CELLS HAVE EXPECTED CELL COUNT < 5).

Cross reference: M14-033 Induction_Japan Sub-study Final CSR Table 14.2__4.3_J

表 2.7.3.6-204. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（ベースラインの副腎皮質ステロイドの投与の有無別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=39)	HIGHER INDUCTION DOSE (N=61)
JAPAN ITT SET		
BASELINE CORTICOSTEROID USE (YES)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=19)	(N=32)
YES, n (%)	5 (26.3)	9 (28.1)
NO, n (%)	14 (73.7)	23 (71.9)
RISK DIFFERENCE[A]		1.8
95% CONFIDENCE INTERVAL[B]		(-23.4,27.0)
P-VALUE[C]		0.889
BASELINE CORTICOSTEROID USE (NO)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=20)	(N=29)
YES, n (%)	2 (10.0)	2 (6.9)
NO, n (%)	18 (90.0)	27 (93.1)
RISK DIFFERENCE[A]		-3.1
95% CONFIDENCE INTERVAL[B]		(-19.2,13.0)
P-VALUE[C]		1.000

表 2.7.3.6-204. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（ベースラインの副腎皮質ステロイドの投与の有無別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=379)	HIGHER INDUCTION DOSE (N=573)
INTERGRATED ITT SET		
BASELINE CORTICOSTEROID USE (YES)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=227)	(N=328)
YES, n (%)	30 (13.2)	55 (16.8)
NO, n (%)	197 (86.8)	273 (83.2)
RISK DIFFERENCE[A]		3.6
95% CONFIDENCE INTERVAL[B]		(-2.4,9.5)
P-VALUE[C]		0.253
BASELINE CORTICOSTEROID USE (NO)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=152)	(N=245)
YES, n (%)	14 (9.2)	24 (9.8)
NO, n (%)	138 (90.8)	221 (90.2)
RISK DIFFERENCE[A]		0.6
95% CONFIDENCE INTERVAL[B]		(-5.3,6.5)
P-VALUE[C]		0.847

表 2.7.3.6-204. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（ベースラインの副腎皮質ステロイドの投与の有無別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=340)	HIGHER INDUCTION DOSE (N=512)
ITT SET		
BASELINE CORTICOSTEROID USE (YES)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=208)	(N=296)
YES, n (%)	25 (12.0)	46 (15.5)
NO, n (%)	183 (88.0)	250 (84.5)
RISK DIFFERENCE[A]		3.5
95% CONFIDENCE INTERVAL[B]		(-2.5,9.6)
P-VALUE[C]		0.263
BASELINE CORTICOSTEROID USE (NO)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=132)	(N=216)
YES, n (%)	12 (9.1)	22 (10.2)
NO, n (%)	120 (90.9)	194 (89.8)
RISK DIFFERENCE[A]		1.1
95% CONFIDENCE INTERVAL[B]		(-5.3,7.4)
P-VALUE[C]		0.739

表 2.7.3.6-204. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（ベースラインの副腎皮質ステロイドの投与の有無別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: 95% CONFIDENCE INTERVALS FOR RISK DIFFERENCE WERE CALCULATED BASED ON NORMAL APPROXIMATION USING PROC FREQ.
[C]: P-VALUE WAS CALCULATED BASED ON CHI-SQUARE TEST (OR FISHER'S EXACT TEST IF >= 20% OF THE CELLS HAVE EXPECTED CELL COUNT < 5).

Cross reference: M14-033 Induction_Japan Sub-study Final CSR Table 14.2__4.4_J

表 2.7.3.6-205. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（ベースラインの免疫抑制剤の投与の有無別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=39)	HIGHER INDUCTION DOSE (N=61)
JAPAN ITT SET		
BASELINE IMMUNOSUPPRESSANT USE (YES)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=23)	(N=33)
YES, n (%)	5 (21.7)	3 (9.1)
NO, n (%)	18 (78.3)	30 (90.9)
RISK DIFFERENCE[A]		-12.6
95% CONFIDENCE INTERVAL[B]		(-32.2,6.9)
P-VALUE[C]		0.252
BASELINE IMMUNOSUPPRESSANT USE (NO)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=16)	(N=28)
YES, n (%)	2 (12.5)	8 (28.6)
NO, n (%)	14 (87.5)	20 (71.4)
RISK DIFFERENCE[A]		16.1
95% CONFIDENCE INTERVAL[B]		(-7.2,39.4)
P-VALUE[C]		0.283

表 2.7.3.6-205. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（ベースラインの免疫抑制剤の投与の有無別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=379)	HIGHER INDUCTION DOSE (N=573)
INTERGRATED ITT SET		
BASELINE IMMUNOSUPPRESSANT USE (YES)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=104)	(N=164)
YES, n (%)	14 (13.5)	18 (11.0)
NO, n (%)	90 (86.5)	146 (89.0)
RISK DIFFERENCE[A]		-2.5
95% CONFIDENCE INTERVAL[B]		(-10.6,5.6)
P-VALUE[C]		0.541
BASELINE IMMUNOSUPPRESSANT USE (NO)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=275)	(N=409)
YES, n (%)	30 (10.9)	61 (14.9)
NO, n (%)	245 (89.1)	348 (85.1)
RISK DIFFERENCE[A]		4.0
95% CONFIDENCE INTERVAL[B]		(-1.0,9.1)
P-VALUE[C]		0.130

表 2.7.3.6-205. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（ベースラインの免疫抑制剤の投与の有無別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=340)	HIGHER INDUCTION DOSE (N=512)
ITT SET		
BASELINE IMMUNOSUPPRESSANT USE (YES)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=81)	(N=131)
YES, n (%)	9 (11.1)	15 (11.5)
NO, n (%)	72 (88.9)	116 (88.5)
RISK DIFFERENCE[A]		0.3
95% CONFIDENCE INTERVAL[B]		(-8.4,9.1)
P-VALUE[C]		0.940
BASELINE IMMUNOSUPPRESSANT USE (NO)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=259)	(N=381)
YES, n (%)	28 (10.8)	53 (13.9)
NO, n (%)	231 (89.2)	328 (86.1)
RISK DIFFERENCE[A]		3.1
95% CONFIDENCE INTERVAL[B]		(-2.0,8.2)
P-VALUE[C]		0.247

表 2.7.3.6-205. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（ベースラインの免疫抑制剤の投与の有無別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: 95% CONFIDENCE INTERVALS FOR RISK DIFFERENCE WERE CALCULATED BASED ON NORMAL APPROXIMATION USING PROC FREQ.
[C]: P-VALUE WAS CALCULATED BASED ON CHI-SQUARE TEST (OR FISHER'S EXACT TEST IF >= 20% OF THE CELLS HAVE EXPECTED CELL COUNT < 5).

Cross reference: M14-033 Induction_Japan Sub-study Final CSR Table 14.2__4.5_J

表 2.7.3.6-206. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）［ベースラインの Mayo スコア（9 以下，9 を上回る）別］（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE	HIGHER INDUCTION DOSE
	(N=39)	(N=61)
JAPAN ITT SET		
BASELINE FULL MAYO SCORE <= 9		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=24)	(N=42)
YES, n (%)	3 (12.5)	7 (16.7)
NO, n (%)	21 (87.5)	35 (83.3)
RISK DIFFERENCE[A]		4.2
95% CONFIDENCE INTERVAL[B]		(-13.2,21.5)
P-VALUE[C]		0.736
BASELINE FULL MAYO SCORE > 9		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=15)	(N=19)
YES, n (%)	4 (26.7)	4 (21.1)
NO, n (%)	11 (73.3)	15 (78.9)
RISK DIFFERENCE[A]		-5.6
95% CONFIDENCE INTERVAL[B]		(-34.5,23.3)
P-VALUE[C]		1.000

表 2.7.3.6-206. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）［ベースラインの Mayo スコア（9 以下，9 を上回る）別］（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=379)	HIGHER INDUCTION DOSE (N=573)
INTERGRATED ITT SET		
BASELINE FULL MAYO SCORE <= 9		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=244)	(N=325)
YES, n (%)	33 (13.5)	55 (16.9)
NO, n (%)	211 (86.5)	270 (83.1)
RISK DIFFERENCE[A]		3.4
95% CONFIDENCE INTERVAL[B]		(-2.5,9.3)
P-VALUE[C]		0.267
BASELINE FULL MAYO SCORE > 9		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=135)	(N=245)
YES, n (%)	11 (8.1)	24 (9.8)
NO, n (%)	124 (91.9)	221 (90.2)
RISK DIFFERENCE[A]		1.6
95% CONFIDENCE INTERVAL[B]		(-4.3,7.6)
P-VALUE[C]		0.595

表 2.7.3.6-206. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）［ベースラインの Mayo スコア（9 以下，9 を上回る）別］（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=379)	HIGHER INDUCTION DOSE (N=573)
BASELINE FULL MAYO SCORE (MISSING)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=0)	(N=3)
YES, n (%)	0	0
NO, n (%)	0	3 (100)

表 2.7.3.6-206. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）［ベースラインの Mayo スコア（9 以下，9 を上回る）別］（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=340)	HIGHER INDUCTION DOSE (N=512)
ITT SET		
BASELINE FULL MAYO SCORE <= 9		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=220)	(N=283)
YES, n (%)	30 (13.6)	48 (17.0)
NO, n (%)	190 (86.4)	235 (83.0)
RISK DIFFERENCE[A]		3.3
95% CONFIDENCE INTERVAL[B]		(-3.0,9.6)
P-VALUE[C]		0.307
BASELINE FULL MAYO SCORE > 9		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=120)	(N=226)
YES, n (%)	7 (5.8)	20 (8.8)
NO, n (%)	113 (94.2)	206 (91.2)
RISK DIFFERENCE[A]		3.0
95% CONFIDENCE INTERVAL[B]		(-2.6,8.6)
P-VALUE[C]		0.319

表 2.7.3.6-206. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）［ベースラインの Mayo スコア（9 以下，9 を上回る）別］（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=340)	HIGHER INDUCTION DOSE (N=512)
BASELINE FULL MAYO SCORE (MISSING)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=0)	(N=3)
YES, n (%)	0	0
NO, n (%)	0	3 (100)

[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: 95% CONFIDENCE INTERVALS FOR RISK DIFFERENCE WERE CALCULATED BASED ON NORMAL APPROXIMATION USING PROC FREQ.
[C]: P-VALUE WAS CALCULATED BASED ON CHI-SQUARE TEST (OR FISHER'S EXACT TEST IF >= 20% OF THE CELLS HAVE EXPECTED CELL COUNT < 5).

Cross reference: M14-033 Induction_Japan Sub-study Final CSR Table 14.2__4.6_J

表 2.7.3.6-207. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）［ベースラインの Mayo スコア（中央値以下，中央値を上回る）］
（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=39)	HIGHER INDUCTION DOSE (N=61)
JAPAN ITT SET		
BASELINE FULL MAYO SCORE <= MEDIAN (8.3)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=21)	(N=29)
YES, n (%)	3 (14.3)	6 (20.7)
NO, n (%)	18 (85.7)	23 (79.3)
RISK DIFFERENCE[A]		6.4
95% CONFIDENCE INTERVAL[B]		(-14.6,27.4)
P-VALUE[C]		0.716
BASELINE FULL MAYO SCORE > MEDIAN (8.3)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=18)	(N=32)
YES, n (%)	4 (22.2)	5 (15.6)
NO, n (%)	14 (77.8)	27 (84.4)
RISK DIFFERENCE[A]		-6.6
95% CONFIDENCE INTERVAL[B]		(-29.6,16.4)
P-VALUE[C]		0.705

表 2.7.3.6-207. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）［ベースラインの Mayo スコア（中央値以下，中央値を上回る）］（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=379)	HIGHER INDUCTION DOSE (N=573)
INTERGRATED ITT SET		
BASELINE FULL MAYO SCORE <= MEDIAN (8.8)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=213)	(N=282)
YES, n (%)	31 (14.6)	49 (17.4)
NO, n (%)	182 (85.4)	233 (82.6)
RISK DIFFERENCE[A]		2.8
95% CONFIDENCE INTERVAL[B]		(-3.7,9.3)
P-VALUE[C]		0.398
BASELINE FULL MAYO SCORE > MEDIAN (8.8)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=166)	(N=288)
YES, n (%)	13 (7.8)	30 (10.4)
NO, n (%)	153 (92.2)	258 (89.6)
RISK DIFFERENCE[A]		2.6
95% CONFIDENCE INTERVAL[B]		(-2.8,8.0)
P-VALUE[C]		0.365
BASELINE FULL MAYO SCORE (MISSING)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=0)	(N=3)
YES, n (%)	0	0
NO, n (%)	0	3 (100)

表 2.7.3.6-207. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）［ベースラインの Mayo スコア（中央値以下，中央値を上回る）］（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=340)	HIGHER INDUCTION DOSE (N=512)
ITT SET		
BASELINE FULL MAYO SCORE <= MEDIAN (8.8)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=192)	(N=245)
YES, n (%)	28 (14.6)	42 (17.1)
NO, n (%)	164 (85.4)	203 (82.9)
RISK DIFFERENCE[A]		2.6
95% CONFIDENCE INTERVAL[B]		(-4.3,9.4)
P-VALUE[C]		0.469
BASELINE FULL MAYO SCORE > MEDIAN (8.8)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=148)	(N=264)
YES, n (%)	9 (6.1)	26 (9.8)
NO, n (%)	139 (93.9)	238 (90.2)
RISK DIFFERENCE[A]		3.8
95% CONFIDENCE INTERVAL[B]		(-1.5,9.0)
P-VALUE[C]		0.188

表 2.7.3.6-207. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）［ベースラインの Mayo スコア（中央値以下，中央値を上回る）］（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=340)	HIGHER INDUCTION DOSE (N=512)
BASELINE FULL MAYO SCORE (MISSING)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=0)	(N=3)
YES, n (%)	0	0
NO, n (%)	0	3 (100)

[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: 95% CONFIDENCE INTERVALS FOR RISK DIFFERENCE WERE CALCULATED BASED ON NORMAL APPROXIMATION USING PROC FREQ.
[C]: P-VALUE WAS CALCULATED BASED ON CHI-SQUARE TEST (OR FISHER'S EXACT TEST IF >= 20% OF THE CELLS HAVE EXPECTED CELL COUNT < 5).

Cross reference: M14-033 Induction_Japan Sub-study Final CSR Table 14.2__4.7_J

表 2.7.3.6-208. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（抗 TNF 製剤の治療歴の有無別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=39)	HIGHER INDUCTION DOSE (N=61)
JAPAN ITT SET		
PRIOR EXPOSURE TO ANTI-TNF (YES)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=10)	(N=15)
YES, n (%)	0	3 (20.0)
NO, n (%)	10 (100)	12 (80.0)
RISK DIFFERENCE[A]		20.0
95% CONFIDENCE INTERVAL[B]		(-0.2,40.2)
P-VALUE[C]		0.250
PRIOR EXPOSURE TO ANTI-TNF (NO)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=29)	(N=46)
YES, n (%)	7 (24.1)	8 (17.4)
NO, n (%)	22 (75.9)	38 (82.6)
RISK DIFFERENCE[A]		-6.7
95% CONFIDENCE INTERVAL[B]		(-25.8,12.3)
P-VALUE[C]		0.477

表 2.7.3.6-208. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（抗 TNF 製剤の治療歴の有無別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=379)	HIGHER INDUCTION DOSE (N=573)
INTERGRATED ITT SET		
PRIOR EXPOSURE TO ANTI-TNF (YES)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=53)	(N=82)
YES, n (%)	4 (7.5)	7 (8.5)
NO, n (%)	49 (92.5)	75 (91.5)
RISK DIFFERENCE[A]		1.0
95% CONFIDENCE INTERVAL[B]		(-8.3,10.3)
P-VALUE[C]		1.000
PRIOR EXPOSURE TO ANTI-TNF (NO)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=326)	(N=491)
YES, n (%)	40 (12.3)	72 (14.7)
NO, n (%)	286 (87.7)	419 (85.3)
RISK DIFFERENCE[A]		2.4
95% CONFIDENCE INTERVAL[B]		(-2.3,7.1)
P-VALUE[C]		0.330

表 2.7.3.6-208. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（抗 TNF 製剤の治療歴の有無別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=340)	HIGHER INDUCTION DOSE (N=512)
ITT SET		
PRIOR EXPOSURE TO ANTI-TNF (YES)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=43)	(N=67)
YES, n (%)	4 (9.3)	4 (6.0)
NO, n (%)	39 (90.7)	63 (94.0)
RISK DIFFERENCE[A]		-3.3
95% CONFIDENCE INTERVAL[B]		(-13.7,7.0)
P-VALUE[C]		0.709
PRIOR EXPOSURE TO ANTI-TNF (NO)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=297)	(N=445)
YES, n (%)	33 (11.1)	64 (14.4)
NO, n (%)	264 (88.9)	381 (85.6)
RISK DIFFERENCE[A]		3.3
95% CONFIDENCE INTERVAL[B]		(-1.6,8.1)
P-VALUE[C]		0.195

表 2.7.3.6-208.　投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（抗 TNF 製剤の治療歴の有無別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: 95% CONFIDENCE INTERVALS FOR RISK DIFFERENCE WERE CALCULATED BASED ON NORMAL APPROXIMATION USING PROC FREQ.
[C]: P-VALUE WAS CALCULATED BASED ON CHI-SQUARE TEST (OR FISHER'S EXACT TEST IF >= 20% OF THE CELLS HAVE EXPECTED CELL COUNT < 5).

Cross reference: M14-033 Induction_Japan Sub-study Final CSR Table 14.2__4.8_J

表 2.7.3.6-209. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（ベースラインの体重別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE	HIGHER INDUCTION DOSE
	(N=39)	(N=61)
JAPAN ITT SET		
BASELINE WEIGHT <= MEDIAN (61.95 KG)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=21)	(N=29)
YES, n (%)	1 (4.8)	4 (13.8)
NO, n (%)	20 (95.2)	25 (86.2)
RISK DIFFERENCE[A]		9.0
95% CONFIDENCE INTERVAL[B]		(-6.5,24.5)
P-VALUE[C]		0.383
BASELINE WEIGHT > MEDIAN (61.95 KG)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=18)	(N=32)
YES, n (%)	6 (33.3)	7 (21.9)
NO, n (%)	12 (66.7)	25 (78.1)
RISK DIFFERENCE[A]		-11.5
95% CONFIDENCE INTERVAL[B]		(-37.5,14.6)
P-VALUE[C]		0.504

表 2.7.3.6-209. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（ベースラインの体重別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=379)	HIGHER INDUCTION DOSE (N=573)
INTERGRATED ITT SET		
BASELINE WEIGHT <= MEDIAN (72.00 KG)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=193)	(N=286)
YES, n (%)	23 (11.9)	51 (17.8)
NO, n (%)	170 (88.1)	235 (82.2)
RISK DIFFERENCE[A]		5.9
95% CONFIDENCE INTERVAL[B]		(-0.5,12.3)
P-VALUE[C]		0.079+
BASELINE WEIGHT > MEDIAN (72.00 KG)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=186)	(N=287)
YES, n (%)	21 (11.3)	28 (9.8)
NO, n (%)	165 (88.7)	259 (90.2)
RISK DIFFERENCE[A]		-1.5
95% CONFIDENCE INTERVAL[B]		(-7.2,4.2)
P-VALUE[C]		0.593

表 2.7.3.6-209. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（ベースラインの体重別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=340)	HIGHER INDUCTION DOSE (N=512)
ITT SET		
BASELINE WEIGHT <= MEDIAN (74.05 KG)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=173)	(N=253)
YES, n (%)	22 (12.7)	46 (18.2)
NO, n (%)	151 (87.3)	207 (81.8)
RISK DIFFERENCE[A]		5.5
95% CONFIDENCE INTERVAL[B]		(-1.4,12.3)
P-VALUE[C]		0.130
BASELINE WEIGHT > MEDIAN (74.05 KG)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=167)	(N=259)
YES, n (%)	15 (9.0)	22 (8.5)
NO, n (%)	152 (91.0)	237 (91.5)
RISK DIFFERENCE[A]		-0.5
95% CONFIDENCE INTERVAL[B]		(-6.0,5.0)
P-VALUE[C]		0.861

表 2.7.3.6-209. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）（ベースラインの体重別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: 95% CONFIDENCE INTERVALS FOR RISK DIFFERENCE WERE CALCULATED BASED ON NORMAL APPROXIMATION USING PROC FREQ.
[C]: P-VALUE WAS CALCULATED BASED ON CHI-SQUARE TEST (OR FISHER'S EXACT TEST IF >= 20% OF THE CELLS HAVE EXPECTED CELL COUNT < 5).
***, **, *, + STATISTICALLY SIGNIFICANT AT 0.001, 0.01, 0.05 AND 0.1 LEVEL, RESPECTIVELY.

Cross reference: M14-033 Induction_Japan Sub-study Final CSR Table 14.2__4.9_J

表 2.7.3.6-210. 投与 8 週時に FMS により寛解を達成した被験者の割合（NRI）（ベースラインの全大腸炎の有無別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=39)	HIGHER INDUCTION DOSE (N=61)
JAPAN ITT SET		
PRESENCE OF PANCOLITIS AT BASELINE (YES)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=23)	(N=35)
YES, n (%)	5 (21.7)	7 (20.0)
NO, n (%)	18 (78.3)	28 (80.0)
RISK DIFFERENCE[A]		-1.7
95% CONFIDENCE INTERVAL[B]		(-23.2,19.7)
P-VALUE[C]		1.000
PRESENCE OF PANCOLITIS AT BASELINE (NO)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=16)	(N=26)
YES, n (%)	2 (12.5)	4 (15.4)
NO, n (%)	14 (87.5)	22 (84.6)
RISK DIFFERENCE[A]		2.9
95% CONFIDENCE INTERVAL[B]		(-18.4,24.2)
P-VALUE[C]		1.000

表 2.7.3.6-210. 投与 8 週時に FMS により寛解を達成した被験者の割合（NRI）（ベースラインの全大腸炎の有無別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=379)	HIGHER INDUCTION DOSE (N=573)
INTERGRATED ITT SET		
PRESENCE OF PANCOLITIS AT BASELINE (YES)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=174)	(N=280)
YES, n (%)	20 (11.5)	49 (17.5)
NO, n (%)	154 (88.5)	231 (82.5)
RISK DIFFERENCE[A]		6.0
95% CONFIDENCE INTERVAL[B]		(-0.5,12.5)
P-VALUE[C]		0.083+
PRESENCE OF PANCOLITIS AT BASELINE (NO)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=205)	(N=293)
YES, n (%)	24 (11.7)	30 (10.2)
NO, n (%)	181 (88.3)	263 (89.8)
RISK DIFFERENCE[A]		-1.5
95% CONFIDENCE INTERVAL[B]		(-7.1,4.1)
P-VALUE[C]		0.604

表 2.7.3.6-210. 投与 8 週時に FMS により寛解を達成した被験者の割合（NRI）（ベースラインの全大腸炎の有無別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=340)	HIGHER INDUCTION DOSE (N=512)
ITT SET		
PRESENCE OF PANCOLITIS AT BASELINE (YES)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=151)	(N=245)
YES, n (%)	15 (9.9)	42 (17.1)
NO, n (%)	136 (90.1)	203 (82.9)
RISK DIFFERENCE[A]		7.2
95% CONFIDENCE INTERVAL[B]		(0.5,13.9)
P-VALUE[C]		0.047*
PRESENCE OF PANCOLITIS AT BASELINE (NO)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=189)	(N=267)
YES, n (%)	22 (11.6)	26 (9.7)
NO, n (%)	167 (88.4)	241 (90.3)
RISK DIFFERENCE[A]		-1.9
95% CONFIDENCE INTERVAL[B]		(-7.7,3.9)
P-VALUE[C]		0.514

表 2.7.3.6-210. 投与 8 週時に FMS により寛解を達成した被験者の割合（NRI）（ベースラインの全大腸炎の有無別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: 95% CONFIDENCE INTERVALS FOR RISK DIFFERENCE WERE CALCULATED BASED ON NORMAL APPROXIMATION USING PROC FREQ.
[C]: P-VALUE WAS CALCULATED BASED ON CHI-SQUARE TEST (OR FISHER'S EXACT TEST IF >= 20% OF THE CELLS HAVE EXPECTED CELL COUNT < 5).
***, **, *, + STATISTICALLY SIGNIFICANT AT 0.001, 0.01, 0.05 AND 0.1 LEVEL, RESPECTIVELY.

Cross reference: M14-033 Induction_Japan Sub-study Final CSR Table 14.2__4.10_J

表 2.7.3.6-211. 投与 8 週時に FMS により寛解を達成した被験者の割合（NRI）（ベースライン時点での罹患期間別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=39)	HIGHER INDUCTION DOSE (N=61)
JAPAN ITT SET		
DISEASE DURATION AT BASELINE <= MEDIAN (5.07 YEARS)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=21)	(N=29)
YES, n (%)	2 (9.5)	8 (27.6)
NO, n (%)	19 (90.5)	21 (72.4)
RISK DIFFERENCE[A]		18.1
95% CONFIDENCE INTERVAL[B]		(-2.5,38.6)
P-VALUE[C]		0.160
DISEASE DURATION AT BASELINE > MEDIAN (5.07 YEARS)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=18)	(N=32)
YES, n (%)	5 (27.8)	3 (9.4)
NO, n (%)	13 (72.2)	29 (90.6)
RISK DIFFERENCE[A]		-18.4
95% CONFIDENCE INTERVAL[B]		(-41.4,4.6)
P-VALUE[C]		0.118

表 2.7.3.6-211. 投与 8 週時に FMS により寛解を達成した被験者の割合（NRI）（ベースライン時点での罹患期間別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=379)	HIGHER INDUCTION DOSE (N=573)
INTERGRATED ITT SET		
DISEASE DURATION AT BASELINE <= MEDIAN (4.53 YEARS)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=198)	(N=278)
YES, n (%)	23 (11.6)	32 (11.5)
NO, n (%)	175 (88.4)	246 (88.5)
RISK DIFFERENCE[A]		-0.1
95% CONFIDENCE INTERVAL[B]		(-5.9,5.7)
P-VALUE[C]		0.972
DISEASE DURATION AT BASELINE > MEDIAN (4.53 YEARS)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=181)	(N=295)
YES, n (%)	21 (11.6)	47 (15.9)
NO, n (%)	160 (88.4)	248 (84.1)
RISK DIFFERENCE[A]		4.3
95% CONFIDENCE INTERVAL[B]		(-1.9,10.6)
P-VALUE[C]		0.190

表 2.7.3.6-211. 投与 8 週時に FMS により寛解を達成した被験者の割合（NRI）（ベースライン時点での罹患期間別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=340)	HIGHER INDUCTION DOSE (N=512)
ITT SET		
DISEASE DURATION AT BASELINE <= MEDIAN (4.49 YEARS)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=175)	(N=251)
YES, n (%)	21 (12.0)	25 (10.0)
NO, n (%)	154 (88.0)	226 (90.0)
RISK DIFFERENCE[A]		-2.0
95% CONFIDENCE INTERVAL[B]		(-8.1,4.0)
P-VALUE[C]		0.505
DISEASE DURATION AT BASELINE > MEDIAN (4.49 YEARS)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=165)	(N=261)
YES, n (%)	16 (9.7)	43 (16.5)
NO, n (%)	149 (90.3)	218 (83.5)
RISK DIFFERENCE[A]		6.8
95% CONFIDENCE INTERVAL[B]		(0.4,13.2)
P-VALUE[C]		0.049*

表 2.7.3.6-211.　投与 8 週時に FMS により寛解を達成した被験者の割合（NRI）（ベースライン時点での罹患期間別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: 95% CONFIDENCE INTERVALS FOR RISK DIFFERENCE WERE CALCULATED BASED ON NORMAL APPROXIMATION USING PROC FREQ.
[C]: P-VALUE WAS CALCULATED BASED ON CHI-SQUARE TEST (OR FISHER'S EXACT TEST IF >= 20% OF THE CELLS HAVE EXPECTED CELL COUNT < 5).
***, **, *, + STATISTICALLY SIGNIFICANT AT 0.001, 0.01, 0.05 AND 0.1 LEVEL, RESPECTIVELY.

Cross reference: M14-033 Induction_Japan Sub-study Final CSR Table 14.2__4.11_J

表 2.7.3.6-212. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）［ベースラインの高感度 CRP（5 mg/L 以下，5 mg/L を上回る）別］（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=39)	HIGHER INDUCTION DOSE (N=61)
JAPAN ITT SET		
BASELINE HS-CRP <= 5 MG/L		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=24)	(N=41)
YES, n (%)	6 (25.0)	9 (22.0)
NO, n (%)	18 (75.0)	32 (78.0)
RISK DIFFERENCE[A]		-3.0
95% CONFIDENCE INTERVAL[B]		(-24.5,18.4)
P-VALUE[C]		0.778
BASELINE HS-CRP > 5 MG/L		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=15)	(N=20)
YES, n (%)	1 (6.7)	2 (10.0)
NO, n (%)	14 (93.3)	18 (90.0)
RISK DIFFERENCE[A]		3.3
95% CONFIDENCE INTERVAL[B]		(-14.9,21.6)
P-VALUE[C]		1.000

表 2.7.3.6-212. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）［ベースラインの高感度 CRP（5 mg/L 以下，5 mg/L を上回る）別］（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=379)	HIGHER INDUCTION DOSE (N=573)
INTERGRATED ITT SET		
BASELINE HS-CRP <= 5 MG/L		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=196)	(N=300)
YES, n (%)	27 (13.8)	53 (17.7)
NO, n (%)	169 (86.2)	247 (82.3)
RISK DIFFERENCE[A]		3.9
95% CONFIDENCE INTERVAL[B]		(-2.6,10.4)
P-VALUE[C]		0.249
BASELINE HS-CRP > 5 MG/L		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=183)	(N=273)
YES, n (%)	17 (9.3)	26 (9.5)
NO, n (%)	166 (90.7)	247 (90.5)
RISK DIFFERENCE[A]		0.2
95% CONFIDENCE INTERVAL[B]		(-5.2,5.7)
P-VALUE[C]		0.933

表 2.7.3.6-212. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）［ベースラインの高感度 CRP（5 mg/L 以下，5 mg/L を上回る）別］（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=340)	HIGHER INDUCTION DOSE (N=512)
ITT SET		
BASELINE HS-CRP <= 5 MG/L		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=172)	(N=259)
YES, n (%)	21 (12.2)	44 (17.0)
NO, n (%)	151 (87.8)	215 (83.0)
RISK DIFFERENCE[A]		4.8
95% CONFIDENCE INTERVAL[B]		(-1.9,11.5)
P-VALUE[C]		0.175
BASELINE HS-CRP > 5 MG/L		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=168)	(N=253)
YES, n (%)	16 (9.5)	24 (9.5)
NO, n (%)	152 (90.5)	229 (90.5)
RISK DIFFERENCE[A]		-0.0
95% CONFIDENCE INTERVAL[B]		(-5.8,5.7)
P-VALUE[C]		0.990

表 2.7.3.6-212.　投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）［ベースラインの高感度 CRP（5 mg/L 以下，5 mg/L を上回る）別］（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: 95% CONFIDENCE INTERVALS FOR RISK DIFFERENCE WERE CALCULATED BASED ON NORMAL APPROXIMATION USING PROC FREQ.
[C]: P-VALUE WAS CALCULATED BASED ON CHI-SQUARE TEST (OR FISHER'S EXACT TEST IF >= 20% OF THE CELLS HAVE EXPECTED CELL COUNT < 5).

Cross reference: M14-033 Induction_Japan Sub-study Final CSR Table 14.2__4.12_J

表 2.7.3.6-213. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）［ベースラインの高感度 CRP（中央値以下，中央値を上回る）別］
（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE	HIGHER INDUCTION DOSE
	(N=39)	(N=61)
JAPAN ITT SET		
BASELINE HS-CRP <= MEDIAN (2.78 MG/L)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=19)	(N=31)
YES, n (%)	4 (21.1)	9 (29.0)
NO, n (%)	15 (78.9)	22 (71.0)
RISK DIFFERENCE[A]		8.0
95% CONFIDENCE INTERVAL[B]		(-16.3,32.3)
P-VALUE[C]		0.742
BASELINE HS-CRP > MEDIAN (2.78 MG/L)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=20)	(N=30)
YES, n (%)	3 (15.0)	2 (6.7)
NO, n (%)	17 (85.0)	28 (93.3)
RISK DIFFERENCE[A]		-8.3
95% CONFIDENCE INTERVAL[B]		(-26.3,9.7)
P-VALUE[C]		0.377

表 2.7.3.6-213. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）［ベースラインの高感度 CRP（中央値以下，中央値を上回る）別］（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=379)	HIGHER INDUCTION DOSE (N=573)
INTERGRATED ITT SET		
BASELINE HS-CRP <= MEDIAN (4.60 MG/L)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=186)	(N=290)
YES, n (%)	26 (14.0)	52 (17.9)
NO, n (%)	160 (86.0)	238 (82.1)
RISK DIFFERENCE[A]		4.0
95% CONFIDENCE INTERVAL[B]		(-2.7,10.6)
P-VALUE[C]		0.256
BASELINE HS-CRP > MEDIAN (4.60 MG/L)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=193)	(N=283)
YES, n (%)	18 (9.3)	27 (9.5)
NO, n (%)	175 (90.7)	256 (90.5)
RISK DIFFERENCE[A]		0.2
95% CONFIDENCE INTERVAL[B]		(-5.1,5.6)
P-VALUE[C]		0.937

表 2.7.3.6-213. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）［ベースラインの高感度 CRP（中央値以下，中央値を上回る）別］（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=340)	HIGHER INDUCTION DOSE (N=512)
ITT SET		
BASELINE HS-CRP <= MEDIAN (4.88 MG/L)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=171)	(N=255)
YES, n (%)	21 (12.3)	44 (17.3)
NO, n (%)	150 (87.7)	211 (82.7)
RISK DIFFERENCE[A]		5.0
95% CONFIDENCE INTERVAL[B]		(-1.8,11.7)
P-VALUE[C]		0.162
BASELINE HS-CRP > MEDIAN (4.88 MG/L)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=169)	(N=257)
YES, n (%)	16 (9.5)	24 (9.3)
NO, n (%)	153 (90.5)	233 (90.7)
RISK DIFFERENCE[A]		-0.1
95% CONFIDENCE INTERVAL[B]		(-5.8,5.5)
P-VALUE[C]		0.964

表 2.7.3.6-213. 投与 8 週時に Mayo スコアにより寛解を達成した被験者の割合（NRI）［ベースラインの高感度 CRP（中央値以下，中央値を上回る）別］（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: 95% CONFIDENCE INTERVALS FOR RISK DIFFERENCE WERE CALCULATED BASED ON NORMAL APPROXIMATION USING PROC FREQ.
[C]: P-VALUE WAS CALCULATED BASED ON CHI-SQUARE TEST (OR FISHER'S EXACT TEST IF >= 20% OF THE CELLS HAVE EXPECTED CELL COUNT < 5).

Cross reference: M14-033 Induction_Japan Sub-study Final CSR Table 14.2__4.13_J

表 2.7.3.6-214. 投与 8 週時に FMS により寛解を達成した被験者の割合（NRI）（ベースラインのアルブミン別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=39)	HIGHER INDUCTION DOSE (N=61)
JAPAN ITT SET		
BASELINE ALBUMIN <= MEDIAN (40.00 G/L)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=23)	(N=32)
YES, n (%)	5 (21.7)	1 (3.1)
NO, n (%)	18 (78.3)	31 (96.9)
RISK DIFFERENCE[A]		-18.6
95% CONFIDENCE INTERVAL[B]		(-36.5,-0.7)
P-VALUE[C]		0.072+
BASELINE ALBUMIN > MEDIAN (40.00 G/L)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=16)	(N=29)
YES, n (%)	2 (12.5)	10 (34.5)
NO, n (%)	14 (87.5)	19 (65.5)
RISK DIFFERENCE[A]		22.0
95% CONFIDENCE INTERVAL[B]		(-1.7,45.7)
P-VALUE[C]		0.164

表 2.7.3.6-214. 投与 8 週時に FMS により寛解を達成した被験者の割合（NRI）（ベースラインのアルブミン別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=379)	HIGHER INDUCTION DOSE (N=573)
INTERGRATED ITT SET		
BASELINE ALBUMIN <= MEDIAN (40.00 G/L)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=202)	(N=313)
YES, n (%)	18 (8.9)	34 (10.9)
NO, n (%)	184 (91.1)	279 (89.1)
RISK DIFFERENCE[A]		2.0
95% CONFIDENCE INTERVAL[B]		(-3.3,7.2)
P-VALUE[C]		0.473
BASELINE ALBUMIN > MEDIAN (40.00 G/L)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=177)	(N=260)
YES, n (%)	26 (14.7)	45 (17.3)
NO, n (%)	151 (85.3)	215 (82.7)
RISK DIFFERENCE[A]		2.6
95% CONFIDENCE INTERVAL[B]		(-4.3,9.6)
P-VALUE[C]		0.466

表 2.7.3.6-214. 投与 8 週時に FMS により寛解を達成した被験者の割合（NRI）（ベースラインのアルブミン別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

	ADALIMUMAB	
	STANDARD INDUCTION DOSE (N=340)	HIGHER INDUCTION DOSE (N=512)
ITT SET		
BASELINE ALBUMIN <= MEDIAN (40.00 G/L)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=179)	(N=281)
YES, n (%)	13 (7.3)	33 (11.7)
NO, n (%)	166 (92.7)	248 (88.3)
RISK DIFFERENCE[A]		4.5
95% CONFIDENCE INTERVAL[B]		(-0.9,9.8)
P-VALUE[C]		0.118
BASELINE ALBUMIN > MEDIAN (40.00 G/L)		
CLINICAL REMISSION PER FULL MAYO SCORE AT WEEK 8	(N=161)	(N=231)
YES, n (%)	24 (14.9)	35 (15.2)
NO, n (%)	137 (85.1)	196 (84.8)
RISK DIFFERENCE[A]		0.2
95% CONFIDENCE INTERVAL[B]		(-6.9,7.4)
P-VALUE[C]		0.947

表 2.7.3.6-214.　投与 8 週時に FMS により寛解を達成した被験者の割合（NRI）（ベースラインのアルブミン別）（導入療法試験，J-ITT 集団，I-ITT 集団，ITT 集団，M14-033 日本サブ試験）（続き）

[A]: RISK DIFFERENCE = (ADALIMUMAB HIGHER INDUCTION DOSE - ADALIMUMAB STANDARD INDUCTION DOSE).
[B]: 95% CONFIDENCE INTERVALS FOR RISK DIFFERENCE WERE CALCULATED BASED ON NORMAL APPROXIMATION USING PROC FREQ.
[C]: P-VALUE WAS CALCULATED BASED ON CHI-SQUARE TEST (OR FISHER'S EXACT TEST IF >= 20% OF THE CELLS HAVE EXPECTED CELL COUNT < 5).
***, **, *, + STATISTICALLY SIGNIFICANT AT 0.001, 0.01, 0.05 AND 0.1 LEVEL, RESPECTIVELY.

Cross reference: M14-033 Induction_Japan Sub-study Final CSR Table 14.2__4.14_J

表 2.7.3.6-215. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（性別）（維持療法試験，ITT-RP 集団，M14-033 主試験）

	Adalimumab	
	40mg EOW (N=145)	40mg EW (N=152)
Gender (Male)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=83)	(N=85)
Yes, n (%)	19 (22.9)	34 (40.0)
No, n (%)	64 (77.1)	51 (60.0)
Risk Difference[A]		17.1
95% Confidence Interval[B]		(3.3,30.9)
P-Value[C]		0.017*
Gender (Female)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=62)	(N=67)
Yes, n (%)	23 (37.1)	26 (38.8)
No, n (%)	39 (62.9)	41 (61.2)
Risk Difference[A]		1.7
95% Confidence Interval[B]		(-15.0,18.5)
P-Value[C]		0.842

Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided by the central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: 95% Confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[C]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count< 5).
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__4.1

表 2.7.3.6-216. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（年齢別）（維持療法試験，ITT-RP 集団，M14-033 主試験）

	Adalimumab	
	40mg EOW (N=145)	40mg EW (N=152)
Age <= Median (38.00 years)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=78)	(N=69)
Yes, n (%)	21 (26.9)	25 (36.2)
No, n (%)	57 (73.1)	44 (63.8)
Risk Difference[A]		9.3
95% Confidence Interval[B]		(-5.7,24.3)
P-Value[C]		0.224
Age > Median (38.00 years)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=67)	(N=83)
Yes, n (%)	21 (31.3)	35 (42.2)
No, n (%)	46 (68.7)	48 (57.8)
Risk Difference[A]		10.8
95% Confidence Interval[B]		(-4.5,26.2)
P-Value[C]		0.173

Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided by the central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: 95% Confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[C]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count< 5).

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__4.2

表 2.7.3.6-217. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（人種別）（維持療法試験，ITT-RP 集団，M14-033 主試験）

	Adalimumab	
	40mg EOW (N=145)	40mg EW (N=152)
Race (White)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=138)	(N=145)
Yes, n (%)	41 (29.7)	57 (39.3)
No, n (%)	97 (70.3)	88 (60.7)
Risk Difference[A]		9.6
95% Confidence Interval[B]		(-1.4,20.6)
P-Value[C]		0.090+
Race (Non-white)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=7)	(N=7)
Yes, n (%)	1 (14.3)	3 (42.9)
No, n (%)	6 (85.7)	4 (57.1)
Risk Difference[A]		28.6
95% Confidence Interval[B]		(-16.3,73.5)
P-Value[C]		0.559

Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided by the central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: 95% Confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[C]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count< 5).
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__4.3

表 2.7.3.6-218. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（ベースラインの副腎皮質ステロイドの投与の有無別）（維持療法試験，ITT-RP 集団，M14-033 主試験）

	Adalimumab	
	40mg EOW (N=145)	40mg EW (N=152)
Baseline Corticosteroid Use (Yes)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=92)	(N=96)
Yes, n (%)	27 (29.3)	40 (41.7)
No, n (%)	65 (70.7)	56 (58.3)
Risk Difference[A]		12.3
95% Confidence Interval[B]		(-1.2,25.9)
P-Value[C]		0.078+
Baseline Corticosteroid Use (No)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=53)	(N=56)
Yes, n (%)	15 (28.3)	20 (35.7)
No, n (%)	38 (71.7)	36 (64.3)
Risk Difference[A]		7.4
95% Confidence Interval[B]		(-10.0,24.9)
P-Value[C]		0.407

Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided by the central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: 95% Confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[C]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count< 5).
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__4.4

表 2.7.3.6-219. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（ベースラインの免疫抑制剤の投与の有無別）（維持療法試験，ITT-RP 集団，M14-033 主試験）

	Adalimumab 40mg EOW (N=145)	Adalimumab 40mg EW (N=152)
Baseline Immunosuppressant Use (Yes)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=39)	(N=38)
Yes, n (%)	14 (35.9)	19 (50.0)
No, n (%)	25 (64.1)	19 (50.0)
Risk Difference[A]		14.1
95% Confidence Interval[B]		(-7.8,36.0)
P-Value[C]		0.211
Baseline Immunosuppressant Use (No)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=106)	(N=114)
Yes, n (%)	28 (26.4)	41 (36.0)
No, n (%)	78 (73.6)	73 (64.0)
Risk Difference[A]		9.5
95% Confidence Interval[B]		(-2.6,21.7)
P-Value[C]		0.127

Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided by the central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: 95% Confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[C]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count< 5).

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__4.5

表 2.7.3.6-220. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）［ベースラインの Mayo スコア（9 以下，9 を上回る）別］（維持療法試験，ITT-RP 集団，M14-033 主試験）

	Adalimumab	
	40mg EOW (N=145)	40mg EW (N=152)
Baseline Full Mayo Score <= 9		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=90)	(N=87)
Yes, n (%)	27 (30.0)	39 (44.8)
No, n (%)	63 (70.0)	48 (55.2)
Risk Difference[A]		14.8
95% Confidence Interval[B]		(0.7,28.9)
P-Value[C]		0.041*
Baseline Full Mayo Score > 9		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=55)	(N=65)
Yes, n (%)	15 (27.3)	21 (32.3)
No, n (%)	40 (72.7)	44 (67.7)
Risk Difference[A]		5.0
95% Confidence Interval[B]		(-11.3,21.4)
P-Value[C]		0.549

Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided by the central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: 95% Confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[C]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count< 5).
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__4.6

表 2.7.3.6-221. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）［ベースラインの Mayo スコア（中央値以下，中央値を上回る）］（維持療法試験，ITT-RP 集団，M14-033 主試験）

	Adalimumab	
	40mg EOW (N=145)	40mg EW (N=152)
Baseline Full Mayo Score <= Median (8.80)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=75)	(N=77)
Yes, n (%)	25 (33.3)	33 (42.9)
No, n (%)	50 (66.7)	44 (57.1)
Risk Difference[A]		9.5
95% Confidence Interval[B]		(-5.8,24.9)
P-Value[C]		0.227
Baseline Full Mayo Score > Median (8.80)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=70)	(N=75)
Yes, n (%)	17 (24.3)	27 (36.0)
No, n (%)	53 (75.7)	48 (64.0)
Risk Difference[A]		11.7
95% Confidence Interval[B]		(-3.1,26.5)
P-Value[C]		0.125

Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided by the central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: 95% Confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[C]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count< 5).

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__4.7

表 2.7.3.6-222. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（抗 TNF 製剤の治療歴の有無別）（維持療法試験，ITT-RP 集団，M14-033 主試験）

	Adalimumab	
	40mg EOW (N=145)	40mg EW (N=152)
Prior Exposure to Anti-TNF (Yes)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=17)	(N=14)
Yes, n (%)	5 (29.4)	7 (50.0)
No, n (%)	12 (70.6)	7 (50.0)
Risk Difference[A]		20.6
95% Confidence Interval[B]		(-13.4,54.6)
P-Value[C]		0.242
Prior Exposure to Anti-TNF (No)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=128)	(N=138)
Yes, n (%)	37 (28.9)	53 (38.4)
No, n (%)	91 (71.1)	85 (61.6)
Risk Difference[A]		9.5
95% Confidence Interval[B]		(-1.8,20.8)
P-Value[C]		0.102

Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided by the central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: 95% Confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[C]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count< 5).

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__4.8

表 2.7.3.6-223. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（ベースラインの体重別）（維持療法試験，ITT-RP 集団，M14-033 主試験）

	Adalimumab	
	40mg EOW (N=145)	40mg EW (N=152)
Baseline Weight <= Median (73.00 kg)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=79)	(N=70)
Yes, n (%)	23 (29.1)	25 (35.7)
No, n (%)	56 (70.9)	45 (64.3)
Risk Difference[A]		6.6
95% Confidence Interval[B]		(-8.4,21.6)
P-Value[C]		0.390
Baseline Weight > Median (73.00 kg)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=66)	(N=82)
Yes, n (%)	19 (28.8)	35 (42.7)
No, n (%)	47 (71.2)	47 (57.3)
Risk Difference[A]		13.9
95% Confidence Interval[B]		(-1.4,29.2)
P-Value[C]		0.081+

Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided by the central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: 95% Confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[C]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count< 5).
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__4.9

表 2.7.3.6-224. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（ベースラインの全大腸炎の有無別）（維持療法試験，ITT-RP 集団，M14-033 主試験）

	Adalimumab	
	40mg EOW (N=145)	40mg EW (N=152)
Presence of Pancolitis at Baseline (Yes)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=68)	(N=70)
Yes, n (%)	13 (19.1)	27 (38.6)
No, n (%)	55 (80.9)	43 (61.4)
Risk Difference[A]		19.5
95% Confidence Interval[B]		(4.7,34.2)
P-Value[C]		0.012*
Presence of Pancolitis at Baseline (No)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=77)	(N=82)
Yes, n (%)	29 (37.7)	33 (40.2)
No, n (%)	48 (62.3)	49 (59.8)
Risk Difference[A]		2.6
95% Confidence Interval[B]		(-12.6,17.7)
P-Value[C]		0.739

Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided by the central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: 95% Confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[C]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count< 5).
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__4.10

表 2.7.3.6-225. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（ベースライン時点での罹患期間別）（維持療法試験，ITT-RP 集団，M14-033 主試験）

	Adalimumab	
	40mg EOW (N=145)	40mg EW (N=152)
Disease Duration at Baseline <= Median (4.65 years)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=67)	(N=80)
Yes, n (%)	22 (32.8)	24 (30.0)
No, n (%)	45 (67.2)	56 (70.0)
Risk Difference[A]		-2.8
95% Confidence Interval[B]		(-17.9,12.2)
P-Value[C]		0.712
Disease Duration at Baseline > Median (4.65 years)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=78)	(N=72)
Yes, n (%)	20 (25.6)	36 (50.0)
No, n (%)	58 (74.4)	36 (50.0)
Risk Difference[A]		24.4
95% Confidence Interval[B]		(9.3,39.4)
P-Value[C]		0.002**

Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided by the central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: 95% Confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[C]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count< 5).
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__4.11

表 2.7.3.6-226. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）［ベースラインの高感度 CRP（5 mg/L 以下，5 mg/L を上回る）別］（維持療法試験，ITT-RP 集団，M14-033 主試験）

	Adalimumab	
	40mg EOW (N=145)	40mg EW (N=152)
Baseline HS-CRP <= 5 mg/L		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=82)	(N=83)
Yes, n (%)	27 (32.9)	31 (37.3)
No, n (%)	55 (67.1)	52 (62.7)
Risk Difference[A]		4.4
95% Confidence Interval[B]		(-10.1,19.0)
P-Value[C]		0.552
Baseline HS-CRP > 5 mg/L		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=63)	(N=69)
Yes, n (%)	15 (23.8)	29 (42.0)
No, n (%)	48 (76.2)	40 (58.0)
Risk Difference[A]		18.2
95% Confidence Interval[B]		(2.5,33.9)
P-Value[C]		0.027*

Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided by the central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: 95% Confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[C]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count< 5).
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__4.12

表 2.7.3.6-227.　投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）［ベースラインの高感度 CRP（中央値以下，中央値を上回る）別］（維持療法試験，ITT-RP 集団，M14-033 主試験）

	Adalimumab	
	40mg EOW (N=145)	40mg EW (N=152)
Baseline HS-CRP <= Median (3.82 mg/L)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=75)	(N=75)
Yes, n (%)	24 (32.0)	30 (40.0)
No, n (%)	51 (68.0)	45 (60.0)
Risk Difference[A]		8.0
95% Confidence Interval[B]		(-7.3,23.3)
P-Value[C]		0.307
Baseline HS-CRP > Median (3.82 mg/L)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=70)	(N=77)
Yes, n (%)	18 (25.7)	30 (39.0)
No, n (%)	52 (74.3)	47 (61.0)
Risk Difference[A]		13.2
95% Confidence Interval[B]		(-1.7,28.2)
P-Value[C]		0.087+

Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided by the central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: 95% Confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[C]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count< 5).
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__4.13

表 2.7.3.6-228. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（ベースラインのアルブミン別）（維持療法試験，ITT-RP 集団，M14-033 主試験）

	Adalimumab	
	40mg EOW (N=145)	40mg EW (N=152)
Baseline Albumin <= Median (41.00 g/L)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=84)	(N=95)
Yes, n (%)	19 (22.6)	41 (43.2)
No, n (%)	65 (77.4)	54 (56.8)
Risk Difference[A]		20.5
95% Confidence Interval[B]		(7.2,33.9)
P-Value[C]		0.004**
Baseline Albumin > Median (41.00 g/L)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=61)	(N=57)
Yes, n (%)	23 (37.7)	19 (33.3)
No, n (%)	38 (62.3)	38 (66.7)
Risk Difference[A]		-4.4
95% Confidence Interval[B]		(-21.6,12.9)
P-Value[C]		0.620

Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided by the central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: 95% Confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[C]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count< 5).
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__4.14

表 2.7.3.6-229. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（地域別）（維持療法試験，ITT-RP 集団，M14-033 主試験）

	Adalimumab	
	40mg EOW (N=145)	40mg EW (N=152)
Region (US)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=26)	(N=24)
Yes, n (%)	7 (26.9)	8 (33.3)
No, n (%)	19 (73.1)	16 (66.7)
Risk Difference[A]		6.4
95% Confidence Interval[B]		(-19.0,31.8)
P-Value[C]		0.621
Region (Non-US)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=119)	(N=128)
Yes, n (%)	35 (29.4)	52 (40.6)
No, n (%)	84 (70.6)	76 (59.4)
Risk Difference[A]		11.2
95% Confidence Interval[B]		(-0.6,23.0)
P-Value[C]		0.065+

Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided by the central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: 95% Confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[C]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count< 5).
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.2__4.15

表 2.7.3.6-230. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（性別）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

	Adalimumab	
	40mg EOW (N=18)	40mg EW (N=23)
Japan		
Gender (Male)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=13)	(N=17)
Yes, n (%)	5 (38.5)	10 (58.8)
No, n (%)	8 (61.5)	7 (41.2)
Risk Difference[A]		20.4
95% Confidence Interval[B]		(-14.9,55.7)
P-Value[C]		0.269
Gender (Female)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=5)	(N=6)
Yes, n (%)	2 (40.0)	2 (33.3)
No, n (%)	3 (60.0)	4 (66.7)
Risk Difference[A]		-6.7
95% Confidence Interval[B]		(-63.8,50.5)
P-Value[C]		1.000

表 2.7.3.6-230. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（性別）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

	Adalimumab	
	40mg EOW (N=163)	40mg EW (N=175)
Integrated		
Gender (Male)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=96)	(N=102)
Yes, n (%)	24 (25.0)	44 (43.1)
No, n (%)	72 (75.0)	58 (56.9)
Risk Difference[A]		18.1
95% Confidence Interval[B]		(5.2,31.1)
P-Value[C]		0.007**
Gender (Female)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=67)	(N=73)
Yes, n (%)	25 (37.3)	28 (38.4)
No, n (%)	42 (62.7)	45 (61.6)
Risk Difference[A]		1.0
95% Confidence Interval[B]		(-15.0,17.1)
P-Value[C]		0.899

表 2.7.3.6-230. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（性別）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided by the central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: 95% Confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[C]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count< 5).
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__4.1_J

表 2.7.3.6-231. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（年齢別）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

	Adalimumab	
	40mg EOW (N=18)	40mg EW (N=23)
Japan		
Age <= Median (43.00 years)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=11)	(N=11)
Yes, n (%)	4 (36.4)	6 (54.5)
No, n (%)	7 (63.6)	5 (45.5)
Risk Difference[A]		18.2
95% Confidence Interval[B]		(-22.7,59.1)
P-Value[C]		0.392
Age > Median (43.00 years)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=7)	(N=12)
Yes, n (%)	3 (42.9)	6 (50.0)
No, n (%)	4 (57.1)	6 (50.0)
Risk Difference[A]		7.1
95% Confidence Interval[B]		(-39.2,53.4)
P-Value[C]		1.000

表 2.7.3.6-231. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（年齢別）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

	Adalimumab 40mg EOW (N=163)	Adalimumab 40mg EW (N=175)
Integrated		
Age <= Median (39.00 years)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=90)	(N=81)
Yes, n (%)	25 (27.8)	31 (38.3)
No, n (%)	65 (72.2)	50 (61.7)
Risk Difference[A]		10.5
95% Confidence Interval[B]		(-3.6,24.6)
P-Value[C]		0.144
Age > Median (39.00 years)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=73)	(N=94)
Yes, n (%)	24 (32.9)	41 (43.6)
No, n (%)	49 (67.1)	53 (56.4)
Risk Difference[A]		10.7
95% Confidence Interval[B]		(-4.0,25.5)
P-Value[C]		0.158

Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided by the central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: 95% Confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[C]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count< 5).

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__4.2_J

表 2.7.3.6-232. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（人種別）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

	Adalimumab	
	40mg EOW (N=18)	40mg EW (N=23)
Japan		
Race (Non-White)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=18)	(N=23)
Yes, n (%)	7 (38.9)	12 (52.2)
No, n (%)	11 (61.1)	11 (47.8)
Risk Difference[A]		13.3
95% Confidence Interval[B]		(-17.1,43.7)
P-Value[C]		0.397

表 2.7.3.6-232. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（人種別）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

	Adalimumab	
	40mg EOW (N=163)	40mg EW (N=175)
Integrated		
Race (White)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=138)	(N=145)
Yes, n (%)	41 (29.7)	57 (39.3)
No, n (%)	97 (70.3)	88 (60.7)
Risk Difference[A]		9.6
95% Confidence Interval[B]		(-1.4,20.6)
P-Value[C]		0.090+
Race (Non-White)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=25)	(N=30)
Yes, n (%)	8 (32.0)	15 (50.0)
No, n (%)	17 (68.0)	15 (50.0)
Risk Difference[A]		18.0
95% Confidence Interval[B]		(-7.6,43.6)
P-Value[C]		0.178

表 2.7.3.6-232.　投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（人種別）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

```
Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided
      by the central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: 95% Confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[C]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count< 5).
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.
```

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__4.3_J

表 2.7.3.6-233. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（ベースラインの副腎皮質ステロイドの投与の有無別）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

	Adalimumab	
	40mg EOW (N=18)	40mg EW (N=23)
Japan		
Baseline Corticosteroid Use (Yes)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=11)	(N=13)
Yes, n (%)	4 (36.4)	7 (53.8)
No, n (%)	7 (63.6)	6 (46.2)
Risk Difference[A]		17.5
95% Confidence Interval[B]		(-21.8,56.8)
P-Value[C]		0.392
Baseline Corticosteroid Use (No)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=7)	(N=10)
Yes, n (%)	3 (42.9)	5 (50.0)
No, n (%)	4 (57.1)	5 (50.0)
Risk Difference[A]		7.1
95% Confidence Interval[B]		(-40.9,55.1)
P-Value[C]		1.000

表 2.7.3.6-233. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（ベースラインの副腎皮質ステロイドの投与の有無別）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

	Adalimumab	
	40mg EOW (N=163)	40mg EW (N=175)
Integrated		
Baseline Corticosteroid Use (Yes)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=103)	(N=109)
Yes, n (%)	31 (30.1)	47 (43.1)
No, n (%)	72 (69.9)	62 (56.9)
Risk Difference[A]		13.0
95% Confidence Interval[B]		(0.2,25.9)
P-Value[C]		0.049*
Baseline Corticosteroid Use (No)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=60)	(N=66)
Yes, n (%)	18 (30.0)	25 (37.9)
No, n (%)	42 (70.0)	41 (62.1)
Risk Difference[A]		7.9
95% Confidence Interval[B]		(-8.6,24.4)
P-Value[C]		0.352

表 2.7.3.6-233.　投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（ベースラインの副腎皮質ステロイドの投与の有無別）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

```
Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided
      by the central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: 95% Confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[C]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count< 5).
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.
```

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__4.4_J

表 2.7.3.6-234. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（ベースラインの免疫抑制剤の投与の有無別）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

	Adalimumab	
	40mg EOW (N=18)	40mg EW (N=23)
Japan		
Baseline Immunosuppressant Use (Yes)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=11)	(N=16)
Yes, n (%)	4 (36.4)	9 (56.3)
No, n (%)	7 (63.6)	7 (43.8)
Risk Difference[A]		19.9
95% Confidence Interval[B]		(-17.5,57.3)
P-Value[C]		0.310
Baseline Immunosuppressant Use (No)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=7)	(N=7)
Yes, n (%)	3 (42.9)	3 (42.9)
No, n (%)	4 (57.1)	4 (57.1)
Risk Difference[A]		0.0
95% Confidence Interval[B]		(-51.8,51.8)
P-Value[C]		1.000

表 2.7.3.6-234. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（ベースラインの免疫抑制剤の投与の有無別）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

	Adalimumab	
	40mg EOW (N=163)	40mg EW (N=175)
Integrated		
Baseline Immunosuppressant Use (Yes)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=50)	(N=54)
Yes, n (%)	18 (36.0)	28 (51.9)
No, n (%)	32 (64.0)	26 (48.1)
Risk Difference[A]		15.9
95% Confidence Interval[B]		(-3.0,34.7)
P-Value[C]		0.104
Baseline Immunosuppressant Use (No)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=113)	(N=121)
Yes, n (%)	31 (27.4)	44 (36.4)
No, n (%)	82 (72.6)	77 (63.6)
Risk Difference[A]		8.9
95% Confidence Interval[B]		(-3.0,20.8)
P-Value[C]		0.144

Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided by the central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: 95% Confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[C]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count< 5).

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__4.5_J

表 2.7.3.6-235. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）［ベースラインの Mayo スコア（9 以下，9 を上回る）別］（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

	Adalimumab	
	40mg EOW (N=18)	40mg EW (N=23)
Japan		
Baseline Full Mayo Score <= 9		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=11)	(N=14)
Yes, n (%)	6 (54.5)	7 (50.0)
No, n (%)	5 (45.5)	7 (50.0)
Risk Difference[A]		-4.5
95% Confidence Interval[B]		(-43.9,34.8)
P-Value[C]		0.821
Baseline Full Mayo Score > 9		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=7)	(N=9)
Yes, n (%)	1 (14.3)	5 (55.6)
No, n (%)	6 (85.7)	4 (44.4)
Risk Difference[A]		41.3
95% Confidence Interval[B]		(-0.3,82.8)
P-Value[C]		0.145

表 2.7.3.6-235. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）［ベースラインの Mayo スコア（9 以下，9 を上回る）別］（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

	Adalimumab	
	40mg EOW (N=163)	40mg EW (N=175)
Integrated		
Baseline Full Mayo Score <= 9		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=101)	(N=101)
Yes, n (%)	33 (32.7)	46 (45.5)
No, n (%)	68 (67.3)	55 (54.5)
Risk Difference[A]		12.9
95% Confidence Interval[B]		(-0.5,26.2)
P-Value[C]		0.061+
Baseline Full Mayo Score > 9		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=62)	(N=74)
Yes, n (%)	16 (25.8)	26 (35.1)
No, n (%)	46 (74.2)	48 (64.9)
Risk Difference[A]		9.3
95% Confidence Interval[B]		(-6.1,24.7)
P-Value[C]		0.241

表 2.7.3.6-235. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）［ベースラインの Mayo スコア（9 以下，9 を上回る）別］（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

```
Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided
      by the central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: 95% Confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[C]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count< 5).
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.
```

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__4.6_J

表 2.7.3.6-236. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）［ベースラインの Mayo スコア（中央値以下，中央値を上回る）］（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

	Adalimumab	
	40mg EOW (N=18)	40mg EW (N=23)
Japan		
Baseline Full Mayo Score <= Median (8.00)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=10)	(N=12)
Yes, n (%)	6 (60.0)	6 (50.0)
No, n (%)	4 (40.0)	6 (50.0)
Risk Difference[A]		-10.0
95% Confidence Interval[B]		(-51.5,31.5)
P-Value[C]		0.691
Baseline Full Mayo Score > Median (8.00)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=8)	(N=11)
Yes, n (%)	1 (12.5)	6 (54.5)
No, n (%)	7 (87.5)	5 (45.5)
Risk Difference[A]		42.0
95% Confidence Interval[B]		(4.7,79.3)
P-Value[C]		0.147

表 2.7.3.6-236. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）［ベースラインの Mayo スコア（中央値以下，中央値を上回る）］（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

	Adalimumab	
	40mg EOW (N=163)	40mg EW (N=175)
Integrated		
Baseline Full Mayo Score <= Median (8.80)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=86)	(N=91)
Yes, n (%)	31 (36.0)	40 (44.0)
No, n (%)	55 (64.0)	51 (56.0)
Risk Difference[A]		7.9
95% Confidence Interval[B]		(-6.5,22.3)
P-Value[C]		0.283
Baseline Full Mayo Score > Median (8.80)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=77)	(N=84)
Yes, n (%)	18 (23.4)	32 (38.1)
No, n (%)	59 (76.6)	52 (61.9)
Risk Difference[A]		14.7
95% Confidence Interval[B]		(0.7,28.8)
P-Value[C]		0.044*

表 2.7.3.6-236.　投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）［ベースラインの Mayo スコア（中央値以下，中央値を上回る）］（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

```
Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided
      by the central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: 95% Confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[C]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count< 5).
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.
```

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__4.7_J

表 2.7.3.6-237. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（抗 TNF 製剤の治療歴の有無別）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

	Adalimumab	
	40mg EOW (N=18)	40mg EW (N=23)
Japan		
Prior Exposure to Anti-TNF (Yes)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=3)	(N=7)
Yes, n (%)	1 (33.3)	5 (71.4)
No, n (%)	2 (66.7)	2 (28.6)
Risk Difference[A]		38.1
95% Confidence Interval[B]		(-24.9,100.0)
P-Value[C]		0.500
Prior Exposure to Anti-TNF (No)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=15)	(N=16)
Yes, n (%)	6 (40.0)	7 (43.8)
No, n (%)	9 (60.0)	9 (56.3)
Risk Difference[A]		3.7
95% Confidence Interval[B]		(-31.0,38.5)
P-Value[C]		0.833

表 2.7.3.6-237. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（抗 TNF 製剤の治療歴の有無別）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

	Adalimumab 40mg EOW (N=163)	Adalimumab 40mg EW (N=175)
Integrated		
Prior Exposure to Anti-TNF (Yes)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=20)	(N=21)
Yes, n (%)	6 (30.0)	12 (57.1)
No, n (%)	14 (70.0)	9 (42.9)
Risk Difference[A]		27.1
95% Confidence Interval[B]		(-2.0,56.3)
P-Value[C]		0.080+
Prior Exposure to Anti-TNF (No)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=143)	(N=154)
Yes, n (%)	43 (30.1)	60 (39.0)
No, n (%)	100 (69.9)	94 (61.0)
Risk Difference[A]		8.9
95% Confidence Interval[B]		(-1.9,19.7)
P-Value[C]		0.108

表 2.7.3.6-237.　投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（抗 TNF 製剤の治療歴の有無別）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

```
Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided
      by the central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: 95% Confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[C]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count< 5).
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.
```

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__4.8_J

表 2.7.3.6-238. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（ベースラインの体重別）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

	Adalimumab	
	40mg EOW (N=18)	40mg EW (N=23)
Japan		
Baseline Weight <= Median (65.00 kg)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=9)	(N=12)
Yes, n (%)	3 (33.3)	5 (41.7)
No, n (%)	6 (66.7)	7 (58.3)
Risk Difference[A]		8.3
95% Confidence Interval[B]		(-33.2,49.9)
P-Value[C]		1.000
Baseline Weight > Median (65.00 kg)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=9)	(N=11)
Yes, n (%)	4 (44.4)	7 (63.6)
No, n (%)	5 (55.6)	4 (36.4)
Risk Difference[A]		19.2
95% Confidence Interval[B]		(-24.0,62.3)
P-Value[C]		0.653

表 2.7.3.6-238. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（ベースラインの体重別）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

	Adalimumab 40mg EOW (N=163)	Adalimumab 40mg EW (N=175)
Integrated		
Baseline Weight <= Median (72.00 kg)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=85)	(N=84)
Yes, n (%)	25 (29.4)	33 (39.3)
No, n (%)	60 (70.6)	51 (60.7)
Risk Difference[A]		9.9
95% Confidence Interval[B]		(-4.4,24.1)
P-Value[C]		0.176
Baseline Weight > Median (72.00 kg)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=78)	(N=91)
Yes, n (%)	24 (30.8)	39 (42.9)
No, n (%)	54 (69.2)	52 (57.1)
Risk Difference[A]		12.1
95% Confidence Interval[B]		(-2.3,26.5)
P-Value[C]		0.105

Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided by the central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: 95% Confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[C]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count< 5).

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__4.9_J

表 2.7.3.6-239. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（ベースラインの全大腸炎の有無別）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

	Adalimumab	
	40mg EOW (N=18)	40mg EW (N=23)
Japan		
Presence of Pancolitis at Baseline (Yes)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=11)	(N=12)
Yes, n (%)	5 (45.5)	5 (41.7)
No, n (%)	6 (54.5)	7 (58.3)
Risk Difference[A]		-3.8
95% Confidence Interval[B]		(-44.3,36.8)
P-Value[C]		1.000
Presence of Pancolitis at Baseline (No)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=7)	(N=11)
Yes, n (%)	2 (28.6)	7 (63.6)
No, n (%)	5 (71.4)	4 (36.4)
Risk Difference[A]		35.1
95% Confidence Interval[B]		(-8.8,79.0)
P-Value[C]		0.335

表 2.7.3.6-239. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（ベースラインの全大腸炎の有無別）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

	Adalimumab 40mg EOW (N=163)	Adalimumab 40mg EW (N=175)
Integrated		
Presence of Pancolitis at Baseline (Yes)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=79)	(N=82)
Yes, n (%)	18 (22.8)	32 (39.0)
No, n (%)	61 (77.2)	50 (61.0)
Risk Difference[A]		16.2
95% Confidence Interval[B]		(2.2,30.3)
P-Value[C]		0.026*
Presence of Pancolitis at Baseline (No)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=84)	(N=93)
Yes, n (%)	31 (36.9)	40 (43.0)
No, n (%)	53 (63.1)	53 (57.0)
Risk Difference[A]		6.1
95% Confidence Interval[B]		(-8.3,20.5)
P-Value[C]		0.408

表 2.7.3.6-239.　投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（ベースラインの全大腸炎の有無別）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided by the central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: 95% Confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[C]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count< 5).
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__4.10_J

表 2.7.3.6-240.　投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（ベースライン時点での罹患期間別）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

	Adalimumab 40mg EOW (N=18)	Adalimumab 40mg EW (N=23)
Japan		
Disease Duration at Baseline <= Median (8.51 years)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=8)	(N=13)
Yes, n (%)	3 (37.5)	7 (53.8)
No, n (%)	5 (62.5)	6 (46.2)
Risk Difference[A]		16.3
95% Confidence Interval[B]		(-26.8,59.5)
P-Value[C]		0.659
Disease Duration at Baseline > Median (8.51 years)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=10)	(N=10)
Yes, n (%)	4 (40.0)	5 (50.0)
No, n (%)	6 (60.0)	5 (50.0)
Risk Difference[A]		10.0
95% Confidence Interval[B]		(-33.4,53.4)
P-Value[C]		1.000

表 2.7.3.6-240. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（ベースライン時点での罹患期間別）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

	Adalimumab 40mg EOW (N=163)	Adalimumab 40mg EW (N=175)
Integrated		
Disease Duration at Baseline <= Median (5.04 years)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=76)	(N=89)
Yes, n (%)	25 (32.9)	29 (32.6)
No, n (%)	51 (67.1)	60 (67.4)
Risk Difference[A]		-0.3
95% Confidence Interval[B]		(-14.7,14.1)
P-Value[C]		0.966
Disease Duration at Baseline > Median (5.04 years)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=87)	(N=86)
Yes, n (%)	24 (27.6)	43 (50.0)
No, n (%)	63 (72.4)	43 (50.0)
Risk Difference[A]		22.4
95% Confidence Interval[B]		(8.3,36.6)
P-Value[C]		0.002**

表 2.7.3.6-240.　投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（ベースライン時点での罹患期間別）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided by the central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: 95% Confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[C]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count< 5).
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__4.11_J

表 2.7.3.6-241. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）［ベースラインの高感度 CRP（5 mg/L 以下，5 mg/L を上回る）別］（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

	Adalimumab	
	40mg EOW (N=18)	40mg EW (N=23)
Japan		
Baseline HS-CRP <= 5 mg/L		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=11)	(N=19)
Yes, n (%)	7 (63.6)	9 (47.4)
No, n (%)	4 (36.4)	10 (52.6)
Risk Difference[A]		-16.3
95% Confidence Interval[B]		(-52.5,20.0)
P-Value[C]		0.389
Baseline HS-CRP > 5 mg/L		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=7)	(N=4)
Yes, n (%)	0	3 (75.0)
No, n (%)	7 (100)	1 (25.0)
Risk Difference[A]		75.0
95% Confidence Interval[B]		(32.6,100.0)
P-Value[C]		0.024*

表 2.7.3.6-241. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）［ベースラインの高感度 CRP（5 mg/L 以下，5 mg/L を上回る）別］（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

	Adalimumab	
	40mg EOW (N=163)	40mg EW (N=175)
Integrated		
Baseline HS-CRP <= 5 mg/L		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=93)	(N=102)
Yes, n (%)	34 (36.6)	40 (39.2)
No, n (%)	59 (63.4)	62 (60.8)
Risk Difference[A]		2.7
95% Confidence Interval[B]		(-11.0,16.3)
P-Value[C]		0.703
Baseline HS-CRP > 5 mg/L		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=70)	(N=73)
Yes, n (%)	15 (21.4)	32 (43.8)
No, n (%)	55 (78.6)	41 (56.2)
Risk Difference[A]		22.4
95% Confidence Interval[B]		(7.5,37.3)
P-Value[C]		0.004**

表 2.7.3.6-241.　投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）［ベースラインの高感度 CRP（5 mg/L 以下，5 mg/L を上回る）別］（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

```
Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided
      by the central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: 95% Confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[C]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count< 5).
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.
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Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__4.12_J

表 2.7.3.6-242. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）［ベースラインの高感度 CRP（中央値以下，中央値を上回る）別］（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

	Adalimumab	
	40mg EOW (N=18)	40mg EW (N=23)
Japan		
Baseline HS-CRP <= Median (1.47 mg/L)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=9)	(N=13)
Yes, n (%)	5 (55.6)	7 (53.8)
No, n (%)	4 (44.4)	6 (46.2)
Risk Difference[A]		-1.7
95% Confidence Interval[B]		(-44.0,40.6)
P-Value[C]		1.000
Baseline HS-CRP > Median (1.47 mg/L)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=9)	(N=10)
Yes, n (%)	2 (22.2)	5 (50.0)
No, n (%)	7 (77.8)	5 (50.0)
Risk Difference[A]		27.8
95% Confidence Interval[B]		(-13.4,69.0)
P-Value[C]		0.350

表 2.7.3.6-242. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）［ベースラインの高感度 CRP（中央値以下，中央値を上回る）別］（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

	Adalimumab	
	40mg EOW (N=163)	40mg EW (N=175)
Integrated		
Baseline HS-CRP <= Median (3.56 mg/L)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=83)	(N=88)
Yes, n (%)	30 (36.1)	36 (40.9)
No, n (%)	53 (63.9)	52 (59.1)
Risk Difference[A]		4.8
95% Confidence Interval[B]		(-9.8,19.3)
P-Value[C]		0.522
Baseline HS-CRP > Median (3.56 mg/L)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=80)	(N=87)
Yes, n (%)	19 (23.8)	36 (41.4)
No, n (%)	61 (76.3)	51 (58.6)
Risk Difference[A]		17.6
95% Confidence Interval[B]		(3.7,31.6)
P-Value[C]		0.015*

表 2.7.3.6-242.　投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）［ベースラインの高感度 CRP（中央値以下，中央値を上回る）別］（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

```
Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided
      by the central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: 95% Confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[C]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count< 5).
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.
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Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__4.13_J

表 2.7.3.6-243. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（ベースラインのアルブミン別）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

	Adalimumab	
	40mg EOW (N=18)	40mg EW (N=23)
Japan		
Baseline Albumin <= Median (41.00 g/L)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=9)	(N=14)
Yes, n (%)	2 (22.2)	8 (57.1)
No, n (%)	7 (77.8)	6 (42.9)
Risk Difference[A]		34.9
95% Confidence Interval[B]		(-2.6,72.5)
P-Value[C]		0.197
Baseline Albumin > Median (41.00 g/L)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=9)	(N=9)
Yes, n (%)	5 (55.6)	4 (44.4)
No, n (%)	4 (44.4)	5 (55.6)
Risk Difference[A]		-11.1
95% Confidence Interval[B]		(-57.0,34.8)
P-Value[C]		1.000

表 2.7.3.6-243. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（ベースラインのアルブミン別）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

	Adalimumab	
	40mg EOW (N=163)	40mg EW (N=175)
Integrated		
Baseline Albumin <= Median (41.00 g/L)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=93)	(N=109)
Yes, n (%)	21 (22.6)	49 (45.0)
No, n (%)	72 (77.4)	60 (55.0)
Risk Difference[A]		22.4
95% Confidence Interval[B]		(9.7,35.0)
P-Value[C]		<0.001***
Baseline Albumin > Median (41.00 g/L)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=70)	(N=66)
Yes, n (%)	28 (40.0)	23 (34.8)
No, n (%)	42 (60.0)	43 (65.2)
Risk Difference[A]		-5.2
95% Confidence Interval[B]		(-21.4,11.1)
P-Value[C]		0.535

表 2.7.3.6-243.　投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（ベースラインのアルブミン別）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

```
Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided
      by the central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: 95% Confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[C]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count< 5).
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.
```

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__4.14_J

表 2.7.3.6-244. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（地域別）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）

	Adalimumab	
	40mg EOW (N=18)	40mg EW (N=23)
Japan		
Region (Non-US)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=18)	(N=23)
Yes, n (%)	7 (38.9)	12 (52.2)
No, n (%)	11 (61.1)	11 (47.8)
Risk Difference[A]		13.3
95% Confidence Interval[B]		(-17.1,43.7)
P-Value[C]		0.397

表 2.7.3.6-244. 投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（地域別）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

	Adalimumab	
	40mg EOW (N=163)	40mg EW (N=175)
Integrated		
Region (US)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=26)	(N=24)
Yes, n (%)	7 (26.9)	8 (33.3)
No, n (%)	19 (73.1)	16 (66.7)
Risk Difference[A]		6.4
95% Confidence Interval[B]		(-19.0,31.8)
, P-Value[C]		0.621
Region (Non-US)		
Week 8 Responders with Clinical Remission per Full Mayo Score at Week 52 (Week 44 of Maintenance Study)	(N=137)	(N=151)
Yes, n (%)	42 (30.7)	64 (42.4)
No, n (%)	95 (69.3)	87 (57.6)
Risk Difference[A]		11.7
95% Confidence Interval[B]		(0.7,22.8)
P-Value[C]		0.039*

表 2.7.3.6-244.　投与 8 週時 FMS 改善例における投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（地域別）（維持療法試験，ITT-RP 集団，M14-033 日本サブ試験）（続き）

Note: Clinical remission is defined as Full Mayo Score <= 2 with no subscore > 1 utilising the endoscopy subscore provided by the central reader.
[A]: Risk difference = Adalimumab 40mg EW - Adalimumab 40mg EOW.
[B]: 95% Confidence intervals for risk difference were calculated based on normal approximation using proc freq.
[C]: P-value was calculated based on Chi-square test (or Fisher's exact test if >= 20% of the cells have expected cell count< 5).
***, **, *, + Statistically significant at 0.001, 0.01, 0.05 and 0.1 level, respectively.

Cross reference: M14-033 Maintenance _Japan Sub-study Final CSR Table 14.2__4.15_J

表 2.7.3.6-245.　TDM 群における評価時点ごとの用量を増量した被験者の割合（維持療法試験，ITT-RP 集団，安全性解析対象集団，M14-033 主試験）

Population Time Point	Adalimumab TDM Regimen n (%)
ITT-RP Population	(N=74)
Week 12	30 (40.5)
Week 24	41 (55.4)
Week 37	16 (21.6)
Safety Population	(N=151)
Week 12	85 (56.3)
Week 24	72 (47.7)
Week 37	44 (29.1)

Cross reference: M14-033 Maintenance_Main study Final CSR Table 14.1__1.4

2.7.3.6 小児 付録

表 2.7.3.6-1. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験の日本サブ試験）（中間 CSR）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
All Sites	100	100	83	79	67	83	61	100	25	68
I-SD	32	32	32	21	17	32	15	32	5	18
I-SD/-	10	10	10	--	--	10	--	10	--	--
I-SD/M-PL	4	4	4	4	--	4	0	4	2	4
I-SD/M-SD	8	8	8	8	8	8	8	8	0	5
I-SD/M-HD	10	10	10	9	9	10	7	10	3	9
I-HD	51	51	51	43	35	51	31	51	16	38
I-HD/-	8	8	8	--	--	8	--	8	--	--
I-HD/M-PL	8	8	8	8	--	8	0	8	5	7
I-HD/M-SD	17	17	17	17	17	17	15	17	5	14
I-HD/M-HD	18	18	18	18	18	18	16	18	6	17
I-HD-OL	17	17	--	15	15	0	15	17	4	12
I-HD-OL/-	2	2	--	--	--	0	--	2	--	--
I-HD-OL/M-SD	8	8	--	8	8	0	8	8	3	6
I-HD-OL/M-HD	7	7	--	7	7	0	7	7	1	6
M-SD + M-HD total	68	68	53	67	67	53	61	68	18	57
M-SD total	33	33	25	33	33	25	31	33	8	25
M-HD total	35	35	28	34	34	28	30	35	10	32

表 2.7.3.6-1. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験の日本サブ試験）（中間 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	8	8	8	8	7	8	6	8	1	8
I-SD	3	3	3	3	3	3	2	3	1	3
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	1	1	1	1	1	1	1	1	0	1
I-SD/M-HD	2	2	2	2	2	2	1	2	1	2
I-HD	5	5	5	5	4	5	4	5	0	5
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	1	1	1	1	--	1	0	1	0	1
I-HD/M-SD	1	1	1	1	1	1	1	1	0	1
I-HD/M-HD	3	3	3	3	3	3	3	3	0	3
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	7	7	7	7	7	7	6	7	1	7
M-SD total	2	2	2	2	2	2	2	2	0	2
M-HD total	5	5	5	5	5	5	4	5	1	5

表 2.7.3.6-1. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験の日本サブ試験）（中間 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	13	13	9	9	7	9	7	13	3	9
I-SD	3	3	3	1	1	3	1	3	0	1
I-SD/-	2	2	2	--	--	2	--	2	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	1	1	1	1	1	1	1	1	0	1
I-HD	6	6	6	5	3	6	3	6	3	5
I-HD/-	1	1	1	--	--	1	--	1	--	--
I-HD/M-PL	2	2	2	2	--	2	0	2	2	2
I-HD/M-SD	1	1	1	1	1	1	1	1	0	1
I-HD/M-HD	2	2	2	2	2	2	2	2	1	2
I-HD-OL	4	4	--	3	3	0	3	4	0	3
I-HD-OL/-	1	1	--	--	--	0	--	1	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	3	3	--	3	3	0	3	3	0	3
M-SD + M-HD total	7	7	4	7	7	4	7	7	1	7
M-SD total	1	1	1	1	1	1	1	1	0	1
M-HD total	6	6	3	6	6	3	6	6	1	6

表 2.7.3.6-1. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験の日本サブ試験）（中間 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	1	1	1	0	0	1	0	1	0	0
I-SD	0	0	0	0	0	0	0	0	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	1	1	1	0	0	1	0	1	0	0
I-HD/-	1	1	1	--	--	1	--	1	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	0	0	0	0	0	0	0	0	0	0
M-SD total	0	0	0	0	0	0	0	0	0	0
M-HD total	0	0	0	0	0	0	0	0	0	0

表 2.7.3.6-1. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験の日本サブ試験）（中間 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	4	4	2	4	3	2	2	4	0	3
I-SD	0	0	0	0	0	0	0	0	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	2	2	2	2	1	2	0	2	0	2
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	1	1	1	1	--	1	0	1	0	1
I-HD/M-SD	1	1	1	1	1	1	0	1	0	1
I-HD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD-OL	2	2	--	2	2	0	2	2	0	1
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	1	1	--	1	1	0	1	1	0	1
I-HD-OL/M-HD	1	1	--	1	1	0	1	1	0	0
M-SD + M-HD total	3	3	1	3	3	1	2	3	0	2
M-SD total	2	2	1	2	2	1	1	2	0	2
M-HD total	1	1	0	1	1	0	1	1	0	0

表 2.7.3.6-1. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験の日本サブ試験）（中間 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted]	2	2	2	0	0	2	0	2	0	0
I-SD	0	0	0	0	0	0	0	0	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	2	2	2	0	0	2	0	2	0	0
I-HD/-	2	2	2	--	--	2	--	2	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	0	0	0	0	0	0	0	0	0	0
M-SD total	0	0	0	0	0	0	0	0	0	0
M-HD total	0	0	0	0	0	0	0	0	0	0

表 2.7.3.6-1. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験の日本サブ試験）（中間 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	1	1	1	0	0	1	0	1	0	0
I-SD	1	1	1	0	0	1	0	1	0	0
I-SD/-	1	1	1	--	--	1	--	1	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	0	0	0	0	0	0	0	0	0	0
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	0	0	0	0	0	0	0	0	0	0
M-SD total	0	0	0	0	0	0	0	0	0	0
M-HD total	0	0	0	0	0	0	0	0	0	0

表 2.7.3.6-1. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験の日本サブ試験）（中間 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	2	2	2	2	2	2	2	2	0	0
I-SD	1	1	1	1	1	1	1	1	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	1	1	1	1	1	1	1	1	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	1	1	1	1	1	1	1	1	0	0
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	1	1	1	1	1	1	1	1	0	0
I-HD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	2	2	2	2	2	2	2	2	0	0
M-SD total	2	2	2	2	2	2	2	2	0	0
M-HD total	0	0	0	0	0	0	0	0	0	0

表 2.7.3.6-1. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験の日本サブ試験）（中間 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	39	39	35	30	24	35	22	39	12	28
I-SD	17	17	17	11	8	17	7	17	4	11
I-SD/-	6	6	6	--	--	6	--	6	--	--
I-SD/M-PL	3	3	3	3	--	3	0	3	2	3
I-SD/M-SD	3	3	3	3	3	3	3	3	0	3
I-SD/M-HD	5	5	5	5	5	5	4	5	2	5
I-HD	18	18	18	15	12	18	11	18	7	13
I-HD/-	3	3	3	--	--	3	--	3	--	--
I-HD/M-PL	3	3	3	3	--	3	0	3	2	3
I-HD/M-SD	7	7	7	7	7	7	7	7	3	6
I-HD/M-HD	5	5	5	5	5	5	4	5	2	4
I-HD-OL	4	4	--	4	4	0	4	4	1	4
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	3	3	--	3	3	0	3	3	1	3
I-HD-OL/M-HD	1	1	--	1	1	0	1	1	0	1
M-SD + M-HD total	24	24	20	24	24	20	22	24	8	22
M-SD total	13	13	10	13	13	10	13	13	4	12
M-HD total	11	11	10	11	11	10	9	11	4	10

表 2.7.3.6-1. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験の日本サブ試験）（中間 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	1	1	1	1	1	1	1	1	1	1
I-SD	0	0	0	0	0	0	0	0	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	1	1	1	1	1	1	1	1	1	1
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	1	1	1	1	1	1	1	1	1	1
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	1	1	1	1	1	1	1	1	1	1
M-SD total	0	0	0	0	0	0	0	0	0	0
M-HD total	1	1	1	1	1	1	1	1	1	1

表 2.7.3.6-1. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験の日本サブ試験）（中間 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	1	1	1	1	1	1	1	1	0	1
I-SD	0	0	0	0	0	0	0	0	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	1	1	1	1	1	1	1	1	0	1
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	1	1	1	1	1	1	1	1	0	1
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	1	1	1	1	1	1	1	1	0	1
M-SD total	0	0	0	0	0	0	0	0	0	0
M-HD total	1	1	1	1	1	1	1	1	0	1

表 2.7.3.6-1. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験の日本サブ試験）（中間 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	1	1	0	0	0	0	0	1	0	0
I-SD	0	0	0	0	0	0	0	0	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	0	0	0	0	0	0	0	0	0	0
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD-OL	1	1	--	0	0	0	0	1	0	0
I-HD-OL/-	1	1	--	--	--	0	--	1	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	0	0	0	0	0	0	0	0	0	0
M-SD total	0	0	0	0	0	0	0	0	0	0
M-HD total	0	0	0	0	0	0	0	0	0	0

表 2.7.3.6-1. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験の日本サブ試験）（中間 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	2	2	0	2	2	0	2	2	0	2
I-SD	0	0	0	0	0	0	0	0	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	0	0	0	0	0	0	0	0	0	0
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD-OL	2	2	--	2	2	0	2	2	0	2
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	1	1	--	1	1	0	1	1	0	1
I-HD-OL/M-HD	1	1	--	1	1	0	1	1	0	1
M-SD + M-HD total	2	2	0	2	2	0	2	2	0	2
M-SD total	1	1	0	1	1	0	1	1	0	1
M-HD total	1	1	0	1	1	0	1	1	0	1

表 2.7.3.6-1. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験の日本サブ試験）（中間 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	1	1	1	1	0	1	0	1	0	1
I-SD	1	1	1	1	0	1	0	1	0	1
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	1	1	1	1	--	1	0	1	0	1
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	0	0	0	0	0	0	0	0	0	0
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	0	0	0	0	0	0	0	0	0	0
M-SD total	0	0	0	0	0	0	0	0	0	0
M-HD total	0	0	0	0	0	0	0	0	0	0

表 2.7.3.6-1. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験の日本サブ試験）（中間 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	2	2	2	1	1	2	0	2	0	1
I-SD	0	0	0	0	0	0	0	0	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	2	2	2	1	1	2	0	2	0	1
I-HD/-	1	1	1	--	--	1	--	1	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	1	1	1	1	1	1	0	1	0	1
I-HD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	1	1	1	1	1	1	0	1	0	1
M-SD total	1	1	1	1	1	1	0	1	0	1
M-HD total	0	0	0	0	0	0	0	0	0	0

表 2.7.3.6-1. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験の日本サブ試験）（中間 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	2	2	1	2	2	1	2	2	1	2
I-SD	1	1	1	1	1	1	1	1	0	1
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	1	1	1	1	1	1	1	1	0	1
I-HD	0	0	0	0	0	0	0	0	0	0
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD-OL	1	1	--	1	1	0	1	1	1	1
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	1	1	--	1	1	0	1	1	1	1
M-SD + M-HD total	2	2	1	2	2	1	2	2	1	2
M-SD total	0	0	0	0	0	0	0	0	0	0
M-HD total	2	2	1	2	2	1	2	2	1	2

表 2.7.3.6-1. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験の日本サブ試験）（中間 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	1	1	1	1	1	1	1	1	0	1
I-SD	0	0	0	0	0	0	0	0	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	1	1	1	1	1	1	1	1	0	1
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	1	1	1	1	1	1	1	1	0	1
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	1	1	1	1	1	1	1	1	0	1
M-SD total	0	0	0	0	0	0	0	0	0	0
M-HD total	1	1	1	1	1	1	1	1	0	1

表 2.7.3.6-1. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験の日本サブ試験）（中間 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	4	4	2	4	4	2	4	4	2	3
I-SD	0	0	0	0	0	0	0	0	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	2	2	2	2	2	2	2	2	1	2
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	1	1	1	1	1	1	1	1	0	1
I-HD/M-HD	1	1	1	1	1	1	1	1	1	1
I-HD-OL	2	2	--	2	2	0	2	2	1	1
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	2	2	--	2	2	0	2	2	1	1
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	4	4	2	4	4	2	4	4	2	3
M-SD total	3	3	1	3	3	1	3	3	1	2
M-HD total	1	1	1	1	1	1	1	1	1	1

表 2.7.3.6-1. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験の日本サブ試験）（中間 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	4	4	4	4	4	4	4	4	1	4
I-SD	1	1	1	1	1	1	1	1	0	1
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	1	1	1	1	1	1	1	1	0	1
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	3	3	3	3	3	3	3	3	1	3
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	2	2	2	2	2	2	2	2	1	2
I-HD/M-HD	1	1	1	1	1	1	1	1	0	1
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	4	4	4	4	4	4	4	4	1	4
M-SD total	3	3	3	3	3	3	3	3	1	3
M-HD total	1	1	1	1	1	1	1	1	0	1

表 2.7.3.6-1. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験の日本サブ試験）（中間 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	1	1	1	0	0	1	0	1	0	0
I-SD	1	1	1	0	0	1	0	1	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	1	1	1	0	0	1	0	1	0	0
I-HD	0	0	0	0	0	0	0	0	0	0
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	1	1	1	0	0	1	0	1	0	0
M-SD total	0	0	0	0	0	0	0	0	0	0
M-HD total	1	1	1	0	0	1	0	1	0	0

表 2.7.3.6-1. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験の日本サブ試験）（中間 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	1	1	0	1	1	0	1	1	1	0
I-SD	0	0	0	0	0	0	0	0	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	0	0	0	0	0	0	0	0	0	0
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD-OL	1	1	--	1	1	0	1	1	1	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	1	1	--	1	1	0	1	1	1	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	1	1	0	1	1	0	1	1	1	0
M-SD total	1	1	0	1	1	0	1	1	1	0
M-HD total	0	0	0	0	0	0	0	0	0	0

表 2.7.3.6-1. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験の日本サブ試験）（中間 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	1	1	1	1	1	1	1	1	0	0
I-SD	1	1	1	1	1	1	1	1	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	1	1	1	1	1	1	1	1	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	0	0	0	0	0	0	0	0	0	0
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	1	1	1	1	1	1	1	1	0	0
M-SD total	1	1	1	1	1	1	1	1	0	0
M-HD total	0	0	0	0	0	0	0	0	0	0

表 2.7.3.6-1. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験の日本サブ試験）（中間 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	2	2	2	1	1	2	1	2	0	1
I-SD	1	1	1	0	0	1	0	1	0	0
I-SD/-	1	1	1	--	--	1	--	1	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	1	1	1	1	1	1	1	1	0	1
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	1	1	1	1	1	1	1	1	0	1
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	1	1	1	1	1	1	1	1	0	1
M-SD total	0	0	0	0	0	0	0	0	0	0
M-HD total	1	1	1	1	1	1	1	1	0	1

表 2.7.3.6-1. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験の日本サブ試験）（中間 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted]	2	2	2	2	2	2	2	2	2	2
I-SD	0	0	0	0	0	0	0	0	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	2	2	2	2	2	2	2	2	2	2
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	1	1	1	1	1	1	1	1	1	1
I-HD/M-HD	1	1	1	1	1	1	1	1	1	1
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	2	2	2	2	2	2	2	2	2	2
M-SD total	1	1	1	1	1	1	1	1	1	1
M-HD total	1	1	1	1	1	1	1	1	1	1

表 2.7.3.6-1. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験の日本サブ試験）（中間 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	4	4	4	4	3	4	2	4	1	1
I-SD	1	1	1	1	1	1	1	1	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	1	1	1	1	1	1	1	1	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	3	3	3	3	2	3	1	3	1	1
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	1	1	1	1	--	1	0	1	1	0
I-HD/M-SD	1	1	1	1	1	1	1	1	0	0
I-HD/M-HD	1	1	1	1	1	1	0	1	0	1
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	3	3	3	3	3	3	2	3	0	1
M-SD total	2	2	2	2	2	2	2	2	0	0
M-HD total	1	1	1	1	1	1	0	1	0	1

I-SD = induction standard dose group; I-HD = induction high dose group; I-HD-OL = induction high dose open-label group;
M-PL = maintenance placebo group; M-SD = maintenance standard dose group; M-HD = maintenance high dose group.
Note: 'randomized' group includes all patients randomized to a treatment or enrolled under amendment 4 into the OL treatment group. Screening Failures are excluded.
One patient ([redacted]) who is ongoing study is excluded from interim analysis.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.1__1.1_A

表 2.7.3.6-2. 治験責任医師別の被験者の内訳（無作為化した日本人被験者集団，M11-290 試験）（中間 CSR）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
All Sites	7	7	6	5	5	6	5	7	3	4
I-SD	2	2	2	0	0	2	0	2	0	0
I-SD/-	2	2	2	--	--	2	--	2	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	4	4	4	4	4	4	4	4	2	4
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	1	1	1	1	1	1	1	1	1	1
I-HD/M-HD	3	3	3	3	3	3	3	3	1	3
I-HD-OL	1	1	--	1	1	0	1	1	1	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	1	1	--	1	1	0	1	1	1	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	5	5	4	5	5	4	5	5	3	4
M-SD total	2	2	1	2	2	1	2	2	2	1
M-HD total	3	3	3	3	3	3	3	3	1	3

表 2.7.3.6-2. 治験責任医師別の被験者の内訳（無作為化した日本人被験者集団，M11-290 試験）（中間 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	1	1	1	0	0	1	0	1	0	0
I-SD	1	1	1	0	0	1	0	1	0	0
I-SD/-	1	1	1	--	--	1	--	1	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	0	0	0	0	0	0	0	0	0	0
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	0	0	0	0	0	0	0	0	0	0
M-SD total	0	0	0	0	0	0	0	0	0	0
M-HD total	0	0	0	0	0	0	0	0	0	0

表 2.7.3.6-2. 治験責任医師別の被験者の内訳（無作為化した日本人被験者集団，M11-290 試験）（中間 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	1	1	1	1	1	1	1	1	0	1
I-SD	0	0	0	0	0	0	0	0	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	1	1	1	1	1	1	1	1	0	1
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	1	1	1	1	1	1	1	1	0	1
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	1	1	1	1	1	1	1	1	0	1
M-SD total	0	0	0	0	0	0	0	0	0	0
M-HD total	1	1	1	1	1	1	1	1	0	1

表 2.7.3.6-2. 治験責任医師別の被験者の内訳（無作為化した日本人被験者集団，M11-290 試験）（中間 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted]	1	1	0	1	1	0	1	1	1	0
I-SD	0	0	0	0	0	0	0	0	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	0	0	0	0	0	0	0	0	0	0
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD-OL	1	1	--	1	1	0	1	1	1	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	1	1	--	1	1	0	1	1	1	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	1	1	0	1	1	0	1	1	1	0
M-SD total	1	1	0	1	1	0	1	1	1	0
M-HD total	0	0	0	0	0	0	0	0	0	0

表 2.7.3.6-2. 治験責任医師別の被験者の内訳（無作為化した日本人被験者集団，M11-290 試験）（中間 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	2	2	2	1	1	2	1	2	0	1
I-SD	1	1	1	0	0	1	0	1	0	0
I-SD/-	1	1	1	--	--	1	--	1	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	1	1	1	1	1	1	1	1	0	1
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	1	1	1	1	1	1	1	1	0	1
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	1	1	1	1	1	1	1	1	0	1
M-SD total	0	0	0	0	0	0	0	0	0	0
M-HD total	1	1	1	1	1	1	1	1	0	1

表 2.7.3.6-2. 治験責任医師別の被験者の内訳（無作為化した日本人被験者集団，M11-290 試験）（中間 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	2	2	2	2	2	2	2	2	2	2
I-SD	0	0	0	0	0	0	0	0	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	2	2	2	2	2	2	2	2	2	2
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	1	1	1	1	1	1	1	1	1	1
I-HD/M-HD	1	1	1	1	1	1	1	1	1	1
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	2	2	2	2	2	2	2	2	2	2
M-SD total	1	1	1	1	1	1	1	1	1	1
M-HD total	1	1	1	1	1	1	1	1	1	1

I-SD = induction standard dose group; I-HD = induction high dose group; I-HD-OL = induction high dose open-label group;
M-PL = maintenance placebo group; M-SD = maintenance standard dose group; M-HD = maintenance high dose group.
Note: 'randomized' group includes all patients randomized to a treatment or enrolled under amendment 4 into the OL treatment group. Screening Failures are excluded.
One patient ([redacted] who is ongoing study is excluded from interim analysis.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.1__1.1_J

表 2.7.3.6-3. 被験者の最終状況（統合集団，M11-290 試験）（中間 CSR）

Category Treatment	ITT (N=100) n	ITT-E (N=83) n	mITT (N=79) n	mITT-E (N=67) n	RR (N=25) n	Safety (N=100) n
Disc. in induction period	20	18	--	--	--	20
I-SD	10	10	--	--	--	10
I-HD	8	8	--	--	--	8
I-HD-OL	2	0	--	--	--	2
Disc. in maintenance period	--	--	11	10	5	12
M-PL	--	--	1	0	1	1
M-SD	--	--	8	8	3	8
M-HD	--	--	2	2	1	3
On DB TRT w/o re-rand. due to disease flare	--	--	6	6	--	7
M-PL	--	--	0	0	--	0
M-SD	--	--	5	5	--	5
M-HD	--	--	1	1	--	2
On DB TRT after re-rand. due to disease flare	--	--	4	3	4	4
M-PL	--	--	1	0	1	1
M-SD	--	--	2	2	2	2
M-HD	--	--	1	1	1	1
On OL TRT after re-rand. due to disease flare	--	--	1	1	1	1
M-PL	--	--	0	0	0	0
M-SD	--	--	1	1	1	1
M-HD	--	--	0	0	0	0

表 2.7.3.6-3. 被験者の最終状況（統合集団，M11-290 試験）（中間 CSR）（続き）

Category Treatment	ITT (N=100) n	ITT-E (N=83) n	mITT (N=79) n	mITT-E (N=67) n	RR (N=25) n	Safety (N=100) n
Completed week 52	--	--	68	57	20	68
M-PL	--	--	11	0	6	11
I-SD	--	--	4	0	2	4
I-HD	--	--	7	0	4	7
M-SD	--	--	25	25	5	25
I-SD	--	--	5	5	0	5
I-HD/I-HD-OL	--	--	20	20	5	20
I-HD	--	--	14	14	4	14
I-HD-OL	--	--	6	6	1	6
M-HD	--	--	32	32	9	32
I-SD	--	--	9	9	3	9
I-HD/I-HD-OL	--	--	23	23	6	23
I-HD	--	--	17	17	5	17
I-HD-OL	--	--	6	6	1	6
On DB TRT w/o disease flare	--	--	48	43	--	48
M-PL	--	--	5	0	--	5
I-SD	--	--	2	0	--	2
I-HD	--	--	3	0	--	3
M-SD	--	--	20	20	--	20
I-SD	--	--	5	5	--	5
I-HD/I-HD-OL	--	--	15	15	--	15
I-HD	--	--	10	10	--	10
I-HD-OL	--	--	5	5	--	5
M-HD	--	--	23	23	--	23
I-SD	--	--	6	6	--	6
I-HD/I-HD-OL	--	--	17	17	--	17
I-HD	--	--	12	12	--	12
I-HD-OL	--	--	5	5	--	5

表 2.7.3.6-3. 被験者の最終状況（統合集団，M11-290 試験）（中間 CSR）（続き）

Category Treatment	ITT (N=100) n	ITT-E (N=83) n	mITT (N=79) n	mITT-E (N=67) n	RR (N=25) n	Safety (N=100) n
On DB TRT after re-rand. due to disease flare	--	--	11	8	11	11
M-PL	--	--	3	0	3	3
I-SD	--	--	2	0	2	2
I-HD	--	--	1	0	1	1
M-SD	--	--	3	3	3	3
I-SD	--	--	0	0	0	0
I-HD/I-HD-OL	--	--	3	3	3	3
I-HD	--	--	3	3	3	3
I-HD-OL	--	--	0	0	0	0
M-HD	--	--	5	5	5	5
I-SD	--	--	2	2	2	2
I-HD/I-HD-OL	--	--	3	3	3	3
I-HD	--	--	3	3	3	3
I-HD-OL	--	--	0	0	0	0
On OL TRT after re-rand. due to disease flare	--	--	9	6	9	9
M-PL	--	--	3	0	3	3
I-SD	--	--	0	0	0	0
I-HD	--	--	3	0	3	3
M-SD	--	--	2	2	2	2
I-SD	--	--	0	0	0	0
I-HD/I-HD-OL	--	--	2	2	2	2
I-HD	--	--	1	1	1	1
I-HD-OL	--	--	1	1	1	1
M-HD	--	--	4	4	4	4
I-SD	--	--	1	1	1	1
I-HD/I-HD-OL	--	--	3	3	3	3
I-HD	--	--	2	2	2	2
I-HD-OL	--	--	1	1	1	1

表 2.7.3.6-3.　　被験者の最終状況（統合集団，M11-290 試験）（中間 CSR）（続き）

I-SD = induction standard dose group; I-HD = induction high dose group; I-HD-OL = induction high dose open-label group;
M-PL = maintenance placebo group; M-SD = maintenance standard dose group; M-HD = maintenance high dose group.
One patient ([redacted]) who is ongoing study is excluded from interim analysis.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.1__2.1_A

表 2.7.3.6-4. 被験者の最終状況（日本人被験者集団，M11-290 試験）（中間 CSR）

Category Treatment	ITT (N=7) n	ITT-E (N=6) n	mITT (N=5) n	mITT-E (N=5) n	RR (N=3) n	Safety (N=7) n
Disc. in induction period	2	2	--	--	--	2
I-SD	2	2	--	--	--	2
I-HD	0	0	--	--	--	0
I-HD-OL	0	0	--	--	--	0
Disc. in maintenance period	--	--	1	1	1	1
M-PL	--	--	0	0	0	0
M-SD	--	--	1	1	1	1
M-HD	--	--	0	0	0	0
On DB TRT w/o re-rand. due to disease flare	--	--	0	0	--	0
M-PL	--	--	0	0	--	0
M-SD	--	--	0	0	--	0
M-HD	--	--	0	0	--	0
On DB TRT after re-rand. due to disease flare	--	--	0	0	0	0
M-PL	--	--	0	0	0	0
M-SD	--	--	0	0	0	0
M-HD	--	--	0	0	0	0
On OL TRT after re-rand. due to disease flare	--	--	1	1	1	1
M-PL	--	--	0	0	0	0
M-SD	--	--	1	1	1	1
M-HD	--	--	0	0	0	0

表 2.7.3.6-4. 被験者の最終状況（日本人被験者集団，M11-290 試験）（中間 CSR）（続き）

Category Treatment	ITT (N=7) n	ITT-E (N=6) n	mITT (N=5) n	mITT-E (N=5) n	RR (N=3) n	Safety (N=7) n
Completed week 52	--	--	4	4	2	4
M-PL	--	--	0	0	0	0
I-SD	--	--	0	0	0	0
I-HD	--	--	0	0	0	0
M-SD	--	--	1	1	1	1
I-SD	--	--	0	0	0	0
I-HD/I-HD-OL	--	--	1	1	1	1
I-HD	--	--	1	1	1	1
I-HD-OL	--	--	0	0	0	0
M-HD	--	--	3	3	1	3
I-SD	--	--	0	0	0	0
I-HD/I-HD-OL	--	--	3	3	1	3
I-HD	--	--	3	3	1	3
I-HD-OL	--	--	0	0	0	0
On DB TRT w/o disease flare	--	--	2	2	--	2
M-PL	--	--	0	0	--	0
I-SD	--	--	0	0	--	0
I-HD	--	--	0	0	--	0
M-SD	--	--	0	0	--	0
I-SD	--	--	0	0	--	0
I-HD/I-HD-OL	--	--	0	0	--	0
I-HD	--	--	0	0	--	0
I-HD-OL	--	--	0	0	--	0
M-HD	--	--	2	2	--	2
I-SD	--	--	0	0	--	0
I-HD/I-HD-OL	--	--	2	2	--	2
I-HD	--	--	2	2	--	2
I-HD-OL	--	--	0	0	--	0

表 2.7.3.6-4. 被験者の最終状況（日本人被験者集団，M11-290 試験）（中間 CSR）（続き）

Category Treatment	ITT (N=7) n	ITT-E (N=6) n	mITT (N=5) n	mITT-E (N=5) n	RR (N=3) n	Safety (N=7) n
On DB TRT after re-rand. due to disease flare	--	--	0	0	0	0
M-PL	--	--	0	0	0	0
I-SD	--	--	0	0	0	0
I-HD	--	--	0	0	0	0
M-SD	--	--	0	0	0	0
I-SD	--	--	0	0	0	0
I-HD/I-HD-OL	--	--	0	0	0	0
I-HD	--	--	0	0	0	0
I-HD-OL	--	--	0	0	0	0
M-HD	--	--	0	0	0	0
I-SD	--	--	0	0	0	0
I-HD/I-HD-OL	--	--	0	0	0	0
I-HD	--	--	0	0	0	0
I-HD-OL	--	--	0	0	0	0
On OL TRT after re-rand. due to disease flare	--	--	2	2	2	2
M-PL	--	--	0	0	0	0
I-SD	--	--	0	0	0	0
I-HD	--	--	0	0	0	0
M-SD	--	--	1	1	1	1
I-SD	--	--	0	0	0	0
I-HD/I-HD-OL	--	--	1	1	1	1
I-HD	--	--	1	1	1	1
I-HD-OL	--	--	0	0	0	0
M-HD	--	--	1	1	1	1
I-SD	--	--	0	0	0	0
I-HD/I-HD-OL	--	--	1	1	1	1
I-HD	--	--	1	1	1	1
I-HD-OL	--	--	0	0	0	0

表 2.7.3.6-4.　　被験者の最終状況（日本人被験者集団，M11-290 試験）（中間 CSR）（続き）

I-SD = induction standard dose group; I-HD = induction high dose group; I-HD-OL = induction high dose open-label group;
M-PL = maintenance placebo group; M-SD = maintenance standard dose group; M-HD = maintenance high dose group.
One patient ([redacted] who is ongoing study is excluded from interim analysis.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.1__2.1_J

表 2.7.3.6-5. 被験者の中止理由（統合被験者集団，M11-290 試験）（中間 CSR）

Study Period Treatment Discontinuation due to	ITT (N=100) n (%)	ITT-E (N=83) n (%)	mITT (N=79) n (%)	mITT-E (N=67) n (%)	RR (N=25) n (%)	Safety (N=100) n (%)
Disc. in induction period	20 (20.0)	18 (21.7)	--	--	--	20 (20.0)
I-SD						
All reasons$	10 (10.0)	10 (12.0)	--	--	--	10 (10.0)
Adverse event	3 (3.0)	3 (3.6)	--	--	--	3 (3.0)
Withdrew consent	3 (3.0)	3 (3.6)	--	--	--	3 (3.0)
Lost to follow-up	0	0	--	--	--	0
Lack of efficacy	2 (2.0)	2 (2.4)	--	--	--	2 (2.0)
Requires alternative (or prohibited) therapy	1 (1.0)	1 (1.2)	--	--	--	1 (1.0)
Subject non-compliance	0	0	--	--	--	0
Non-Responder at week 8	4 (4.0)	4 (4.8)	--	--	--	4 (4.0)
Other	0	0	--	--	--	0
Primary reason	10 (10.0)	10 (12.0)	--	--	--	10 (10.0)
Adverse event	1 (1.0)	1 (1.2)	--	--	--	1 (1.0)
Withdrew consent	2 (2.0)	2 (2.4)	--	--	--	2 (2.0)
Lost to follow-up	0	0	--	--	--	0
Lack of efficacy	2 (2.0)	2 (2.4)	--	--	--	2 (2.0)
Requires alternative (or prohibited) therapy	1 (1.0)	1 (1.2)	--	--	--	1 (1.0)
Subject non-compliance	0	0	--	--	--	0
Non-Responder at week 8	4 (4.0)	4 (4.8)	--	--	--	4 (4.0)
Other	0	0	--	--	--	0

表 2.7.3.6-5. 被験者の中止理由（統合被験者集団，M11-290 試験）（中間 CSR）（続き）

Study Period Treatment Discontinuation due to	ITT (N=100) n (%)	ITT-E (N=83) n (%)	mITT (N=79) n (%)	mITT-E (N=67) n (%)	RR (N=25) n (%)	Safety (N=100) n (%)
I-HD						
All reasons$	8 (8.0)	8 (9.6)	--	--	--	8 (8.0)
Adverse event	1 (1.0)	1 (1.2)	--	--	--	1 (1.0)
Withdrew consent	1 (1.0)	1 (1.2)	--	--	--	1 (1.0)
Lost to follow-up	0	0	--	--	--	0
Lack of efficacy	2 (2.0)	2 (2.4)	--	--	--	2 (2.0)
Requires alternative (or prohibited) therapy	1 (1.0)	1 (1.2)	--	--	--	1 (1.0)
Subject non-compliance	0	0	--	--	--	0
Non-Responder at week 8	6 (6.0)	6 (7.2)	--	--	--	6 (6.0)
Other	0	0	--	--	--	0
Primary reason	8 (8.0)	8 (9.6)	--	--	--	8 (8.0)
Adverse event	1 (1.0)	1 (1.2)	--	--	--	1 (1.0)
Withdrew consent	1 (1.0)	1 (1.2)	--	--	--	1 (1.0)
Lost to follow-up	0	0	--	--	--	0
Lack of efficacy	1 (1.0)	1 (1.2)	--	--	--	1 (1.0)
Requires alternative (or prohibited) therapy	1 (1.0)	1 (1.2)	--	--	--	1 (1.0)
Subject non-compliance	0	0	--	--	--	0
Non-Responder at week 8	4 (4.0)	4 (4.8)	--	--	--	4 (4.0)
Other	0	0	--	--	--	0

表 2.7.3.6-5. 被験者の中止理由（統合被験者集団，M11-290 試験）（中間 CSR）（続き）

Study Period Treatment Discontinuation due to	ITT (N=100) n (%)	ITT-E (N=83) n (%)	mITT (N=79) n (%)	mITT-E (N=67) n (%)	RR (N=25) n (%)	Safety (N=100) n (%)
I-HD-OL						
All reasons$	2 (2.0)	--	--	--	--	2 (2.0)
Adverse event	0	--	--	--	--	0
Withdrew consent	0	--	--	--	--	0
Lost to follow-up	0	--	--	--	--	0
Lack of efficacy	2 (2.0)	--	--	--	--	2 (2.0)
Requires alternative (or prohibited) therapy	2 (2.0)	--	--	--	--	2 (2.0)
Subject non-compliance	0	--	--	--	--	0
Non-Responder at week 8	0	--	--	--	--	0
Other	0	--	--	--	--	0
Primary reason	2 (2.0)	--	--	--	--	2 (2.0)
Adverse event	0	--	--	--	--	0
Withdrew consent	0	--	--	--	--	0
Lost to follow-up	0	--	--	--	--	0
Lack of efficacy	1 (1.0)	--	--	--	--	1 (1.0)
Requires alternative (or prohibited) therapy	1 (1.0)	--	--	--	--	1 (1.0)
Subject non-compliance	0	--	--	--	--	0
Non-Responder at week 8	0	--	--	--	--	0
Other	0	--	--	--	--	0

表 2.7.3.6-5. 被験者の中止理由（統合被験者集団，M11-290 試験）（中間 CSR）（続き）

Study Period Treatment Discontinuation due to	ITT (N=100) n (%)	ITT-E (N=83) n (%)	mITT (N=79) n (%)	mITT-E (N=67) n (%)	RR (N=25) n (%)	Safety (N=100) n (%)
Disc. in maintenance period	--	--	11 (13.9)	10 (14.9)	5 (20.0)	12 (12.0)
M-PL						
All reasons$	--	--	1 (1.3)	0	1 (4.0)	1 (1.0)
Adverse event	--	--	0	0	0	0
Withdrew consent	--	--	0	0	0	0
Lost to follow-up	--	--	0	0	0	0
Lack of efficacy	--	--	0	0	0	0
Requires alternative (or prohibited) therapy	--	--	1 (1.3)	0	1 (4.0)	1 (1.0)
Subject non-compliance	--	--	0	0	0	0
Non-Responder at week 8	--	--	0	0	0	0
Other	--	--	0	0	0	0
Primary reason	--	--	1 (1.3)	0	1 (4.0)	1 (1.0)
Adverse event	--	--	0	0	0	0
Withdrew consent	--	--	0	0	0	0
Lost to follow-up	--	--	0	0	0	0
Lack of efficacy	--	--	0	0	0	0
Requires alternative (or prohibited) therapy	--	--	1 (1.3)	0	1 (4.0)	1 (1.0)
Subject non-compliance	--	--	0	0	0	0
Non-Responder at week 8	--	--	0	0	0	0
Other	--	--	0	0	0	0

表 2.7.3.6-5. 被験者の中止理由（統合被験者集団，M11-290 試験）（中間 CSR）（続き）

Study Period Treatment Discontinuation due to	ITT (N=100) n (%)	ITT-E (N=83) n (%)	mITT (N=79) n (%)	mITT-E (N=67) n (%)	RR (N=25) n (%)	Safety (N=100) n (%)
M-SD + M-HD total	--	--	10 (12.7)	10 (14.9)	4 (16.0)	11 (11.0)
M-SD						
All reasons$	--	--	8 (10.1)	8 (11.9)	3 (12.0)	8 (8.0)
Adverse event	--	--	2 (2.5)	2 (3.0)	0	2 (2.0)
Withdrew consent	--	--	2 (2.5)	2 (3.0)	0	2 (2.0)
Lost to follow-up	--	--	0	0	0	0
Lack of efficacy	--	--	5 (6.3)	5 (7.5)	2 (8.0)	5 (5.0)
Requires alternative (or prohibited) therapy	--	--	2 (2.5)	2 (3.0)	2 (8.0)	2 (2.0)
Subject non-compliance	--	--	0	0	0	0
Non-Responder at week 8	--	--	0	0	0	0
Other	--	--	0	0	0	0
Primary reason	--	--	8 (10.1)	8 (11.9)	3 (12.0)	8 (8.0)
Adverse event	--	--	0	0	0	0
Withdrew consent	--	--	2 (2.5)	2 (3.0)	0	2 (2.0)
Lost to follow-up	--	--	0	0	0	0
Lack of efficacy	--	--	5 (6.3)	5 (7.5)	2 (8.0)	5 (5.0)
Requires alternative (or prohibited) therapy	--	--	1 (1.3)	1 (1.5)	1 (4.0)	1 (1.0)
Subject non-compliance	--	--	0	0	0	0
Non-Responder at week 8	--	--	0	0	0	0
Other	--	--	0	0	0	0

表 2.7.3.6-5. 被験者の中止理由（統合被験者集団，M11-290 試験）（中間 CSR）（続き）

Study Period Treatment Discontinuation due to	ITT (N=100) n (%)	ITT-E (N=83) n (%)	mITT (N=79) n (%)	mITT-E (N=67) n (%)	RR (N=25) n (%)	Safety (N=100) n (%)
M-HD						
All reasons$	--	--	2 (2.5)	2 (3.0)	1 (4.0)	3 (3.0)
Adverse event	--	--	0	0	0	0
Withdrew consent	--	--	1 (1.3)	1 (1.5)	0	1 (1.0)
Lost to follow-up	--	--	1 (1.3)	1 (1.5)	0	1 (1.0)
Lack of efficacy	--	--	0	0	0	1 (1.0)
Requires alternative (or prohibited) therapy	--	--	1 (1.3)	1 (1.5)	0	1 (1.0)
Subject non-compliance	--	--	1 (1.3)	1 (1.5)	1 (4.0)	1 (1.0)
Non-Responder at week 8	--	--	0	0	0	0
Other	--	--	0	0	0	0
Primary reason	--	--	2 (2.5)	2 (3.0)	1 (4.0)	3 (3.0)
Adverse event	--	--	0	0	0	0
Withdrew consent	--	--	1 (1.3)	1 (1.5)	0	1 (1.0)
Lost to follow-up	--	--	0	0	0	0
Lack of efficacy	--	--	0	0	0	1 (1.0)
Requires alternative (or prohibited) therapy	--	--	0	0	0	0
Subject non-compliance	--	--	1 (1.3)	1 (1.5)	1 (4.0)	1 (1.0)
Non-Responder at week 8	--	--	0	0	0	0
Other	--	--	0	0	0	0

I-SD = induction standard dose group; I-HD = induction high dose group; I-HD-OL = induction high dose open-label group;
M-PL = maintenance placebo group; M-SD = maintenance standard dose group; M-HD = maintenance high dose group.
$ Subjects who discontinued study drug are counted under each reason given for discontinuation, therefore,
the sum of the counts given for the reasons may be greater than the overall number of discontinuations.
One patient ([redacted]) who is ongoing study is excluded from interim analysis.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.1__2.2_A

表 2.7.3.6-6. 被験者の中止理由（日本人被験者，M11-290 試験）（中間 CSR）

Study Period Treatment Discontinuation due to	ITT (N=7) n (%)	ITT-E (N=6) n (%)	mITT (N=5) n (%)	mITT-E (N=5) n (%)	RR (N=3) n (%)	Safety (N=7) n (%)
Disc. in induction period	2 (28.6)	2 (33.3)	--	--	--	2 (28.6)
I-SD						
All reasons$	2 (28.6)	2 (33.3)	--	--	--	2 (28.6)
Adverse event	1 (14.3)	1 (16.7)	--	--	--	1 (14.3)
Withdrew consent	1 (14.3)	1 (16.7)	--	--	--	1 (14.3)
Lost to follow-up	0	0	--	--	--	0
Lack of efficacy	0	0	--	--	--	0
Requires alternative (or prohibited) therapy	0	0	--	--	--	0
Subject non-compliance	0	0	--	--	--	0
Non-Responder at week 8	1 (14.3)	1 (16.7)	--	--	--	1 (14.3)
Other	0	0	--	--	--	0
Primary reason	2 (28.6)	2 (33.3)	--	--	--	2 (28.6)
Adverse event	1 (14.3)	1 (16.7)	--	--	--	1 (14.3)
Withdrew consent	0	0	--	--	--	0
Lost to follow-up	0	0	--	--	--	0
Lack of efficacy	0	0	--	--	--	0
Requires alternative (or prohibited) therapy	0	0	--	--	--	0
Subject non-compliance	0	0	--	--	--	0
Non-Responder at week 8	1 (14.3)	1 (16.7)	--	--	--	1 (14.3)
Other	0	0	--	--	--	0

表 2.7.3.6-6. 被験者の中止理由（日本人被験者，M11-290 試験）（中間 CSR）（続き）

Study Period Treatment Discontinuation due to	ITT (N=7) n (%)	ITT-E (N=6) n (%)	mITT (N=5) n (%)	mITT-E (N=5) n (%)	RR (N=3) n (%)	Safety (N=7) n (%)
I-HD						
All reasons$	0	0	--	--	--	0
Adverse event	0	0	--	--	--	0
Withdrew consent	0	0	--	--	--	0
Lost to follow-up	0	0	--	--	--	0
Lack of efficacy	0	0	--	--	--	0
Requires alternative (or prohibited) therapy	0	0	--	--	--	0
Subject non-compliance	0	0	--	--	--	0
Non-Responder at week 8	0	0	--	--	--	0
Other	0	0	--	--	--	0
Primary reason	0	0	--	--	--	0
Adverse event	0	0	--	--	--	0
Withdrew consent	0	0	--	--	--	0
Lost to follow-up	0	0	--	--	--	0
Lack of efficacy	0	0	--	--	--	0
Requires alternative (or prohibited) therapy	0	0	--	--	--	0
Subject non-compliance	0	0	--	--	--	0
Non-Responder at week 8	0	0	--	--	--	0
Other	0	0	--	--	--	0

表 2.7.3.6-6. 被験者の中止理由（日本人被験者，M11-290 試験）（中間 CSR）（続き）

Study Period Treatment Discontinuation due to	ITT (N=7) n (%)	ITT-E (N=6) n (%)	mITT (N=5) n (%)	mITT-E (N=5) n (%)	RR (N=3) n (%)	Safety (N=7) n (%)
I-HD-OL						
All reasons$	0	--	--	--	--	0
Adverse event	0	--	--	--	--	0
Withdrew consent	0	--	--	--	--	0
Lost to follow-up	0	--	--	--	--	0
Lack of efficacy	0	--	--	--	--	0
Requires alternative (or prohibited) therapy	0	--	--	--	--	0
Subject non-compliance	0	--	--	--	--	0
Non-Responder at week 8	0	--	--	--	--	0
Other	0	--	--	--	--	0
Primary reason	0	--	--	--	--	0
Adverse event	0	--	--	--	--	0
Withdrew consent	0	--	--	--	--	0
Lost to follow-up	0	--	--	--	--	0
Lack of efficacy	0	--	--	--	--	0
Requires alternative (or prohibited) therapy	0	--	--	--	--	0
Subject non-compliance	0	--	--	--	--	0
Non-Responder at week 8	0	--	--	--	--	0
Other	0	--	--	--	--	0

表 2.7.3.6-6. 被験者の中止理由（日本人被験者，M11-290 試験）（中間 CSR）（続き）

Study Period Treatment Discontinuation due to	ITT (N=7) n (%)	ITT-E (N=6) n (%)	mITT (N=5) n (%)	mITT-E (N=5) n (%)	RR (N=3) n (%)	Safety (N=7) n (%)
Disc. in maintenance period	--	--	1 (20.0)	1 (20.0)	1 (33.3)	1 (14.3)
M-PL						
All reasons$	--	--	0	0	0	0
Adverse event	--	--	0	0	0	0
Withdrew consent	--	--	0	0	0	0
Lost to follow-up	--	--	0	0	0	0
Lack of efficacy	--	--	0	0	0	0
Requires alternative (or prohibited) therapy	--	--	0	0	0	0
Subject non-compliance	--	--	0	0	0	0
Non-Responder at week 8	--	--	0	0	0	0
Other	--	--	0	0	0	0
Primary reason	--	--	0	0	0	0
Adverse event	--	--	0	0	0	0
Withdrew consent	--	--	0	0	0	0
Lost to follow-up	--	--	0	0	0	0
Lack of efficacy	--	--	0	0	0	0
Requires alternative (or prohibited) therapy	--	--	0	0	0	0
Subject non-compliance	--	--	0	0	0	0
Non-Responder at week 8	--	--	0	0	0	0
Other	--	--	0	0	0	0

表 2.7.3.6-6. 被験者の中止理由（日本人被験者，M11-290 試験）（中間 CSR）（続き）

Study Period Treatment Discontinuation due to	ITT (N=7) n (%)	ITT-E (N=6) n (%)	mITT (N=5) n (%)	mITT-E (N=5) n (%)	RR (N=3) n (%)	Safety (N=7) n (%)
M-SD + M-HD total	--	--	1 (20.0)	1 (20.0)	1 (33.3)	1 (14.3)
M-SD						
All reasons$	--	--	1 (20.0)	1 (20.0)	1 (33.3)	1 (14.3)
Adverse event	--	--	0	0	0	0
Withdrew consent	--	--	0	0	0	0
Lost to follow-up	--	--	0	0	0	0
Lack of efficacy	--	--	1 (20.0)	1 (20.0)	1 (33.3)	1 (14.3)
Requires alternative (or prohibited) therapy	--	--	1 (20.0)	1 (20.0)	1 (33.3)	1 (14.3)
Subject non-compliance	--	--	0	0	0	0
Non-Responder at week 8	--	--	0	0	0	0
Other	--	--	0	0	0	0
Primary reason	--	--	1 (20.0)	1 (20.0)	1 (33.3)	1 (14.3)
Adverse event	--	--	0	0	0	0
Withdrew consent	--	--	0	0	0	0
Lost to follow-up	--	--	0	0	0	0
Lack of efficacy	--	--	1 (20.0)	1 (20.0)	1 (33.3)	1 (14.3)
Requires alternative (or prohibited) therapy	--	--	0	0	0	0
Subject non-compliance	--	--	0	0	0	0
Non-Responder at week 8	--	--	0	0	0	0
Other	--	--	0	0	0	0

表 2.7.3.6-6. 被験者の中止理由（日本人被験者，M11-290 試験）（中間 CSR）（続き）

Study Period Treatment Discontinuation due to	ITT (N=7) n (%)	ITT-E (N=6) n (%)	mITT (N=5) n (%)	mITT-E (N=5) n (%)	RR (N=3) n (%)	Safety (N=7) n (%)
M-HD						
All reasons$	--	--	0	0	0	0
Adverse event	--	--	0	0	0	0
Withdrew consent	--	--	0	0	0	0
Lost to follow-up	--	--	0	0	0	0
Lack of efficacy	--	--	0	0	0	0
Requires alternative (or prohibited) therapy	--	--	0	0	0	0
Subject non-compliance	--	--	0	0	0	0
Non-Responder at week 8	--	--	0	0	0	0
Other	--	--	0	0	0	0
Primary reason	--	--	0	0	0	0
Adverse event	--	--	0	0	0	0
Withdrew consent	--	--	0	0	0	0
Lost to follow-up	--	--	0	0	0	0
Lack of efficacy	--	--	0	0	0	0
Requires alternative (or prohibited) therapy	--	--	0	0	0	0
Subject non-compliance	--	--	0	0	0	0
Non-Responder at week 8	--	--	0	0	0	0
Other	--	--	0	0	0	0

I-SD = induction standard dose group; I-HD = induction high dose group; I-HD-OL = induction high dose open-label group;
M-PL = maintenance placebo group; M-SD = maintenance standard dose group; M-HD = maintenance high dose group.
$ Subjects who discontinued study drug are counted under each reason given for discontinuation, therefore,
the sum of the counts given for the reasons may be greater than the overall number of discontinuations.
One patient ([redacted]) who is ongoing study is excluded from interim analysis.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.1__2.2_J

表 2.7.3.6-7. 治験実施計画書からの逸脱（無作為化した統合被験者集団，M11-290 試験）（中間 CSR）

		I-SD				I-HD/HD-OL				
		--$ (N=10)	M-PL (N=4)	M-SD (N=8)	M-HD (N=10)	--$ (N=10)	M-PL (N=8)	M-SD (N=25)	M-HD (N=25)	Total (N=100)
Subjects who had at least one protocol deviation		0	1 (25.0)	0	4 (40.0)	1 (10.0)	3 (37.5)	8 (32.0)	5 (20.0)	22 (22.0)
Subject entered into the study even though did not satisfy entry criteria		0	0	0	1 (10.0)	0	1 (12.5)	2 (8.0)	1 (4.0)	5 (5.0)
Inclusion criteria violated	6	0	0	0	1 (10.0)	0	1 (12.5)	0	1 (4.0)	3 (3.0)
Exclusion criteria violated	24	0	0	0	0	0	0	1 (4.0)	0	1 (1.0)
	27	0	0	0	0	0	0	1 (4.0)	0	1 (1.0)
Subject received wrong treatment or incorrect dose		0	1 (25.0)	0	2 (20.0)	1 (10.0)	2 (25.0)	4 (16.0)	4 (16.0)	14 (14.0)
Subject received excluded concomitant treatment		0	0	0	0	0	0	2 (8.0)	0	2 (2.0)
Subject developed withdrawal criteria during the study and was not withdrawn		0	0	0	1 (10.0)	0	0	0	0	1 (1.0)

表 2.7.3.6-7. 治験実施計画書からの逸脱（無作為化した統合被験者集団，M11-290 試験）（中間 CSR）（続き）

	I-SD				I-HD/HD-OL				
	--$ (N=10)	M-PL (N=4)	M-SD (N=8)	M-HD (N=10)	--$ (N=10)	M-PL (N=8)	M-SD (N=25)	M-HD (N=25)	Total (N=100)

Inclusion Criteria Violated

6: Subject has a neg TB Screening Assessment. If a subject has a pos (>= 5 mm induration) PPD test and/or IGRA test at Screening, a CXR (PA and lateral view) for evaluation of active TB disease.

表 2.7.3.6-7. 治験実施計画書からの逸脱（無作為化した統合被験者集団，M11-290 試験）（中間 CSR）（続き）

	I-SD				I-HD/HD-OL				
	--$	M-PL	M-SD	M-HD	--$	M-PL	M-SD	M-HD	Total
	(N=10)	(N=4)	(N=8)	(N=10)	(N=10)	(N=8)	(N=25)	(N=25)	(N=100)
Exclusion Criteria Violated									
24: Subject with a positive result for the Hepatitis B surface antigen (HBs Ag) or any HBV DNA PCR result that meets or exceeds detection sensitivity will be excluded.									
27: Infection(s) requiring treatment with intravenous (IV) anti-infectives within 30 days prior to the Baseline Visit or oral anti-infectives within 14 days prior to the Baseline Visit.									

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group,
M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
NOTE: All Randomized = includes all patients randomized to a treatment or enrolled under amendment 4 into the OL treatment group.
Screening Failures are excluded.
$ patients who discontinued as non-responders from the study at week 8.
One patient ([redacted]) who is ongoing study is excluded from interim analysis.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.1__9_A

表 2.7.3.6-8. 治験実施計画書からの逸脱（無作為化した日本人被験者集団，M11-290 試験）（中間 CSR）

		I-SD				I-HD/HD-OL				
		--$ (N=2)	M-PL (N=0)	M-SD (N=0)	M-HD (N=0)	--$ (N=0)	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=7)
Subjects who had at least one protocol deviation		0	0	0	0	0	0	2 (100)	0	2 (28.6)
Subject entered into the study even though did not satisfy entry criteria		0	0	0	0	0	0	1 (50.0)	0	1 (14.3)
Exclusion criteria violated	27	0	0	0	0	0	0	1 (50.0)	0	1 (14.3)
Subject received wrong treatment or incorrect dose		0	0	0	0	0	0	0	0	0
Subject received excluded concomitant treatment		0	0	0	0	0	0	1 (50.0)	0	1 (14.3)
Subject developed withdrawal criteria during the study and was not withdrawn		0	0	0	0	0	0	0	0	0

表 2.7.3.6-8. 治験実施計画書からの逸脱（無作為化した日本人被験者集団，M11-290 試験）（中間 CSR）（続き）

	I-SD				I-HD/HD-OL				
	--$ (N=2)	M-PL (N=0)	M-SD (N=0)	M-HD (N=0)	--$ (N=0)	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=7)
Inclusion Criteria Violated									
No subject has inclusion criteria violated									

表 2.7.3.6-8. 治験実施計画書からの逸脱（無作為化した日本人被験者集団，M11-290 試験）（中間 CSR）（続き）

	I-SD				I-HD/HD-OL				
	--$ (N=2)	M-PL (N=0)	M-SD (N=0)	M-HD (N=0)	--$ (N=0)	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=7)
Exclusion Criteria Violated									
27: Infection(s) requiring treatment with intravenous (IV) anti-infectives within 30 days prior to the Baseline Visit or oral anti-infectives within 14 days prior to the Baseline Visit.									

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group,
M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
NOTE: All Randomized = includes all patients randomized to a treatment or enrolled under amendment 4 into the OL treatment group.
Screening Failures are excluded.
$ patients who discontinued as non-responders from the study at week 8.
One patient ([redacted]) who is ongoing study is excluded from interim analysis.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.1__9_J

表 2.7.3.6-9. 人口統計学的特性（統合 ITT 集団，M11-290 試験）（中間 CSR）

	ITT					
	ITT-E					
	I-SD (N=32)	I-HD (N=51)	Total (N=83)	I-HD-OL (N=17)	Total (N=100)	P-Value@
Sex - n (%)						
Female	15 (46.9)	23 (45.1)	38 (45.8)	13 (76.5)	51 (51.0)	0.874
Male	17 (53.1)	28 (54.9)	45 (54.2)	4 (23.5)	49 (49.0)	
Age (year)						
n	32	51	83	17	100	0.182
Mean (SD)	14.7 (2.66)	13.8 (3.06)	14.1 (2.93)	13.7 (2.89)	14.1 (2.91)	
Median	15.5	15.0	15.0	14.0	15.0	
Min, Max	6, 17	5, 17	5, 17	7, 17	5, 17	
Age group 1 (year) - n (%)						
< 13	4 (12.5)	17 (33.3)	21 (25.3)	5 (29.4)	26 (26.0)	0.040*
>= 13	28 (87.5)	34 (66.7)	62 (74.7)	12 (70.6)	74 (74.0)	
Age group 2 (year) - n (%)						
< 12	3 (9.4)	12 (23.5)	15 (18.1)	4 (23.5)	19 (19.0)	0.145
>= 12	29 (90.6)	39 (76.5)	68 (81.9)	13 (76.5)	81 (81.0)	
Race - n (%)						
White	28 (87.5)	45 (88.2)	73 (88.0)	15 (88.2)	88 (88.0)	1.000
Black	1 (3.1)	2 (3.9)	3 (3.6)	0	3 (3.0)	
Asian	3 (9.4)	4 (7.8)	7 (8.4)	1 (5.9)	8 (8.0)	
American Indian/Alaska Native	0	0	0	0	0	
Other	0	0	0	0	0	
Multiple	0	0	0	1 (5.9)	1 (1.0)	

表 2.7.3.6-9. 人口統計学的特性（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=32)	I-HD (N=51)	Total (N=83)	I-HD-OL (N=17)	Total (N=100)	P-Value@
Ethnicity - n (%)						
Hispanic or Latino	1 (3.1)	2 (3.9)	3 (3.6)	1 (5.9)	4 (4.0)	1.000
Japanese	2 (6.3)	4 (7.8)	6 (7.2)	1 (5.9)	7 (7.0)	
No ethnicity	29 (90.6)	45 (88.2)	74 (89.2)	15 (88.2)	89 (89.0)	
Geographic region - n (%)						
North America	2 (6.3)	8 (15.7)	10 (12.0)	3 (17.6)	13 (13.0)	0.666
Western Europe	3 (9.4)	4 (7.8)	7 (8.4)	1 (5.9)	8 (8.0)	
Eastern Europe	25 (78.1)	35 (68.6)	60 (72.3)	12 (70.6)	72 (72.0)	
Japan	2 (6.3)	4 (7.8)	6 (7.2)	1 (5.9)	7 (7.0)	
Disease severity per baseline Mayo Score& - n (%)						
<= 9	27 (84.4)	42 (82.4)	69 (83.1)	14 (82.4)	83 (83.0)	0.811
> 9	5 (15.6)	9 (17.6)	14 (16.9)	3 (17.6)	17 (17.0)	
Prior exposure to anti-TNF - n (%)						
Yes	7 (21.9)	8 (15.7)	15 (18.1)	1 (5.9)	16 (16.0)	0.476
No	25 (78.1)	43 (84.3)	68 (81.9)	16 (94.1)	84 (84.0)	
Baseline systemic corticosteroid use# - n (%)						
Yes	15 (46.9)	24 (47.1)	39 (47.0)	10 (58.8)	49 (49.0)	0.987
No	17 (53.1)	27 (52.9)	44 (53.0)	7 (41.2)	51 (51.0)	

表 2.7.3.6-9. 人口統計学的特性（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=32)	I-HD (N=51)	Total (N=83)	I-HD-OL (N=17)	Total (N=100)	P-Value@
Baseline immunosuppressants (IMM) use - n (%)						
Yes	23 (71.9)	33 (64.7)	56 (67.5)	6 (35.3)	62 (62.0)	0.497
No	9 (28.1)	18 (35.3)	27 (32.5)	11 (64.7)	38 (38.0)	
Weight (kg)						
n	32	51	83	17	100	0.817
Mean (SD)	56.6 (15.07)	55.7 (19.17)	56.0 (17.61)	52.2 (18.03)	55.4 (17.65)	
Median	57.0	53.0	55.0	52.8	53.6	
Min, Max	22.2, 92.9	15.0, 110.0	15.0, 110.0	20.0, 97.4	15.0, 110.0	
Weight (kg) by sex						
Female						
n	15	23	38	13	51	0.597
Mean (SD)	53.4 (12.78)	51.0 (13.93)	52.0 (13.36)	48.8 (15.80)	51.2 (13.93)	
Median	57.0	51.0	52.5	50.1	52.0	
Min, Max	22.2, 76.0	21.5, 89.0	21.5, 89.0	20.0, 76.5	20.0, 89.0	
Male						
n	17	28	45	4	49	0.990
Mean (SD)	59.4 (16.69)	59.5 (22.10)	59.5 (20.03)	63.1 (22.94)	59.8 (20.04)	
Median	57.0	59.0	58.0	53.2	57.0	
Min, Max	22.9, 92.9	15.0, 110.0	15.0, 110.0	48.8, 97.4	15.0, 110.0	
Weight (kg) - n (%)						
< 40	3 (9.4)	10 (19.6)	13 (15.7)	3 (17.6)	16 (16.0)	0.345
40 - < 60	19 (59.4)	23 (45.1)	42 (50.6)	10 (58.8)	52 (52.0)	
>= 60	10 (31.3)	18 (35.3)	28 (33.7)	4 (23.5)	32 (32.0)	

表 2.7.3.6-9. 人口統計学的特性（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=32)	I-HD (N=51)	Total (N=83)	I-HD-OL (N=17)	Total (N=100)	P-Value@
Height (cm)						
n	32	51	83	17	100	0.077
Mean (SD)	166.9 (14.95)	160.1 (18.09)	162.7 (17.19)	160.0 (14.10)	162.3 (16.67)	
Median	169.5	160.0	162.0	162.0	162.0	
Min, Max	120.1, 190.5	104.5, 193.0	104.5, 193.0	119.0, 182.4	104.5, 193.0	
Body mass index (kg/m^2)						
n	32	51	83	17	100	0.236
Mean (SD)	20.0 (3.60)	21.0 (4.00)	20.6 (3.86)	19.9 (4.71)	20.5 (4.00)	
Median	19.5	20.3	20.1	19.1	20.0	
Min, Max	14.7, 32.1	13.7, 32.7	13.7, 32.7	12.1, 29.3	12.1, 32.7	
Tobacco/Nicotine$ - n (%)						
Current	0	0	0	0	0	
Former	0	0	0	0	0	
Never	32 (100)	51 (100)	83 (100)	17 (100)	100 (100)	
Unknown	0	0	0	0	0	

表 2.7.3.6-9. 人口統計学的特性（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=32)	I-HD (N=51)	Total (N=83)	I-HD-OL (N=17)	Total (N=100)	P-Value@
Alcohol$ - n (%)						
Current	0	0	0	0	0	
Former	0	0	0	0	0	
Never	32 (100)	50 (100)	82 (100)	17 (100)	99 (100)	
Unknown	0	1	1	0	1	

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
Note: percentages calculated on non-missing values.
& true baseline Mayo Score is displayed. Subject [redacted] was randomized in the stratum '> 9', but actually had a baseline Mayo Score of 8.8 (corrected by the site from 9.8 to 8.8 after randomization).
# true baseline systemic corticosteroid use is displayed. Subject [redacted] was randomized in the stratum 'No', but actually has baseline systemic corticosteroid use documented.
$ percentages calculated on non-unknown values. A subject may be a current user of one type of tobacco, A former user of another type of tobacco and never used another type of tobacco.
A subject will be counted in the category closest to user.
@ p-value for differences between the treatment groups I-SD and I-HD from chi-square test (or fisher's exact test if expected number of counts in a cell is < 5) for categorical variables or from one-way anova for continuous variables.
One patient ([redacted]) who is ongoing study is excluded from interim analysis.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.1__3.1_A

表 2.7.3.6-10.　人口統計学的特性（日本人 ITT 集団，M11-290 試験）（中間 CSR）

	ITT					
	ITT-E					
	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=1)	Total (N=7)	P-Value@
Sex - n (%)						
Female	0	0	0	0	0	
Male	2 (100)	4 (100)	6 (100)	1 (100)	7 (100)	
Age (year)						
n	2	4	6	1	7	0.428
Mean (SD)	15.0 (1.41)	13.8 (1.71)	14.2 (1.60)	15.0 (NA)	14.3 (1.50)	
Median	15.0	13.5	14.0	15.0	14.0	
Min, Max	14, 16	12, 16	12, 16	15, 15	12, 16	
Age group 1 (year) - n (%)						
< 13	0	1 (25.0)	1 (16.7)	0	1 (14.3)	1.000
>= 13	2 (100)	3 (75.0)	5 (83.3)	1 (100)	6 (85.7)	
Age group 2 (year) - n (%)						
< 12	0	0	0	0	0	
>= 12	2 (100)	4 (100)	6 (100)	1 (100)	7 (100)	
Race - n (%)						
White	0	0	0	0	0	
Black	0	0	0	0	0	
Asian	2 (100)	4 (100)	6 (100)	1 (100)	7 (100)	
American Indian/Alaska Native	0	0	0	0	0	
Other	0	0	0	0	0	
Multiple	0	0	0	0	0	

表 2.7.3.6-10. 人口統計学的特性（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=1)	Total (N=7)	P-Value@
Ethnicity - n (%)						
Hispanic or Latino	0	0	0	0	0	
Japanese	2 (100)	4 (100)	6 (100)	1 (100)	7 (100)	
No ethnicity	0	0	0	0	0	
Geographic region - n (%)						
Japan	2 (100)	4 (100)	6 (100)	1 (100)	7 (100)	
Disease severity per baseline Mayo Score - n (%)						
<= 9	2 (100)	4 (100)	6 (100)	1 (100)	7 (100)	
> 9	0	0	0	0	0	
Prior exposure to anti-TNF - n (%)						
Yes	1 (50.0)	0	1 (16.7)	0	1 (14.3)	0.333
No	1 (50.0)	4 (100)	5 (83.3)	1 (100)	6 (85.7)	
Baseline systemic corticosteroid use - n (%)						
Yes	2 (100)	2 (50.0)	4 (66.7)	1 (100)	5 (71.4)	0.467
No	0	2 (50.0)	2 (33.3)	0	2 (28.6)	

表 2.7.3.6-10. 人口統計学的特性（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=1)	Total (N=7)	P-Value@
Baseline immunosuppressants (IMM) use - n (%)						
Yes	2 (100)	4 (100)	6 (100)	1 (100)	7 (100)	
No	0	0	0	0	0	
Weight (kg)						
n	2	4	6	1	7	0.980
Mean (SD)	47.2 (3.32)	47.0 (6.00)	47.1 (4.88)	53.5 (NA)	48.0 (5.07)	
Median	47.2	48.9	48.1	53.5	49.5	
Min, Max	44.8, 49.5	38.7, 51.6	38.7, 51.6	53.5, 53.5	38.7, 53.5	
Weight (kg) by sex						
Female						
n	0	0	0	0	0	
Mean (SD)						
Median						
Min, Max						
Male						
n	2	4	6	1	7	0.980
Mean (SD)	47.2 (3.32)	47.0 (6.00)	47.1 (4.88)	53.5 (NA)	48.0 (5.07)	
Median	47.2	48.9	48.1	53.5	49.5	
Min, Max	44.8, 49.5	38.7, 51.6	38.7, 51.6	53.5, 53.5	38.7, 53.5	
Weight (kg) - n (%)						
< 40	0	1 (25.0)	1 (16.7)	0	1 (14.3)	1.000
40 - < 60	2 (100)	3 (75.0)	5 (83.3)	1 (100)	6 (85.7)	
>= 60	0	0	0	0	0	

表 2.7.3.6-10. 人口統計学的特性（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=1)	Total (N=7)	P-Value@
Height (cm)						
n	2	4	6	1	7	0.639
Mean (SD)	158.2 (5.02)	154.8 (8.38)	155.9 (7.09)	172.4 (NA)	158.3 (8.99)	
Median	158.2	158.3	158.3	172.4	159.0	
Min, Max	154.6, 161.7	142.3, 160.2	142.3, 161.7	172.4, 172.4	142.3, 172.4	
Body mass index (kg/m^2)						
n	2	4	6	1	7	0.631
Mean (SD)	18.9 (2.53)	19.6 (0.73)	19.3 (1.31)	18.0 (NA)	19.2 (1.30)	
Median	18.9	19.6	19.6	18.0	19.1	
Min, Max	17.1, 20.7	18.8, 20.3	17.1, 20.7	18.0, 18.0	17.1, 20.7	
Tobacco/Nicotine$ - n (%)						
Current	0	0	0	0	0	
Former	0	0	0	0	0	
Never	2 (100)	4 (100)	6 (100)	1 (100)	7 (100)	
Unknown	0	0	0	0	0	

表 2.7.3.6-10.　人口統計学的特性（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=1)	Total (N=7)	P-Value@
Alcohol$ - n (%)						
Current	0	0	0	0	0	
Former	0	0	0	0	0	
Never	2 (100)	4 (100)	6 (100)	1 (100)	7 (100)	
Unknown	0	0	0	0	0	

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
Note: percentages calculated on non-missing values.
$ percentages calculated on non-unknown values. A subject may be a current user of one type of tobacco, A former user of another type of tobacco and never used another type of tobacco.
A subject will be counted in the category closest to user.
@ p-value for differences between the treatment groups I-SD and I-HD from chi-square test (or fisher's exact test if expected number of counts in a cell is < 5) for categorical variables or from one-way anova for continuous variables.
One patient ([redacted]) who is ongoing study is excluded from interim analysis.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.1__3.1_J

表 2.7.3.6-11. 人口統計学的特性（統合 mITT 集団，M11-290 試験）（中間 CSR）

	mITT					
	mITT-E					
	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)	P-Value@
Sex - n (%)						
Female	3 (25.0)	18 (54.5)	18 (52.9)	36 (53.7)	39 (49.4)	0.895
Male	9 (75.0)	15 (45.5)	16 (47.1)	31 (46.3)	40 (50.6)	
Age (year)						
n	12	33	34	67	79	0.236
Mean (SD)	14.9 (2.54)	13.2 (3.04)	14.1 (3.34)	13.7 (3.21)	13.9 (3.13)	
Median	15.5	14.0	16.0	14.0	15.0	
Min, Max	9, 17	6, 17	5, 17	5, 17	5, 17	
Age group 1 (year) - n (%)						
< 13	2 (16.7)	12 (36.4)	9 (26.5)	21 (31.3)	23 (29.1)	0.383
>= 13	10 (83.3)	21 (63.6)	25 (73.5)	46 (68.7)	56 (70.9)	
Age group 2 (year) - n (%)						
< 12	2 (16.7)	10 (30.3)	7 (20.6)	17 (25.4)	19 (24.1)	0.361
>= 12	10 (83.3)	23 (69.7)	27 (79.4)	50 (74.6)	60 (75.9)	
Race - n (%)						
White	11 (91.7)	29 (87.9)	30 (88.2)	59 (88.1)	70 (88.6)	1.000
Black	0	2 (6.1)	1 (2.9)	3 (4.5)	3 (3.8)	
Asian	1 (8.3)	2 (6.1)	3 (8.8)	5 (7.5)	6 (7.6)	
American Indian/Alaska Native	0	0	0	0	0	
Other	0	0	0	0	0	
Multiple	0	0	0	0	0	

表 2.7.3.6-11. 人口統計学的特性（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT					
	mITT-E					
	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)	P-Value@
Ethnicity - n (%)						
Hispanic or Latino	0	3 (9.1)	1 (2.9)	4 (6.0)	4 (5.1)	0.666
Japanese	0	2 (6.1)	3 (8.8)	5 (7.5)	5 (6.3)	
No ethnicity	12 (100)	28 (84.8)	30 (88.2)	58 (86.6)	70 (88.6)	
Geographic region - n (%)						
North America	1 (8.3)	7 (21.2)	3 (8.8)	10 (14.9)	11 (13.9)	0.229
Western Europe	1 (8.3)	0	3 (8.8)	3 (4.5)	4 (5.1)	
Eastern Europe	10 (83.3)	24 (72.7)	25 (73.5)	49 (73.1)	59 (74.7)	
Japan	0	2 (6.1)	3 (8.8)	5 (7.5)	5 (6.3)	
Disease severity per baseline Mayo Score - n (%)						
<= 9	11 (91.7)	27 (81.8)	29 (85.3)	56 (83.6)	67 (84.8)	0.701
> 9	1 (8.3)	6 (18.2)	5 (14.7)	11 (16.4)	12 (15.2)	
Prior exposure to anti-TNF - n (%)						
Yes	2 (16.7)	2 (6.1)	6 (17.6)	8 (11.9)	10 (12.7)	0.259
No	10 (83.3)	31 (93.9)	28 (82.4)	59 (88.1)	69 (87.3)	
Baseline systemic corticosteroid use - n (%)						
Yes	5 (41.7)	15 (45.5)	17 (50.0)	32 (47.8)	37 (46.8)	0.710
No	7 (58.3)	18 (54.5)	17 (50.0)	35 (52.2)	42 (53.2)	

表 2.7.3.6-11. 人口統計学的特性（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT					
	mITT-E					
	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)	P-Value@
Baseline immunosuppressants (IMM) use - n (%)						
Yes	8 (66.7)	19 (57.6)	24 (70.6)	43 (64.2)	51 (64.6)	0.267
No	4 (33.3)	14 (42.4)	10 (29.4)	24 (35.8)	28 (35.4)	
Weight (kg)						
n	12	33	34	67	79	0.426
Mean (SD)	61.7 (14.55)	53.1 (15.26)	56.8 (22.18)	55.0 (19.04)	56.0 (18.51)	
Median	58.5	53.5	57.0	54.0	56.3	
Min, Max	43.0, 92.9	21.5, 91.6	15.0, 110.0	15.0, 110.0	15.0, 110.0	
Weight (kg) by sex						
Female						
n	3	18	18	36	39	0.220
Mean (SD)	51.9 (7.05)	48.1 (14.85)	54.9 (17.35)	51.5 (16.28)	51.5 (15.70)	
Median	48.1	50.6	56.1	53.3	53.0	
Min, Max	47.5, 60.0	21.5, 76.5	20.0, 89.0	20.0, 89.0	20.0, 89.0	
Male						
n	9	15	16	31	40	0.999
Mean (SD)	65.0 (15.17)	59.0 (14.01)	59.0 (27.05)	59.0 (21.39)	60.3 (20.14)	
Median	59.0	56.3	58.0	57.0	58.5	
Min, Max	43.0, 92.9	31.5, 91.6	15.0, 110.0	15.0, 110.0	15.0, 110.0	
Weight (kg) - n (%)						
< 40	0	7 (21.2)	8 (23.5)	15 (22.4)	15 (19.0)	0.372
40 - < 60	7 (58.3)	16 (48.5)	11 (32.4)	27 (40.3)	34 (43.0)	
>= 60	5 (41.7)	10 (30.3)	15 (44.1)	25 (37.3)	30 (38.0)	

表 2.7.3.6-11. 人口統計学的特性（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT					
	mITT-E					
	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)	P-Value@
Height (cm)						
n	12	33	34	67	79	0.923
Mean (SD)	170.9 (13.13)	159.8 (16.39)	160.2 (19.50)	160.0 (17.90)	161.6 (17.63)	
Median	172.0	162.0	161.5	162.0	162.1	
Min, Max	149.0, 190.5	120.0, 184.0	104.5, 193.0	104.5, 193.0	104.5, 193.0	
Body mass index (kg/m^2)						
n	12	33	34	67	79	0.447
Mean (SD)	20.9 (2.54)	20.3 (3.51)	21.2 (5.01)	20.8 (4.32)	20.8 (4.09)	
Median	20.4	20.0	20.4	20.2	20.2	
Min, Max	17.8, 25.6	14.7, 32.1	12.1, 30.4	12.1, 32.1	12.1, 32.1	
Tobacco/Nicotine$ - n (%)						
Current	0	0	0	0	0	
Former	0	0	0	0	0	
Never	12 (100)	33 (100)	34 (100)	67 (100)	79 (100)	
Unknown	0	0	0	0	0	

表 2.7.3.6-11. 人口統計学的特性（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT					
	mITT-E					
	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)	P-Value@
Alcohol$ - n (%)						
Current	0	0	0	0	0	
Former	0	0	0	0	0	
Never	12 (100)	33 (100)	34 (100)	67 (100)	79 (100)	
Unknown	0	0	0	0	0	

M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
Note: percentages calculated on non-missing values.
$ percentages calculated on non-unknown values. A subject may be a current user of one type of tobacco, A former user of another type of tobacco and never used another type of tobacco.
A subject will be counted in the category closest to user.
@ p-value for differences between the treatment groups M-SD and M-HD from chi-square test (or fisher's exact test if expected number of counts in a cell is < 5) for categorical variables or from one-way anova for continuous variables.
One patient ([redacted]) who is ongoing study is excluded from interim analysis.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.1__3.2_A

表 2.7.3.6-12. 人口統計学的特性（日本人 mITT 集団，M11-290 試験）（中間 CSR）

	mITT					
		mITT-E				
	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)	P-Value@
Sex - n (%)						
Female	0	0	0	0	0	
Male	0	2 (100)	3 (100)	5 (100)	5 (100)	
Age (year)						
n	0	2	3	5	5	1.000
Mean (SD)		14.0 (1.41)	14.0 (2.00)	14.0 (1.58)	14.0 (1.58)	
Median		14.0	14.0	14.0	14.0	
Min, Max		13, 15	12, 16	12, 16	12, 16	
Age group 1 (year) - n (%)						
< 13	0	0	1 (33.3)	1 (20.0)	1 (20.0)	1.000
>= 13	0	2 (100)	2 (66.7)	4 (80.0)	4 (80.0)	
Age group 2 (year) - n (%)						
< 12	0	0	0	0	0	
>= 12	0	2 (100)	3 (100)	5 (100)	5 (100)	
Race - n (%)						
White	0	0	0	0	0	
Black	0	0	0	0	0	
Asian	0	2 (100)	3 (100)	5 (100)	5 (100)	
American Indian/Alaska Native	0	0	0	0	0	
Other	0	0	0	0	0	
Multiple	0	0	0	0	0	

表 2.7.3.6-12. 人口統計学的特性（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT					
	mITT-E					
	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)	P-Value@
Ethnicity - n (%)						
Hispanic or Latino	0	0	0	0	0	
Japanese	0	2 (100)	3 (100)	5 (100)	5 (100)	
No ethnicity	0	0	0	0	0	
Geographic region - n (%)						
Japan	0	2 (100)	3 (100)	5 (100)	5 (100)	
Disease severity per baseline Mayo Score - n (%)						
<= 9	0	2 (100)	3 (100)	5 (100)	5 (100)	
> 9	0	0	0	0	0	
Prior exposure to anti-TNF - n (%)						
Yes	0	0	0	0	0	
No	0	2 (100)	3 (100)	5 (100)	5 (100)	
Baseline systemic corticosteroid use - n (%)						
Yes	0	2 (100)	1 (33.3)	3 (60.0)	3 (60.0)	0.400
No	0	0	2 (66.7)	2 (40.0)	2 (40.0)	

表 2.7.3.6-12. 人口統計学的特性（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT					
		mITT-E				
	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)	P-Value@
Baseline immunosuppressants (IMM) use - n (%)						
Yes	0	2 (100)	3 (100)	5 (100)	5 (100)	
No	0	0	0	0	0	
Weight (kg)						
n	0	2	3	5	5	0.236
Mean (SD)		52.6 (1.34)	45.5 (6.32)	48.3 (5.95)	48.3 (5.95)	
Median		52.6	46.6	51.2	51.2	
Min, Max		51.6, 53.5	38.7, 51.2	38.7, 53.5	38.7, 53.5	
Weight (kg) by sex						
Female						
n	0	0	0	0	0	
Mean (SD)						
Median						
Min, Max						
Male						
n	0	2	3	5	5	0.236
Mean (SD)		52.6 (1.34)	45.5 (6.32)	48.3 (5.95)	48.3 (5.95)	
Median		52.6	46.6	51.2	51.2	
Min, Max		51.6, 53.5	38.7, 51.2	38.7, 53.5	38.7, 53.5	
Weight (kg) - n (%)						
< 40	0	0	1 (33.3)	1 (20.0)	1 (20.0)	1.000
40 - < 60	0	2 (100)	2 (66.7)	4 (80.0)	4 (80.0)	
>= 60	0	0	0	0	0	

表 2.7.3.6-12. 人口統計学的特性（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT					
		mITT-E				
	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)	P-Value@
Height (cm)						
n	0	2	3	5	5	0.205
Mean (SD)		166.3 (8.63)	153.0 (9.26)	158.3 (10.72)	158.3 (10.72)	
Median		166.3	157.6	159.0	159.0	
Min, Max		160.2, 172.4	142.3, 159.0	142.3, 172.4	142.3, 172.4	
Body mass index (kg/m^2)						
n	0	2	3	5	5	0.763
Mean (SD)		19.1 (1.49)	19.4 (0.78)	19.2 (0.94)	19.2 (0.94)	
Median		19.1	19.1	19.1	19.1	
Min, Max		18.0, 20.1	18.8, 20.3	18.0, 20.3	18.0, 20.3	
Tobacco/Nicotine$ - n (%)						
Current	0	0	0	0	0	
Former	0	0	0	0	0	
Never	0	2 (100)	3 (100)	5 (100)	5 (100)	
Unknown	0	0	0	0	0	

表 2.7.3.6-12. 人口統計学的特性（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT					
		mITT-E				
	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)	P-Value@
Alcohol$ - n (%)						
Current	0	0	0	0	0	
Former	0	0	0	0	0	
Never	0	2 (100)	3 (100)	5 (100)	5 (100)	
Unknown	0	0	0	0	0	

M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
Note: percentages calculated on non-missing values.
$ percentages calculated on non-unknown values. A subject may be a current user of one type of tobacco, A former user of another type of tobacco and never used another type of tobacco.
A subject will be counted in the category closest to user.
@ p-value for differences between the treatment groups M-SD and M-HD from chi-square test (or fisher's exact test if expected number of counts in a cell is < 5) for categorical variables or from one-way anova for continuous variables.
One patient ([redacted]) who is ongoing study is excluded from interim analysis.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.1__3.2_J

表 2.7.3.6-13. 疾患特性（統合 ITT 集団，M11-290 試験）（中間 CSR）

	ITT					
	ITT-E					
	I-SD (N=32)	I-HD (N=51)	Total (N=83)	I-HD-OL (N=17)	Total (N=100)	P-Value@
Duration of UC (month)						
n	32	51	83	17	100	0.118
Mean (SD)	23.6 (19.77)	33.4 (31.58)	29.6 (27.92)	22.5 (25.18)	28.4 (27.48)	
Median	13.8	22.8	20.0	11.7	19.1	
Min, Max	3.7, 63.9	4.5, 136.9	3.7, 136.9	3.9, 108.0	3.7, 136.9	
Duration of UC (year)						
n	32	51	83	17	100	0.118
Mean (SD)	2.0 (1.65)	2.8 (2.63)	2.5 (2.33)	1.9 (2.10)	2.4 (2.29)	
Median	1.1	1.9	1.7	1.0	1.6	
Min, Max	0.3, 5.3	0.4, 11.4	0.3, 11.4	0.3, 9.0	0.3, 11.4	
Site of UC - n (%)						
Left sided UC	11 (34.4)	22 (43.1)	33 (39.8)	5 (29.4)	38 (38.0)	0.427
Extensive UC/pancolitis	21 (65.6)	29 (56.9)	50 (60.2)	12 (70.6)	62 (62.0)	
Mayo Score						
n	32	51	83	17	100	0.858
Mean (SD)	7.8 (1.22)	7.7 (1.25)	7.8 (1.23)	7.8 (1.05)	7.8 (1.20)	
Median	7.8	7.4	7.6	7.4	7.6	
Min, Max	6.0, 10.0	6.0, 10.8	6.0, 10.8	6.0, 9.6	6.0, 10.8	

表 2.7.3.6-13. 疾患特性（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=32)	I-HD (N=51)	Total (N=83)	I-HD-OL (N=17)	Total (N=100)	P-Value@
Partial Mayo Score						
n	32	51	83	17	100	0.656
Mean (SD)	5.7 (1.14)	5.5 (1.24)	5.6 (1.20)	5.6 (1.03)	5.6 (1.16)	
Median	5.8	5.2	5.4	5.4	5.4	
Min, Max	4.0, 8.0	3.4, 8.8	3.4, 8.8	4.0, 7.6	3.4, 8.8	
Endoscopy Subscore						
n	32	51	83	17	100	0.406
Mean (SD)	2.1 (0.34)	2.2 (0.40)	2.2 (0.38)	2.2 (0.44)	2.2 (0.39)	
Median	2.0	2.0	2.0	2.0	2.0	
Min, Max	2.0, 3.0	2.0, 3.0	2.0, 3.0	2.0, 3.0	2.0, 3.0	
Rectal Bleeding Subscore						
n	32	51	83	17	100	0.391
Mean (SD)	1.4 (0.93)	1.5 (0.88)	1.5 (0.90)	1.5 (0.94)	1.5 (0.90)	
Median	1.5	1.2	1.4	1.2	1.4	
Min, Max	0.0, 3.0	0.0, 3.0	0.0, 3.0	0.0, 3.0	0.0, 3.0	
PGA Subscore						
n	32	51	83	17	100	0.612
Mean (SD)	2.2 (0.40)	2.2 (0.43)	2.2 (0.41)	2.2 (0.39)	2.2 (0.41)	
Median	2.0	2.0	2.0	2.0	2.0	
Min, Max	2.0, 3.0	2.0, 3.0	2.0, 3.0	2.0, 3.0	2.0, 3.0	

表 2.7.3.6-13. 疾患特性（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=32)	I-HD (N=51)	Total (N=83)	I-HD-OL (N=17)	Total (N=100)	P-Value@
Stool Frequency Subscore						
n	32	51	83	17	100	0.074
Mean (SD)	2.1 (0.78)	1.8 (0.88)	1.9 (0.85)	1.9 (0.75)	1.9 (0.83)	
Median	2.1	1.6	2.0	2.0	2.0	
Min, Max	0.6, 3.0	0.0, 3.0	0.0, 3.0	0.0, 3.0	0.0, 3.0	
Number of stools in the last 24 hours prior to baseline						
n	32	51	83	17	100	0.849
Mean (SD)	3.9 (2.15)	4.0 (2.47)	4.0 (2.34)	4.5 (2.43)	4.1 (2.35)	
Median	4.0	4.0	4.0	4.0	4.0	
Min, Max	0.0, 9.0	0.0, 13.0	0.0, 13.0	2.0, 13.0	0.0, 13.0	
PUCAI total score						
n	32	51	83	17	100	0.775
Mean (SD)	39.8 (18.00)	40.9 (16.78)	40.5 (17.16)	43.4 (13.43)	41.0 (16.56)	
Median	38.8	40.0	40.0	45.0	42.5	
Min, Max	0.0, 72.5	5.0, 80.0	0.0, 80.0	25.0, 72.5	0.0, 80.0	
IMPACT III total score						
n	29	48	77	16	93	0.883
Mean (SD)	110.0 (21.71)	110.8 (23.57)	110.5 (22.74)	108.3 (18.91)	110.1 (22.05)	
Median	103.0	114.0	112.0	114.5	112.0	
Min, Max	78.0, 155.0	63.0, 159.0	63.0, 159.0	76.0, 144.0	63.0, 159.0	

表 2.7.3.6-13. 疾患特性（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=32)	I-HD (N=51)	Total (N=83)	I-HD-OL (N=17)	Total (N=100)	P-Value@
IMPACT III - body image						
n	29	48	77	16	93	0.170
Mean (SD)	10.4 (2.03)	9.7 (2.30)	10.0 (2.22)	9.4 (2.45)	9.9 (2.26)	
Median	11.0	10.0	10.0	9.5	10.0	
Min, Max	7.0, 15.0	4.0, 14.0	4.0, 15.0	4.0, 12.0	4.0, 15.0	
IMPACT III - bowel symptoms						
n	29	48	77	16	93	0.689
Mean (SD)	21.1 (5.28)	20.6 (5.12)	20.7 (5.15)	18.8 (4.16)	20.4 (5.03)	
Median	21.0	20.0	20.0	18.5	20.0	
Min, Max	10.5, 32.0	11.0, 30.0	10.5, 32.0	12.0, 28.0	10.5, 32.0	
IMPACT III - emotional functioning						
n	29	48	77	16	93	0.603
Mean (SD)	20.1 (6.68)	20.9 (6.87)	20.6 (6.76)	19.8 (5.71)	20.5 (6.57)	
Median	18.0	22.0	21.0	19.0	21.0	
Min, Max	11.0, 34.0	8.0, 35.0	8.0, 35.0	13.0, 29.0	8.0, 35.0	
IMPACT III - social functioning						
n	29	48	77	16	93	0.644
Mean (SD)	40.0 (7.65)	40.9 (8.53)	40.6 (8.17)	41.3 (6.99)	40.7 (7.95)	
Median	40.0	42.0	41.0	42.5	41.0	
Min, Max	27.0, 55.0	22.0, 57.0	22.0, 57.0	24.0, 52.0	22.0, 57.0	

表 2.7.3.6-13. 疾患特性（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=32)	I-HD (N=51)	Total (N=83)	I-HD-OL (N=17)	Total (N=100)	P-Value@
IMPACT III - systemic symptoms						
n	29	48	77	16	93	0.692
Mean (SD)	8.2 (2.83)	8.4 (2.21)	8.4 (2.45)	8.4 (2.16)	8.4 (2.39)	
Median	8.0	9.0	8.0	8.0	8.0	
Min, Max	3.0, 14.0	4.0, 12.0	3.0, 14.0	3.0, 12.0	3.0, 14.0	
IMPACT III - treatment/interventions						
n	29	48	77	16	93	0.946
Mean (SD)	10.2 (2.47)	10.3 (2.85)	10.2 (2.70)	10.8 (2.24)	10.3 (2.62)	
Median	11.0	11.0	11.0	11.0	11.0	
Min, Max	5.0, 14.0	4.0, 15.0	4.0, 15.0	7.0, 15.0	4.0, 15.0	
WPAI - absenteeism (%)						
n	22	33	55	8	63	0.754
Mean (SD)	11.7 (16.35)	13.3 (20.53)	12.6 (18.83)	23.1 (29.27)	14.0 (20.44)	
Median	0.0	7.9	3.9	13.4	4.8	
Min, Max	0.0, 50.0	0.0, 100.0	0.0, 100.0	0.0, 71.1	0.0, 100.0	
WPAI - presenteeism (%)						
n	22	34	56	8	64	0.889
Mean (SD)	42.3 (26.54)	41.2 (29.62)	41.6 (28.21)	42.5 (23.75)	41.7 (27.52)	
Median	40.0	35.0	40.0	45.0	40.0	
Min, Max	0.0, 80.0	0.0, 100.0	0.0, 100.0	0.0, 80.0	0.0, 100.0	

表 2.7.3.6-13. 疾患特性（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=32)	I-HD (N=51)	Total (N=83)	I-HD-OL (N=17)	Total (N=100)	P-Value@
WPAI - work impairment (%)						
n	22	33	55	8	63	0.929
Mean (SD)	47.0 (29.53)	47.7 (28.94)	47.4 (28.91)	50.8 (30.64)	47.8 (28.90)	
Median	48.2	53.9	53.9	48.6	53.9	
Min, Max	0.0, 86.0	0.0, 100.0	0.0, 100.0	0.0, 94.2	0.0, 100.0	
WPAI - activity impairment (%)						
n	32	51	83	17	100	0.432
Mean (SD)	41.6 (25.79)	46.3 (26.83)	44.5 (26.38)	52.9 (28.67)	45.9 (26.82)	
Median	45.0	40.0	40.0	50.0	50.0	
Min, Max	0.0, 80.0	0.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0	
hs-CRP [mg/l]						
n	30	45	75	17	92	0.538
Mean (SD)	7.2 (25.86)	4.7 (8.33)	5.7 (17.46)	5.7 (11.80)	5.7 (16.51)	
Median	1.2	1.2	1.2	1.5	1.3	
Min, Max	0.1, 142.6	0.1, 35.2	0.1, 142.6	0.1, 37.8	0.1, 142.6	
Tuberculin PPD skin test - n (%)						
Negative	2 (100)	4 (100)	6 (100)	1 (100)	7 (100)	
Positive&	0	0	0	0	0	
Missing	30	47	77	16	93	

表 2.7.3.6-13. 疾患特性（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=32)	I-HD (N=51)	Total (N=83)	I-HD-OL (N=17)	Total (N=100)	P-Value@
QuantiFERON-TB Gold test - n (%)						
Negative	29 (93.5)	44 (89.8)	73 (91.3)	16 (100)	89 (92.7)	0.829
Positive	0	2 (4.1)	2 (2.5)	0	2 (2.1)	
Indeterminate	2 (6.5)	3 (6.1)	5 (6.3)	0	5 (5.2)	
Missing	1	2	3	1	4	
Tuberculin positive - n (%)						
Yes$	0	2 (3.9)	2 (2.4)	0	2 (2.0)	0.520
No	32 (100)	49 (96.1)	81 (97.6)	17 (100)	98 (98.0)	
Enrollment under TB prophylaxis - n (%)						
Yes	0	2 (3.9)	2 (2.4)	0	2 (2.0)	0.520
No	32 (100)	49 (96.1)	81 (97.6)	17 (100)	98 (98.0)	

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
Note: percentages calculated on non-missing values.
Duration of UC in months: (baseline date - date of diagnosis of UC + 1) / (365.25/12).
Duration of UC in years: (baseline date - date of diagnosis of UC + 1) / 365.25.
& positive defined as >= 5 mm.
$ tuberculin PPD skin test >= 5 mm or QuantiFERON-TB Gold test is positive.
@ p-value for differences between the treatment groups I-SD and I-HD from chi-square test (or fisher's exact test if expected number of counts in a cell is < 5) for categorical variables or from one-way anova for continuous variables.
One patient ([redacted]) who is ongoing study is excluded from interim analysis.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.1__4.1_A

表 2.7.3.6-14. 疾患特性（日本人 ITT 集団，M11-290 試験）（中間 CSR）

	ITT					
	ITT-E					
	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=1)	Total (N=7)	P-Value@
Duration of UC (month)						
n	2	4	6	1	7	0.459
Mean (SD)	40.1 (10.85)	58.9 (29.99)	52.7 (25.64)	3.9 (NA)	45.7 (29.80)	
Median	40.1	55.2	45.5	3.9	43.3	
Min, Max	32.5, 47.8	28.3, 97.0	28.3, 97.0	3.9, 3.9	3.9, 97.0	
Duration of UC (year)						
n	2	4	6	1	7	0.459
Mean (SD)	3.3 (0.90)	4.9 (2.50)	4.4 (2.14)	0.3 (NA)	3.8 (2.48)	
Median	3.3	4.6	3.8	0.3	3.6	
Min, Max	2.7, 4.0	2.4, 8.1	2.4, 8.1	0.3, 0.3	0.3, 8.1	
Site of UC - n (%)						
Left sided UC	1 (50.0)	0	1 (16.7)	0	1 (14.3)	0.333
Extensive UC/pancolitis	1 (50.0)	4 (100)	5 (83.3)	1 (100)	6 (85.7)	
Mayo Score						
n	2	4	6	1	7	0.478
Mean (SD)	6.6 (0.57)	7.0 (0.50)	6.8 (0.50)	8.3 (NA)	7.0 (0.73)	
Median	6.6	6.9	6.9	8.3	7.0	
Min, Max	6.2, 7.0	6.4, 7.6	6.2, 7.6	8.3, 8.3	6.2, 8.3	

表 2.7.3.6-14. 疾患特性（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=1)	Total (N=7)	P-Value@
Partial Mayo Score						
n	2	4	6	1	7	0.899
Mean (SD)	4.6 (0.57)	4.7 (0.93)	4.7 (0.77)	6.3 (NA)	4.9 (0.94)	
Median	4.6	4.9	4.9	6.3	5.0	
Min, Max	4.2, 5.0	3.4, 5.6	3.4, 5.6	6.3, 6.3	3.4, 6.3	
Endoscopy Subscore						
n	2	4	6	1	7	0.541
Mean (SD)	2.0 (0.00)	2.3 (0.50)	2.2 (0.41)	2.0 (NA)	2.1 (0.38)	
Median	2.0	2.0	2.0	2.0	2.0	
Min, Max	2.0, 2.0	2.0, 3.0	2.0, 3.0	2.0, 2.0	2.0, 3.0	
Rectal Bleeding Subscore						
n	2	4	6	1	7	0.498
Mean (SD)	1.8 (0.28)	1.4 (0.79)	1.5 (0.67)	1.3 (NA)	1.5 (0.61)	
Median	1.8	1.5	1.8	1.3	1.6	
Min, Max	1.6, 2.0	0.4, 2.0	0.4, 2.0	1.3, 1.3	0.4, 2.0	
PGA Subscore						
n	2	4	6	1	7	0.541
Mean (SD)	2.0 (0.00)	2.3 (0.50)	2.2 (0.41)	2.0 (NA)	2.1 (0.38)	
Median	2.0	2.0	2.0	2.0	2.0	
Min, Max	2.0, 2.0	2.0, 3.0	2.0, 3.0	2.0, 2.0	2.0, 3.0	

表 2.7.3.6-14. 疾患特性（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=1)	Total (N=7)	P-Value@
Stool Frequency Subscore						
n	2	4	6	1	7	0.653
Mean (SD)	0.8 (0.28)	1.1 (0.81)	1.0 (0.66)	3.0 (NA)	1.3 (0.97)	
Median	0.8	1.3	1.0	3.0	1.0	
Min, Max	0.6, 1.0	0.0, 1.8	0.0, 1.8	3.0, 3.0	0.0, 3.0	
Number of stools in the last 24 hours prior to baseline						
n	2	4	6	1	7	0.506
Mean (SD)	2.5 (0.71)	3.0 (0.82)	2.8 (0.75)	4.0 (NA)	3.0 (0.82)	
Median	2.5	3.0	3.0	4.0	3.0	
Min, Max	2.0, 3.0	2.0, 4.0	2.0, 4.0	4.0, 4.0	2.0, 4.0	
PUCAI total score						
n	2	4	6	1	7	0.719
Mean (SD)	38.8 (5.30)	31.9 (23.57)	34.2 (18.75)	42.5 (NA)	35.4 (17.41)	
Median	38.8	30.0	32.5	42.5	35.0	
Min, Max	35.0, 42.5	5.0, 62.5	5.0, 62.5	42.5, 42.5	5.0, 62.5	
IMPACT III total score						
n	2	4	6	1	7	0.186
Mean (SD)	98.5 (3.54)	119.8 (17.63)	112.7 (17.59)	121.0 (NA)	113.9 (16.36)	
Median	98.5	121.0	110.5	121.0	120.0	
Min, Max	96.0, 101.0	97.0, 140.0	96.0, 140.0	121.0, 121.0	96.0, 140.0	

表 2.7.3.6-14. 疾患特性（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=1)	Total (N=7)	P-Value@
IMPACT III - body image						
n	2	4	6	1	7	0.685
Mean (SD)	8.0 (1.41)	8.5 (1.29)	8.3 (1.21)	10.0 (NA)	8.6 (1.27)	
Median	8.0	8.5	8.5	10.0	9.0	
Min, Max	7.0, 9.0	7.0, 10.0	7.0, 10.0	10.0, 10.0	7.0, 10.0	
IMPACT III - bowel symptoms						
n	2	4	6	1	7	0.460
Mean (SD)	21.0 (1.41)	24.0 (4.83)	23.0 (4.10)	20.0 (NA)	22.6 (3.91)	
Median	21.0	25.5	23.5	20.0	22.0	
Min, Max	20.0, 22.0	17.0, 28.0	17.0, 28.0	20.0, 20.0	17.0, 28.0	
IMPACT III - emotional functioning						
n	2	4	6	1	7	0.179
Mean (SD)	15.5 (2.12)	23.3 (6.24)	20.7 (6.35)	25.0 (NA)	21.3 (6.02)	
Median	15.5	24.0	20.0	25.0	23.0	
Min, Max	14.0, 17.0	15.0, 30.0	14.0, 30.0	25.0, 25.0	14.0, 30.0	
IMPACT III - social functioning						
n	2	4	6	1	7	0.139
Mean (SD)	37.5 (2.12)	44.3 (4.72)	42.0 (5.14)	43.0 (NA)	42.1 (4.71)	
Median	37.5	42.5	41.0	43.0	41.0	
Min, Max	36.0, 39.0	41.0, 51.0	36.0, 51.0	43.0, 43.0	36.0, 51.0	

表 2.7.3.6-14. 疾患特性（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=1)	Total (N=7)	P-Value@
IMPACT III - systemic symptoms						
n	2	4	6	1	7	0.896
Mean (SD)	8.5 (2.12)	8.3 (2.06)	8.3 (1.86)	8.0 (NA)	8.3 (1.70)	
Median	8.5	8.0	8.0	8.0	8.0	
Min, Max	7.0, 10.0	6.0, 11.0	6.0, 11.0	8.0, 8.0	6.0, 11.0	
IMPACT III - treatment/interventions						
n	2	4	6	1	7	0.054
Mean (SD)	8.0 (2.83)	11.5 (0.58)	10.3 (2.25)	15.0 (NA)	11.0 (2.71)	
Median	8.0	11.5	11.0	15.0	11.0	
Min, Max	6.0, 10.0	11.0, 12.0	6.0, 12.0	15.0, 15.0	6.0, 15.0	
WPAI - absenteeism (%)						
n	2	4	6	0	6	0.415
Mean (SD)	0.0 (0.00)	19.3 (28.32)	12.9 (24.10)		12.9 (24.10)	
Median	0.0	8.6	0.0		0.0	
Min, Max	0.0, 0.0	0.0, 60.0	0.0, 60.0		0.0, 60.0	
WPAI - presenteeism (%)						
n	2	4	6	0	6	1.000
Mean (SD)	20.0 (28.28)	20.0 (33.67)	20.0 (28.98)		20.0 (28.98)	
Median	20.0	5.0	5.0		5.0	
Min, Max	0.0, 40.0	0.0, 70.0	0.0, 70.0		0.0, 70.0	

表 2.7.3.6-14. 疾患特性（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=1)	Total (N=7)	P-Value@
WPAI - work impairment (%)						
n	2	4	6	0	6	0.815
Mean (SD)	20.0 (28.28)	28.4 (41.53)	25.6 (34.83)		25.6 (34.83)	
Median	20.0	12.8	12.8		12.8	
Min, Max	0.0, 40.0	0.0, 88.0	0.0, 88.0		0.0, 88.0	
WPAI - activity impairment (%)						
n	2	4	6	1	7	0.923
Mean (SD)	35.0 (7.07)	37.5 (32.02)	36.7 (25.03)	50.0 (NA)	38.6 (23.40)	
Median	35.0	35.0	35.0	50.0	40.0	
Min, Max	30.0, 40.0	10.0, 70.0	10.0, 70.0	50.0, 50.0	10.0, 70.0	
hs-CRP [mg/l]						
n	2	4	6	1	7	0.774
Mean (SD)	1.7 (1.27)	2.5 (3.29)	2.2 (2.65)	37.8 (NA)	7.3 (13.65)	
Median	1.7	1.1	1.1	37.8	1.1	
Min, Max	0.8, 2.6	0.3, 7.4	0.3, 7.4	37.8, 37.8	0.3, 37.8	
Tuberculin PPD skin test - n (%)						
Negative	1 (100)	0	1 (100)	0	1 (100)	
Positive&	0	0	0	0	0	
Missing	1	4	5	1	6	

表 2.7.3.6-14. 疾患特性（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=1)	Total (N=7)	P-Value@
QuantiFERON-TB Gold test - n (%)						
Negative	1 (50.0)	4 (100)	5 (83.3)	1 (100)	6 (85.7)	0.333
Positive	0	0	0	0	0	
Indeterminate	1 (50.0)	0	1 (16.7)	0	1 (14.3)	
Tuberculin positive - n (%)						
Yes$	0	0	0	0	0	
No	2 (100)	4 (100)	6 (100)	1 (100)	7 (100)	
Enrollment under TB prophylaxis - n (%)						
Yes	0	0	0	0	0	
No	2 (100)	4 (100)	6 (100)	1 (100)	7 (100)	

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
Note: percentages calculated on non-missing values.
& positive defined as >= 5 mm.
$ tuberculin PPD skin test >= 5 mm or QuantiFERON-TB Gold test is positive.
Duration of UC in months: (baseline date - date of diagnosis of UC + 1) / (365.25/12).
Duration of UC in years: (baseline date - date of diagnosis of UC + 1) / 365.25.
@ p-value for differences between the treatment groups I-SD and I-HD from chi-square test (or fisher's exact test if expected number of counts in a cell is < 5) for categorical variables or from one-way anova for continuous variables.
One patient ([redacted]) who is ongoing study is excluded from interim analysis.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.1__4.1_J

表 2.7.3.6-15. 疾患特性（統合 mITT 集団，M11-290 試験）（中間 CSR）

	mITT					
	mITT-E					
	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)	P-Value@
Duration of UC (month)						
n	12	33	34	67	79	0.054
Mean (SD)	38.0 (35.55)	22.5 (16.75)	34.4 (30.76)	28.5 (25.40)	30.0 (27.13)	
Median	29.8	16.1	27.4	18.9	19.4	
Min, Max	6.2, 131.9	3.9, 67.2	5.3, 123.4	3.9, 123.4	3.9, 131.9	
Duration of UC (year)						
n	12	33	34	67	79	0.054
Mean (SD)	3.2 (2.96)	1.9 (1.40)	2.9 (2.56)	2.4 (2.12)	2.5 (2.26)	
Median	2.5	1.3	2.3	1.6	1.6	
Min, Max	0.5, 11.0	0.3, 5.6	0.4, 10.3	0.3, 10.3	0.3, 11.0	
Site of UC - n (%)						
Left sided UC	5 (41.7)	11 (33.3)	14 (41.2)	25 (37.3)	30 (38.0)	0.507
Extensive UC/pancolitis	7 (58.3)	22 (66.7)	20 (58.8)	42 (62.7)	49 (62.0)	
Mayo Score						
n	12	33	34	67	79	0.266
Mean (SD)	7.4 (0.91)	7.9 (1.19)	7.6 (1.10)	7.8 (1.15)	7.7 (1.12)	
Median	7.2	7.8	7.5	7.6	7.6	
Min, Max	6.0, 9.2	6.0, 10.8	6.0, 9.8	6.0, 10.8	6.0, 10.8	

表 2.7.3.6-15. 疾患特性（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT					
		mITT-E				
	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)	P-Value@
Partial Mayo Score						
n	12	33	34	67	79	0.102
Mean (SD)	5.3 (0.77)	5.9 (1.21)	5.4 (1.05)	5.7 (1.15)	5.6 (1.10)	
Median	5.2	5.8	5.4	5.6	5.4	
Min, Max	4.0, 6.6	4.0, 8.8	3.4, 7.8	3.4, 8.8	3.4, 8.8	
Endoscopy Subscore						
n	12	33	34	67	79	0.084
Mean (SD)	2.1 (0.29)	2.1 (0.24)	2.2 (0.41)	2.1 (0.34)	2.1 (0.33)	
Median	2.0	2.0	2.0	2.0	2.0	
Min, Max	2.0, 3.0	2.0, 3.0	2.0, 3.0	2.0, 3.0	2.0, 3.0	
Rectal Bleeding Subscore						
n	12	33	34	67	79	0.351
Mean (SD)	1.2 (0.78)	1.6 (0.94)	1.4 (0.89)	1.5 (0.91)	1.5 (0.90)	
Median	1.0	1.8	1.0	1.4	1.3	
Min, Max	0.0, 2.6	0.0, 3.0	0.0, 3.0	0.0, 3.0	0.0, 3.0	
PGA Subscore						
n	12	33	34	67	79	0.091
Mean (SD)	2.2 (0.39)	2.2 (0.44)	2.1 (0.29)	2.2 (0.37)	2.2 (0.37)	
Median	2.0	2.0	2.0	2.0	2.0	
Min, Max	2.0, 3.0	2.0, 3.0	2.0, 3.0	2.0, 3.0	2.0, 3.0	

表 2.7.3.6-15. 疾患特性（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT					
		mITT-E				
	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)	P-Value@
Stool Frequency Subscore						
n	12	33	34	67	79	0.627
Mean (SD)	2.0 (0.89)	2.0 (0.75)	1.9 (0.84)	2.0 (0.80)	2.0 (0.80)	
Median	2.2	2.0	1.7	2.0	2.0	
Min, Max	0.0, 3.0	0.6, 3.0	0.0, 3.0	0.0, 3.0	0.0, 3.0	
Number of stools in the last 24 hours prior to baseline						
n	12	33	34	67	79	0.680
Mean (SD)	3.6 (1.93)	4.5 (3.10)	4.2 (1.59)	4.3 (2.44)	4.2 (2.37)	
Median	3.5	3.0	4.0	4.0	4.0	
Min, Max	1.0, 7.0	1.0, 13.0	1.0, 7.0	1.0, 13.0	1.0, 13.0	
PUCAI total score						
n	12	33	34	67	79	0.304
Mean (SD)	40.0 (13.98)	43.3 (14.52)	39.3 (16.93)	41.3 (15.80)	41.1 (15.46)	
Median	42.5	42.5	36.3	42.5	42.5	
Min, Max	10.0, 55.0	20.0, 72.5	5.0, 72.5	5.0, 72.5	5.0, 72.5	
IMPACT III total score						
n	12	31	31	62	74	0.645
Mean (SD)	110.5 (22.75)	112.2 (20.19)	114.8 (24.04)	113.5 (22.05)	113.0 (22.04)	
Median	112.5	116.0	117.0	116.5	115.0	
Min, Max	69.0, 154.0	77.0, 144.0	71.0, 159.0	71.0, 159.0	69.0, 159.0	

表 2.7.3.6-15. 疾患特性（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT					
	mITT-E					
	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)	P-Value@
IMPACT III - body image						
n	12	31	31	62	74	0.560
Mean (SD)	10.1 (2.07)	10.0 (2.15)	10.3 (2.18)	10.1 (2.15)	10.1 (2.13)	
Median	9.0	10.0	11.0	10.0	10.0	
Min, Max	8.0, 15.0	4.0, 14.0	6.0, 14.0	4.0, 14.0	4.0, 15.0	
IMPACT III - bowel symptoms						
n	12	31	31	62	74	0.270
Mean (SD)	20.9 (6.19)	20.0 (4.91)	21.5 (5.46)	20.7 (5.20)	20.8 (5.33)	
Median	20.5	19.0	21.0	20.0	20.0	
Min, Max	11.0, 29.0	12.0, 30.0	10.5, 32.0	10.5, 32.0	10.5, 32.0	
IMPACT III - emotional functioning						
n	12	31	31	62	74	0.474
Mean (SD)	21.1 (6.75)	20.8 (6.31)	22.0 (7.08)	21.4 (6.68)	21.3 (6.64)	
Median	22.0	21.0	23.0	22.0	22.0	
Min, Max	11.0, 34.0	10.0, 31.0	10.0, 35.0	10.0, 35.0	10.0, 35.0	
IMPACT III - social functioning						
n	12	31	31	62	74	0.662
Mean (SD)	38.9 (7.03)	42.4 (6.99)	41.5 (8.83)	42.0 (7.91)	41.5 (7.81)	
Median	40.0	45.0	41.0	43.0	42.5	
Min, Max	24.0, 48.0	27.0, 54.0	22.0, 57.0	22.0, 57.0	22.0, 57.0	

表 2.7.3.6-15. 疾患特性（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT					
		mITT-E				
	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)	P-Value@
IMPACT III - systemic symptoms						
n	12	31	31	62	74	0.747
Mean (SD)	9.3 (2.60)	8.4 (2.33)	8.5 (2.38)	8.5 (2.34)	8.6 (2.38)	
Median	8.5	9.0	8.0	8.5	8.5	
Min, Max	6.0, 14.0	3.0, 12.0	4.0, 12.0	3.0, 12.0	3.0, 14.0	
IMPACT III - treatment/interventions						
n	12	31	31	62	74	0.617
Mean (SD)	10.3 (3.33)	10.6 (2.35)	10.9 (2.21)	10.8 (2.26)	10.7 (2.45)	
Median	11.5	11.0	11.0	11.0	11.0	
Min, Max	4.0, 14.0	6.0, 15.0	5.0, 15.0	5.0, 15.0	4.0, 15.0	
WPAI - absenteeism (%)						
n	9	19	23	42	51	0.581
Mean (SD)	5.5 (9.03)	15.5 (21.55)	12.2 (16.81)	13.7 (18.93)	12.2 (17.80)	
Median	0.0	4.8	3.9	4.3	0.0	
Min, Max	0.0, 22.5	0.0, 71.1	0.0, 66.7	0.0, 71.1	0.0, 71.1	
WPAI - presenteeism (%)						
n	10	19	23	42	52	0.061
Mean (SD)	46.0 (25.47)	46.8 (29.07)	30.4 (26.02)	37.9 (28.33)	39.4 (27.75)	
Median	50.0	40.0	30.0	30.0	35.0	
Min, Max	0.0, 80.0	0.0, 90.0	0.0, 80.0	0.0, 90.0	0.0, 90.0	

表 2.7.3.6-15. 疾患特性（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT					
	mITT-E					
	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)	P-Value@
WPAI - work impairment (%)						
n	9	19	23	42	51	0.089
Mean (SD)	54.3 (19.77)	52.4 (30.43)	36.1 (30.03)	43.5 (30.95)	45.4 (29.42)	
Median	60.0	44.0	36.4	40.0	40.9	
Min, Max	20.0, 80.0	0.0, 94.2	0.0, 86.7	0.0, 94.2	0.0, 94.2	
WPAI - activity impairment (%)						
n	12	33	34	67	79	0.621
Mean (SD)	50.8 (22.75)	41.5 (27.96)	45.0 (29.46)	43.3 (28.57)	44.4 (27.77)	
Median	50.0	40.0	40.0	40.0	40.0	
Min, Max	0.0, 80.0	0.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0	
hs-CRP [mg/l]						
n	11	30	32	62	73	0.380
Mean (SD)	2.2 (3.10)	4.9 (8.50)	3.2 (6.46)	4.0 (7.50)	3.7 (7.03)	
Median	0.9	1.8	1.1	1.4	1.2	
Min, Max	0.1, 9.9	0.1, 37.8	0.1, 35.9	0.1, 37.8	0.1, 37.8	
Tuberculin PPD skin test - n (%)						
Negative	0	0	1 (100)	1 (100)	1 (100)	
Positive&	0	0	0	0	0	
Missing	12	33	33	66	78	

表 2.7.3.6-15. 疾患特性（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT					
	mITT-E					
	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)	P-Value@
QuantiFERON-TB Gold test - n (%)						
Negative	10 (83.3)	33 (100)	31 (91.2)	64 (95.5)	74 (93.7)	0.364
Positive	1 (8.3)	0	1 (2.9)	1 (1.5)	2 (2.5)	
Indeterminate	1 (8.3)	0	2 (5.9)	2 (3.0)	3 (3.8)	
Tuberculin positive - n (%)						
Yes$	1 (8.3)	0	1 (2.9)	1 (1.5)	2 (2.5)	1.000
No	11 (91.7)	33 (100)	33 (97.1)	66 (98.5)	77 (97.5)	
Enrollment under TB prophylaxis - n (%)						
Yes	1 (8.3)	0	1 (2.9)	1 (1.5)	2 (2.5)	1.000
No	11 (91.7)	33 (100)	33 (97.1)	66 (98.5)	77 (97.5)	

M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
Note: percentages calculated on non-missing values.
Duration of UC in months: (baseline date - date of diagnosis of UC + 1) / (365.25/12).
Duration of UC in years: (baseline date - date of diagnosis of UC + 1) / 365.25.
& positive defined as >= 5 mm.
$ tuberculin PPD skin test >= 5 mm or QuantiFERON-TB Gold test is positive.
@ p-value for differences between the treatment groups M-SD and M-HD from chi-square test (or fisher's exact test if expected number of counts in a cell is < 5) for categorical variables or from one-way anova for continuous variables.
One patient ([redacted]) who is ongoing study is excluded from interim analysis.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.1__4.2_A

表 2.7.3.6-16. 疾患特性（日本人 mITT 集団，M11-290 試験）（中間 CSR）

	mITT					
		mITT-E				
	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)	P-Value@
Duration of UC (month)						
n	0	2	3	5	5	0.605
Mean (SD)		35.5 (44.77)	56.2 (36.10)	47.9 (35.79)	47.9 (35.79)	
Median		35.5	43.3	43.3	43.3	
Min, Max		3.9, 67.2	28.3, 97.0	3.9, 97.0	3.9, 97.0	
Duration of UC (year)						
n	0	2	3	5	5	0.605
Mean (SD)		3.0 (3.73)	4.7 (3.01)	4.0 (2.98)	4.0 (2.98)	
Median		3.0	3.6	3.6	3.6	
Min, Max		0.3, 5.6	2.4, 8.1	0.3, 8.1	0.3, 8.1	
Site of UC - n (%)						
Left sided UC	0	0	0	0	0	
Extensive UC/pancolitis	0	2 (100)	3 (100)	5 (100)	5 (100)	
Mayo Score						
n	0	2	3	5	5	0.492
Mean (SD)		7.6 (1.08)	7.0 (0.60)	7.2 (0.76)	7.2 (0.76)	
Median		7.6	7.0	7.0	7.0	
Min, Max		6.8, 8.3	6.4, 7.6	6.4, 8.3	6.4, 8.3	

表 2.7.3.6-16. 疾患特性（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT					
		mITT-E				
	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)	P-Value@
Partial Mayo Score						
n	0	2	3	5	5	0.443
Mean (SD)		5.6 (1.08)	4.7 (1.14)	5.0 (1.09)	5.0 (1.09)	
Median		5.6	5.0	5.0	5.0	
Min, Max		4.8, 6.3	3.4, 5.6	3.4, 6.3	3.4, 6.3	
Endoscopy Subscore						
n	0	2	3	5	5	0.495
Mean (SD)		2.0 (0.00)	2.3 (0.58)	2.2 (0.45)	2.2 (0.45)	
Median		2.0	2.0	2.0	2.0	
Min, Max		2.0, 2.0	2.0, 3.0	2.0, 3.0	2.0, 3.0	
Rectal Bleeding Subscore						
n	0	2	3	5	5	0.697
Mean (SD)		1.2 (0.24)	1.5 (0.92)	1.3 (0.68)	1.3 (0.68)	
Median		1.2	2.0	1.3	1.3	
Min, Max		1.0, 1.3	0.4, 2.0	0.4, 2.0	0.4, 2.0	
PGA Subscore						
n	0	2	3	5	5	0.495
Mean (SD)		2.0 (0.00)	2.3 (0.58)	2.2 (0.45)	2.2 (0.45)	
Median		2.0	2.0	2.0	2.0	
Min, Max		2.0, 2.0	2.0, 3.0	2.0, 3.0	2.0, 3.0	

表 2.7.3.6-16. 疾患特性（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT					
		mITT-E				
	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)	P-Value@
Stool Frequency Subscore						
n	0	2	3	5	5	0.134
Mean (SD)		2.4 (0.85)	0.9 (0.81)	1.5 (1.10)	1.5 (1.10)	
Median		2.4	1.0	1.6	1.6	
Min, Max		1.8, 3.0	0.0, 1.6	0.0, 3.0	0.0, 3.0	
Number of stools in the last 24 hours prior to baseline						
n	0	2	3	5	5	0.591
Mean (SD)		3.5 (0.71)	3.0 (1.00)	3.2 (0.84)	3.2 (0.84)	
Median		3.5	3.0	3.0	3.0	
Min, Max		3.0, 4.0	2.0, 4.0	2.0, 4.0	2.0, 4.0	
PUCAI total score						
n	0	2	3	5	5	0.875
Mean (SD)		36.3 (8.84)	32.5 (28.83)	34.0 (20.96)	34.0 (20.96)	
Median		36.3	30.0	30.0	30.0	
Min, Max		30.0, 42.5	5.0, 62.5	5.0, 62.5	5.0, 62.5	
IMPACT III total score						
n	0	2	3	5	5	0.886
Mean (SD)		121.5 (0.71)	119.0 (21.52)	120.0 (15.28)	120.0 (15.28)	
Median		121.5	120.0	121.0	121.0	
Min, Max		121.0, 122.0	97.0, 140.0	97.0, 140.0	97.0, 140.0	

表 2.7.3.6-16. 疾患特性（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT					
		mITT-E				
	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)	P-Value@
IMPACT III - body image						
n	0	2	3	5	5	0.402
Mean (SD)		9.5 (0.71)	8.3 (1.53)	8.8 (1.30)	8.8 (1.30)	
Median		9.5	8.0	9.0	9.0	
Min, Max		9.0, 10.0	7.0, 10.0	7.0, 10.0	7.0, 10.0	
IMPACT III - bowel symptoms						
n	0	2	3	5	5	0.822
Mean (SD)		22.5 (3.54)	23.7 (5.86)	23.2 (4.55)	23.2 (4.55)	
Median		22.5	26.0	25.0	25.0	
Min, Max		20.0, 25.0	17.0, 28.0	17.0, 28.0	17.0, 28.0	
IMPACT III - emotional functioning						
n	0	2	3	5	5	0.705
Mean (SD)		25.0 (0.00)	22.7 (7.51)	23.6 (5.46)	23.6 (5.46)	
Median		25.0	23.0	25.0	25.0	
Min, Max		25.0, 25.0	15.0, 30.0	15.0, 30.0	15.0, 30.0	
IMPACT III - social functioning						
n	0	2	3	5	5	0.859
Mean (SD)		43.5 (0.71)	44.3 (5.77)	44.0 (4.12)	44.0 (4.12)	
Median		43.5	41.0	43.0	43.0	
Min, Max		43.0, 44.0	41.0, 51.0	41.0, 51.0	41.0, 51.0	

表 2.7.3.6-16. 疾患特性（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT					
		mITT-E				
	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)	P-Value@
IMPACT III - systemic symptoms						
n	0	2	3	5	5	0.870
Mean (SD)		8.0 (0.00)	8.3 (2.52)	8.2 (1.79)	8.2 (1.79)	
Median		8.0	8.0	8.0	8.0	
Min, Max		8.0, 8.0	6.0, 11.0	6.0, 11.0	6.0, 11.0	
IMPACT III - treatment/interventions						
n	0	2	3	5	5	0.453
Mean (SD)		13.0 (2.83)	11.7 (0.58)	12.2 (1.64)	12.2 (1.64)	
Median		13.0	12.0	12.0	12.0	
Min, Max		11.0, 15.0	11.0, 12.0	11.0, 15.0	11.0, 15.0	
WPAI - absenteeism (%)						
n	0	1	3	4	4	0.042*
Mean (SD)		60.0 (NA)	5.7 (9.95)	19.3 (28.32)	19.3 (28.32)	
Median		60.0	0.0	8.6	8.6	
Min, Max		60.0, 60.0	0.0, 17.2	0.0, 60.0	0.0, 60.0	
WPAI - presenteeism (%)						
n	0	1	3	4	4	0.010**
Mean (SD)		70.0 (NA)	3.3 (5.77)	20.0 (33.67)	20.0 (33.67)	
Median		70.0	0.0	5.0	5.0	
Min, Max		70.0, 70.0	0.0, 10.0	0.0, 70.0	0.0, 70.0	

表 2.7.3.6-16. 疾患特性（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT					
		mITT-E				
	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)	P-Value@
WPAI - work impairment (%)						
n	0	1	3	4	4	0.043*
Mean (SD)		88.0 (NA)	8.5 (14.73)	28.4 (41.53)	28.4 (41.53)	
Median		88.0	0.0	12.8	12.8	
Min, Max		88.0, 88.0	0.0, 25.5	0.0, 88.0	0.0, 88.0	
WPAI - activity impairment (%)						
n	0	2	3	5	5	0.239
Mean (SD)		60.0 (14.14)	26.7 (28.87)	40.0 (28.28)	40.0 (28.28)	
Median		60.0	10.0	50.0	50.0	
Min, Max		50.0, 70.0	10.0, 60.0	10.0, 70.0	10.0, 70.0	
hs-CRP [mg/l]						
n	0	2	3	5	5	0.151
Mean (SD)		22.6 (21.47)	0.8 (0.43)	9.5 (16.03)	9.5 (16.03)	
Median		22.6	1.1	1.1	1.1	
Min, Max		7.4, 37.8	0.3, 1.1	0.3, 37.8	0.3, 37.8	
Tuberculin PPD skin test - n (%)						
Negative	0	0	0	0	0	
Positive&	0	0	0	0	0	
Missing		2	3	5	5	

表 2.7.3.6-16. 疾患特性（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT					
		mITT-E				
	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)	P-Value@
QuantiFERON-TB Gold test - n (%)						
Negative	0	2 (100)	3 (100)	5 (100)	5 (100)	
Positive	0	0	0	0	0	
Indeterminate	0	0	0	0	0	
Tuberculin positive - n (%)						
Yes$	0	0	0	0	0	
No	0	2 (100)	3 (100)	5 (100)	5 (100)	
Enrollment under TB prophylaxis - n (%)						
Yes	0	0	0	0	0	
No	0	2 (100)	3 (100)	5 (100)	5 (100)	

M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
Note: percentages calculated on non-missing values.
Duration of UC in months: (baseline date - date of diagnosis of UC + 1) / (365.25/12).
Duration of UC in years: (baseline date - date of diagnosis of UC + 1) / 365.25.
& positive defined as >= 5 mm.
$ tuberculin PPD skin test >= 5 mm or QuantiFERON-TB Gold test is positive.
@ p-value for differences between the treatment groups M-SD and M-HD from chi-square test (or fisher's exact test if expected number of counts in a cell is < 5) for categorical variables or from one-way anova for continuous variables.
***, **, * Statistically significant at 0.001, 0.01, and 0.05 level, respectively.
One patient ([redacted]) who is ongoing study is excluded from interim analysis.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.1__4.2_J

表 2.7.3.6-17.　UC に関連した前治療薬（一般名）（統合 ITT 集団，M11-290 試験）（中間 CSR）

Generic Name (WHO Q1 2018)	ITT / ITT-E: I-SD (N=32) n (%)	I-HD (N=51) n (%)	Total (N=83) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
Any prior UC-related medication	32 (100)	51 (100)	83 (100)	17 (100)	100 (100)
AZATHIOPRINE	26 (81.3)	39 (76.5)	65 (78.3)	6 (35.3)	71 (71.0)
BALSALAZIDE	0	2 (3.9)	2 (2.4)	1 (5.9)	3 (3.0)
BECLOMETASONE	0	1 (2.0)	1 (1.2)	0	1 (1.0)
BUDESONIDE	4 (12.5)	10 (19.6)	14 (16.9)	6 (35.3)	20 (20.0)
CICLOSPORIN	4 (12.5)	4 (7.8)	8 (9.6)	0	8 (8.0)
CIPROFLOXACIN	2 (6.3)	0	2 (2.4)	1 (5.9)	3 (3.0)
HYDROCORTISONE	2 (6.3)	1 (2.0)	3 (3.6)	1 (5.9)	4 (4.0)
IMIPENEM	0	0	0	1 (5.9)	1 (1.0)
INFLIXIMAB	7 (21.9)	8 (15.7)	15 (18.1)	1 (5.9)	16 (16.0)
LOPERAMIDE	0	1 (2.0)	1 (1.2)	0	1 (1.0)
MERCAPTOPURINE	2 (6.3)	2 (3.9)	4 (4.8)	0	4 (4.0)
MESALAZINE	28 (87.5)	42 (82.4)	70 (84.3)	13 (76.5)	83 (83.0)
METHOTREXATE	0	1 (2.0)	1 (1.2)	0	1 (1.0)
METHYLPREDNISOLONE	2 (6.3)	6 (11.8)	8 (9.6)	2 (11.8)	10 (10.0)
METRONIDAZOLE	3 (9.4)	3 (5.9)	6 (7.2)	1 (5.9)	7 (7.0)
MYCOPHENOLIC ACID	1 (3.1)	0	1 (1.2)	0	1 (1.0)
PREDNISOLONE	4 (12.5)	4 (7.8)	8 (9.6)	1 (5.9)	9 (9.0)

表 2.7.3.6-17. UC に関連した前治療薬（一般名）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

	ITT				
	ITT-E				
Generic Name (WHO Q1 2018)	I-SD (N=32) n (%)	I-HD (N=51) n (%)	Total (N=83) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
PREDNISONE	14 (43.8)	23 (45.1)	37 (44.6)	11 (64.7)	48 (48.0)
SULFASALAZINE	3 (9.4)	2 (3.9)	5 (6.0)	1 (5.9)	6 (6.0)
VANCOMYCIN	1 (3.1)	0	1 (1.2)	0	1 (1.0)

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
Note: all medications with a start date prior to the first study drug dose are included. Subjects are counted once in each row, regardless of the number of medications they may have taken.
One patient ([redacted]) who is ongoing study is excluded from interim analysis.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.1__6.1.2_A

表 2.7.3.6-18.　UC に関連した前治療薬（一般名）（日本人 ITT 集団，M11-290 試験）（中間 CSR）

	ITT				
	ITT-E				
Generic Name (WHO Q1 2018)	I-SD (N=2) n (%)	I-HD (N=4) n (%)	Total (N=6) n (%)	I-HD-OL (N=1) n (%)	Total (N=7) n (%)
Any prior UC-related medication	2 (100)	4 (100)	6 (100)	1 (100)	7 (100)
AZATHIOPRINE	1 (50.0)	3 (75.0)	4 (66.7)	1 (100)	5 (71.4)
INFLIXIMAB	1 (50.0)	0	1 (16.7)	0	1 (14.3)
MERCAPTOPURINE	1 (50.0)	1 (25.0)	2 (33.3)	0	2 (28.6)
MESALAZINE	2 (100)	4 (100)	6 (100)	0	6 (85.7)
PREDNISOLONE	2 (100)	2 (50.0)	4 (66.7)	1 (100)	5 (71.4)

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
Note: all medications with a start date prior to the first study drug dose are included. Subjects are counted once in each row, regardless of the number of medications they may have taken.
One patient ([redacted]) who is ongoing study is excluded from interim analysis.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.1__6.1.2_J

表 2.7.3.6-19.　ベースラインの UC に関連した治療薬（一般名）（統合 ITT 集団，M11-290 試験）（中間 CSR）

	ITT				
	ITT-E				
Generic Name (WHO Q1 2018)	I-SD (N=32) n (%)	I-HD (N=51) n (%)	Total (N=83) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
Any baseline UC-related medication	31 (96.9)	47 (92.2)	78 (94.0)	17 (100)	95 (95.0)
AZATHIOPRINE	22 (68.8)	31 (60.8)	53 (63.9)	6 (35.3)	59 (59.0)
BALSALAZIDE	0	1 (2.0)	1 (1.2)	1 (5.9)	2 (2.0)
BECLOMETASONE	0	1 (2.0)	1 (1.2)	0	1 (1.0)
BUDESONIDE	1 (3.1)	4 (7.8)	5 (6.0)	4 (23.5)	9 (9.0)
LOPERAMIDE	0	1 (2.0)	1 (1.2)	0	1 (1.0)
MERCAPTOPURINE	1 (3.1)	1 (2.0)	2 (2.4)	0	2 (2.0)
MESALAZINE	26 (81.3)	38 (74.5)	64 (77.1)	13 (76.5)	77 (77.0)
METHYLPREDNISOLONE	2 (6.3)	3 (5.9)	5 (6.0)	0	5 (5.0)
PREDNISOLONE	3 (9.4)	2 (3.9)	5 (6.0)	1 (5.9)	6 (6.0)
PREDNISONE	9 (28.1)	13 (25.5)	22 (26.5)	5 (29.4)	27 (27.0)
SULFASALAZINE	2 (6.3)	1 (2.0)	3 (3.6)	1 (5.9)	4 (4.0)

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
Note: all medications with started prior to the first dose of study drug and continued after the first dose of study drug or ended at the time of the first dose of study drug, including medications taken on the day of the first dose of study drug.
Subjects are counted once in each row regardless of the number of medications they may have taken.
One patient ([redacted]) who is ongoing study is excluded from interim analysis.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.1__6.2.2_A

表 2.7.3.6-20.　ベースラインの UC に関連した治療薬（一般名）（日本人 ITT 集団，M11-290 試験）（中間 CSR）

	ITT				
	ITT-E				
Generic Name (WHO Q1 2018)	I-SD (N=2) n (%)	I-HD (N=4) n (%)	Total (N=6) n (%)	I-HD-OL (N=1) n (%)	Total (N=7) n (%)
Any baseline UC-related medication	2 (100)	4 (100)	6 (100)	1 (100)	7 (100)
AZATHIOPRINE	1 (50.0)	3 (75.0)	4 (66.7)	1 (100)	5 (71.4)
MERCAPTOPURINE	1 (50.0)	1 (25.0)	2 (33.3)	0	2 (28.6)
MESALAZINE	2 (100)	4 (100)	6 (100)	0	6 (85.7)
PREDNISOLONE	2 (100)	2 (50.0)	4 (66.7)	1 (100)	5 (71.4)

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
Note: all medications with started prior to the first dose of study drug and continued after the first dose of study drug or ended at the time of the first dose of study drug, including medications taken on the day of the first dose of study drug.
Subjects are counted once in each row regardless of the number of medications they may have taken.
One patient ([redacted]) who is ongoing study is excluded from interim analysis.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.1__6.2.2_J

表 2.7.3.6-21. 導入療法期間中の UC に関連した併用薬（一般名）（統合 ITT 集団，M11-290 試験）（中間 CSR）

	ITT				
	ITT-E				
Generic Name (WHO Q1 2018)	I-SD (N=32) n (%)	I-HD (N=51) n (%)	Total (N=83) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
Any concomitant UC-related medication during induction period	31 (96.9)	47 (92.2)	78 (94.0)	17 (100)	95 (95.0)
AZATHIOPRINE	22 (68.8)	31 (60.8)	53 (63.9)	6 (35.3)	59 (59.0)
BALSALAZIDE	0	1 (2.0)	1 (1.2)	1 (5.9)	2 (2.0)
BECLOMETASONE	0	1 (2.0)	1 (1.2)	0	1 (1.0)
BUDESONIDE	1 (3.1)	4 (7.8)	5 (6.0)	4 (23.5)	9 (9.0)
CICLOSPORIN	0	1 (2.0)	1 (1.2)	0	1 (1.0)
CIPROFLOXACIN	0	1 (2.0)	1 (1.2)	0	1 (1.0)
HYDROCORTISONE	1 (3.1)	0	1 (1.2)	0	1 (1.0)
LOPERAMIDE	0	1 (2.0)	1 (1.2)	0	1 (1.0)
MERCAPTOPURINE	1 (3.1)	1 (2.0)	2 (2.4)	0	2 (2.0)
MESALAZINE	26 (81.3)	38 (74.5)	64 (77.1)	13 (76.5)	77 (77.0)
METHYLPREDNISOLONE	2 (6.3)	3 (5.9)	5 (6.0)	1 (5.9)	6 (6.0)
PREDNISOLONE	3 (9.4)	2 (3.9)	5 (6.0)	1 (5.9)	6 (6.0)
PREDNISONE	10 (31.3)	13 (25.5)	23 (27.7)	5 (29.4)	28 (28.0)
SULFASALAZINE	2 (6.3)	1 (2.0)	3 (3.6)	1 (5.9)	4 (4.0)

表 2.7.3.6-21.　導入療法期間中の UC に関連した併用薬（一般名）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
Note: this table includes all medications with a start date between first study drug in induction period and last study drug in induction period + (max.*) 14 days, including medications with a start date prior to first dose date of study drug in induction period and which are ongoing after first dose date of study drug in induction period and taken on the day of the first dose date of study drug in induction period.
* cutting before first dose of study drug in the maintenance period.
Subjects are counted once in each row, regardless of the number of medications they may have taken.
One patient ([redacted]) who is ongoing study is excluded from interim analysis.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.1__6.3.2_A

表 2.7.3.6-22.　導入療法期間中の UC に関連した併用薬（一般名）（日本人 ITT 集団，M11-290 試験）（中間 CSR）

	ITT				
	ITT-E				
Generic Name (WHO Q1 2018)	I-SD (N=2) n (%)	I-HD (N=4) n (%)	Total (N=6) n (%)	I-HD-OL (N=1) n (%)	Total (N=7) n (%)
Any concomitant UC-related medication during induction period	2 (100)	4 (100)	6 (100)	1 (100)	7 (100)
AZATHIOPRINE	1 (50.0)	3 (75.0)	4 (66.7)	1 (100)	5 (71.4)
MERCAPTOPURINE	1 (50.0)	1 (25.0)	2 (33.3)	0	2 (28.6)
MESALAZINE	2 (100)	4 (100)	6 (100)	0	6 (85.7)
PREDNISOLONE	2 (100)	2 (50.0)	4 (66.7)	1 (100)	5 (71.4)

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
Note: this table includes all medications with a start date between first study drug in induction period and last study drug in induction period + (max.*) 14 days, including medications with a start date prior to first dose date of study drug in induction period and which are ongoing after first dose date of study drug in induction period and taken on the day of the first dose date of study drug in induction period.
* cutting before first dose of study drug in the maintenance period.
Subjects are counted once in each row, regardless of the number of medications they may have taken.
One patient ([redacted]) who is ongoing study is excluded from interim analysis.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.1__6.3.2_J

表 2.7.3.6-23. 維持療法期間中の UC に関連した併用薬（一般名）（統合 mITT 集団，M11-290 試験）（中間 CSR）

Generic Name (WHO Q1 2018)	mITT / mITT-E: M-PL (N=12) n (%)	M-SD (N=33) n (%)	M-HD (N=34) n (%)	Total (N=67) n (%)	Total (N=79) n (%)
Any concomitant UC-related medication during maintenance period	12 (100)	31 (93.9)	33 (97.1)	64 (95.5)	76 (96.2)
ADALIMUMAB	0	1 (3.0)	0	1 (1.5)	1 (1.3)
AZATHIOPRINE	9 (75.0)	19 (57.6)	22 (64.7)	41 (61.2)	50 (63.3)
BALSALAZIDE	0	2 (6.1)	0	2 (3.0)	2 (2.5)
BECLOMETASONE	0	0	1 (2.9)	1 (1.5)	1 (1.3)
BUDESONIDE	4 (33.3)	2 (6.1)	3 (8.8)	5 (7.5)	9 (11.4)
CIPROFLOXACIN	2 (16.7)	1 (3.0)	2 (5.9)	3 (4.5)	5 (6.3)
LOPERAMIDE	0	1 (3.0)	2 (5.9)	3 (4.5)	3 (3.8)
MERCAPTOPURINE	0	0	1 (2.9)	1 (1.5)	1 (1.3)
MESALAZINE	10 (83.3)	25 (75.8)	30 (88.2)	55 (82.1)	65 (82.3)
METHYLPREDNISOLONE	0	3 (9.1)	3 (8.8)	6 (9.0)	6 (7.6)
METRONIDAZOLE	2 (16.7)	2 (6.1)	0	2 (3.0)	4 (5.1)
PREDNISOLONE	0	3 (9.1)	2 (5.9)	5 (7.5)	5 (6.3)
PREDNISONE	3 (25.0)	9 (27.3)	8 (23.5)	17 (25.4)	20 (25.3)
SULFASALAZINE	1 (8.3)	2 (6.1)	0	2 (3.0)	3 (3.8)

表 2.7.3.6-23.　維持療法期間中の UC に関連した併用薬（一般名）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
Note: this table includes all medications with a start date between first study drug in maintenance period and last study drug in maintenance period + (max.*) 14 days, including medications with a start date prior to first dose date of study drug in maintenance period and which are ongoing after first dose date of study drug in maintenance period and taken on the day of the first dose date of study drug in maintenance period.
* cutting before first dose of study drug in M10-870, if applicable.
Subjects are counted once in each row, regardless of the number of medications they may have taken.
One patient ([redacted]) who is ongoing study is excluded from interim analysis.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.1__6.3.4_A

表 2.7.3.6-24.　維持療法期間中の UC に関連した併用薬（一般名）（日本人 mITT 集団，M11-290 試験）（中間 CSR）

Generic Name (WHO Q1 2018)	M-PL (N=0) n (%)	M-SD (N=2) n (%)	M-HD (N=3) n (%)	Total (N=5) n (%)	Total (N=5) n (%)
	mITT				
		mITT-E			
Any concomitant UC-related medication during maintenance period	0	2 (100)	3 (100)	5 (100)	5 (100)
AZATHIOPRINE	0	2 (100)	2 (66.7)	4 (80.0)	4 (80.0)
MERCAPTOPURINE	0	0	1 (33.3)	1 (20.0)	1 (20.0)
MESALAZINE	0	1 (50.0)	3 (100)	4 (80.0)	4 (80.0)
PREDNISOLONE	0	2 (100)	2 (66.7)	4 (80.0)	4 (80.0)

M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
Note: this table includes all medications with a start date between first study drug in maintenance period and last study drug in maintenance period + (max.*) 14 days, including medications with a start date prior to first dose date of study drug in maintenance period and which are ongoing after first dose date of study drug in maintenance period and taken on the day of the first dose date of study drug in maintenance period.
* cutting before first dose of study drug in M10-870, if applicable.
Subjects are counted once in each row, regardless of the number of medications they may have taken.
One patient ([redacted]) who is ongoing study is excluded from interim analysis.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.1__6.3.4_J

表 2.7.3.6-25.　治験薬の服薬順守率（統合安全性解析対象集団，M11-290 試験）（中間 CSR）

Treatment	N	Mean	SD	Min	Q1	Median	Q3	Max
Treatment Compliance (%)								
I-SD + I-HD Total	83	97.93	8.733	25.0	99.15	100.00	100.00	103.6
I-SD	32	96.50	13.267	25.0	98.21	100.00	100.00	100.0
I-SD/-	10	90.76	23.388	25.0	91.67	100.00	100.00	100.0
I-SD/M-PL	4	100.00	0.000	100.0	100.00	100.00	100.00	100.0
I-SD/M-SD	8	98.67	2.018	95.5	96.93	100.00	100.00	100.0
I-SD/M-HD	10	99.13	1.483	96.4	98.21	100.00	100.00	100.0
I-HD	51	98.82	3.721	82.1	100.00	100.00	100.00	103.6
I-HD/-	8	100.00	0.000	100.0	100.00	100.00	100.00	100.0
I-HD/M-PL	8	99.30	3.359	91.7	99.58	100.00	100.00	103.6
I-HD/M-SD	17	98.49	4.275	83.9	100.00	100.00	100.00	101.8
I-HD/M-HD	18	98.38	4.219	82.1	98.31	100.00	100.00	100.0
I-HD-OL	17	98.61	6.136	78.0	98.21	100.00	100.00	106.8
I-HD-OL/-	2	95.83	5.893	91.7	91.67	95.83	100.00	100.0
I-HD-OL/M-SD	8	97.79	8.202	78.0	99.11	100.00	100.85	104.4
I-HD-OL/M-HD	7	100.35	3.024	97.4	98.21	100.00	100.00	106.8

Note: I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
One patient ([redacted]) who is ongoing study is excluded from interim analysis.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.1__8_A

表 2.7.3.6-26.　治験薬の服薬順守率（日本人安全性解析対象集団，M11-290 試験）（中間 CSR）

Treatment	N	Mean	SD	Min	Q1	Median	Q3	Max
Treatment Compliance (%)								
I-SD + I-HD Total	6	87.50	30.619	25.0	100.00	100.00	100.00	100.0
I-SD	2	62.50	53.033	25.0	25.00	62.50	100.00	100.0
I-SD/-	2	62.50	53.033	25.0	25.00	62.50	100.00	100.0
I-SD/M-PL	0							
I-SD/M-SD	0							
I-SD/M-HD	0							
I-HD	4	100.00	0.000	100.0	100.00	100.00	100.00	100.0
I-HD/-	0							
I-HD/M-PL	0							
I-HD/M-SD	1	100.00		100.0	100.00	100.00	100.00	100.0
I-HD/M-HD	3	100.00	0.000	100.0	100.00	100.00	100.00	100.0
I-HD-OL	1	104.44		104.4	104.44	104.44	104.44	104.4
I-HD-OL/-	0							
I-HD-OL/M-SD	1	104.44		104.4	104.44	104.44	104.44	104.4
I-HD-OL/M-HD	0							

Note: I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
One patient ([redacted]) who is ongoing study is excluded from interim analysis.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.1__8_J

表 2.7.3.6-27.　導入療法期における治験薬の曝露期間（統合安全性解析対象集団，M11-290 試験）（中間 CSR）

	I-SD (N=32)	I-HD (N=51)	I-HD-OL (N=17)	Total (N=100)
Duration (day)				
n	32	51	17	100
Mean (SD)	52.8(9.30)	55.4(2.22)	53.6(5.04)	54.3(5.93)
Median	56.0	56.0	56.0	56.0
Min, Max	14, 59	42, 58	41, 58	14, 59
Patient-Years of exposure	4.6	7.7	2.5	14.9

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
Note: duration of induction-exposure = last induction dose date - first induction dose date + (max.*) 14 days.
* cutting before first dose of study drug in the maintenance period.
One patient ([redacted]) who is ongoing study is excluded from interim analysis.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.1__7.1_A

表 2.7.3.6-28.　維持療法期における治験薬の曝露期間（統合安全性解析対象集団，M11-290 試験）（中間 CSR）

	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	ADA-Total (N=68)	Total (N=80)
Duration (day)					
n	12	33	35	68	80
Mean (SD)	184.2(123.02)	226.8(110.20)	242.2(104.52)	234.7(106.78)	227.2(110.04)
Median	196.5	307.0	308.0	308.0	307.0
Min, Max	26, 310	30, 316	28, 316	28, 316	26, 316
Patient-Years of exposure	6.1	20.5	23.2	43.7	49.8

M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
Note: duration of maintenance-exposure = last maintenance dose date (prior to potential re-randomization due to 1st disease flare) - first maintenance dose date + (max.*) 14 days. * cutting before first dose of study drug after re-randomization due to 1st disease flare, if applicable, or the first dose of study drug in M10-870, if applicable.
One patient ([redacted]) who is ongoing study is excluded from interim analysis.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.1__7.3_A

表 2.7.3.6-29. 治験期間を通したアダリムマブの曝露期間（統合安全性解析対象集団，M11-290 試験）（中間 CSR）

	Any ADA								
	I-SD				I-HD/HD-OL				
	--$ (N=10)	M-PL (N=4)	M-SD (N=8)	M-HD (N=10)	--$ (N=10)	M-PL (N=8)	M-SD (N=25)	M-HD (N=25)	Total (N=100)
Duration (day)									
n	10	4	8	10	10	8	25	25	100
Mean (SD)	45.7(14.60)	145.3(133.98)	278.9(121.10)	343.2(73.94)	51.9(7.13)	168.5(118.84)	330.7(74.56)	351.8(52.86)	256.3(139.47)
Median	54.0	93.5	364.5	364.5	55.5	145.5	364.0	364.0	363.0
Min, Max	14, 56	55, 339	132, 372	133, 372	41, 58	55, 329	134, 371	112, 371	14, 372
Patient-Years of exposure	1.3	1.6	6.1	9.4	1.4	3.7	22.6	24.1	70.2

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group,
M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
Note: subjects who are randomized to placebo at week 8 and who have not been re-randomized due to a disease flare:
Overall ADA exposure = duration of induction-exposure.
Subjects who are randomized to placebo at week 8 and are re-randomized due to at least one disease flare during maintenance:
Overall ADA exposure = duration of induction-exposure + (last adalimumab dose date in the study after re-randomization due to 1st disease flare - first dose date of adalimumab after re-randomization due to 1st disease flare + (max.*) 14 days).
Subjects who are not randomized to placebo:
Overall ADA exposure = last adalimumab dose date in the study - first dose of adalimumab + (max.*) 14 days.
* cutting before first dose of study drug in M10-870, if applicable.
$ patients who discontinued as non-responders from the study at week 8.
One patient ([redacted]) who is ongoing study is excluded from interim analysis.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.1__7.5_A

表 2.7.3.6-30. 治験責任医師別の被験者の内訳（統合被験者集団，M10-870 試験の日本サブ試験）（中間 CSR）

Current Investigator (Site Number)	Enrolled n	Treated n	Completed n	Completed Week 288 n	Switched to Adult Care n	Switched to Commercial Humira n	Discontinued Study Drug n	Full Analysis Set n
All Sites	59	59	0	--	--	--	17	59
[redacted]	8	8	0	--	--	--	1	8
[redacted]	8	8	0	--	--	--	0	8
[redacted]	3	3	0	--	--	--	0	3
[redacted]	22	22	0	--	--	--	8	22
[redacted]	1	1	0	--	--	--	1	1
[redacted]	2	2	0	--	--	--	0	2
[redacted]	1	1	0	--	--	--	1	1
[redacted]	1	1	0	--	--	--	1	1
[redacted]	2	2	0	--	--	--	0	2
[redacted]	3	3	0	--	--	--	0	3
[redacted]	4	4	0	--	--	--	2	4
[redacted]	1	1	0	--	--	--	0	1

表 2.7.3.6-30. 治験責任医師別の被験者の内訳（統合被験者集団，M10-870 試験の日本サブ試験）（中間 CSR）（続き）

Current Investigator (Site Number)	Enrolled n	Treated n	Completed n	Completed Week 288 n	Switched to Adult Care n	Switched to Commercial Humira n	Discontinued Study Drug n	Full Analysis Set n
[redacted]	2	2	0	--	--	--	2	2
[redacted]	1	1	0	--	--	--	1	1

Note: Enrolled group includes all patients who have successfully completed Protocol M11-290 through Week 52 and meet all of the inclusion criteria and none of the exclusion criteria.

Cross reference: M10-870 Japan Sub-study CSR_Interim Table 14.1__1.1_A

表 2.7.3.6-31.　用量調整（統合 FAS 集団，M10-870 試験）（中間 CSR）

Dose Adjustments	Adalimumab (N=59) n (%)
Subjects with EW dosing at baseline	N*=5 (8.5)
Subjects with EOW dosing at baseline	N**=54 (91.5)
At least one dose escalation (EOW to EW)[A]	18 (33.3)
At least one dose de-escalation (EW to EOW)[B]	0
At least one dose de-escalation (EW to EOW) and re-escalation (EOW to EW)[B]	0

[A] Percentages are relative to N**.
[B] Percentages are relative to N*.

Cross reference: M10-870 Japan Sub-study CSR_Interim Table 14.1__1.2_A

表 2.7.3.6-32.　被験者の中止理由（統合 FAS 集団，M10-870 試験）（中間 CSR）

Discontinuation due to	Adalimumab (N=59) n (%)
All reasons$	17 (28.8)
Adverse event	2 (3.4)
Withdrew consent	3 (5.1)
Lost to follow-up	1 (1.7)
Lack of efficacy	12 (20.3)
Requires alternative (or prohibited) therapy	1 (1.7)
Subject non-compliance	1 (1.7)
Other	0
Primary reason	17 (28.8)
Adverse event	0
Withdrew consent	3 (5.1)
Lost to follow-up	1 (1.7)
Lack of efficacy	11 (18.6)
Requires alternative (or prohibited) therapy	1 (1.7)
Subject non-compliance	1 (1.7)
Other	0

$ Subjects who discontinued study drug are counted under each reason given for discontinuation, therefore, the sum of the counts given for the reasons may be greater than the overall number of discontinuations.

Cross reference: M10-870 Japan Sub-study CSR_Interim Table 14.1__2_A

表 2.7.3.6-33.　治験実施計画書からの逸脱（統合被験者集団，M10-870 試験）（中間 CSR）

	Adalimumab (N=59)
Subjects who had at least one protocol deviation	7 (11.9)
Subject entered into the study even though did not satisfy entry criteria	0
Subject received wrong treatment or incorrect dose	7 (11.9)
Subject received excluded concomitant treatment	0
Subject developed withdrawal criteria during the study and was not withdrawn	0

Cross reference: M10-870 Japan Sub-study CSR_Interim Table 14.1__9_A

表 2.7.3.6-34.　人口統計学的特性（統合 FAS 集団，M10-870 試験）（中間 CSR）

	Adalimumab (N=59)
Sex# - n (%)	
Female	30 (50.8)
Male	29 (49.2)
Age (years)#	
n	59
Mean (SD)	14.7 (3.27)
Median	15.0
Min, Max	6, 19
Age categories (years)# - n (%)	
< 13	16 (27.1)
>= 13	43 (72.9)
Race# - n (%)	
White	52 (88.1)
Black	2 (3.4)
Asian	5 (8.5)
American Indian/Alaska Native	0
Other	0
Ethnicity# - n (%)	
Hispanic or Latino	1 (1.7)
Japanese	4 (6.8)
No ethnicity	54 (91.5)
Geographic region# - n (%)	
North America	5 (8.5)
Western Europe	3 (5.1)
Eastern Europe	47 (79.7)
Japan	4 (6.8)

表 2.7.3.6-34. 人口統計学的特性（統合 FAS 集団，M10-870 試験）（中間 CSR）（続き）

	Adalimumab (N=59)
Body weight (kg)#	
n	59
Mean (SD)	59.8 (19.50)
Median	61.1
Min, Max	17.4, 110.0
Body weight (kg)# by sex	
Female	
n	30
Mean (SD)	54.7 (15.21)
Median	56.1
Min, Max	22.5, 95.0
Male	
n	29
Mean (SD)	65.2 (22.14)
Median	64.0
Min, Max	17.4, 110.0
Body weight categories (kg) - n (%)	
< 40	8 (13.6)
40 - < 60	20 (33.9)
>= 60	31 (52.5)
Height (cm)#	
n	59
Mean (SD)	163.6 (17.65)
Median	164.7
Min, Max	112.5, 198.0

表 2.7.3.6-34.　人口統計学的特性（統合 FAS 集団，M10-870 試験）（中間 CSR）（続き）

	Adalimumab (N=59)
Body mass index (kg/m^2)	
n	59
Mean (SD)	21.6 (4.09)
Median	21.5
Min, Max	13.7, 32.1
Tobacco/Nicotine use$#* - n (%)	
Current	0
Former	0
Never	59 (100)
Unknown	0
Alcohol use$#* - n (%)	
Current	0
Former	0
Never	59 (100)
Unknown	0

Note: Percentages calculated on non-missing values.
$ Percentages calculated on non-unknown values. A subject may be a current user of one type of tobacco. A former user of another type of tobacco and never used another type of tobacco. A subject will be counted in the category closest to user.
# The source data from Study M11-290.
* Data from Study M11-290-Baseline.

Cross reference: M10-870 Japan Sub-study CSR_Interim Table 14.1__3_A

表 2.7.3.6-35.　疾患特性（統合 FAS 集団，M10-870 試験）（中間 CSR）

	Adalimumab (N=59)
Duration of UC (months)	
n	59
Mean (SD)	45.5 (26.26)
Median	40.1
Min, Max	16.4, 135.9
Duration of UC (years)	
n	59
Mean (SD)	3.8 (2.19)
Median	3.3
Min, Max	1.4, 11.3
Site of UC# - n (%)	
Left sided UC	21 (35.6)
Extensive UC/pancolitis	38 (64.4)
Mayo Score#	
n	59
Mean (SD)	2.2 (2.10)
Median	1.2
Min, Max	0.0, 9.6
Mayo Score at M11-290-Baseline#	
n	59
Mean (SD)	7.7 (1.16)
Median	7.6
Min, Max	6.0, 10.8

表 2.7.3.6-35. 疾患特性（統合 FAS 集団，M10-870 試験）（中間 CSR）（続き）

	Adalimumab (N=59)
Partial Mayo Score#	
n	59
Mean (SD)	1.2 (1.52)
Median	0.8
Min, Max	0.0, 7.6
Partial Mayo Score at M11-290-Baseline#	
n	59
Mean (SD)	5.6 (1.16)
Median	5.4
Min, Max	3.4, 8.8
Endoscopy Subscore#	
n	59
Mean (SD)	1.0 (1.00)
Median	1.0
Min, Max	0.0, 3.0
Rectal Bleeding Subscore#	
n	59
Mean (SD)	0.2 (0.41)
Median	0.0
Min, Max	0.0, 2.0
Physician's Global Assessment (PGA) Subscore#	
n	59
Mean (SD)	0.5 (0.73)
Median	0.0
Min, Max	0.0, 3.0

表 2.7.3.6-35. 疾患特性（統合 FAS 集団，M10-870 試験）（中間 CSR）（続き）

	Adalimumab (N=59)
Stool Frequency Subscore#	
n	59
Mean (SD)	0.6 (0.73)
Median	0.4
Min, Max	0.0, 3.0
Number of stools in the last 24 hours prior to baseline#	
n	49
Mean (SD)	3.0 (3.45)
Median	2.0
Min, Max	0.0, 22.0
PUCAI total score#	
n	59
Mean (SD)	6.9 (13.23)
Median	0.0
Min, Max	0.0, 70.0
PUCAI total score at M11-290-Baseline#	
n	59
Mean (SD)	40.4 (15.81)
Median	40.0
Min, Max	5.0, 72.5
IMPACT III total score#	
n	55
Mean (SD)	138.1 (19.89)
Median	142.0
Min, Max	82.0, 169.0

表 2.7.3.6-35. 疾患特性（統合 FAS 集団，M10-870 試験）（中間 CSR）（続き）

	Adalimumab (N=59)
IMPACT III - body image#	
n	55
Mean (SD)	10.8 (1.97)
Median	11.0
Min, Max	5.0, 15.0
IMPACT III - bowel symptoms#	
n	55
Mean (SD)	28.5 (4.94)
Median	29.0
Min, Max	14.0, 35.0
IMPACT III - emotional functioning#	
n	55
Mean (SD)	26.6 (5.52)
Median	28.0
Min, Max	11.0, 35.0
IMPACT III - social functioning#	
n	55
Mean (SD)	49.3 (6.24)
Median	50.0
Min, Max	30.0, 58.0
IMPACT III - systemic symptoms#	
n	55
Mean (SD)	11.4 (2.47)
Median	12.0
Min, Max	4.0, 15.0

表 2.7.3.6-35. 疾患特性（統合 FAS 集団，M10-870 試験）（中間 CSR）（続き）

	Adalimumab (N=59)
IMPACT III - treatment/interventions#	
n	55
Mean (SD)	11.5 (2.31)
Median	12.0
Min, Max	4.0, 15.0
WPAI - absenteeism (%)#	
n	43
Mean (SD)	7.4 (19.17)
Median	0.0
Min, Max	0.0, 100.0
WPAI - presenteeism (%)#	
n	43
Mean (SD)	13.0 (20.65)
Median	0.0
Min, Max	0.0, 100.0
WPAI - work impairment (%)#	
n	43
Mean (SD)	18.2 (24.15)
Median	10.0
Min, Max	0.0, 100.0
WPAI - activity impairment (%)#	
n	59
Mean (SD)	16.4 (20.49)
Median	10.0
Min, Max	0.0, 80.0

表 2.7.3.6-35. 疾患特性（統合 FAS 集団，M10-870 試験）（中間 CSR）（続き）

	Adalimumab (N=59)
hs-CRP [mg/l]#	
n	59
Mean (SD)	1.8 (2.93)
Median	0.4
Min, Max	0.1, 13.9
Tuberculin PPD skin test# - n (%)	
Negative	0
Positive&	0
Missing	59
QuantiFERON-TB Gold test# - n (%)	
Negative	40 (90.9)
Positive	3 (6.8)
Indeterminate	1 (2.3)
Missing	15
Tuberculin positive# - n (%)	
Yes$	3 (6.8)
No	41 (93.2)
Missing	15
Enrollment under TB prophylaxis# - n (%)	
Yes	0
No	59 (100)

表 2.7.3.6-35.　　疾患特性（統合 FAS 集団，M10-870 試験）（中間 CSR）（続き）

Note: Percentages calculated on non-missing values.
Duration of UC in months: (Baseline date - date of diagnosis of UC#+ 1)/(365.25/12).
Duration of UC in years: (Baseline date - date of diagnosis of UC#+ 1)/365.25.
The source data from Study M11-290.
& Positive defined as >= 5 mm.
$ Tuberculin PPD skin test >= 5 mm or QuantiFERON-TB Gold test is positive.

Cross reference: M10-870 Japan Sub-study CSR_Interim Table 14.1__4_A

表 2.7.3.6-36.　　UC に関連した前治療薬（一般名）（統合 FAS 集団，M10-870 試験）（中間 CSR）

Generic Name (WHO Q1 2018)	Adalimumab (N=59) n (%)
Any prior UC-related medication	59 (100)
AZATHIOPRINE	40 (67.8)
BALSALAZIDE	1 (1.7)
BUDESONIDE	5 (8.5)
CICLOSPORIN	3 (5.1)
CIPROFLOXACIN	2 (3.4)
HYDROCORTISONE	2 (3.4)
INFLIXIMAB	7 (11.9)
LOPERAMIDE	1 (1.7)
MERCAPTOPURINE	2 (3.4)
MESALAZINE	47 (79.7)
METHOTREXATE	1 (1.7)
METHYLPREDNISOLONE	3 (5.1)
METRONIDAZOLE	3 (5.1)
MYCOPHENOLIC ACID	1 (1.7)
PREDNISOLONE	4 (6.8)
PREDNISONE	19 (32.2)
SULFASALAZINE	4 (6.8)
VANCOMYCIN	1 (1.7)

Note: All medications with a start date prior to the first study drug dose in Study M11-290 are included.
Subjects are counted once in each row regardless of the number of medications they may have taken.

Cross reference: M10-870 Japan Sub-study CSR_Interim Table 14.1__6.1.2_A

表 2.7.3.6-37.　UC に関連した併用薬（一般名）（統合 FAS 集団，M10-870 試験）（中間 CSR）

Generic Name (WHO Q1 2018)	Adalimumab (N=59) n (%)
Any concomitant UC-related medication	55 (93.2)
AZATHIOPRINE	37 (62.7)
BUDESONIDE	4 (6.8)
CIPROFLOXACIN	3 (5.1)
FLUCONAZOLE	1 (1.7)
FURAZOLIDONE	1 (1.7)
INFLIXIMAB	1 (1.7)
LOPERAMIDE	2 (3.4)
MERCAPTOPURINE	1 (1.7)
MESALAZINE	50 (84.7)
METHOTREXATE	1 (1.7)
METHYLPREDNISOLONE	1 (1.7)
METRONIDAZOLE	1 (1.7)
PREDNISOLONE	3 (5.1)
PREDNISONE	6 (10.2)
RIFAXIMIN	1 (1.7)
SULFASALAZINE	1 (1.7)

Note: All medications with a start date between first study drug in Study M10-870 and last study drug in Study M10-870 + 14 days, including medications with a start date prior to first dose date of study drug and which are ongoing after first dose date of study drug or taken on the day of the first dose date of study drug in Study M10-870.
Subjects are counted once in each row regardless of the number of medications they may have taken.

Cross reference: M10-870 Japan Sub-study CSR_Interim Table 14.1__6.3.2_A

表 2.7.3.6-38.　治験薬の服薬順守率（統合 FAS 集団，M10-870 試験）（中間 CSR）

	N	Mean	SD	Min	Q1	Median	Q3	Max
Treatment compliance (%)	59	119.99	33.734	82.6	100.00	101.03	135.71	200.0

Cross reference: M10-870 Japan Sub-study CSR_Interim Table 14.1__8_A

表 2.7.3.6-39.　治験薬の曝露期間（統合 FAS 集団，M10-870 試験の日本サブ試験）（中間 CSR）

	Adalimumab (N=59)
Duration (days)	
n	59
Mean (SD)	522.0(371.58)
Median	421.0
Min, Max	1, 1370
Patient-Years of exposure	84.3

Note: ADA exposure in Study M10-870 = last dose date of ADA in Study M10-870 - first dose date of ADA in Study M10-870 + 14 days.

Cross reference: M10-870 Japan Sub-study CSR_Interim Table 14.1__7.1_A

表 2.7.3.6-40.　投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（統合 ITT 集団，M11-290 試験）（中間 CSR）

	ITT				
	ITT-E				
Category Endpoint Met	I-SD (N=32)	I-HD (N=51)	Total (N=83)	I-HD-OL (N=17)	Total (N=100)
Overall	N=32	N=51	N=83	N=17	N=100
Yes	13 (40.6)	30 (58.8)	43 (51.8)	11 (64.7)	54 (54.0)
No	19 (59.4)	21 (41.2)	40 (48.2)	6 (35.3)	46 (46.0)
95% Confidence Interval [A]	(23.70, 59.36)	(44.17, 72.42)	(40.56, 62.92)	(38.33, 85.79)	(43.74, 64.02)
P-Value [B1]	0.003	<0.001	<0.001		
ADJ. P-Value [B2]	0.344	<0.001	<0.001		
P-Value [C]	0.106				
Baseline Mayo Score <= 9 &	N=27	N=42	N=69	N=14	N=83
Yes	11 (40.7)	26 (61.9)	37 (53.6)	9 (64.3)	46 (55.4)
No	16 (59.3)	16 (38.1)	32 (46.4)	5 (35.7)	37 (44.6)
95% Confidence Interval [A]	(22.39, 61.20)	(45.64, 76.43)	(41.20, 65.72)	(35.14, 87.24)	(44.10, 66.34)
Baseline Mayo Score > 9 &	N=5	N=9	N=14	N=3	N=17
Yes	2 (40.0)	4 (44.4)	6 (42.9)	2 (66.7)	8 (47.1)
No	3 (60.0)	5 (55.6)	8 (57.1)	1 (33.3)	9 (52.9)
95% Confidence Interval [A]	(5.27, 85.34)	(13.70, 78.80)	(17.66, 71.14)	(9.43, 99.16)	(22.98, 72.19)

表 2.7.3.6-40. 投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

	ITT				
	ITT-E				
Category Endpoint Met	I-SD (N=32)	I-HD (N=51)	Total (N=83)	I-HD-OL (N=17)	Total (N=100)
Prior Anti-TNF Use	N=7	N=8	N=15	N=1	N=16
Yes	1 (14.3)	3 (37.5)	4 (26.7)	1 (100)	5 (31.3)
No	6 (85.7)	5 (62.5)	11 (73.3)	0	11 (68.8)
95% Confidence Interval [A]	(0.36, 57.87)	(8.52, 75.51)	(7.79, 55.10)	(2.50, 100.00)	(11.02, 58.66)
Prior Anti-TNF Naive	N=25	N=43	N=68	N=16	N=84
Yes	12 (48.0)	27 (62.8)	39 (57.4)	10 (62.5)	49 (58.3)
No	13 (52.0)	16 (37.2)	29 (42.6)	6 (37.5)	35 (41.7)
95% Confidence Interval [A]	(27.80, 68.69)	(46.73, 77.02)	(44.77, 69.28)	(35.43, 84.80)	(47.06, 69.00)
Baseline Corticosteroid Use - Yes #	N=15	N=24	N=39	N=10	N=49
Yes	4 (26.7)	15 (62.5)	19 (48.7)	6 (60.0)	25 (51.0)
No	11 (73.3)	9 (37.5)	20 (51.3)	4 (40.0)	24 (49.0)
95% Confidence Interval [A]	(7.79, 55.10)	(40.59, 81.20)	(32.42, 65.22)	(26.24, 87.84)	(36.34, 65.58)
Baseline Corticosteroid Use - No #	N=17	N=27	N=44	N=7	N=51
Yes	9 (52.9)	15 (55.6)	24 (54.5)	5 (71.4)	29 (56.9)
No	8 (47.1)	12 (44.4)	20 (45.5)	2 (28.6)	22 (43.1)
95% Confidence Interval [A]	(27.81, 77.02)	(35.33, 74.52)	(38.85, 69.61)	(29.04, 96.33)	(42.25, 70.65)

表 2.7.3.6-40. 投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Category Endpoint Met	ITT ITT-E I-SD (N=32)	ITT ITT-E I-HD (N=51)	ITT ITT-E Total (N=83)	ITT I-HD-OL (N=17)	ITT Total (N=100)
Sex - Male	N=17	N=28	N=45	N=4	N=49
Yes	4 (23.5)	18 (64.3)	22 (48.9)	3 (75.0)	25 (51.0)
No	13 (76.5)	10 (35.7)	23 (51.1)	1 (25.0)	24 (49.0)
95% Confidence Interval [A]	(6.81, 49.90)	(44.07, 81.36)	(33.70, 64.23)	(19.41, 99.37)	(36.34, 65.58)
Sex - Female	N=15	N=23	N=38	N=13	N=51
Yes	9 (60.0)	12 (52.2)	21 (55.3)	8 (61.5)	29 (56.9)
No	6 (40.0)	11 (47.8)	17 (44.7)	5 (38.5)	22 (43.1)
95% Confidence Interval [A]	(32.29, 83.66)	(30.59, 73.18)	(38.30, 71.38)	(31.58, 86.14)	(42.25, 70.65)
Age < 13 Years	N=4	N=17	N=21	N=5	N=26
Yes	2 (50.0)	11 (64.7)	13 (61.9)	3 (60.0)	16 (61.5)
No	2 (50.0)	6 (35.3)	8 (38.1)	2 (40.0)	10 (38.5)
95% Confidence Interval [A]	(6.76, 93.24)	(38.33, 85.79)	(38.44, 81.89)	(14.66, 94.73)	(40.57, 79.77)
Age >= 13 Years	N=28	N=34	N=62	N=12	N=74
Yes	11 (39.3)	19 (55.9)	30 (48.4)	8 (66.7)	38 (51.4)
No	17 (60.7)	15 (44.1)	32 (51.6)	4 (33.3)	36 (48.6)
95% Confidence Interval [A]	(21.50, 59.42)	(37.89, 72.81)	(35.50, 61.44)	(34.89, 90.08)	(39.44, 63.15)

表 2.7.3.6-40. 投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Category Endpoint Met	ITT ITT-E I-SD (N=32)	ITT ITT-E I-HD (N=51)	ITT ITT-E Total (N=83)	ITT I-HD-OL (N=17)	ITT Total (N=100)
Ethnicity - White	N=28	N=45	N=73	N=15	N=88
Yes	11 (39.3)	27 (60.0)	38 (52.1)	11 (73.3)	49 (55.7)
No	17 (60.7)	18 (40.0)	35 (47.9)	4 (26.7)	39 (44.3)
95% Confidence Interval [A]	(21.50, 59.42)	(44.33, 74.30)	(40.04, 63.90)	(44.90, 92.21)	(44.70, 66.27)
Ethnicity - Non-white	N=4	N=6	N=10	N=2	N=12
Yes	2 (50.0)	3 (50.0)	5 (50.0)	0	5 (41.7)
No	2 (50.0)	3 (50.0)	5 (50.0)	2 (100)	7 (58.3)
95% Confidence Interval [A]	(6.76, 93.24)	(11.81, 88.19)	(18.71, 81.29)	(0.00, 84.19)	(15.17, 72.33)
Geographic Region - Japan	N=2	N=4	N=6	N=1	N=7
Yes	0	2 (50.0)	2 (33.3)	0	2 (28.6)
No	2 (100)	2 (50.0)	4 (66.7)	1 (100)	5 (71.4)
95% Confidence Interval [A]	(0.00, 84.19)	(6.76, 93.24)	(4.33, 77.72)	(0.00, 97.50)	(3.67, 70.96)

表 2.7.3.6-40. 投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

	ITT				
	ITT-E				
Category Endpoint Met	I-SD (N=32)	I-HD (N=51)	Total (N=83)	I-HD-OL (N=17)	Total (N=100)
Baseline IMM Use - Yes	N=23	N=33	N=56	N=6	N=62
Yes	11 (47.8)	20 (60.6)	31 (55.4)	4 (66.7)	35 (56.5)
No	12 (52.2)	13 (39.4)	25 (44.6)	2 (33.3)	27 (43.5)
95% Confidence Interval [A]	(26.82, 69.41)	(42.14, 77.09)	(41.47, 68.66)	(22.28, 95.67)	(43.26, 69.01)
Baseline IMM Use - No	N=9	N=18	N=27	N=11	N=38
Yes	2 (22.2)	10 (55.6)	12 (44.4)	7 (63.6)	19 (50.0)
No	7 (77.8)	8 (44.4)	15 (55.6)	4 (36.4)	19 (50.0)
95% Confidence Interval [A]	(2.81, 60.01)	(30.76, 78.47)	(25.48, 64.67)	(30.79, 89.07)	(33.38, 66.62)
Weight < 40 kg	N=3	N=10	N=13	N=3	N=16
Yes	2 (66.7)	5 (50.0)	7 (53.8)	2 (66.7)	9 (56.3)
No	1 (33.3)	5 (50.0)	6 (46.2)	1 (33.3)	7 (43.8)
95% Confidence Interval [A]	(9.43, 99.16)	(18.71, 81.29)	(25.13, 80.78)	(9.43, 99.16)	(29.88, 80.25)

表 2.7.3.6-40. 投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

	ITT				
	ITT-E				
Category Endpoint Met	I-SD (N=32)	I-HD (N=51)	Total (N=83)	I-HD-OL (N=17)	Total (N=100)
Weight >= 40 kg	N=29	N=41	N=70	N=14	N=84
Yes	11 (37.9)	25 (61.0)	36 (51.4)	9 (64.3)	45 (53.6)
No	18 (62.1)	16 (39.0)	34 (48.6)	5 (35.7)	39 (46.4)
95% Confidence Interval [A]	(20.69, 57.74)	(44.50, 75.80)	(39.17, 63.56)	(35.14, 87.24)	(42.35, 64.53)
Pancolitis - Yes	N=21	N=29	N=50	N=12	N=62
Yes	7 (33.3)	15 (51.7)	22 (44.0)	9 (75.0)	31 (50.0)
No	14 (66.7)	14 (48.3)	28 (56.0)	3 (25.0)	31 (50.0)
95% Confidence Interval [A]	(14.59, 56.97)	(32.53, 70.55)	(29.99, 58.75)	(42.81, 94.51)	(37.02, 62.98)
Pancolitis - No	N=11	N=22	N=33	N=5	N=38
Yes	6 (54.5)	15 (68.2)	21 (63.6)	2 (40.0)	23 (60.5)
No	5 (45.5)	7 (31.8)	12 (36.4)	3 (60.0)	15 (39.5)
95% Confidence Interval [A]	(23.38, 83.25)	(45.13, 86.14)	(45.12, 79.60)	(5.27, 85.34)	(43.39, 75.96)
Disease Duration <= Baseline Median (19.1 Months)	N=19	N=21	N=40	N=10	N=50
Yes	7 (36.8)	9 (42.9)	16 (40.0)	6 (60.0)	22 (44.0)
No	12 (63.2)	12 (57.1)	24 (60.0)	4 (40.0)	28 (56.0)
95% Confidence Interval [A]	(16.29, 61.64)	(21.82, 65.98)	(24.86, 56.67)	(26.24, 87.84)	(29.99, 58.75)

表 2.7.3.6-40. 投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

	ITT				
	ITT-E				
Category Endpoint Met	I-SD (N=32)	I-HD (N=51)	Total (N=83)	I-HD-OL (N=17)	Total (N=100)
Disease Duration > Baseline Median (19.1 Months)	N=13	N=30	N=43	N=7	N=50
Yes	6 (46.2)	21 (70.0)	27 (62.8)	5 (71.4)	32 (64.0)
No	7 (53.8)	9 (30.0)	16 (37.2)	2 (28.6)	18 (36.0)
95% Confidence Interval [A]	(19.22, 74.87)	(50.60, 85.27)	(46.73, 77.02)	(29.04, 96.33)	(49.19, 77.08)
Baseline hs-CRP <= Baseline Median (1.29 mg/L)	N=15	N=23	N=38	N=8	N=46
Yes	7 (46.7)	15 (65.2)	22 (57.9)	5 (62.5)	27 (58.7)
No	8 (53.3)	8 (34.8)	16 (42.1)	3 (37.5)	19 (41.3)
95% Confidence Interval [A]	(21.27, 73.41)	(42.73, 83.62)	(40.82, 73.69)	(24.49, 91.48)	(43.23, 73.00)
Baseline hs-CRP > Baseline Median (1.29 mg/L)	N=15	N=22	N=37	N=9	N=46
Yes	5 (33.3)	12 (54.5)	17 (45.9)	6 (66.7)	23 (50.0)
No	10 (66.7)	10 (45.5)	20 (54.1)	3 (33.3)	23 (50.0)
95% Confidence Interval [A]	(11.82, 61.62)	(32.21, 75.61)	(29.49, 63.08)	(29.93, 92.51)	(34.90, 65.10)
Baseline Fecal Calprotectin <= Baseline Median (2302.5 ug/g)	N=7	N=7	N=14	N=0	N=14
Yes	2 (28.6)	3 (42.9)	5 (35.7)	0	5 (35.7)
No	5 (71.4)	4 (57.1)	9 (64.3)	0	9 (64.3)
95% Confidence Interval [A]	(3.67, 70.96)	(9.90, 81.59)	(12.76, 64.86)	(NA, NA)	(12.76, 64.86)

表 2.7.3.6-40.　投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

	ITT				
	ITT-E				
Category Endpoint Met	I-SD (N=32)	I-HD (N=51)	Total (N=83)	I-HD-OL (N=17)	Total (N=100)
Baseline Fecal Calprotectin > Baseline Median (2302.5 ug/g)	N=6	N=8	N=14	N=0	N=14
Yes	2 (33.3)	3 (37.5)	5 (35.7)	0	5 (35.7)
No	4 (66.7)	5 (62.5)	9 (64.3)	0	9 (64.3)
95% Confidence Interval [A]	(4.33, 77.72)	(8.52, 75.51)	(12.76, 64.86)	(NA, NA)	(12.76, 64.86)

One patient ([redacted] who is ongoing study is excluded from interim analysis.
Note: I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
[A] Clopper-Pearson confidence interval for proportion in remission.
[B1] Nominal p-values from a one-sample two-sided chi-square test.
[B2] Adjusted p-values from a sequentially rejective multiple test procedure (details in SAP), testing co-primary and ranked secondary endpoints first for I-SD/I-HD combined (p-value in 'Total' column) and then for individual ADA dose groups (p-values in 'I-HD' column and in 'I-SD' column, respectively) against the respective external placebo rate (here: 19.83%).
[C] Nominal p-value for the exploratory comparison of I-SD vs. I-HD.
Non-responder imputation (NRI): missing data is imputed as not having met the endpoint. Subjects re-randomized due to disease flare are considered as not having met the endpoint at and after their 1st disease flare.
Clinical remission per Partial Mayo Score (PMS) is defined as PMS <= 2 and no individual subscore > 1.
& True baseline Mayo Score is displayed. Subject [redacted] was randomized in the stratum '> 9', but actually had a baseline Mayo Score of 8.8 (corrected by the site from 9.8 to 8.8 after randomization).
# True baseline systemic corticosteroid use is displayed. Subject [redacted] was randomized in the stratum 'No', but actually has baseline systemic corticosteroid use documented.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.2__1.1.1_A

表 2.7.3.6-41. 投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（日本人 ITT 集団，M11-290 試験）（中間 CSR）

	ITT				
	ITT-E				
Category Endpoint Met	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=1)	Total (N=7)
Overall	N=2	N=4	N=6	N=1	N=7
Yes	0	2 (50.0)	2 (33.3)	0	2 (28.6)
No	2 (100)	2 (50.0)	4 (66.7)	1 (100)	5 (71.4)
95% Confidence Interval [A]	(0.00, 84.19)	(6.76, 93.24)	(4.33, 77.72)	(0.00, 97.50)	(3.67, 70.96)
P-Value [B1]	0.482	0.130	0.407		
P-Value [C]	0.221				
Baseline Mayo Score <= 9	N=2	N=4	N=6	N=1	N=7
Yes	0	2 (50.0)	2 (33.3)	0	2 (28.6)
No	2 (100)	2 (50.0)	4 (66.7)	1 (100)	5 (71.4)
95% Confidence Interval [A]	(0.00, 84.19)	(6.76, 93.24)	(4.33, 77.72)	(0.00, 97.50)	(3.67, 70.96)
Baseline Mayo Score > 9	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)

表 2.7.3.6-41. 投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Category Endpoint Met	ITT ITT-E I-SD (N=2)	ITT ITT-E I-HD (N=4)	ITT ITT-E Total (N=6)	ITT I-HD-OL (N=1)	ITT Total (N=7)
Prior Anti-TNF Use	N=1	N=0	N=1	N=0	N=1
Yes	0	0	0	0	0
No	1 (100)	0	1 (100)	0	1 (100)
95% Confidence Interval [A]	(0.00, 97.50)	(NA, NA)	(0.00, 97.50)	(NA, NA)	(0.00, 97.50)
Prior Anti-TNF Naive	N=1	N=4	N=5	N=1	N=6
Yes	0	2 (50.0)	2 (40.0)	0	2 (33.3)
No	1 (100)	2 (50.0)	3 (60.0)	1 (100)	4 (66.7)
95% Confidence Interval [A]	(0.00, 97.50)	(6.76, 93.24)	(5.27, 85.34)	(0.00, 97.50)	(4.33, 77.72)
Baseline Corticosteroid Use - Yes	N=2	N=2	N=4	N=1	N=5
Yes	0	1 (50.0)	1 (25.0)	0	1 (20.0)
No	2 (100)	1 (50.0)	3 (75.0)	1 (100)	4 (80.0)
95% Confidence Interval [A]	(0.00, 84.19)	(1.26, 98.74)	(0.63, 80.59)	(0.00, 97.50)	(0.51, 71.64)
Baseline Corticosteroid Use - No	N=0	N=2	N=2	N=0	N=2
Yes	0	1 (50.0)	1 (50.0)	0	1 (50.0)
No	0	1 (50.0)	1 (50.0)	0	1 (50.0)
95% Confidence Interval [A]	(NA, NA)	(1.26, 98.74)	(1.26, 98.74)	(NA, NA)	(1.26, 98.74)

表 2.7.3.6-41. 投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

	ITT				
	ITT-E				
Category Endpoint Met	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=1)	Total (N=7)
Sex - Male	N=2	N=4	N=6	N=1	N=7
Yes	0	2 (50.0)	2 (33.3)	0	2 (28.6)
No	2 (100)	2 (50.0)	4 (66.7)	1 (100)	5 (71.4)
95% Confidence Interval [A]	(0.00, 84.19)	(6.76, 93.24)	(4.33, 77.72)	(0.00, 97.50)	(3.67, 70.96)
Sex - Female	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Age < 13 Years	N=0	N=1	N=1	N=0	N=1
Yes	0	1 (100)	1 (100)	0	1 (100)
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(2.50, 100.00)	(2.50, 100.00)	(NA, NA)	(2.50, 100.00)
Age >= 13 Years	N=2	N=3	N=5	N=1	N=6
Yes	0	1 (33.3)	1 (20.0)	0	1 (16.7)
No	2 (100)	2 (66.7)	4 (80.0)	1 (100)	5 (83.3)
95% Confidence Interval [A]	(0.00, 84.19)	(0.84, 90.57)	(0.51, 71.64)	(0.00, 97.50)	(0.42, 64.12)

表 2.7.3.6-41. 投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

	ITT				
	ITT-E				
Category Endpoint Met	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=1)	Total (N=7)
Ethnicity - White	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Ethnicity - Non-white	N=2	N=4	N=6	N=1	N=7
Yes	0	2 (50.0)	2 (33.3)	0	2 (28.6)
No	2 (100)	2 (50.0)	4 (66.7)	1 (100)	5 (71.4)
95% Confidence Interval [A]	(0.00, 84.19)	(6.76, 93.24)	(4.33, 77.72)	(0.00, 97.50)	(3.67, 70.96)
Geographic Region - Japan	N=2	N=4	N=6	N=1	N=7
Yes	0	2 (50.0)	2 (33.3)	0	2 (28.6)
No	2 (100)	2 (50.0)	4 (66.7)	1 (100)	5 (71.4)
95% Confidence Interval [A]	(0.00, 84.19)	(6.76, 93.24)	(4.33, 77.72)	(0.00, 97.50)	(3.67, 70.96)

表 2.7.3.6-41. 投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

	ITT				
	ITT-E				
Category Endpoint Met	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=1)	Total (N=7)
Baseline IMM Use - Yes	N=2	N=4	N=6	N=1	N=7
Yes	0	2 (50.0)	2 (33.3)	0	2 (28.6)
No	2 (100)	2 (50.0)	4 (66.7)	1 (100)	5 (71.4)
95% Confidence Interval [A]	(0.00, 84.19)	(6.76, 93.24)	(4.33, 77.72)	(0.00, 97.50)	(3.67, 70.96)
Baseline IMM Use - No	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Weight < 40 kg	N=0	N=1	N=1	N=0	N=1
Yes	0	1 (100)	1 (100)	0	1 (100)
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(2.50, 100.00)	(2.50, 100.00)	(NA, NA)	(2.50, 100.00)

表 2.7.3.6-41. 投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

	ITT				
	ITT-E				
Category Endpoint Met	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=1)	Total (N=7)
Weight >= 40 kg	N=2	N=3	N=5	N=1	N=6
Yes	0	1 (33.3)	1 (20.0)	0	1 (16.7)
No	2 (100)	2 (66.7)	4 (80.0)	1 (100)	5 (83.3)
95% Confidence Interval [A]	(0.00, 84.19)	(0.84, 90.57)	(0.51, 71.64)	(0.00, 97.50)	(0.42, 64.12)
Pancolitis - Yes	N=1	N=4	N=5	N=1	N=6
Yes	0	2 (50.0)	2 (40.0)	0	2 (33.3)
No	1 (100)	2 (50.0)	3 (60.0)	1 (100)	4 (66.7)
95% Confidence Interval [A]	(0.00, 97.50)	(6.76, 93.24)	(5.27, 85.34)	(0.00, 97.50)	(4.33, 77.72)
Pancolitis - No	N=1	N=0	N=1	N=0	N=1
Yes	0	0	0	0	0
No	1 (100)	0	1 (100)	0	1 (100)
95% Confidence Interval [A]	(0.00, 97.50)	(NA, NA)	(0.00, 97.50)	(NA, NA)	(0.00, 97.50)
Disease Duration <= Baseline Median (19.1 Months)	N=0	N=0	N=0	N=1	N=1
Yes	0	0	0	0	0
No	0	0	0	1 (100)	1 (100)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)

表 2.7.3.6-41. 投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Category Endpoint Met	ITT ITT-E I-SD (N=2)	ITT ITT-E I-HD (N=4)	ITT ITT-E Total (N=6)	ITT I-HD-OL (N=1)	ITT Total (N=7)
Disease Duration > Baseline Median (19.1 Months)	N=2	N=4	N=6	N=0	N=6
Yes	0	2 (50.0)	2 (33.3)	0	2 (33.3)
No	2 (100)	2 (50.0)	4 (66.7)	0	4 (66.7)
95% Confidence Interval [A]	(0.00, 84.19)	(6.76, 93.24)	(4.33, 77.72)	(NA, NA)	(4.33, 77.72)
Baseline hs-CRP <= Baseline Median (1.29 mg/L)	N=1	N=3	N=4	N=0	N=4
Yes	0	2 (66.7)	2 (50.0)	0	2 (50.0)
No	1 (100)	1 (33.3)	2 (50.0)	0	2 (50.0)
95% Confidence Interval [A]	(0.00, 97.50)	(9.43, 99.16)	(6.76, 93.24)	(NA, NA)	(6.76, 93.24)
Baseline hs-CRP > Baseline Median (1.29 mg/L)	N=1	N=1	N=2	N=1	N=3
Yes	0	0	0	0	0
No	1 (100)	1 (100)	2 (100)	1 (100)	3 (100)
95% Confidence Interval [A]	(0.00, 97.50)	(0.00, 97.50)	(0.00, 84.19)	(0.00, 97.50)	(0.00, 70.76)
Baseline Fecal Calprotectin <= Baseline Median (2302.5 ug/g)	N=1	N=0	N=1	N=0	N=1
Yes	0	0	0	0	0
No	1 (100)	0	1 (100)	0	1 (100)
95% Confidence Interval [A]	(0.00, 97.50)	(NA, NA)	(0.00, 97.50)	(NA, NA)	(0.00, 97.50)

表 2.7.3.6-41. 投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

	ITT				
	ITT-E				
Category Endpoint Met	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=1)	Total (N=7)
Baseline Fecal Calprotectin > Baseline Median (2302.5 ug/g)	N=1	N=1	N=2	N=0	N=2
Yes	0	1 (100)	1 (50.0)	0	1 (50.0)
No	1 (100)	0	1 (50.0)	0	1 (50.0)
95% Confidence Interval [A]	(0.00, 97.50)	(2.50, 100.00)	(1.26, 98.74)	(NA, NA)	(1.26, 98.74)

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
Note: I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
[A] Clopper-Pearson confidence interval for proportion in remission.
[B1] Nominal p-values from a one-sample two-sided chi-square test.
[C] Nominal p-value for the exploratory comparison of I-SD vs. I-HD.
Non-responder imputation (NRI): missing data is imputed as not having met the endpoint. Subjects re-randomized due to disease flare are considered as not having met the endpoint at and after their 1st disease flare.
Clinical remission per Partial Mayo Score (PMS) is defined as PMS <= 2 and no individual subscore > 1.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.2__1.1.1_J

表 2.7.3.6-42. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Overall	N=12	N=33	N=34	N=67	N=79
Yes	4 (33.3)	9 (27.3)	15 (44.1)	24 (35.8)	28 (35.4)
No	8 (66.7)	24 (72.7)	19 (55.9)	43 (64.2)	51 (64.6)
95% Confidence Interval [A]	(9.92, 65.11)	(13.30, 45.52)	(27.19, 62.11)	(24.47, 48.47)	(25.00, 47.01)
P-Value [B1]		0.187	<0.001	<0.001	
ADJ. P-Value [B2]		0.344	<0.001	<0.001	
P-Value [C]		0.151			
PMS Remission at Week 8 - Yes	N=8	N=21	N=24	N=45	N=53
Yes	3 (37.5)	9 (42.9)	11 (45.8)	20 (44.4)	23 (43.4)
No	5 (62.5)	12 (57.1)	13 (54.2)	25 (55.6)	30 (56.6)
95% Confidence Interval [A]	(8.52, 75.51)	(21.82, 65.98)	(25.55, 67.18)	(29.64, 60.00)	(29.84, 57.72)

表 2.7.3.6-42. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
PMS Remission at Week 8 - No	N=4	N=12	N=10	N=22	N=26
Yes	1 (25.0)	0	4 (40.0)	4 (18.2)	5 (19.2)
No	3 (75.0)	12 (100)	6 (60.0)	18 (81.8)	21 (80.8)
95% Confidence Interval [A]	(0.63, 80.59)	(0.00, 26.46)	(12.16, 73.76)	(5.19, 40.28)	(6.55, 39.35)
I-SD	N=4	N=8	N=9	N=17	N=21
Yes	1 (25.0)	0	4 (44.4)	4 (23.5)	5 (23.8)
No	3 (75.0)	8 (100)	5 (55.6)	13 (76.5)	16 (76.2)
95% Confidence Interval [A]	(0.63, 80.59)	(0.00, 36.94)	(13.70, 78.80)	(6.81, 49.90)	(8.22, 47.17)
I-HD/I-HD-OL	N=8	N=25	N=25	N=50	N=58
Yes	3 (37.5)	9 (36.0)	11 (44.0)	20 (40.0)	23 (39.7)
No	5 (62.5)	16 (64.0)	14 (56.0)	30 (60.0)	35 (60.3)
95% Confidence Interval [A]	(8.52, 75.51)	(17.97, 57.48)	(24.40, 65.07)	(26.41, 54.82)	(27.05, 53.36)

表 2.7.3.6-42. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

Category Endpoint Met	mITT M-PL (N=12)	mITT-E M-SD (N=33)	mITT-E M-HD (N=34)	mITT-E Total (N=67)	mITT Total (N=79)
I-HD	N=8	N=17	N=18	N=35	N=43
Yes	3 (37.5)	7 (41.2)	8 (44.4)	15 (42.9)	18 (41.9)
No	5 (62.5)	10 (58.8)	10 (55.6)	20 (57.1)	25 (58.1)
95% Confidence Interval [A]	(8.52, 75.51)	(18.44, 67.08)	(21.53, 69.24)	(26.32, 60.65)	(27.01, 57.87)
I-HD-OL	N=0	N=8	N=7	N=15	N=15
Yes	0	2 (25.0)	3 (42.9)	5 (33.3)	5 (33.3)
No	0	6 (75.0)	4 (57.1)	10 (66.7)	10 (66.7)
95% Confidence Interval [A]	(NA, NA)	(3.19, 65.09)	(9.90, 81.59)	(11.82, 61.62)	(11.82, 61.62)
Sex - Male	N=9	N=15	N=16	N=31	N=40
Yes	2 (22.2)	4 (26.7)	7 (43.8)	11 (35.5)	13 (32.5)
No	7 (77.8)	11 (73.3)	9 (56.3)	20 (64.5)	27 (67.5)
95% Confidence Interval [A]	(2.81, 60.01)	(7.79, 55.10)	(19.75, 70.12)	(19.23, 54.63)	(18.57, 49.13)

表 2.7.3.6-42. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Sex - Female	N=3	N=18	N=18	N=36	N=39
Yes	2 (66.7)	5 (27.8)	8 (44.4)	13 (36.1)	15 (38.5)
No	1 (33.3)	13 (72.2)	10 (55.6)	23 (63.9)	24 (61.5)
95% Confidence Interval [A]	(9.43, 99.16)	(9.69, 53.48)	(21.53, 69.24)	(20.82, 53.78)	(23.36, 55.38)
Age < 13 Years	N=2	N=12	N=9	N=21	N=23
Yes	1 (50.0)	5 (41.7)	4 (44.4)	9 (42.9)	10 (43.5)
No	1 (50.0)	7 (58.3)	5 (55.6)	12 (57.1)	13 (56.5)
95% Confidence Interval [A]	(1.26, 98.74)	(15.17, 72.33)	(13.70, 78.80)	(21.82, 65.98)	(23.19, 65.51)
Age >= 13 Years	N=10	N=21	N=25	N=46	N=56
Yes	3 (30.0)	4 (19.0)	11 (44.0)	15 (32.6)	18 (32.1)
No	7 (70.0)	17 (81.0)	14 (56.0)	31 (67.4)	38 (67.9)
95% Confidence Interval [A]	(6.67, 65.25)	(5.45, 41.91)	(24.40, 65.07)	(19.53, 48.02)	(20.29, 45.96)

表 2.7.3.6-42. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

Category Endpoint Met	mITT M-PL (N=12)	mITT-E M-SD (N=33)	mITT-E M-HD (N=34)	mITT-E Total (N=67)	mITT Total (N=79)
Ethnicity - White	N=11	N=29	N=30	N=59	N=70
Yes	4 (36.4)	8 (27.6)	14 (46.7)	22 (37.3)	26 (37.1)
No	7 (63.6)	21 (72.4)	16 (53.3)	37 (62.7)	44 (62.9)
95% Confidence Interval [A]	(10.93, 69.21)	(12.73, 47.24)	(28.34, 65.67)	(25.04, 50.85)	(25.89, 49.52)
Ethnicity - Non-white	N=1	N=4	N=4	N=8	N=9
Yes	0	1 (25.0)	1 (25.0)	2 (25.0)	2 (22.2)
No	1 (100)	3 (75.0)	3 (75.0)	6 (75.0)	7 (77.8)
95% Confidence Interval [A]	(0.00, 97.50)	(0.63, 80.59)	(0.63, 80.59)	(3.19, 65.09)	(2.81, 60.01)
Geographic Region - Japan	N=0	N=2	N=3	N=5	N=5
Yes	0	0	1 (33.3)	1 (20.0)	1 (20.0)
No	0	2 (100)	2 (66.7)	4 (80.0)	4 (80.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.84, 90.57)	(0.51, 71.64)	(0.51, 71.64)

表 2.7.3.6-42. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Baseline Mayo Score <= 9	N=11	N=27	N=29	N=56	N=67
Yes	4 (36.4)	8 (29.6)	11 (37.9)	19 (33.9)	23 (34.3)
No	7 (63.6)	19 (70.4)	18 (62.1)	37 (66.1)	44 (65.7)
95% Confidence Interval [A]	(10.93, 69.21)	(13.75, 50.18)	(20.69, 57.74)	(21.81, 47.81)	(23.15, 46.94)
Baseline Mayo Score > 9	N=1	N=6	N=5	N=11	N=12
Yes	0	1 (16.7)	4 (80.0)	5 (45.5)	5 (41.7)
No	1 (100)	5 (83.3)	1 (20.0)	6 (54.5)	7 (58.3)
95% Confidence Interval [A]	(0.00, 97.50)	(0.42, 64.12)	(28.36, 99.49)	(16.75, 76.62)	(15.17, 72.33)
Prior Anti-TNF Use	N=2	N=2	N=6	N=8	N=10
Yes	1 (50.0)	0	2 (33.3)	2 (25.0)	3 (30.0)
No	1 (50.0)	2 (100)	4 (66.7)	6 (75.0)	7 (70.0)
95% Confidence Interval [A]	(1.26, 98.74)	(0.00, 84.19)	(4.33, 77.72)	(3.19, 65.09)	(6.67, 65.25)

表 2.7.3.6-42. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Prior Anti-TNF Naive	N=10	N=31	N=28	N=59	N=69
Yes	3 (30.0)	9 (29.0)	13 (46.4)	22 (37.3)	25 (36.2)
No	7 (70.0)	22 (71.0)	15 (53.6)	37 (62.7)	44 (63.8)
95% Confidence Interval [A]	(6.67, 65.25)	(14.22, 48.04)	(27.51, 66.13)	(25.04, 50.85)	(24.99, 48.69)
Baseline Corticosteroid Use - Yes	N=5	N=15	N=17	N=32	N=37
Yes	2 (40.0)	4 (26.7)	6 (35.3)	10 (31.3)	12 (32.4)
No	3 (60.0)	11 (73.3)	11 (64.7)	22 (68.8)	25 (67.6)
95% Confidence Interval [A]	(5.27, 85.34)	(7.79, 55.10)	(14.21, 61.67)	(16.12, 50.01)	(18.01, 49.79)
Baseline Corticosteroid Use - No	N=7	N=18	N=17	N=35	N=42
Yes	2 (28.6)	5 (27.8)	9 (52.9)	14 (40.0)	16 (38.1)
No	5 (71.4)	13 (72.2)	8 (47.1)	21 (60.0)	26 (61.9)
95% Confidence Interval [A]	(3.67, 70.96)	(9.69, 53.48)	(27.81, 77.02)	(23.87, 57.89)	(23.57, 54.36)

表 2.7.3.6-42. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

Category Endpoint Met	mITT M-PL (N=12)	mITT-E M-SD (N=33)	mITT-E M-HD (N=34)	mITT-E Total (N=67)	mITT Total (N=79)
Baseline IMM Use - Yes	N=8	N=19	N=24	N=43	N=51
Yes	3 (37.5)	4 (21.1)	11 (45.8)	15 (34.9)	18 (35.3)
No	5 (62.5)	15 (78.9)	13 (54.2)	28 (65.1)	33 (64.7)
95% Confidence Interval [A]	(8.52, 75.51)	(6.05, 45.57)	(25.55, 67.18)	(21.01, 50.93)	(22.43, 49.93)
Baseline IMM Use - No	N=4	N=14	N=10	N=24	N=28
Yes	1 (25.0)	5 (35.7)	4 (40.0)	9 (37.5)	10 (35.7)
No	3 (75.0)	9 (64.3)	6 (60.0)	15 (62.5)	18 (64.3)
95% Confidence Interval [A]	(0.63, 80.59)	(12.76, 64.86)	(12.16, 73.76)	(18.80, 59.41)	(18.64, 55.93)
Weight < 40 kg	N=0	N=7	N=8	N=15	N=15
Yes	0	3 (42.9)	4 (50.0)	7 (46.7)	7 (46.7)
No	0	4 (57.1)	4 (50.0)	8 (53.3)	8 (53.3)
95% Confidence Interval [A]	(NA, NA)	(9.90, 81.59)	(15.70, 84.30)	(21.27, 73.41)	(21.27, 73.41)

表 2.7.3.6-42. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Weight >= 40 kg	N=12	N=26	N=26	N=52	N=64
Yes	4 (33.3)	6 (23.1)	11 (42.3)	17 (32.7)	21 (32.8)
No	8 (66.7)	20 (76.9)	15 (57.7)	35 (67.3)	43 (67.2)
95% Confidence Interval [A]	(9.92, 65.11)	(8.97, 43.65)	(23.35, 63.08)	(20.33, 47.11)	(21.59, 45.69)
Pancolitis - Yes	N=7	N=22	N=20	N=42	N=49
Yes	2 (28.6)	5 (22.7)	11 (55.0)	16 (38.1)	18 (36.7)
No	5 (71.4)	17 (77.3)	9 (45.0)	26 (61.9)	31 (63.3)
95% Confidence Interval [A]	(3.67, 70.96)	(7.82, 45.37)	(31.53, 76.94)	(23.57, 54.36)	(23.42, 51.71)
Pancolitis - No	N=5	N=11	N=14	N=25	N=30
Yes	2 (40.0)	4 (36.4)	4 (28.6)	8 (32.0)	10 (33.3)
No	3 (60.0)	7 (63.6)	10 (71.4)	17 (68.0)	20 (66.7)
95% Confidence Interval [A]	(5.27, 85.34)	(10.93, 69.21)	(8.39, 58.10)	(14.95, 53.50)	(17.29, 52.81)

表 2.7.3.6-42. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Disease Duration <= Baseline Median (19.1 Months)	N=5	N=19	N=15	N=34	N=39
Yes	0	3 (15.8)	7 (46.7)	10 (29.4)	10 (25.6)
No	5 (100)	16 (84.2)	8 (53.3)	24 (70.6)	29 (74.4)
95% Confidence Interval [A]	(0.00, 52.18)	(3.38, 39.58)	(21.27, 73.41)	(15.10, 47.48)	(13.04, 42.13)
Disease Duration > Baseline Median (19.1 Months)	N=7	N=14	N=19	N=33	N=40
Yes	4 (57.1)	6 (42.9)	8 (42.1)	14 (42.4)	18 (45.0)
No	3 (42.9)	8 (57.1)	11 (57.9)	19 (57.6)	22 (55.0)
95% Confidence Interval [A]	(18.41, 90.10)	(17.66, 71.14)	(20.25, 66.50)	(25.48, 60.78)	(29.26, 61.51)
Baseline hs-CRP <= Baseline Median (1.29 mg/L)	N=8	N=12	N=17	N=29	N=37
Yes	3 (37.5)	3 (25.0)	8 (47.1)	11 (37.9)	14 (37.8)
No	5 (62.5)	9 (75.0)	9 (52.9)	18 (62.1)	23 (62.2)
95% Confidence Interval [A]	(8.52, 75.51)	(5.49, 57.19)	(22.98, 72.19)	(20.69, 57.74)	(22.46, 55.24)

表 2.7.3.6-42. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

Category Endpoint Met	mITT M-PL (N=12)	mITT-E M-SD (N=33)	mITT-E M-HD (N=34)	mITT-E Total (N=67)	mITT Total (N=79)
Baseline hs-CRP > Baseline Median (1.29 mg/L)	N=3	N=18	N=15	N=33	N=36
Yes	0	4 (22.2)	6 (40.0)	10 (30.3)	10 (27.8)
No	3 (100)	14 (77.8)	9 (60.0)	23 (69.7)	26 (72.2)
95% Confidence Interval [A]	(0.00, 70.76)	(6.41, 47.64)	(16.34, 67.71)	(15.59, 48.71)	(14.20, 45.19)
Baseline Fecal Calprotectin <= Baseline Median (2302.5 ug/g)	N=3	N=5	N=2	N=7	N=10
Yes	1 (33.3)	1 (20.0)	1 (50.0)	2 (28.6)	3 (30.0)
No	2 (66.7)	4 (80.0)	1 (50.0)	5 (71.4)	7 (70.0)
95% Confidence Interval [A]	(0.84, 90.57)	(0.51, 71.64)	(1.26, 98.74)	(3.67, 70.96)	(6.67, 65.25)
Baseline Fecal Calprotectin > Baseline Median (2302.5 ug/g)	N=1	N=4	N=5	N=9	N=10
Yes	0	0	4 (80.0)	4 (44.4)	4 (40.0)
No	1 (100)	4 (100)	1 (20.0)	5 (55.6)	6 (60.0)
95% Confidence Interval [A]	(0.00, 97.50)	(0.00, 60.24)	(28.36, 99.49)	(13.70, 78.80)	(12.16, 73.76)

表 2.7.3.6-42.　投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
Note: M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
[A] Clopper-Pearson confidence interval for proportion in remission.
[B1] Nominal p-values from a one-sample two-sided chi-square test.
[B2] Adjusted p-values from a sequentially rejective multiple test procedure (details in SAP), testing co-primary and ranked secondary endpoints first for M-SD/M-HD combined (p-value in 'Total' column) and then for individual ADA dose groups (p-values in 'M-HD' column and in 'M-SD' column, respectively) against the respective external placebo rate (here: 18.37%).
[C] Nominal p-value for the exploratory comparison of M-SD vs. M-HD.
Non-responder imputation (NRI): missing data is imputed as not having met the endpoint. Subjects re-randomized due to disease flare are considered as not having met the endpoint at and after their 1st disease flare.
Clinical remission per Full Mayo Score (FMS) is defined as Mayo Score <= 2 and no individual subscore > 1.
Clinical response per Partial Mayo Score (PMS) is defined as decrease in PMS >= 2 points and >= 30% from baseline.
Clinical remission per Partial Mayo Score (PMS) is defined as PMS <= 2 and no individual subscore > 1.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.2__1.1.2_A

表 2.7.3.6-43. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Overall	N=0	N=2	N=3	N=5	N=5
Yes	0	0	1 (33.3)	1 (20.0)	1 (20.0)
No	0	2 (100)	2 (66.7)	4 (80.0)	4 (80.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.84, 90.57)	(0.51, 71.64)	(0.51, 71.64)
P-Value [B1]		0.502	0.503	0.925	
P-Value [C]		0.361			
PMS Remission at Week 8 - Yes	N=0	N=0	N=2	N=2	N=2
Yes	0	0	1 (50.0)	1 (50.0)	1 (50.0)
No	0	0	1 (50.0)	1 (50.0)	1 (50.0)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(1.26, 98.74)	(1.26, 98.74)	(1.26, 98.74)

表 2.7.3.6-43. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
PMS Remission at Week 8 - No	N=0	N=2	N=1	N=3	N=3
Yes	0	0	0	0	0
No	0	2 (100)	1 (100)	3 (100)	3 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.00, 97.50)	(0.00, 70.76)	(0.00, 70.76)
I-SD	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
I-HD/I-HD-OL	N=0	N=2	N=3	N=5	N=5
Yes	0	0	1 (33.3)	1 (20.0)	1 (20.0)
No	0	2 (100)	2 (66.7)	4 (80.0)	4 (80.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.84, 90.57)	(0.51, 71.64)	(0.51, 71.64)

表 2.7.3.6-43. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
I-HD	N=0	N=1	N=3	N=4	N=4
Yes	0	0	1 (33.3)	1 (25.0)	1 (25.0)
No	0	1 (100)	2 (66.7)	3 (75.0)	3 (75.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 97.50)	(0.84, 90.57)	(0.63, 80.59)	(0.63, 80.59)
I-HD-OL	N=0	N=1	N=0	N=1	N=1
Yes	0	0	0	0	0
No	0	1 (100)	0	1 (100)	1 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 97.50)	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)
Sex - Male	N=0	N=2	N=3	N=5	N=5
Yes	0	0	1 (33.3)	1 (20.0)	1 (20.0)
No	0	2 (100)	2 (66.7)	4 (80.0)	4 (80.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.84, 90.57)	(0.51, 71.64)	(0.51, 71.64)

表 2.7.3.6-43. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Sex - Female	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Age < 13 Years	N=0	N=0	N=1	N=1	N=1
Yes	0	0	1 (100)	1 (100)	1 (100)
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(2.50, 100.00)	(2.50, 100.00)	(2.50, 100.00)
Age >= 13 Years	N=0	N=2	N=2	N=4	N=4
Yes	0	0	0	0	0
No	0	2 (100)	2 (100)	4 (100)	4 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.00, 84.19)	(0.00, 60.24)	(0.00, 60.24)

表 2.7.3.6-43. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Ethnicity - White	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Ethnicity - Non-white	N=0	N=2	N=3	N=5	N=5
Yes	0	0	1 (33.3)	1 (20.0)	1 (20.0)
No	0	2 (100)	2 (66.7)	4 (80.0)	4 (80.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.84, 90.57)	(0.51, 71.64)	(0.51, 71.64)
Geographic Region - Japan	N=0	N=2	N=3	N=5	N=5
Yes	0	0	1 (33.3)	1 (20.0)	1 (20.0)
No	0	2 (100)	2 (66.7)	4 (80.0)	4 (80.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.84, 90.57)	(0.51, 71.64)	(0.51, 71.64)

表 2.7.3.6-43. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Baseline Mayo Score <= 9	N=0	N=2	N=3	N=5	N=5
Yes	0	0	1 (33.3)	1 (20.0)	1 (20.0)
No	0	2 (100)	2 (66.7)	4 (80.0)	4 (80.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.84, 90.57)	(0.51, 71.64)	(0.51, 71.64)
Baseline Mayo Score > 9	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Prior Anti-TNF Use	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)

表 2.7.3.6-43. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Prior Anti-TNF Naive	N=0	N=2	N=3	N=5	N=5
Yes	0	0	1 (33.3)	1 (20.0)	1 (20.0)
No	0	2 (100)	2 (66.7)	4 (80.0)	4 (80.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.84, 90.57)	(0.51, 71.64)	(0.51, 71.64)
Baseline Corticosteroid Use - Yes	N=0	N=2	N=1	N=3	N=3
Yes	0	0	1 (100)	1 (33.3)	1 (33.3)
No	0	2 (100)	0	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(2.50, 100.00)	(0.84, 90.57)	(0.84, 90.57)
Baseline Corticosteroid Use - No	N=0	N=0	N=2	N=2	N=2
Yes	0	0	0	0	0
No	0	0	2 (100)	2 (100)	2 (100)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.00, 84.19)	(0.00, 84.19)	(0.00, 84.19)

表 2.7.3.6-43. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Baseline IMM Use - Yes	N=0	N=2	N=3	N=5	N=5
Yes	0	0	1 (33.3)	1 (20.0)	1 (20.0)
No	0	2 (100)	2 (66.7)	4 (80.0)	4 (80.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.84, 90.57)	(0.51, 71.64)	(0.51, 71.64)
Baseline IMM Use - No	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Weight < 40 kg	N=0	N=0	N=1	N=1	N=1
Yes	0	0	1 (100)	1 (100)	1 (100)
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(2.50, 100.00)	(2.50, 100.00)	(2.50, 100.00)

表 2.7.3.6-43. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Weight >= 40 kg	N=0	N=2	N=2	N=4	N=4
Yes	0	0	0	0	0
No	0	2 (100)	2 (100)	4 (100)	4 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.00, 84.19)	(0.00, 60.24)	(0.00, 60.24)
Pancolitis - Yes	N=0	N=2	N=3	N=5	N=5
Yes	0	0	1 (33.3)	1 (20.0)	1 (20.0)
No	0	2 (100)	2 (66.7)	4 (80.0)	4 (80.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.84, 90.57)	(0.51, 71.64)	(0.51, 71.64)
Pancolitis - No	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)

表 2.7.3.6-43. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Disease Duration <= Baseline Median (19.1 Months)	N=0	N=1	N=0	N=1	N=1
Yes	0	0	0	0	0
No	0	1 (100)	0	1 (100)	1 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 97.50)	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)
Disease Duration > Baseline Median (19.1 Months)	N=0	N=1	N=3	N=4	N=4
Yes	0	0	1 (33.3)	1 (25.0)	1 (25.0)
No	0	1 (100)	2 (66.7)	3 (75.0)	3 (75.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 97.50)	(0.84, 90.57)	(0.63, 80.59)	(0.63, 80.59)
Baseline hs-CRP <= Baseline Median (1.29 mg/L)	N=0	N=0	N=3	N=3	N=3
Yes	0	0	1 (33.3)	1 (33.3)	1 (33.3)
No	0	0	2 (66.7)	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.84, 90.57)	(0.84, 90.57)	(0.84, 90.57)

表 2.7.3.6-43. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Baseline hs-CRP > Baseline Median (1.29 mg/L)	N=0	N=2	N=0	N=2	N=2
Yes	0	0	0	0	0
No	0	2 (100)	0	2 (100)	2 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(NA, NA)	(0.00, 84.19)	(0.00, 84.19)
Baseline Fecal Calprotectin <= Baseline Median (2302.5 ug/g)	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Baseline Fecal Calprotectin > Baseline Median (2302.5 ug/g)	N=0	N=0	N=1	N=1	N=1
Yes	0	0	0	0	0
No	0	0	1 (100)	1 (100)	1 (100)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)	(0.00, 97.50)

表 2.7.3.6-43. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
Note: M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
[A] Clopper-Pearson confidence interval for proportion in remission.
[B1] Nominal p-values from a one-sample two-sided chi-square test.
[C] Nominal p-value for the exploratory comparison of M-SD vs. M-HD.
Non-responder imputation (NRI): missing data is imputed as not having met the endpoint. Subjects re-randomized due to disease flare are considered as not having met the endpoint at and after their 1st disease flare.
Clinical remission per Full Mayo Score (FMS) is defined as Mayo Score <= 2 and no individual subscore > 1.
Clinical response per Partial Mayo Score (PMS) is defined as decrease in PMS >= 2 points and >= 30% from baseline.
Clinical remission per Partial Mayo Score (PMS) is defined as PMS <= 2 and no individual subscore > 1.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.2__1.1.2_J

表 2.7.3.6-44. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Overall	N=12	N=33	N=34	N=67	N=79
Yes	4 (33.3)	19 (57.6)	23 (67.6)	42 (62.7)	46 (58.2)
No	8 (66.7)	14 (42.4)	11 (32.4)	25 (37.3)	33 (41.8)
95% Confidence Interval [A]	(9.92, 65.11)	(39.22, 74.52)	(49.47, 82.61)	(50.01, 74.20)	(46.59, 69.23)
P-Value [B1]		<0.001	<0.001	<0.001	
ADJ. P-Value [B2]		0.038	<0.001	<0.001	
P-Value [C]		0.394			
PMS Remission at Week 8 - Yes	N=8	N=21	N=24	N=45	N=53
Yes	3 (37.5)	16 (76.2)	17 (70.8)	33 (73.3)	36 (67.9)
No	5 (62.5)	5 (23.8)	7 (29.2)	12 (26.7)	17 (32.1)
95% Confidence Interval [A]	(8.52, 75.51)	(52.83, 91.78)	(48.91, 87.38)	(58.06, 85.40)	(53.68, 80.08)

表 2.7.3.6-44. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
PMS Remission at Week 8 - No	N=4	N=12	N=10	N=22	N=26
Yes	1 (25.0)	3 (25.0)	6 (60.0)	9 (40.9)	10 (38.5)
No	3 (75.0)	9 (75.0)	4 (40.0)	13 (59.1)	16 (61.5)
95% Confidence Interval [A]	(0.63, 80.59)	(5.49, 57.19)	(26.24, 87.84)	(20.71, 63.65)	(20.23, 59.43)
I-SD	N=4	N=8	N=9	N=17	N=21
Yes	1 (25.0)	5 (62.5)	6 (66.7)	11 (64.7)	12 (57.1)
No	3 (75.0)	3 (37.5)	3 (33.3)	6 (35.3)	9 (42.9)
95% Confidence Interval [A]	(0.63, 80.59)	(24.49, 91.48)	(29.93, 92.51)	(38.33, 85.79)	(34.02, 78.18)
I-HD/I-HD-OL	N=8	N=25	N=25	N=50	N=58
Yes	3 (37.5)	14 (56.0)	17 (68.0)	31 (62.0)	34 (58.6)
No	5 (62.5)	11 (44.0)	8 (32.0)	19 (38.0)	24 (41.4)
95% Confidence Interval [A]	(8.52, 75.51)	(34.93, 75.60)	(46.50, 85.05)	(47.17, 75.35)	(44.93, 71.40)

表 2.7.3.6-44. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

Category Endpoint Met	mITT M-PL (N=12)	mITT-E M-SD (N=33)	mITT-E M-HD (N=34)	mITT-E Total (N=67)	mITT Total (N=79)
I-HD	N=8	N=17	N=18	N=35	N=43
Yes	3 (37.5)	10 (58.8)	12 (66.7)	22 (62.9)	25 (58.1)
No	5 (62.5)	7 (41.2)	6 (33.3)	13 (37.1)	18 (41.9)
95% Confidence Interval [A]	(8.52, 75.51)	(32.92, 81.56)	(40.99, 86.66)	(44.92, 78.53)	(42.13, 72.99)
I-HD-OL	N=0	N=8	N=7	N=15	N=15
Yes	0	4 (50.0)	5 (71.4)	9 (60.0)	9 (60.0)
No	0	4 (50.0)	2 (28.6)	6 (40.0)	6 (40.0)
95% Confidence Interval [A]	(NA, NA)	(15.70, 84.30)	(29.04, 96.33)	(32.29, 83.66)	(32.29, 83.66)
Sex - Male	N=9	N=15	N=16	N=31	N=40
Yes	2 (22.2)	8 (53.3)	9 (56.3)	17 (54.8)	19 (47.5)
No	7 (77.8)	7 (46.7)	7 (43.8)	14 (45.2)	21 (52.5)
95% Confidence Interval [A]	(2.81, 60.01)	(26.59, 78.73)	(29.88, 80.25)	(36.03, 72.68)	(31.51, 63.87)

表 2.7.3.6-44. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Sex - Female	N=3	N=18	N=18	N=36	N=39
Yes	2 (66.7)	11 (61.1)	14 (77.8)	25 (69.4)	27 (69.2)
No	1 (33.3)	7 (38.9)	4 (22.2)	11 (30.6)	12 (30.8)
95% Confidence Interval [A]	(9.43, 99.16)	(35.75, 82.70)	(52.36, 93.59)	(51.89, 83.65)	(52.43, 82.98)
Age < 13 Years	N=2	N=12	N=9	N=21	N=23
Yes	1 (50.0)	8 (66.7)	8 (88.9)	16 (76.2)	17 (73.9)
No	1 (50.0)	4 (33.3)	1 (11.1)	5 (23.8)	6 (26.1)
95% Confidence Interval [A]	(1.26, 98.74)	(34.89, 90.08)	(51.75, 99.72)	(52.83, 91.78)	(51.59, 89.77)
Age >= 13 Years	N=10	N=21	N=25	N=46	N=56
Yes	3 (30.0)	11 (52.4)	15 (60.0)	26 (56.5)	29 (51.8)
No	7 (70.0)	10 (47.6)	10 (40.0)	20 (43.5)	27 (48.2)
95% Confidence Interval [A]	(6.67, 65.25)	(29.78, 74.29)	(38.67, 78.87)	(41.11, 71.07)	(38.03, 65.34)

表 2.7.3.6-44. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

Category Endpoint Met	mITT M-PL (N=12)	mITT-E M-SD (N=33)	mITT-E M-HD (N=34)	mITT-E Total (N=67)	mITT Total (N=79)
Ethnicity - White	N=11	N=29	N=30	N=59	N=70
Yes	4 (36.4)	18 (62.1)	21 (70.0)	39 (66.1)	43 (61.4)
No	7 (63.6)	11 (37.9)	9 (30.0)	20 (33.9)	27 (38.6)
95% Confidence Interval [A]	(10.93, 69.21)	(42.26, 79.31)	(50.60, 85.27)	(52.61, 77.92)	(49.03, 72.83)
Ethnicity - Non-white	N=1	N=4	N=4	N=8	N=9
Yes	0	1 (25.0)	2 (50.0)	3 (37.5)	3 (33.3)
No	1 (100)	3 (75.0)	2 (50.0)	5 (62.5)	6 (66.7)
95% Confidence Interval [A]	(0.00, 97.50)	(0.63, 80.59)	(6.76, 93.24)	(8.52, 75.51)	(7.49, 70.07)
Geographic Region - Japan	N=0	N=2	N=3	N=5	N=5
Yes	0	0	2 (66.7)	2 (40.0)	2 (40.0)
No	0	2 (100)	1 (33.3)	3 (60.0)	3 (60.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(9.43, 99.16)	(5.27, 85.34)	(5.27, 85.34)

表 2.7.3.6-44. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Baseline Mayo Score <= 9	N=11	N=27	N=29	N=56	N=67
Yes	4 (36.4)	17 (63.0)	19 (65.5)	36 (64.3)	40 (59.7)
No	7 (63.6)	10 (37.0)	10 (34.5)	20 (35.7)	27 (40.3)
95% Confidence Interval [A]	(10.93, 69.21)	(42.37, 80.60)	(45.67, 82.06)	(50.36, 76.64)	(47.00, 71.51)
Baseline Mayo Score > 9	N=1	N=6	N=5	N=11	N=12
Yes	0	2 (33.3)	4 (80.0)	6 (54.5)	6 (50.0)
No	1 (100)	4 (66.7)	1 (20.0)	5 (45.5)	6 (50.0)
95% Confidence Interval [A]	(0.00, 97.50)	(4.33, 77.72)	(28.36, 99.49)	(23.38, 83.25)	(21.09, 78.91)
Prior Anti-TNF Use	N=2	N=2	N=6	N=8	N=10
Yes	1 (50.0)	1 (50.0)	3 (50.0)	4 (50.0)	5 (50.0)
No	1 (50.0)	1 (50.0)	3 (50.0)	4 (50.0)	5 (50.0)
95% Confidence Interval [A]	(1.26, 98.74)	(1.26, 98.74)	(11.81, 88.19)	(15.70, 84.30)	(18.71, 81.29)

表 2.7.3.6-44. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Prior Anti-TNF Naive	N=10	N=31	N=28	N=59	N=69
Yes	3 (30.0)	18 (58.1)	20 (71.4)	38 (64.4)	41 (59.4)
No	7 (70.0)	13 (41.9)	8 (28.6)	21 (35.6)	28 (40.6)
95% Confidence Interval [A]	(6.67, 65.25)	(39.08, 75.45)	(51.33, 86.78)	(50.87, 76.45)	(46.92, 71.09)
Baseline Corticosteroid Use - Yes	N=5	N=15	N=17	N=32	N=37
Yes	2 (40.0)	7 (46.7)	11 (64.7)	18 (56.3)	20 (54.1)
No	3 (60.0)	8 (53.3)	6 (35.3)	14 (43.8)	17 (45.9)
95% Confidence Interval [A]	(5.27, 85.34)	(21.27, 73.41)	(38.33, 85.79)	(37.66, 73.64)	(36.92, 70.51)
Baseline Corticosteroid Use - No	N=7	N=18	N=17	N=35	N=42
Yes	2 (28.6)	12 (66.7)	12 (70.6)	24 (68.6)	26 (61.9)
No	5 (71.4)	6 (33.3)	5 (29.4)	11 (31.4)	16 (38.1)
95% Confidence Interval [A]	(3.67, 70.96)	(40.99, 86.66)	(44.04, 89.69)	(50.71, 83.15)	(45.64, 76.43)

表 2.7.3.6-44. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Baseline IMM Use - Yes	N=8	N=19	N=24	N=43	N=51
Yes	3 (37.5)	11 (57.9)	16 (66.7)	27 (62.8)	30 (58.8)
No	5 (62.5)	8 (42.1)	8 (33.3)	16 (37.2)	21 (41.2)
95% Confidence Interval [A]	(8.52, 75.51)	(33.50, 79.75)	(44.68, 84.37)	(46.73, 77.02)	(44.17, 72.42)
Baseline IMM Use - No	N=4	N=14	N=10	N=24	N=28
Yes	1 (25.0)	8 (57.1)	7 (70.0)	15 (62.5)	16 (57.1)
No	3 (75.0)	6 (42.9)	3 (30.0)	9 (37.5)	12 (42.9)
95% Confidence Interval [A]	(0.63, 80.59)	(28.86, 82.34)	(34.75, 93.33)	(40.59, 81.20)	(37.18, 75.54)
Weight < 40 kg	N=0	N=7	N=8	N=15	N=15
Yes	0	4 (57.1)	6 (75.0)	10 (66.7)	10 (66.7)
No	0	3 (42.9)	2 (25.0)	5 (33.3)	5 (33.3)
95% Confidence Interval [A]	(NA, NA)	(18.41, 90.10)	(34.91, 96.81)	(38.38, 88.18)	(38.38, 88.18)

表 2.7.3.6-44. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Weight >= 40 kg	N=12	N=26	N=26	N=52	N=64
Yes	4 (33.3)	15 (57.7)	17 (65.4)	32 (61.5)	36 (56.3)
No	8 (66.7)	11 (42.3)	9 (34.6)	20 (38.5)	28 (43.8)
95% Confidence Interval [A]	(9.92, 65.11)	(36.92, 76.65)	(44.33, 82.79)	(47.02, 74.70)	(43.28, 68.63)
Pancolitis - Yes	N=7	N=22	N=20	N=42	N=49
Yes	2 (28.6)	12 (54.5)	14 (70.0)	26 (61.9)	28 (57.1)
No	5 (71.4)	10 (45.5)	6 (30.0)	16 (38.1)	21 (42.9)
95% Confidence Interval [A]	(3.67, 70.96)	(32.21, 75.61)	(45.72, 88.11)	(45.64, 76.43)	(42.21, 71.18)
Pancolitis - No	N=5	N=11	N=14	N=25	N=30
Yes	2 (40.0)	7 (63.6)	9 (64.3)	16 (64.0)	18 (60.0)
No	3 (60.0)	4 (36.4)	5 (35.7)	9 (36.0)	12 (40.0)
95% Confidence Interval [A]	(5.27, 85.34)	(30.79, 89.07)	(35.14, 87.24)	(42.52, 82.03)	(40.60, 77.34)

表 2.7.3.6-44. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Disease Duration <= Baseline Median (19.1 Months)	N=5	N=19	N=15	N=34	N=39
Yes	0	10 (52.6)	9 (60.0)	19 (55.9)	19 (48.7)
No	5 (100)	9 (47.4)	6 (40.0)	15 (44.1)	20 (51.3)
95% Confidence Interval [A]	(0.00, 52.18)	(28.86, 75.55)	(32.29, 83.66)	(37.89, 72.81)	(32.42, 65.22)
Disease Duration > Baseline Median (19.1 Months)	N=7	N=14	N=19	N=33	N=40
Yes	4 (57.1)	9 (64.3)	14 (73.7)	23 (69.7)	27 (67.5)
No	3 (42.9)	5 (35.7)	5 (26.3)	10 (30.3)	13 (32.5)
95% Confidence Interval [A]	(18.41, 90.10)	(35.14, 87.24)	(48.80, 90.85)	(51.29, 84.41)	(50.87, 81.43)
Baseline hs-CRP <= Baseline Median (1.29 mg/L)	N=8	N=12	N=17	N=29	N=37
Yes	3 (37.5)	6 (50.0)	13 (76.5)	19 (65.5)	22 (59.5)
No	5 (62.5)	6 (50.0)	4 (23.5)	10 (34.5)	15 (40.5)
95% Confidence Interval [A]	(8.52, 75.51)	(21.09, 78.91)	(50.10, 93.19)	(45.67, 82.06)	(42.10, 75.25)

表 2.7.3.6-44. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Baseline hs-CRP > Baseline Median (1.29 mg/L)	N=3	N=18	N=15	N=33	N=36
Yes	0	11 (61.1)	9 (60.0)	20 (60.6)	20 (55.6)
No	3 (100)	7 (38.9)	6 (40.0)	13 (39.4)	16 (44.4)
95% Confidence Interval [A]	(0.00, 70.76)	(35.75, 82.70)	(32.29, 83.66)	(42.14, 77.09)	(38.10, 72.06)
Baseline Fecal Calprotectin <= Baseline Median (2302.5 ug/g)	N=3	N=5	N=2	N=7	N=10
Yes	1 (33.3)	3 (60.0)	1 (50.0)	4 (57.1)	5 (50.0)
No	2 (66.7)	2 (40.0)	1 (50.0)	3 (42.9)	5 (50.0)
95% Confidence Interval [A]	(0.84, 90.57)	(14.66, 94.73)	(1.26, 98.74)	(18.41, 90.10)	(18.71, 81.29)
Baseline Fecal Calprotectin > Baseline Median (2302.5 ug/g)	N=1	N=4	N=5	N=9	N=10
Yes	0	1 (25.0)	4 (80.0)	5 (55.6)	5 (50.0)
No	1 (100)	3 (75.0)	1 (20.0)	4 (44.4)	5 (50.0)
95% Confidence Interval [A]	(0.00, 97.50)	(0.63, 80.59)	(28.36, 99.49)	(21.20, 86.30)	(18.71, 81.29)

表 2.7.3.6-44.　投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

One patient ([redacted] who is ongoing study is excluded from interim analysis.
Note: M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
[A] Clopper-Pearson confidence interval for proportion in response.
[B1] Nominal p-values from a one-sample two-sided chi-square test.
[B2] Adjusted p-values from a sequentially rejective multiple test procedure (details in SAP), testing co-primary and ranked secondary endpoints first for M-SD/M-HD combined (p-value in 'Total' column) and then for individual ADA dose groups (p-values in 'M-HD' column and in 'M-SD' column, respectively) against the respective external placebo rate (here: 26.10%).
[C] Nominal p-value for the exploratory comparison of M-SD vs. M-HD.
Non-responder imputation (NRI): missing data is imputed as not having met the endpoint. Subjects re-randomized due to disease flare are considered as not having met the endpoint at and after their 1st disease flare.
Clinical response per Full Mayo Score (FMS) is defined as decrease in Mayo Score >= 3 points and >= 30% from baseline.
Clinical response per Partial Mayo Score (PMS) is defined as decrease in PMS >= 2 points and >= 30% from baseline.
Clinical remission per Partial Mayo Score (PMS) is defined as PMS <= 2 and no individual subscore > 1.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.2__1.2.1_A

表 2.7.3.6-45.　投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Overall	N=0	N=2	N=3	N=5	N=5
Yes	0	0	2 (66.7)	2 (40.0)	2 (40.0)
No	0	2 (100)	1 (33.3)	3 (60.0)	3 (60.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(9.43, 99.16)	(5.27, 85.34)	(5.27, 85.34)
P-Value [B1]		0.401	0.110	0.479	
P-Value [C]		0.136			
PMS Remission at Week 8 - Yes	N=0	N=0	N=2	N=2	N=2
Yes	0	0	1 (50.0)	1 (50.0)	1 (50.0)
No	0	0	1 (50.0)	1 (50.0)	1 (50.0)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(1.26, 98.74)	(1.26, 98.74)	(1.26, 98.74)

表 2.7.3.6-45. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
PMS Remission at Week 8 - No	N=0	N=2	N=1	N=3	N=3
Yes	0	0	1 (100)	1 (33.3)	1 (33.3)
No	0	2 (100)	0	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(2.50, 100.00)	(0.84, 90.57)	(0.84, 90.57)
I-SD	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
I-HD/I-HD-OL	N=0	N=2	N=3	N=5	N=5
Yes	0	0	2 (66.7)	2 (40.0)	2 (40.0)
No	0	2 (100)	1 (33.3)	3 (60.0)	3 (60.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(9.43, 99.16)	(5.27, 85.34)	(5.27, 85.34)

表 2.7.3.6-45. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
I-HD	N=0	N=1	N=3	N=4	N=4
Yes	0	0	2 (66.7)	2 (50.0)	2 (50.0)
No	0	1 (100)	1 (33.3)	2 (50.0)	2 (50.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 97.50)	(9.43, 99.16)	(6.76, 93.24)	(6.76, 93.24)
I-HD-OL	N=0	N=1	N=0	N=1	N=1
Yes	0	0	0	0	0
No	0	1 (100)	0	1 (100)	1 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 97.50)	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)
Sex - Male	N=0	N=2	N=3	N=5	N=5
Yes	0	0	2 (66.7)	2 (40.0)	2 (40.0)
No	0	2 (100)	1 (33.3)	3 (60.0)	3 (60.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(9.43, 99.16)	(5.27, 85.34)	(5.27, 85.34)

表 2.7.3.6-45. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Sex - Female	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Age < 13 Years	N=0	N=0	N=1	N=1	N=1
Yes	0	0	1 (100)	1 (100)	1 (100)
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(2.50, 100.00)	(2.50, 100.00)	(2.50, 100.00)
Age >= 13 Years	N=0	N=2	N=2	N=4	N=4
Yes	0	0	1 (50.0)	1 (25.0)	1 (25.0)
No	0	2 (100)	1 (50.0)	3 (75.0)	3 (75.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(1.26, 98.74)	(0.63, 80.59)	(0.63, 80.59)

表 2.7.3.6-45. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Ethnicity - White	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Ethnicity - Non-white	N=0	N=2	N=3	N=5	N=5
Yes	0	0	2 (66.7)	2 (40.0)	2 (40.0)
No	0	2 (100)	1 (33.3)	3 (60.0)	3 (60.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(9.43, 99.16)	(5.27, 85.34)	(5.27, 85.34)
Geographic Region - Japan	N=0	N=2	N=3	N=5	N=5
Yes	0	0	2 (66.7)	2 (40.0)	2 (40.0)
No	0	2 (100)	1 (33.3)	3 (60.0)	3 (60.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(9.43, 99.16)	(5.27, 85.34)	(5.27, 85.34)

表 2.7.3.6-45. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Baseline Mayo Score <= 9	N=0	N=2	N=3	N=5	N=5
Yes	0	0	2 (66.7)	2 (40.0)	2 (40.0)
No	0	2 (100)	1 (33.3)	3 (60.0)	3 (60.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(9.43, 99.16)	(5.27, 85.34)	(5.27, 85.34)
Baseline Mayo Score > 9	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Prior Anti-TNF Use	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)

表 2.7.3.6-45. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Prior Anti-TNF Naive	N=0	N=2	N=3	N=5	N=5
Yes	0	0	2 (66.7)	2 (40.0)	2 (40.0)
No	0	2 (100)	1 (33.3)	3 (60.0)	3 (60.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(9.43, 99.16)	(5.27, 85.34)	(5.27, 85.34)
Baseline Corticosteroid Use - Yes	N=0	N=2	N=1	N=3	N=3
Yes	0	0	1 (100)	1 (33.3)	1 (33.3)
No	0	2 (100)	0	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(2.50, 100.00)	(0.84, 90.57)	(0.84, 90.57)
Baseline Corticosteroid Use - No	N=0	N=0	N=2	N=2	N=2
Yes	0	0	1 (50.0)	1 (50.0)	1 (50.0)
No	0	0	1 (50.0)	1 (50.0)	1 (50.0)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(1.26, 98.74)	(1.26, 98.74)	(1.26, 98.74)

表 2.7.3.6-45. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Baseline IMM Use - Yes	N=0	N=2	N=3	N=5	N=5
Yes	0	0	2 (66.7)	2 (40.0)	2 (40.0)
No	0	2 (100)	1 (33.3)	3 (60.0)	3 (60.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(9.43, 99.16)	(5.27, 85.34)	(5.27, 85.34)
Baseline IMM Use - No	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Weight < 40 kg	N=0	N=0	N=1	N=1	N=1
Yes	0	0	1 (100)	1 (100)	1 (100)
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(2.50, 100.00)	(2.50, 100.00)	(2.50, 100.00)

表 2.7.3.6-45. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Weight >= 40 kg	N=0	N=2	N=2	N=4	N=4
Yes	0	0	1 (50.0)	1 (25.0)	1 (25.0)
No	0	2 (100)	1 (50.0)	3 (75.0)	3 (75.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(1.26, 98.74)	(0.63, 80.59)	(0.63, 80.59)
Pancolitis - Yes	N=0	N=2	N=3	N=5	N=5
Yes	0	0	2 (66.7)	2 (40.0)	2 (40.0)
No	0	2 (100)	1 (33.3)	3 (60.0)	3 (60.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(9.43, 99.16)	(5.27, 85.34)	(5.27, 85.34)
Pancolitis - No	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)

表 2.7.3.6-45. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Disease Duration <= Baseline Median (19.1 Months)	N=0	N=1	N=0	N=1	N=1
Yes	0	0	0	0	0
No	0	1 (100)	0	1 (100)	1 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 97.50)	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)
Disease Duration > Baseline Median (19.1 Months)	N=0	N=1	N=3	N=4	N=4
Yes	0	0	2 (66.7)	2 (50.0)	2 (50.0)
No	0	1 (100)	1 (33.3)	2 (50.0)	2 (50.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 97.50)	(9.43, 99.16)	(6.76, 93.24)	(6.76, 93.24)
Baseline hs-CRP <= Baseline Median (1.29 mg/L)	N=0	N=0	N=3	N=3	N=3
Yes	0	0	2 (66.7)	2 (66.7)	2 (66.7)
No	0	0	1 (33.3)	1 (33.3)	1 (33.3)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(9.43, 99.16)	(9.43, 99.16)	(9.43, 99.16)

表 2.7.3.6-45. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Baseline hs-CRP > Baseline Median (1.29 mg/L)	N=0	N=2	N=0	N=2	N=2
Yes	0	0	0	0	0
No	0	2 (100)	0	2 (100)	2 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(NA, NA)	(0.00, 84.19)	(0.00, 84.19)
Baseline Fecal Calprotectin <= Baseline Median (2302.5 ug/g)	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Baseline Fecal Calprotectin > Baseline Median (2302.5 ug/g)	N=0	N=0	N=1	N=1	N=1
Yes	0	0	0	0	0
No	0	0	1 (100)	1 (100)	1 (100)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)	(0.00, 97.50)

表 2.7.3.6-45.　投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

One patient ([redacted] who is ongoing study is excluded from interim analysis.
Note: M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
[A] Clopper-Pearson confidence interval for proportion in response.
[B1] Nominal p-values from a one-sample two-sided chi-square test.
[C] Nominal p-value for the exploratory comparison of M-SD vs. M-HD.
Non-responder imputation (NRI): missing data is imputed as not having met the endpoint. Subjects re-randomized due to disease flare are considered as not having met the endpoint at and after their 1st disease flare.
Clinical response per Full Mayo Score (FMS) is defined as decrease in Mayo Score >= 3 points and >= 30% from baseline.
Clinical response per Partial Mayo Score (PMS) is defined as decrease in PMS >= 2 points and >= 30% from baseline.
Clinical remission per Partial Mayo Score (PMS) is defined as PMS <= 2 and no individual subscore > 1.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.2__1.2.1_J

表 2.7.3.6-46. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Overall	N=12	N=33	N=34	N=67	N=79
Yes	4 (33.3)	12 (36.4)	17 (50.0)	29 (43.3)	33 (41.8)
No	8 (66.7)	21 (63.6)	17 (50.0)	38 (56.7)	46 (58.2)
95% Confidence Interval [A]	(9.92, 65.11)	(20.40, 54.88)	(32.43, 67.57)	(31.22, 55.96)	(30.77, 53.41)
P-Value [B1]		0.047	<0.001	<0.001	
ADJ. P-Value [B2]		0.344	<0.001	<0.001	
P-Value [C]		0.260			
PMS Remission at Week 8 - Yes	N=8	N=21	N=24	N=45	N=53
Yes	3 (37.5)	11 (52.4)	13 (54.2)	24 (53.3)	27 (50.9)
No	5 (62.5)	10 (47.6)	11 (45.8)	21 (46.7)	26 (49.1)
95% Confidence Interval [A]	(8.52, 75.51)	(29.78, 74.29)	(32.82, 74.45)	(37.87, 68.34)	(36.84, 64.94)

表 2.7.3.6-46. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
PMS Remission at Week 8 - No	N=4	N=12	N=10	N=22	N=26
Yes	1 (25.0)	1 (8.3)	4 (40.0)	5 (22.7)	6 (23.1)
No	3 (75.0)	11 (91.7)	6 (60.0)	17 (77.3)	20 (76.9)
95% Confidence Interval [A]	(0.63, 80.59)	(0.21, 38.48)	(12.16, 73.76)	(7.82, 45.37)	(8.97, 43.65)
I-SD	N=4	N=8	N=9	N=17	N=21
Yes	1 (25.0)	2 (25.0)	5 (55.6)	7 (41.2)	8 (38.1)
No	3 (75.0)	6 (75.0)	4 (44.4)	10 (58.8)	13 (61.9)
95% Confidence Interval [A]	(0.63, 80.59)	(3.19, 65.09)	(21.20, 86.30)	(18.44, 67.08)	(18.11, 61.56)
I-HD/I-HD-OL	N=8	N=25	N=25	N=50	N=58
Yes	3 (37.5)	10 (40.0)	12 (48.0)	22 (44.0)	25 (43.1)
No	5 (62.5)	15 (60.0)	13 (52.0)	28 (56.0)	33 (56.9)
95% Confidence Interval [A]	(8.52, 75.51)	(21.13, 61.33)	(27.80, 68.69)	(29.99, 58.75)	(30.16, 56.77)

表 2.7.3.6-46. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
I-HD	N=8	N=17	N=18	N=35	N=43
Yes	3 (37.5)	8 (47.1)	9 (50.0)	17 (48.6)	20 (46.5)
No	5 (62.5)	9 (52.9)	9 (50.0)	18 (51.4)	23 (53.5)
95% Confidence Interval [A]	(8.52, 75.51)	(22.98, 72.19)	(26.02, 73.98)	(31.38, 66.01)	(31.18, 62.35)
I-HD-OL	N=0	N=8	N=7	N=15	N=15
Yes	0	2 (25.0)	3 (42.9)	5 (33.3)	5 (33.3)
No	0	6 (75.0)	4 (57.1)	10 (66.7)	10 (66.7)
95% Confidence Interval [A]	(NA, NA)	(3.19, 65.09)	(9.90, 81.59)	(11.82, 61.62)	(11.82, 61.62)
Sex - Male	N=9	N=15	N=16	N=31	N=40
Yes	2 (22.2)	5 (33.3)	7 (43.8)	12 (38.7)	14 (35.0)
No	7 (77.8)	10 (66.7)	9 (56.3)	19 (61.3)	26 (65.0)
95% Confidence Interval [A]	(2.81, 60.01)	(11.82, 61.62)	(19.75, 70.12)	(21.85, 57.81)	(20.63, 51.68)

表 2.7.3.6-46. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Sex - Female	N=3	N=18	N=18	N=36	N=39
Yes	2 (66.7)	7 (38.9)	10 (55.6)	17 (47.2)	19 (48.7)
No	1 (33.3)	11 (61.1)	8 (44.4)	19 (52.8)	20 (51.3)
95% Confidence Interval [A]	(9.43, 99.16)	(17.30, 64.25)	(30.76, 78.47)	(30.41, 64.51)	(32.42, 65.22)
Age < 13 Years	N=2	N=12	N=9	N=21	N=23
Yes	1 (50.0)	6 (50.0)	5 (55.6)	11 (52.4)	12 (52.2)
No	1 (50.0)	6 (50.0)	4 (44.4)	10 (47.6)	11 (47.8)
95% Confidence Interval [A]	(1.26, 98.74)	(21.09, 78.91)	(21.20, 86.30)	(29.78, 74.29)	(30.59, 73.18)
Age >= 13 Years	N=10	N=21	N=25	N=46	N=56
Yes	3 (30.0)	6 (28.6)	12 (48.0)	18 (39.1)	21 (37.5)
No	7 (70.0)	15 (71.4)	13 (52.0)	28 (60.9)	35 (62.5)
95% Confidence Interval [A]	(6.67, 65.25)	(11.28, 52.18)	(27.80, 68.69)	(25.09, 54.63)	(24.92, 51.45)

表 2.7.3.6-46. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Ethnicity - White	N=11	N=29	N=30	N=59	N=70
Yes	4 (36.4)	11 (37.9)	16 (53.3)	27 (45.8)	31 (44.3)
No	7 (63.6)	18 (62.1)	14 (46.7)	32 (54.2)	39 (55.7)
95% Confidence Interval [A]	(10.93, 69.21)	(20.69, 57.74)	(34.33, 71.66)	(32.72, 59.25)	(32.41, 56.66)
Ethnicity - Non-white	N=1	N=4	N=4	N=8	N=9
Yes	0	1 (25.0)	1 (25.0)	2 (25.0)	2 (22.2)
No	1 (100)	3 (75.0)	3 (75.0)	6 (75.0)	7 (77.8)
95% Confidence Interval [A]	(0.00, 97.50)	(0.63, 80.59)	(0.63, 80.59)	(3.19, 65.09)	(2.81, 60.01)
Geographic Region - Japan	N=0	N=2	N=3	N=5	N=5
Yes	0	0	1 (33.3)	1 (20.0)	1 (20.0)
No	0	2 (100)	2 (66.7)	4 (80.0)	4 (80.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.84, 90.57)	(0.51, 71.64)	(0.51, 71.64)

表 2.7.3.6-46. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Baseline Mayo Score <= 9	N=11	N=27	N=29	N=56	N=67
Yes	4 (36.4)	11 (40.7)	13 (44.8)	24 (42.9)	28 (41.8)
No	7 (63.6)	16 (59.3)	16 (55.2)	32 (57.1)	39 (58.2)
95% Confidence Interval [A]	(10.93, 69.21)	(22.39, 61.20)	(26.45, 64.31)	(29.71, 56.78)	(29.85, 54.48)
Baseline Mayo Score > 9	N=1	N=6	N=5	N=11	N=12
Yes	0	1 (16.7)	4 (80.0)	5 (45.5)	5 (41.7)
No	1 (100)	5 (83.3)	1 (20.0)	6 (54.5)	7 (58.3)
95% Confidence Interval [A]	(0.00, 97.50)	(0.42, 64.12)	(28.36, 99.49)	(16.75, 76.62)	(15.17, 72.33)
Prior Anti-TNF Use	N=2	N=2	N=6	N=8	N=10
Yes	1 (50.0)	0	3 (50.0)	3 (37.5)	4 (40.0)
No	1 (50.0)	2 (100)	3 (50.0)	5 (62.5)	6 (60.0)
95% Confidence Interval [A]	(1.26, 98.74)	(0.00, 84.19)	(11.81, 88.19)	(8.52, 75.51)	(12.16, 73.76)

表 2.7.3.6-46. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Prior Anti-TNF Naive	N=10	N=31	N=28	N=59	N=69
Yes	3 (30.0)	12 (38.7)	14 (50.0)	26 (44.1)	29 (42.0)
No	7 (70.0)	19 (61.3)	14 (50.0)	33 (55.9)	40 (58.0)
95% Confidence Interval [A]	(6.67, 65.25)	(21.85, 57.81)	(30.65, 69.35)	(31.16, 57.60)	(30.24, 54.52)
Baseline Corticosteroid Use - Yes	N=5	N=15	N=17	N=32	N=37
Yes	2 (40.0)	5 (33.3)	7 (41.2)	12 (37.5)	14 (37.8)
No	3 (60.0)	10 (66.7)	10 (58.8)	20 (62.5)	23 (62.2)
95% Confidence Interval [A]	(5.27, 85.34)	(11.82, 61.62)	(18.44, 67.08)	(21.10, 56.31)	(22.46, 55.24)
Baseline Corticosteroid Use - No	N=7	N=18	N=17	N=35	N=42
Yes	2 (28.6)	7 (38.9)	10 (58.8)	17 (48.6)	19 (45.2)
No	5 (71.4)	11 (61.1)	7 (41.2)	18 (51.4)	23 (54.8)
95% Confidence Interval [A]	(3.67, 70.96)	(17.30, 64.25)	(32.92, 81.56)	(31.38, 66.01)	(29.85, 61.33)

表 2.7.3.6-46. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Baseline IMM Use - Yes	N=8	N=19	N=24	N=43	N=51
Yes	3 (37.5)	7 (36.8)	12 (50.0)	19 (44.2)	22 (43.1)
No	5 (62.5)	12 (63.2)	12 (50.0)	24 (55.8)	29 (56.9)
95% Confidence Interval [A]	(8.52, 75.51)	(16.29, 61.64)	(29.12, 70.88)	(29.08, 60.12)	(29.35, 57.75)
Baseline IMM Use - No	N=4	N=14	N=10	N=24	N=28
Yes	1 (25.0)	5 (35.7)	5 (50.0)	10 (41.7)	11 (39.3)
No	3 (75.0)	9 (64.3)	5 (50.0)	14 (58.3)	17 (60.7)
95% Confidence Interval [A]	(0.63, 80.59)	(12.76, 64.86)	(18.71, 81.29)	(22.11, 63.36)	(21.50, 59.42)
Weight < 40 kg	N=0	N=7	N=8	N=15	N=15
Yes	0	3 (42.9)	4 (50.0)	7 (46.7)	7 (46.7)
No	0	4 (57.1)	4 (50.0)	8 (53.3)	8 (53.3)
95% Confidence Interval [A]	(NA, NA)	(9.90, 81.59)	(15.70, 84.30)	(21.27, 73.41)	(21.27, 73.41)

表 2.7.3.6-46. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Weight >= 40 kg	N=12	N=26	N=26	N=52	N=64
Yes	4 (33.3)	9 (34.6)	13 (50.0)	22 (42.3)	26 (40.6)
No	8 (66.7)	17 (65.4)	13 (50.0)	30 (57.7)	38 (59.4)
95% Confidence Interval [A]	(9.92, 65.11)	(17.21, 55.67)	(29.93, 70.07)	(28.73, 56.80)	(28.51, 53.63)
Pancolitis - Yes	N=7	N=22	N=20	N=42	N=49
Yes	2 (28.6)	7 (31.8)	11 (55.0)	18 (42.9)	20 (40.8)
No	5 (71.4)	15 (68.2)	9 (45.0)	24 (57.1)	29 (59.2)
95% Confidence Interval [A]	(3.67, 70.96)	(13.86, 54.87)	(31.53, 76.94)	(27.72, 59.04)	(27.00, 55.79)
Pancolitis - No	N=5	N=11	N=14	N=25	N=30
Yes	2 (40.0)	5 (45.5)	6 (42.9)	11 (44.0)	13 (43.3)
No	3 (60.0)	6 (54.5)	8 (57.1)	14 (56.0)	17 (56.7)
95% Confidence Interval [A]	(5.27, 85.34)	(16.75, 76.62)	(17.66, 71.14)	(24.40, 65.07)	(25.46, 62.57)

表 2.7.3.6-46. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Disease Duration <= Baseline Median (19.1 Months)	N=5	N=19	N=15	N=34	N=39
Yes	0	6 (31.6)	7 (46.7)	13 (38.2)	13 (33.3)
No	5 (100)	13 (68.4)	8 (53.3)	21 (61.8)	26 (66.7)
95% Confidence Interval [A]	(0.00, 52.18)	(12.58, 56.55)	(21.27, 73.41)	(22.17, 56.44)	(19.09, 50.22)
Disease Duration > Baseline Median (19.1 Months)	N=7	N=14	N=19	N=33	N=40
Yes	4 (57.1)	6 (42.9)	10 (52.6)	16 (48.5)	20 (50.0)
No	3 (42.9)	8 (57.1)	9 (47.4)	17 (51.5)	20 (50.0)
95% Confidence Interval [A]	(18.41, 90.10)	(17.66, 71.14)	(28.86, 75.55)	(30.80, 66.46)	(33.80, 66.20)
Baseline hs-CRP <= Baseline Median (1.29 mg/L)	N=8	N=12	N=17	N=29	N=37
Yes	3 (37.5)	4 (33.3)	8 (47.1)	12 (41.4)	15 (40.5)
No	5 (62.5)	8 (66.7)	9 (52.9)	17 (58.6)	22 (59.5)
95% Confidence Interval [A]	(8.52, 75.51)	(9.92, 65.11)	(22.98, 72.19)	(23.52, 61.06)	(24.75, 57.90)

表 2.7.3.6-46. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Baseline hs-CRP > Baseline Median (1.29 mg/L)	N=3	N=18	N=15	N=33	N=36
Yes	0	6 (33.3)	8 (53.3)	14 (42.4)	14 (38.9)
No	3 (100)	12 (66.7)	7 (46.7)	19 (57.6)	22 (61.1)
95% Confidence Interval [A]	(0.00, 70.76)	(13.34, 59.01)	(26.59, 78.73)	(25.48, 60.78)	(23.14, 56.54)
Baseline Fecal Calprotectin <= Baseline Median (2302.5 ug/g)	N=3	N=5	N=2	N=7	N=10
Yes	1 (33.3)	1 (20.0)	1 (50.0)	2 (28.6)	3 (30.0)
No	2 (66.7)	4 (80.0)	1 (50.0)	5 (71.4)	7 (70.0)
95% Confidence Interval [A]	(0.84, 90.57)	(0.51, 71.64)	(1.26, 98.74)	(3.67, 70.96)	(6.67, 65.25)
Baseline Fecal Calprotectin > Baseline Median (2302.5 ug/g)	N=1	N=4	N=5	N=9	N=10
Yes	0	0	4 (80.0)	4 (44.4)	4 (40.0)
No	1 (100)	4 (100)	1 (20.0)	5 (55.6)	6 (60.0)
95% Confidence Interval [A]	(0.00, 97.50)	(0.00, 60.24)	(28.36, 99.49)	(13.70, 78.80)	(12.16, 73.76)

表 2.7.3.6-46. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

One patient ([redacted] who is ongoing study is excluded from interim analysis.
Note: M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
[A] Clopper-Pearson confidence interval for proportion in mucosal healing.
[B1] Nominal p-values from a one-sample two-sided chi-square test.
[B2] Adjusted p-values from a sequentially rejective multiple test procedure (details in SAP), testing co-primary and ranked secondary endpoints first for M-SD/M-HD combined (p-value in 'Total' column) and then for individual ADA dose groups (p-values in 'M-HD' column and in 'M-SD' column, respectively) against the respective external placebo rate (here: 22.03%).
[C] Nominal p-value for the exploratory comparison of M-SD vs. M-HD.
Non-responder imputation (NRI): missing data is imputed as not having met the endpoint. Subjects re-randomized due to disease flare are considered as not having met the endpoint at and after their 1st disease flare.
Clinical response per Partial Mayo Score (PMS) is defined as decrease in PMS >= 2 points and >= 30% from baseline.
Clinical remission per Partial Mayo Score (PMS) is defined as PMS <= 2 and no individual subscore > 1.
Mucosal healing is defined as endoscopy subscore of 0 or 1.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.2__1.2.2_A

表 2.7.3.6-47. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Overall	N=0	N=2	N=3	N=5	N=5
Yes	0	0	1 (33.3)	1 (20.0)	1 (20.0)
No	0	2 (100)	2 (66.7)	4 (80.0)	4 (80.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.84, 90.57)	(0.51, 71.64)	(0.51, 71.64)
P-Value [B1]		0.452	0.637	0.913	
P-Value [C]		0.361			
PMS Remission at Week 8 - Yes	N=0	N=0	N=2	N=2	N=2
Yes	0	0	1 (50.0)	1 (50.0)	1 (50.0)
No	0	0	1 (50.0)	1 (50.0)	1 (50.0)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(1.26, 98.74)	(1.26, 98.74)	(1.26, 98.74)

表 2.7.3.6-47. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
	mITT-E				
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
PMS Remission at Week 8 - No	N=0	N=2	N=1	N=3	N=3
Yes	0	0	0	0	0
No	0	2 (100)	1 (100)	3 (100)	3 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.00, 97.50)	(0.00, 70.76)	(0.00, 70.76)
I-SD	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
I-HD/I-HD-OL	N=0	N=2	N=3	N=5	N=5
Yes	0	0	1 (33.3)	1 (20.0)	1 (20.0)
No	0	2 (100)	2 (66.7)	4 (80.0)	4 (80.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.84, 90.57)	(0.51, 71.64)	(0.51, 71.64)

表 2.7.3.6-47. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
I-HD	N=0	N=1	N=3	N=4	N=4
Yes	0	0	1 (33.3)	1 (25.0)	1 (25.0)
No	0	1 (100)	2 (66.7)	3 (75.0)	3 (75.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 97.50)	(0.84, 90.57)	(0.63, 80.59)	(0.63, 80.59)
I-HD-OL	N=0	N=1	N=0	N=1	N=1
Yes	0	0	0	0	0
No	0	1 (100)	0	1 (100)	1 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 97.50)	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)
Sex - Male	N=0	N=2	N=3	N=5	N=5
Yes	0	0	1 (33.3)	1 (20.0)	1 (20.0)
No	0	2 (100)	2 (66.7)	4 (80.0)	4 (80.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.84, 90.57)	(0.51, 71.64)	(0.51, 71.64)

表 2.7.3.6-47. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Sex - Female	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Age < 13 Years	N=0	N=0	N=1	N=1	N=1
Yes	0	0	1 (100)	1 (100)	1 (100)
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(2.50, 100.00)	(2.50, 100.00)	(2.50, 100.00)
Age >= 13 Years	N=0	N=2	N=2	N=4	N=4
Yes	0	0	0	0	0
No	0	2 (100)	2 (100)	4 (100)	4 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.00, 84.19)	(0.00, 60.24)	(0.00, 60.24)

表 2.7.3.6-47. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Ethnicity - White	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Ethnicity - Non-white	N=0	N=2	N=3	N=5	N=5
Yes	0	0	1 (33.3)	1 (20.0)	1 (20.0)
No	0	2 (100)	2 (66.7)	4 (80.0)	4 (80.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.84, 90.57)	(0.51, 71.64)	(0.51, 71.64)
Geographic Region - Japan	N=0	N=2	N=3	N=5	N=5
Yes	0	0	1 (33.3)	1 (20.0)	1 (20.0)
No	0	2 (100)	2 (66.7)	4 (80.0)	4 (80.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.84, 90.57)	(0.51, 71.64)	(0.51, 71.64)

表 2.7.3.6-47. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Baseline Mayo Score <= 9	N=0	N=2	N=3	N=5	N=5
Yes	0	0	1 (33.3)	1 (20.0)	1 (20.0)
No	0	2 (100)	2 (66.7)	4 (80.0)	4 (80.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.84, 90.57)	(0.51, 71.64)	(0.51, 71.64)
Baseline Mayo Score > 9	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Prior Anti-TNF Use	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)

表 2.7.3.6-47. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Prior Anti-TNF Naive	N=0	N=2	N=3	N=5	N=5
Yes	0	0	1 (33.3)	1 (20.0)	1 (20.0)
No	0	2 (100)	2 (66.7)	4 (80.0)	4 (80.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.84, 90.57)	(0.51, 71.64)	(0.51, 71.64)
Baseline Corticosteroid Use - Yes	N=0	N=2	N=1	N=3	N=3
Yes	0	0	1 (100)	1 (33.3)	1 (33.3)
No	0	2 (100)	0	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(2.50, 100.00)	(0.84, 90.57)	(0.84, 90.57)
Baseline Corticosteroid Use - No	N=0	N=0	N=2	N=2	N=2
Yes	0	0	0	0	0
No	0	0	2 (100)	2 (100)	2 (100)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.00, 84.19)	(0.00, 84.19)	(0.00, 84.19)

表 2.7.3.6-47. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Baseline IMM Use - Yes	N=0	N=2	N=3	N=5	N=5
Yes	0	0	1 (33.3)	1 (20.0)	1 (20.0)
No	0	2 (100)	2 (66.7)	4 (80.0)	4 (80.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.84, 90.57)	(0.51, 71.64)	(0.51, 71.64)
Baseline IMM Use - No	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Weight < 40 kg	N=0	N=0	N=1	N=1	N=1
Yes	0	0	1 (100)	1 (100)	1 (100)
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(2.50, 100.00)	(2.50, 100.00)	(2.50, 100.00)

表 2.7.3.6-47. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Weight >= 40 kg	N=0	N=2	N=2	N=4	N=4
Yes	0	0	0	0	0
No	0	2 (100)	2 (100)	4 (100)	4 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.00, 84.19)	(0.00, 60.24)	(0.00, 60.24)
Pancolitis - Yes	N=0	N=2	N=3	N=5	N=5
Yes	0	0	1 (33.3)	1 (20.0)	1 (20.0)
No	0	2 (100)	2 (66.7)	4 (80.0)	4 (80.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.84, 90.57)	(0.51, 71.64)	(0.51, 71.64)
Pancolitis - No	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)

表 2.7.3.6-47. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Disease Duration <= Baseline Median (19.1 Months)	N=0	N=1	N=0	N=1	N=1
Yes	0	0	0	0	0
No	0	1 (100)	0	1 (100)	1 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 97.50)	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)
Disease Duration > Baseline Median (19.1 Months)	N=0	N=1	N=3	N=4	N=4
Yes	0	0	1 (33.3)	1 (25.0)	1 (25.0)
No	0	1 (100)	2 (66.7)	3 (75.0)	3 (75.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 97.50)	(0.84, 90.57)	(0.63, 80.59)	(0.63, 80.59)
Baseline hs-CRP <= Baseline Median (1.29 mg/L)	N=0	N=0	N=3	N=3	N=3
Yes	0	0	1 (33.3)	1 (33.3)	1 (33.3)
No	0	0	2 (66.7)	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.84, 90.57)	(0.84, 90.57)	(0.84, 90.57)

表 2.7.3.6-47. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Baseline hs-CRP > Baseline Median (1.29 mg/L)	N=0	N=2	N=0	N=2	N=2
Yes	0	0	0	0	0
No	0	2 (100)	0	2 (100)	2 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(NA, NA)	(0.00, 84.19)	(0.00, 84.19)
Baseline Fecal Calprotectin <= Baseline Median (2302.5 ug/g)	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Baseline Fecal Calprotectin > Baseline Median (2302.5 ug/g)	N=0	N=0	N=1	N=1	N=1
Yes	0	0	0	0	0
No	0	0	1 (100)	1 (100)	1 (100)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)	(0.00, 97.50)

表 2.7.3.6-47. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
Note: M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
[A] Clopper-Pearson confidence interval for proportion in mucosal healing.
[B1] Nominal p-values from a one-sample two-sided chi-square test.
[C] Nominal p-value for the exploratory comparison of M-SD vs. M-HD.
Non-responder imputation (NRI): missing data is imputed as not having met the endpoint. Subjects re-randomized due to disease flare are considered as not having met the endpoint at and after their 1st disease flare.
Clinical response per Partial Mayo Score (PMS) is defined as decrease in PMS >= 2 points and >= 30% from baseline.
Clinical remission per Partial Mayo Score (PMS) is defined as PMS <= 2 and no individual subscore > 1.
Mucosal healing is defined as endoscopy subscore of 0 or 1.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.2__1.2.2_J

表 2.7.3.6-48. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Overall	N=8	N=21	N=24	N=45	N=53
Yes	3 (37.5)	9 (42.9)	11 (45.8)	20 (44.4)	23 (43.4)
No	5 (62.5)	12 (57.1)	13 (54.2)	25 (55.6)	30 (56.6)
95% Confidence Interval [A]	(8.52, 75.51)	(21.82, 65.98)	(25.55, 67.18)	(29.64, 60.00)	(29.84, 57.72)
P-Value [B1]		<0.001	<0.001	<0.001	
ADJ. P-Value [B2]		0.292	<0.001	<0.001	
PMS Remission at Week 8 - Yes	N=8	N=21	N=24	N=45	N=53
Yes	3 (37.5)	9 (42.9)	11 (45.8)	20 (44.4)	23 (43.4)
No	5 (62.5)	12 (57.1)	13 (54.2)	25 (55.6)	30 (56.6)
95% Confidence Interval [A]	(8.52, 75.51)	(21.82, 65.98)	(25.55, 67.18)	(29.64, 60.00)	(29.84, 57.72)

表 2.7.3.6-48. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
PMS Remission at Week 8 - No	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
I-SD	N=2	N=4	N=6	N=10	N=12
Yes	0	0	2 (33.3)	2 (20.0)	2 (16.7)
No	2 (100)	4 (100)	4 (66.7)	8 (80.0)	10 (83.3)
95% Confidence Interval [A]	(0.00, 84.19)	(0.00, 60.24)	(4.33, 77.72)	(2.52, 55.61)	(2.09, 48.41)
I-HD/I-HD-OL	N=6	N=17	N=18	N=35	N=41
Yes	3 (50.0)	9 (52.9)	9 (50.0)	18 (51.4)	21 (51.2)
No	3 (50.0)	8 (47.1)	9 (50.0)	17 (48.6)	20 (48.8)
95% Confidence Interval [A]	(11.81, 88.19)	(27.81, 77.02)	(26.02, 73.98)	(33.99, 68.62)	(35.13, 67.12)

表 2.7.3.6-48. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

Category Endpoint Met	mITT M-PL (N=12)	mITT-E M-SD (N=33)	mITT-E M-HD (N=34)	mITT-E Total (N=67)	mITT Total (N=79)
I-HD	N=6	N=12	N=12	N=24	N=30
Yes	3 (50.0)	7 (58.3)	6 (50.0)	13 (54.2)	16 (53.3)
No	3 (50.0)	5 (41.7)	6 (50.0)	11 (45.8)	14 (46.7)
95% Confidence Interval [A]	(11.81, 88.19)	(27.67, 84.83)	(21.09, 78.91)	(32.82, 74.45)	(34.33, 71.66)
I-HD-OL	N=0	N=5	N=6	N=11	N=11
Yes	0	2 (40.0)	3 (50.0)	5 (45.5)	5 (45.5)
No	0	3 (60.0)	3 (50.0)	6 (54.5)	6 (54.5)
95% Confidence Interval [A]	(NA, NA)	(5.27, 85.34)	(11.81, 88.19)	(16.75, 76.62)	(16.75, 76.62)
Sex - Male	N=5	N=10	N=10	N=20	N=25
Yes	1 (20.0)	4 (40.0)	5 (50.0)	9 (45.0)	10 (40.0)
No	4 (80.0)	6 (60.0)	5 (50.0)	11 (55.0)	15 (60.0)
95% Confidence Interval [A]	(0.51, 71.64)	(12.16, 73.76)	(18.71, 81.29)	(23.06, 68.47)	(21.13, 61.33)

表 2.7.3.6-48. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Sex - Female	N=3	N=11	N=14	N=25	N=28
Yes	2 (66.7)	5 (45.5)	6 (42.9)	11 (44.0)	13 (46.4)
No	1 (33.3)	6 (54.5)	8 (57.1)	14 (56.0)	15 (53.6)
95% Confidence Interval [A]	(9.43, 99.16)	(16.75, 76.62)	(17.66, 71.14)	(24.40, 65.07)	(27.51, 66.13)
Age < 13 Years	N=2	N=8	N=6	N=14	N=16
Yes	1 (50.0)	5 (62.5)	2 (33.3)	7 (50.0)	8 (50.0)
No	1 (50.0)	3 (37.5)	4 (66.7)	7 (50.0)	8 (50.0)
95% Confidence Interval [A]	(1.26, 98.74)	(24.49, 91.48)	(4.33, 77.72)	(23.04, 76.96)	(24.65, 75.35)
Age >= 13 Years	N=6	N=13	N=18	N=31	N=37
Yes	2 (33.3)	4 (30.8)	9 (50.0)	13 (41.9)	15 (40.5)
No	4 (66.7)	9 (69.2)	9 (50.0)	18 (58.1)	22 (59.5)
95% Confidence Interval [A]	(4.33, 77.72)	(9.09, 61.43)	(26.02, 73.98)	(24.55, 60.92)	(24.75, 57.90)

表 2.7.3.6-48. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

Category Endpoint Met	mITT M-PL (N=12)	mITT-E M-SD (N=33)	mITT-E M-HD (N=34)	mITT-E Total (N=67)	mITT Total (N=79)
Ethnicity - White	N=7	N=19	N=22	N=41	N=48
Yes	3 (42.9)	8 (42.1)	10 (45.5)	18 (43.9)	21 (43.8)
No	4 (57.1)	11 (57.9)	12 (54.5)	23 (56.1)	27 (56.3)
95% Confidence Interval [A]	(9.90, 81.59)	(20.25, 66.50)	(24.39, 67.79)	(28.47, 60.25)	(29.48, 58.82)
Ethnicity - Non-white	N=1	N=2	N=2	N=4	N=5
Yes	0	1 (50.0)	1 (50.0)	2 (50.0)	2 (40.0)
No	1 (100)	1 (50.0)	1 (50.0)	2 (50.0)	3 (60.0)
95% Confidence Interval [A]	(0.00, 97.50)	(1.26, 98.74)	(1.26, 98.74)	(6.76, 93.24)	(5.27, 85.34)
Geographic Region - Japan	N=0	N=0	N=2	N=2	N=2
Yes	0	0	1 (50.0)	1 (50.0)	1 (50.0)
No	0	0	1 (50.0)	1 (50.0)	1 (50.0)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(1.26, 98.74)	(1.26, 98.74)	(1.26, 98.74)

表 2.7.3.6-48. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Baseline Mayo Score <= 9	N=7	N=18	N=20	N=38	N=45
Yes	3 (42.9)	8 (44.4)	8 (40.0)	16 (42.1)	19 (42.2)
No	4 (57.1)	10 (55.6)	12 (60.0)	22 (57.9)	26 (57.8)
95% Confidence Interval [A]	(9.90, 81.59)	(21.53, 69.24)	(19.12, 63.95)	(26.31, 59.18)	(27.66, 57.85)
Baseline Mayo Score > 9	N=1	N=3	N=4	N=7	N=8
Yes	0	1 (33.3)	3 (75.0)	4 (57.1)	4 (50.0)
No	1 (100)	2 (66.7)	1 (25.0)	3 (42.9)	4 (50.0)
95% Confidence Interval [A]	(0.00, 97.50)	(0.84, 90.57)	(19.41, 99.37)	(18.41, 90.10)	(15.70, 84.30)
Prior Anti-TNF Use	N=0	N=2	N=3	N=5	N=5
Yes	0	0	0	0	0
No	0	2 (100)	3 (100)	5 (100)	5 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.00, 70.76)	(0.00, 52.18)	(0.00, 52.18)

表 2.7.3.6-48. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Prior Anti-TNF Naive	N=8	N=19	N=21	N=40	N=48
Yes	3 (37.5)	9 (47.4)	11 (52.4)	20 (50.0)	23 (47.9)
No	5 (62.5)	10 (52.6)	10 (47.6)	20 (50.0)	25 (52.1)
95% Confidence Interval [A]	(8.52, 75.51)	(24.45, 71.14)	(29.78, 74.29)	(33.80, 66.20)	(33.29, 62.81)
Baseline Corticosteroid Use - Yes	N=5	N=8	N=12	N=20	N=25
Yes	2 (40.0)	4 (50.0)	6 (50.0)	10 (50.0)	12 (48.0)
No	3 (60.0)	4 (50.0)	6 (50.0)	10 (50.0)	13 (52.0)
95% Confidence Interval [A]	(5.27, 85.34)	(15.70, 84.30)	(21.09, 78.91)	(27.20, 72.80)	(27.80, 68.69)
Baseline Corticosteroid Use - No	N=3	N=13	N=12	N=25	N=28
Yes	1 (33.3)	5 (38.5)	5 (41.7)	10 (40.0)	11 (39.3)
No	2 (66.7)	8 (61.5)	7 (58.3)	15 (60.0)	17 (60.7)
95% Confidence Interval [A]	(0.84, 90.57)	(13.86, 68.42)	(15.17, 72.33)	(21.13, 61.33)	(21.50, 59.42)

表 2.7.3.6-48. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

Category Endpoint Met	mITT M-PL (N=12)	mITT-E M-SD (N=33)	mITT-E M-HD (N=34)	mITT-E Total (N=67)	mITT Total (N=79)
Baseline IMM Use - Yes	N=5	N=11	N=18	N=29	N=34
Yes	2 (40.0)	4 (36.4)	8 (44.4)	12 (41.4)	14 (41.2)
No	3 (60.0)	7 (63.6)	10 (55.6)	17 (58.6)	20 (58.8)
95% Confidence Interval [A]	(5.27, 85.34)	(10.93, 69.21)	(21.53, 69.24)	(23.52, 61.06)	(24.65, 59.30)
Baseline IMM Use - No	N=3	N=10	N=6	N=16	N=19
Yes	1 (33.3)	5 (50.0)	3 (50.0)	8 (50.0)	9 (47.4)
No	2 (66.7)	5 (50.0)	3 (50.0)	8 (50.0)	10 (52.6)
95% Confidence Interval [A]	(0.84, 90.57)	(18.71, 81.29)	(11.81, 88.19)	(24.65, 75.35)	(24.45, 71.14)
Weight < 40 kg	N=0	N=3	N=6	N=9	N=9
Yes	0	3 (100)	3 (50.0)	6 (66.7)	6 (66.7)
No	0	0	3 (50.0)	3 (33.3)	3 (33.3)
95% Confidence Interval [A]	(NA, NA)	(29.24, 100.00)	(11.81, 88.19)	(29.93, 92.51)	(29.93, 92.51)

表 2.7.3.6-48. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Weight >= 40 kg	N=8	N=18	N=18	N=36	N=44
Yes	3 (37.5)	6 (33.3)	8 (44.4)	14 (38.9)	17 (38.6)
No	5 (62.5)	12 (66.7)	10 (55.6)	22 (61.1)	27 (61.4)
95% Confidence Interval [A]	(8.52, 75.51)	(13.34, 59.01)	(21.53, 69.24)	(23.14, 56.54)	(24.36, 54.50)
Pancolitis - Yes	N=4	N=12	N=15	N=27	N=31
Yes	1 (25.0)	5 (41.7)	8 (53.3)	13 (48.1)	14 (45.2)
No	3 (75.0)	7 (58.3)	7 (46.7)	14 (51.9)	17 (54.8)
95% Confidence Interval [A]	(0.63, 80.59)	(15.17, 72.33)	(26.59, 78.73)	(28.67, 68.05)	(27.32, 63.97)
Pancolitis - No	N=4	N=9	N=9	N=18	N=22
Yes	2 (50.0)	4 (44.4)	3 (33.3)	7 (38.9)	9 (40.9)
No	2 (50.0)	5 (55.6)	6 (66.7)	11 (61.1)	13 (59.1)
95% Confidence Interval [A]	(6.76, 93.24)	(13.70, 78.80)	(7.49, 70.07)	(17.30, 64.25)	(20.71, 63.65)

表 2.7.3.6-48. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Disease Duration <= Baseline Median (19.1 Months)	N=3	N=10	N=9	N=19	N=22
Yes	0	3 (30.0)	5 (55.6)	8 (42.1)	8 (36.4)
No	3 (100)	7 (70.0)	4 (44.4)	11 (57.9)	14 (63.6)
95% Confidence Interval [A]	(0.00, 70.76)	(6.67, 65.25)	(21.20, 86.30)	(20.25, 66.50)	(17.20, 59.34)
Disease Duration > Baseline Median (19.1 Months)	N=5	N=11	N=15	N=26	N=31
Yes	3 (60.0)	6 (54.5)	6 (40.0)	12 (46.2)	15 (48.4)
No	2 (40.0)	5 (45.5)	9 (60.0)	14 (53.8)	16 (51.6)
95% Confidence Interval [A]	(14.66, 94.73)	(23.38, 83.25)	(16.34, 67.71)	(26.59, 66.63)	(30.15, 66.94)
Baseline hs-CRP <= Baseline Median (1.29 mg/L)	N=6	N=7	N=13	N=20	N=26
Yes	2 (33.3)	3 (42.9)	8 (61.5)	11 (55.0)	13 (50.0)
No	4 (66.7)	4 (57.1)	5 (38.5)	9 (45.0)	13 (50.0)
95% Confidence Interval [A]	(4.33, 77.72)	(9.90, 81.59)	(31.58, 86.14)	(31.53, 76.94)	(29.93, 70.07)

表 2.7.3.6-48. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Baseline hs-CRP > Baseline Median (1.29 mg/L)	N=1	N=12	N=10	N=22	N=23
Yes	0	4 (33.3)	3 (30.0)	7 (31.8)	7 (30.4)
No	1 (100)	8 (66.7)	7 (70.0)	15 (68.2)	16 (69.6)
95% Confidence Interval [A]	(0.00, 97.50)	(9.92, 65.11)	(6.67, 65.25)	(13.86, 54.87)	(13.21, 52.92)
Baseline Fecal Calprotectin <= Baseline Median (2302.5 ug/g)	N=1	N=3	N=1	N=4	N=5
Yes	0	1 (33.3)	1 (100)	2 (50.0)	2 (40.0)
No	1 (100)	2 (66.7)	0	2 (50.0)	3 (60.0)
95% Confidence Interval [A]	(0.00, 97.50)	(0.84, 90.57)	(2.50, 100.00)	(6.76, 93.24)	(5.27, 85.34)
Baseline Fecal Calprotectin > Baseline Median (2302.5 ug/g)	N=0	N=2	N=3	N=5	N=5
Yes	0	0	2 (66.7)	2 (40.0)	2 (40.0)
No	0	2 (100)	1 (33.3)	3 (60.0)	3 (60.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(9.43, 99.16)	(5.27, 85.34)	(5.27, 85.34)

表 2.7.3.6-48. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
Note: M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
[A] Clopper-Pearson confidence interval for proportion in remission.
[B1] Nominal p-values from a one-sample two-sided chi-square test.
[B2] Adjusted p-values from a sequentially rejective multiple test procedure (details in SAP), testing co-primary and ranked secondary endpoints first for M-SD/M-HD combined (p-value in 'Total' column) and then for individual ADA dose groups (p-values in 'M-HD' column and in 'M-SD' column, respectively) against the respective external placebo rate (here: 14.79%).
Non-responder imputation (NRI): missing data is imputed as not having met the endpoint. Subjects re-randomized due to disease flare are considered as not having met the endpoint at and after their 1st disease flare.
Clinical remission per Full Mayo Score (FMS) is defined as Mayo Score <= 2 and no individual subscore > 1.
Clinical remission per Partial Mayo Score (PMS) is defined as PMS <= 2 and no individual subscore > 1.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.2__1.2.3_A

表 2.7.3.6-49. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Overall	N=0	N=0	N=2	N=2	N=2
Yes	0	0	1 (50.0)	1 (50.0)	1 (50.0)
No	0	0	1 (50.0)	1 (50.0)	1 (50.0)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(1.26, 98.74)	(1.26, 98.74)	(1.26, 98.74)
P-Value [B1]		NA	0.161	0.161	
PMS Remission at Week 8 - Yes	N=0	N=0	N=2	N=2	N=2
Yes	0	0	1 (50.0)	1 (50.0)	1 (50.0)
No	0	0	1 (50.0)	1 (50.0)	1 (50.0)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(1.26, 98.74)	(1.26, 98.74)	(1.26, 98.74)

表 2.7.3.6-49. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
PMS Remission at Week 8 - No	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
I-SD	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
I-HD/I-HD-OL	N=0	N=0	N=2	N=2	N=2
Yes	0	0	1 (50.0)	1 (50.0)	1 (50.0)
No	0	0	1 (50.0)	1 (50.0)	1 (50.0)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(1.26, 98.74)	(1.26, 98.74)	(1.26, 98.74)

表 2.7.3.6-49. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
I-HD	N=0	N=0	N=2	N=2	N=2
Yes	0	0	1 (50.0)	1 (50.0)	1 (50.0)
No	0	0	1 (50.0)	1 (50.0)	1 (50.0)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(1.26, 98.74)	(1.26, 98.74)	(1.26, 98.74)
I-HD-OL	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Sex - Male	N=0	N=0	N=2	N=2	N=2
Yes	0	0	1 (50.0)	1 (50.0)	1 (50.0)
No	0	0	1 (50.0)	1 (50.0)	1 (50.0)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(1.26, 98.74)	(1.26, 98.74)	(1.26, 98.74)

表 2.7.3.6-49. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Sex - Female	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Age < 13 Years	N=0	N=0	N=1	N=1	N=1
Yes	0	0	1 (100)	1 (100)	1 (100)
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(2.50, 100.00)	(2.50, 100.00)	(2.50, 100.00)
Age >= 13 Years	N=0	N=0	N=1	N=1	N=1
Yes	0	0	0	0	0
No	0	0	1 (100)	1 (100)	1 (100)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)	(0.00, 97.50)

表 2.7.3.6-49. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Ethnicity - White	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Ethnicity - Non-white	N=0	N=0	N=2	N=2	N=2
Yes	0	0	1 (50.0)	1 (50.0)	1 (50.0)
No	0	0	1 (50.0)	1 (50.0)	1 (50.0)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(1.26, 98.74)	(1.26, 98.74)	(1.26, 98.74)
Geographic Region - Japan	N=0	N=0	N=2	N=2	N=2
Yes	0	0	1 (50.0)	1 (50.0)	1 (50.0)
No	0	0	1 (50.0)	1 (50.0)	1 (50.0)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(1.26, 98.74)	(1.26, 98.74)	(1.26, 98.74)

表 2.7.3.6-49. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Baseline Mayo Score <= 9	N=0	N=0	N=2	N=2	N=2
Yes	0	0	1 (50.0)	1 (50.0)	1 (50.0)
No	0	0	1 (50.0)	1 (50.0)	1 (50.0)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(1.26, 98.74)	(1.26, 98.74)	(1.26, 98.74)
Baseline Mayo Score > 9	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Prior Anti-TNF Use	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)

表 2.7.3.6-49. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Prior Anti-TNF Naive	N=0	N=0	N=2	N=2	N=2
Yes	0	0	1 (50.0)	1 (50.0)	1 (50.0)
No	0	0	1 (50.0)	1 (50.0)	1 (50.0)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(1.26, 98.74)	(1.26, 98.74)	(1.26, 98.74)
Baseline Corticosteroid Use - Yes	N=0	N=0	N=1	N=1	N=1
Yes	0	0	1 (100)	1 (100)	1 (100)
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(2.50, 100.00)	(2.50, 100.00)	(2.50, 100.00)
Baseline Corticosteroid Use - No	N=0	N=0	N=1	N=1	N=1
Yes	0	0	0	0	0
No	0	0	1 (100)	1 (100)	1 (100)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)	(0.00, 97.50)

表 2.7.3.6-49. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Baseline IMM Use - Yes	N=0	N=0	N=2	N=2	N=2
Yes	0	0	1 (50.0)	1 (50.0)	1 (50.0)
No	0	0	1 (50.0)	1 (50.0)	1 (50.0)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(1.26, 98.74)	(1.26, 98.74)	(1.26, 98.74)
Baseline IMM Use - No	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Weight < 40 kg	N=0	N=0	N=1	N=1	N=1
Yes	0	0	1 (100)	1 (100)	1 (100)
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(2.50, 100.00)	(2.50, 100.00)	(2.50, 100.00)

表 2.7.3.6-49. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Weight >= 40 kg	N=0	N=0	N=1	N=1	N=1
Yes	0	0	0	0	0
No	0	0	1 (100)	1 (100)	1 (100)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)	(0.00, 97.50)
Pancolitis - Yes	N=0	N=0	N=2	N=2	N=2
Yes	0	0	1 (50.0)	1 (50.0)	1 (50.0)
No	0	0	1 (50.0)	1 (50.0)	1 (50.0)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(1.26, 98.74)	(1.26, 98.74)	(1.26, 98.74)
Pancolitis - No	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)

表 2.7.3.6-49. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Disease Duration <= Baseline Median (19.1 Months)	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Disease Duration > Baseline Median (19.1 Months)	N=0	N=0	N=2	N=2	N=2
Yes	0	0	1 (50.0)	1 (50.0)	1 (50.0)
No	0	0	1 (50.0)	1 (50.0)	1 (50.0)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(1.26, 98.74)	(1.26, 98.74)	(1.26, 98.74)
Baseline hs-CRP <= Baseline Median (1.29 mg/L)	N=0	N=0	N=2	N=2	N=2
Yes	0	0	1 (50.0)	1 (50.0)	1 (50.0)
No	0	0	1 (50.0)	1 (50.0)	1 (50.0)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(1.26, 98.74)	(1.26, 98.74)	(1.26, 98.74)

表 2.7.3.6-49. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Baseline hs-CRP > Baseline Median (1.29 mg/L)	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Baseline Fecal Calprotectin <= Baseline Median (2302.5 ug/g)	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Baseline Fecal Calprotectin > Baseline Median (2302.5 ug/g)	N=0	N=0	N=1	N=1	N=1
Yes	0	0	0	0	0
No	0	0	1 (100)	1 (100)	1 (100)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)	(0.00, 97.50)

表 2.7.3.6-49.　投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
Note: M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
[A] Clopper-Pearson confidence interval for proportion in remission.
[B1] Nominal p-values from a one-sample two-sided chi-square test.
Non-responder imputation (NRI): missing data is imputed as not having met the endpoint. Subjects re-randomized due to disease flare are considered as not having met the endpoint at and after their 1st disease flare.
Clinical remission per Full Mayo Score (FMS) is defined as Mayo Score <= 2 and no individual subscore > 1.
Clinical remission per Partial Mayo Score (PMS) is defined as PMS <= 2 and no individual subscore > 1.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.2__1.2.3_J

表 2.7.3.6-50. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Overall	N=5	N=15	N=17	N=32	N=37
Yes	2 (40.0)	4 (26.7)	6 (35.3)	10 (31.3)	12 (32.4)
No	3 (60.0)	11 (73.3)	11 (64.7)	22 (68.8)	25 (67.6)
95% Confidence Interval [A]	(5.27, 85.34)	(7.79, 55.10)	(14.21, 61.67)	(16.12, 50.01)	(18.01, 49.79)
P-Value [B1]		0.815	0.280	0.343	
ADJ. P-Value [B2]		0.815	0.559	0.344	
P-Value [C]		0.599			
PMS Remission at Week 8 - Yes	N=5	N=8	N=12	N=20	N=25
Yes	2 (40.0)	4 (50.0)	6 (50.0)	10 (50.0)	12 (48.0)
No	3 (60.0)	4 (50.0)	6 (50.0)	10 (50.0)	13 (52.0)
95% Confidence Interval [A]	(5.27, 85.34)	(15.70, 84.30)	(21.09, 78.91)	(27.20, 72.80)	(27.80, 68.69)

表 2.7.3.6-50. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
PMS Remission at Week 8 - No	N=0	N=7	N=5	N=12	N=12
Yes	0	0	0	0	0
No	0	7 (100)	5 (100)	12 (100)	12 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 40.96)	(0.00, 52.18)	(0.00, 26.46)	(0.00, 26.46)
I-SD	N=0	N=5	N=3	N=8	N=8
Yes	0	0	0	0	0
No	0	5 (100)	3 (100)	8 (100)	8 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 52.18)	(0.00, 70.76)	(0.00, 36.94)	(0.00, 36.94)
I-HD/I-HD-OL	N=5	N=10	N=14	N=24	N=29
Yes	2 (40.0)	4 (40.0)	6 (42.9)	10 (41.7)	12 (41.4)
No	3 (60.0)	6 (60.0)	8 (57.1)	14 (58.3)	17 (58.6)
95% Confidence Interval [A]	(5.27, 85.34)	(12.16, 73.76)	(17.66, 71.14)	(22.11, 63.36)	(23.52, 61.06)

表 2.7.3.6-50. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
I-HD	N=5	N=6	N=9	N=15	N=20
Yes	2 (40.0)	3 (50.0)	4 (44.4)	7 (46.7)	9 (45.0)
No	3 (60.0)	3 (50.0)	5 (55.6)	8 (53.3)	11 (55.0)
95% Confidence Interval [A]	(5.27, 85.34)	(11.81, 88.19)	(13.70, 78.80)	(21.27, 73.41)	(23.06, 68.47)
I-HD-OL	N=0	N=4	N=5	N=9	N=9
Yes	0	1 (25.0)	2 (40.0)	3 (33.3)	3 (33.3)
No	0	3 (75.0)	3 (60.0)	6 (66.7)	6 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.63, 80.59)	(5.27, 85.34)	(7.49, 70.07)	(7.49, 70.07)
Sex - Male	N=4	N=7	N=8	N=15	N=19
Yes	1 (25.0)	1 (14.3)	4 (50.0)	5 (33.3)	6 (31.6)
No	3 (75.0)	6 (85.7)	4 (50.0)	10 (66.7)	13 (68.4)
95% Confidence Interval [A]	(0.63, 80.59)	(0.36, 57.87)	(15.70, 84.30)	(11.82, 61.62)	(12.58, 56.55)

表 2.7.3.6-50. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Sex - Female	N=1	N=8	N=9	N=17	N=18
Yes	1 (100)	3 (37.5)	2 (22.2)	5 (29.4)	6 (33.3)
No	0	5 (62.5)	7 (77.8)	12 (70.6)	12 (66.7)
95% Confidence Interval [A]	(2.50, 100.00)	(8.52, 75.51)	(2.81, 60.01)	(10.31, 55.96)	(13.34, 59.01)
Age < 13 Years	N=1	N=3	N=7	N=10	N=11
Yes	0	2 (66.7)	2 (28.6)	4 (40.0)	4 (36.4)
No	1 (100)	1 (33.3)	5 (71.4)	6 (60.0)	7 (63.6)
95% Confidence Interval [A]	(0.00, 97.50)	(9.43, 99.16)	(3.67, 70.96)	(12.16, 73.76)	(10.93, 69.21)
Age >= 13 Years	N=4	N=12	N=10	N=22	N=26
Yes	2 (50.0)	2 (16.7)	4 (40.0)	6 (27.3)	8 (30.8)
No	2 (50.0)	10 (83.3)	6 (60.0)	16 (72.7)	18 (69.2)
95% Confidence Interval [A]	(6.76, 93.24)	(2.09, 48.41)	(12.16, 73.76)	(10.73, 50.22)	(14.33, 51.79)

表 2.7.3.6-50. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Ethnicity - White	N=5	N=11	N=15	N=26	N=31
Yes	2 (40.0)	3 (27.3)	5 (33.3)	8 (30.8)	10 (32.3)
No	3 (60.0)	8 (72.7)	10 (66.7)	18 (69.2)	21 (67.7)
95% Confidence Interval [A]	(5.27, 85.34)	(6.02, 60.97)	(11.82, 61.62)	(14.33, 51.79)	(16.68, 51.37)
Ethnicity - Non-white	N=0	N=4	N=2	N=6	N=6
Yes	0	1 (25.0)	1 (50.0)	2 (33.3)	2 (33.3)
No	0	3 (75.0)	1 (50.0)	4 (66.7)	4 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.63, 80.59)	(1.26, 98.74)	(4.33, 77.72)	(4.33, 77.72)
Geographic Region - Japan	N=0	N=2	N=1	N=3	N=3
Yes	0	0	1 (100)	1 (33.3)	1 (33.3)
No	0	2 (100)	0	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(2.50, 100.00)	(0.84, 90.57)	(0.84, 90.57)

表 2.7.3.6-50. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Baseline Mayo Score <= 9	N=4	N=13	N=16	N=29	N=33
Yes	2 (50.0)	3 (23.1)	5 (31.3)	8 (27.6)	10 (30.3)
No	2 (50.0)	10 (76.9)	11 (68.8)	21 (72.4)	23 (69.7)
95% Confidence Interval [A]	(6.76, 93.24)	(5.04, 53.81)	(11.02, 58.66)	(12.73, 47.24)	(15.59, 48.71)
Baseline Mayo Score > 9	N=1	N=2	N=1	N=3	N=4
Yes	0	1 (50.0)	1 (100)	2 (66.7)	2 (50.0)
No	1 (100)	1 (50.0)	0	1 (33.3)	2 (50.0)
95% Confidence Interval [A]	(0.00, 97.50)	(1.26, 98.74)	(2.50, 100.00)	(9.43, 99.16)	(6.76, 93.24)
Prior Anti-TNF Use	N=0	N=0	N=4	N=4	N=4
Yes	0	0	0	0	0
No	0	0	4 (100)	4 (100)	4 (100)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.00, 60.24)	(0.00, 60.24)	(0.00, 60.24)

表 2.7.3.6-50. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Prior Anti-TNF Naive	N=5	N=15	N=13	N=28	N=33
Yes	2 (40.0)	4 (26.7)	6 (46.2)	10 (35.7)	12 (36.4)
No	3 (60.0)	11 (73.3)	7 (53.8)	18 (64.3)	21 (63.6)
95% Confidence Interval [A]	(5.27, 85.34)	(7.79, 55.10)	(19.22, 74.87)	(18.64, 55.93)	(20.40, 54.88)
Baseline Corticosteroid Use - Yes	N=5	N=15	N=17	N=32	N=37
Yes	2 (40.0)	4 (26.7)	6 (35.3)	10 (31.3)	12 (32.4)
No	3 (60.0)	11 (73.3)	11 (64.7)	22 (68.8)	25 (67.6)
95% Confidence Interval [A]	(5.27, 85.34)	(7.79, 55.10)	(14.21, 61.67)	(16.12, 50.01)	(18.01, 49.79)
Baseline Corticosteroid Use - No	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)

表 2.7.3.6-50. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Baseline IMM Use - Yes	N=2	N=6	N=8	N=14	N=16
Yes	1 (50.0)	1 (16.7)	3 (37.5)	4 (28.6)	5 (31.3)
No	1 (50.0)	5 (83.3)	5 (62.5)	10 (71.4)	11 (68.8)
95% Confidence Interval [A]	(1.26, 98.74)	(0.42, 64.12)	(8.52, 75.51)	(8.39, 58.10)	(11.02, 58.66)
Baseline IMM Use - No	N=3	N=9	N=9	N=18	N=21
Yes	1 (33.3)	3 (33.3)	3 (33.3)	6 (33.3)	7 (33.3)
No	2 (66.7)	6 (66.7)	6 (66.7)	12 (66.7)	14 (66.7)
95% Confidence Interval [A]	(0.84, 90.57)	(7.49, 70.07)	(7.49, 70.07)	(13.34, 59.01)	(14.59, 56.97)
Weight < 40 kg	N=0	N=2	N=6	N=8	N=8
Yes	0	1 (50.0)	2 (33.3)	3 (37.5)	3 (37.5)
No	0	1 (50.0)	4 (66.7)	5 (62.5)	5 (62.5)
95% Confidence Interval [A]	(NA, NA)	(1.26, 98.74)	(4.33, 77.72)	(8.52, 75.51)	(8.52, 75.51)

表 2.7.3.6-50. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Weight >= 40 kg	N=5	N=13	N=11	N=24	N=29
Yes	2 (40.0)	3 (23.1)	4 (36.4)	7 (29.2)	9 (31.0)
No	3 (60.0)	10 (76.9)	7 (63.6)	17 (70.8)	20 (69.0)
95% Confidence Interval [A]	(5.27, 85.34)	(5.04, 53.81)	(10.93, 69.21)	(12.62, 51.09)	(15.28, 50.83)
Pancolitis - Yes	N=1	N=12	N=7	N=19	N=20
Yes	0	3 (25.0)	4 (57.1)	7 (36.8)	7 (35.0)
No	1 (100)	9 (75.0)	3 (42.9)	12 (63.2)	13 (65.0)
95% Confidence Interval [A]	(0.00, 97.50)	(5.49, 57.19)	(18.41, 90.10)	(16.29, 61.64)	(15.39, 59.22)
Pancolitis - No	N=4	N=3	N=10	N=13	N=17
Yes	2 (50.0)	1 (33.3)	2 (20.0)	3 (23.1)	5 (29.4)
No	2 (50.0)	2 (66.7)	8 (80.0)	10 (76.9)	12 (70.6)
95% Confidence Interval [A]	(6.76, 93.24)	(0.84, 90.57)	(2.52, 55.61)	(5.04, 53.81)	(10.31, 55.96)

表 2.7.3.6-50. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Disease Duration <= Baseline Median (19.1 Months)	N=1	N=12	N=10	N=22	N=23
Yes	0	3 (25.0)	3 (30.0)	6 (27.3)	6 (26.1)
No	1 (100)	9 (75.0)	7 (70.0)	16 (72.7)	17 (73.9)
95% Confidence Interval [A]	(0.00, 97.50)	(5.49, 57.19)	(6.67, 65.25)	(10.73, 50.22)	(10.23, 48.41)
Disease Duration > Baseline Median (19.1 Months)	N=4	N=3	N=7	N=10	N=14
Yes	2 (50.0)	1 (33.3)	3 (42.9)	4 (40.0)	6 (42.9)
No	2 (50.0)	2 (66.7)	4 (57.1)	6 (60.0)	8 (57.1)
95% Confidence Interval [A]	(6.76, 93.24)	(0.84, 90.57)	(9.90, 81.59)	(12.16, 73.76)	(17.66, 71.14)
Baseline hs-CRP <= Baseline Median (1.29 mg/L)	N=4	N=8	N=11	N=19	N=23
Yes	2 (50.0)	1 (12.5)	5 (45.5)	6 (31.6)	8 (34.8)
No	2 (50.0)	7 (87.5)	6 (54.5)	13 (68.4)	15 (65.2)
95% Confidence Interval [A]	(6.76, 93.24)	(0.32, 52.65)	(16.75, 76.62)	(12.58, 56.55)	(16.38, 57.27)

表 2.7.3.6-50. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=34)	Total (N=67)	Total (N=79)
Baseline hs-CRP > Baseline Median (1.29 mg/L)	N=1	N=6	N=5	N=11	N=12
Yes	0	2 (33.3)	1 (20.0)	3 (27.3)	3 (25.0)
No	1 (100)	4 (66.7)	4 (80.0)	8 (72.7)	9 (75.0)
95% Confidence Interval [A]	(0.00, 97.50)	(4.33, 77.72)	(0.51, 71.64)	(6.02, 60.97)	(5.49, 57.19)
Baseline Fecal Calprotectin <= Baseline Median (2302.5 ug/g)	N=0	N=1	N=1	N=2	N=2
Yes	0	0	0	0	0
No	0	1 (100)	1 (100)	2 (100)	2 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)	(0.00, 84.19)	(0.00, 84.19)
Baseline Fecal Calprotectin > Baseline Median (2302.5 ug/g)	N=0	N=3	N=1	N=4	N=4
Yes	0	0	1 (100)	1 (25.0)	1 (25.0)
No	0	3 (100)	0	3 (75.0)	3 (75.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 70.76)	(2.50, 100.00)	(0.63, 80.59)	(0.63, 80.59)

表 2.7.3.6-50. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（中間 CSR）（続き）

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
Note: M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
[A] Clopper-Pearson confidence interval for proportion in remission.
[B1] Nominal p-values from a one-sample two-sided chi-square test.
[B2] Adjusted p-values from a sequentially rejective multiple test procedure (details in SAP), testing co-primary and ranked secondary endpoints first for M-SD/M-HD combined (p-value in 'Total' column) and then for individual ADA dose groups (p-values in 'M-HD' column and in 'M-SD' column, respectively) against the respective external placebo rate (here: 24.08%).
[C] Nominal p-value for the exploratory comparison of M-SD vs. M-HD.
Non-responder imputation (NRI): missing data is imputed as not having met the endpoint. Subjects re-randomized due to disease flare are considered as not having met the endpoint at and after their 1st disease flare.
Corticosteroid-Free is defined as subjects receiving systemic corticosteroids (UC related or non-UC related) at baseline who have discontinued systemic corticosteroids prior to week 52.
Clinical remission per Full Mayo Score (FMS) is defined as Mayo Score <= 2 and no individual subscore > 1.
Clinical response per Partial Mayo Score (PMS) is defined as decrease in PMS >= 2 points and >= 30% from baseline.
Clinical remission per Partial Mayo Score (PMS) is defined as PMS <= 2 and no individual subscore > 1.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.2__1.2.4_A

表 2.7.3.6-51. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Overall	N=0	N=2	N=1	N=3	N=3
Yes	0	0	1 (100)	1 (33.3)	1 (33.3)
No	0	2 (100)	0	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(2.50, 100.00)	(0.84, 90.57)	(0.84, 90.57)
P-Value [B1]		0.426	0.076	0.708	
P-Value [C]		0.083			
PMS Remission at Week 8 - Yes	N=0	N=0	N=1	N=1	N=1
Yes	0	0	1 (100)	1 (100)	1 (100)
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(2.50, 100.00)	(2.50, 100.00)	(2.50, 100.00)

表 2.7.3.6-51. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
PMS Remission at Week 8 - No	N=0	N=2	N=0	N=2	N=2
Yes	0	0	0	0	0
No	0	2 (100)	0	2 (100)	2 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(NA, NA)	(0.00, 84.19)	(0.00, 84.19)
I-SD	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
I-HD/I-HD-OL	N=0	N=2	N=1	N=3	N=3
Yes	0	0	1 (100)	1 (33.3)	1 (33.3)
No	0	2 (100)	0	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(2.50, 100.00)	(0.84, 90.57)	(0.84, 90.57)

表 2.7.3.6-51. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
I-HD	N=0	N=1	N=1	N=2	N=2
Yes	0	0	1 (100)	1 (50.0)	1 (50.0)
No	0	1 (100)	0	1 (50.0)	1 (50.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 97.50)	(2.50, 100.00)	(1.26, 98.74)	(1.26, 98.74)
I-HD-OL	N=0	N=1	N=0	N=1	N=1
Yes	0	0	0	0	0
No	0	1 (100)	0	1 (100)	1 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 97.50)	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)
Sex - Male	N=0	N=2	N=1	N=3	N=3
Yes	0	0	1 (100)	1 (33.3)	1 (33.3)
No	0	2 (100)	0	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(2.50, 100.00)	(0.84, 90.57)	(0.84, 90.57)

表 2.7.3.6-51. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Sex - Female	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Age < 13 Years	N=0	N=0	N=1	N=1	N=1
Yes	0	0	1 (100)	1 (100)	1 (100)
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(2.50, 100.00)	(2.50, 100.00)	(2.50, 100.00)
Age >= 13 Years	N=0	N=2	N=0	N=2	N=2
Yes	0	0	0	0	0
No	0	2 (100)	0	2 (100)	2 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(NA, NA)	(0.00, 84.19)	(0.00, 84.19)

表 2.7.3.6-51. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Ethnicity - White	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Ethnicity - Non-white	N=0	N=2	N=1	N=3	N=3
Yes	0	0	1 (100)	1 (33.3)	1 (33.3)
No	0	2 (100)	0	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(2.50, 100.00)	(0.84, 90.57)	(0.84, 90.57)
Geographic Region - Japan	N=0	N=2	N=1	N=3	N=3
Yes	0	0	1 (100)	1 (33.3)	1 (33.3)
No	0	2 (100)	0	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(2.50, 100.00)	(0.84, 90.57)	(0.84, 90.57)

表 2.7.3.6-51. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Baseline Mayo Score <= 9	N=0	N=2	N=1	N=3	N=3
Yes	0	0	1 (100)	1 (33.3)	1 (33.3)
No	0	2 (100)	0	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(2.50, 100.00)	(0.84, 90.57)	(0.84, 90.57)
Baseline Mayo Score > 9	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Prior Anti-TNF Use	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)

表 2.7.3.6-51. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Prior Anti-TNF Naive	N=0	N=2	N=1	N=3	N=3
Yes	0	0	1 (100)	1 (33.3)	1 (33.3)
No	0	2 (100)	0	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(2.50, 100.00)	(0.84, 90.57)	(0.84, 90.57)
Baseline Corticosteroid Use - Yes	N=0	N=2	N=1	N=3	N=3
Yes	0	0	1 (100)	1 (33.3)	1 (33.3)
No	0	2 (100)	0	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(2.50, 100.00)	(0.84, 90.57)	(0.84, 90.57)
Baseline Corticosteroid Use - No	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)

表 2.7.3.6-51. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Baseline IMM Use - Yes	N=0	N=2	N=1	N=3	N=3
Yes	0	0	1 (100)	1 (33.3)	1 (33.3)
No	0	2 (100)	0	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(2.50, 100.00)	(0.84, 90.57)	(0.84, 90.57)
Baseline IMM Use - No	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Weight < 40 kg	N=0	N=0	N=1	N=1	N=1
Yes	0	0	1 (100)	1 (100)	1 (100)
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(2.50, 100.00)	(2.50, 100.00)	(2.50, 100.00)

表 2.7.3.6-51. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Weight >= 40 kg	N=0	N=2	N=0	N=2	N=2
Yes	0	0	0	0	0
No	0	2 (100)	0	2 (100)	2 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(NA, NA)	(0.00, 84.19)	(0.00, 84.19)
Pancolitis - Yes	N=0	N=2	N=1	N=3	N=3
Yes	0	0	1 (100)	1 (33.3)	1 (33.3)
No	0	2 (100)	0	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(2.50, 100.00)	(0.84, 90.57)	(0.84, 90.57)
Pancolitis - No	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)

表 2.7.3.6-51. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Disease Duration <= Baseline Median (19.1 Months)	N=0	N=1	N=0	N=1	N=1
Yes	0	0	0	0	0
No	0	1 (100)	0	1 (100)	1 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 97.50)	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)
Disease Duration > Baseline Median (19.1 Months)	N=0	N=1	N=1	N=2	N=2
Yes	0	0	1 (100)	1 (50.0)	1 (50.0)
No	0	1 (100)	0	1 (50.0)	1 (50.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 97.50)	(2.50, 100.00)	(1.26, 98.74)	(1.26, 98.74)
Baseline hs-CRP <= Baseline Median (1.29 mg/L)	N=0	N=0	N=1	N=1	N=1
Yes	0	0	1 (100)	1 (100)	1 (100)
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(2.50, 100.00)	(2.50, 100.00)	(2.50, 100.00)

表 2.7.3.6-51. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	Total (N=5)	Total (N=5)
Baseline hs-CRP > Baseline Median (1.29 mg/L)	N=0	N=2	N=0	N=2	N=2
Yes	0	0	0	0	0
No	0	2 (100)	0	2 (100)	2 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(NA, NA)	(0.00, 84.19)	(0.00, 84.19)
Baseline Fecal Calprotectin <= Baseline Median (2302.5 ug/g)	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Baseline Fecal Calprotectin > Baseline Median (2302.5 ug/g)	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)

表 2.7.3.6-51. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（中間 CSR）（続き）

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
Note: M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
[A] Clopper-Pearson confidence interval for proportion in remission.
[B1] Nominal p-values from a one-sample two-sided chi-square test.
[C] Nominal p-value for the exploratory comparison of M-SD vs. M-HD.
Non-responder imputation (NRI): missing data is imputed as not having met the endpoint. Subjects re-randomized due to disease flare are considered as not having met the endpoint at and after their 1st disease flare.
Corticosteroid-Free is defined as subjects receiving systemic corticosteroids (UC related or non-UC related) at baseline who have discontinued systemic corticosteroids prior to week 52.
Clinical remission per Full Mayo Score (FMS) is defined as Mayo Score <= 2 and no individual subscore > 1.
Clinical response per Partial Mayo Score (PMS) is defined as decrease in PMS >= 2 points and >= 30% from baseline.
Clinical remission per Partial Mayo Score (PMS) is defined as PMS <= 2 and no individual subscore > 1.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.2__1.2.4_J

表 2.7.3.6-52. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善，寛解を達成した被験者の割合（mNRI）（統合 RR 集団，M11-290 試験）（中間 CSR）

Endpoint Endpoint Met	With Re-Induction Dose M-SD	 M-HD	 Total	 M-PL	 Total
FMS Response at Week 52 in Week 8 PMS Responders	N=4	N=3	N=7	N=4	N=11
Yes	1 (25.0)	1 (33.3)	2 (28.6)	1 (25.0)	3 (27.3)
No	3 (75.0)	2 (66.7)	5 (71.4)	3 (75.0)	8 (72.7)
95% Confidence Interval [A]	(0.63, 80.59)	(0.84, 90.57)	(3.67, 70.96)	(0.63, 80.59)	(6.02, 60.97)
FMS Remission at Week 52 in Week 8 PMS Responders	N=4	N=3	N=7	N=4	N=11
Yes	0	0	0	1 (25.0)	1 (9.1)
No	4 (100)	3 (100)	7 (100)	3 (75.0)	10 (90.9)
95% Confidence Interval [A]	(0.00, 60.24)	(0.00, 70.76)	(0.00, 40.96)	(0.63, 80.59)	(0.23, 41.28)

表 2.7.3.6-52. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善，寛解を達成した被験者の割合（mNRI）（統合 RR 集団，M11-290 試験）（中間 CSR）（続き）

Endpoint Endpoint Met	Without Re-Induction Dose M-SD	 M-HD	 Total	 M-PL	 Total
FMS Response at Week 52 in Week 8 PMS Responders	N=4	N=7	N=11	N=3	N=14
Yes	1 (25.0)	1 (14.3)	2 (18.2)	1 (33.3)	3 (21.4)
No	3 (75.0)	6 (85.7)	9 (81.8)	2 (66.7)	11 (78.6)
95% Confidence Interval [A]	(0.63, 80.59)	(0.36, 57.87)	(2.28, 51.78)	(0.84, 90.57)	(4.66, 50.80)
FMS Remission at Week 52 in Week 8 PMS Responders	N=4	N=7	N=11	N=3	N=14
Yes	0	0	0	0	0
No	4 (100)	7 (100)	11 (100)	3 (100)	14 (100)
95% Confidence Interval [A]	(0.00, 60.24)	(0.00, 40.96)	(0.00, 28.49)	(0.00, 70.76)	(0.00, 23.16)

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
Note: M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
[A] Clopper-Pearson confidence interval for proportion in remission, response.
Modified NRI (mNRI): missing data is imputed as not having met the endpoint. Subjects re-randomized due to disease flare are considered as 'Non-Responders' at and after the switch to the open-label therapy (2nd disease flare).
FMS = full mayo score, PMS = partial mayo score.
Clinical response per full Mayo Score (FMS) is defined as decrease in Mayo Score >= 3 points and >= 30% from baseline.
Clinical remission per full Mayo Score (FMS) is defined as Mayo Score <= 2 and no individual subscore > 1.
Clinical response per Partial Mayo Score (PMS) is defined as decrease in PMS >= 2 points and >= 30% from baseline.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.2__3_A

表 2.7.3.6-53. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（中間 CSR）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Body						
Week 8						
I-SD	29	10.4	10.3	-0.1	(-0.73, 0.53)	0.31
I-SD/-	9	9.7	9.1	-0.6	(-1.78, 0.67)	0.53
I-SD/M-PL	4	12.0	12.3	0.3	(-1.75, 2.25)	0.63
I-SD/M-SD	7	10.0	10.6	0.6	(-1.34, 2.49)	0.78
I-SD/M-HD	9	10.9	10.6	-0.3	(-1.55, 0.88)	0.53
I-HD	47	9.8	10.0	0.2	(-0.26, 0.72)	0.24
I-HD/-	7	8.0	8.6	0.6	(-0.72, 1.86)	0.53
I-HD/M-PL	8	9.1	10.3	1.1	(-0.99, 3.24)	0.90
I-HD/M-SD	15	10.6	10.8	0.2	(-0.59, 0.99)	0.37
I-HD/M-HD	17	10.1	9.8	-0.3	(-1.02, 0.43)	0.34
I-SD + I-HD Total	76	10.0	10.1	0.1	(-0.27, 0.49)	0.19
I-HD-OL	16	9.4	9.8	0.4	(-0.34, 1.22)	0.36
I-HD-OL/-	2	8.5	9.5	1.0		0.00
I-HD-OL/M-SD	8	9.1	9.5	0.4	(-0.80, 1.55)	0.50
I-HD-OL/M-HD	6	10.0	10.3	0.3	(-1.62, 2.29)	0.76
M-SD Total	30	10.1	10.4	0.3	(-0.24, 0.91)	0.28
M-HD Total	32	10.3	10.1	-0.2	(-0.73, 0.36)	0.27
M-SD + M-HD Total	62	10.2	10.3	0.1	(-0.33, 0.45)	0.19

表 2.7.3.6-53. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Body (Cont.)						
Week 26						
I-SD	19	10.8	11.1	0.3	(-0.47, 1.00)	0.35
I-SD/M-PL	4	12.0	11.8	-0.3	(-2.97, 2.47)	0.85
I-SD/M-SD	7	10.0	10.1	0.1	(-1.58, 1.87)	0.70
I-SD/M-HD	8	10.9	11.5	0.6	(-0.37, 1.62)	0.42
I-HD	40	10.1	10.3	0.2	(-0.38, 0.83)	0.30
I-HD/M-PL	8	9.1	9.5	0.4	(-2.03, 2.78)	1.02
I-HD/M-SD	15	10.6	11.1	0.5	(-0.40, 1.47)	0.43
I-HD/M-HD	17	10.1	10.0	-0.1	(-0.91, 0.67)	0.37
I-SD + I-HD Total	59	10.3	10.6	0.2	(-0.22, 0.70)	0.23
I-HD-OL	14	9.5	9.8	0.3	(-0.60, 1.18)	0.41
I-HD-OL/M-SD	8	9.1	9.5	0.4	(-0.80, 1.55)	0.50
I-HD-OL/M-HD	6	10.0	10.2	0.2	(-1.76, 2.09)	0.75
M-SD Total	30	10.1	10.5	0.4	(-0.20, 1.00)	0.29
M-HD Total	31	10.3	10.4	0.1	(-0.42, 0.68)	0.27
M-SD + M-HD Total	61	10.2	10.4	0.3	(-0.13, 0.66)	0.20

表 2.7.3.6-53. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Body (Cont.)						
Week 52						
I-SD	19	10.8	11.4	0.6	(-0.31, 1.46)	0.42
I-SD/M-PL	4	12.0	11.5	-0.5	(-3.81, 2.81)	1.04
I-SD/M-SD	7	10.0	10.9	0.9	(-1.03, 2.74)	0.77
I-SD/M-HD	8	10.9	11.8	0.9	(-0.42, 2.17)	0.55
I-HD	40	10.1	10.5	0.4	(-0.22, 1.02)	0.31
I-HD/M-PL	8	9.1	9.9	0.8	(-1.47, 2.97)	0.94
I-HD/M-SD	15	10.6	11.3	0.7	(-0.12, 1.58)	0.40
I-HD/M-HD	17	10.1	10.1	-0.1	(-1.05, 0.93)	0.47
I-SD + I-HD Total	59	10.3	10.8	0.5	(-0.04, 0.95)	0.25
I-HD-OL	14	9.5	9.9	0.4	(-0.67, 1.53)	0.51
I-HD-OL/M-SD	8	9.1	9.6	0.5	(-1.29, 2.29)	0.76
I-HD-OL/M-HD	6	10.0	10.3	0.3	(-1.50, 2.17)	0.71
M-SD Total	30	10.1	10.8	0.7	(0.04, 1.36)	0.32
M-HD Total	31	10.3	10.5	0.3	(-0.40, 0.91)	0.32
M-SD + M-HD Total	61	10.2	10.7	0.5	(0.02, 0.93)	0.23

表 2.7.3.6-53. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Bowel						
Week 8						
I-SD	29	21.05	25.38	4.33	(2.079, 6.574)	1.097
I-SD/-	9	21.11	22.78	1.67	(-1.408, 4.741)	1.333
I-SD/M-PL	4	25.00	28.00	3.00	(0.402, 5.598)	0.816
I-SD/M-SD	7	20.71	27.00	6.29	(-0.334, 12.906)	2.705
I-SD/M-HD	9	19.50	25.56	6.05	(0.554, 11.551)	2.384
I-HD	47	20.66	25.94	5.28	(3.721, 6.832)	0.773
I-HD/-	7	16.71	15.86	-0.86	(-3.386, 1.672)	1.033
I-HD/M-PL	8	18.88	26.50	7.63	(1.548, 13.702)	2.570
I-HD/M-SD	15	20.33	26.93	6.60	(4.377, 8.823)	1.036
I-HD/M-HD	17	23.41	28.94	5.53	(3.244, 7.815)	1.078
I-SD + I-HD Total	76	20.81	25.72	4.91	(3.653, 6.175)	0.633
I-HD-OL	16	18.75	25.25	6.50	(2.336, 10.664)	1.954
I-HD-OL/-	2	18.50	11.50	-7.00	(-57.825, 43.825)	4.000
I-HD-OL/M-SD	8	19.25	25.88	6.63	(1.834, 11.416)	2.026
I-HD-OL/M-HD	6	18.17	29.00	10.83	(4.592, 17.074)	2.428
M-SD Total	30	20.13	26.67	6.53	(4.617, 8.449)	0.937
M-HD Total	32	21.33	28.00	6.67	(4.591, 8.751)	1.020
M-SD + M-HD Total	62	20.75	27.35	6.60	(5.226, 7.982)	0.689

表 2.7.3.6-53. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Bowel (Cont.)						
Week 26						
I-SD	19	21.24	28.32	7.08	(3.757, 10.398)	1.580
I-SD/M-PL	4	25.00	29.50	4.50	(-0.274, 9.274)	1.500
I-SD/M-SD	7	20.71	26.86	6.14	(-1.167, 13.453)	2.988
I-SD/M-HD	8	19.82	29.00	9.18	(2.990, 15.378)	2.619
I-HD	40	21.35	27.90	6.55	(4.616, 8.484)	0.956
I-HD/M-PL	8	18.88	25.75	6.88	(-0.054, 13.804)	2.930
I-HD/M-SD	15	20.33	26.47	6.13	(2.785, 9.481)	1.561
I-HD/M-HD	17	23.41	30.18	6.76	(4.102, 9.427)	1.256
I-SD + I-HD Total	59	21.31	28.03	6.72	(5.085, 8.355)	0.817
I-HD-OL	14	18.79	27.14	8.36	(3.707, 13.007)	2.152
I-HD-OL/M-SD	8	19.25	25.50	6.25	(-1.076, 13.576)	3.098
I-HD-OL/M-HD	6	18.17	29.33	11.17	(4.161, 18.173)	2.725
M-SD Total	30	20.13	26.30	6.17	(3.550, 8.783)	1.279
M-HD Total	31	21.47	29.71	8.24	(5.988, 10.494)	1.103
M-SD + M-HD Total	61	20.81	28.03	7.22	(5.528, 8.914)	0.846

表 2.7.3.6-53. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Bowel (Cont.)						
Week 52						
I-SD	19	21.24	27.55	6.32	(2.580, 10.052)	1.778
I-SD/M-PL	4	25.00	29.50	4.50	(-0.274, 9.274)	1.500
I-SD/M-SD	7	20.71	25.43	4.71	(-1.552, 10.980)	2.561
I-SD/M-HD	8	19.82	28.44	8.63	(0.234, 17.016)	3.548
I-HD	40	21.35	27.85	6.50	(4.582, 8.418)	0.948
I-HD/M-PL	8	18.88	26.63	7.75	(0.860, 14.640)	2.914
I-HD/M-SD	15	20.33	27.47	7.13	(3.779, 10.488)	1.564
I-HD/M-HD	17	23.41	28.76	5.35	(2.874, 7.832)	1.169
I-SD + I-HD Total	59	21.31	27.75	6.44	(4.735, 8.146)	0.852
I-HD-OL	14	18.79	27.64	8.86	(5.394, 12.320)	1.603
I-HD-OL/M-SD	8	19.25	26.25	7.00	(2.714, 11.286)	1.813
I-HD-OL/M-HD	6	18.17	29.50	11.33	(4.383, 18.284)	2.704
M-SD Total	30	20.13	26.67	6.53	(4.337, 8.730)	1.074
M-HD Total	31	21.47	28.82	7.35	(4.785, 9.925)	1.258
M-SD + M-HD Total	61	20.81	27.76	6.95	(5.302, 8.599)	0.824

表 2.7.3.6-53. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Emotional						
Week 8						
I-SD	29	20.1	23.3	3.2	(1.01, 5.33)	1.05
I-SD/-	9	18.3	19.6	1.2	(-3.74, 6.19)	2.15
I-SD/M-PL	4	23.0	27.8	4.8	(-0.51, 10.01)	1.65
I-SD/M-SD	7	20.9	24.3	3.4	(-3.30, 10.16)	2.75
I-SD/M-HD	9	20.0	24.2	4.2	(0.75, 7.70)	1.51
I-HD	47	21.2	24.2	3.0	(1.73, 4.27)	0.63
I-HD/-	7	16.1	14.6	-1.6	(-3.49, 0.34)	0.78
I-HD/M-PL	8	20.1	25.1	5.0	(-0.29, 10.29)	2.24
I-HD/M-SD	15	21.3	25.4	4.1	(2.01, 6.12)	0.96
I-HD/M-HD	17	23.6	26.6	3.0	(1.32, 4.68)	0.79
I-SD + I-HD Total	76	20.8	23.8	3.1	(1.96, 4.17)	0.56
I-HD-OL	16	19.8	24.1	4.4	(2.15, 6.60)	1.04
I-HD-OL/-	2	17.0	17.5	0.5	(-18.56, 19.56)	1.50
I-HD-OL/M-SD	8	21.0	25.0	4.0	(-0.17, 8.17)	1.76
I-HD-OL/M-HD	6	19.0	25.2	6.2	(3.48, 8.86)	1.05
M-SD Total	30	21.1	25.0	3.9	(2.08, 5.72)	0.89
M-HD Total	32	21.7	25.7	3.9	(2.62, 5.25)	0.64
M-SD + M-HD Total	62	21.4	25.4	3.9	(2.84, 5.00)	0.54

表 2.7.3.6-53. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Emotional (Cont.)						
Week 26						
I-SD	19	21.3	27.9	6.6	(3.29, 9.87)	1.57
I-SD/M-PL	4	23.0	29.8	6.8	(-3.83, 17.33)	3.33
I-SD/M-SD	7	20.9	25.7	4.9	(-3.03, 12.75)	3.23
I-SD/M-HD	8	20.9	28.9	8.0	(3.17, 12.83)	2.04
I-HD	40	22.1	26.8	4.7	(3.11, 6.29)	0.79
I-HD/M-PL	8	20.1	25.5	5.4	(-0.17, 10.92)	2.34
I-HD/M-SD	15	21.3	25.5	4.1	(1.43, 6.84)	1.26
I-HD/M-HD	17	23.6	28.5	4.9	(2.60, 7.17)	1.08
I-SD + I-HD Total	59	21.8	27.1	5.3	(3.83, 6.78)	0.74
I-HD-OL	14	20.1	26.1	6.0	(3.11, 8.89)	1.34
I-HD-OL/M-SD	8	21.0	26.3	5.3	(1.21, 9.29)	1.71
I-HD-OL/M-HD	6	19.0	26.0	7.0	(1.21, 12.79)	2.25
M-SD Total	30	21.1	25.7	4.6	(2.47, 6.73)	1.04
M-HD Total	31	22.0	28.1	6.1	(4.25, 7.94)	0.90
M-SD + M-HD Total	61	21.6	26.9	5.4	(3.98, 6.74)	0.69

表 2.7.3.6-53. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Emotional (Cont.)						
Week 52						
I-SD	19	21.3	27.8	6.5	(2.98, 10.08)	1.69
I-SD/M-PL	4	23.0	29.8	6.8	(-4.97, 18.47)	3.68
I-SD/M-SD	7	20.9	25.4	4.6	(-1.86, 11.00)	2.63
I-SD/M-HD	8	20.9	29.0	8.1	(1.22, 15.03)	2.92
I-HD	40	22.1	26.0	3.9	(2.15, 5.70)	0.88
I-HD/M-PL	8	20.1	25.0	4.9	(-0.40, 10.15)	2.23
I-HD/M-SD	15	21.3	26.7	5.3	(2.25, 8.41)	1.44
I-HD/M-HD	17	23.6	25.8	2.2	(-0.33, 4.80)	1.21
I-SD + I-HD Total	59	21.8	26.6	4.8	(3.14, 6.39)	0.81
I-HD-OL	14	20.1	26.0	5.9	(2.55, 9.16)	1.53
I-HD-OL/M-SD	8	21.0	27.1	6.1	(3.18, 9.07)	1.25
I-HD-OL/M-HD	6	19.0	24.5	5.5	(-3.12, 14.12)	3.35
M-SD Total	30	21.1	26.5	5.4	(3.38, 7.35)	0.97
M-HD Total	31	22.0	26.4	4.4	(1.87, 6.90)	1.23
M-SD + M-HD Total	61	21.6	26.4	4.9	(3.30, 6.44)	0.78

表 2.7.3.6-53. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Social						
Week 8						
I-SD	29	40.01	43.17	3.16	(0.678, 5.644)	1.212
I-SD/-	9	38.54	38.44	-0.10	(-3.875, 3.679)	1.638
I-SD/M-PL	4	43.00	46.00	3.00	(-1.684, 7.684)	1.472
I-SD/M-SD	7	43.00	47.71	4.71	(-4.295, 13.724)	3.682
I-SD/M-HD	9	37.83	43.11	5.28	(0.976, 9.592)	1.868
I-HD	47	41.18	46.53	5.34	(3.653, 7.036)	0.840
I-HD/-	7	36.29	35.43	-0.86	(-4.832, 3.118)	1.625
I-HD/M-PL	8	36.88	45.25	8.38	(1.439, 15.311)	2.933
I-HD/M-SD	15	42.37	49.45	7.08	(4.864, 9.296)	1.033
I-HD/M-HD	17	44.18	49.12	4.94	(2.646, 7.237)	1.083
I-SD + I-HD Total	76	40.74	45.25	4.51	(3.114, 5.909)	0.702
I-HD-OL	16	41.25	46.88	5.63	(2.675, 8.575)	1.384
I-HD-OL/-	2	41.50	36.50	-5.00		0.000
I-HD-OL/M-SD	8	43.88	50.13	6.25	(2.626, 9.874)	1.532
I-HD-OL/M-HD	6	37.67	46.00	8.33	(4.842, 11.824)	1.358
M-SD Total	30	42.92	49.23	6.31	(4.168, 8.446)	1.046
M-HD Total	32	41.17	46.84	5.67	(3.987, 7.360)	0.827
M-SD + M-HD Total	62	42.02	48.00	5.98	(4.665, 7.295)	0.658

表 2.7.3.6-53. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Social (Cont.)						
Week 26						
I-SD	19	41.26	48.68	7.42	(3.020, 11.822)	2.095
I-SD/M-PL	4	43.00	48.75	5.75	(-5.455, 16.955)	3.521
I-SD/M-SD	7	43.00	48.14	5.14	(-6.622, 16.907)	4.808
I-SD/M-HD	8	38.88	49.13	10.25	(5.063, 15.437)	2.194
I-HD	40	42.04	48.29	6.26	(4.268, 8.242)	0.982
I-HD/M-PL	8	36.88	44.75	7.88	(0.789, 14.961)	2.997
I-HD/M-SD	15	42.37	48.18	5.81	(2.913, 8.715)	1.353
I-HD/M-HD	17	44.18	50.06	5.88	(2.756, 9.009)	1.475
I-SD + I-HD Total	59	41.79	48.42	6.63	(4.749, 8.512)	0.940
I-HD-OL	14	41.21	49.07	7.86	(5.296, 10.418)	1.185
I-HD-OL/M-SD	8	43.88	50.75	6.88	(4.806, 8.944)	0.875
I-HD-OL/M-HD	6	37.67	46.83	9.17	(2.616, 15.718)	2.548
M-SD Total	30	42.92	48.86	5.94	(3.337, 8.544)	1.273
M-HD Total	31	41.55	49.19	7.65	(5.348, 9.943)	1.125
M-SD + M-HD Total	61	42.22	49.03	6.81	(5.111, 8.503)	0.848

表 2.7.3.6-53. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Social (Cont.)						
Week 52						
I-SD	19	41.26	50.00	8.74	(3.867, 13.607)	2.318
I-SD/M-PL	4	43.00	50.75	7.75	(-1.653, 17.153)	2.955
I-SD/M-SD	7	43.00	48.14	5.14	(-5.285, 15.571)	4.262
I-SD/M-HD	8	38.88	51.25	12.38	(3.607, 21.143)	3.708
I-HD	40	42.04	48.02	5.98	(4.051, 7.909)	0.954
I-HD/M-PL	8	36.88	45.00	8.13	(1.153, 15.097)	2.949
I-HD/M-SD	15	42.37	48.72	6.35	(3.211, 9.483)	1.462
I-HD/M-HD	17	44.18	48.82	4.65	(2.032, 7.262)	1.234
I-SD + I-HD Total	59	41.79	48.66	6.87	(4.886, 8.850)	0.990
I-HD-OL	14	41.21	48.93	7.71	(3.888, 11.540)	1.771
I-HD-OL/M-SD	8	43.88	50.13	6.25	(3.294, 9.206)	1.250
I-HD-OL/M-HD	6	37.67	47.33	9.67	(-0.215, 19.548)	3.844
M-SD Total	30	42.92	48.96	6.04	(3.534, 8.547)	1.226
M-HD Total	31	41.55	49.16	7.61	(4.630, 10.595)	1.460
M-SD + M-HD Total	61	42.22	49.06	6.84	(4.932, 8.747)	0.954

表 2.7.3.6-53. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Systemic						
Week 8						
I-SD	29	8.21	9.42	1.22	(-0.010, 2.442)	0.598
I-SD/-	9	7.22	6.89	-0.33	(-1.665, 0.998)	0.577
I-SD/M-PL	4	11.00	10.25	-0.75	(-3.468, 1.968)	0.854
I-SD/M-SD	7	7.86	10.89	3.04	(-0.402, 6.478)	1.406
I-SD/M-HD	9	8.22	10.44	2.22	(-0.570, 5.014)	1.211
I-HD	47	8.40	10.81	2.40	(1.586, 3.223)	0.407
I-HD/-	7	7.71	7.29	-0.43	(-3.196, 2.339)	1.131
I-HD/M-PL	8	8.38	11.25	2.88	(0.855, 4.895)	0.854
I-HD/M-SD	15	8.33	11.53	3.20	(1.941, 4.459)	0.587
I-HD/M-HD	17	8.76	11.41	2.65	(1.228, 4.066)	0.669
I-SD + I-HD Total	76	8.33	10.28	1.95	(1.266, 2.636)	0.344
I-HD-OL	16	8.38	10.44	2.06	(0.600, 3.525)	0.686
I-HD-OL/-	2	7.50	4.00	-3.50	(-9.853, 2.853)	0.500
I-HD-OL/M-SD	8	8.63	10.75	2.13	(0.681, 3.569)	0.611
I-HD-OL/M-HD	6	8.33	12.17	3.83	(2.289, 5.378)	0.601
M-SD Total	30	8.30	11.18	2.88	(1.939, 3.812)	0.458
M-HD Total	32	8.53	11.28	2.75	(1.730, 3.770)	0.500
M-SD + M-HD Total	62	8.42	11.23	2.81	(2.136, 3.486)	0.337

表 2.7.3.6-53. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Systemic (Cont.)						
Week 26						
I-SD	19	8.68	10.95	2.26	(0.855, 3.672)	0.670
I-SD/M-PL	4	11.00	11.00	0.00	(-3.898, 3.898)	1.225
I-SD/M-SD	7	7.86	10.14	2.29	(-1.079, 5.651)	1.375
I-SD/M-HD	8	8.25	11.63	3.38	(1.768, 4.982)	0.680
I-HD	40	8.53	11.23	2.70	(1.852, 3.548)	0.419
I-HD/M-PL	8	8.38	10.50	2.13	(0.056, 4.194)	0.875
I-HD/M-SD	15	8.33	11.60	3.27	(1.599, 4.934)	0.777
I-HD/M-HD	17	8.76	11.24	2.47	(1.210, 3.732)	0.595
I-SD + I-HD Total	59	8.58	11.14	2.56	(1.849, 3.269)	0.355
I-HD-OL	14	8.50	11.29	2.79	(1.134, 4.437)	0.764
I-HD-OL/M-SD	8	8.63	11.13	2.50	(-0.218, 5.218)	1.150
I-HD-OL/M-HD	6	8.33	11.50	3.17	(0.561, 5.773)	1.014
M-SD Total	30	8.30	11.13	2.83	(1.660, 4.006)	0.574
M-HD Total	31	8.55	11.39	2.84	(1.996, 3.681)	0.412
M-SD + M-HD Total	61	8.43	11.26	2.84	(2.139, 3.533)	0.348

表 2.7.3.6-53. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Systemic (Cont.)						
Week 52						
I-SD	19	8.68	11.21	2.53	(0.966, 4.087)	0.743
I-SD/M-PL	4	11.00	11.50	0.50	(-4.447, 5.447)	1.555
I-SD/M-SD	7	7.86	10.57	2.71	(-0.097, 5.525)	1.149
I-SD/M-HD	8	8.25	11.63	3.38	(0.516, 6.234)	1.209
I-HD	40	8.53	11.13	2.60	(1.732, 3.468)	0.429
I-HD/M-PL	8	8.38	10.75	2.38	(0.330, 4.420)	0.865
I-HD/M-SD	15	8.33	11.47	3.13	(1.500, 4.766)	0.761
I-HD/M-HD	17	8.76	11.00	2.24	(0.845, 3.626)	0.656
I-SD + I-HD Total	59	8.58	11.15	2.58	(1.829, 3.323)	0.373
I-HD-OL	14	8.50	10.93	2.43	(0.738, 4.119)	0.782
I-HD-OL/M-SD	8	8.63	11.13	2.50	(0.311, 4.689)	0.926
I-HD-OL/M-HD	6	8.33	10.67	2.33	(-1.402, 6.068)	1.453
M-SD Total	30	8.30	11.17	2.87	(1.821, 3.912)	0.511
M-HD Total	31	8.55	11.10	2.55	(1.449, 3.648)	0.538
M-SD + M-HD Total	61	8.43	11.13	2.70	(1.967, 3.443)	0.369

表 2.7.3.6-53. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Treatment						
Week 8						
I-SD	29	10.2	10.8	0.6	(-0.06, 1.31)	0.33
I-SD/-	9	8.9	9.0	0.1	(-1.54, 1.76)	0.72
I-SD/M-PL	4	12.5	11.8	-0.8	(-4.51, 3.01)	1.18
I-SD/M-SD	7	10.3	11.9	1.6	(0.67, 2.47)	0.37
I-SD/M-HD	9	10.4	11.4	1.0	(-0.02, 2.02)	0.44
I-HD	47	10.3	11.0	0.7	(-0.00, 1.36)	0.34
I-HD/-	7	8.3	7.4	-0.9	(-1.98, 0.27)	0.46
I-HD/M-PL	8	9.1	11.1	2.0	(-0.86, 4.86)	1.21
I-HD/M-SD	15	10.8	11.5	0.7	(-0.35, 1.68)	0.47
I-HD/M-HD	17	11.4	12.1	0.7	(-0.44, 1.85)	0.54
I-SD + I-HD Total	76	10.3	10.9	0.7	(0.17, 1.14)	0.24
I-HD-OL	16	10.8	11.6	0.8	(0.03, 1.60)	0.37
I-HD-OL/-	2	11.5	12.0	0.5	(-18.56, 19.56)	1.50
I-HD-OL/M-SD	8	11.3	11.6	0.4	(-0.96, 1.71)	0.56
I-HD-OL/M-HD	6	9.8	11.3	1.5	(0.40, 2.60)	0.43
M-SD Total	30	10.8	11.6	0.8	(0.19, 1.41)	0.30
M-HD Total	32	10.8	11.8	0.9	(0.28, 1.59)	0.32
M-SD + M-HD Total	62	10.8	11.7	0.9	(0.44, 1.31)	0.22

表 2.7.3.6-53. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Treatment (Cont.)						
Week 26						
I-SD	19	11.0	11.9	0.9	(0.03, 1.76)	0.41
I-SD/M-PL	4	12.5	13.3	0.8	(-0.77, 2.27)	0.48
I-SD/M-SD	7	10.3	11.0	0.7	(-1.26, 2.69)	0.81
I-SD/M-HD	8	10.9	12.0	1.1	(-0.51, 2.76)	0.69
I-HD	40	10.7	11.6	0.9	(0.06, 1.69)	0.40
I-HD/M-PL	8	9.1	11.3	2.1	(-1.02, 5.27)	1.33
I-HD/M-SD	15	10.8	11.6	0.8	(-0.37, 1.97)	0.55
I-HD/M-HD	17	11.4	11.7	0.4	(-0.77, 1.47)	0.53
I-SD + I-HD Total	59	10.8	11.7	0.9	(0.28, 1.49)	0.30
I-HD-OL	14	10.6	12.1	1.5	(0.16, 2.84)	0.62
I-HD-OL/M-SD	8	11.3	13.0	1.8	(-0.65, 4.15)	1.01
I-HD-OL/M-HD	6	9.8	11.0	1.2	(-0.38, 2.71)	0.60
M-SD Total	30	10.8	11.8	1.0	(0.18, 1.89)	0.42
M-HD Total	31	10.9	11.6	0.7	(-0.02, 1.44)	0.36
M-SD + M-HD Total	61	10.9	11.7	0.9	(0.32, 1.42)	0.27

表 2.7.3.6-53. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Treatment (Cont.)						
Week 52						
I-SD	19	11.0	12.0	1.0	(0.02, 1.98)	0.47
I-SD/M-PL	4	12.5	13.5	1.0	(-1.25, 3.25)	0.71
I-SD/M-SD	7	10.3	10.9	0.6	(-1.02, 2.16)	0.65
I-SD/M-HD	8	10.9	12.3	1.4	(-0.81, 3.56)	0.92
I-HD	40	10.7	11.4	0.7	(-0.03, 1.48)	0.37
I-HD/M-PL	8	9.1	10.9	1.8	(-0.77, 4.27)	1.06
I-HD/M-SD	15	10.8	11.7	0.9	(-0.16, 2.03)	0.51
I-HD/M-HD	17	11.4	11.4	0.1	(-1.11, 1.23)	0.55
I-SD + I-HD Total	59	10.8	11.6	0.8	(0.23, 1.40)	0.29
I-HD-OL	14	10.6	11.9	1.3	(0.02, 2.56)	0.59
I-HD-OL/M-SD	8	11.3	12.3	1.0	(-1.10, 3.10)	0.89
I-HD-OL/M-HD	6	9.8	11.5	1.7	(-0.29, 3.62)	0.76
M-SD Total	30	10.8	11.7	0.9	(0.12, 1.62)	0.37
M-HD Total	31	10.9	11.6	0.7	(-0.15, 1.57)	0.42
M-SD + M-HD Total	61	10.9	11.7	0.8	(0.23, 1.34)	0.28

表 2.7.3.6-53. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III Total						
Week 8						
I-SD	29	110.03	122.42	12.39	(4.627, 20.160)	3.791
I-SD/-	9	103.76	105.78	2.01	(-9.864, 13.890)	5.151
I-SD/M-PL	4	126.50	136.00	9.50	(1.232, 17.768)	2.598
I-SD/M-SD	7	112.71	132.32	19.61	(-6.687, 45.905)	10.747
I-SD/M-HD	9	106.89	125.33	18.45	(3.237, 33.658)	6.596
I-HD	47	111.54	128.48	16.94	(11.827, 22.055)	2.541
I-HD/-	7	93.14	89.14	-4.00	(-11.920, 3.920)	3.237
I-HD/M-PL	8	102.50	129.50	27.00	(6.352, 47.648)	8.732
I-HD/M-SD	15	113.77	135.58	21.81	(14.943, 28.684)	3.203
I-HD/M-HD	17	121.41	137.94	16.53	(9.665, 23.394)	3.238
I-SD + I-HD Total	76	110.97	126.17	15.21	(10.951, 19.460)	2.136
I-HD-OL	16	108.25	128.06	19.81	(9.749, 29.876)	4.722
I-HD-OL/-	2	104.50	91.00	-13.50	(-32.559, 5.559)	1.500
I-HD-OL/M-SD	8	113.13	132.88	19.75	(6.685, 32.815)	5.525
I-HD-OL/M-HD	6	103.00	134.00	31.00	(18.888, 43.112)	4.712
M-SD Total	30	113.35	134.10	20.75	(14.263, 27.235)	3.171
M-HD Total	32	113.87	133.66	19.78	(14.136, 25.428)	2.768
M-SD + M-HD Total	62	113.62	133.87	20.25	(16.090, 24.410)	2.080

表 2.7.3.6-53. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III Total (Cont.)						
Week 26						
I-SD	19	114.29	138.79	24.50	(12.122, 36.874)	5.891
I-SD/M-PL	4	126.50	144.00	17.50	(-10.920, 45.920)	8.930
I-SD/M-SD	7	112.71	132.00	19.29	(-13.784, 52.356)	13.515
I-SD/M-HD	8	109.57	142.13	32.56	(17.295, 47.823)	6.455
I-HD	40	114.76	136.07	21.31	(15.131, 27.479)	3.052
I-HD/M-PL	8	102.50	127.25	24.75	(2.772, 46.728)	9.294
I-HD/M-SD	15	113.77	134.45	20.68	(10.345, 31.015)	4.819
I-HD/M-HD	17	121.41	141.65	20.24	(11.424, 29.047)	4.156
I-SD + I-HD Total	59	114.61	136.95	22.33	(16.760, 27.907)	2.784
I-HD-OL	14	108.79	135.57	26.79	(16.657, 36.914)	4.688
I-HD-OL/M-SD	8	113.13	136.13	23.00	(10.243, 35.757)	5.395
I-HD-OL/M-HD	6	103.00	134.83	31.83	(10.312, 53.355)	8.372
M-SD Total	30	113.35	134.33	20.97	(12.702, 29.246)	4.045
M-HD Total	31	114.79	140.45	25.66	(18.882, 32.439)	3.319
M-SD + M-HD Total	61	114.08	137.44	23.36	(18.147, 28.563)	2.604

表 2.7.3.6-53. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III Total (Cont.)						
Week 52						
I-SD	19	114.29	139.98	25.68	(11.614, 39.754)	6.697
I-SD/M-PL	4	126.50	146.50	20.00	(-11.100, 51.100)	9.772
I-SD/M-SD	7	112.71	131.29	18.57	(-8.780, 45.923)	11.178
I-SD/M-HD	8	109.57	144.32	34.75	(6.836, 62.664)	11.805
I-HD	40	114.76	134.89	20.13	(13.814, 26.446)	3.122
I-HD/M-PL	8	102.50	128.13	25.63	(4.045, 47.205)	9.126
I-HD/M-SD	15	113.77	137.38	23.61	(13.014, 34.214)	4.942
I-HD/M-HD	17	121.41	135.88	14.47	(5.898, 23.043)	4.044
I-SD + I-HD Total	59	114.61	136.53	21.92	(15.899, 27.938)	3.007
I-HD-OL	14	108.79	135.36	26.57	(15.622, 37.521)	5.068
I-HD-OL/M-SD	8	113.13	136.50	23.38	(15.533, 31.217)	3.316
I-HD-OL/M-HD	6	103.00	133.83	30.83	(1.642, 60.025)	11.356
M-SD Total	30	113.35	135.73	22.37	(15.060, 29.687)	3.576
M-HD Total	31	114.79	137.66	22.87	(13.681, 32.061)	4.500
M-SD + M-HD Total	61	114.08	136.71	22.63	(16.903, 28.349)	2.861

表 2.7.3.6-53. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
Note: I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group,
M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
Note: baseline is defined as the last non-missing value prior to the first dose of study drug. Subjects with non-missing baseline and at least one post-baseline value are included in the analyses.
Last observation carried forward (LOCF): missing data is imputed by carrying forward the last non-missing post-baseline observation. For subjects re-randomized due to disease flare, the last non-missing value before the re-randomization after the first disease flare are carried forward.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.2__1.3.7_A

表 2.7.3.6-54. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（中間 CSR）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Body						
Week 8						
I-SD	2	8.0	8.5	0.5	(-5.85, 6.85)	0.50
I-SD/-	2	8.0	8.5	0.5	(-5.85, 6.85)	0.50
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	8.5	8.8	0.3	(-0.55, 1.05)	0.25
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	9.0	9.0	0.0		
I-HD/M-HD	3	8.3	8.7	0.3	(-1.10, 1.77)	0.33
I-SD + I-HD Total	6	8.3	8.7	0.3	(-0.21, 0.88)	0.21
I-HD-OL	1	10.0	10.0	0.0		
I-HD-OL/-	0					
I-HD-OL/M-SD	1	10.0	10.0	0.0		
I-HD-OL/M-HD	0					
M-SD Total	2	9.5	9.5	0.0		
M-HD Total	3	8.3	8.7	0.3	(-1.10, 1.77)	0.33
M-SD + M-HD Total	5	8.8	9.0	0.2	(-0.36, 0.76)	0.20

表 2.7.3.6-54. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Body (Cont.)						
Week 26						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	8.5	8.8	0.3	(-0.55, 1.05)	0.25
I-HD/M-PL	0					
I-HD/M-SD	1	9.0	9.0	0.0		
I-HD/M-HD	3	8.3	8.7	0.3	(-1.10, 1.77)	0.33
I-SD + I-HD Total	4	8.5	8.8	0.3	(-0.55, 1.05)	0.25
I-HD-OL	1	10.0	10.0	0.0		
I-HD-OL/M-SD	1	10.0	10.0	0.0		
I-HD-OL/M-HD	0					
M-SD Total	2	9.5	9.5	0.0		
M-HD Total	3	8.3	8.7	0.3	(-1.10, 1.77)	0.33
M-SD + M-HD Total	5	8.8	9.0	0.2	(-0.36, 0.76)	0.20

表 2.7.3.6-54. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Body (Cont.)						
Week 52						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	8.5	8.8	0.3	(-0.55, 1.05)	0.25
I-HD/M-PL	0					
I-HD/M-SD	1	9.0	9.0	0.0		
I-HD/M-HD	3	8.3	8.7	0.3	(-1.10, 1.77)	0.33
I-SD + I-HD Total	4	8.5	8.8	0.3	(-0.55, 1.05)	0.25
I-HD-OL	1	10.0	10.0	0.0		
I-HD-OL/M-SD	1	10.0	10.0	0.0		
I-HD-OL/M-HD	0					
M-SD Total	2	9.5	9.5	0.0		
M-HD Total	3	8.3	8.7	0.3	(-1.10, 1.77)	0.33
M-SD + M-HD Total	5	8.8	9.0	0.2	(-0.36, 0.76)	0.20

表 2.7.3.6-54. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Bowel						
Week 8						
I-SD	2	21.0	24.5	3.5	(-40.97, 47.97)	3.50
I-SD/-	2	21.0	24.5	3.5	(-40.97, 47.97)	3.50
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	24.0	27.0	3.0	(-3.87, 9.87)	2.16
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	25.0	24.0	-1.0		0.00
I-HD/M-HD	3	23.7	28.0	4.3	(-6.01, 14.68)	2.40
I-SD + I-HD Total	6	23.0	26.2	3.2	(-1.05, 7.39)	1.64
I-HD-OL	1	20.0	26.0	6.0		0.00
I-HD-OL/-	0					
I-HD-OL/M-SD	1	20.0	26.0	6.0		0.00
I-HD-OL/M-HD	0					
M-SD Total	2	22.5	25.0	2.5	(-41.97, 46.97)	3.50
M-HD Total	3	23.7	28.0	4.3	(-6.01, 14.68)	2.40
M-SD + M-HD Total	5	23.2	26.8	3.6	(-1.34, 8.54)	1.78

表 2.7.3.6-54. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Bowel (Cont.)						
Week 26						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	24.0	29.0	5.0	(-5.15, 15.15)	3.19
I-HD/M-PL	0					
I-HD/M-SD	1	25.0	24.0	-1.0		0.00
I-HD/M-HD	3	23.7	30.7	7.0	(-8.11, 22.11)	3.51
I-SD + I-HD Total	4	24.0	29.0	5.0	(-5.15, 15.15)	3.19
I-HD-OL	1	20.0	26.0	6.0		0.00
I-HD-OL/M-SD	1	20.0	26.0	6.0		0.00
I-HD-OL/M-HD	0					
M-SD Total	2	22.5	25.0	2.5	(-41.97, 46.97)	3.50
M-HD Total	3	23.7	30.7	7.0	(-8.11, 22.11)	3.51
M-SD + M-HD Total	5	23.2	28.4	5.2	(-1.68, 12.08)	2.48

表 2.7.3.6-54. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Bowel (Cont.)						
Week 52						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	24.0	27.0	3.0	(-1.68, 7.68)	1.47
I-HD/M-PL	0					
I-HD/M-SD	1	25.0	24.0	-1.0		0.00
I-HD/M-HD	3	23.7	28.0	4.3	(0.54, 8.13)	0.88
I-SD + I-HD Total	4	24.0	27.0	3.0	(-1.68, 7.68)	1.47
I-HD-OL	1	20.0	26.0	6.0		0.00
I-HD-OL/M-SD	1	20.0	26.0	6.0		0.00
I-HD-OL/M-HD	0					
M-SD Total	2	22.5	25.0	2.5	(-41.97, 46.97)	3.50
M-HD Total	3	23.7	28.0	4.3	(0.54, 8.13)	0.88
M-SD + M-HD Total	5	23.2	26.8	3.6	(0.02, 7.18)	1.29

表 2.7.3.6-54. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Emotional						
Week 8						
I-SD	2	15.5	19.5	4.0	(-59.53, 67.53)	5.00
I-SD/-	2	15.5	19.5	4.0	(-59.53, 67.53)	5.00
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	23.3	25.5	2.3	(-4.55, 9.05)	2.14
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	25.0	24.0	-1.0		0.00
I-HD/M-HD	3	22.7	26.0	3.3	(-7.87, 14.53)	2.60
I-SD + I-HD Total	6	20.7	23.5	2.8	(-2.06, 7.73)	1.90
I-HD-OL	1	25.0	29.0	4.0		0.00
I-HD-OL/-	0					
I-HD-OL/M-SD	1	25.0	29.0	4.0		0.00
I-HD-OL/M-HD	0					
M-SD Total	2	25.0	26.5	1.5	(-30.27, 33.27)	2.50
M-HD Total	3	22.7	26.0	3.3	(-7.87, 14.53)	2.60
M-SD + M-HD Total	5	23.6	26.2	2.6	(-2.10, 7.30)	1.69

表 2.7.3.6-54. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Emotional (Cont.)						
Week 26						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	23.3	27.8	4.5	(-3.46, 12.46)	2.50
I-HD/M-PL	0					
I-HD/M-SD	1	25.0	24.0	-1.0		0.00
I-HD/M-HD	3	22.7	29.0	6.3	(-4.01, 16.68)	2.40
I-SD + I-HD Total	4	23.3	27.8	4.5	(-3.46, 12.46)	2.50
I-HD-OL	1	25.0	29.0	4.0		0.00
I-HD-OL/M-SD	1	25.0	29.0	4.0		0.00
I-HD-OL/M-HD	0					
M-SD Total	2	25.0	26.5	1.5	(-30.27, 33.27)	2.50
M-HD Total	3	22.7	29.0	6.3	(-4.01, 16.68)	2.40
M-SD + M-HD Total	5	23.6	28.0	4.4	(-0.98, 9.78)	1.94

表 2.7.3.6-54. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Emotional (Cont.)						
Week 52						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	23.3	27.3	4.0	(-2.62, 10.62)	2.08
I-HD/M-PL	0					
I-HD/M-SD	1	25.0	24.0	-1.0		0.00
I-HD/M-HD	3	22.7	28.3	5.7	(-1.92, 13.26)	1.76
I-SD + I-HD Total	4	23.3	27.3	4.0	(-2.62, 10.62)	2.08
I-HD-OL	1	25.0	29.0	4.0		0.00
I-HD-OL/M-SD	1	25.0	29.0	4.0		0.00
I-HD-OL/M-HD	0					
M-SD Total	2	25.0	26.5	1.5	(-30.27, 33.27)	2.50
M-HD Total	3	22.7	28.3	5.7	(-1.92, 13.26)	1.76
M-SD + M-HD Total	5	23.6	27.6	4.0	(-0.48, 8.48)	1.61

表 2.7.3.6-54. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Social						
Week 8						
I-SD	2	37.5	42.0	4.5	(-1.85, 10.85)	0.50
I-SD/-	2	37.5	42.0	4.5	(-1.85, 10.85)	0.50
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	44.3	48.8	4.5	(-0.45, 9.45)	1.55
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	44.0	47.0	3.0		0.00
I-HD/M-HD	3	44.3	49.3	5.0	(-3.96, 13.96)	2.08
I-SD + I-HD Total	6	42.0	46.5	4.5	(1.95, 7.05)	0.99
I-HD-OL	1	43.0	52.0	9.0		0.00
I-HD-OL/-	0					
I-HD-OL/M-SD	1	43.0	52.0	9.0		0.00
I-HD-OL/M-HD	0					
M-SD Total	2	43.5	49.5	6.0	(-32.12, 44.12)	3.00
M-HD Total	3	44.3	49.3	5.0	(-3.96, 13.96)	2.08
M-SD + M-HD Total	5	44.0	49.4	5.4	(1.23, 9.57)	1.50

表 2.7.3.6-54. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Social (Cont.)						
Week 26						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	44.3	50.8	6.5	(0.34, 12.66)	1.94
I-HD/M-PL	0					
I-HD/M-SD	1	44.0	47.0	3.0		0.00
I-HD/M-HD	3	44.3	52.0	7.7	(-1.74, 17.07)	2.19
I-SD + I-HD Total	4	44.3	50.8	6.5	(0.34, 12.66)	1.94
I-HD-OL	1	43.0	52.0	9.0		0.00
I-HD-OL/M-SD	1	43.0	52.0	9.0		0.00
I-HD-OL/M-HD	0					
M-SD Total	2	43.5	49.5	6.0	(-32.12, 44.12)	3.00
M-HD Total	3	44.3	52.0	7.7	(-1.74, 17.07)	2.19
M-SD + M-HD Total	5	44.0	51.0	7.0	(2.61, 11.39)	1.58

表 2.7.3.6-54. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Social (Cont.)						
Week 52						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	44.3	48.3	4.0	(1.09, 6.91)	0.91
I-HD/M-PL	0					
I-HD/M-SD	1	44.0	47.0	3.0		0.00
I-HD/M-HD	3	44.3	48.7	4.3	(-0.84, 9.50)	1.20
I-SD + I-HD Total	4	44.3	48.3	4.0	(1.09, 6.91)	0.91
I-HD-OL	1	43.0	52.0	9.0		0.00
I-HD-OL/M-SD	1	43.0	52.0	9.0		0.00
I-HD-OL/M-HD	0					
M-SD Total	2	43.5	49.5	6.0	(-32.12, 44.12)	3.00
M-HD Total	3	44.3	48.7	4.3	(-0.84, 9.50)	1.20
M-SD + M-HD Total	5	44.0	49.0	5.0	(1.60, 8.40)	1.22

表 2.7.3.6-54. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Systemic						
Week 8						
I-SD	2	8.5	9.0	0.5	(-18.56, 19.56)	1.50
I-SD/-	2	8.5	9.0	0.5	(-18.56, 19.56)	1.50
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	8.3	11.0	2.8	(1.23, 4.27)	0.48
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	8.0	10.0	2.0		0.00
I-HD/M-HD	3	8.3	11.3	3.0	(0.52, 5.48)	0.58
I-SD + I-HD Total	6	8.3	10.3	2.0	(0.24, 3.76)	0.68
I-HD-OL	1	8.0	11.0	3.0		0.00
I-HD-OL/-	0					
I-HD-OL/M-SD	1	8.0	11.0	3.0		0.00
I-HD-OL/M-HD	0					
M-SD Total	2	8.0	10.5	2.5	(-3.85, 8.85)	0.50
M-HD Total	3	8.3	11.3	3.0	(0.52, 5.48)	0.58
M-SD + M-HD Total	5	8.2	11.0	2.8	(1.76, 3.84)	0.37

表 2.7.3.6-54. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Systemic (Cont.)						
Week 26						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	8.3	10.8	2.5	(0.45, 4.55)	0.65
I-HD/M-PL	0					
I-HD/M-SD	1	8.0	10.0	2.0		0.00
I-HD/M-HD	3	8.3	11.0	2.7	(-1.13, 6.46)	0.88
I-SD + I-HD Total	4	8.3	10.8	2.5	(0.45, 4.55)	0.65
I-HD-OL	1	8.0	11.0	3.0		0.00
I-HD-OL/M-SD	1	8.0	11.0	3.0		0.00
I-HD-OL/M-HD	0					
M-SD Total	2	8.0	10.5	2.5	(-3.85, 8.85)	0.50
M-HD Total	3	8.3	11.0	2.7	(-1.13, 6.46)	0.88
M-SD + M-HD Total	5	8.2	10.8	2.6	(1.18, 4.02)	0.51

表 2.7.3.6-54. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Systemic (Cont.)						
Week 52						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	8.3	11.5	3.3	(1.73, 4.77)	0.48
I-HD/M-PL	0					
I-HD/M-SD	1	8.0	10.0	2.0		0.00
I-HD/M-HD	3	8.3	12.0	3.7	(2.23, 5.10)	0.33
I-SD + I-HD Total	4	8.3	11.5	3.3	(1.73, 4.77)	0.48
I-HD-OL	1	8.0	11.0	3.0		0.00
I-HD-OL/M-SD	1	8.0	11.0	3.0		0.00
I-HD-OL/M-HD	0					
M-SD Total	2	8.0	10.5	2.5	(-3.85, 8.85)	0.50
M-HD Total	3	8.3	12.0	3.7	(2.23, 5.10)	0.33
M-SD + M-HD Total	5	8.2	11.4	3.2	(2.16, 4.24)	0.37

表 2.7.3.6-54. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Treatment						
Week 8						
I-SD	2	8.0	7.0	-1.0	(-26.41, 24.41)	2.00
I-SD/-	2	8.0	7.0	-1.0	(-26.41, 24.41)	2.00
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	11.5	11.8	0.3	(-2.47, 2.97)	0.85
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	11.0	12.0	1.0		0.00
I-HD/M-HD	3	11.7	11.7	0.0	(-4.97, 4.97)	1.15
I-SD + I-HD Total	6	10.3	10.2	-0.2	(-2.20, 1.87)	0.79
I-HD-OL	1	15.0	15.0	0.0		
I-HD-OL/-	0					
I-HD-OL/M-SD	1	15.0	15.0	0.0		
I-HD-OL/M-HD	0					
M-SD Total	2	13.0	13.5	0.5	(-5.85, 6.85)	0.50
M-HD Total	3	11.7	11.7	0.0	(-4.97, 4.97)	1.15
M-SD + M-HD Total	5	12.2	12.4	0.2	(-1.64, 2.04)	0.66

表 2.7.3.6-54. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Treatment (Cont.)						
Week 26						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	11.5	11.5	0.0	(-2.91, 2.91)	0.91
I-HD/M-PL	0					
I-HD/M-SD	1	11.0	12.0	1.0		0.00
I-HD/M-HD	3	11.7	11.3	-0.3	(-5.50, 4.84)	1.20
I-SD + I-HD Total	4	11.5	11.5	0.0	(-2.91, 2.91)	0.91
I-HD-OL	1	15.0	15.0	0.0		
I-HD-OL/M-SD	1	15.0	15.0	0.0		
I-HD-OL/M-HD	0					
M-SD Total	2	13.0	13.5	0.5	(-5.85, 6.85)	0.50
M-HD Total	3	11.7	11.3	-0.3	(-5.50, 4.84)	1.20
M-SD + M-HD Total	5	12.2	12.2	0.0	(-1.96, 1.96)	0.71

表 2.7.3.6-54. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Treatment (Cont.)						
Week 52						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	11.5	10.8	-0.8	(-2.75, 1.25)	0.63
I-HD/M-PL	0					
I-HD/M-SD	1	11.0	12.0	1.0		0.00
I-HD/M-HD	3	11.7	10.3	-1.3	(-2.77, 0.10)	0.33
I-SD + I-HD Total	4	11.5	10.8	-0.8	(-2.75, 1.25)	0.63
I-HD-OL	1	15.0	15.0	0.0		
I-HD-OL/M-SD	1	15.0	15.0	0.0		
I-HD-OL/M-HD	0					
M-SD Total	2	13.0	13.5	0.5	(-5.85, 6.85)	0.50
M-HD Total	3	11.7	10.3	-1.3	(-2.77, 0.10)	0.33
M-SD + M-HD Total	5	12.2	11.6	-0.6	(-2.02, 0.82)	0.51

表 2.7.3.6-54. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III Total						
Week 8						
I-SD	2	98.5	110.5	12.0	(-153.18, 177.18)	13.00
I-SD/-	2	98.5	110.5	12.0	(-153.18, 177.18)	13.00
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	119.8	132.8	13.0	(-4.33, 30.33)	5.45
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	122.0	126.0	4.0		0.00
I-HD/M-HD	3	119.0	135.0	16.0	(-11.66, 43.66)	6.43
I-SD + I-HD Total	6	112.7	125.3	12.7	(0.29, 25.04)	4.81
I-HD-OL	1	121.0	143.0	22.0		0.00
I-HD-OL/-	0					
I-HD-OL/M-SD	1	121.0	143.0	22.0		0.00
I-HD-OL/M-HD	0					
M-SD Total	2	121.5	134.5	13.0	(-101.36, 127.36)	9.00
M-HD Total	3	119.0	135.0	16.0	(-11.66, 43.66)	6.43
M-SD + M-HD Total	5	120.0	134.8	14.8	(2.06, 27.54)	4.59

表 2.7.3.6-54. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III Total (Cont.)						
Week 26						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	119.8	138.5	18.8	(-7.15, 44.65)	8.14
I-HD/M-PL	0					
I-HD/M-SD	1	122.0	126.0	4.0		0.00
I-HD/M-HD	3	119.0	142.7	23.7	(-15.79, 63.13)	9.17
I-SD + I-HD Total	4	119.8	138.5	18.8	(-7.15, 44.65)	8.14
I-HD-OL	1	121.0	143.0	22.0		0.00
I-HD-OL/M-SD	1	121.0	143.0	22.0		0.00
I-HD-OL/M-HD	0					
M-SD Total	2	121.5	134.5	13.0	(-101.36, 127.36)	9.00
M-HD Total	3	119.0	142.7	23.7	(-15.79, 63.13)	9.17
M-SD + M-HD Total	5	120.0	139.4	19.4	(1.81, 36.99)	6.34

表 2.7.3.6-54. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III Total (Cont.)						
Week 52						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	119.8	133.5	13.8	(0.73, 26.77)	4.09
I-HD/M-PL	0					
I-HD/M-SD	1	122.0	126.0	4.0		0.00
I-HD/M-HD	3	119.0	136.0	17.0	(1.89, 32.11)	3.51
I-SD + I-HD Total	4	119.8	133.5	13.8	(0.73, 26.77)	4.09
I-HD-OL	1	121.0	143.0	22.0		0.00
I-HD-OL/M-SD	1	121.0	143.0	22.0		0.00
I-HD-OL/M-HD	0					
M-SD Total	2	121.5	134.5	13.0	(-101.36, 127.36)	9.00
M-HD Total	3	119.0	136.0	17.0	(1.89, 32.11)	3.51
M-SD + M-HD Total	5	120.0	135.4	15.4	(5.48, 25.32)	3.57

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
Note: I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group, M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
Note: baseline is defined as the last non-missing value prior to the first dose of study drug. Subjects with non-missing baseline and at least one post-baseline value are included in the analyses.
Last observation carried forward (LOCF): missing data is imputed by carrying forward the last non-missing post-baseline observation. For subjects re-randomized due to disease flare, the last non-missing value before the re-randomization after the first disease flare are carried forward.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.2__1.3.7_J

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%)						
Week 1						
I-SD	31	41.9	30.6	-11.3	(-17.41, -5.17)	3.00
I-SD/-	9	44.4	41.1	-3.3	(-11.02, 4.35)	3.33
I-SD/M-PL	4	60.0	37.5	-22.5	(-55.30, 10.30)	10.31
I-SD/M-SD	8	25.0	18.8	-6.3	(-21.03, 8.53)	6.25
I-SD/M-HD	10	46.0	28.0	-18.0	(-29.58, -6.42)	5.12
I-HD	49	46.7	35.7	-11.0	(-16.86, -5.18)	2.91
I-HD/-	8	58.8	48.8	-10.0	(-25.48, 5.48)	6.55
I-HD/M-PL	7	52.9	42.9	-10.0	(-20.68, 0.68)	4.36
I-HD/M-SD	16	48.8	38.8	-10.0	(-24.56, 4.56)	6.83
I-HD/M-HD	18	37.2	24.4	-12.8	(-21.61, -3.95)	4.19
I-SD + I-HD Total	80	44.9	33.8	-11.1	(-15.33, -6.92)	2.11
I-HD-OL	15	53.3	46.7	-6.7	(-20.66, 7.32)	6.52
I-HD-OL/-	2	50.0	55.0	5.0	(-58.53, 68.53)	5.00
I-HD-OL/M-SD	7	41.4	45.7	4.3	(-18.28, 26.85)	9.22
I-HD-OL/M-HD	6	68.3	45.0	-23.3	(-46.96, 0.29)	9.19
M-SD Total	31	41.0	35.2	-5.8	(-14.78, 3.17)	4.39
M-HD Total	34	45.3	29.1	-16.2	(-22.49, -9.86)	3.10
M-SD + M-HD Total	65	43.2	32.0	-11.2	(-16.64, -5.82)	2.71

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 2						
I-SD	32	41.6	26.9	-14.7	(-22.98, -6.40)	4.07
I-SD/-	10	43.0	38.0	-5.0	(-15.26, 5.26)	4.53
I-SD/M-PL	4	60.0	40.0	-20.0	(-49.05, 9.05)	9.13
I-SD/M-SD	8	25.0	20.0	-5.0	(-19.82, 9.82)	6.27
I-SD/M-HD	10	46.0	16.0	-30.0	(-50.23, -9.77)	8.94
I-HD	50	47.2	29.0	-18.2	(-24.02, -12.38)	2.90
I-HD/-	8	58.8	41.3	-17.5	(-29.11, -5.89)	4.91
I-HD/M-PL	7	52.9	28.6	-24.3	(-48.08, -0.49)	9.72
I-HD/M-SD	17	50.0	34.1	-15.9	(-28.35, -3.41)	5.88
I-HD/M-HD	18	37.2	18.9	-18.3	(-27.24, -9.43)	4.22
I-SD + I-HD Total	82	45.0	28.2	-16.8	(-21.54, -12.12)	2.37
I-HD-OL	16	54.4	34.4	-20.0	(-37.94, -2.06)	8.42
I-HD-OL/-	2	50.0	45.0	-5.0	(-195.59, 185.59)	15.00
I-HD-OL/M-SD	7	41.4	32.9	-8.6	(-45.34, 28.20)	15.03
I-HD-OL/M-HD	7	68.6	32.9	-35.7	(-59.51, -11.92)	9.72
M-SD Total	32	41.9	30.3	-11.6	(-21.13, -2.00)	4.69
M-HD Total	35	46.0	20.9	-25.1	(-33.15, -17.14)	3.94
M-SD + M-HD Total	67	44.0	25.4	-18.7	(-24.91, -12.40)	3.13

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 4						
I-SD	32	41.6	28.1	-13.4	(-20.63, -6.25)	3.52
I-SD/-	10	43.0	41.0	-2.0	(-10.12, 6.12)	3.59
I-SD/M-PL	4	60.0	32.5	-27.5	(-62.78, 7.78)	11.09
I-SD/M-SD	8	25.0	18.8	-6.3	(-18.02, 5.52)	4.98
I-SD/M-HD	10	46.0	21.0	-25.0	(-40.91, -9.09)	7.03
I-HD	50	47.2	25.2	-22.0	(-28.32, -15.68)	3.14
I-HD/-	8	58.8	25.0	-33.8	(-49.82, -17.68)	6.80
I-HD/M-PL	7	52.9	28.6	-24.3	(-44.16, -4.41)	8.12
I-HD/M-SD	17	50.0	30.6	-19.4	(-32.45, -6.37)	6.15
I-HD/M-HD	18	37.2	18.9	-18.3	(-28.46, -8.21)	4.80
I-SD + I-HD Total	82	45.0	26.3	-18.7	(-23.41, -13.90)	2.39
I-HD-OL	17	52.9	34.7	-18.2	(-39.99, 3.52)	10.26
I-HD-OL/-	2	50.0	40.0	-10.0	(-518.25, 498.25)	40.00
I-HD-OL/M-SD	8	40.0	42.5	2.5	(-24.96, 29.96)	11.61
I-HD-OL/M-HD	7	68.6	24.3	-44.3	(-81.22, -7.35)	15.10
M-SD Total	33	41.5	30.6	-10.9	(-20.22, -1.60)	4.57
M-HD Total	35	46.0	20.6	-25.4	(-34.64, -16.21)	4.53
M-SD + M-HD Total	68	43.8	25.4	-18.4	(-25.00, -11.76)	3.32

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 8						
I-SD	32	41.6	31.3	-10.3	(-20.53, -0.10)	5.01
I-SD/-	10	43.0	49.0	6.0	(-5.78, 17.78)	5.21
I-SD/M-PL	4	60.0	25.0	-35.0	(-55.54, -14.46)	6.45
I-SD/M-SD	8	25.0	22.5	-2.5	(-28.07, 23.07)	10.82
I-SD/M-HD	10	46.0	23.0	-23.0	(-44.61, -1.39)	9.55
I-HD	50	47.2	23.6	-23.6	(-30.58, -16.62)	3.47
I-HD/-	8	58.8	50.0	-8.8	(-36.09, 18.59)	11.56
I-HD/M-PL	7	52.9	24.3	-28.6	(-43.12, -14.02)	5.95
I-HD/M-SD	17	50.0	22.9	-27.1	(-40.51, -13.61)	6.35
I-HD/M-HD	18	37.2	12.2	-25.0	(-35.41, -14.59)	4.93
I-SD + I-HD Total	82	45.0	26.6	-18.4	(-24.29, -12.54)	2.95
I-HD-OL	17	52.9	38.8	-14.1	(-34.61, 6.37)	9.67
I-HD-OL/-	2	50.0	85.0	35.0	(-28.53, 98.53)	5.00
I-HD-OL/M-SD	8	40.0	30.0	-10.0	(-42.53, 22.53)	13.76
I-HD-OL/M-HD	7	68.6	35.7	-32.9	(-65.21, -0.50)	13.22
M-SD Total	33	41.5	24.5	-17.0	(-28.16, -5.77)	5.50
M-HD Total	35	46.0	20.0	-26.0	(-35.02, -16.98)	4.44
M-SD + M-HD Total	68	43.8	22.2	-21.6	(-28.66, -14.57)	3.53

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 12						
I-SD	21	39.0	21.4	-17.6	(-32.22, -3.02)	7.00
I-SD/M-PL	4	60.0	37.5	-22.5	(-55.30, 10.30)	10.31
I-SD/M-SD	8	25.0	20.0	-5.0	(-32.91, 22.91)	11.80
I-SD/M-HD	9	42.2	15.6	-26.7	(-53.02, -0.32)	11.43
I-HD	43	44.0	17.7	-26.3	(-35.06, -17.50)	4.35
I-HD/M-PL	8	46.3	16.3	-30.0	(-49.98, -10.02)	8.45
I-HD/M-SD	17	50.0	24.1	-25.9	(-45.13, -6.64)	9.08
I-HD/M-HD	18	37.2	12.2	-25.0	(-35.55, -14.45)	5.00
I-SD + I-HD Total	64	42.3	18.9	-23.4	(-30.87, -16.00)	3.72
I-HD-OL	15	53.3	34.0	-19.3	(-42.02, 3.35)	10.58
I-HD-OL/M-SD	8	40.0	42.5	2.5	(-26.37, 31.37)	12.21
I-HD-OL/M-HD	7	68.6	24.3	-44.3	(-75.81, -12.76)	12.88
M-SD Total	33	41.5	27.6	-13.9	(-27.06, -0.82)	6.44
M-HD Total	34	45.0	15.6	-29.4	(-39.20, -19.62)	4.81
M-SD + M-HD Total	67	43.3	21.5	-21.8	(-29.95, -13.64)	4.08

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 18						
I-SD	21	39.0	18.1	-21.0	(-34.52, -7.38)	6.51
I-SD/M-PL	4	60.0	22.5	-37.5	(-61.37, -13.63)	7.50
I-SD/M-SD	8	25.0	21.3	-3.8	(-28.20, 20.70)	10.34
I-SD/M-HD	9	42.2	13.3	-28.9	(-51.77, -6.01)	9.92
I-HD	43	44.0	17.7	-26.3	(-33.82, -18.74)	3.74
I-HD/M-PL	8	46.3	23.8	-22.5	(-45.61, 0.61)	9.77
I-HD/M-SD	17	50.0	22.9	-27.1	(-41.46, -12.66)	6.79
I-HD/M-HD	18	37.2	10.0	-27.2	(-37.43, -17.02)	4.84
I-SD + I-HD Total	64	42.3	17.8	-24.5	(-31.09, -17.98)	3.28
I-HD-OL	15	53.3	28.7	-24.7	(-46.80, -2.53)	10.32
I-HD-OL/M-SD	8	40.0	31.3	-8.8	(-42.32, 24.82)	14.20
I-HD-OL/M-HD	7	68.6	25.7	-42.9	(-73.86, -11.85)	12.67
M-SD Total	33	41.5	24.5	-17.0	(-28.44, -5.50)	5.63
M-HD Total	34	45.0	14.1	-30.9	(-39.95, -21.82)	4.46
M-SD + M-HD Total	67	43.3	19.3	-24.0	(-31.32, -16.74)	3.65

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 26						
I-SD	21	39.0	16.7	-22.4	(-36.70, -8.07)	6.86
I-SD/M-PL	4	60.0	25.0	-35.0	(-55.54, -14.46)	6.45
I-SD/M-SD	8	25.0	25.0	0.0	(-24.06, 24.06)	10.18
I-SD/M-HD	9	42.2	5.6	-36.7	(-59.40, -13.93)	9.86
I-HD	43	44.0	18.1	-25.8	(-33.54, -18.09)	3.83
I-HD/M-PL	8	46.3	20.0	-26.3	(-50.70, -1.80)	10.34
I-HD/M-SD	17	50.0	24.7	-25.3	(-39.51, -11.08)	6.70
I-HD/M-HD	18	37.2	11.1	-26.1	(-37.05, -15.17)	5.19
I-SD + I-HD Total	64	42.3	17.7	-24.7	(-31.47, -17.91)	3.39
I-HD-OL	15	53.3	28.0	-25.3	(-49.37, -1.30)	11.21
I-HD-OL/M-SD	8	40.0	32.5	-7.5	(-43.18, 28.18)	15.09
I-HD-OL/M-HD	7	68.6	22.9	-45.7	(-79.84, -11.58)	13.95
M-SD Total	33	41.5	26.7	-14.8	(-26.55, -3.15)	5.74
M-HD Total	34	45.0	12.1	-32.9	(-42.64, -23.24)	4.77
M-SD + M-HD Total	67	43.3	19.3	-24.0	(-31.73, -16.33)	3.86

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 34						
I-SD	21	39.0	15.7	-23.3	(-36.47, -10.19)	6.30
I-SD/M-PL	4	60.0	25.0	-35.0	(-55.54, -14.46)	6.45
I-SD/M-SD	8	25.0	23.8	-1.3	(-17.63, 15.13)	6.93
I-SD/M-HD	9	42.2	4.4	-37.8	(-60.77, -14.79)	9.97
I-HD	43	44.0	17.0	-27.0	(-34.88, -19.07)	3.92
I-HD/M-PL	8	46.3	20.0	-26.3	(-50.70, -1.80)	10.34
I-HD/M-SD	17	50.0	22.4	-27.6	(-42.91, -12.38)	7.20
I-HD/M-HD	18	37.2	10.6	-26.7	(-37.18, -16.15)	4.98
I-SD + I-HD Total	64	42.3	16.6	-25.8	(-32.42, -19.14)	3.32
I-HD-OL	15	53.3	26.0	-27.3	(-50.78, -3.89)	10.93
I-HD-OL/M-SD	8	40.0	30.0	-10.0	(-43.44, 23.44)	14.14
I-HD-OL/M-HD	7	68.6	21.4	-47.1	(-82.45, -11.84)	14.43
M-SD Total	33	41.5	24.5	-17.0	(-28.23, -5.70)	5.53
M-HD Total	34	45.0	11.2	-33.8	(-43.58, -24.07)	4.80
M-SD + M-HD Total	67	43.3	17.8	-25.5	(-33.05, -17.99)	3.77

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 42						
I-SD	21	39.0	14.3	-24.8	(-39.56, -9.97)	7.09
I-SD/M-PL	4	60.0	12.5	-47.5	(-87.28, -7.72)	12.50
I-SD/M-SD	8	25.0	23.8	-1.3	(-17.63, 15.13)	6.93
I-SD/M-HD	9	42.2	6.7	-35.6	(-61.37, -9.74)	11.19
I-HD	43	44.0	16.3	-27.7	(-35.30, -20.05)	3.78
I-HD/M-PL	8	46.3	20.0	-26.3	(-50.70, -1.80)	10.34
I-HD/M-SD	17	50.0	21.2	-28.8	(-43.24, -14.41)	6.80
I-HD/M-HD	18	37.2	10.0	-27.2	(-37.43, -17.02)	4.84
I-SD + I-HD Total	64	42.3	15.6	-26.7	(-33.54, -19.90)	3.41
I-HD-OL	15	53.3	21.3	-32.0	(-50.86, -13.14)	8.79
I-HD-OL/M-SD	8	40.0	22.5	-17.5	(-41.87, 6.87)	10.31
I-HD-OL/M-HD	7	68.6	20.0	-48.6	(-79.44, -17.70)	12.62
M-SD Total	33	41.5	22.1	-19.4	(-29.38, -9.41)	4.90
M-HD Total	34	45.0	11.2	-33.8	(-43.47, -24.18)	4.74
M-SD + M-HD Total	67	43.3	16.6	-26.7	(-33.70, -19.73)	3.50

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 52						
I-SD	21	39.0	12.9	-26.2	(-41.04, -11.34)	7.12
I-SD/M-PL	4	60.0	10.0	-50.0	(-88.98, -11.02)	12.25
I-SD/M-SD	8	25.0	22.5	-2.5	(-21.85, 16.85)	8.18
I-SD/M-HD	9	42.2	5.6	-36.7	(-60.97, -12.36)	10.54
I-HD	43	44.0	17.4	-26.5	(-34.71, -18.32)	4.06
I-HD/M-PL	8	46.3	20.0	-26.3	(-50.70, -1.80)	10.34
I-HD/M-SD	17	50.0	19.4	-30.6	(-46.89, -14.28)	7.69
I-HD/M-HD	18	37.2	14.4	-22.8	(-32.98, -12.57)	4.84
I-SD + I-HD Total	64	42.3	15.9	-26.4	(-33.52, -19.29)	3.56
I-HD-OL	15	53.3	22.0	-31.3	(-52.25, -10.42)	9.75
I-HD-OL/M-SD	8	40.0	25.0	-15.0	(-42.91, 12.91)	11.80
I-HD-OL/M-HD	7	68.6	18.6	-50.0	(-82.92, -17.08)	13.45
M-SD Total	33	41.5	21.5	-20.0	(-31.25, -8.75)	5.52
M-HD Total	34	45.0	12.9	-32.1	(-41.99, -22.12)	4.88
M-SD + M-HD Total	67	43.3	17.2	-26.1	(-33.56, -18.68)	3.73

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%)						
Week 1						
I-SD	21	44.3	35.7	-8.6	(-17.36, 0.22)	4.21
I-SD/-	6	55.0	41.7	-13.3	(-26.04, -0.62)	4.94
I-SD/M-PL	3	53.3	43.3	-10.0	(-75.72, 55.72)	15.28
I-SD/M-SD	4	42.5	32.5	-10.0	(-44.37, 24.37)	10.80
I-SD/M-HD	8	33.8	30.0	-3.8	(-22.68, 15.18)	8.00
I-HD	32	41.6	28.8	-12.8	(-22.90, -2.73)	4.94
I-HD/-	4	60.0	45.0	-15.0	(-89.07, 59.07)	23.27
I-HD/M-PL	6	50.0	46.7	-3.3	(-8.75, 2.09)	2.11
I-HD/M-SD	11	49.1	27.3	-21.8	(-45.63, 1.99)	10.69
I-HD/M-HD	11	22.7	14.5	-8.2	(-20.50, 4.14)	5.53
I-SD + I-HD Total	53	42.6	31.5	-11.1	(-17.96, -4.30)	3.40
I-HD-OL	6	38.3	36.7	-1.7	(-13.94, 10.60)	4.77
I-HD-OL/-	1	50.0	60.0	10.0		0.00
I-HD-OL/M-SD	1	0.0	10.0	10.0		0.00
I-HD-OL/M-HD	4	45.0	37.5	-7.5	(-22.73, 7.73)	4.79
M-SD Total	16	44.4	27.5	-16.9	(-33.81, 0.06)	7.94
M-HD Total	23	30.4	23.9	-6.5	(-14.41, 1.37)	3.80
M-SD + M-HD Total	39	36.2	25.4	-10.8	(-18.83, -2.71)	3.98

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 2						
I-SD	22	42.3	29.5	-12.7	(-21.61, -3.84)	4.27
I-SD/-	7	47.1	38.6	-8.6	(-26.62, 9.48)	7.38
I-SD/M-PL	3	53.3	40.0	-13.3	(-70.70, 44.04)	13.33
I-SD/M-SD	4	42.5	25.0	-17.5	(-57.28, 22.28)	12.50
I-SD/M-HD	8	33.8	20.0	-13.8	(-31.02, 3.52)	7.30
I-HD	33	42.4	23.0	-19.4	(-27.89, -10.89)	4.17
I-HD/-	4	60.0	30.0	-30.0	(-48.37, -11.63)	5.77
I-HD/M-PL	6	50.0	28.3	-21.7	(-49.37, 6.03)	10.78
I-HD/M-SD	12	50.8	27.5	-23.3	(-42.74, -3.92)	8.82
I-HD/M-HD	11	22.7	12.7	-10.0	(-20.83, 0.83)	4.86
I-SD + I-HD Total	55	42.4	25.6	-16.7	(-22.82, -10.64)	3.04
I-HD-OL	6	38.3	33.3	-5.0	(-24.63, 14.63)	7.64
I-HD-OL/-	1	50.0	60.0	10.0		0.00
I-HD-OL/M-SD	1	0.0	20.0	20.0		0.00
I-HD-OL/M-HD	4	45.0	30.0	-15.0	(-35.54, 5.54)	6.45
M-SD Total	17	45.9	26.5	-19.4	(-34.56, -4.26)	7.15
M-HD Total	23	30.4	18.3	-12.2	(-19.43, -4.92)	3.50
M-SD + M-HD Total	40	37.0	21.8	-15.3	(-22.60, -7.90)	3.63

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 4						
I-SD	22	42.3	27.7	-14.5	(-25.89, -3.20)	5.45
I-SD/-	7	47.1	38.6	-8.6	(-28.14, 11.00)	8.00
I-SD/M-PL	3	53.3	43.3	-10.0	(-99.57, 79.57)	20.82
I-SD/M-SD	4	42.5	20.0	-22.5	(-52.62, 7.62)	9.46
I-SD/M-HD	8	33.8	16.3	-17.5	(-43.46, 8.46)	10.98
I-HD	33	42.4	21.5	-20.9	(-30.59, -11.22)	4.75
I-HD/-	4	60.0	25.0	-35.0	(-72.88, 2.88)	11.90
I-HD/M-PL	6	50.0	30.0	-20.0	(-51.13, 11.13)	12.11
I-HD/M-SD	12	50.8	25.0	-25.8	(-46.90, -4.77)	9.57
I-HD/M-HD	11	22.7	11.8	-10.9	(-23.46, 1.64)	5.63
I-SD + I-HD Total	55	42.4	24.0	-18.4	(-25.55, -11.18)	3.58
I-HD-OL	7	37.1	27.1	-10.0	(-32.02, 12.02)	9.00
I-HD-OL/-	1	50.0	80.0	30.0		0.00
I-HD-OL/M-SD	2	15.0	10.0	-5.0	(-195.59, 185.59)	15.00
I-HD-OL/M-HD	4	45.0	22.5	-22.5	(-46.37, 1.37)	7.50
M-SD Total	18	45.0	22.2	-22.8	(-37.23, -8.32)	6.85
M-HD Total	23	30.4	15.2	-15.2	(-25.05, -5.38)	4.74
M-SD + M-HD Total	41	36.8	18.3	-18.5	(-26.63, -10.44)	4.01

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 8						
I-SD	22	42.3	25.5	-16.8	(-27.88, -5.75)	5.32
I-SD/-	7	47.1	44.3	-2.9	(-20.34, 14.62)	7.14
I-SD/M-PL	3	53.3	26.7	-26.7	(-89.18, 35.85)	14.53
I-SD/M-SD	4	42.5	15.0	-27.5	(-75.02, 20.02)	14.93
I-SD/M-HD	8	33.8	13.8	-20.0	(-41.89, 1.89)	9.26
I-HD	33	42.4	16.4	-26.1	(-35.40, -16.72)	4.58
I-HD/-	4	60.0	35.0	-25.0	(-77.77, 27.77)	16.58
I-HD/M-PL	6	50.0	26.7	-23.3	(-51.23, 4.56)	10.85
I-HD/M-SD	12	50.8	12.5	-38.3	(-56.67, -19.99)	8.33
I-HD/M-HD	11	22.7	8.2	-14.5	(-25.93, -3.16)	5.11
I-SD + I-HD Total	55	42.4	20.0	-22.4	(-29.38, -15.35)	3.50
I-HD-OL	7	37.1	30.0	-7.1	(-27.63, 13.34)	8.37
I-HD-OL/-	1	50.0	80.0	30.0		0.00
I-HD-OL/M-SD	2	15.0	5.0	-10.0	(-264.12, 244.12)	20.00
I-HD-OL/M-HD	4	45.0	30.0	-15.0	(-35.54, 5.54)	6.45
M-SD Total	18	45.0	12.2	-32.8	(-47.13, -18.43)	6.80
M-HD Total	23	30.4	13.9	-16.5	(-24.93, -8.11)	4.06
M-SD + M-HD Total	41	36.8	13.2	-23.7	(-31.57, -15.74)	3.92

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 12						
I-SD	15	40.0	17.3	-22.7	(-39.60, -5.73)	7.90
I-SD/M-PL	3	53.3	36.7	-16.7	(-88.38, 55.04)	16.67
I-SD/M-SD	4	42.5	10.0	-32.5	(-74.35, 9.35)	13.15
I-SD/M-HD	8	33.8	13.8	-20.0	(-49.64, 9.64)	12.54
I-HD	30	38.7	15.0	-23.7	(-35.37, -11.96)	5.72
I-HD/M-PL	7	42.9	21.4	-21.4	(-47.82, 4.96)	10.79
I-HD/M-SD	12	50.8	15.8	-35.0	(-59.00, -11.00)	10.91
I-HD/M-HD	11	22.7	10.0	-12.7	(-27.78, 2.32)	6.75
I-SD + I-HD Total	45	39.1	15.8	-23.3	(-32.57, -14.10)	4.58
I-HD-OL	7	41.4	30.0	-11.4	(-23.87, 1.01)	5.08
I-HD-OL/M-SD	3	36.7	33.3	-3.3	(-41.28, 34.61)	8.82
I-HD-OL/M-HD	4	45.0	27.5	-17.5	(-32.73, -2.27)	4.79
M-SD Total	19	46.8	17.4	-29.5	(-45.82, -13.13)	7.78
M-HD Total	23	30.4	14.3	-16.1	(-27.13, -5.04)	5.32
M-SD + M-HD Total	42	37.9	15.7	-22.1	(-31.49, -12.79)	4.63

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 18						
I-SD	15	40.0	16.0	-24.0	(-42.46, -5.54)	8.61
I-SD/M-PL	3	53.3	20.0	-33.3	(-85.04, 18.38)	12.02
I-SD/M-SD	4	42.5	20.0	-22.5	(-87.95, 42.95)	20.56
I-SD/M-HD	8	33.8	12.5	-21.3	(-51.70, 9.20)	12.88
I-HD	30	38.7	13.7	-25.0	(-35.82, -14.18)	5.29
I-HD/M-PL	7	42.9	25.7	-17.1	(-45.76, 11.47)	11.69
I-HD/M-SD	12	50.8	13.3	-37.5	(-56.68, -18.32)	8.71
I-HD/M-HD	11	22.7	6.4	-16.4	(-32.05, -0.67)	7.04
I-SD + I-HD Total	45	39.1	14.4	-24.7	(-33.72, -15.62)	4.49
I-HD-OL	7	41.4	20.0	-21.4	(-49.39, 6.54)	11.43
I-HD-OL/M-SD	3	36.7	6.7	-30.0	(-143.84, 83.84)	26.46
I-HD-OL/M-HD	4	45.0	30.0	-15.0	(-42.56, 12.56)	8.66
M-SD Total	19	46.8	13.7	-33.2	(-49.23, -17.09)	7.65
M-HD Total	23	30.4	12.6	-17.8	(-29.41, -6.24)	5.59
M-SD + M-HD Total	42	37.9	13.1	-24.8	(-34.28, -15.24)	4.71

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 26						
I-SD	15	40.0	14.0	-26.0	(-43.86, -8.14)	8.33
I-SD/M-PL	3	53.3	20.0	-33.3	(-71.28, 4.61)	8.82
I-SD/M-SD	4	42.5	25.0	-17.5	(-82.95, 47.95)	20.56
I-SD/M-HD	8	33.8	6.3	-27.5	(-56.72, 1.72)	12.36
I-HD	30	38.7	15.0	-23.7	(-36.17, -11.17)	6.11
I-HD/M-PL	7	42.9	20.0	-22.9	(-48.31, 2.59)	10.40
I-HD/M-SD	12	50.8	20.0	-30.8	(-58.79, -2.88)	12.70
I-HD/M-HD	11	22.7	6.4	-16.4	(-32.05, -0.67)	7.04
I-SD + I-HD Total	45	39.1	14.7	-24.4	(-34.28, -14.61)	4.88
I-HD-OL	7	41.4	15.7	-25.7	(-55.38, 3.95)	12.12
I-HD-OL/M-SD	3	36.7	6.7	-30.0	(-143.84, 83.84)	26.46
I-HD-OL/M-HD	4	45.0	22.5	-22.5	(-62.28, 17.28)	12.50
M-SD Total	19	46.8	18.9	-27.9	(-47.93, -7.86)	9.54
M-HD Total	23	30.4	9.1	-21.3	(-33.13, -9.48)	5.70
M-SD + M-HD Total	42	37.9	13.6	-24.3	(-34.95, -13.62)	5.28

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 34						
I-SD	15	40.0	15.3	-24.7	(-43.02, -6.32)	8.56
I-SD/M-PL	3	53.3	20.0	-33.3	(-71.28, 4.61)	8.82
I-SD/M-SD	4	42.5	27.5	-15.0	(-80.61, 50.61)	20.62
I-SD/M-HD	8	33.8	7.5	-26.3	(-56.54, 4.04)	12.81
I-HD	30	38.7	15.0	-23.7	(-36.28, -11.05)	6.17
I-HD/M-PL	7	42.9	20.0	-22.9	(-48.31, 2.59)	10.40
I-HD/M-SD	12	50.8	20.0	-30.8	(-59.18, -2.49)	12.88
I-HD/M-HD	11	22.7	6.4	-16.4	(-32.05, -0.67)	7.04
I-SD + I-HD Total	45	39.1	15.1	-24.0	(-33.97, -14.03)	4.95
I-HD-OL	7	41.4	18.6	-22.9	(-44.02, -1.69)	8.65
I-HD-OL/M-SD	3	36.7	13.3	-23.3	(-110.57, 63.91)	20.28
I-HD-OL/M-HD	4	45.0	22.5	-22.5	(-46.37, 1.37)	7.50
M-SD Total	19	46.8	20.5	-26.3	(-46.07, -6.56)	9.40
M-HD Total	23	30.4	9.6	-20.9	(-32.45, -9.29)	5.58
M-SD + M-HD Total	42	37.9	14.5	-23.3	(-33.81, -12.86)	5.19

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 42						
I-SD	15	40.0	12.7	-27.3	(-47.13, -7.54)	9.23
I-SD/M-PL	3	53.3	6.7	-46.7	(-109.18, 15.85)	14.53
I-SD/M-SD	4	42.5	25.0	-17.5	(-82.95, 47.95)	20.56
I-SD/M-HD	8	33.8	8.8	-25.0	(-56.60, 6.60)	13.36
I-HD	30	38.7	15.0	-23.7	(-36.24, -11.09)	6.15
I-HD/M-PL	7	42.9	20.0	-22.9	(-48.31, 2.59)	10.40
I-HD/M-SD	12	50.8	20.0	-30.8	(-59.05, -2.62)	12.82
I-HD/M-HD	11	22.7	6.4	-16.4	(-32.05, -0.67)	7.04
I-SD + I-HD Total	45	39.1	14.2	-24.9	(-35.11, -14.67)	5.07
I-HD-OL	7	41.4	14.3	-27.1	(-48.97, -5.31)	8.92
I-HD-OL/M-SD	3	36.7	13.3	-23.3	(-110.57, 63.91)	20.28
I-HD-OL/M-HD	4	45.0	15.0	-30.0	(-55.98, -4.02)	8.16
M-SD Total	19	46.8	20.0	-26.8	(-46.46, -7.23)	9.34
M-HD Total	23	30.4	8.7	-21.7	(-33.74, -9.74)	5.78
M-SD + M-HD Total	42	37.9	13.8	-24.0	(-34.60, -13.50)	5.23

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 52						
I-SD	15	40.0	10.7	-29.3	(-49.02, -9.65)	9.18
I-SD/M-PL	3	53.3	3.3	-50.0	(-99.68, -0.32)	11.55
I-SD/M-SD	4	42.5	25.0	-17.5	(-82.95, 47.95)	20.56
I-SD/M-HD	8	33.8	6.3	-27.5	(-59.02, 4.02)	13.33
I-HD	30	38.7	14.7	-24.0	(-36.96, -11.04)	6.34
I-HD/M-PL	7	42.9	20.0	-22.9	(-48.31, 2.59)	10.40
I-HD/M-SD	12	50.8	18.3	-32.5	(-61.95, -3.05)	13.38
I-HD/M-HD	11	22.7	7.3	-15.5	(-30.59, -0.32)	6.79
I-SD + I-HD Total	45	39.1	13.3	-25.8	(-36.19, -15.36)	5.17
I-HD-OL	7	41.4	14.3	-27.1	(-50.24, -4.04)	9.44
I-HD-OL/M-SD	3	36.7	10.0	-26.7	(-127.06, 73.73)	23.33
I-HD-OL/M-HD	4	45.0	17.5	-27.5	(-47.52, -7.48)	6.29
M-SD Total	19	46.8	18.4	-28.4	(-48.95, -7.89)	9.77
M-HD Total	23	30.4	8.7	-21.7	(-33.52, -9.96)	5.68
M-SD + M-HD Total	42	37.9	13.1	-24.8	(-35.58, -13.94)	5.36

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%)						
Week 1						
I-SD	20	48.892	37.969	-10.924	(-22.1023, 0.2551)	5.3409
I-SD/-	5	66.000	43.345	-22.655	(-44.5405, -0.7686)	7.8827
I-SD/M-PL	3	53.333	46.667	-6.667	(-82.5583, 69.2250)	17.6383
I-SD/M-SD	4	47.962	34.604	-13.357	(-56.2986, 29.5836)	13.4931
I-SD/M-HD	8	37.000	33.029	-3.971	(-24.9138, 16.9715)	8.8567
I-HD	31	45.916	32.777	-13.139	(-23.1646, -3.1139)	4.9089
I-HD/-	4	64.063	50.714	-13.348	(-84.7354, 58.0390)	22.4316
I-HD/M-PL	6	54.720	47.599	-7.121	(-16.2301, 1.9880)	3.5436
I-HD/M-SD	10	52.986	34.250	-18.736	(-44.6235, 7.1510)	11.4436
I-HD/M-HD	11	28.089	16.831	-11.258	(-24.0749, 1.5594)	5.7524
I-SD + I-HD Total	51	47.083	34.813	-12.270	(-19.5298, -5.0110)	3.6142
I-HD-OL	6	47.093	47.343	0.250	(-20.7508, 21.2511)	8.1697
I-HD-OL/-	1	57.143	62.353	5.210		0.0000
I-HD-OL/M-SD	1	0.000	10.000	10.000		0.0000
I-HD-OL/M-HD	4	56.354	52.927	-3.427	(-42.7123, 35.8578)	12.3443
M-SD Total	15	48.114	32.728	-15.386	(-33.3576, 2.5853)	8.3791
M-HD Total	23	36.104	28.743	-7.361	(-16.6645, 1.9416)	4.4858
M-SD + M-HD Total	38	40.845	30.316	-10.529	(-19.1599, -1.8983)	4.2596

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 2						
I-SD	22	46.973	32.660	-14.313	(-25.4994, -3.1265)	5.3791
I-SD/-	7	55.079	41.429	-13.651	(-36.3349, 9.0333)	9.2705
I-SD/M-PL	3	53.333	40.000	-13.333	(-70.7020, 44.0354)	13.3333
I-SD/M-SD	4	47.962	28.879	-19.082	(-71.7865, 33.6218)	16.5609
I-SD/M-HD	8	37.000	24.125	-12.875	(-35.8506, 10.1006)	9.7164
I-HD	33	47.692	25.845	-21.848	(-30.5273, -13.1678)	4.2612
I-HD/-	4	64.063	39.000	-25.063	(-55.5674, 5.4424)	9.5853
I-HD/M-PL	6	54.720	29.736	-24.984	(-52.5054, 2.5369)	10.7062
I-HD/M-SD	12	56.691	29.688	-27.003	(-45.8998, -8.1070)	8.5854
I-HD/M-HD	11	28.089	14.746	-13.343	(-26.2456, -0.4403)	5.7908
I-SD + I-HD Total	55	47.404	28.571	-18.834	(-25.5461, -12.1213)	3.3480
I-HD-OL	6	47.093	36.841	-10.252	(-31.6227, 11.1182)	8.3135
I-HD-OL/-	1	57.143	61.379	4.236		0.0000
I-HD-OL/M-SD	1	0.000	20.000	20.000		0.0000
I-HD-OL/M-HD	4	56.354	34.917	-21.438	(-40.8794, -1.9956)	6.1091
M-SD Total	17	51.302	28.927	-22.375	(-38.1786, -6.5709)	7.4550
M-HD Total	23	36.104	21.516	-14.588	(-23.6454, -5.5305)	4.3674
M-SD + M-HD Total	40	42.563	24.666	-17.897	(-26.0528, -9.7418)	4.0320

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 4						
I-SD	22	46.973	29.331	-17.642	(-30.4356, -4.8477)	6.1521
I-SD/-	7	55.079	42.592	-12.488	(-35.4517, 10.4766)	9.3850
I-SD/M-PL	3	53.333	43.333	-10.000	(-99.5669, 79.5669)	20.8167
I-SD/M-SD	4	47.962	20.000	-27.962	(-66.2793, 10.3560)	12.0403
I-SD/M-HD	8	37.000	17.143	-19.857	(-49.1955, 9.4812)	12.4072
I-HD	33	47.692	27.235	-20.457	(-30.9730, -9.9418)	5.1625
I-HD/-	4	64.063	39.000	-25.063	(-62.1252, 12.0002)	11.6460
I-HD/M-PL	6	54.720	33.179	-21.541	(-52.8604, 9.7777)	12.1837
I-HD/M-SD	12	56.691	33.431	-23.260	(-48.5004, 1.9803)	11.4678
I-HD/M-HD	11	28.089	12.955	-15.134	(-28.9114, -1.3568)	6.1833
I-SD + I-HD Total	55	47.404	28.073	-19.331	(-27.1985, -11.4637)	3.9241
I-HD-OL	6	47.093	32.417	-14.677	(-49.6736, 20.3204)	13.6144
I-HD-OL/-	1	57.143	82.500	25.357		0.0000
I-HD-OL/M-SD	1	0.000	10.000	10.000		0.0000
I-HD-OL/M-HD	4	56.354	25.500	-30.854	(-74.9331, 13.2248)	13.8507
M-SD Total	17	51.302	28.892	-22.410	(-40.7152, -4.1044)	8.6350
M-HD Total	23	36.104	16.593	-19.511	(-31.1196, -7.9021)	5.5976
M-SD + M-HD Total	40	42.563	21.820	-20.743	(-30.4890, -10.9968)	4.8184

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 8						
I-SD	22	46.973	27.866	-19.107	(-31.0191, -7.1943)	5.7282
I-SD/-	7	55.079	49.008	-6.072	(-26.1403, 13.9970)	8.2016
I-SD/M-PL	3	53.333	26.667	-26.667	(-89.1828, 35.8494)	14.5297
I-SD/M-SD	4	47.962	15.000	-32.962	(-87.7571, 21.8338)	17.2180
I-SD/M-HD	8	37.000	16.250	-20.750	(-43.8829, 2.3829)	9.7829
I-HD	33	47.692	17.792	-29.900	(-39.7914, -20.0094)	4.8558
I-HD/-	4	64.063	40.000	-24.063	(-78.0082, 29.8832)	16.9510
I-HD/M-PL	6	54.720	28.750	-25.970	(-54.9021, 2.9613)	11.2549
I-HD/M-SD	12	56.691	13.598	-43.093	(-62.1805, -24.0062)	8.6721
I-HD/M-HD	11	28.089	8.314	-19.775	(-33.6713, -5.8779)	6.2369
I-SD + I-HD Total	55	47.404	21.821	-25.583	(-33.0860, -18.0798)	3.7424
I-HD-OL	7	44.651	30.136	-14.515	(-36.6539, 7.6232)	9.0475
I-HD-OL/-	1	57.143	80.952	23.810		0.0000
I-HD-OL/M-SD	2	15.000	5.000	-10.000	(-264.1241, 244.1241)	20.0000
I-HD-OL/M-HD	4	56.354	30.000	-26.354	(-48.2460, -4.4623)	6.8789
M-SD Total	18	50.119	12.954	-37.165	(-52.5410, -21.7886)	7.2879
M-HD Total	23	36.104	14.846	-21.258	(-30.6314, -11.8849)	4.5197
M-SD + M-HD Total	41	42.257	14.015	-28.242	(-36.7615, -19.7216)	4.2155

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 12						
I-SD	15	43.190	20.000	-23.190	(-41.5453, -4.8343)	8.5582
I-SD/M-PL	3	53.333	36.667	-16.667	(-88.3775, 55.0442)	16.6667
I-SD/M-SD	4	47.962	17.500	-30.462	(-87.7734, 26.8501)	18.0087
I-SD/M-HD	8	37.000	15.000	-22.000	(-52.7531, 8.7531)	13.0055
I-HD	29	45.434	17.572	-27.862	(-40.1998, -15.5237)	6.0233
I-HD/M-PL	6	54.720	25.079	-29.641	(-60.0787, 0.7966)	11.8408
I-HD/M-SD	12	56.691	18.000	-38.691	(-63.4796, -13.9022)	11.2625
I-HD/M-HD	11	28.089	13.011	-15.078	(-30.5225, 0.3673)	6.9317
I-SD + I-HD Total	44	44.669	18.400	-26.269	(-36.1104, -16.4277)	4.8799
I-HD-OL	7	49.947	32.071	-17.875	(-32.5706, -3.1801)	6.0056
I-HD-OL/M-SD	3	41.404	30.000	-11.404	(-61.4519, 38.6449)	11.6320
I-HD-OL/M-HD	4	56.354	33.625	-22.729	(-42.9222, -2.5361)	6.3451
M-SD Total	19	52.439	19.789	-32.650	(-49.9754, -15.3244)	8.2466
M-HD Total	23	36.104	17.288	-18.816	(-30.3078, -7.3244)	5.5412
M-SD + M-HD Total	42	43.494	18.420	-25.074	(-34.9029, -15.2456)	4.8668

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter Timepoint Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 18						
I-SD	15	43.190	19.000	-24.190	(-45.5200, -2.8595)	9.9452
I-SD/M-PL	3	53.333	20.000	-33.333	(-85.0448, 18.3781)	12.0185
I-SD/M-SD	4	47.962	31.250	-16.712	(-99.5288, 66.1055)	26.0231
I-SD/M-HD	8	37.000	12.500	-24.500	(-58.0928, 9.0928)	14.2064
I-HD	29	45.434	17.682	-27.753	(-39.5956, -15.9095)	5.7816
I-HD/M-PL	6	54.720	31.052	-23.669	(-59.8295, 12.4919)	14.0671
I-HD/M-SD	12	56.691	19.583	-37.108	(-59.5113, -14.7038)	10.1790
I-HD/M-HD	11	28.089	8.314	-19.775	(-35.7841, -3.7651)	7.1851
I-SD + I-HD Total	44	44.669	18.131	-26.538	(-36.6998, -16.3761)	5.0389
I-HD-OL	7	49.947	30.429	-19.518	(-34.2557, -4.7807)	6.0229
I-HD-OL/M-SD	3	41.404	30.000	-11.404	(-61.4519, 38.6449)	11.6320
I-HD-OL/M-HD	4	56.354	30.750	-25.604	(-43.1809, -8.0274)	5.5230
M-SD Total	19	52.439	23.684	-28.755	(-46.6945, -10.8158)	8.5388
M-HD Total	23	36.104	13.672	-22.432	(-34.6280, -10.2361)	5.8807
M-SD + M-HD Total	42	43.494	18.201	-25.293	(-35.3668, -15.2182)	4.9884

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 26						
I-SD	15	43.190	15.067	-28.123	(-48.9806, -7.2656)	9.7247
I-SD/M-PL	3	53.333	20.000	-33.333	(-71.2792, 4.6125)	8.8192
I-SD/M-SD	4	47.962	29.000	-18.962	(-102.5639, 64.6406)	26.2698
I-SD/M-HD	8	37.000	6.250	-30.750	(-63.3433, 1.8433)	13.7837
I-HD	29	45.434	17.972	-27.462	(-40.4653, -14.4586)	6.3480
I-HD/M-PL	6	54.720	23.413	-31.308	(-59.8424, -2.7730)	11.1005
I-HD/M-SD	12	56.691	24.028	-32.663	(-61.2384, -4.0879)	12.9829
I-HD/M-HD	11	28.089	8.398	-19.690	(-35.7264, -3.6541)	7.1971
I-SD + I-HD Total	44	44.669	16.982	-27.687	(-38.3193, -17.0554)	5.2720
I-HD-OL	7	49.947	27.568	-22.379	(-43.7754, -0.9829)	8.7442
I-HD-OL/M-SD	3	41.404	30.000	-11.404	(-61.4519, 38.6449)	11.6320
I-HD-OL/M-HD	4	56.354	25.743	-30.611	(-69.2298, 8.0080)	12.1350
M-SD Total	19	52.439	26.018	-26.422	(-46.9680, -5.8756)	9.7796
M-HD Total	23	36.104	10.668	-25.436	(-38.0777, -12.7950)	6.0955
M-SD + M-HD Total	42	43.494	17.612	-25.882	(-36.9286, -14.8357)	5.4698

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 34						
I-SD	15	43.190	16.768	-26.422	(-47.6812, -5.1627)	9.9121
I-SD/M-PL	3	53.333	20.000	-33.333	(-71.2792, 4.6125)	8.8192
I-SD/M-SD	4	47.962	32.879	-15.082	(-97.7145, 67.5498)	25.9650
I-SD/M-HD	8	37.000	7.500	-29.500	(-63.1522, 4.1522)	14.2315
I-HD	29	45.434	17.940	-27.494	(-40.5751, -14.4128)	6.3860
I-HD/M-PL	6	54.720	23.413	-31.308	(-59.8424, -2.7730)	11.1005
I-HD/M-SD	12	56.691	24.028	-32.663	(-61.5107, -3.8156)	13.1066
I-HD/M-HD	11	28.089	8.314	-19.775	(-35.7841, -3.7651)	7.1851
I-SD + I-HD Total	44	44.669	17.540	-27.128	(-37.8783, -16.3787)	5.3304
I-HD-OL	7	49.947	20.238	-29.709	(-56.5250, -2.8923)	10.9593
I-HD-OL/M-SD	3	41.404	10.000	-31.404	(-136.0424, 73.2353)	24.3196
I-HD-OL/M-HD	4	56.354	27.917	-28.438	(-63.7885, 6.9135)	11.1081
M-SD Total	19	52.439	23.676	-28.763	(-50.0973, -7.4288)	10.1547
M-HD Total	23	36.104	11.440	-24.664	(-37.3750, -11.9529)	6.1291
M-SD + M-HD Total	42	43.494	16.976	-26.518	(-37.8745, -15.1620)	5.6232

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 42						
I-SD	15	43.190	14.101	-29.089	(-51.5404, -6.6369)	10.4681
I-SD/M-PL	3	53.333	6.667	-46.667	(-109.1828, 15.8494)	14.5297
I-SD/M-SD	4	47.962	30.379	-17.582	(-100.0783, 64.9136)	25.9222
I-SD/M-HD	8	37.000	8.750	-28.250	(-63.1797, 6.6797)	14.7718
I-HD	29	45.434	18.492	-26.942	(-39.8686, -14.0158)	6.3105
I-HD/M-PL	6	54.720	23.413	-31.308	(-59.8424, -2.7730)	11.1005
I-HD/M-SD	12	56.691	24.028	-32.663	(-61.3153, -4.0110)	13.0179
I-HD/M-HD	11	28.089	9.769	-18.320	(-33.2584, -3.3817)	6.7044
I-SD + I-HD Total	44	44.669	16.995	-27.674	(-38.5860, -16.7619)	5.4109
I-HD-OL	7	49.947	14.286	-35.661	(-60.4712, -10.8508)	10.1394
I-HD-OL/M-SD	3	41.404	10.000	-31.404	(-136.0424, 73.2353)	24.3196
I-HD-OL/M-HD	4	56.354	17.500	-38.854	(-62.7064, -15.0019)	7.4949
M-SD Total	19	52.439	23.150	-29.289	(-50.4454, -8.1333)	10.0699
M-HD Total	23	36.104	10.759	-25.345	(-38.1128, -12.5774)	6.1564
M-SD + M-HD Total	42	43.494	16.364	-27.129	(-38.4407, -15.8181)	5.6009

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 52						
I-SD	15	43.190	19.071	-24.119	(-44.9224, -3.3155)	9.6996
I-SD/M-PL	3	53.333	21.515	-31.818	(-74.9039, 11.2676)	10.0138
I-SD/M-SD	4	47.962	30.379	-17.582	(-100.0783, 64.9136)	25.9222
I-SD/M-HD	8	37.000	12.500	-24.500	(-57.2500, 8.2500)	13.8500
I-HD	29	45.434	17.998	-27.436	(-40.7526, -14.1204)	6.5007
I-HD/M-PL	6	54.720	23.413	-31.308	(-59.8424, -2.7730)	11.1005
I-HD/M-SD	12	56.691	22.361	-34.330	(-64.0952, -4.5644)	13.5237
I-HD/M-HD	11	28.089	10.284	-17.805	(-32.5172, -3.0926)	6.6030
I-SD + I-HD Total	44	44.669	18.363	-26.305	(-37.0974, -15.5135)	5.3513
I-HD-OL	7	49.947	16.429	-33.518	(-59.0279, -8.0085)	10.4253
I-HD-OL/M-SD	3	41.404	6.667	-34.737	(-152.1957, 82.7220)	27.2992
I-HD-OL/M-HD	4	56.354	23.750	-32.604	(-41.1013, -24.1070)	2.6700
M-SD Total	19	52.439	21.571	-30.868	(-52.8886, -8.8480)	10.4813
M-HD Total	23	36.104	13.397	-22.707	(-34.4800, -10.9348)	5.6766
M-SD + M-HD Total	42	43.494	17.095	-26.399	(-37.7679, -15.0305)	5.6293

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%)						
Week 1						
I-SD	20	12.266	4.842	-7.424	(-15.5656, 0.7181)	3.8900
I-SD/-	5	20.667	5.818	-14.848	(-42.5108, 12.8138)	9.9632
I-SD/M-PL	3	0.000	5.556	5.556	(-18.3481, 29.4592)	5.5556
I-SD/M-SD	4	12.997	2.708	-10.289	(-38.7282, 18.1505)	8.9363
I-SD/M-HD	8	11.250	5.032	-6.218	(-19.6088, 7.1729)	5.6630
I-HD	32	12.779	7.539	-5.240	(-10.3482, -0.1315)	2.5047
I-HD/-	4	31.696	28.571	-3.125	(-13.0701, 6.8201)	3.1250
I-HD/M-PL	6	8.191	1.699	-6.492	(-17.1682, 4.1841)	4.1532
I-HD/M-SD	11	12.860	7.133	-5.727	(-21.0584, 9.6039)	6.8807
I-HD/M-HD	11	8.322	3.483	-4.838	(-8.8080, -0.8688)	1.7816
I-SD + I-HD Total	52	12.582	6.502	-6.080	(-10.3560, -1.8036)	2.1300
I-HD-OL	6	18.909	17.750	-1.159	(-34.2100, 31.8918)	12.8574
I-HD-OL/-	1	14.286	5.882	-8.403		0.0000
I-HD-OL/M-SD	1	0.000	0.000	0.000		
I-HD-OL/M-HD	4	24.792	25.154	0.362	(-63.9219, 64.6462)	20.1996
M-SD Total	16	12.091	5.581	-6.510	(-17.4062, 4.3868)	5.1122
M-HD Total	23	12.205	7.791	-4.414	(-12.2153, 3.3878)	3.7618
M-SD + M-HD Total	39	12.158	6.884	-5.274	(-11.3778, 0.8305)	3.0153

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 2						
I-SD	22	11.656	5.313	-6.343	(-13.9083, 1.2231)	3.6380
I-SD/-	7	16.349	5.714	-10.635	(-27.5604, 6.2905)	6.9171
I-SD/M-PL	3	0.000	0.000	0.000		
I-SD/M-SD	4	12.997	6.724	-6.273	(-43.4897, 30.9437)	11.6944
I-SD/M-HD	8	11.250	6.250	-5.000	(-19.8211, 9.8211)	6.2678
I-HD	33	13.301	6.257	-7.044	(-11.3883, -2.7005)	2.1326
I-HD/-	4	31.696	30.000	-1.696	(-26.8361, 23.4432)	7.8995
I-HD/M-PL	6	8.191	2.269	-5.922	(-17.1293, 5.2848)	4.3597
I-HD/M-SD	12	14.289	3.244	-11.045	(-19.9549, -2.1344)	4.0483
I-HD/M-HD	11	8.322	3.084	-5.237	(-11.8544, 1.3800)	2.9698
I-SD + I-HD Total	55	12.643	5.879	-6.764	(-10.6086, -2.9187)	1.9178
I-HD-OL	6	18.909	6.686	-12.223	(-30.7964, 6.3506)	7.2254
I-HD-OL/-	1	14.286	3.448	-10.837		0.0000
I-HD-OL/M-SD	1	0.000	0.000	0.000		
I-HD-OL/M-HD	4	24.792	9.167	-15.625	(-49.6114, 18.3614)	10.6793
M-SD Total	17	13.144	3.872	-9.272	(-17.3651, -1.1794)	3.8176
M-HD Total	23	12.205	5.243	-6.961	(-13.4166, -0.5060)	3.1127
M-SD + M-HD Total	40	12.604	4.661	-7.943	(-12.7798, -3.1071)	2.3911

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 4						
I-SD	22	11.656	3.831	-7.825	(-16.9933, 1.3436)	4.4087
I-SD/-	7	16.349	11.020	-5.329	(-33.6101, 22.9525)	11.5580
I-SD/M-PL	3	0.000	0.000	0.000		
I-SD/M-SD	4	12.997	0.000	-12.997	(-40.4160, 14.4216)	8.6156
I-SD/M-HD	8	11.250	0.893	-10.357	(-24.8128, 4.0985)	6.1133
I-HD	33	13.301	10.266	-3.035	(-8.3150, 2.2457)	2.5923
I-HD/-	4	31.696	30.000	-1.696	(-26.8361, 23.4432)	7.8995
I-HD/M-PL	6	8.191	5.693	-2.498	(-15.5414, 10.5449)	5.0740
I-HD/M-SD	12	14.289	13.303	-0.986	(-14.1198, 12.1480)	5.9673
I-HD/M-HD	11	8.322	2.273	-6.049	(-11.7325, -0.3653)	2.5508
I-SD + I-HD Total	55	12.643	7.692	-4.951	(-9.6590, -0.2425)	2.3484
I-HD-OL	6	18.909	5.417	-13.492	(-41.3038, 14.3196)	10.8192
I-HD-OL/-	1	14.286	12.500	-1.786		0.0000
I-HD-OL/M-SD	1	0.000	0.000	0.000		
I-HD-OL/M-HD	4	24.792	5.000	-19.792	(-70.3937, 30.8103)	15.9004
M-SD Total	17	13.144	9.390	-3.754	(-13.7428, 6.2346)	4.7119
M-HD Total	23	12.205	2.267	-9.937	(-17.3123, -2.5627)	3.5561
M-SD + M-HD Total	40	12.604	5.294	-7.310	(-13.1060, -1.5131)	2.8657

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 8						
I-SD	22	11.656	5.217	-6.439	(-14.8965, 2.0184)	4.0668
I-SD/-	7	16.349	13.539	-2.810	(-30.1191, 24.4992)	11.1607
I-SD/M-PL	3	0.000	0.000	0.000		
I-SD/M-SD	4	12.997	0.000	-12.997	(-40.4160, 14.4216)	8.6156
I-SD/M-HD	8	11.250	2.500	-8.750	(-19.1704, 1.6704)	4.4068
I-HD	33	13.301	4.286	-9.015	(-14.0676, -3.9616)	2.4807
I-HD/-	4	31.696	25.000	-6.696	(-19.0549, 5.6621)	3.8833
I-HD/M-PL	6	8.191	4.167	-4.024	(-19.2553, 11.2071)	5.9252
I-HD/M-SD	12	14.289	1.220	-13.069	(-25.0134, -1.1251)	5.4267
I-HD/M-HD	11	8.322	0.165	-8.156	(-14.8764, -1.4363)	3.0160
I-SD + I-HD Total	55	12.643	4.659	-7.984	(-12.3724, -3.5963)	2.1887
I-HD-OL	7	16.207	0.680	-15.527	(-37.5550, 6.5006)	9.0023
I-HD-OL/-	1	14.286	4.762	-9.524		0.0000
I-HD-OL/M-SD	2	0.000	0.000	0.000		
I-HD-OL/M-HD	4	24.792	0.000	-24.792	(-71.1123, 21.5289)	14.5550
M-SD Total	18	12.414	0.813	-11.601	(-20.1982, -3.0039)	4.0748
M-HD Total	23	12.205	0.949	-11.256	(-18.1051, -4.4067)	3.3026
M-SD + M-HD Total	41	12.297	0.889	-11.407	(-16.5460, -6.2689)	2.5425

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 12						
I-SD	15	9.466	0.000	-9.466	(-17.7362, -1.1957)	3.8560
I-SD/M-PL	3	0.000	0.000	0.000		
I-SD/M-SD	4	12.997	0.000	-12.997	(-40.4160, 14.4216)	8.6156
I-SD/M-HD	8	11.250	0.000	-11.250	(-24.9781, 2.4781)	5.8056
I-HD	29	10.764	1.874	-8.889	(-14.4742, -3.3044)	2.7264
I-HD/M-PL	6	8.191	2.646	-5.545	(-16.3270, 5.2365)	4.1943
I-HD/M-SD	12	14.289	1.667	-12.622	(-24.7326, -0.5115)	5.5023
I-HD/M-HD	11	8.322	1.680	-6.641	(-14.0675, 0.7851)	3.3330
I-SD + I-HD Total	44	10.321	1.235	-9.086	(-13.5237, -4.6481)	2.2005
I-HD-OL	7	24.317	6.429	-17.888	(-43.7755, 7.9986)	10.5795
I-HD-OL/M-SD	3	23.684	0.000	-23.684	(-125.5891, 78.2207)	23.6842
I-HD-OL/M-HD	4	24.792	11.250	-13.542	(-44.8158, 17.7324)	9.8271
M-SD Total	19	15.500	1.053	-14.448	(-24.9567, -3.9387)	5.0021
M-HD Total	23	12.205	2.760	-9.444	(-15.5931, -3.2956)	2.9649
M-SD + M-HD Total	42	13.695	1.988	-11.708	(-17.3131, -6.1025)	2.7755

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 18						
I-SD	15	9.466	3.333	-6.133	(-16.8971, 4.6320)	5.0189
I-SD/M-PL	3	0.000	0.000	0.000		
I-SD/M-SD	4	12.997	12.500	-0.497	(-50.4200, 49.4257)	15.6870
I-SD/M-HD	8	11.250	0.000	-11.250	(-24.9781, 2.4781)	5.8056
I-HD	29	10.764	3.675	-7.089	(-13.2654, -0.9117)	3.0154
I-HD/M-PL	6	8.191	4.960	-3.230	(-17.5574, 11.0965)	5.5734
I-HD/M-SD	12	14.289	6.250	-8.039	(-22.0356, 5.9581)	6.3594
I-HD/M-HD	11	8.322	0.165	-8.156	(-14.8764, -1.4363)	3.0160
I-SD + I-HD Total	44	10.321	3.559	-6.763	(-11.9839, -1.5413)	2.5890
I-HD-OL	7	24.317	1.429	-22.888	(-49.9805, 4.2035)	11.0719
I-HD-OL/M-SD	3	23.684	0.000	-23.684	(-125.5891, 78.2207)	23.6842
I-HD-OL/M-HD	4	24.792	2.500	-22.292	(-61.0480, 16.4646)	12.1781
M-SD Total	19	15.500	6.579	-8.921	(-21.6755, 3.8327)	6.0707
M-HD Total	23	12.205	0.514	-11.691	(-18.3748, -5.0066)	3.2230
M-SD + M-HD Total	42	13.695	3.258	-10.438	(-16.9564, -3.9194)	3.2277

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 26						
I-SD	15	9.466	2.667	-6.799	(-17.6481, 4.0496)	5.0582
I-SD/M-PL	3	0.000	0.000	0.000		
I-SD/M-SD	4	12.997	10.000	-2.997	(-54.3990, 48.4047)	16.1517
I-SD/M-HD	8	11.250	0.000	-11.250	(-24.9781, 2.4781)	5.8056
I-HD	29	10.764	3.519	-7.245	(-13.5084, -0.9807)	3.0579
I-HD/M-PL	6	8.191	2.646	-5.545	(-16.3270, 5.2365)	4.1943
I-HD/M-SD	12	14.289	6.944	-7.344	(-22.2105, 7.5220)	6.7544
I-HD/M-HD	11	8.322	0.259	-8.063	(-14.8421, -1.2831)	3.0427
I-SD + I-HD Total	44	10.321	3.229	-7.093	(-12.3725, -1.8130)	2.6180
I-HD-OL	7	24.317	6.178	-18.139	(-41.5672, 5.2883)	9.5744
I-HD-OL/M-SD	3	23.684	0.000	-23.684	(-125.5891, 78.2207)	23.6842
I-HD-OL/M-HD	4	24.792	10.811	-13.981	(-30.4931, 2.5313)	5.1885
M-SD Total	19	15.500	6.491	-9.009	(-22.1314, 4.1132)	6.2460
M-HD Total	23	12.205	2.004	-10.201	(-15.5329, -4.8682)	2.5712
M-SD + M-HD Total	42	13.695	4.034	-9.662	(-15.9511, -3.3720)	3.1144

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 34						
I-SD	15	9.466	3.126	-6.339	(-17.1099, 4.4310)	5.0217
I-SD/M-PL	3	0.000	0.000	0.000		
I-SD/M-SD	4	12.997	11.724	-1.273	(-51.5249, 48.9789)	15.7903
I-SD/M-HD	8	11.250	0.000	-11.250	(-24.9781, 2.4781)	5.8056
I-HD	29	10.764	3.484	-7.280	(-13.5374, -1.0228)	3.0547
I-HD/M-PL	6	8.191	2.646	-5.545	(-16.3270, 5.2365)	4.1943
I-HD/M-SD	12	14.289	6.944	-7.344	(-22.2105, 7.5220)	6.7544
I-HD/M-HD	11	8.322	0.165	-8.156	(-14.8764, -1.4363)	3.0160
I-SD + I-HD Total	44	10.321	3.362	-6.959	(-12.2215, -1.6973)	2.6093
I-HD-OL	7	24.317	5.238	-19.079	(-47.1112, 8.9533)	11.4562
I-HD-OL/M-SD	3	23.684	0.000	-23.684	(-125.5891, 78.2207)	23.6842
I-HD-OL/M-HD	4	24.792	9.167	-15.625	(-57.0706, 25.8206)	13.0232
M-SD Total	19	15.500	6.854	-8.646	(-21.7457, 4.4534)	6.2351
M-HD Total	23	12.205	1.673	-10.531	(-17.1110, -3.9516)	3.1727
M-SD + M-HD Total	42	13.695	4.017	-9.678	(-16.2847, -3.0722)	3.2712

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 42						
I-SD	15	9.466	3.126	-6.339	(-17.1099, 4.4310)	5.0217
I-SD/M-PL	3	0.000	0.000	0.000		
I-SD/M-SD	4	12.997	11.724	-1.273	(-51.5249, 48.9789)	15.7903
I-SD/M-HD	8	11.250	0.000	-11.250	(-24.9781, 2.4781)	5.8056
I-HD	29	10.764	4.173	-6.590	(-12.7131, -0.4678)	2.9890
I-HD/M-PL	6	8.191	2.646	-5.545	(-16.3270, 5.2365)	4.1943
I-HD/M-SD	12	14.289	6.944	-7.344	(-22.2105, 7.5220)	6.7544
I-HD/M-HD	11	8.322	1.983	-6.338	(-11.9205, -0.7558)	2.5054
I-SD + I-HD Total	44	10.321	3.816	-6.505	(-11.6990, -1.3108)	2.5756
I-HD-OL	7	24.317	2.857	-21.460	(-46.9528, 4.0330)	10.4184
I-HD-OL/M-SD	3	23.684	0.000	-23.684	(-125.5891, 78.2207)	23.6842
I-HD-OL/M-HD	4	24.792	5.000	-19.792	(-51.1780, 11.5947)	9.8623
M-SD Total	19	15.500	6.854	-8.646	(-21.7457, 4.4534)	6.2351
M-HD Total	23	12.205	1.818	-10.386	(-16.4216, -4.3511)	2.9101
M-SD + M-HD Total	42	13.695	4.096	-9.599	(-16.0579, -3.1404)	3.1981

表 2.7.3.6-55. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 52						
I-SD	15	9.466	10.096	0.630	(-13.6947, 14.9551)	6.6789
I-SD/M-PL	3	0.000	18.182	18.182	(-60.0482, 96.4119)	18.1818
I-SD/M-SD	4	12.997	11.724	-1.273	(-51.5249, 48.9789)	15.7903
I-SD/M-HD	8	11.250	6.250	-5.000	(-22.8749, 12.8749)	7.5593
I-HD	29	10.764	4.058	-6.705	(-12.8281, -0.5827)	2.9890
I-HD/M-PL	6	8.191	2.646	-5.545	(-16.3270, 5.2365)	4.1943
I-HD/M-SD	12	14.289	6.944	-7.344	(-22.2105, 7.5220)	6.7544
I-HD/M-HD	11	8.322	1.680	-6.641	(-12.2283, -1.0540)	2.5075
I-SD + I-HD Total	44	10.321	6.117	-4.205	(-10.2771, 1.8678)	3.0111
I-HD-OL	7	24.317	5.238	-19.079	(-45.3614, 7.2035)	10.7411
I-HD-OL/M-SD	3	23.684	0.000	-23.684	(-125.5891, 78.2207)	23.6842
I-HD-OL/M-HD	4	24.792	9.167	-15.625	(-49.6114, 18.3614)	10.6793
M-SD Total	19	15.500	6.854	-8.646	(-21.7457, 4.4534)	6.2351
M-HD Total	23	12.205	4.572	-7.633	(-14.5209, -0.7446)	3.3214
M-SD + M-HD Total	42	13.695	5.604	-8.091	(-14.7798, -1.4026)	3.3119

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
Note: I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group, M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
Note: baseline is defined as the last non-missing value prior to the first dose of study drug. Subjects with non-missing baseline and at least one post-baseline value are included in the analyses.
Last observation carried forward (LOCF): missing data is imputed by carrying forward the last non-missing post-baseline observation. For subjects re-randomized due to disease flare, the last non-missing value before the re-randomization after the first disease flare are carried forward.
WPAI = work productivity and activity impairment.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.2__1.3.8_A

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%)						
Week 1						
I-SD	1	40.0	30.0	-10.0		0.00
I-SD/-	1	40.0	30.0	-10.0		0.00
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	37.5	12.5	-25.0	(-62.88, 12.88)	11.90
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	50.0	-20.0		0.00
I-HD/M-HD	3	26.7	0.0	-26.7	(-98.38, 45.04)	16.67
I-SD + I-HD Total	5	38.0	16.0	-22.0	(-48.92, 4.92)	9.70
I-HD-OL	1	50.0	60.0	10.0		0.00
I-HD-OL/-	0					
I-HD-OL/M-SD	1	50.0	60.0	10.0		0.00
I-HD-OL/M-HD	0					
M-SD Total	2	60.0	55.0	-5.0	(-195.59, 185.59)	15.00
M-HD Total	3	26.7	0.0	-26.7	(-98.38, 45.04)	16.67
M-SD + M-HD Total	5	40.0	22.0	-18.0	(-50.14, 14.14)	11.58

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 2						
I-SD	2	35.0	40.0	5.0	(-58.53, 68.53)	5.00
I-SD/-	2	35.0	40.0	5.0	(-58.53, 68.53)	5.00
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	37.5	12.5	-25.0	(-62.88, 12.88)	11.90
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	50.0	-20.0		0.00
I-HD/M-HD	3	26.7	0.0	-26.7	(-98.38, 45.04)	16.67
I-SD + I-HD Total	6	36.7	21.7	-15.0	(-40.49, 10.49)	9.92
I-HD-OL	1	50.0	60.0	10.0		0.00
I-HD-OL/-	0					
I-HD-OL/M-SD	1	50.0	60.0	10.0		0.00
I-HD-OL/M-HD	0					
M-SD Total	2	60.0	55.0	-5.0	(-195.59, 185.59)	15.00
M-HD Total	3	26.7	0.0	-26.7	(-98.38, 45.04)	16.67
M-SD + M-HD Total	5	40.0	22.0	-18.0	(-50.14, 14.14)	11.58

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 4						
I-SD	2	35.0	35.0	0.0		
I-SD/-	2	35.0	35.0	0.0		
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	37.5	22.5	-15.0	(-64.47, 34.47)	15.55
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	80.0	10.0		0.00
I-HD/M-HD	3	26.7	3.3	-23.3	(-103.19, 56.52)	18.56
I-SD + I-HD Total	6	36.7	26.7	-10.0	(-36.55, 16.55)	10.33
I-HD-OL	1	50.0	70.0	20.0		0.00
I-HD-OL/-	0					
I-HD-OL/M-SD	1	50.0	70.0	20.0		0.00
I-HD-OL/M-HD	0					
M-SD Total	2	60.0	75.0	15.0	(-48.53, 78.53)	5.00
M-HD Total	3	26.7	3.3	-23.3	(-103.19, 56.52)	18.56
M-SD + M-HD Total	5	40.0	32.0	-8.0	(-46.67, 30.67)	13.93

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 8						
I-SD	2	35.0	25.0	-10.0	(-137.06, 117.06)	10.00
I-SD/-	2	35.0	25.0	-10.0	(-137.06, 117.06)	10.00
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	37.5	2.5	-35.0	(-90.88, 20.88)	17.56
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	0.0	-70.0		0.00
I-HD/M-HD	3	26.7	3.3	-23.3	(-103.19, 56.52)	18.56
I-SD + I-HD Total	6	36.7	10.0	-26.7	(-58.96, 5.62)	12.56
I-HD-OL	1	50.0	60.0	10.0		0.00
I-HD-OL/-	0					
I-HD-OL/M-SD	1	50.0	60.0	10.0		0.00
I-HD-OL/M-HD	0					
M-SD Total	2	60.0	30.0	-30.0	(-538.25, 478.25)	40.00
M-HD Total	3	26.7	3.3	-23.3	(-103.19, 56.52)	18.56
M-SD + M-HD Total	5	40.0	14.0	-26.0	(-71.28, 19.28)	16.31

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 12						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	37.5	2.5	-35.0	(-90.88, 20.88)	17.56
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	0.0	-70.0		0.00
I-HD/M-HD	3	26.7	3.3	-23.3	(-103.19, 56.52)	18.56
I-SD + I-HD Total	4	37.5	2.5	-35.0	(-90.88, 20.88)	17.56
I-HD-OL	1	50.0	50.0	0.0		
I-HD-OL/M-SD	1	50.0	50.0	0.0		
I-HD-OL/M-HD	0					
M-SD Total	2	60.0	25.0	-35.0	(-479.72, 409.72)	35.00
M-HD Total	3	26.7	3.3	-23.3	(-103.19, 56.52)	18.56
M-SD + M-HD Total	5	40.0	12.0	-28.0	(-70.47, 14.47)	15.30

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 18						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	37.5	2.5	-35.0	(-90.88, 20.88)	17.56
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	0.0	-70.0		0.00
I-HD/M-HD	3	26.7	3.3	-23.3	(-103.19, 56.52)	18.56
I-SD + I-HD Total	4	37.5	2.5	-35.0	(-90.88, 20.88)	17.56
I-HD-OL	1	50.0	50.0	0.0		
I-HD-OL/M-SD	1	50.0	50.0	0.0		
I-HD-OL/M-HD	0					
M-SD Total	2	60.0	25.0	-35.0	(-479.72, 409.72)	35.00
M-HD Total	3	26.7	3.3	-23.3	(-103.19, 56.52)	18.56
M-SD + M-HD Total	5	40.0	12.0	-28.0	(-70.47, 14.47)	15.30

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 26						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	37.5	5.0	-32.5	(-93.96, 28.96)	19.31
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	0.0	-70.0		0.00
I-HD/M-HD	3	26.7	6.7	-20.0	(-109.57, 69.57)	20.82
I-SD + I-HD Total	4	37.5	5.0	-32.5	(-93.96, 28.96)	19.31
I-HD-OL	1	50.0	50.0	0.0		
I-HD-OL/M-SD	1	50.0	50.0	0.0		
I-HD-OL/M-HD	0					
M-SD Total	2	60.0	25.0	-35.0	(-479.72, 409.72)	35.00
M-HD Total	3	26.7	6.7	-20.0	(-109.57, 69.57)	20.82
M-SD + M-HD Total	5	40.0	14.0	-26.0	(-71.28, 19.28)	16.31

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 34						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	37.5	2.5	-35.0	(-90.88, 20.88)	17.56
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	0.0	-70.0		0.00
I-HD/M-HD	3	26.7	3.3	-23.3	(-103.19, 56.52)	18.56
I-SD + I-HD Total	4	37.5	2.5	-35.0	(-90.88, 20.88)	17.56
I-HD-OL	1	50.0	50.0	0.0		
I-HD-OL/M-SD	1	50.0	50.0	0.0		
I-HD-OL/M-HD	0					
M-SD Total	2	60.0	25.0	-35.0	(-479.72, 409.72)	35.00
M-HD Total	3	26.7	3.3	-23.3	(-103.19, 56.52)	18.56
M-SD + M-HD Total	5	40.0	12.0	-28.0	(-70.47, 14.47)	15.30

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 42						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	37.5	2.5	-35.0	(-90.88, 20.88)	17.56
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	0.0	-70.0		0.00
I-HD/M-HD	3	26.7	3.3	-23.3	(-103.19, 56.52)	18.56
I-SD + I-HD Total	4	37.5	2.5	-35.0	(-90.88, 20.88)	17.56
I-HD-OL	1	50.0	50.0	0.0		
I-HD-OL/M-SD	1	50.0	50.0	0.0		
I-HD-OL/M-HD	0					
M-SD Total	2	60.0	25.0	-35.0	(-479.72, 409.72)	35.00
M-HD Total	3	26.7	3.3	-23.3	(-103.19, 56.52)	18.56
M-SD + M-HD Total	5	40.0	12.0	-28.0	(-70.47, 14.47)	15.30

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 52						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	37.5	2.5	-35.0	(-90.88, 20.88)	17.56
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	0.0	-70.0		0.00
I-HD/M-HD	3	26.7	3.3	-23.3	(-103.19, 56.52)	18.56
I-SD + I-HD Total	4	37.5	2.5	-35.0	(-90.88, 20.88)	17.56
I-HD-OL	1	50.0	50.0	0.0		
I-HD-OL/M-SD	1	50.0	50.0	0.0		
I-HD-OL/M-HD	0					
M-SD Total	2	60.0	25.0	-35.0	(-479.72, 409.72)	35.00
M-HD Total	3	26.7	3.3	-23.3	(-103.19, 56.52)	18.56
M-SD + M-HD Total	5	40.0	12.0	-28.0	(-70.47, 14.47)	15.30

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%)						
Week 1						
I-SD	1	40.0	10.0	-30.0		0.00
I-SD/-	1	40.0	10.0	-30.0		0.00
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	20.0	12.5	-7.5	(-22.73, 7.73)	4.79
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	50.0	-20.0		0.00
I-HD/M-HD	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
I-SD + I-HD Total	5	24.0	12.0	-12.0	(-28.19, 4.19)	5.83
I-HD-OL	0					
I-HD-OL/-	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	70.0	50.0	-20.0		0.00
M-HD Total	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
M-SD + M-HD Total	4	20.0	12.5	-7.5	(-22.73, 7.73)	4.79

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 2						
I-SD	2	20.0	30.0	10.0	(-244.12, 264.12)	20.00
I-SD/-	2	20.0	30.0	10.0	(-244.12, 264.12)	20.00
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	20.0	15.0	-5.0	(-14.19, 4.19)	2.89
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	60.0	-10.0		0.00
I-HD/M-HD	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
I-SD + I-HD Total	6	20.0	20.0	0.0	(-16.26, 16.26)	6.32
I-HD-OL	0					
I-HD-OL/-	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	70.0	60.0	-10.0		0.00
M-HD Total	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
M-SD + M-HD Total	4	20.0	15.0	-5.0	(-14.19, 4.19)	2.89

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 4						
I-SD	2	20.0	20.0	0.0	(-381.19, 381.19)	30.00
I-SD/-	2	20.0	20.0	0.0	(-381.19, 381.19)	30.00
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	20.0	22.5	2.5	(-17.52, 22.52)	6.29
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	90.0	20.0		0.00
I-HD/M-HD	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
I-SD + I-HD Total	6	20.0	21.7	1.7	(-20.76, 24.09)	8.72
I-HD-OL	0					
I-HD-OL/-	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	70.0	90.0	20.0		0.00
M-HD Total	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
M-SD + M-HD Total	4	20.0	22.5	2.5	(-17.52, 22.52)	6.29

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 8						
I-SD	2	20.0	20.0	0.0	(-381.19, 381.19)	30.00
I-SD/-	2	20.0	20.0	0.0	(-381.19, 381.19)	30.00
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	0.0	-70.0		0.00
I-HD/M-HD	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
I-SD + I-HD Total	6	20.0	6.7	-13.3	(-48.87, 22.20)	13.82
I-HD-OL	0					
I-HD-OL/-	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	70.0	0.0	-70.0		0.00
M-HD Total	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
M-SD + M-HD Total	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 12						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	0.0	-70.0		0.00
I-HD/M-HD	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
I-SD + I-HD Total	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	70.0	0.0	-70.0		0.00
M-HD Total	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
M-SD + M-HD Total	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 18						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	0.0	-70.0		0.00
I-HD/M-HD	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
I-SD + I-HD Total	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	70.0	0.0	-70.0		0.00
M-HD Total	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
M-SD + M-HD Total	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 26						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	0.0	-70.0		0.00
I-HD/M-HD	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
I-SD + I-HD Total	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	70.0	0.0	-70.0		0.00
M-HD Total	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
M-SD + M-HD Total	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 34						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	0.0	-70.0		0.00
I-HD/M-HD	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
I-SD + I-HD Total	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	70.0	0.0	-70.0		0.00
M-HD Total	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
M-SD + M-HD Total	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 42						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	0.0	-70.0		0.00
I-HD/M-HD	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
I-SD + I-HD Total	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	70.0	0.0	-70.0		0.00
M-HD Total	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
M-SD + M-HD Total	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 52						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	0.0	-70.0		0.00
I-HD/M-HD	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
I-SD + I-HD Total	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	70.0	0.0	-70.0		0.00
M-HD Total	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
M-SD + M-HD Total	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%)						
Week 1						
I-SD	1	40.0	10.0	-30.0		0.00
I-SD/-	1	40.0	10.0	-30.0		0.00
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	28.4	12.5	-15.9	(-46.16, 14.40)	9.52
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	88.0	50.0	-38.0		0.00
I-HD/M-HD	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
I-SD + I-HD Total	5	30.7	12.0	-18.7	(-40.62, 3.21)	7.89
I-HD-OL	0					
I-HD-OL/-	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	88.0	50.0	-38.0		0.00
M-HD Total	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
M-SD + M-HD Total	4	28.4	12.5	-15.9	(-46.16, 14.40)	9.52

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 2						
I-SD	2	20.0	30.0	10.0	(-244.12, 264.12)	20.00
I-SD/-	2	20.0	30.0	10.0	(-244.12, 264.12)	20.00
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	28.4	17.0	-11.4	(-32.59, 9.83)	6.67
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	88.0	68.0	-20.0		0.00
I-HD/M-HD	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
I-SD + I-HD Total	6	25.6	21.3	-4.3	(-24.94, 16.43)	8.05
I-HD-OL	0					
I-HD-OL/-	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	88.0	68.0	-20.0		0.00
M-HD Total	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
M-SD + M-HD Total	4	28.4	17.0	-11.4	(-32.59, 9.83)	6.67

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 4						
I-SD	2	20.0	20.0	0.0	(-381.19, 381.19)	30.00
I-SD/-	2	20.0	20.0	0.0	(-381.19, 381.19)	30.00
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	28.4	24.0	-4.4	(-27.59, 18.83)	7.29
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	88.0	96.0	8.0		0.00
I-HD/M-HD	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
I-SD + I-HD Total	6	25.6	22.7	-2.9	(-26.22, 20.38)	9.06
I-HD-OL	0					
I-HD-OL/-	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	88.0	96.0	8.0		0.00
M-HD Total	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
M-SD + M-HD Total	4	28.4	24.0	-4.4	(-27.59, 18.83)	7.29

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 8						
I-SD	2	20.0	20.0	0.0	(-381.19, 381.19)	30.00
I-SD/-	2	20.0	20.0	0.0	(-381.19, 381.19)	30.00
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	88.0	0.0	-88.0		0.00
I-HD/M-HD	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
I-SD + I-HD Total	6	25.6	6.7	-18.9	(-61.02, 23.18)	16.38
I-HD-OL	0					
I-HD-OL/-	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	88.0	0.0	-88.0		0.00
M-HD Total	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
M-SD + M-HD Total	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 12						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76
I-HD/M-PL	0					
I-HD/M-SD	1	88.0	0.0	-88.0		0.00
I-HD/M-HD	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
I-SD + I-HD Total	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	88.0	0.0	-88.0		0.00
M-HD Total	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
M-SD + M-HD Total	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 18						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76
I-HD/M-PL	0					
I-HD/M-SD	1	88.0	0.0	-88.0		0.00
I-HD/M-HD	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
I-SD + I-HD Total	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	88.0	0.0	-88.0		0.00
M-HD Total	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
M-SD + M-HD Total	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 26						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76
I-HD/M-PL	0					
I-HD/M-SD	1	88.0	0.0	-88.0		0.00
I-HD/M-HD	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
I-SD + I-HD Total	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	88.0	0.0	-88.0		0.00
M-HD Total	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
M-SD + M-HD Total	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 34						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76
I-HD/M-PL	0					
I-HD/M-SD	1	88.0	0.0	-88.0		0.00
I-HD/M-HD	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
I-SD + I-HD Total	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	88.0	0.0	-88.0		0.00
M-HD Total	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
M-SD + M-HD Total	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 42						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76
I-HD/M-PL	0					
I-HD/M-SD	1	88.0	0.0	-88.0		0.00
I-HD/M-HD	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
I-SD + I-HD Total	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	88.0	0.0	-88.0		0.00
M-HD Total	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
M-SD + M-HD Total	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 52						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76
I-HD/M-PL	0					
I-HD/M-SD	1	88.0	0.0	-88.0		0.00
I-HD/M-HD	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
I-SD + I-HD Total	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	88.0	0.0	-88.0		0.00
M-HD Total	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
M-SD + M-HD Total	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%)						
Week 1						
I-SD	1	0.0	0.0	0.0		
I-SD/-	1	0.0	0.0	0.0		
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	60.0	0.0	-60.0		0.00
I-HD/M-HD	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
I-SD + I-HD Total	5	15.4	0.0	-15.4	(-47.73, 16.84)	11.63
I-HD-OL	0					
I-HD-OL/-	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	60.0	0.0	-60.0		0.00
M-HD Total	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
M-SD + M-HD Total	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 2						
I-SD	2	0.0	0.0	0.0		
I-SD/-	2	0.0	0.0	0.0		
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	19.3	5.0	-14.3	(-44.48, 15.85)	9.48
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	60.0	20.0	-40.0		0.00
I-HD/M-HD	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
I-SD + I-HD Total	6	12.9	3.3	-9.5	(-26.79, 7.71)	6.71
I-HD-OL	0					
I-HD-OL/-	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	60.0	20.0	-40.0		0.00
M-HD Total	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
M-SD + M-HD Total	4	19.3	5.0	-14.3	(-44.48, 15.85)	9.48

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 4						
I-SD	2	0.0	0.0	0.0		
I-SD/-	2	0.0	0.0	0.0		
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	19.3	15.0	-4.3	(-18.03, 9.41)	4.31
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	60.0	60.0	0.0		
I-HD/M-HD	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
I-SD + I-HD Total	6	12.9	10.0	-2.9	(-10.26, 4.51)	2.87
I-HD-OL	0					
I-HD-OL/-	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	60.0	60.0	0.0		
M-HD Total	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
M-SD + M-HD Total	4	19.3	15.0	-4.3	(-18.03, 9.41)	4.31

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 8						
I-SD	2	0.0	0.0	0.0		
I-SD/-	2	0.0	0.0	0.0		
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	60.0	0.0	-60.0		0.00
I-HD/M-HD	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
I-SD + I-HD Total	6	12.9	0.0	-12.9	(-38.16, 12.41)	9.84
I-HD-OL	0					
I-HD-OL/-	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	60.0	0.0	-60.0		0.00
M-HD Total	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
M-SD + M-HD Total	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 12						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16
I-HD/M-PL	0					
I-HD/M-SD	1	60.0	0.0	-60.0		0.00
I-HD/M-HD	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
I-SD + I-HD Total	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	60.0	0.0	-60.0		0.00
M-HD Total	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
M-SD + M-HD Total	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 18						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16
I-HD/M-PL	0					
I-HD/M-SD	1	60.0	0.0	-60.0		0.00
I-HD/M-HD	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
I-SD + I-HD Total	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	60.0	0.0	-60.0		0.00
M-HD Total	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
M-SD + M-HD Total	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 26						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16
I-HD/M-PL	0					
I-HD/M-SD	1	60.0	0.0	-60.0		0.00
I-HD/M-HD	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
I-SD + I-HD Total	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	60.0	0.0	-60.0		0.00
M-HD Total	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
M-SD + M-HD Total	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 34						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16
I-HD/M-PL	0					
I-HD/M-SD	1	60.0	0.0	-60.0		0.00
I-HD/M-HD	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
I-SD + I-HD Total	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	60.0	0.0	-60.0		0.00
M-HD Total	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
M-SD + M-HD Total	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 42						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16
I-HD/M-PL	0					
I-HD/M-SD	1	60.0	0.0	-60.0		0.00
I-HD/M-HD	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
I-SD + I-HD Total	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	60.0	0.0	-60.0		0.00
M-HD Total	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
M-SD + M-HD Total	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16

表 2.7.3.6-56. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 52						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16
I-HD/M-PL	0					
I-HD/M-SD	1	60.0	0.0	-60.0		0.00
I-HD/M-HD	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
I-SD + I-HD Total	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	60.0	0.0	-60.0		0.00
M-HD Total	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
M-SD + M-HD Total	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
Note: I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group,
M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
Note: baseline is defined as the last non-missing value prior to the first dose of study drug. Subjects with non-missing baseline and at least one post-baseline value are included in the analyses.
Last observation carried forward (LOCF): missing data is imputed by carrying forward the last non-missing post-baseline observation. For subjects re-randomized due to disease flare, the last non-missing value before the re-randomization after the first disease flare are carried forward.
WPAI = work productivity and activity impairment.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.2__1.3.8_J

表 2.7.3.6-57.　治験期間中に入院した，又は結腸切除を行った被験者の割合（OC）（統合 ITT 集団，M11-290 試験）（中間 CSR）

Parameter / Timepoint / Treatment Group	N	Endpoint Met n (%)	Endpoint Met 95% CI $
Hospitalized (All Cause)			
During Induction	100	24 (24.0)	(16.02, 33.57)
I-SD	32	9 (28.1)	(13.75, 46.75)
I-HD	51	11 (21.6)	(11.29, 35.32)
I-HD-OL	17	4 (23.5)	(6.81, 49.90)
During Maintenance	79	15 (19.0)	(11.03, 29.38)
M-PL	12	1 (8.3)	(0.21, 38.48)
I-SD	4	0	(0.00, 60.24)
I-HD	8	1 (12.5)	(0.32, 52.65)
M-SD	33	8 (24.2)	(11.09, 42.26)
I-SD	8	2 (25.0)	(3.19, 65.09)
I-HD/I-HD-OL	25	6 (24.0)	(9.36, 45.13)
M-HD	34	6 (17.6)	(6.76, 34.53)
I-SD	9	2 (22.2)	(2.81, 60.01)
I-HD/I-HD-OL	25	4 (16.0)	(4.54, 36.08)

表 2.7.3.6-57. 治験期間中に入院した，又は結腸切除を行った被験者の割合（OC）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Endpoint Met n (%)	Endpoint Met 95% CI $
Hospitalized (UC-Related)			
During Induction	100	14 (14.0)	(7.87, 22.37)
I-SD	32	5 (15.6)	(5.28, 32.79)
I-HD	51	6 (11.8)	(4.44, 23.87)
I-HD-OL	17	3 (17.6)	(3.80, 43.43)
During Maintenance	79	7 (8.9)	(3.64, 17.41)
M-PL	12	0	(0.00, 26.46)
I-SD	4	0	(0.00, 60.24)
I-HD	8	0	(0.00, 36.94)
M-SD	33	6 (18.2)	(6.98, 35.46)
I-SD	8	1 (12.5)	(0.32, 52.65)
I-HD/I-HD-OL	25	5 (20.0)	(6.83, 40.70)
M-HD	34	1 (2.9)	(0.07, 15.33)
I-SD	9	1 (11.1)	(0.28, 48.25)
I-HD/I-HD-OL	25	0	(0.00, 13.72)

表 2.7.3.6-57.　治験期間中に入院した，又は結腸切除を行った被験者の割合（OC）（統合 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Endpoint Met n (%)	Endpoint Met 95% CI $
Underwent Colectomy			
During Induction	100	1 (1.0)	(0.03, 5.45)
I-SD	32	0	(0.00, 10.89)
I-HD	51	1 (2.0)	(0.05, 10.45)
I-HD-OL	17	0	(0.00, 19.51)
During Maintenance	79	0	(0.00, 4.56)
M-PL	12	0	(0.00, 26.46)
I-SD	4	0	(0.00, 60.24)
I-HD	8	0	(0.00, 36.94)
M-SD	33	0	(0.00, 10.58)
I-SD	8	0	(0.00, 36.94)
I-HD/I-HD-OL	25	0	(0.00, 13.72)
M-HD	34	0	(0.00, 10.28)
I-SD	9	0	(0.00, 33.63)
I-HD/I-HD-OL	25	0	(0.00, 13.72)

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
Note: I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group, M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
$ Clopper-Pearson confidence interval for proportion of patients with adjudicated event.
Observed cases (OC): missing values are not imputed for the observed case analysis. For subjects re-randomized due to disease flare, only non-missing data up to before the first disease flare is used.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.2__1.3.28_A

表 2.7.3.6-58.　治験期間中に入院した，又は結腸切除を行った被験者の割合（OC）（日本人 ITT 集団，M11-290 試験）（中間 CSR）

Parameter / Timepoint / Treatment Group	N	Endpoint Met n (%)	Endpoint Met 95% CI $
Hospitalized (All Cause)			
During Induction	7	2 (28.6)	(3.67, 70.96)
I-SD	2	0	(0.00, 84.19)
I-HD	4	1 (25.0)	(0.63, 80.59)
I-HD-OL	1	1 (100)	(2.50, 100.00)
During Maintenance	5	2 (40.0)	(5.27, 85.34)
M-PL	0	0	
I-SD	0	0	
I-HD	0	0	
M-SD	2	2 (100)	(15.81, 100.00)
I-SD	0	0	
I-HD/I-HD-OL	2	2 (100)	(15.81, 100.00)
M-HD	3	0	(0.00, 70.76)
I-SD	0	0	
I-HD/I-HD-OL	3	0	(0.00, 70.76)

表 2.7.3.6-58. 治験期間中に入院した，又は結腸切除を行った被験者の割合（OC）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Endpoint Met n (%)	Endpoint Met 95% CI $
Hospitalized (UC-Related)			
During Induction	7	1 (14.3)	(0.36, 57.87)
I-SD	2	0	(0.00, 84.19)
I-HD	4	0	(0.00, 60.24)
I-HD-OL	1	1 (100)	(2.50, 100.00)
During Maintenance	5	1 (20.0)	(0.51, 71.64)
M-PL	0	0	
I-SD	0	0	
I-HD	0	0	
M-SD	2	1 (50.0)	(1.26, 98.74)
I-SD	0	0	
I-HD/I-HD-OL	2	1 (50.0)	(1.26, 98.74)
M-HD	3	0	(0.00, 70.76)
I-SD	0	0	
I-HD/I-HD-OL	3	0	(0.00, 70.76)

表 2.7.3.6-58. 治験期間中に入院した，又は結腸切除を行った被験者の割合（OC）（日本人 ITT 集団，M11-290 試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Endpoint Met n (%)	Endpoint Met 95% CI $
Underwent Colectomy			
During Induction	7	0	(0.00, 40.96)
I-SD	2	0	(0.00, 84.19)
I-HD	4	0	(0.00, 60.24)
I-HD-OL	1	0	(0.00, 97.50)
During Maintenance	5	0	(0.00, 52.18)
M-PL	0	0	
I-SD	0	0	
I-HD	0	0	
M-SD	2	0	(0.00, 84.19)
I-SD	0	0	
I-HD/I-HD-OL	2	0	(0.00, 84.19)
M-HD	3	0	(0.00, 70.76)
I-SD	0	0	
I-HD/I-HD-OL	3	0	(0.00, 70.76)

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
Note: I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group, M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
$ Clopper-Pearson confidence interval for proportion of patients with adjudicated event.
Observed cases (OC): missing values are not imputed for the observed case analysis. For subjects re-randomized due to disease flare, only non-missing data up to before the first disease flare is used.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.2__1.3.28_J

表 2.7.3.6-59. 治験期間中に Mayo 内視鏡所見サブスコアにより粘膜治癒を達成した被験者の割合（OC）（統合 FAS 集団，M10-870 試験の日本サブ試験）（中間 CSR）

	Adalimumab		
		Endpoint Met	
Timepoint	N	n (%)	95% CI $
Baseline	59	37 (62.7)	(49.15, 74.96)
Week 48	2	1 (50.0)	(1.26, 98.74)
Week 96	10	7 (70.0)	(34.75, 93.33)

$ Clopper-Pearson confidence interval for proportion of subjects with mucosal healing.
Note: baseline is defined as the last non-missing value before the baseline visit date (i.e., at or before the Week 52 visit from the Study M11-290) and prior to first dose of M10-870.
Observed cases (OC): missing values are not imputed for the observed case analysis.
Mucosal healing is defined as endoscopy subscore of 0 or 1.

Cross reference: M10-870 Japan Sub-study CSR_Interim Table 14.2__2.3_A

表 2.7.3.6-60. 被験者の最終状況（無作為化した被験者集団，M11-290 試験の主試験）（中間 CSR）

Category Treatment	ITT (N=93) n	ITT-E (N=77) n	mITT (N=74) n	mITT-E (N=62) n	RR (N=22) n	Safety (N=93) n
Disc. in induction period	18	16	--	--	--	18
I-SD	8	8	--	--	--	8
I-HD	8	8	--	--	--	8
I-HD-OL	2	0	--	--	--	2
Disc. in maintenance period	--	--	10	9	4	11
M-PL	--	--	1	0	1	1
M-SD	--	--	7	7	2	7
M-HD	--	--	2	2	1	3
On DB TRT w/o re-rand. due to disease flare	--	--	6	6	--	7
M-PL	--	--	0	0	--	0
M-SD	--	--	5	5	--	5
M-HD	--	--	1	1	--	2
On DB TRT after re-rand. due to disease flare	--	--	4	3	4	4
M-PL	--	--	1	0	1	1
M-SD	--	--	2	2	2	2
M-HD	--	--	1	1	1	1
On OL TRT after re-rand. due to disease flare	--	--	0	0	0	0
M-PL	--	--	0	0	0	0
M-SD	--	--	0	0	0	0
M-HD	--	--	0	0	0	0

表 2.7.3.6-60. 被験者の最終状況（無作為化した被験者集団，M11-290 試験の主試験）（中間 CSR）（続き）

Category Treatment	ITT (N=93) n	ITT-E (N=77) n	mITT (N=74) n	mITT-E (N=62) n	RR (N=22) n	Safety (N=93) n
Completed week 52	--	--	64	53	18	64
M-PL	--	--	11	0	6	11
I-SD	--	--	4	0	2	4
I-HD	--	--	7	0	4	7
M-SD	--	--	24	24	4	24
I-SD	--	--	5	5	0	5
I-HD/I-HD-OL	--	--	19	19	4	19
I-HD	--	--	13	13	3	13
I-HD-OL	--	--	6	6	1	6
M-HD	--	--	29	29	8	29
I-SD	--	--	9	9	3	9
I-HD/I-HD-OL	--	--	20	20	5	20
I-HD	--	--	14	14	4	14
I-HD-OL	--	--	6	6	1	6
On DB TRT w/o disease flare	--	--	46	41	--	46
M-PL	--	--	5	0	--	5
I-SD	--	--	2	0	--	2
I-HD	--	--	3	0	--	3
M-SD	--	--	20	20	--	20
I-SD	--	--	5	5	--	5
I-HD/I-HD-OL	--	--	15	15	--	15
I-HD	--	--	10	10	--	10
I-HD-OL	--	--	5	5	--	5
M-HD	--	--	21	21	--	21
I-SD	--	--	6	6	--	6
I-HD/I-HD-OL	--	--	15	15	--	15
I-HD	--	--	10	10	--	10
I-HD-OL	--	--	5	5	--	5

表 2.7.3.6-60. 被験者の最終状況（無作為化した被験者集団，M11-290 試験の主試験）（中間 CSR）（続き）

Category Treatment	ITT (N=93) n	ITT-E (N=77) n	mITT (N=74) n	mITT-E (N=62) n	RR (N=22) n	Safety (N=93) n
On DB TRT after re-rand. due to disease flare	--	--	11	8	11	11
M-PL	--	--	3	0	3	3
I-SD	--	--	2	0	2	2
I-HD	--	--	1	0	1	1
M-SD	--	--	3	3	3	3
I-SD	--	--	0	0	0	0
I-HD/I-HD-OL	--	--	3	3	3	3
I-HD	--	--	3	3	3	3
I-HD-OL	--	--	0	0	0	0
M-HD	--	--	5	5	5	5
I-SD	--	--	2	2	2	2
I-HD/I-HD-OL	--	--	3	3	3	3
I-HD	--	--	3	3	3	3
I-HD-OL	--	--	0	0	0	0
On OL TRT after re-rand. due to disease flare	--	--	7	4	7	7
M-PL	--	--	3	0	3	3
I-SD	--	--	0	0	0	0
I-HD	--	--	3	0	3	3
M-SD	--	--	1	1	1	1
I-SD	--	--	0	0	0	0
I-HD/I-HD-OL	--	--	1	1	1	1
I-HD	--	--	0	0	0	0
I-HD-OL	--	--	1	1	1	1
M-HD	--	--	3	3	3	3
I-SD	--	--	1	1	1	1
I-HD/I-HD-OL	--	--	2	2	2	2
I-HD	--	--	1	1	1	1
I-HD-OL	--	--	1	1	1	1

表 2.7.3.6-60.　　被験者の最終状況（無作為化した被験者集団，M11-290 試験の主試験）（中間 CSR）（続き）

I-SD = induction standard dose group; I-HD = induction high dose group; I-HD-OL = induction high dose open-label group;
M-PL = maintenance placebo group; M-SD = maintenance standard dose group; M-HD = maintenance high dose group.

Cross reference: M11-290 Main-study CSR_Interim Table 14.1__2.1

表 2.7.3.6-61. 被験者の中止理由（無作為化した被験者集団，M11-290 試験の主試験）（中間 CSR）

Study Period Treatment Discontinuation due to	ITT (N=93) n (%)	ITT-E (N=77) n (%)	mITT (N=74) n (%)	mITT-E (N=62) n (%)	RR (N=22) n (%)	Safety (N=93) n (%)
Disc. in induction period	18 (19.4)	16 (20.8)	--	--	--	18 (19.4)
I-SD						
All reasons$	8 (8.6)	8 (10.4)	--	--	--	8 (8.6)
Adverse event	2 (2.2)	2 (2.6)	--	--	--	2 (2.2)
Withdrew consent	2 (2.2)	2 (2.6)	--	--	--	2 (2.2)
Lost to follow-up	0	0	--	--	--	0
Lack of efficacy	2 (2.2)	2 (2.6)	--	--	--	2 (2.2)
Requires alternative (or prohibited) therapy	1 (1.1)	1 (1.3)	--	--	--	1 (1.1)
Subject non-compliance	0	0	--	--	--	0
Non-Responder at week 8	3 (3.2)	3 (3.9)	--	--	--	3 (3.2)
Other	0	0	--	--	--	0
Primary reason	8 (8.6)	8 (10.4)	--	--	--	8 (8.6)
Adverse event	0	0	--	--	--	0
Withdrew consent	2 (2.2)	2 (2.6)	--	--	--	2 (2.2)
Lost to follow-up	0	0	--	--	--	0
Lack of efficacy	2 (2.2)	2 (2.6)	--	--	--	2 (2.2)
Requires alternative (or prohibited) therapy	1 (1.1)	1 (1.3)	--	--	--	1 (1.1)
Subject non-compliance	0	0	--	--	--	0
Non-Responder at week 8	3 (3.2)	3 (3.9)	--	--	--	3 (3.2)
Other	0	0	--	--	--	0

表 2.7.3.6-61. 被験者の中止理由（無作為化した被験者集団，M11-290 試験の主試験）（中間 CSR）（続き）

Study Period Treatment Discontinuation due to	ITT (N=93) n (%)	ITT-E (N=77) n (%)	mITT (N=74) n (%)	mITT-E (N=62) n (%)	RR (N=22) n (%)	Safety (N=93) n (%)
I-HD						
All reasons$	8 (8.6)	8 (10.4)	--	--	--	8 (8.6)
Adverse event	1 (1.1)	1 (1.3)	--	--	--	1 (1.1)
Withdrew consent	1 (1.1)	1 (1.3)	--	--	--	1 (1.1)
Lost to follow-up	0	0	--	--	--	0
Lack of efficacy	2 (2.2)	2 (2.6)	--	--	--	2 (2.2)
Requires alternative (or prohibited) therapy	1 (1.1)	1 (1.3)	--	--	--	1 (1.1)
Subject non-compliance	0	0	--	--	--	0
Non-Responder at week 8	6 (6.5)	6 (7.8)	--	--	--	6 (6.5)
Other	0	0	--	--	--	0
Primary reason	8 (8.6)	8 (10.4)	--	--	--	8 (8.6)
Adverse event	1 (1.1)	1 (1.3)	--	--	--	1 (1.1)
Withdrew consent	1 (1.1)	1 (1.3)	--	--	--	1 (1.1)
Lost to follow-up	0	0	--	--	--	0
Lack of efficacy	1 (1.1)	1 (1.3)	--	--	--	1 (1.1)
Requires alternative (or prohibited) therapy	1 (1.1)	1 (1.3)	--	--	--	1 (1.1)
Subject non-compliance	0	0	--	--	--	0
Non-Responder at week 8	4 (4.3)	4 (5.2)	--	--	--	4 (4.3)
Other	0	0	--	--	--	0

表 2.7.3.6-61. 被験者の中止理由（無作為化した被験者集団，M11-290 試験の主試験）（中間 CSR）（続き）

Study Period Treatment Discontinuation due to	ITT (N=93) n (%)	ITT-E (N=77) n (%)	mITT (N=74) n (%)	mITT-E (N=62) n (%)	RR (N=22) n (%)	Safety (N=93) n (%)
I-HD-OL						
All reasons$	2 (2.2)	--	--	--	--	2 (2.2)
Adverse event	0	--	--	--	--	0
Withdrew consent	0	--	--	--	--	0
Lost to follow-up	0	--	--	--	--	0
Lack of efficacy	2 (2.2)	--	--	--	--	2 (2.2)
Requires alternative (or prohibited) therapy	2 (2.2)	--	--	--	--	2 (2.2)
Subject non-compliance	0	--	--	--	--	0
Non-Responder at week 8	0	--	--	--	--	0
Other	0	--	--	--	--	0
Primary reason	2 (2.2)	--	--	--	--	2 (2.2)
Adverse event	0	--	--	--	--	0
Withdrew consent	0	--	--	--	--	0
Lost to follow-up	0	--	--	--	--	0
Lack of efficacy	1 (1.1)	--	--	--	--	1 (1.1)
Requires alternative (or prohibited) therapy	1 (1.1)	--	--	--	--	1 (1.1)
Subject non-compliance	0	--	--	--	--	0
Non-Responder at week 8	0	--	--	--	--	0
Other	0	--	--	--	--	0

表 2.7.3.6-61. 被験者の中止理由（無作為化した被験者集団，M11-290 試験の主試験）（中間 CSR）（続き）

Study Period Treatment Discontinuation due to	ITT (N=93) n (%)	ITT-E (N=77) n (%)	mITT (N=74) n (%)	mITT-E (N=62) n (%)	RR (N=22) n (%)	Safety (N=93) n (%)
Disc. in maintenance period	--	--	10 (13.5)	9 (14.5)	4 (18.2)	11 (11.8)
M-PL						
All reasons$	--	--	1 (1.4)	0	1 (4.5)	1 (1.1)
Adverse event	--	--	0	0	0	0
Withdrew consent	--	--	0	0	0	0
Lost to follow-up	--	--	0	0	0	0
Lack of efficacy	--	--	0	0	0	0
Requires alternative (or prohibited) therapy	--	--	1 (1.4)	0	1 (4.5)	1 (1.1)
Subject non-compliance	--	--	0	0	0	0
Non-Responder at week 8	--	--	0	0	0	0
Other	--	--	0	0	0	0
Primary reason	--	--	1 (1.4)	0	1 (4.5)	1 (1.1)
Adverse event	--	--	0	0	0	0
Withdrew consent	--	--	0	0	0	0
Lost to follow-up	--	--	0	0	0	0
Lack of efficacy	--	--	0	0	0	0
Requires alternative (or prohibited) therapy	--	--	1 (1.4)	0	1 (4.5)	1 (1.1)
Subject non-compliance	--	--	0	0	0	0
Non-Responder at week 8	--	--	0	0	0	0
Other	--	--	0	0	0	0

表 2.7.3.6-61. 被験者の中止理由（無作為化した被験者集団，M11-290 試験の主試験）（中間 CSR）（続き）

Study Period Treatment Discontinuation due to	ITT (N=93) n (%)	ITT-E (N=77) n (%)	mITT (N=74) n (%)	mITT-E (N=62) n (%)	RR (N=22) n (%)	Safety (N=93) n (%)
M-SD + M-HD total	--	--	9 (12.2)	9 (14.5)	3 (13.6)	10 (10.8)
M-SD						
All reasons$	--	--	7 (9.5)	7 (11.3)	2 (9.1)	7 (7.5)
Adverse event	--	--	2 (2.7)	2 (3.2)	0	2 (2.2)
Withdrew consent	--	--	2 (2.7)	2 (3.2)	0	2 (2.2)
Lost to follow-up	--	--	0	0	0	0
Lack of efficacy	--	--	4 (5.4)	4 (6.5)	1 (4.5)	4 (4.3)
Requires alternative (or prohibited) therapy	--	--	1 (1.4)	1 (1.6)	1 (4.5)	1 (1.1)
Subject non-compliance	--	--	0	0	0	0
Non-Responder at week 8	--	--	0	0	0	0
Other	--	--	0	0	0	0
Primary reason	--	--	7 (9.5)	7 (11.3)	2 (9.1)	7 (7.5)
Adverse event	--	--	0	0	0	0
Withdrew consent	--	--	2 (2.7)	2 (3.2)	0	2 (2.2)
Lost to follow-up	--	--	0	0	0	0
Lack of efficacy	--	--	4 (5.4)	4 (6.5)	1 (4.5)	4 (4.3)
Requires alternative (or prohibited) therapy	--	--	1 (1.4)	1 (1.6)	1 (4.5)	1 (1.1)
Subject non-compliance	--	--	0	0	0	0
Non-Responder at week 8	--	--	0	0	0	0
Other	--	--	0	0	0	0

表 2.7.3.6-61. 被験者の中止理由（無作為化した被験者集団，M11-290 試験の主試験）（中間 CSR）（続き）

Study Period Treatment Discontinuation due to	ITT (N=93) n (%)	ITT-E (N=77) n (%)	mITT (N=74) n (%)	mITT-E (N=62) n (%)	RR (N=22) n (%)	Safety (N=93) n (%)
M-HD						
All reasons$	--	--	2 (2.7)	2 (3.2)	1 (4.5)	3 (3.2)
Adverse event	--	--	0	0	0	0
Withdrew consent	--	--	1 (1.4)	1 (1.6)	0	1 (1.1)
Lost to follow-up	--	--	1 (1.4)	1 (1.6)	0	1 (1.1)
Lack of efficacy	--	--	0	0	0	1 (1.1)
Requires alternative (or prohibited) therapy	--	--	1 (1.4)	1 (1.6)	0	1 (1.1)
Subject non-compliance	--	--	1 (1.4)	1 (1.6)	1 (4.5)	1 (1.1)
Non-Responder at week 8	--	--	0	0	0	0
Other	--	--	0	0	0	0
Primary reason	--	--	2 (2.7)	2 (3.2)	1 (4.5)	3 (3.2)
Adverse event	--	--	0	0	0	0
Withdrew consent	--	--	1 (1.4)	1 (1.6)	0	1 (1.1)
Lost to follow-up	--	--	0	0	0	0
Lack of efficacy	--	--	0	0	0	1 (1.1)
Requires alternative (or prohibited) therapy	--	--	0	0	0	0
Subject non-compliance	--	--	1 (1.4)	1 (1.6)	1 (4.5)	1 (1.1)
Non-Responder at week 8	--	--	0	0	0	0
Other	--	--	0	0	0	0

I-SD = induction standard dose group; I-HD = induction high dose group; I-HD-OL = induction high dose open-label group;
M-PL = maintenance placebo group; M-SD = maintenance standard dose group; M-HD = maintenance high dose group.
$ Subjects who discontinued study drug are counted under each reason given for discontinuation, therefore,
the sum of the counts given for the reasons may be greater than the overall number of discontinuations.

Cross reference: M11-290 Main-study CSR_Interim Table 14.1__2.2

表 2.7.3.6-62. 治験実施計画書からの逸脱（無作為化した被験者集団，M11-290 試験の主試験）（中間 CSR）

		I-SD				I-HD/HD-OL				
		--$ (N=8)	M-PL (N=4)	M-SD (N=8)	M-HD (N=10)	--$ (N=10)	M-PL (N=8)	M-SD (N=23)	M-HD (N=22)	Total (N=93)
Subjects who had at least one protocol deviation		0	1 (25.0)	0	4 (40.0)	1 (10.0)	3 (37.5)	6 (26.1)	5 (22.7)	20 (21.5)
Subject entered into the study even though did not satisfy entry criteria		0	0	0	1 (10.0)	0	1 (12.5)	1 (4.3)	1 (4.5)	4 (4.3)
Inclusion criteria violated	6	0	0	0	1 (10.0)	0	1 (12.5)	0	1 (4.5)	3 (3.2)
Exclusion criteria violated	24	0	0	0	0	0	0	1 (4.3)	0	1 (1.1)
Subject received wrong treatment or incorrect dose		0	1 (25.0)	0	2 (20.0)	1 (10.0)	2 (25.0)	4 (17.4)	4 (18.2)	14 (15.1)
Subject received excluded concomitant treatment		0	0	0	0	0	0	1 (4.3)	0	1 (1.1)
Subject developed withdrawal criteria during the study and was not withdrawn		0	0	0	1 (10.0)	0	0	0	0	1 (1.1)

表 2.7.3.6-62. 治験実施計画書からの逸脱（無作為化した被験者集団，M11-290 試験の主試験）（中間 CSR）（続き）

	I-SD				I-HD/HD-OL				
	--$ (N=8)	M-PL (N=4)	M-SD (N=8)	M-HD (N=10)	--$ (N=10)	M-PL (N=8)	M-SD (N=23)	M-HD (N=22)	Total (N=93)
Inclusion Criteria Violated									
6: Subject has a neg TB Screening Assessment. If a subject has a pos (>= 5 mm induration) PPD test and/or IGRA test at Screening, a CXR (PA and lateral view) for evaluation of active TB disease.									

表 2.7.3.6-62. 治験実施計画書からの逸脱（無作為化した被験者集団，M11-290 試験の主試験）（中間 CSR）（続き）

	I-SD				I-HD/HD-OL				
	--$ (N=8)	M-PL (N=4)	M-SD (N=8)	M-HD (N=10)	--$ (N=10)	M-PL (N=8)	M-SD (N=23)	M-HD (N=22)	Total (N=93)

Exclusion Criteria Violated

24: Subject with a positive result for the Hepatitis B surface antigen (HBs Ag) or any HBV DNA PCR result that meets or exceeds detection sensitivity will be excluded.

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group,
M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
NOTE: All Randomized = includes all patients randomized to a treatment or enrolled under amendment 4 into the OL treatment group.
Screening Failures are excluded.
$ patients who discontinued as non-responders from the study at week 8.

Cross reference: M11-290 Main-study CSR_Interim Table 14.1__9

表 2.7.3.6-63. 人口統計学的特性（ITT 集団／安全性解析対象集団，M11-290 試験の主試験）（中間 CSR）

	ITT					
	ITT-E					
	I-SD (N=30)	I-HD (N=47)	Total (N=77)	I-HD-OL (N=16)	Total (N=93)	P-Value@
Sex - n (%)						
Female	15 (50.0)	23 (48.9)	38 (49.4)	13 (81.3)	51 (54.8)	0.927
Male	15 (50.0)	24 (51.1)	39 (50.6)	3 (18.8)	42 (45.2)	
Age (year)						
n	30	47	77	16	93	0.225
Mean (SD)	14.7 (2.73)	13.8 (3.16)	14.1 (3.01)	13.6 (2.96)	14.1 (2.99)	
Median	15.5	15.0	15.0	13.5	15.0	
Min, Max	6, 17	5, 17	5, 17	7, 17	5, 17	
Age group 1 (year) - n (%)						
< 13	4 (13.3)	16 (34.0)	20 (26.0)	5 (31.3)	25 (26.9)	0.062
>= 13	26 (86.7)	31 (66.0)	57 (74.0)	11 (68.8)	68 (73.1)	
Age group 2 (year) - n (%)						
< 12	3 (10.0)	12 (25.5)	15 (19.5)	4 (25.0)	19 (20.4)	0.140
>= 12	27 (90.0)	35 (74.5)	62 (80.5)	12 (75.0)	74 (79.6)	
Race - n (%)						
White	28 (93.3)	45 (95.7)	73 (94.8)	15 (93.8)	88 (94.6)	0.730
Black	1 (3.3)	2 (4.3)	3 (3.9)	0	3 (3.2)	
Asian	1 (3.3)	0	1 (1.3)	0	1 (1.1)	
American Indian/Alaska Native	0	0	0	0	0	
Other	0	0	0	0	0	
Multiple	0	0	0	1 (6.3)	1 (1.1)	

表 2.7.3.6-63. 人口統計学的特性（ITT 集団／安全性解析対象集団，M11-290 試験の主試験）（中間 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=30)	I-HD (N=47)	Total (N=77)	I-HD-OL (N=16)	Total (N=93)	P-Value@
Ethnicity - n (%)						
Hispanic or Latino	1 (3.3)	2 (4.3)	3 (3.9)	1 (6.3)	4 (4.3)	1.000
Japanese	0	0	0	0	0	
No ethnicity	29 (96.7)	45 (95.7)	74 (96.1)	15 (93.8)	89 (95.7)	
Geographic region - n (%)						
North America	2 (6.7)	8 (17.0)	10 (13.0)	3 (18.8)	13 (14.0)	0.497
Western Europe	3 (10.0)	4 (8.5)	7 (9.1)	1 (6.3)	8 (8.6)	
Eastern Europe	25 (83.3)	35 (74.5)	60 (77.9)	12 (75.0)	72 (77.4)	
Disease severity per baseline Mayo Score& - n (%)						
<= 9	25 (83.3)	38 (80.9)	63 (81.8)	13 (81.3)	76 (81.7)	0.783
> 9	5 (16.7)	9 (19.1)	14 (18.2)	3 (18.8)	17 (18.3)	
Prior exposure to anti-TNF - n (%)						
Yes	6 (20.0)	8 (17.0)	14 (18.2)	1 (6.3)	15 (16.1)	0.741
No	24 (80.0)	39 (83.0)	63 (81.8)	15 (93.8)	78 (83.9)	
Baseline systemic corticosteroid use# - n (%)						
Yes	13 (43.3)	22 (46.8)	35 (45.5)	9 (56.3)	44 (47.3)	0.765
No	17 (56.7)	25 (53.2)	42 (54.5)	7 (43.8)	49 (52.7)	

表 2.7.3.6-63. 人口統計学的特性（ITT 集団／安全性解析対象集団，M11-290 試験の主試験）（中間 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=30)	I-HD (N=47)	Total (N=77)	I-HD-OL (N=16)	Total (N=93)	P-Value@
Baseline immunosuppressants (IMM) use - n (%)						
Yes	21 (70.0)	29 (61.7)	50 (64.9)	5 (31.3)	55 (59.1)	0.457
No	9 (30.0)	18 (38.3)	27 (35.1)	11 (68.8)	38 (40.9)	
Weight (kg)						
n	30	47	77	16	93	0.847
Mean (SD)	57.2 (15.35)	56.4 (19.74)	56.7 (18.06)	52.1 (18.62)	55.9 (18.14)	
Median	57.5	53.7	56.3	51.5	55.0	
Min, Max	22.2, 92.9	15.0, 110.0	15.0, 110.0	20.0, 97.4	15.0, 110.0	
Weight (kg) by sex						
Female						
n	15	23	38	13	51	0.597
Mean (SD)	53.4 (12.78)	51.0 (13.93)	52.0 (13.36)	48.8 (15.80)	51.2 (13.93)	
Median	57.0	51.0	52.5	50.1	52.0	
Min, Max	22.2, 76.0	21.5, 89.0	21.5, 89.0	20.0, 76.5	20.0, 89.0	
Male						
n	15	24	39	3	42	0.940
Mean (SD)	61.1 (17.13)	61.6 (23.17)	61.4 (20.81)	66.3 (26.98)	61.7 (20.94)	
Median	58.0	61.5	59.0	52.8	59.0	
Min, Max	22.9, 92.9	15.0, 110.0	15.0, 110.0	48.8, 97.4	15.0, 110.0	
Weight (kg) - n (%)						
< 40	3 (10.0)	9 (19.1)	12 (15.6)	3 (18.8)	15 (16.1)	0.415
40 - < 60	17 (56.7)	20 (42.6)	37 (48.1)	9 (56.3)	46 (49.5)	
>= 60	10 (33.3)	18 (38.3)	28 (36.4)	4 (25.0)	32 (34.4)	

表 2.7.3.6-63. 人口統計学的特性（ITT 集団／安全性解析対象集団，M11-290 試験の主試験）（中間 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=30)	I-HD (N=47)	Total (N=77)	I-HD-OL (N=16)	Total (N=93)	P-Value@
Height (cm)						
n	30	47	77	16	93	0.091
Mean (SD)	167.5 (15.25)	160.6 (18.67)	163.3 (17.65)	159.2 (14.18)	162.6 (17.10)	
Median	170.0	160.1	167.0	161.8	163.7	
Min, Max	120.1, 190.5	104.5, 193.0	104.5, 193.0	119.0, 182.4	104.5, 193.0	
Body mass index (kg/m^2)						
n	30	47	77	16	93	0.243
Mean (SD)	20.1 (3.68)	21.1 (4.14)	20.7 (3.98)	20.0 (4.83)	20.6 (4.12)	
Median	19.5	20.6	20.1	19.2	20.0	
Min, Max	14.7, 32.1	13.7, 32.7	13.7, 32.7	12.1, 29.3	12.1, 32.7	
Tobacco/Nicotine$ - n (%)						
Current	0	0	0	0	0	
Former	0	0	0	0	0	
Never	30 (100)	47 (100)	77 (100)	16 (100)	93 (100)	
Unknown	0	0	0	0	0	
Alcohol$ - n (%)						
Current	0	0	0	0	0	
Former	0	0	0	0	0	
Never	30 (100)	46 (100)	76 (100)	16 (100)	92 (100)	
Unknown	0	1	1	0	1	

表 2.7.3.6-63.　　人口統計学的特性（ITT 集団／安全性解析対象集団，M11-290 試験の主試験）（中間 CSR）（続き）

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
Note: percentages calculated on non-missing values.
& true baseline Mayo Score is displayed. Subject [redacted] was randomized in the stratum '> 9', but actually had a baseline Mayo Score of 8.8 (corrected by the site from 9.8 to 8.8 after randomization).
# true baseline systemic corticosteroid use is displayed. Subject [redacted] was randomized in the stratum 'No', but actually has baseline systemic corticosteroid use documented.
$ percentages calculated on non-unknown values. A subject may be a current user of one type of tobacco, A former user of another type of tobacco and never used another type of tobacco.
A subject will be counted in the category closest to user.
@ p-value for differences between the treatment groups I-SD and I-HD from chi-square test (or fisher's exact test if expected number of counts in a cell is < 5) for categorical variables or from one-way anova for continuous variables.

Cross reference: M11-290 Main-study CSR_Interim Table 14.1__3.1

表 2.7.3.6-64. 人口統計学的特性（mITT 集団，M11-290 試験の主試験）（中間 CSR）

	mITT					
	mITT-E					
	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)	P-Value@
Sex - n (%)						
Female	3 (25.0)	18 (58.1)	18 (58.1)	36 (58.1)	39 (52.7)	1.000
Male	9 (75.0)	13 (41.9)	13 (41.9)	26 (41.9)	35 (47.3)	
Age (year)						
n	12	31	31	62	74	0.237
Mean (SD)	14.9 (2.54)	13.2 (3.12)	14.2 (3.47)	13.7 (3.31)	13.9 (3.22)	
Median	15.5	14.0	16.0	14.0	15.0	
Min, Max	9, 17	6, 17	5, 17	5, 17	5, 17	
Age group 1 (year) - n (%)						
< 13	2 (16.7)	12 (38.7)	8 (25.8)	20 (32.3)	22 (29.7)	0.277
>= 13	10 (83.3)	19 (61.3)	23 (74.2)	42 (67.7)	52 (70.3)	
Age group 2 (year) - n (%)						
< 12	2 (16.7)	10 (32.3)	7 (22.6)	17 (27.4)	19 (25.7)	0.393
>= 12	10 (83.3)	21 (67.7)	24 (77.4)	45 (72.6)	55 (74.3)	
Race - n (%)						
White	11 (91.7)	29 (93.5)	30 (96.8)	59 (95.2)	70 (94.6)	1.000
Black	0	2 (6.5)	1 (3.2)	3 (4.8)	3 (4.1)	
Asian	1 (8.3)	0	0	0	1 (1.4)	
American Indian/Alaska Native	0	0	0	0	0	
Other	0	0	0	0	0	
Multiple	0	0	0	0	0	

表 2.7.3.6-64. 人口統計学的特性（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT					
	mITT-E					
	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)	P-Value@
Ethnicity - n (%)						
Hispanic or Latino	0	3 (9.7)	1 (3.2)	4 (6.5)	4 (5.4)	0.612
Japanese	0	0	0	0	0	
No ethnicity	12 (100)	28 (90.3)	30 (96.8)	58 (93.5)	70 (94.6)	
Geographic region - n (%)						
North America	1 (8.3)	7 (22.6)	3 (9.7)	10 (16.1)	11 (14.9)	0.133
Western Europe	1 (8.3)	0	3 (9.7)	3 (4.8)	4 (5.4)	
Eastern Europe	10 (83.3)	24 (77.4)	25 (80.6)	49 (79.0)	59 (79.7)	
Disease severity per baseline Mayo Score - n (%)						
<= 9	11 (91.7)	25 (80.6)	26 (83.9)	51 (82.3)	62 (83.8)	0.740
> 9	1 (8.3)	6 (19.4)	5 (16.1)	11 (17.7)	12 (16.2)	
Prior exposure to anti-TNF - n (%)						
Yes	2 (16.7)	2 (6.5)	6 (19.4)	8 (12.9)	10 (13.5)	0.255
No	10 (83.3)	29 (93.5)	25 (80.6)	54 (87.1)	64 (86.5)	
Baseline systemic corticosteroid use - n (%)						
Yes	5 (41.7)	13 (41.9)	16 (51.6)	29 (46.8)	34 (45.9)	0.445
No	7 (58.3)	18 (58.1)	15 (48.4)	33 (53.2)	40 (54.1)	

表 2.7.3.6-64. 人口統計学的特性（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT					
	mITT-E					
	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)	P-Value@
Baseline immunosuppressants (IMM) use - n (%)						
Yes	8 (66.7)	17 (54.8)	21 (67.7)	38 (61.3)	46 (62.2)	0.297
No	4 (33.3)	14 (45.2)	10 (32.3)	24 (38.7)	28 (37.8)	
Weight (kg)						
n	12	31	31	62	74	0.340
Mean (SD)	61.7 (14.55)	53.1 (15.76)	57.9 (22.90)	55.5 (19.65)	56.5 (18.97)	
Median	58.5	53.5	58.9	56.7	57.5	
Min, Max	43.0, 92.9	21.5, 91.6	15.0, 110.0	15.0, 110.0	15.0, 110.0	
Weight (kg) by sex						
Female						
n	3	18	18	36	39	0.220
Mean (SD)	51.9 (7.05)	48.1 (14.85)	54.9 (17.35)	51.5 (16.28)	51.5 (15.70)	
Median	48.1	50.6	56.1	53.3	53.0	
Min, Max	47.5, 60.0	21.5, 76.5	20.0, 89.0	20.0, 89.0	20.0, 89.0	
Male						
n	9	13	13	26	35	0.817
Mean (SD)	65.0 (15.17)	60.0 (14.86)	62.1 (29.19)	61.0 (22.72)	62.0 (20.90)	
Median	59.0	60.0	67.0	60.0	60.0	
Min, Max	43.0, 92.9	31.5, 91.6	15.0, 110.0	15.0, 110.0	15.0, 110.0	
Weight (kg) - n (%)						
< 40	0	7 (22.6)	7 (22.6)	14 (22.6)	14 (18.9)	0.352
40 - < 60	7 (58.3)	14 (45.2)	9 (29.0)	23 (37.1)	30 (40.5)	
>= 60	5 (41.7)	10 (32.3)	15 (48.4)	25 (40.3)	30 (40.5)	

表 2.7.3.6-64. 人口統計学的特性（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT					
	mITT-E					
	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)	P-Value@
Height (cm)						
n	12	31	31	62	74	0.744
Mean (SD)	170.9 (13.13)	159.3 (16.77)	160.9 (20.17)	160.1 (18.41)	161.9 (18.03)	
Median	172.0	162.0	162.0	162.0	163.9	
Min, Max	149.0, 190.5	120.0, 184.0	104.5, 193.0	104.5, 193.0	104.5, 193.0	
Body mass index (kg/m^2)						
n	12	31	31	62	74	0.432
Mean (SD)	20.9 (2.54)	20.4 (3.60)	21.3 (5.22)	20.9 (4.47)	20.9 (4.20)	
Median	20.4	20.0	20.9	20.3	20.3	
Min, Max	17.8, 25.6	14.7, 32.1	12.1, 30.4	12.1, 32.1	12.1, 32.1	
Tobacco/Nicotine$ - n (%)						
Current	0	0	0	0	0	
Former	0	0	0	0	0	
Never	12 (100)	31 (100)	31 (100)	62 (100)	74 (100)	
Unknown	0	0	0	0	0	
Alcohol$ - n (%)						
Current	0	0	0	0	0	
Former	0	0	0	0	0	
Never	12 (100)	31 (100)	31 (100)	62 (100)	74 (100)	
Unknown	0	0	0	0	0	

表 2.7.3.6-64.　　人口統計学的特性（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
Note: percentages calculated on non-missing values.
$ percentages calculated on non-unknown values. A subject may be a current user of one type of tobacco, A former user of another type of tobacco and never used another type of tobacco.
A subject will be counted in the category closest to user.
@ p-value for differences between the treatment groups M-SD and M-HD from chi-square test (or fisher's exact test if expected number of counts in a cell is < 5) for categorical variables or from one-way anova for continuous variables.

Cross reference: M11-290 Main-study CSR_Interim Table 14.1__3.2

表 2.7.3.6-65.　疾患特性（ITT 集団／安全性解析対象集団，M11-290 試験の主試験）（中間 CSR）

	ITT					
	ITT-E					
	I-SD (N=30)	I-HD (N=47)	Total (N=77)	I-HD-OL (N=16)	Total (N=93)	P-Value@
Duration of UC (month)						
n	30	47	77	16	93	0.171
Mean (SD)	22.5 (19.84)	31.3 (31.06)	27.8 (27.43)	23.7 (25.53)	27.1 (27.03)	
Median	13.0	21.8	18.4	15.1	18.4	
Min, Max	3.7, 63.9	4.5, 136.9	3.7, 136.9	4.0, 108.0	3.7, 136.9	
Duration of UC (year)						
n	30	47	77	16	93	0.171
Mean (SD)	1.9 (1.65)	2.6 (2.59)	2.3 (2.29)	2.0 (2.13)	2.3 (2.25)	
Median	1.1	1.8	1.5	1.3	1.5	
Min, Max	0.3, 5.3	0.4, 11.4	0.3, 11.4	0.3, 9.0	0.3, 11.4	
Site of UC - n (%)						
Left sided UC	10 (33.3)	22 (46.8)	32 (41.6)	5 (31.3)	37 (39.8)	0.242
Extensive UC/pancolitis	20 (66.7)	25 (53.2)	45 (58.4)	11 (68.8)	56 (60.2)	
Mayo Score						
n	30	47	77	16	93	0.832
Mean (SD)	7.9 (1.21)	7.8 (1.28)	7.8 (1.24)	7.8 (1.08)	7.8 (1.21)	
Median	7.9	7.6	7.8	7.4	7.8	
Min, Max	6.0, 10.0	6.0, 10.8	6.0, 10.8	6.0, 9.6	6.0, 10.8	

表 2.7.3.6-65. 疾患特性（ITT 集団／安全性解析対象集団，M11-290 試験の主試験）（中間 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=30)	I-HD (N=47)	Total (N=77)	I-HD-OL (N=16)	Total (N=93)	P-Value@
Partial Mayo Score						
n	30	47	77	16	93	0.669
Mean (SD)	5.7 (1.14)	5.6 (1.24)	5.7 (1.20)	5.6 (1.05)	5.6 (1.17)	
Median	5.8	5.4	5.6	5.3	5.6	
Min, Max	4.0, 8.0	3.6, 8.8	3.6, 8.8	4.0, 7.6	3.6, 8.8	
Endoscopy Subscore						
n	30	47	77	16	93	0.513
Mean (SD)	2.1 (0.35)	2.2 (0.40)	2.2 (0.38)	2.3 (0.45)	2.2 (0.39)	
Median	2.0	2.0	2.0	2.0	2.0	
Min, Max	2.0, 3.0	2.0, 3.0	2.0, 3.0	2.0, 3.0	2.0, 3.0	
Rectal Bleeding Subscore						
n	30	47	77	16	93	0.308
Mean (SD)	1.3 (0.95)	1.6 (0.90)	1.5 (0.92)	1.5 (0.97)	1.5 (0.92)	
Median	1.4	1.2	1.4	1.1	1.2	
Min, Max	0.0, 3.0	0.0, 3.0	0.0, 3.0	0.0, 3.0	0.0, 3.0	
PGA Subscore						
n	30	47	77	16	93	0.730
Mean (SD)	2.2 (0.41)	2.2 (0.43)	2.2 (0.42)	2.2 (0.40)	2.2 (0.41)	
Median	2.0	2.0	2.0	2.0	2.0	
Min, Max	2.0, 3.0	2.0, 3.0	2.0, 3.0	2.0, 3.0	2.0, 3.0	

表 2.7.3.6-65. 疾患特性（ITT 集団／安全性解析対象集団，M11-290 試験の主試験）（中間 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=30)	I-HD (N=47)	Total (N=77)	I-HD-OL (N=16)	Total (N=93)	P-Value@
Stool Frequency Subscore						
n	30	47	77	16	93	0.053
Mean (SD)	2.2 (0.73)	1.8 (0.87)	2.0 (0.83)	1.9 (0.72)	1.9 (0.81)	
Median	2.2	1.8	2.0	1.9	2.0	
Min, Max	0.6, 3.0	0.0, 3.0	0.0, 3.0	0.0, 3.0	0.0, 3.0	
Number of stools in the last 24 hours prior to baseline						
n	30	47	77	16	93	0.868
Mean (SD)	4.0 (2.19)	4.1 (2.55)	4.1 (2.40)	4.5 (2.50)	4.2 (2.41)	
Median	4.0	4.0	4.0	4.0	4.0	
Min, Max	0.0, 9.0	0.0, 13.0	0.0, 13.0	2.0, 13.0	0.0, 13.0	
PUCAI total score						
n	30	47	77	16	93	0.652
Mean (SD)	39.8 (18.58)	41.6 (16.20)	40.9 (17.07)	43.4 (13.87)	41.4 (16.52)	
Median	40.0	42.5	42.5	45.0	45.0	
Min, Max	0.0, 72.5	15.0, 80.0	0.0, 80.0	25.0, 72.5	0.0, 80.0	
IMPACT III total score						
n	27	44	71	15	86	0.879
Mean (SD)	110.9 (22.27)	110.0 (24.03)	110.3 (23.22)	107.4 (19.25)	109.8 (22.50)	
Median	105.0	113.0	112.0	111.0	111.5	
Min, Max	78.0, 155.0	63.0, 159.0	63.0, 159.0	76.0, 144.0	63.0, 159.0	

表 2.7.3.6-65. 疾患特性（ITT 集団／安全性解析対象集団，M11-290 試験の主試験）（中間 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=30)	I-HD (N=47)	Total (N=77)	I-HD-OL (N=16)	Total (N=93)	P-Value@
IMPACT III - body image						
n	27	44	71	15	86	0.150
Mean (SD)	10.6 (1.96)	9.8 (2.35)	10.1 (2.23)	9.3 (2.53)	10.0 (2.29)	
Median	11.0	10.0	10.0	9.0	10.0	
Min, Max	8.0, 15.0	4.0, 14.0	4.0, 15.0	4.0, 12.0	4.0, 15.0	
IMPACT III - bowel symptoms						
n	27	44	71	15	86	0.530
Mean (SD)	21.1 (5.47)	20.3 (5.09)	20.6 (5.21)	18.7 (4.29)	20.2 (5.09)	
Median	21.0	19.5	20.0	18.0	19.0	
Min, Max	10.5, 32.0	11.0, 30.0	10.5, 32.0	12.0, 28.0	10.5, 32.0	
IMPACT III - emotional functioning						
n	27	44	71	15	86	0.867
Mean (SD)	20.4 (6.79)	20.7 (6.95)	20.6 (6.84)	19.4 (5.73)	20.4 (6.65)	
Median	19.0	21.5	21.0	19.0	20.5	
Min, Max	11.0, 34.0	8.0, 35.0	8.0, 35.0	13.0, 29.0	8.0, 35.0	
IMPACT III - social functioning						
n	27	44	71	15	86	0.845
Mean (SD)	40.2 (7.90)	40.6 (8.77)	40.4 (8.39)	41.1 (7.22)	40.6 (8.16)	
Median	40.0	42.0	41.0	42.0	41.0	
Min, Max	27.0, 55.0	22.0, 57.0	22.0, 57.0	24.0, 52.0	22.0, 57.0	

表 2.7.3.6-65. 疾患特性（ITT 集団／安全性解析対象集団，M11-290 試験の主試験）（中間 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=30)	I-HD (N=47)	Total (N=77)	I-HD-OL (N=16)	Total (N=93)	P-Value@
IMPACT III - systemic symptoms						
n	27	44	71	15	86	0.663
Mean (SD)	8.2 (2.91)	8.5 (2.25)	8.4 (2.50)	8.4 (2.23)	8.4 (2.44)	
Median	8.0	9.0	8.0	8.0	8.0	
Min, Max	3.0, 14.0	4.0, 12.0	3.0, 14.0	3.0, 12.0	3.0, 14.0	
IMPACT III - treatment/interventions						
n	27	44	71	15	86	0.730
Mean (SD)	10.4 (2.42)	10.1 (2.95)	10.2 (2.75)	10.5 (2.00)	10.3 (2.62)	
Median	11.0	11.0	11.0	11.0	11.0	
Min, Max	5.0, 14.0	4.0, 15.0	4.0, 15.0	7.0, 14.0	4.0, 15.0	
WPAI - absenteeism (%)						
n	20	29	49	8	57	0.949
Mean (SD)	12.8 (16.72)	12.5 (19.75)	12.6 (18.39)	23.1 (29.27)	14.1 (20.26)	
Median	0.0	7.9	4.8	13.4	7.9	
Min, Max	0.0, 50.0	0.0, 100.0	0.0, 100.0	0.0, 71.1	0.0, 100.0	
WPAI - presenteeism (%)						
n	20	30	50	8	58	0.950
Mean (SD)	44.5 (26.05)	44.0 (28.48)	44.2 (27.26)	42.5 (23.75)	44.0 (26.62)	
Median	45.0	45.0	45.0	45.0	45.0	
Min, Max	0.0, 80.0	0.0, 100.0	0.0, 100.0	0.0, 80.0	0.0, 100.0	

表 2.7.3.6-65. 疾患特性（ITT 集団／安全性解析対象集団，M11-290 試験の主試験）（中間 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=30)	I-HD (N=47)	Total (N=77)	I-HD-OL (N=16)	Total (N=93)	P-Value@
WPAI - work impairment (%)						
n	20	29	49	8	57	0.932
Mean (SD)	49.7 (28.94)	50.4 (26.68)	50.1 (27.33)	50.8 (30.64)	50.2 (27.52)	
Median	57.8	54.3	55.6	48.6	55.6	
Min, Max	0.0, 86.0	0.0, 100.0	0.0, 100.0	0.0, 94.2	0.0, 100.0	
WPAI - activity impairment (%)						
n	30	47	77	16	93	0.422
Mean (SD)	42.0 (26.57)	47.0 (26.61)	45.1 (26.54)	53.1 (29.60)	46.5 (27.09)	
Median	50.0	40.0	50.0	50.0	50.0	
Min, Max	0.0, 80.0	0.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0	
hs-CRP [mg/l]						
n	28	41	69	16	85	0.543
Mean (SD)	7.6 (26.76)	4.9 (8.66)	6.0 (18.17)	3.7 (8.70)	5.6 (16.78)	
Median	1.2	1.4	1.3	1.3	1.3	
Min, Max	0.1, 142.6	0.1, 35.2	0.1, 142.6	0.1, 35.9	0.1, 142.6	
Tuberculin PPD skin test - n (%)						
Negative	1 (100)	4 (100)	5 (100)	1 (100)	6 (100)	
Positive&	0	0	0	0	0	
Missing	29	43	72	15	87	

表 2.7.3.6-65. 疾患特性（ITT 集団／安全性解析対象集団，M11-290 試験の主試験）（中間 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=30)	I-HD (N=47)	Total (N=77)	I-HD-OL (N=16)	Total (N=93)	P-Value@
QuantiFERON-TB Gold test - n (%)						
Negative	28 (96.6)	40 (88.9)	68 (91.9)	15 (100)	83 (93.3)	0.527
Positive	0	2 (4.4)	2 (2.7)	0	2 (2.2)	
Indeterminate	1 (3.4)	3 (6.7)	4 (5.4)	0	4 (4.5)	
Missing	1	2	3	1	4	
Tuberculin positive - n (%)						
Yes$	0	2 (4.3)	2 (2.6)	0	2 (2.2)	0.518
No	30 (100)	45 (95.7)	75 (97.4)	16 (100)	91 (97.8)	
Enrollment under TB prophylaxis - n (%)						
Yes	0	2 (4.3)	2 (2.6)	0	2 (2.2)	0.518
No	30 (100)	45 (95.7)	75 (97.4)	16 (100)	91 (97.8)	

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
Note: percentages calculated on non-missing values.
Duration of UC in months: (baseline date - date of diagnosis of UC + 1) / (365.25/12).
Duration of UC in years: (baseline date - date of diagnosis of UC + 1) / 365.25.
& positive defined as >= 5 mm.
$ tuberculin PPD skin test >= 5 mm or QuantiFERON-TB Gold test is positive.
@ p-value for differences between the treatment groups I-SD and I-HD from chi-square test (or fisher's exact test if expected number of counts in a cell is < 5) for categorical variables or from one-way anova for continuous variables.

Cross reference: M11-290 Main-study CSR_Interim Table 14.1__4.1

表 2.7.3.6-66. 疾患特性（mITT 集団，M11-290 試験の主試験）（中間 CSR）

	mITT					
	mITT-E					
	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)	P-Value@
Duration of UC (month)						
n	12	31	31	62	74	0.081
Mean (SD)	38.0 (35.55)	21.6 (14.85)	32.3 (30.04)	27.0 (24.10)	28.8 (26.32)	
Median	29.8	16.1	19.4	18.5	18.7	
Min, Max	6.2, 131.9	4.4, 53.7	5.3, 123.4	4.4, 123.4	4.4, 131.9	
Duration of UC (year)						
n	12	31	31	62	74	0.081
Mean (SD)	3.2 (2.96)	1.8 (1.24)	2.7 (2.50)	2.2 (2.01)	2.4 (2.19)	
Median	2.5	1.3	1.6	1.5	1.6	
Min, Max	0.5, 11.0	0.4, 4.5	0.4, 10.3	0.4, 10.3	0.4, 11.0	
Site of UC - n (%)						
Left sided UC	5 (41.7)	11 (35.5)	14 (45.2)	25 (40.3)	30 (40.5)	0.437
Extensive UC/pancolitis	7 (58.3)	20 (64.5)	17 (54.8)	37 (59.7)	44 (59.5)	
Mayo Score						
n	12	31	31	62	74	0.353
Mean (SD)	7.4 (0.91)	8.0 (1.21)	7.7 (1.13)	7.8 (1.17)	7.8 (1.14)	
Median	7.2	7.8	7.6	7.8	7.6	
Min, Max	6.0, 9.2	6.0, 10.8	6.0, 9.8	6.0, 10.8	6.0, 10.8	

表 2.7.3.6-66. 疾患特性（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT					
	mITT-E					
	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)	P-Value@
Partial Mayo Score						
n	12	31	31	62	74	0.164
Mean (SD)	5.3 (0.77)	5.9 (1.24)	5.5 (1.03)	5.7 (1.15)	5.6 (1.10)	
Median	5.2	5.8	5.4	5.6	5.5	
Min, Max	4.0, 6.6	4.0, 8.8	4.0, 7.8	4.0, 8.8	4.0, 8.8	
Endoscopy Subscore						
n	12	31	31	62	74	0.134
Mean (SD)	2.1 (0.29)	2.1 (0.25)	2.2 (0.40)	2.1 (0.34)	2.1 (0.33)	
Median	2.0	2.0	2.0	2.0	2.0	
Min, Max	2.0, 3.0	2.0, 3.0	2.0, 3.0	2.0, 3.0	2.0, 3.0	
Rectal Bleeding Subscore						
n	12	31	31	62	74	0.307
Mean (SD)	1.2 (0.78)	1.7 (0.96)	1.4 (0.90)	1.6 (0.93)	1.5 (0.92)	
Median	1.0	1.8	1.0	1.5	1.3	
Min, Max	0.0, 2.6	0.0, 3.0	0.0, 3.0	0.0, 3.0	0.0, 3.0	
PGA Subscore						
n	12	31	31	62	74	0.039*
Mean (SD)	2.2 (0.39)	2.3 (0.44)	2.1 (0.25)	2.2 (0.37)	2.2 (0.37)	
Median	2.0	2.0	2.0	2.0	2.0	
Min, Max	2.0, 3.0	2.0, 3.0	2.0, 3.0	2.0, 3.0	2.0, 3.0	

表 2.7.3.6-66. 疾患特性（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT					
		mITT-E				
	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)	P-Value@
Stool Frequency Subscore						
n	12	31	31	62	74	0.876
Mean (SD)	2.0 (0.89)	2.0 (0.76)	2.0 (0.79)	2.0 (0.77)	2.0 (0.78)	
Median	2.2	2.0	1.8	2.0	2.0	
Min, Max	0.0, 3.0	0.6, 3.0	0.6, 3.0	0.6, 3.0	0.0, 3.0	
Number of stools in the last 24 hours prior to baseline						
n	12	31	31	62	74	0.764
Mean (SD)	3.6 (1.93)	4.5 (3.19)	4.3 (1.60)	4.4 (2.51)	4.3 (2.43)	
Median	3.5	3.0	4.0	4.0	4.0	
Min, Max	1.0, 7.0	1.0, 13.0	1.0, 7.0	1.0, 13.0	1.0, 13.0	
PUCAI total score						
n	12	31	31	62	74	0.336
Mean (SD)	40.0 (13.98)	43.8 (14.79)	40.0 (15.96)	41.9 (15.38)	41.6 (15.08)	
Median	42.5	45.0	37.5	43.8	43.8	
Min, Max	10.0, 55.0	20.0, 72.5	15.0, 72.5	15.0, 72.5	10.0, 72.5	
IMPACT III total score						
n	12	29	28	57	69	0.643
Mean (SD)	110.5 (22.75)	111.5 (20.74)	114.3 (24.61)	112.9 (22.56)	112.5 (22.44)	
Median	112.5	111.0	116.5	116.0	114.0	
Min, Max	69.0, 154.0	77.0, 144.0	71.0, 159.0	71.0, 159.0	69.0, 159.0	

表 2.7.3.6-66. 疾患特性（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT					
		mITT-E				
	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)	P-Value@
IMPACT III - body image						
n	12	29	28	57	69	0.392
Mean (SD)	10.1 (2.07)	10.0 (2.22)	10.5 (2.15)	10.2 (2.18)	10.2 (2.15)	
Median	9.0	10.0	11.0	10.0	10.0	
Min, Max	8.0, 15.0	4.0, 14.0	6.0, 14.0	4.0, 14.0	4.0, 15.0	
IMPACT III - bowel symptoms						
n	12	29	28	57	69	0.315
Mean (SD)	20.9 (6.19)	19.8 (4.99)	21.2 (5.47)	20.5 (5.23)	20.6 (5.36)	
Median	20.5	19.0	20.5	20.0	20.0	
Min, Max	11.0, 29.0	12.0, 30.0	10.5, 32.0	10.5, 32.0	10.5, 32.0	
IMPACT III - emotional functioning						
n	12	29	28	57	69	0.426
Mean (SD)	21.1 (6.75)	20.5 (6.42)	21.9 (7.17)	21.2 (6.78)	21.2 (6.72)	
Median	22.0	20.0	23.5	21.0	21.0	
Min, Max	11.0, 34.0	10.0, 31.0	10.0, 35.0	10.0, 35.0	10.0, 35.0	
IMPACT III - social functioning						
n	12	29	28	57	69	0.611
Mean (SD)	38.9 (7.03)	42.4 (7.22)	41.3 (9.12)	41.8 (8.16)	41.3 (8.00)	
Median	40.0	45.0	41.5	43.0	42.0	
Min, Max	24.0, 48.0	27.0, 54.0	22.0, 57.0	22.0, 57.0	22.0, 57.0	

表 2.7.3.6-66. 疾患特性（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT					
		mITT-E				
	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)	P-Value@
IMPACT III - systemic symptoms						
n	12	29	28	57	69	0.765
Mean (SD)	9.3 (2.60)	8.4 (2.41)	8.6 (2.41)	8.5 (2.39)	8.6 (2.43)	
Median	8.5	9.0	8.5	9.0	9.0	
Min, Max	6.0, 14.0	3.0, 12.0	4.0, 12.0	3.0, 12.0	3.0, 14.0	
IMPACT III - treatment/interventions						
n	12	29	28	57	69	0.540
Mean (SD)	10.3 (3.33)	10.5 (2.28)	10.9 (2.30)	10.7 (2.28)	10.6 (2.47)	
Median	11.5	11.0	11.0	11.0	11.0	
Min, Max	4.0, 14.0	6.0, 14.0	5.0, 15.0	5.0, 15.0	4.0, 15.0	
WPAI - absenteeism (%)						
n	9	18	20	38	47	0.981
Mean (SD)	5.5 (9.03)	13.0 (19.20)	13.2 (17.59)	13.1 (18.12)	11.6 (16.95)	
Median	0.0	2.4	6.5	4.3	0.0	
Min, Max	0.0, 22.5	0.0, 71.1	0.0, 66.7	0.0, 71.1	0.0, 71.1	
WPAI - presenteeism (%)						
n	10	18	20	38	48	0.222
Mean (SD)	46.0 (25.47)	45.6 (29.35)	34.5 (25.44)	39.7 (27.56)	41.0 (26.99)	
Median	50.0	35.0	35.0	35.0	40.0	
Min, Max	0.0, 80.0	0.0, 90.0	0.0, 80.0	0.0, 90.0	0.0, 90.0	

表 2.7.3.6-66. 疾患特性（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT					
		mITT-E				
	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)	P-Value@
WPAI - work impairment (%)						
n	9	18	20	38	47	0.299
Mean (SD)	54.3 (19.77)	50.5 (30.03)	40.2 (29.71)	45.1 (29.91)	46.8 (28.30)	
Median	60.0	42.5	39.4	40.0	43.1	
Min, Max	20.0, 80.0	0.0, 94.2	0.0, 86.7	0.0, 94.2	0.0, 94.2	
WPAI - activity impairment (%)						
n	12	31	31	62	74	0.382
Mean (SD)	50.8 (22.75)	40.3 (28.34)	46.8 (29.37)	43.5 (28.81)	44.7 (27.91)	
Median	50.0	30.0	40.0	40.0	40.0	
Min, Max	0.0, 80.0	0.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0	
hs-CRP [mg/l]						
n	11	28	29	57	68	0.914
Mean (SD)	2.2 (3.10)	3.6 (5.96)	3.4 (6.75)	3.5 (6.32)	3.3 (5.92)	
Median	0.9	1.6	1.3	1.5	1.3	
Min, Max	0.1, 9.9	0.1, 29.3	0.1, 35.9	0.1, 35.9	0.1, 35.9	
Tuberculin PPD skin test - n (%)						
Negative	0	0	1 (100)	1 (100)	1 (100)	
Positive&	0	0	0	0	0	
Missing	12	31	30	61	73	

表 2.7.3.6-66. 疾患特性（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT					
	mITT-E					
	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)	P-Value@
QuantiFERON-TB Gold test - n (%)						
Negative	10 (83.3)	31 (100)	28 (90.3)	59 (95.2)	69 (93.2)	0.238
Positive	1 (8.3)	0	1 (3.2)	1 (1.6)	2 (2.7)	
Indeterminate	1 (8.3)	0	2 (6.5)	2 (3.2)	3 (4.1)	
Tuberculin positive - n (%)						
Yes$	1 (8.3)	0	1 (3.2)	1 (1.6)	2 (2.7)	1.000
No	11 (91.7)	31 (100)	30 (96.8)	61 (98.4)	72 (97.3)	
Enrollment under TB prophylaxis - n (%)						
Yes	1 (8.3)	0	1 (3.2)	1 (1.6)	2 (2.7)	1.000
No	11 (91.7)	31 (100)	30 (96.8)	61 (98.4)	72 (97.3)	

M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
Note: percentages calculated on non-missing values.
Duration of UC in months: (baseline date - date of diagnosis of UC + 1) / (365.25/12).
Duration of UC in years: (baseline date - date of diagnosis of UC + 1) / 365.25.
& positive defined as >= 5 mm.
$ tuberculin PPD skin test >= 5 mm or QuantiFERON-TB Gold test is positive.
@ p-value for differences between the treatment groups M-SD and M-HD from chi-square test (or fisher's exact test if expected number of counts in a cell is < 5) for categorical variables or from one-way anova for continuous variables.
***, **, * Statistically significant at 0.001, 0.01, and 0.05 level, respectively.

Cross reference: M11-290 Main-study CSR_Interim Table 14.1__4.2

表 2.7.3.6-67. UC に関連した前治療薬（一般名）（ITT 集団／安全性解析対象集団，M11-290 試験の主試験）（中間 CSR）

Generic Name (WHO Q1 2018)	ITT / ITT-E: I-SD (N=30) n (%)	ITT / ITT-E: I-HD (N=47) n (%)	ITT / ITT-E: Total (N=77) n (%)	ITT: I-HD-OL (N=16) n (%)	ITT: Total (N=93) n (%)
Any prior UC-related medication	30 (100)	47 (100)	77 (100)	16 (100)	93 (100)
AZATHIOPRINE	25 (83.3)	36 (76.6)	61 (79.2)	5 (31.3)	66 (71.0)
BALSALAZIDE	0	2 (4.3)	2 (2.6)	1 (6.3)	3 (3.2)
BECLOMETASONE	0	1 (2.1)	1 (1.3)	0	1 (1.1)
BUDESONIDE	4 (13.3)	10 (21.3)	14 (18.2)	6 (37.5)	20 (21.5)
CICLOSPORIN	4 (13.3)	4 (8.5)	8 (10.4)	0	8 (8.6)
CIPROFLOXACIN	2 (6.7)	0	2 (2.6)	1 (6.3)	3 (3.2)
HYDROCORTISONE	2 (6.7)	1 (2.1)	3 (3.9)	1 (6.3)	4 (4.3)
IMIPENEM	0	0	0	1 (6.3)	1 (1.1)
INFLIXIMAB	6 (20.0)	8 (17.0)	14 (18.2)	1 (6.3)	15 (16.1)
LOPERAMIDE	0	1 (2.1)	1 (1.3)	0	1 (1.1)
MERCAPTOPURINE	1 (3.3)	1 (2.1)	2 (2.6)	0	2 (2.2)
MESALAZINE	26 (86.7)	38 (80.9)	64 (83.1)	13 (81.3)	77 (82.8)
METHOTREXATE	0	1 (2.1)	1 (1.3)	0	1 (1.1)
METHYLPREDNISOLONE	2 (6.7)	6 (12.8)	8 (10.4)	2 (12.5)	10 (10.8)
METRONIDAZOLE	3 (10.0)	3 (6.4)	6 (7.8)	1 (6.3)	7 (7.5)
MYCOPHENOLIC ACID	1 (3.3)	0	1 (1.3)	0	1 (1.1)
PREDNISOLONE	2 (6.7)	2 (4.3)	4 (5.2)	0	4 (4.3)
PREDNISONE	14 (46.7)	23 (48.9)	37 (48.1)	11 (68.8)	48 (51.6)
SULFASALAZINE	3 (10.0)	2 (4.3)	5 (6.5)	1 (6.3)	6 (6.5)
VANCOMYCIN	1 (3.3)	0	1 (1.3)	0	1 (1.1)

表 2.7.3.6-67.　　UC に関連した前治療薬（一般名）（ITT 集団／安全性解析対象集団，M11-290 試験の主試験）（中間 CSR）（続き）

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
Note: all medications with a start date prior to the first study drug dose are included. Subjects are counted once in each row, regardless of the number of medications they may have taken.

Cross reference: M11-290 Main-study CSR_Interim Table 14.1__6.1.2

表 2.7.3.6-68. ベースラインの UC に関連した治療薬（一般名）（ITT 集団／安全性解析対象集団，M11-290 試験の主試験）（中間 CSR）

	ITT				
	ITT-E				
Generic Name (WHO Q1 2018)	I-SD (N=30) n (%)	I-HD (N=47) n (%)	Total (N=77) n (%)	I-HD-OL (N=16) n (%)	Total (N=93) n (%)
Any baseline UC-related medication	29 (96.7)	43 (91.5)	72 (93.5)	16 (100)	88 (94.6)
AZATHIOPRINE	21 (70.0)	28 (59.6)	49 (63.6)	5 (31.3)	54 (58.1)
BALSALAZIDE	0	1 (2.1)	1 (1.3)	1 (6.3)	2 (2.2)
BECLOMETASONE	0	1 (2.1)	1 (1.3)	0	1 (1.1)
BUDESONIDE	1 (3.3)	4 (8.5)	5 (6.5)	4 (25.0)	9 (9.7)
LOPERAMIDE	0	1 (2.1)	1 (1.3)	0	1 (1.1)
MESALAZINE	24 (80.0)	34 (72.3)	58 (75.3)	13 (81.3)	71 (76.3)
METHYLPREDNISOLONE	2 (6.7)	3 (6.4)	5 (6.5)	0	5 (5.4)
PREDNISOLONE	1 (3.3)	0	1 (1.3)	0	1 (1.1)
PREDNISONE	9 (30.0)	13 (27.7)	22 (28.6)	5 (31.3)	27 (29.0)
SULFASALAZINE	2 (6.7)	1 (2.1)	3 (3.9)	1 (6.3)	4 (4.3)

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
Note: all medications with started prior to the first dose of study drug and continued after the first dose of study drug or ended at the time of the first dose of study drug, including medications taken on the day of the first dose of study drug. Subjects are counted once in each row regardless of the number of medications they may have taken.

Cross reference: M11-290 Main-study CSR_Interim Table 14.1__6.2.2

表 2.7.3.6-69. 導入療法期間中の UC に関連した併用薬（一般名）（ITT 集団／安全性解析対象集団，M11-290 試験の主試験）（中間 CSR）

	ITT				
	ITT-E				
Generic Name (WHO Q1 2018)	I-SD (N=30) n (%)	I-HD (N=47) n (%)	Total (N=77) n (%)	I-HD-OL (N=16) n (%)	Total (N=93) n (%)
Any concomitant UC-related medication during induction period	29 (96.7)	43 (91.5)	72 (93.5)	16 (100)	88 (94.6)
AZATHIOPRINE	21 (70.0)	28 (59.6)	49 (63.6)	5 (31.3)	54 (58.1)
BALSALAZIDE	0	1 (2.1)	1 (1.3)	1 (6.3)	2 (2.2)
BECLOMETASONE	0	1 (2.1)	1 (1.3)	0	1 (1.1)
BUDESONIDE	1 (3.3)	4 (8.5)	5 (6.5)	4 (25.0)	9 (9.7)
CICLOSPORIN	0	1 (2.1)	1 (1.3)	0	1 (1.1)
CIPROFLOXACIN	0	1 (2.1)	1 (1.3)	0	1 (1.1)
HYDROCORTISONE	1 (3.3)	0	1 (1.3)	0	1 (1.1)
LOPERAMIDE	0	1 (2.1)	1 (1.3)	0	1 (1.1)
MESALAZINE	24 (80.0)	34 (72.3)	58 (75.3)	13 (81.3)	71 (76.3)
METHYLPREDNISOLONE	2 (6.7)	3 (6.4)	5 (6.5)	1 (6.3)	6 (6.5)
PREDNISOLONE	1 (3.3)	0	1 (1.3)	0	1 (1.1)
PREDNISONE	10 (33.3)	13 (27.7)	23 (29.9)	5 (31.3)	28 (30.1)
SULFASALAZINE	2 (6.7)	1 (2.1)	3 (3.9)	1 (6.3)	4 (4.3)

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
Note: this table includes all medications with a start date between first study drug in induction period and last study drug in induction period + (max.*) 14 days, including medications with a start date prior to first dose date of study drug in induction period and which are ongoing after first dose date of study drug in induction period and taken on the day of the first dose date of study drug in induction period.
* cutting before first dose of study drug in the maintenance period.
Subjects are counted once in each row, regardless of the number of medications they may have taken.

Cross reference: M11-290 Main-study CSR_Interim Table 14.1__6.3.2

表 2.7.3.6-70. 維持療法期間中の UC に関連した併用薬（一般名）（mITT 集団，M11-290 試験の主試験）（中間 CSR）

	mITT				
		mITT-E			
Generic Name (WHO Q1 2018)	M-PL (N=12) n (%)	M-SD (N=31) n (%)	M-HD (N=31) n (%)	Total (N=62) n (%)	Total (N=74) n (%)
Any concomitant UC-related medication during maintenance period	12 (100)	29 (93.5)	30 (96.8)	59 (95.2)	71 (95.9)
ADALIMUMAB	0	1 (3.2)	0	1 (1.6)	1 (1.4)
AZATHIOPRINE	9 (75.0)	17 (54.8)	20 (64.5)	37 (59.7)	46 (62.2)
BALSALAZIDE	0	2 (6.5)	0	2 (3.2)	2 (2.7)
BECLOMETASONE	0	0	1 (3.2)	1 (1.6)	1 (1.4)
BUDESONIDE	4 (33.3)	2 (6.5)	3 (9.7)	5 (8.1)	9 (12.2)
CIPROFLOXACIN	2 (16.7)	1 (3.2)	2 (6.5)	3 (4.8)	5 (6.8)
LOPERAMIDE	0	1 (3.2)	2 (6.5)	3 (4.8)	3 (4.1)
MESALAZINE	10 (83.3)	24 (77.4)	27 (87.1)	51 (82.3)	61 (82.4)
METHYLPREDNISOLONE	0	3 (9.7)	3 (9.7)	6 (9.7)	6 (8.1)
METRONIDAZOLE	2 (16.7)	2 (6.5)	0	2 (3.2)	4 (5.4)
PREDNISOLONE	0	1 (3.2)	0	1 (1.6)	1 (1.4)
PREDNISONE	3 (25.0)	9 (29.0)	8 (25.8)	17 (27.4)	20 (27.0)
SULFASALAZINE	1 (8.3)	2 (6.5)	0	2 (3.2)	3 (4.1)

M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
Note: this table includes all medications with a start date between first study drug in maintenance period and last study drug in maintenance period + (max.*) 14 days, including medications with a start date prior to first dose date of study drug in maintenance period and which are ongoing after first dose date of study drug in maintenance period and taken on the day of the first dose date of study drug in maintenance period.
* cutting before first dose of study drug in M10-870, if applicable.
Subjects are counted once in each row, regardless of the number of medications they may have taken.

Cross reference: M11-290 Main-study CSR_Interim Table 14.1__6.3.4

表 2.7.3.6-71.　治験薬の服薬順守率（安全性解析対象集団，M11-290 試験の主試験）（中間 CSR）

Treatment	N	Mean	SD	Min	Q1	Median	Q3	Max
Treatment Compliance (%)								
I-SD + I-HD Total	77	98.74	3.370	82.1	99.15	100.00	100.00	103.6
I-SD	30	98.77	2.471	90.9	98.21	100.00	100.00	100.0
I-SD/-	8	97.82	4.038	90.9	95.83	100.00	100.00	100.0
I-SD/M-PL	4	100.00	0.000	100.0	100.00	100.00	100.00	100.0
I-SD/M-SD	8	98.67	2.018	95.5	96.93	100.00	100.00	100.0
I-SD/M-HD	10	99.13	1.483	96.4	98.21	100.00	100.00	100.0
I-HD	47	98.72	3.862	82.1	99.15	100.00	100.00	103.6
I-HD/-	8	100.00	0.000	100.0	100.00	100.00	100.00	100.0
I-HD/M-PL	8	99.30	3.359	91.7	99.58	100.00	100.00	103.6
I-HD/M-SD	16	98.40	4.397	83.9	99.15	100.00	100.00	101.8
I-HD/M-HD	15	98.06	4.577	82.1	98.31	100.00	100.00	100.0
I-HD-OL	16	98.25	6.144	78.0	98.21	100.00	100.00	106.8
I-HD-OL/-	2	95.83	5.893	91.7	91.67	95.83	100.00	100.0
I-HD-OL/M-SD	7	96.84	8.370	78.0	98.21	100.00	100.00	101.7
I-HD-OL/M-HD	7	100.35	3.024	97.4	98.21	100.00	100.00	106.8

Note: I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.

Cross reference: M11-290 Main-study CSR_Interim Table 14.1__8

表 2.7.3.6-72.　導入療法期における治験薬の曝露期間（ITT 集団／安全性解析対象集団，M11-290 試験の主試験）（中間 CSR）

	ITT				
	ITT-E				
	I-SD (N=30)	I-HD (N=47)	Total (N=77)	I-HD-OL (N=16)	Total (N=93)
Duration (day)					
n	30	47	77	16	93
Mean (SD)	54.0(6.22)	55.4(2.30)	54.8(4.30)	53.4(5.12)	54.6(4.45)
Median	56.0	56.0	56.0	55.5	56.0
Min, Max	28, 59	42, 58	28, 59	41, 58	28, 59
Patient-Years of exposure	4.4	7.1	11.6	2.3	13.9

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
Note: duration of induction-exposure = last induction dose date - first induction dose date + (max.*) 14 days.
* cutting before first dose of study drug in the maintenance period.

Cross reference: M11-290 Main-study CSR_Interim Table 14.1__7.1

表 2.7.3.6-73.　維持療法期における治験薬の曝露期間（mITT 集団，M11-290 試験の主試験）（中間 CSR）

	mITT				
	mITT-E				
	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Duration (day)					
n	12	31	31	62	74
Mean (SD)	184.2(123.02)	238.0(104.12)	247.1(103.27)	242.5(102.94)	233.1(107.73)
Median	196.5	308.0	308.0	308.0	307.0
Min, Max	26, 310	30, 316	28, 316	28, 316	26, 316
Patient-Years of exposure	6.1	20.2	21.0	41.2	47.2

M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
Note: duration of maintenance-exposure = last maintenance dose date (prior to potential re-randomization due to 1st disease flare) - first maintenance dose date + (max.*) 14 days. * cutting before first dose of study drug after re-randomization due to 1st disease flare, if applicable, or the first dose of study drug in M10-870, if applicable.

Cross reference: M11-290 Main-study CSR_Interim Table 14.1__7.2

表 2.7.3.6-74.　治験期間を通したアダリムマブの曝露期間（安全性解析対象集団，M11-290 試験の主試験）（中間 CSR）

	Any ADA								
	I-SD				I-HD/HD-OL				
	--$ (N=8)	M-PL (N=4)	M-SD (N=8)	M-HD (N=10)	--$ (N=10)	M-PL (N=8)	M-SD (N=23)	M-HD (N=22)	Total (N=93)
Duration (day)									
n	8	4	8	10	10	8	23	22	93
Mean (SD)	48.4(10.35)	145.3(133.98)	278.9(121.10)	343.2(73.94)	51.9(7.13)	168.5(118.84)	332.0(76.30)	350.0(56.26)	256.3(139.09)
Median	54.0	93.5	364.5	364.5	55.5	145.5	364.0	364.0	363.0
Min, Max	28, 56	55, 339	132, 372	133, 372	41, 58	55, 329	134, 371	112, 371	28, 372
Patient-Years of exposure	1.1	1.6	6.1	9.4	1.4	3.7	20.9	21.1	65.3

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group,
M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
Note: subjects who are randomized to placebo at week 8 and who have not been re-randomized due to a disease flare:
Overall ADA exposure = duration of induction-exposure.

Subjects who are randomized to placebo at week 8 and are re-randomized due to at least one disease flare during maintenance:
Overall ADA exposure = duration of induction-exposure + (last adalimumab dose date in the study after re-randomization due to 1st disease flare - first dose date of adalimumab after re-randomization due to 1st disease flare + (max.*) 14 days).

Subjects who are not randomized to placebo:
Overall ADA exposure = last adalimumab dose date in the study - first dose of adalimumab + (max.*) 14 days.
* cutting before first dose of study drug in M10-870, if applicable.

$ patients who discontinued as non-responders from the study at week 8.

Cross reference: M11-290 Main-study CSR_Interim Table 14.1__7.6

表 2.7.3.6-75. 治験責任医師別の被験者の内訳（登録した被験者集団，M10-870 試験の主試験）（中間 CSR）

Current Investigator (Site Number)	Enrolled n	Treated n	Completed n	Completed Week 288 n	Switched to Adult Care n	Switched to Commercial Humira n	Discontinued Study Drug n	Full Analysis Set n
All Sites	55	55	0	--	--	--	14	55
[redacted]	8	8	0	--	--	--	1	8
[redacted]	8	8	0	--	--	--	0	8
[redacted]	3	3	0	--	--	--	0	3
[redacted]	22	22	0	--	--	--	8	22
[redacted]	2	2	0	--	--	--	0	2
[redacted]	1	1	0	--	--	--	1	1
[redacted]	1	1	0	--	--	--	1	1
[redacted]	2	2	0	--	--	--	0	2
[redacted]	3	3	0	--	--	--	0	3
[redacted]	4	4	0	--	--	--	2	4
[redacted]	1	1	0	--	--	--	1	1

表 2.7.3.6-75.　　治験責任医師別の被験者の内訳（登録した被験者集団，M10-870 試験の主試験）（中間 CSR）（続き）

Note: Enrolled group includes all patients who have successfully completed Protocol M11-290 through Week 52 and meet all of the inclusion criteria and none of the exclusion criteria.

Cross reference: M10-870 Main-study CSR_Interim Table 14.1__1.1

表 2.7.3.6-76.　　用量調整（FAS 集団，M10-870 試験の主試験）（中間 CSR）

Dose Adjustments	Adalimumab (N=55) n (%)
Subjects with EW dosing at baseline	N*=3 (5.5)
Subjects with EOW dosing at baseline	N**=52 (94.5)
At least one dose escalation (EOW to EW)[A]	18 (34.6)
At least one dose de-escalation (EW to EOW)[B]	0
At least one dose de-escalation (EW to EOW) and re-escalation (EOW to EW)[B]	0

[A] Percentages are relative to N**.
[B] Percentages are relative to N*.

Cross reference: M10-870 Main-study CSR_Interim Table 14.1__1.2

表 2.7.3.6-77.　被験者の中止理由（FAS 集団，M10-870 試験の主試験）（中間 CSR）

Discontinuation due to	Adalimumab (N=55) n (%)
All reasons$	14 (25.5)
Adverse event	2 (3.6)
Withdrew consent	2 (3.6)
Lost to follow-up	1 (1.8)
Lack of efficacy	10 (18.2)
Requires alternative (or prohibited) therapy	1 (1.8)
Subject non-compliance	1 (1.8)
Other	0
Primary reason	14 (25.5)
Adverse event	0
Withdrew consent	2 (3.6)
Lost to follow-up	1 (1.8)
Lack of efficacy	9 (16.4)
Requires alternative (or prohibited) therapy	1 (1.8)
Subject non-compliance	1 (1.8)
Other	0

$ Subjects who discontinued study drug are counted under each reason given for discontinuation, therefore, the sum of the counts given for the reasons may be greater than the overall number of discontinuations.

Cross reference: M10-870 Main-study CSR_Interim Table 14.1__2

表 2.7.3.6-78.　治験実施計画書からの逸脱（登録した被験者集団，M10-870 試験の主試験）（中間 CSR）

	Adalimumab (N=55)
Subjects who had at least one protocol deviation	5 (9.1)
Subject entered into the study even though did not satisfy entry criteria	0
Subject received wrong treatment or incorrect dose	5 (9.1)
Subject received excluded concomitant treatment	0
Subject developed withdrawal criteria during the study and was not withdrawn	0

Cross reference: M10-870 Main-study CSR_Interim Table 14.1__9

表 2.7.3.6-79.　人口統計学的特性（FAS 集団，M10-870 試験の主試験）（中間 CSR）

	Adalimumab (N=55)
Sex# - n (%)	
Female	30 (54.5)
Male	25 (45.5)
Age (years)#	
n	55
Mean (SD)	14.7 (3.36)
Median	16.0
Min, Max	6, 19
Age categories (years)# - n (%)	
< 13	16 (29.1)
>= 13	39 (70.9)
Race# - n (%)	
White	52 (94.5)
Black	2 (3.6)
Asian	1 (1.8)
American Indian/Alaska Native	0
Other	0
Ethnicity# - n (%)	
Hispanic or Latino	1 (1.8)
Japanese	0
No ethnicity	54 (98.2)
Geographic region# - n (%)	
North America	5 (9.1)
Western Europe	3 (5.5)
Eastern Europe	47 (85.5)

表 2.7.3.6-79. 人口統計学的特性（FAS 集団，M10-870 試験の主試験）（中間 CSR）（続き）

	Adalimumab (N=55)
Body weight (kg)#	
n	55
Mean (SD)	60.3 (20.05)
Median	62.0
Min, Max	17.4, 110.0
Body weight (kg)# by sex	
Female	
n	30
Mean (SD)	54.7 (15.21)
Median	56.1
Min, Max	22.5, 95.0
Male	
n	25
Mean (SD)	67.1 (23.18)
Median	67.2
Min, Max	17.4, 110.0
Body weight categories (kg) - n (%)	
< 40	8 (14.5)
40 - < 60	17 (30.9)
>= 60	30 (54.5)
Height (cm)#	
n	55
Mean (SD)	163.9 (18.16)
Median	166.0
Min, Max	112.5, 198.0

表 2.7.3.6-79. 人口統計学的特性（FAS 集団，M10-870 試験の主試験）（中間 CSR）（続き）

	Adalimumab (N=55)
Body mass index (kg/m^2)	
n	55
Mean (SD)	21.7 (4.22)
Median	21.5
Min, Max	13.7, 32.1
Tobacco/Nicotine use$#* - n (%)	
Current	0
Former	0
Never	55 (100)
Unknown	0
Alcohol use$#* - n (%)	
Current	0
Former	0
Never	55 (100)
Unknown	0

Note: Percentages calculated on non-missing values.
$ Percentages calculated on non-unknown values. A subject may be a current user of one type of tobacco. A former user of another type of tobacco and never used another type of tobacco. A subject will be counted in the category closest to user.
# The source data from Study M11-290.
* Data from Study M11-290-Baseline.

Cross reference: M10-870 Main-study CSR_Interim Table 14.1__3

表 2.7.3.6-80.　疾患特性（FAS 集団，M10-870 試験の主試験）（中間 CSR）

	Adalimumab (N=55)
Duration of UC (months)	
n	55
Mean (SD)	43.7 (25.29)
Median	39.3
Min, Max	16.4, 135.9
Duration of UC (years)	
n	55
Mean (SD)	3.6 (2.11)
Median	3.3
Min, Max	1.4, 11.3
Site of UC# - n (%)	
Left sided UC	21 (38.2)
Extensive UC/pancolitis	34 (61.8)
Mayo Score#	
n	55
Mean (SD)	2.1 (1.90)
Median	1.2
Min, Max	0.0, 7.2
Mayo Score at M11-290-Baseline#	
n	55
Mean (SD)	7.8 (1.18)
Median	7.8
Min, Max	6.0, 10.8

表 2.7.3.6-80.　疾患特性（FAS 集団，M10-870 試験の主試験）（中間 CSR）（続き）

	Adalimumab (N=55)
Partial Mayo Score#	
n	55
Mean (SD)	1.2 (1.29)
Median	0.8
Min, Max	0.0, 5.2
Partial Mayo Score at M11-290-Baseline#	
n	55
Mean (SD)	5.7 (1.15)
Median	5.6
Min, Max	4.0, 8.8
Endoscopy Subscore#	
n	55
Mean (SD)	0.9 (1.01)
Median	1.0
Min, Max	0.0, 3.0
Rectal Bleeding Subscore#	
n	55
Mean (SD)	0.1 (0.33)
Median	0.0
Min, Max	0.0, 2.0
Physician's Global Assessment (PGA) Subscore#	
n	55
Mean (SD)	0.5 (0.66)
Median	0.0
Min, Max	0.0, 3.0

表 2.7.3.6-80.　疾患特性（FAS 集団，M10-870 試験の主試験）（中間 CSR）（続き）

	Adalimumab (N=55)
Stool Frequency Subscore#	
n	55
Mean (SD)	0.6 (0.69)
Median	0.4
Min, Max	0.0, 3.0
Number of stools in the last 24 hours prior to baseline#	
n	48
Mean (SD)	3.1 (3.47)
Median	2.0
Min, Max	0.0, 22.0
PUCAI total score#	
n	55
Mean (SD)	6.3 (11.95)
Median	0.0
Min, Max	0.0, 70.0
PUCAI total score at M11-290-Baseline#	
n	55
Mean (SD)	41.0 (15.22)
Median	42.5
Min, Max	10.0, 72.5
IMPACT III total score#	
n	51
Mean (SD)	138.6 (20.22)
Median	143.0
Min, Max	82.0, 169.0

表 2.7.3.6-80.　疾患特性（FAS 集団，M10-870 試験の主試験）（中間 CSR）（続き）

	Adalimumab (N=55)
IMPACT III - body image#	
n	51
Mean (SD)	10.9 (1.95)
Median	11.0
Min, Max	5.0, 15.0
IMPACT III - bowel symptoms#	
n	51
Mean (SD)	28.7 (5.02)
Median	30.0
Min, Max	14.0, 35.0
IMPACT III - emotional functioning#	
n	51
Mean (SD)	26.6 (5.56)
Median	28.0
Min, Max	11.0, 35.0
IMPACT III - social functioning#	
n	51
Mean (SD)	49.4 (6.41)
Median	51.0
Min, Max	30.0, 58.0
IMPACT III - systemic symptoms#	
n	51
Mean (SD)	11.4 (2.51)
Median	12.0
Min, Max	4.0, 15.0

表 2.7.3.6-80.　疾患特性（FAS 集団，M10-870 試験の主試験）（中間 CSR）（続き）

	Adalimumab (N=55)
IMPACT III - treatment/interventions#	
n	51
Mean (SD)	11.6 (2.36)
Median	12.0
Min, Max	4.0, 15.0
WPAI - absenteeism (%)#	
n	39
Mean (SD)	5.5 (13.14)
Median	0.0
Min, Max	0.0, 54.5
WPAI - presenteeism (%)#	
n	39
Mean (SD)	11.8 (16.04)
Median	10.0
Min, Max	0.0, 60.0
WPAI - work impairment (%)#	
n	39
Mean (SD)	17.5 (21.02)
Median	10.0
Min, Max	0.0, 66.7
WPAI - activity impairment (%)#	
n	55
Mean (SD)	16.4 (20.13)
Median	10.0
Min, Max	0.0, 80.0

表 2.7.3.6-80. 疾患特性（FAS 集団，M10-870 試験の主試験）（中間 CSR）（続き）

	Adalimumab (N=55)
hs-CRP [mg/l]#	
n	55
Mean (SD)	1.8 (2.78)
Median	0.4
Min, Max	0.1, 13.9
Tuberculin PPD skin test# - n (%)	
Negative	0
Positive&	0
Missing	55
QuantiFERON-TB Gold test# - n (%)	
Negative	40 (90.9)
Positive	3 (6.8)
Indeterminate	1 (2.3)
Missing	11
Tuberculin positive# - n (%)	
Yes$	3 (6.8)
No	41 (93.2)
Missing	11
Enrollment under TB prophylaxis# - n (%)	
Yes	0
No	55 (100)

表 2.7.3.6-80.　　疾患特性（FAS 集団，M10-870 試験の主試験）（中間 CSR）（続き）

Note: Percentages calculated on non-missing values.
Duration of UC in months: (Baseline date - date of diagnosis of UC#+ 1)/(365.25/12).
Duration of UC in years: (Baseline date - date of diagnosis of UC#+ 1)/365.25.
The source data from Study M11-290.
& Positive defined as >= 5 mm.
$ Tuberculin PPD skin test >= 5 mm or QuantiFERON-TB Gold test is positive.

Cross reference: M10-870 Main-study CSR_Interim Table 14.1__4

表 2.7.3.6-81.　UC に関連した前治療薬（一般名）（FAS 集団，M10-870 試験の主試験）（中間 CSR）

Generic Name (WHO Q1 2018)	Adalimumab (N=55) n (%)
Any prior UC-related medication	55 (100)
AZATHIOPRINE	37 (67.3)
BALSALAZIDE	1 (1.8)
BUDESONIDE	5 (9.1)
CICLOSPORIN	3 (5.5)
CIPROFLOXACIN	2 (3.6)
HYDROCORTISONE	2 (3.6)
INFLIXIMAB	7 (12.7)
LOPERAMIDE	1 (1.8)
MERCAPTOPURINE	1 (1.8)
MESALAZINE	43 (78.2)
METHOTREXATE	1 (1.8)
METHYLPREDNISOLONE	3 (5.5)
METRONIDAZOLE	3 (5.5)
MYCOPHENOLIC ACID	1 (1.8)
PREDNISOLONE	2 (3.6)
PREDNISONE	19 (34.5)
SULFASALAZINE	4 (7.3)
VANCOMYCIN	1 (1.8)

Note: All medications with a start date prior to the first study drug dose in Study M11-290 are included.
Subjects are counted once in each row regardless of the number of medications they may have taken.

Cross reference: M10-870 Main-study CSR_Interim Table 14.1__6.1.2

表 2.7.3.6-82.　UC に関連した併用薬（一般名）（FAS 集団，M10-870 試験の主試験）（中間 CSR）

Generic Name (WHO Q1 2018)	Adalimumab (N=55) n (%)
Any concomitant UC-related medication	51 (92.7)
AZATHIOPRINE	34 (61.8)
BUDESONIDE	4 (7.3)
CIPROFLOXACIN	3 (5.5)
FLUCONAZOLE	1 (1.8)
FURAZOLIDONE	1 (1.8)
LOPERAMIDE	2 (3.6)
MESALAZINE	46 (83.6)
METHOTREXATE	1 (1.8)
METHYLPREDNISOLONE	1 (1.8)
METRONIDAZOLE	1 (1.8)
PREDNISOLONE	1 (1.8)
PREDNISONE	6 (10.9)
RIFAXIMIN	1 (1.8)
SULFASALAZINE	1 (1.8)

Note: All medications with a start date between first study drug in Study M10-870 and last study drug in Study M10-870 + 14 days, including medications with a start date prior to first dose date of study drug and which are ongoing after first dose date of study drug and taken on the day of the first dose date of study drug in Study M10-870.
Subjects are counted once in each row regardless of the number of medications they may have taken.

Cross reference: M10-870 Main-study CSR_Interim Table 14.1__6.3.2

表 2.7.3.6-83.　治験薬の服薬順守率（FAS 集団，M10-870 試験の主試験）（中間 CSR）

	N	Mean	SD	Min	Q1	Median	Q3	Max
Treatment compliance (%)	55	120.72	34.561	82.6	100.00	101.03	135.71	200.0

Cross reference: M10-870 Main-study CSR_Interim Table 14.1__8

表 2.7.3.6-84.　治験薬の曝露期間（FAS 集団，M10-870 試験の主試験）（中間 CSR）

	Adalimumab (N=55)
Duration (days)	
n	55
Mean (SD)	529.7(381.13)
Median	447.0
Min, Max	1, 1370
Patient-Years of exposure	79.8

Note: ADA exposure in Study M10-870 = last dose date of ADA in Study M10-870 - first dose date of ADA in Study M10-870 + 14 days.

Cross reference: M10-870 Main-study CSR_Interim Table 14.1__7.1

表 2.7.3.6-85. 投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（ITT 集団，M11-290 試験の主試験）（中間 CSR）

	ITT				
	ITT-E				
Category Endpoint Met	I-SD (N=30)	I-HD (N=47)	Total (N=77)	I-HD-OL (N=16)	Total (N=93)
Overall	N=30	N=47	N=77	N=16	N=93
Yes	13 (43.3)	28 (59.6)	41 (53.2)	11 (68.8)	52 (55.9)
No	17 (56.7)	19 (40.4)	36 (46.8)	5 (31.3)	41 (44.1)
95% Confidence Interval [A]	(25.46, 62.57)	(44.27, 73.63)	(41.52, 64.71)	(41.34, 88.98)	(45.24, 66.20)
P-Value [B1]	0.001	<0.001	<0.001		
ADJ. P-Value [B2]	0.382	<0.001	<0.001		
P-Value [C]	0.164				
Baseline Mayo Score <= 9 &	N=25	N=38	N=63	N=13	N=76
Yes	11 (44.0)	24 (63.2)	35 (55.6)	9 (69.2)	44 (57.9)
No	14 (56.0)	14 (36.8)	28 (44.4)	4 (30.8)	32 (42.1)
95% Confidence Interval [A]	(24.40, 65.07)	(45.99, 78.19)	(42.49, 68.08)	(38.57, 90.91)	(46.02, 69.14)

表 2.7.3.6-85. 投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Category Endpoint Met	ITT ITT-E I-SD (N=30)	ITT ITT-E I-HD (N=47)	ITT ITT-E Total (N=77)	ITT I-HD-OL (N=16)	ITT Total (N=93)
Baseline Mayo Score > 9 &	N=5	N=9	N=14	N=3	N=17
Yes	2 (40.0)	4 (44.4)	6 (42.9)	2 (66.7)	8 (47.1)
No	3 (60.0)	5 (55.6)	8 (57.1)	1 (33.3)	9 (52.9)
95% Confidence Interval [A]	(5.27, 85.34)	(13.70, 78.80)	(17.66, 71.14)	(9.43, 99.16)	(22.98, 72.19)
Prior Anti-TNF Use	N=6	N=8	N=14	N=1	N=15
Yes	1 (16.7)	3 (37.5)	4 (28.6)	1 (100)	5 (33.3)
No	5 (83.3)	5 (62.5)	10 (71.4)	0	10 (66.7)
95% Confidence Interval [A]	(0.42, 64.12)	(8.52, 75.51)	(8.39, 58.10)	(2.50, 100.00)	(11.82, 61.62)
Prior Anti-TNF Naive	N=24	N=39	N=63	N=15	N=78
Yes	12 (50.0)	25 (64.1)	37 (58.7)	10 (66.7)	47 (60.3)
No	12 (50.0)	14 (35.9)	26 (41.3)	5 (33.3)	31 (39.7)
95% Confidence Interval [A]	(29.12, 70.88)	(47.18, 78.80)	(45.62, 70.99)	(38.38, 88.18)	(48.54, 71.17)
Baseline Corticosteroid Use - Yes #	N=13	N=22	N=35	N=9	N=44
Yes	4 (30.8)	14 (63.6)	18 (51.4)	6 (66.7)	24 (54.5)
No	9 (69.2)	8 (36.4)	17 (48.6)	3 (33.3)	20 (45.5)
95% Confidence Interval [A]	(9.09, 61.43)	(40.66, 82.80)	(33.99, 68.62)	(29.93, 92.51)	(38.85, 69.61)

表 2.7.3.6-85. 投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Category Endpoint Met	ITT ITT-E I-SD (N=30)	ITT ITT-E I-HD (N=47)	ITT ITT-E Total (N=77)	ITT I-HD-OL (N=16)	ITT Total (N=93)
Baseline Corticosteroid Use - No #	N=17	N=25	N=42	N=7	N=49
Yes	9 (52.9)	14 (56.0)	23 (54.8)	5 (71.4)	28 (57.1)
No	8 (47.1)	11 (44.0)	19 (45.2)	2 (28.6)	21 (42.9)
95% Confidence Interval [A]	(27.81, 77.02)	(34.93, 75.60)	(38.67, 70.15)	(29.04, 96.33)	(42.21, 71.18)
Sex - Male	N=15	N=24	N=39	N=3	N=42
Yes	4 (26.7)	16 (66.7)	20 (51.3)	3 (100)	23 (54.8)
No	11 (73.3)	8 (33.3)	19 (48.7)	0	19 (45.2)
95% Confidence Interval [A]	(7.79, 55.10)	(44.68, 84.37)	(34.78, 67.58)	(29.24, 100.00)	(38.67, 70.15)
Sex - Female	N=15	N=23	N=38	N=13	N=51
Yes	9 (60.0)	12 (52.2)	21 (55.3)	8 (61.5)	29 (56.9)
No	6 (40.0)	11 (47.8)	17 (44.7)	5 (38.5)	22 (43.1)
95% Confidence Interval [A]	(32.29, 83.66)	(30.59, 73.18)	(38.30, 71.38)	(31.58, 86.14)	(42.25, 70.65)
Age < 13 Years	N=4	N=16	N=20	N=5	N=25
Yes	2 (50.0)	10 (62.5)	12 (60.0)	3 (60.0)	15 (60.0)
No	2 (50.0)	6 (37.5)	8 (40.0)	2 (40.0)	10 (40.0)
95% Confidence Interval [A]	(6.76, 93.24)	(35.43, 84.80)	(36.05, 80.88)	(14.66, 94.73)	(38.67, 78.87)

表 2.7.3.6-85. 投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Category Endpoint Met	ITT ITT-E I-SD (N=30)	ITT ITT-E I-HD (N=47)	ITT ITT-E Total (N=77)	ITT I-HD-OL (N=16)	ITT Total (N=93)
Age >= 13 Years	N=26	N=31	N=57	N=11	N=68
Yes	11 (42.3)	18 (58.1)	29 (50.9)	8 (72.7)	37 (54.4)
No	15 (57.7)	13 (41.9)	28 (49.1)	3 (27.3)	31 (45.6)
95% Confidence Interval [A]	(23.35, 63.08)	(39.08, 75.45)	(37.29, 64.37)	(39.03, 93.98)	(41.88, 66.55)
Ethnicity - White	N=28	N=45	N=73	N=15	N=88
Yes	11 (39.3)	27 (60.0)	38 (52.1)	11 (73.3)	49 (55.7)
No	17 (60.7)	18 (40.0)	35 (47.9)	4 (26.7)	39 (44.3)
95% Confidence Interval [A]	(21.50, 59.42)	(44.33, 74.30)	(40.04, 63.90)	(44.90, 92.21)	(44.70, 66.27)
Ethnicity - Non-white	N=2	N=2	N=4	N=1	N=5
Yes	2 (100)	1 (50.0)	3 (75.0)	0	3 (60.0)
No	0	1 (50.0)	1 (25.0)	1 (100)	2 (40.0)
95% Confidence Interval [A]	(15.81, 100.00)	(1.26, 98.74)	(19.41, 99.37)	(0.00, 97.50)	(14.66, 94.73)
Geographic Region - North America	N=2	N=8	N=10	N=3	N=13
Yes	1 (50.0)	3 (37.5)	4 (40.0)	2 (66.7)	6 (46.2)
No	1 (50.0)	5 (62.5)	6 (60.0)	1 (33.3)	7 (53.8)
95% Confidence Interval [A]	(1.26, 98.74)	(8.52, 75.51)	(12.16, 73.76)	(9.43, 99.16)	(19.22, 74.87)

表 2.7.3.6-85. 投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	ITT				
	ITT-E				
Category Endpoint Met	I-SD (N=30)	I-HD (N=47)	Total (N=77)	I-HD-OL (N=16)	Total (N=93)
Geographic Region - Western Europe	N=3	N=4	N=7	N=1	N=8
Yes	1 (33.3)	1 (25.0)	2 (28.6)	1 (100)	3 (37.5)
No	2 (66.7)	3 (75.0)	5 (71.4)	0	5 (62.5)
95% Confidence Interval [A]	(0.84, 90.57)	(0.63, 80.59)	(3.67, 70.96)	(2.50, 100.00)	(8.52, 75.51)
Geographic Region - Eastern Europe	N=25	N=35	N=60	N=12	N=72
Yes	11 (44.0)	24 (68.6)	35 (58.3)	8 (66.7)	43 (59.7)
No	14 (56.0)	11 (31.4)	25 (41.7)	4 (33.3)	29 (40.3)
95% Confidence Interval [A]	(24.40, 65.07)	(50.71, 83.15)	(44.88, 70.93)	(34.89, 90.08)	(47.50, 71.12)
Baseline IMM Use - Yes	N=21	N=29	N=50	N=5	N=55
Yes	11 (52.4)	18 (62.1)	29 (58.0)	4 (80.0)	33 (60.0)
No	10 (47.6)	11 (37.9)	21 (42.0)	1 (20.0)	22 (40.0)
95% Confidence Interval [A]	(29.78, 74.29)	(42.26, 79.31)	(43.21, 71.81)	(28.36, 99.49)	(45.91, 72.98)
Baseline IMM Use - No	N=9	N=18	N=27	N=11	N=38
Yes	2 (22.2)	10 (55.6)	12 (44.4)	7 (63.6)	19 (50.0)
No	7 (77.8)	8 (44.4)	15 (55.6)	4 (36.4)	19 (50.0)
95% Confidence Interval [A]	(2.81, 60.01)	(30.76, 78.47)	(25.48, 64.67)	(30.79, 89.07)	(33.38, 66.62)

表 2.7.3.6-85. 投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	ITT				
	ITT-E				
Category Endpoint Met	I-SD (N=30)	I-HD (N=47)	Total (N=77)	I-HD-OL (N=16)	Total (N=93)
Weight < 40 kg	N=3	N=9	N=12	N=3	N=15
Yes	2 (66.7)	4 (44.4)	6 (50.0)	2 (66.7)	8 (53.3)
No	1 (33.3)	5 (55.6)	6 (50.0)	1 (33.3)	7 (46.7)
95% Confidence Interval [A]	(9.43, 99.16)	(13.70, 78.80)	(21.09, 78.91)	(9.43, 99.16)	(26.59, 78.73)
Weight >= 40 kg	N=27	N=38	N=65	N=13	N=78
Yes	11 (40.7)	24 (63.2)	35 (53.8)	9 (69.2)	44 (56.4)
No	16 (59.3)	14 (36.8)	30 (46.2)	4 (30.8)	34 (43.6)
95% Confidence Interval [A]	(22.39, 61.20)	(45.99, 78.19)	(41.03, 66.30)	(38.57, 90.91)	(44.70, 67.61)
Pancolitis - Yes	N=20	N=25	N=45	N=11	N=56
Yes	7 (35.0)	13 (52.0)	20 (44.4)	9 (81.8)	29 (51.8)
No	13 (65.0)	12 (48.0)	25 (55.6)	2 (18.2)	27 (48.2)
95% Confidence Interval [A]	(15.39, 59.22)	(31.31, 72.20)	(29.64, 60.00)	(48.22, 97.72)	(38.03, 65.34)
Pancolitis - No	N=10	N=22	N=32	N=5	N=37
Yes	6 (60.0)	15 (68.2)	21 (65.6)	2 (40.0)	23 (62.2)
No	4 (40.0)	7 (31.8)	11 (34.4)	3 (60.0)	14 (37.8)
95% Confidence Interval [A]	(26.24, 87.84)	(45.13, 86.14)	(46.81, 81.43)	(5.27, 85.34)	(44.76, 77.54)

表 2.7.3.6-85. 投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Category Endpoint Met	ITT ITT-E I-SD (N=30)	ITT ITT-E I-HD (N=47)	ITT ITT-E Total (N=77)	ITT I-HD-OL (N=16)	ITT Total (N=93)
Disease Duration <= Baseline Median (19.1 Months)	N=19	N=21	N=40	N=9	N=49
Yes	7 (36.8)	9 (42.9)	16 (40.0)	6 (66.7)	22 (44.9)
No	12 (63.2)	12 (57.1)	24 (60.0)	3 (33.3)	27 (55.1)
95% Confidence Interval [A]	(16.29, 61.64)	(21.82, 65.98)	(24.86, 56.67)	(29.93, 92.51)	(30.67, 59.77)
Disease Duration > Baseline Median (19.1 Months)	N=11	N=26	N=37	N=7	N=44
Yes	6 (54.5)	19 (73.1)	25 (67.6)	5 (71.4)	30 (68.2)
No	5 (45.5)	7 (26.9)	12 (32.4)	2 (28.6)	14 (31.8)
95% Confidence Interval [A]	(23.38, 83.25)	(52.21, 88.43)	(50.21, 81.99)	(29.04, 96.33)	(52.42, 81.39)
Baseline hs-CRP <= Baseline Median (1.29 mg/L)	N=14	N=20	N=34	N=8	N=42
Yes	7 (50.0)	13 (65.0)	20 (58.8)	5 (62.5)	25 (59.5)
No	7 (50.0)	7 (35.0)	14 (41.2)	3 (37.5)	17 (40.5)
95% Confidence Interval [A]	(23.04, 76.96)	(40.78, 84.61)	(40.70, 75.35)	(24.49, 91.48)	(43.28, 74.37)
Baseline hs-CRP > Baseline Median (1.29 mg/L)	N=14	N=21	N=35	N=8	N=43
Yes	5 (35.7)	12 (57.1)	17 (48.6)	6 (75.0)	23 (53.5)
No	9 (64.3)	9 (42.9)	18 (51.4)	2 (25.0)	20 (46.5)
95% Confidence Interval [A]	(12.76, 64.86)	(34.02, 78.18)	(31.38, 66.01)	(34.91, 96.81)	(37.65, 68.82)

表 2.7.3.6-85. 投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Category Endpoint Met	ITT ITT-E I-SD (N=30)	ITT ITT-E I-HD (N=47)	ITT ITT-E Total (N=77)	ITT I-HD-OL (N=16)	ITT Total (N=93)
Baseline Fecal Calprotectin <= Baseline Median (2302.5 ug/g)	N=6	N=7	N=13	N=0	N=13
Yes	2 (33.3)	3 (42.9)	5 (38.5)	0	5 (38.5)
No	4 (66.7)	4 (57.1)	8 (61.5)	0	8 (61.5)
95% Confidence Interval [A]	(4.33, 77.72)	(9.90, 81.59)	(13.86, 68.42)	(NA, NA)	(13.86, 68.42)
Baseline Fecal Calprotectin > Baseline Median (2302.5 ug/g)	N=5	N=7	N=12	N=0	N=12
Yes	2 (40.0)	2 (28.6)	4 (33.3)	0	4 (33.3)
No	3 (60.0)	5 (71.4)	8 (66.7)	0	8 (66.7)
95% Confidence Interval [A]	(5.27, 85.34)	(3.67, 70.96)	(9.92, 65.11)	(NA, NA)	(9.92, 65.11)

表 2.7.3.6-85.　投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Note: I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
[A] Clopper-Pearson confidence interval for proportion in remission.
[B1] Nominal p-values from a one-sample two-sided chi-square test.
[B2] Adjusted p-values from a sequentially rejective multiple test procedure (details in SAP), testing co-primary and ranked secondary endpoints first for I-SD/I-HD combined (p-value in 'Total' column) and then for individual ADA dose groups (p-values in 'I-HD' column and in 'I-SD' column, respectively) against the respective external placebo rate (here: 19.83%).
[C] Nominal p-value for the exploratory comparison of I-SD vs. I-HD.
Non-responder imputation (NRI): missing data is imputed as not having met the endpoint. Subjects re-randomized due to disease flare are considered as not having met the endpoint at and after their 1st disease flare.
Clinical remission per Partial Mayo Score (PMS) is defined as PMS <= 2 and no individual subscore > 1.
& True baseline Mayo Score is displayed. Subject [redacted] was randomized in the stratum '> 9', but actually had a baseline Mayo Score of 8.8 (corrected by the site from 9.8 to 8.8 after randomization).
# True baseline systemic corticosteroid use is displayed. Subject [redacted] was randomized in the stratum 'No', but actually has baseline systemic corticosteroid use documented.

Cross reference: M11-290 Main-study CSR_Interim Table 14.2__1.1.1

表 2.7.3.6-86. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Overall	N=12	N=31	N=31	N=62	N=74
Yes	4 (33.3)	9 (29.0)	14 (45.2)	23 (37.1)	27 (36.5)
No	8 (66.7)	22 (71.0)	17 (54.8)	39 (62.9)	47 (63.5)
95% Confidence Interval [A]	(9.92, 65.11)	(14.22, 48.04)	(27.32, 63.97)	(25.16, 50.31)	(25.60, 48.49)
P-Value [B1]		0.125	<0.001	<0.001	
ADJ. P-Value [B2]		0.382	<0.001	<0.001	
P-Value [C]		0.189			
PMS Remission at Week 8 - Yes	N=8	N=21	N=22	N=43	N=51
Yes	3 (37.5)	9 (42.9)	10 (45.5)	19 (44.2)	22 (43.1)
No	5 (62.5)	12 (57.1)	12 (54.5)	24 (55.8)	29 (56.9)
95% Confidence Interval [A]	(8.52, 75.51)	(21.82, 65.98)	(24.39, 67.79)	(29.08, 60.12)	(29.35, 57.75)

表 2.7.3.6-86. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
PMS Remission at Week 8 - No	N=4	N=10	N=9	N=19	N=23
Yes	1 (25.0)	0	4 (44.4)	4 (21.1)	5 (21.7)
No	3 (75.0)	10 (100)	5 (55.6)	15 (78.9)	18 (78.3)
95% Confidence Interval [A]	(0.63, 80.59)	(0.00, 30.85)	(13.70, 78.80)	(6.05, 45.57)	(7.46, 43.70)
I-SD	N=4	N=8	N=9	N=17	N=21
Yes	1 (25.0)	0	4 (44.4)	4 (23.5)	5 (23.8)
No	3 (75.0)	8 (100)	5 (55.6)	13 (76.5)	16 (76.2)
95% Confidence Interval [A]	(0.63, 80.59)	(0.00, 36.94)	(13.70, 78.80)	(6.81, 49.90)	(8.22, 47.17)
I-HD/I-HD-OL	N=8	N=23	N=22	N=45	N=53
Yes	3 (37.5)	9 (39.1)	10 (45.5)	19 (42.2)	22 (41.5)
No	5 (62.5)	14 (60.9)	12 (54.5)	26 (57.8)	31 (58.5)
95% Confidence Interval [A]	(8.52, 75.51)	(19.71, 61.46)	(24.39, 67.79)	(27.66, 57.85)	(28.14, 55.87)

表 2.7.3.6-86. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
I-HD	N=8	N=16	N=15	N=31	N=39
Yes	3 (37.5)	7 (43.8)	7 (46.7)	14 (45.2)	17 (43.6)
No	5 (62.5)	9 (56.3)	8 (53.3)	17 (54.8)	22 (56.4)
95% Confidence Interval [A]	(8.52, 75.51)	(19.75, 70.12)	(21.27, 73.41)	(27.32, 63.97)	(27.81, 60.38)
I-HD-OL	N=0	N=7	N=7	N=14	N=14
Yes	0	2 (28.6)	3 (42.9)	5 (35.7)	5 (35.7)
No	0	5 (71.4)	4 (57.1)	9 (64.3)	9 (64.3)
95% Confidence Interval [A]	(NA, NA)	(3.67, 70.96)	(9.90, 81.59)	(12.76, 64.86)	(12.76, 64.86)
Sex - Male	N=9	N=13	N=13	N=26	N=35
Yes	2 (22.2)	4 (30.8)	6 (46.2)	10 (38.5)	12 (34.3)
No	7 (77.8)	9 (69.2)	7 (53.8)	16 (61.5)	23 (65.7)
95% Confidence Interval [A]	(2.81, 60.01)	(9.09, 61.43)	(19.22, 74.87)	(20.23, 59.43)	(19.13, 52.21)

表 2.7.3.6-86. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Sex - Female	N=3	N=18	N=18	N=36	N=39
Yes	2 (66.7)	5 (27.8)	8 (44.4)	13 (36.1)	15 (38.5)
No	1 (33.3)	13 (72.2)	10 (55.6)	23 (63.9)	24 (61.5)
95% Confidence Interval [A]	(9.43, 99.16)	(9.69, 53.48)	(21.53, 69.24)	(20.82, 53.78)	(23.36, 55.38)
Age < 13 Years	N=2	N=12	N=8	N=20	N=22
Yes	1 (50.0)	5 (41.7)	3 (37.5)	8 (40.0)	9 (40.9)
No	1 (50.0)	7 (58.3)	5 (62.5)	12 (60.0)	13 (59.1)
95% Confidence Interval [A]	(1.26, 98.74)	(15.17, 72.33)	(8.52, 75.51)	(19.12, 63.95)	(20.71, 63.65)
Age >= 13 Years	N=10	N=19	N=23	N=42	N=52
Yes	3 (30.0)	4 (21.1)	11 (47.8)	15 (35.7)	18 (34.6)
No	7 (70.0)	15 (78.9)	12 (52.2)	27 (64.3)	34 (65.4)
95% Confidence Interval [A]	(6.67, 65.25)	(6.05, 45.57)	(26.82, 69.41)	(21.55, 51.97)	(21.97, 49.09)

表 2.7.3.6-86. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Ethnicity - White	N=11	N=29	N=30	N=59	N=70
Yes	4 (36.4)	8 (27.6)	14 (46.7)	22 (37.3)	26 (37.1)
No	7 (63.6)	21 (72.4)	16 (53.3)	37 (62.7)	44 (62.9)
95% Confidence Interval [A]	(10.93, 69.21)	(12.73, 47.24)	(28.34, 65.67)	(25.04, 50.85)	(25.89, 49.52)
Ethnicity - Non-white	N=1	N=2	N=1	N=3	N=4
Yes	0	1 (50.0)	0	1 (33.3)	1 (25.0)
No	1 (100)	1 (50.0)	1 (100)	2 (66.7)	3 (75.0)
95% Confidence Interval [A]	(0.00, 97.50)	(1.26, 98.74)	(0.00, 97.50)	(0.84, 90.57)	(0.63, 80.59)
Geographic Region - North America	N=1	N=7	N=3	N=10	N=11
Yes	0	2 (28.6)	1 (33.3)	3 (30.0)	3 (27.3)
No	1 (100)	5 (71.4)	2 (66.7)	7 (70.0)	8 (72.7)
95% Confidence Interval [A]	(0.00, 97.50)	(3.67, 70.96)	(0.84, 90.57)	(6.67, 65.25)	(6.02, 60.97)

表 2.7.3.6-86. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Geographic Region - Western Europe	N=1	N=0	N=3	N=3	N=4
Yes	0	0	1 (33.3)	1 (33.3)	1 (25.0)
No	1 (100)	0	2 (66.7)	2 (66.7)	3 (75.0)
95% Confidence Interval [A]	(0.00, 97.50)	(NA, NA)	(0.84, 90.57)	(0.84, 90.57)	(0.63, 80.59)
Geographic Region - Eastern Europe	N=10	N=24	N=25	N=49	N=59
Yes	4 (40.0)	7 (29.2)	12 (48.0)	19 (38.8)	23 (39.0)
No	6 (60.0)	17 (70.8)	13 (52.0)	30 (61.2)	36 (61.0)
95% Confidence Interval [A]	(12.16, 73.76)	(12.62, 51.09)	(27.80, 68.69)	(25.20, 53.76)	(26.55, 52.56)
Baseline Mayo Score <= 9	N=11	N=25	N=26	N=51	N=62
Yes	4 (36.4)	8 (32.0)	10 (38.5)	18 (35.3)	22 (35.5)
No	7 (63.6)	17 (68.0)	16 (61.5)	33 (64.7)	40 (64.5)
95% Confidence Interval [A]	(10.93, 69.21)	(14.95, 53.50)	(20.23, 59.43)	(22.43, 49.93)	(23.74, 48.66)

表 2.7.3.6-86. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Baseline Mayo Score > 9	N=1	N=6	N=5	N=11	N=12
Yes	0	1 (16.7)	4 (80.0)	5 (45.5)	5 (41.7)
No	1 (100)	5 (83.3)	1 (20.0)	6 (54.5)	7 (58.3)
95% Confidence Interval [A]	(0.00, 97.50)	(0.42, 64.12)	(28.36, 99.49)	(16.75, 76.62)	(15.17, 72.33)
Prior Anti-TNF Use	N=2	N=2	N=6	N=8	N=10
Yes	1 (50.0)	0	2 (33.3)	2 (25.0)	3 (30.0)
No	1 (50.0)	2 (100)	4 (66.7)	6 (75.0)	7 (70.0)
95% Confidence Interval [A]	(1.26, 98.74)	(0.00, 84.19)	(4.33, 77.72)	(3.19, 65.09)	(6.67, 65.25)
Prior Anti-TNF Naive	N=10	N=29	N=25	N=54	N=64
Yes	3 (30.0)	9 (31.0)	12 (48.0)	21 (38.9)	24 (37.5)
No	7 (70.0)	20 (69.0)	13 (52.0)	33 (61.1)	40 (62.5)
95% Confidence Interval [A]	(6.67, 65.25)	(15.28, 50.83)	(27.80, 68.69)	(25.92, 53.12)	(25.70, 50.49)

表 2.7.3.6-86. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Baseline Corticosteroid Use - Yes	N=5	N=13	N=16	N=29	N=34
Yes	2 (40.0)	4 (30.8)	5 (31.3)	9 (31.0)	11 (32.4)
No	3 (60.0)	9 (69.2)	11 (68.8)	20 (69.0)	23 (67.6)
95% Confidence Interval [A]	(5.27, 85.34)	(9.09, 61.43)	(11.02, 58.66)	(15.28, 50.83)	(17.39, 50.53)
Baseline Corticosteroid Use - No	N=7	N=18	N=15	N=33	N=40
Yes	2 (28.6)	5 (27.8)	9 (60.0)	14 (42.4)	16 (40.0)
No	5 (71.4)	13 (72.2)	6 (40.0)	19 (57.6)	24 (60.0)
95% Confidence Interval [A]	(3.67, 70.96)	(9.69, 53.48)	(32.29, 83.66)	(25.48, 60.78)	(24.86, 56.67)
Baseline IMM Use - Yes	N=8	N=17	N=21	N=38	N=46
Yes	3 (37.5)	4 (23.5)	10 (47.6)	14 (36.8)	17 (37.0)
No	5 (62.5)	13 (76.5)	11 (52.4)	24 (63.2)	29 (63.0)
95% Confidence Interval [A]	(8.52, 75.51)	(6.81, 49.90)	(25.71, 70.22)	(21.81, 54.01)	(23.21, 52.45)

表 2.7.3.6-86. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Baseline IMM Use - No	N=4	N=14	N=10	N=24	N=28
Yes	1 (25.0)	5 (35.7)	4 (40.0)	9 (37.5)	10 (35.7)
No	3 (75.0)	9 (64.3)	6 (60.0)	15 (62.5)	18 (64.3)
95% Confidence Interval [A]	(0.63, 80.59)	(12.76, 64.86)	(12.16, 73.76)	(18.80, 59.41)	(18.64, 55.93)
Weight < 40 kg	N=0	N=7	N=7	N=14	N=14
Yes	0	3 (42.9)	3 (42.9)	6 (42.9)	6 (42.9)
No	0	4 (57.1)	4 (57.1)	8 (57.1)	8 (57.1)
95% Confidence Interval [A]	(NA, NA)	(9.90, 81.59)	(9.90, 81.59)	(17.66, 71.14)	(17.66, 71.14)
Weight >= 40 kg	N=12	N=24	N=24	N=48	N=60
Yes	4 (33.3)	6 (25.0)	11 (45.8)	17 (35.4)	21 (35.0)
No	8 (66.7)	18 (75.0)	13 (54.2)	31 (64.6)	39 (65.0)
95% Confidence Interval [A]	(9.92, 65.11)	(9.77, 46.71)	(25.55, 67.18)	(22.16, 50.54)	(23.13, 48.40)

表 2.7.3.6-86. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Pancolitis - Yes	N=7	N=20	N=17	N=37	N=44
Yes	2 (28.6)	5 (25.0)	10 (58.8)	15 (40.5)	17 (38.6)
No	5 (71.4)	15 (75.0)	7 (41.2)	22 (59.5)	27 (61.4)
95% Confidence Interval [A]	(3.67, 70.96)	(8.66, 49.10)	(32.92, 81.56)	(24.75, 57.90)	(24.36, 54.50)
Pancolitis - No	N=5	N=11	N=14	N=25	N=30
Yes	2 (40.0)	4 (36.4)	4 (28.6)	8 (32.0)	10 (33.3)
No	3 (60.0)	7 (63.6)	10 (71.4)	17 (68.0)	20 (66.7)
95% Confidence Interval [A]	(5.27, 85.34)	(10.93, 69.21)	(8.39, 58.10)	(14.95, 53.50)	(17.29, 52.81)
Disease Duration <= Baseline Median (19.1 Months)	N=5	N=18	N=15	N=33	N=38
Yes	0	3 (16.7)	7 (46.7)	10 (30.3)	10 (26.3)
No	5 (100)	15 (83.3)	8 (53.3)	23 (69.7)	28 (73.7)
95% Confidence Interval [A]	(0.00, 52.18)	(3.58, 41.42)	(21.27, 73.41)	(15.59, 48.71)	(13.40, 43.10)

表 2.7.3.6-86. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Disease Duration > Baseline Median (19.1 Months)	N=7	N=13	N=16	N=29	N=36
Yes	4 (57.1)	6 (46.2)	7 (43.8)	13 (44.8)	17 (47.2)
No	3 (42.9)	7 (53.8)	9 (56.3)	16 (55.2)	19 (52.8)
95% Confidence Interval [A]	(18.41, 90.10)	(19.22, 74.87)	(19.75, 70.12)	(26.45, 64.31)	(30.41, 64.51)
Baseline hs-CRP <= Baseline Median (1.29 mg/L)	N=8	N=12	N=14	N=26	N=34
Yes	3 (37.5)	3 (25.0)	7 (50.0)	10 (38.5)	13 (38.2)
No	5 (62.5)	9 (75.0)	7 (50.0)	16 (61.5)	21 (61.8)
95% Confidence Interval [A]	(8.52, 75.51)	(5.49, 57.19)	(23.04, 76.96)	(20.23, 59.43)	(22.17, 56.44)
Baseline hs-CRP > Baseline Median (1.29 mg/L)	N=3	N=16	N=15	N=31	N=34
Yes	0	4 (25.0)	6 (40.0)	10 (32.3)	10 (29.4)
No	3 (100)	12 (75.0)	9 (60.0)	21 (67.7)	24 (70.6)
95% Confidence Interval [A]	(0.00, 70.76)	(7.27, 52.38)	(16.34, 67.71)	(16.68, 51.37)	(15.10, 47.48)

表 2.7.3.6-86. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Baseline Fecal Calprotectin <= Baseline Median (2302.5 ug/g)	N=3	N=5	N=2	N=7	N=10
Yes	1 (33.3)	1 (20.0)	1 (50.0)	2 (28.6)	3 (30.0)
No	2 (66.7)	4 (80.0)	1 (50.0)	5 (71.4)	7 (70.0)
95% Confidence Interval [A]	(0.84, 90.57)	(0.51, 71.64)	(1.26, 98.74)	(3.67, 70.96)	(6.67, 65.25)
Baseline Fecal Calprotectin > Baseline Median (2302.5 ug/g)	N=1	N=4	N=4	N=8	N=9
Yes	0	0	4 (100)	4 (50.0)	4 (44.4)
No	1 (100)	4 (100)	0	4 (50.0)	5 (55.6)
95% Confidence Interval [A]	(0.00, 97.50)	(0.00, 60.24)	(39.76, 100.00)	(15.70, 84.30)	(13.70, 78.80)

表 2.7.3.6-86. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Note: M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
[A] Clopper-Pearson confidence interval for proportion in remission.
[B1] Nominal p-values from a one-sample two-sided chi-square test.
[B2] Adjusted p-values from a sequentially rejective multiple test procedure (details in SAP), testing co-primary and ranked secondary endpoints first for M-SD/M-HD combined (p-value in 'Total' column) and then for individual ADA dose groups (p-values in 'M-HD' column and in 'M-SD' column, respectively) against the respective external placebo rate (here: 18.37%).
[C] Nominal p-value for the exploratory comparison of M-SD vs. M-HD.
Non-responder imputation (NRI): missing data is imputed as not having met the endpoint. Subjects re-randomized due to disease flare are considered as not having met the endpoint at and after their 1st disease flare.
Clinical remission per Full Mayo Score (FMS) is defined as Mayo Score <= 2 and no individual subscore > 1.
Clinical response per Partial Mayo Score (PMS) is defined as decrease in PMS >= 2 points and >= 30% from baseline.
Clinical remission per Partial Mayo Score (PMS) is defined as PMS <= 2 and no individual subscore > 1.

Cross reference: M11-290 Main-study CSR_Interim Table 14.2__1.1.2

表 2.7.3.6-87. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Overall	N=12	N=31	N=31	N=62	N=74
Yes	4 (33.3)	19 (61.3)	21 (67.7)	40 (64.5)	44 (59.5)
No	8 (66.7)	12 (38.7)	10 (32.3)	22 (35.5)	30 (40.5)
95% Confidence Interval [A]	(9.92, 65.11)	(42.19, 78.15)	(48.63, 83.32)	(51.34, 76.26)	(47.41, 70.73)
P-Value [B1]		<0.001	<0.001	<0.001	
ADJ. P-Value [B2]		0.008	<0.001	<0.001	
P-Value [C]		0.596			
PMS Remission at Week 8 - Yes	N=8	N=21	N=22	N=43	N=51
Yes	3 (37.5)	16 (76.2)	16 (72.7)	32 (74.4)	35 (68.6)
No	5 (62.5)	5 (23.8)	6 (27.3)	11 (25.6)	16 (31.4)
95% Confidence Interval [A]	(8.52, 75.51)	(52.83, 91.78)	(49.78, 89.27)	(58.83, 86.48)	(54.11, 80.89)

表 2.7.3.6-87. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
PMS Remission at Week 8 - No	N=4	N=10	N=9	N=19	N=23
Yes	1 (25.0)	3 (30.0)	5 (55.6)	8 (42.1)	9 (39.1)
No	3 (75.0)	7 (70.0)	4 (44.4)	11 (57.9)	14 (60.9)
95% Confidence Interval [A]	(0.63, 80.59)	(6.67, 65.25)	(21.20, 86.30)	(20.25, 66.50)	(19.71, 61.46)
I-SD	N=4	N=8	N=9	N=17	N=21
Yes	1 (25.0)	5 (62.5)	6 (66.7)	11 (64.7)	12 (57.1)
No	3 (75.0)	3 (37.5)	3 (33.3)	6 (35.3)	9 (42.9)
95% Confidence Interval [A]	(0.63, 80.59)	(24.49, 91.48)	(29.93, 92.51)	(38.33, 85.79)	(34.02, 78.18)
I-HD/I-HD-OL	N=8	N=23	N=22	N=45	N=53
Yes	3 (37.5)	14 (60.9)	15 (68.2)	29 (64.4)	32 (60.4)
No	5 (62.5)	9 (39.1)	7 (31.8)	16 (35.6)	21 (39.6)
95% Confidence Interval [A]	(8.52, 75.51)	(38.54, 80.29)	(45.13, 86.14)	(48.78, 78.13)	(46.00, 73.55)

表 2.7.3.6-87. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Category Endpoint Met	mITT M-PL (N=12)	mITT-E M-SD (N=31)	mITT-E M-HD (N=31)	mITT-E Total (N=62)	mITT Total (N=74)
I-HD	N=8	N=16	N=15	N=31	N=39
Yes	3 (37.5)	10 (62.5)	10 (66.7)	20 (64.5)	23 (59.0)
No	5 (62.5)	6 (37.5)	5 (33.3)	11 (35.5)	16 (41.0)
95% Confidence Interval [A]	(8.52, 75.51)	(35.43, 84.80)	(38.38, 88.18)	(45.37, 80.77)	(42.10, 74.43)
I-HD-OL	N=0	N=7	N=7	N=14	N=14
Yes	0	4 (57.1)	5 (71.4)	9 (64.3)	9 (64.3)
No	0	3 (42.9)	2 (28.6)	5 (35.7)	5 (35.7)
95% Confidence Interval [A]	(NA, NA)	(18.41, 90.10)	(29.04, 96.33)	(35.14, 87.24)	(35.14, 87.24)
Sex - Male	N=9	N=13	N=13	N=26	N=35
Yes	2 (22.2)	8 (61.5)	7 (53.8)	15 (57.7)	17 (48.6)
No	7 (77.8)	5 (38.5)	6 (46.2)	11 (42.3)	18 (51.4)
95% Confidence Interval [A]	(2.81, 60.01)	(31.58, 86.14)	(25.13, 80.78)	(36.92, 76.65)	(31.38, 66.01)

表 2.7.3.6-87. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Sex - Female	N=3	N=18	N=18	N=36	N=39
Yes	2 (66.7)	11 (61.1)	14 (77.8)	25 (69.4)	27 (69.2)
No	1 (33.3)	7 (38.9)	4 (22.2)	11 (30.6)	12 (30.8)
95% Confidence Interval [A]	(9.43, 99.16)	(35.75, 82.70)	(52.36, 93.59)	(51.89, 83.65)	(52.43, 82.98)
Age < 13 Years	N=2	N=12	N=8	N=20	N=22
Yes	1 (50.0)	8 (66.7)	7 (87.5)	15 (75.0)	16 (72.7)
No	1 (50.0)	4 (33.3)	1 (12.5)	5 (25.0)	6 (27.3)
95% Confidence Interval [A]	(1.26, 98.74)	(34.89, 90.08)	(47.35, 99.68)	(50.90, 91.34)	(49.78, 89.27)
Age >= 13 Years	N=10	N=19	N=23	N=42	N=52
Yes	3 (30.0)	11 (57.9)	14 (60.9)	25 (59.5)	28 (53.8)
No	7 (70.0)	8 (42.1)	9 (39.1)	17 (40.5)	24 (46.2)
95% Confidence Interval [A]	(6.67, 65.25)	(33.50, 79.75)	(38.54, 80.29)	(43.28, 74.37)	(39.47, 67.77)

表 2.7.3.6-87. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Ethnicity - White	N=11	N=29	N=30	N=59	N=70
Yes	4 (36.4)	18 (62.1)	21 (70.0)	39 (66.1)	43 (61.4)
No	7 (63.6)	11 (37.9)	9 (30.0)	20 (33.9)	27 (38.6)
95% Confidence Interval [A]	(10.93, 69.21)	(42.26, 79.31)	(50.60, 85.27)	(52.61, 77.92)	(49.03, 72.83)
Ethnicity - Non-white	N=1	N=2	N=1	N=3	N=4
Yes	0	1 (50.0)	0	1 (33.3)	1 (25.0)
No	1 (100)	1 (50.0)	1 (100)	2 (66.7)	3 (75.0)
95% Confidence Interval [A]	(0.00, 97.50)	(1.26, 98.74)	(0.00, 97.50)	(0.84, 90.57)	(0.63, 80.59)
Geographic Region - North America	N=1	N=7	N=3	N=10	N=11
Yes	0	3 (42.9)	1 (33.3)	4 (40.0)	4 (36.4)
No	1 (100)	4 (57.1)	2 (66.7)	6 (60.0)	7 (63.6)
95% Confidence Interval [A]	(0.00, 97.50)	(9.90, 81.59)	(0.84, 90.57)	(12.16, 73.76)	(10.93, 69.21)

表 2.7.3.6-87. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Geographic Region - Western Europe	N=1	N=0	N=3	N=3	N=4
Yes	0	0	2 (66.7)	2 (66.7)	2 (50.0)
No	1 (100)	0	1 (33.3)	1 (33.3)	2 (50.0)
95% Confidence Interval [A]	(0.00, 97.50)	(NA, NA)	(9.43, 99.16)	(9.43, 99.16)	(6.76, 93.24)
Geographic Region - Eastern Europe	N=10	N=24	N=25	N=49	N=59
Yes	4 (40.0)	16 (66.7)	18 (72.0)	34 (69.4)	38 (64.4)
No	6 (60.0)	8 (33.3)	7 (28.0)	15 (30.6)	21 (35.6)
95% Confidence Interval [A]	(12.16, 73.76)	(44.68, 84.37)	(50.61, 87.93)	(54.58, 81.75)	(50.87, 76.45)
Baseline Mayo Score <= 9	N=11	N=25	N=26	N=51	N=62
Yes	4 (36.4)	17 (68.0)	17 (65.4)	34 (66.7)	38 (61.3)
No	7 (63.6)	8 (32.0)	9 (34.6)	17 (33.3)	24 (38.7)
95% Confidence Interval [A]	(10.93, 69.21)	(46.50, 85.05)	(44.33, 82.79)	(52.08, 79.24)	(48.07, 73.40)

表 2.7.3.6-87. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Baseline Mayo Score > 9	N=1	N=6	N=5	N=11	N=12
Yes	0	2 (33.3)	4 (80.0)	6 (54.5)	6 (50.0)
No	1 (100)	4 (66.7)	1 (20.0)	5 (45.5)	6 (50.0)
95% Confidence Interval [A]	(0.00, 97.50)	(4.33, 77.72)	(28.36, 99.49)	(23.38, 83.25)	(21.09, 78.91)
Prior Anti-TNF Use	N=2	N=2	N=6	N=8	N=10
Yes	1 (50.0)	1 (50.0)	3 (50.0)	4 (50.0)	5 (50.0)
No	1 (50.0)	1 (50.0)	3 (50.0)	4 (50.0)	5 (50.0)
95% Confidence Interval [A]	(1.26, 98.74)	(1.26, 98.74)	(11.81, 88.19)	(15.70, 84.30)	(18.71, 81.29)
Prior Anti-TNF Naive	N=10	N=29	N=25	N=54	N=64
Yes	3 (30.0)	18 (62.1)	18 (72.0)	36 (66.7)	39 (60.9)
No	7 (70.0)	11 (37.9)	7 (28.0)	18 (33.3)	25 (39.1)
95% Confidence Interval [A]	(6.67, 65.25)	(42.26, 79.31)	(50.61, 87.93)	(52.53, 78.91)	(47.93, 72.90)

表 2.7.3.6-87. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Baseline Corticosteroid Use - Yes	N=5	N=13	N=16	N=29	N=34
Yes	2 (40.0)	7 (53.8)	10 (62.5)	17 (58.6)	19 (55.9)
No	3 (60.0)	6 (46.2)	6 (37.5)	12 (41.4)	15 (44.1)
95% Confidence Interval [A]	(5.27, 85.34)	(25.13, 80.78)	(35.43, 84.80)	(38.94, 76.48)	(37.89, 72.81)
Baseline Corticosteroid Use - No	N=7	N=18	N=15	N=33	N=40
Yes	2 (28.6)	12 (66.7)	11 (73.3)	23 (69.7)	25 (62.5)
No	5 (71.4)	6 (33.3)	4 (26.7)	10 (30.3)	15 (37.5)
95% Confidence Interval [A]	(3.67, 70.96)	(40.99, 86.66)	(44.90, 92.21)	(51.29, 84.41)	(45.80, 77.27)
Baseline IMM Use - Yes	N=8	N=17	N=21	N=38	N=46
Yes	3 (37.5)	11 (64.7)	14 (66.7)	25 (65.8)	28 (60.9)
No	5 (62.5)	6 (35.3)	7 (33.3)	13 (34.2)	18 (39.1)
95% Confidence Interval [A]	(8.52, 75.51)	(38.33, 85.79)	(43.03, 85.41)	(48.65, 80.37)	(45.37, 74.91)

表 2.7.3.6-87. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Baseline IMM Use - No	N=4	N=14	N=10	N=24	N=28
Yes	1 (25.0)	8 (57.1)	7 (70.0)	15 (62.5)	16 (57.1)
No	3 (75.0)	6 (42.9)	3 (30.0)	9 (37.5)	12 (42.9)
95% Confidence Interval [A]	(0.63, 80.59)	(28.86, 82.34)	(34.75, 93.33)	(40.59, 81.20)	(37.18, 75.54)
Weight < 40 kg	N=0	N=7	N=7	N=14	N=14
Yes	0	4 (57.1)	5 (71.4)	9 (64.3)	9 (64.3)
No	0	3 (42.9)	2 (28.6)	5 (35.7)	5 (35.7)
95% Confidence Interval [A]	(NA, NA)	(18.41, 90.10)	(29.04, 96.33)	(35.14, 87.24)	(35.14, 87.24)
Weight >= 40 kg	N=12	N=24	N=24	N=48	N=60
Yes	4 (33.3)	15 (62.5)	16 (66.7)	31 (64.6)	35 (58.3)
No	8 (66.7)	9 (37.5)	8 (33.3)	17 (35.4)	25 (41.7)
95% Confidence Interval [A]	(9.92, 65.11)	(40.59, 81.20)	(44.68, 84.37)	(49.46, 77.84)	(44.88, 70.93)

表 2.7.3.6-87. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Pancolitis - Yes	N=7	N=20	N=17	N=37	N=44
Yes	2 (28.6)	12 (60.0)	12 (70.6)	24 (64.9)	26 (59.1)
No	5 (71.4)	8 (40.0)	5 (29.4)	13 (35.1)	18 (40.9)
95% Confidence Interval [A]	(3.67, 70.96)	(36.05, 80.88)	(44.04, 89.69)	(47.46, 79.79)	(43.25, 73.66)
Pancolitis - No	N=5	N=11	N=14	N=25	N=30
Yes	2 (40.0)	7 (63.6)	9 (64.3)	16 (64.0)	18 (60.0)
No	3 (60.0)	4 (36.4)	5 (35.7)	9 (36.0)	12 (40.0)
95% Confidence Interval [A]	(5.27, 85.34)	(30.79, 89.07)	(35.14, 87.24)	(42.52, 82.03)	(40.60, 77.34)
Disease Duration <= Baseline Median (19.1 Months)	N=5	N=18	N=15	N=33	N=38
Yes	0	10 (55.6)	9 (60.0)	19 (57.6)	19 (50.0)
No	5 (100)	8 (44.4)	6 (40.0)	14 (42.4)	19 (50.0)
95% Confidence Interval [A]	(0.00, 52.18)	(30.76, 78.47)	(32.29, 83.66)	(39.22, 74.52)	(33.38, 66.62)

表 2.7.3.6-87. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Category Endpoint Met	mITT M-PL (N=12)	mITT-E M-SD (N=31)	mITT-E M-HD (N=31)	mITT-E Total (N=62)	mITT Total (N=74)
Disease Duration > Baseline Median (19.1 Months)	N=7	N=13	N=16	N=29	N=36
Yes	4 (57.1)	9 (69.2)	12 (75.0)	21 (72.4)	25 (69.4)
No	3 (42.9)	4 (30.8)	4 (25.0)	8 (27.6)	11 (30.6)
95% Confidence Interval [A]	(18.41, 90.10)	(38.57, 90.91)	(47.62, 92.73)	(52.76, 87.27)	(51.89, 83.65)
Baseline hs-CRP <= Baseline Median (1.29 mg/L)	N=8	N=12	N=14	N=26	N=34
Yes	3 (37.5)	6 (50.0)	11 (78.6)	17 (65.4)	20 (58.8)
No	5 (62.5)	6 (50.0)	3 (21.4)	9 (34.6)	14 (41.2)
95% Confidence Interval [A]	(8.52, 75.51)	(21.09, 78.91)	(49.20, 95.34)	(44.33, 82.79)	(40.70, 75.35)
Baseline hs-CRP > Baseline Median (1.29 mg/L)	N=3	N=16	N=15	N=31	N=34
Yes	0	11 (68.8)	9 (60.0)	20 (64.5)	20 (58.8)
No	3 (100)	5 (31.3)	6 (40.0)	11 (35.5)	14 (41.2)
95% Confidence Interval [A]	(0.00, 70.76)	(41.34, 88.98)	(32.29, 83.66)	(45.37, 80.77)	(40.70, 75.35)

表 2.7.3.6-87. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Baseline Fecal Calprotectin <= Baseline Median (2302.5 ug/g)	N=3	N=5	N=2	N=7	N=10
Yes	1 (33.3)	3 (60.0)	1 (50.0)	4 (57.1)	5 (50.0)
No	2 (66.7)	2 (40.0)	1 (50.0)	3 (42.9)	5 (50.0)
95% Confidence Interval [A]	(0.84, 90.57)	(14.66, 94.73)	(1.26, 98.74)	(18.41, 90.10)	(18.71, 81.29)
Baseline Fecal Calprotectin > Baseline Median (2302.5 ug/g)	N=1	N=4	N=4	N=8	N=9
Yes	0	1 (25.0)	4 (100)	5 (62.5)	5 (55.6)
No	1 (100)	3 (75.0)	0	3 (37.5)	4 (44.4)
95% Confidence Interval [A]	(0.00, 97.50)	(0.63, 80.59)	(39.76, 100.00)	(24.49, 91.48)	(21.20, 86.30)

表 2.7.3.6-87.　投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Note: M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
[A] Clopper-Pearson confidence interval for proportion in response.
[B1] Nominal p-values from a one-sample two-sided chi-square test.
[B2] Adjusted p-values from a sequentially rejective multiple test procedure (details in SAP), testing co-primary and ranked secondary endpoints first for M-SD/M-HD combined (p-value in 'Total' column) and then for individual ADA dose groups (p-values in 'M-HD' column and in 'M-SD' column, respectively) against the respective external placebo rate (here: 26.10%).
[C] Nominal p-value for the exploratory comparison of M-SD vs. M-HD.
Non-responder imputation (NRI): missing data is imputed as not having met the endpoint. Subjects re-randomized due to disease flare are considered as not having met the endpoint at and after their 1st disease flare.
Clinical response per Full Mayo Score (FMS) is defined as decrease in Mayo Score >= 3 points and >= 30% from baseline.
Clinical response per Partial Mayo Score (PMS) is defined as decrease in PMS >= 2 points and >= 30% from baseline.
Clinical remission per Partial Mayo Score (PMS) is defined as PMS <= 2 and no individual subscore > 1.

Cross reference: M11-290 Main-study CSR_Interim Table 14.2__1.2.1

表 2.7.3.6-88. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Overall	N=12	N=31	N=31	N=62	N=74
Yes	4 (33.3)	12 (38.7)	16 (51.6)	28 (45.2)	32 (43.2)
No	8 (66.7)	19 (61.3)	15 (48.4)	34 (54.8)	42 (56.8)
95% Confidence Interval [A]	(9.92, 65.11)	(21.85, 57.81)	(33.06, 69.85)	(32.48, 58.32)	(31.77, 55.28)
P-Value [B1]		0.025	<0.001	<0.001	
ADJ. P-Value [B2]		0.382	<0.001	<0.001	
P-Value [C]		0.307			
PMS Remission at Week 8 - Yes	N=8	N=21	N=22	N=43	N=51
Yes	3 (37.5)	11 (52.4)	12 (54.5)	23 (53.5)	26 (51.0)
No	5 (62.5)	10 (47.6)	10 (45.5)	20 (46.5)	25 (49.0)
95% Confidence Interval [A]	(8.52, 75.51)	(29.78, 74.29)	(32.21, 75.61)	(37.65, 68.82)	(36.60, 65.25)

表 2.7.3.6-88. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
PMS Remission at Week 8 - No	N=4	N=10	N=9	N=19	N=23
Yes	1 (25.0)	1 (10.0)	4 (44.4)	5 (26.3)	6 (26.1)
No	3 (75.0)	9 (90.0)	5 (55.6)	14 (73.7)	17 (73.9)
95% Confidence Interval [A]	(0.63, 80.59)	(0.25, 44.50)	(13.70, 78.80)	(9.15, 51.20)	(10.23, 48.41)
I-SD	N=4	N=8	N=9	N=17	N=21
Yes	1 (25.0)	2 (25.0)	5 (55.6)	7 (41.2)	8 (38.1)
No	3 (75.0)	6 (75.0)	4 (44.4)	10 (58.8)	13 (61.9)
95% Confidence Interval [A]	(0.63, 80.59)	(3.19, 65.09)	(21.20, 86.30)	(18.44, 67.08)	(18.11, 61.56)
I-HD/I-HD-OL	N=8	N=23	N=22	N=45	N=53
Yes	3 (37.5)	10 (43.5)	11 (50.0)	21 (46.7)	24 (45.3)
No	5 (62.5)	13 (56.5)	11 (50.0)	24 (53.3)	29 (54.7)
95% Confidence Interval [A]	(8.52, 75.51)	(23.19, 65.51)	(28.22, 71.78)	(31.66, 62.13)	(31.56, 59.55)

表 2.7.3.6-88. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
I-HD	N=8	N=16	N=15	N=31	N=39
Yes	3 (37.5)	8 (50.0)	8 (53.3)	16 (51.6)	19 (48.7)
No	5 (62.5)	8 (50.0)	7 (46.7)	15 (48.4)	20 (51.3)
95% Confidence Interval [A]	(8.52, 75.51)	(24.65, 75.35)	(26.59, 78.73)	(33.06, 69.85)	(32.42, 65.22)
I-HD-OL	N=0	N=7	N=7	N=14	N=14
Yes	0	2 (28.6)	3 (42.9)	5 (35.7)	5 (35.7)
No	0	5 (71.4)	4 (57.1)	9 (64.3)	9 (64.3)
95% Confidence Interval [A]	(NA, NA)	(3.67, 70.96)	(9.90, 81.59)	(12.76, 64.86)	(12.76, 64.86)
Sex - Male	N=9	N=13	N=13	N=26	N=35
Yes	2 (22.2)	5 (38.5)	6 (46.2)	11 (42.3)	13 (37.1)
No	7 (77.8)	8 (61.5)	7 (53.8)	15 (57.7)	22 (62.9)
95% Confidence Interval [A]	(2.81, 60.01)	(13.86, 68.42)	(19.22, 74.87)	(23.35, 63.08)	(21.47, 55.08)

表 2.7.3.6-88. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Sex - Female	N=3	N=18	N=18	N=36	N=39
Yes	2 (66.7)	7 (38.9)	10 (55.6)	17 (47.2)	19 (48.7)
No	1 (33.3)	11 (61.1)	8 (44.4)	19 (52.8)	20 (51.3)
95% Confidence Interval [A]	(9.43, 99.16)	(17.30, 64.25)	(30.76, 78.47)	(30.41, 64.51)	(32.42, 65.22)
Age < 13 Years	N=2	N=12	N=8	N=20	N=22
Yes	1 (50.0)	6 (50.0)	4 (50.0)	10 (50.0)	11 (50.0)
No	1 (50.0)	6 (50.0)	4 (50.0)	10 (50.0)	11 (50.0)
95% Confidence Interval [A]	(1.26, 98.74)	(21.09, 78.91)	(15.70, 84.30)	(27.20, 72.80)	(28.22, 71.78)
Age >= 13 Years	N=10	N=19	N=23	N=42	N=52
Yes	3 (30.0)	6 (31.6)	12 (52.2)	18 (42.9)	21 (40.4)
No	7 (70.0)	13 (68.4)	11 (47.8)	24 (57.1)	31 (59.6)
95% Confidence Interval [A]	(6.67, 65.25)	(12.58, 56.55)	(30.59, 73.18)	(27.72, 59.04)	(27.01, 54.90)

表 2.7.3.6-88. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Ethnicity - White	N=11	N=29	N=30	N=59	N=70
Yes	4 (36.4)	11 (37.9)	16 (53.3)	27 (45.8)	31 (44.3)
No	7 (63.6)	18 (62.1)	14 (46.7)	32 (54.2)	39 (55.7)
95% Confidence Interval [A]	(10.93, 69.21)	(20.69, 57.74)	(34.33, 71.66)	(32.72, 59.25)	(32.41, 56.66)
Ethnicity - Non-white	N=1	N=2	N=1	N=3	N=4
Yes	0	1 (50.0)	0	1 (33.3)	1 (25.0)
No	1 (100)	1 (50.0)	1 (100)	2 (66.7)	3 (75.0)
95% Confidence Interval [A]	(0.00, 97.50)	(1.26, 98.74)	(0.00, 97.50)	(0.84, 90.57)	(0.63, 80.59)
Geographic Region - North America	N=1	N=7	N=3	N=10	N=11
Yes	0	2 (28.6)	1 (33.3)	3 (30.0)	3 (27.3)
No	1 (100)	5 (71.4)	2 (66.7)	7 (70.0)	8 (72.7)
95% Confidence Interval [A]	(0.00, 97.50)	(3.67, 70.96)	(0.84, 90.57)	(6.67, 65.25)	(6.02, 60.97)

表 2.7.3.6-88. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Geographic Region - Western Europe	N=1	N=0	N=3	N=3	N=4
Yes	0	0	2 (66.7)	2 (66.7)	2 (50.0)
No	1 (100)	0	1 (33.3)	1 (33.3)	2 (50.0)
95% Confidence Interval [A]	(0.00, 97.50)	(NA, NA)	(9.43, 99.16)	(9.43, 99.16)	(6.76, 93.24)
Geographic Region - Eastern Europe	N=10	N=24	N=25	N=49	N=59
Yes	4 (40.0)	10 (41.7)	13 (52.0)	23 (46.9)	27 (45.8)
No	6 (60.0)	14 (58.3)	12 (48.0)	26 (53.1)	32 (54.2)
95% Confidence Interval [A]	(12.16, 73.76)	(22.11, 63.36)	(31.31, 72.20)	(32.53, 61.73)	(32.72, 59.25)
Baseline Mayo Score <= 9	N=11	N=25	N=26	N=51	N=62
Yes	4 (36.4)	11 (44.0)	12 (46.2)	23 (45.1)	27 (43.5)
No	7 (63.6)	14 (56.0)	14 (53.8)	28 (54.9)	35 (56.5)
95% Confidence Interval [A]	(10.93, 69.21)	(24.40, 65.07)	(26.59, 66.63)	(31.13, 59.66)	(30.99, 56.74)

表 2.7.3.6-88. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Baseline Mayo Score > 9	N=1	N=6	N=5	N=11	N=12
Yes	0	1 (16.7)	4 (80.0)	5 (45.5)	5 (41.7)
No	1 (100)	5 (83.3)	1 (20.0)	6 (54.5)	7 (58.3)
95% Confidence Interval [A]	(0.00, 97.50)	(0.42, 64.12)	(28.36, 99.49)	(16.75, 76.62)	(15.17, 72.33)
Prior Anti-TNF Use	N=2	N=2	N=6	N=8	N=10
Yes	1 (50.0)	0	3 (50.0)	3 (37.5)	4 (40.0)
No	1 (50.0)	2 (100)	3 (50.0)	5 (62.5)	6 (60.0)
95% Confidence Interval [A]	(1.26, 98.74)	(0.00, 84.19)	(11.81, 88.19)	(8.52, 75.51)	(12.16, 73.76)
Prior Anti-TNF Naive	N=10	N=29	N=25	N=54	N=64
Yes	3 (30.0)	12 (41.4)	13 (52.0)	25 (46.3)	28 (43.8)
No	7 (70.0)	17 (58.6)	12 (48.0)	29 (53.7)	36 (56.3)
95% Confidence Interval [A]	(6.67, 65.25)	(23.52, 61.06)	(31.31, 72.20)	(32.62, 60.39)	(31.37, 56.72)

表 2.7.3.6-88. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Baseline Corticosteroid Use - Yes	N=5	N=13	N=16	N=29	N=34
Yes	2 (40.0)	5 (38.5)	6 (37.5)	11 (37.9)	13 (38.2)
No	3 (60.0)	8 (61.5)	10 (62.5)	18 (62.1)	21 (61.8)
95% Confidence Interval [A]	(5.27, 85.34)	(13.86, 68.42)	(15.20, 64.57)	(20.69, 57.74)	(22.17, 56.44)
Baseline Corticosteroid Use - No	N=7	N=18	N=15	N=33	N=40
Yes	2 (28.6)	7 (38.9)	10 (66.7)	17 (51.5)	19 (47.5)
No	5 (71.4)	11 (61.1)	5 (33.3)	16 (48.5)	21 (52.5)
95% Confidence Interval [A]	(3.67, 70.96)	(17.30, 64.25)	(38.38, 88.18)	(33.54, 69.20)	(31.51, 63.87)
Baseline IMM Use - Yes	N=8	N=17	N=21	N=38	N=46
Yes	3 (37.5)	7 (41.2)	11 (52.4)	18 (47.4)	21 (45.7)
No	5 (62.5)	10 (58.8)	10 (47.6)	20 (52.6)	25 (54.3)
95% Confidence Interval [A]	(8.52, 75.51)	(18.44, 67.08)	(29.78, 74.29)	(30.98, 64.18)	(30.90, 60.99)

表 2.7.3.6-88. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Baseline IMM Use - No	N=4	N=14	N=10	N=24	N=28
Yes	1 (25.0)	5 (35.7)	5 (50.0)	10 (41.7)	11 (39.3)
No	3 (75.0)	9 (64.3)	5 (50.0)	14 (58.3)	17 (60.7)
95% Confidence Interval [A]	(0.63, 80.59)	(12.76, 64.86)	(18.71, 81.29)	(22.11, 63.36)	(21.50, 59.42)
Weight < 40 kg	N=0	N=7	N=7	N=14	N=14
Yes	0	3 (42.9)	3 (42.9)	6 (42.9)	6 (42.9)
No	0	4 (57.1)	4 (57.1)	8 (57.1)	8 (57.1)
95% Confidence Interval [A]	(NA, NA)	(9.90, 81.59)	(9.90, 81.59)	(17.66, 71.14)	(17.66, 71.14)
Weight >= 40 kg	N=12	N=24	N=24	N=48	N=60
Yes	4 (33.3)	9 (37.5)	13 (54.2)	22 (45.8)	26 (43.3)
No	8 (66.7)	15 (62.5)	11 (45.8)	26 (54.2)	34 (56.7)
95% Confidence Interval [A]	(9.92, 65.11)	(18.80, 59.41)	(32.82, 74.45)	(31.37, 60.83)	(30.59, 56.76)

表 2.7.3.6-88. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Pancolitis - Yes	N=7	N=20	N=17	N=37	N=44
Yes	2 (28.6)	7 (35.0)	10 (58.8)	17 (45.9)	19 (43.2)
No	5 (71.4)	13 (65.0)	7 (41.2)	20 (54.1)	25 (56.8)
95% Confidence Interval [A]	(3.67, 70.96)	(15.39, 59.22)	(32.92, 81.56)	(29.49, 63.08)	(28.35, 58.97)
Pancolitis - No	N=5	N=11	N=14	N=25	N=30
Yes	2 (40.0)	5 (45.5)	6 (42.9)	11 (44.0)	13 (43.3)
No	3 (60.0)	6 (54.5)	8 (57.1)	14 (56.0)	17 (56.7)
95% Confidence Interval [A]	(5.27, 85.34)	(16.75, 76.62)	(17.66, 71.14)	(24.40, 65.07)	(25.46, 62.57)
Disease Duration <= Baseline Median (19.1 Months)	N=5	N=18	N=15	N=33	N=38
Yes	0	6 (33.3)	7 (46.7)	13 (39.4)	13 (34.2)
No	5 (100)	12 (66.7)	8 (53.3)	20 (60.6)	25 (65.8)
95% Confidence Interval [A]	(0.00, 52.18)	(13.34, 59.01)	(21.27, 73.41)	(22.91, 57.86)	(19.63, 51.35)

表 2.7.3.6-88. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Disease Duration > Baseline Median (19.1 Months)	N=7	N=13	N=16	N=29	N=36
Yes	4 (57.1)	6 (46.2)	9 (56.3)	15 (51.7)	19 (52.8)
No	3 (42.9)	7 (53.8)	7 (43.8)	14 (48.3)	17 (47.2)
95% Confidence Interval [A]	(18.41, 90.10)	(19.22, 74.87)	(29.88, 80.25)	(32.53, 70.55)	(35.49, 69.59)
Baseline hs-CRP <= Baseline Median (1.29 mg/L)	N=8	N=12	N=14	N=26	N=34
Yes	3 (37.5)	4 (33.3)	7 (50.0)	11 (42.3)	14 (41.2)
No	5 (62.5)	8 (66.7)	7 (50.0)	15 (57.7)	20 (58.8)
95% Confidence Interval [A]	(8.52, 75.51)	(9.92, 65.11)	(23.04, 76.96)	(23.35, 63.08)	(24.65, 59.30)
Baseline hs-CRP > Baseline Median (1.29 mg/L)	N=3	N=16	N=15	N=31	N=34
Yes	0	6 (37.5)	8 (53.3)	14 (45.2)	14 (41.2)
No	3 (100)	10 (62.5)	7 (46.7)	17 (54.8)	20 (58.8)
95% Confidence Interval [A]	(0.00, 70.76)	(15.20, 64.57)	(26.59, 78.73)	(27.32, 63.97)	(24.65, 59.30)

表 2.7.3.6-88. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Baseline Fecal Calprotectin <= Baseline Median (2302.5 ug/g)	N=3	N=5	N=2	N=7	N=10
Yes	1 (33.3)	1 (20.0)	1 (50.0)	2 (28.6)	3 (30.0)
No	2 (66.7)	4 (80.0)	1 (50.0)	5 (71.4)	7 (70.0)
95% Confidence Interval [A]	(0.84, 90.57)	(0.51, 71.64)	(1.26, 98.74)	(3.67, 70.96)	(6.67, 65.25)
Baseline Fecal Calprotectin > Baseline Median (2302.5 ug/g)	N=1	N=4	N=4	N=8	N=9
Yes	0	0	4 (100)	4 (50.0)	4 (44.4)
No	1 (100)	4 (100)	0	4 (50.0)	5 (55.6)
95% Confidence Interval [A]	(0.00, 97.50)	(0.00, 60.24)	(39.76, 100.00)	(15.70, 84.30)	(13.70, 78.80)

表 2.7.3.6-88.　投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Note: M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
[A] Clopper-Pearson confidence interval for proportion in mucosal healing.
[B1] Nominal p-values from a one-sample two-sided chi-square test.
[B2] Adjusted p-values from a sequentially rejective multiple test procedure (details in SAP), testing co-primary and ranked secondary endpoints first for M-SD/M-HD combined (p-value in 'Total' column) and then for individual ADA dose groups (p-values in 'M-HD' column and in 'M-SD' column, respectively) against the respective external placebo rate (here: 22.03%).
[C] Nominal p-value for the exploratory comparison of M-SD vs. M-HD.
Non-responder imputation (NRI): missing data is imputed as not having met the endpoint. Subjects re-randomized due to disease flare are considered as not having met the endpoint at and after their 1st disease flare.
Clinical response per Partial Mayo Score (PMS) is defined as decrease in PMS >= 2 points and >= 30% from baseline.
Clinical remission per Partial Mayo Score (PMS) is defined as PMS <= 2 and no individual subscore > 1.
Mucosal healing is defined as endoscopy subscore of 0 or 1.

Cross reference: M11-290 Main-study CSR_Interim Table 14.2__1.2.2

表 2.7.3.6-89. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Overall	N=8	N=21	N=22	N=43	N=51
Yes	3 (37.5)	9 (42.9)	10 (45.5)	19 (44.2)	22 (43.1)
No	5 (62.5)	12 (57.1)	12 (54.5)	24 (55.8)	29 (56.9)
95% Confidence Interval [A]	(8.52, 75.51)	(21.82, 65.98)	(24.39, 67.79)	(29.08, 60.12)	(29.35, 57.75)
P-Value [B1]		<0.001	<0.001	<0.001	
ADJ. P-Value [B2]		0.292	<0.001	<0.001	
PMS Remission at Week 8 - Yes	N=8	N=21	N=22	N=43	N=51
Yes	3 (37.5)	9 (42.9)	10 (45.5)	19 (44.2)	22 (43.1)
No	5 (62.5)	12 (57.1)	12 (54.5)	24 (55.8)	29 (56.9)
95% Confidence Interval [A]	(8.52, 75.51)	(21.82, 65.98)	(24.39, 67.79)	(29.08, 60.12)	(29.35, 57.75)

表 2.7.3.6-89. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
PMS Remission at Week 8 - No	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
I-SD	N=2	N=4	N=6	N=10	N=12
Yes	0	0	2 (33.3)	2 (20.0)	2 (16.7)
No	2 (100)	4 (100)	4 (66.7)	8 (80.0)	10 (83.3)
95% Confidence Interval [A]	(0.00, 84.19)	(0.00, 60.24)	(4.33, 77.72)	(2.52, 55.61)	(2.09, 48.41)
I-HD/I-HD-OL	N=6	N=17	N=16	N=33	N=39
Yes	3 (50.0)	9 (52.9)	8 (50.0)	17 (51.5)	20 (51.3)
No	3 (50.0)	8 (47.1)	8 (50.0)	16 (48.5)	19 (48.7)
95% Confidence Interval [A]	(11.81, 88.19)	(27.81, 77.02)	(24.65, 75.35)	(33.54, 69.20)	(34.78, 67.58)

表 2.7.3.6-89. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
I-HD	N=6	N=12	N=10	N=22	N=28
Yes	3 (50.0)	7 (58.3)	5 (50.0)	12 (54.5)	15 (53.6)
No	3 (50.0)	5 (41.7)	5 (50.0)	10 (45.5)	13 (46.4)
95% Confidence Interval [A]	(11.81, 88.19)	(27.67, 84.83)	(18.71, 81.29)	(32.21, 75.61)	(33.87, 72.49)
I-HD-OL	N=0	N=5	N=6	N=11	N=11
Yes	0	2 (40.0)	3 (50.0)	5 (45.5)	5 (45.5)
No	0	3 (60.0)	3 (50.0)	6 (54.5)	6 (54.5)
95% Confidence Interval [A]	(NA, NA)	(5.27, 85.34)	(11.81, 88.19)	(16.75, 76.62)	(16.75, 76.62)
Sex - Male	N=5	N=10	N=8	N=18	N=23
Yes	1 (20.0)	4 (40.0)	4 (50.0)	8 (44.4)	9 (39.1)
No	4 (80.0)	6 (60.0)	4 (50.0)	10 (55.6)	14 (60.9)
95% Confidence Interval [A]	(0.51, 71.64)	(12.16, 73.76)	(15.70, 84.30)	(21.53, 69.24)	(19.71, 61.46)

表 2.7.3.6-89. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Sex - Female	N=3	N=11	N=14	N=25	N=28
Yes	2 (66.7)	5 (45.5)	6 (42.9)	11 (44.0)	13 (46.4)
No	1 (33.3)	6 (54.5)	8 (57.1)	14 (56.0)	15 (53.6)
95% Confidence Interval [A]	(9.43, 99.16)	(16.75, 76.62)	(17.66, 71.14)	(24.40, 65.07)	(27.51, 66.13)
Age < 13 Years	N=2	N=8	N=5	N=13	N=15
Yes	1 (50.0)	5 (62.5)	1 (20.0)	6 (46.2)	7 (46.7)
No	1 (50.0)	3 (37.5)	4 (80.0)	7 (53.8)	8 (53.3)
95% Confidence Interval [A]	(1.26, 98.74)	(24.49, 91.48)	(0.51, 71.64)	(19.22, 74.87)	(21.27, 73.41)
Age >= 13 Years	N=6	N=13	N=17	N=30	N=36
Yes	2 (33.3)	4 (30.8)	9 (52.9)	13 (43.3)	15 (41.7)
No	4 (66.7)	9 (69.2)	8 (47.1)	17 (56.7)	21 (58.3)
95% Confidence Interval [A]	(4.33, 77.72)	(9.09, 61.43)	(27.81, 77.02)	(25.46, 62.57)	(25.51, 59.24)

表 2.7.3.6-89. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Ethnicity - White	N=7	N=19	N=22	N=41	N=48
Yes	3 (42.9)	8 (42.1)	10 (45.5)	18 (43.9)	21 (43.8)
No	4 (57.1)	11 (57.9)	12 (54.5)	23 (56.1)	27 (56.3)
95% Confidence Interval [A]	(9.90, 81.59)	(20.25, 66.50)	(24.39, 67.79)	(28.47, 60.25)	(29.48, 58.82)
Ethnicity - Non-white	N=1	N=2	N=0	N=2	N=3
Yes	0	1 (50.0)	0	1 (50.0)	1 (33.3)
No	1 (100)	1 (50.0)	0	1 (50.0)	2 (66.7)
95% Confidence Interval [A]	(0.00, 97.50)	(1.26, 98.74)	(NA, NA)	(1.26, 98.74)	(0.84, 90.57)
Geographic Region - North America	N=0	N=6	N=0	N=6	N=6
Yes	0	2 (33.3)	0	2 (33.3)	2 (33.3)
No	0	4 (66.7)	0	4 (66.7)	4 (66.7)
95% Confidence Interval [A]	(NA, NA)	(4.33, 77.72)	(NA, NA)	(4.33, 77.72)	(4.33, 77.72)

表 2.7.3.6-89. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Geographic Region - Western Europe	N=1	N=0	N=2	N=2	N=3
Yes	0	0	0	0	0
No	1 (100)	0	2 (100)	2 (100)	3 (100)
95% Confidence Interval [A]	(0.00, 97.50)	(NA, NA)	(0.00, 84.19)	(0.00, 84.19)	(0.00, 70.76)
Geographic Region - Eastern Europe	N=7	N=15	N=20	N=35	N=42
Yes	3 (42.9)	7 (46.7)	10 (50.0)	17 (48.6)	20 (47.6)
No	4 (57.1)	8 (53.3)	10 (50.0)	18 (51.4)	22 (52.4)
95% Confidence Interval [A]	(9.90, 81.59)	(21.27, 73.41)	(27.20, 72.80)	(31.38, 66.01)	(32.00, 63.58)
Baseline Mayo Score <= 9	N=7	N=18	N=18	N=36	N=43
Yes	3 (42.9)	8 (44.4)	7 (38.9)	15 (41.7)	18 (41.9)
No	4 (57.1)	10 (55.6)	11 (61.1)	21 (58.3)	25 (58.1)
95% Confidence Interval [A]	(9.90, 81.59)	(21.53, 69.24)	(17.30, 64.25)	(25.51, 59.24)	(27.01, 57.87)

表 2.7.3.6-89. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Baseline Mayo Score > 9	N=1	N=3	N=4	N=7	N=8
Yes	0	1 (33.3)	3 (75.0)	4 (57.1)	4 (50.0)
No	1 (100)	2 (66.7)	1 (25.0)	3 (42.9)	4 (50.0)
95% Confidence Interval [A]	(0.00, 97.50)	(0.84, 90.57)	(19.41, 99.37)	(18.41, 90.10)	(15.70, 84.30)
Prior Anti-TNF Use	N=0	N=2	N=3	N=5	N=5
Yes	0	0	0	0	0
No	0	2 (100)	3 (100)	5 (100)	5 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.00, 70.76)	(0.00, 52.18)	(0.00, 52.18)
Prior Anti-TNF Naive	N=8	N=19	N=19	N=38	N=46
Yes	3 (37.5)	9 (47.4)	10 (52.6)	19 (50.0)	22 (47.8)
No	5 (62.5)	10 (52.6)	9 (47.4)	19 (50.0)	24 (52.2)
95% Confidence Interval [A]	(8.52, 75.51)	(24.45, 71.14)	(28.86, 75.55)	(33.38, 66.62)	(32.89, 63.05)

表 2.7.3.6-89. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Baseline Corticosteroid Use - Yes	N=5	N=8	N=11	N=19	N=24
Yes	2 (40.0)	4 (50.0)	5 (45.5)	9 (47.4)	11 (45.8)
No	3 (60.0)	4 (50.0)	6 (54.5)	10 (52.6)	13 (54.2)
95% Confidence Interval [A]	(5.27, 85.34)	(15.70, 84.30)	(16.75, 76.62)	(24.45, 71.14)	(25.55, 67.18)
Baseline Corticosteroid Use - No	N=3	N=13	N=11	N=24	N=27
Yes	1 (33.3)	5 (38.5)	5 (45.5)	10 (41.7)	11 (40.7)
No	2 (66.7)	8 (61.5)	6 (54.5)	14 (58.3)	16 (59.3)
95% Confidence Interval [A]	(0.84, 90.57)	(13.86, 68.42)	(16.75, 76.62)	(22.11, 63.36)	(22.39, 61.20)
Baseline IMM Use - Yes	N=5	N=11	N=16	N=27	N=32
Yes	2 (40.0)	4 (36.4)	7 (43.8)	11 (40.7)	13 (40.6)
No	3 (60.0)	7 (63.6)	9 (56.3)	16 (59.3)	19 (59.4)
95% Confidence Interval [A]	(5.27, 85.34)	(10.93, 69.21)	(19.75, 70.12)	(22.39, 61.20)	(23.70, 59.36)

表 2.7.3.6-89. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Baseline IMM Use - No	N=3	N=10	N=6	N=16	N=19
Yes	1 (33.3)	5 (50.0)	3 (50.0)	8 (50.0)	9 (47.4)
No	2 (66.7)	5 (50.0)	3 (50.0)	8 (50.0)	10 (52.6)
95% Confidence Interval [A]	(0.84, 90.57)	(18.71, 81.29)	(11.81, 88.19)	(24.65, 75.35)	(24.45, 71.14)
Weight < 40 kg	N=0	N=3	N=5	N=8	N=8
Yes	0	3 (100)	2 (40.0)	5 (62.5)	5 (62.5)
No	0	0	3 (60.0)	3 (37.5)	3 (37.5)
95% Confidence Interval [A]	(NA, NA)	(29.24, 100.00)	(5.27, 85.34)	(24.49, 91.48)	(24.49, 91.48)
Weight >= 40 kg	N=8	N=18	N=17	N=35	N=43
Yes	3 (37.5)	6 (33.3)	8 (47.1)	14 (40.0)	17 (39.5)
No	5 (62.5)	12 (66.7)	9 (52.9)	21 (60.0)	26 (60.5)
95% Confidence Interval [A]	(8.52, 75.51)	(13.34, 59.01)	(22.98, 72.19)	(23.87, 57.89)	(24.98, 55.59)

表 2.7.3.6-89. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Pancolitis - Yes	N=4	N=12	N=13	N=25	N=29
Yes	1 (25.0)	5 (41.7)	7 (53.8)	12 (48.0)	13 (44.8)
No	3 (75.0)	7 (58.3)	6 (46.2)	13 (52.0)	16 (55.2)
95% Confidence Interval [A]	(0.63, 80.59)	(15.17, 72.33)	(25.13, 80.78)	(27.80, 68.69)	(26.45, 64.31)
Pancolitis - No	N=4	N=9	N=9	N=18	N=22
Yes	2 (50.0)	4 (44.4)	3 (33.3)	7 (38.9)	9 (40.9)
No	2 (50.0)	5 (55.6)	6 (66.7)	11 (61.1)	13 (59.1)
95% Confidence Interval [A]	(6.76, 93.24)	(13.70, 78.80)	(7.49, 70.07)	(17.30, 64.25)	(20.71, 63.65)
Disease Duration <= Baseline Median (19.1 Months)	N=3	N=10	N=9	N=19	N=22
Yes	0	3 (30.0)	5 (55.6)	8 (42.1)	8 (36.4)
No	3 (100)	7 (70.0)	4 (44.4)	11 (57.9)	14 (63.6)
95% Confidence Interval [A]	(0.00, 70.76)	(6.67, 65.25)	(21.20, 86.30)	(20.25, 66.50)	(17.20, 59.34)

表 2.7.3.6-89. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Disease Duration > Baseline Median (19.1 Months)	N=5	N=11	N=13	N=24	N=29
Yes	3 (60.0)	6 (54.5)	5 (38.5)	11 (45.8)	14 (48.3)
No	2 (40.0)	5 (45.5)	8 (61.5)	13 (54.2)	15 (51.7)
95% Confidence Interval [A]	(14.66, 94.73)	(23.38, 83.25)	(13.86, 68.42)	(25.55, 67.18)	(29.45, 67.47)
Baseline hs-CRP <= Baseline Median (1.29 mg/L)	N=6	N=7	N=11	N=18	N=24
Yes	2 (33.3)	3 (42.9)	7 (63.6)	10 (55.6)	12 (50.0)
No	4 (66.7)	4 (57.1)	4 (36.4)	8 (44.4)	12 (50.0)
95% Confidence Interval [A]	(4.33, 77.72)	(9.90, 81.59)	(30.79, 89.07)	(30.76, 78.47)	(29.12, 70.88)
Baseline hs-CRP > Baseline Median (1.29 mg/L)	N=1	N=12	N=10	N=22	N=23
Yes	0	4 (33.3)	3 (30.0)	7 (31.8)	7 (30.4)
No	1 (100)	8 (66.7)	7 (70.0)	15 (68.2)	16 (69.6)
95% Confidence Interval [A]	(0.00, 97.50)	(9.92, 65.11)	(6.67, 65.25)	(13.86, 54.87)	(13.21, 52.92)

表 2.7.3.6-89. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Baseline Fecal Calprotectin <= Baseline Median (2302.5 ug/g)	N=1	N=3	N=1	N=4	N=5
Yes	0	1 (33.3)	1 (100)	2 (50.0)	2 (40.0)
No	1 (100)	2 (66.7)	0	2 (50.0)	3 (60.0)
95% Confidence Interval [A]	(0.00, 97.50)	(0.84, 90.57)	(2.50, 100.00)	(6.76, 93.24)	(5.27, 85.34)
Baseline Fecal Calprotectin > Baseline Median (2302.5 ug/g)	N=0	N=2	N=2	N=4	N=4
Yes	0	0	2 (100)	2 (50.0)	2 (50.0)
No	0	2 (100)	0	2 (50.0)	2 (50.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(15.81, 100.00)	(6.76, 93.24)	(6.76, 93.24)

Note: M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
[A] Clopper-Pearson confidence interval for proportion in remission.
[B1] Nominal p-values from a one-sample two-sided chi-square test.
[B2] Adjusted p-values from a sequentially rejective multiple test procedure (details in SAP), testing co-primary and ranked secondary endpoints first for M-SD/M-HD combined (p-value in 'Total' column) and then for individual ADA dose groups (p-values in 'M-HD' column and in 'M-SD' column, respectively) against the respective external placebo rate (here: 14.79%).
Non-responder imputation (NRI): missing data is imputed as not having met the endpoint. Subjects re-randomized due to disease flare are considered as not having met the endpoint at and after their 1st disease flare.
Clinical remission per full Mayo Score (FMS) is defined as Mayo Score <= 2 and no individual subscore > 1.
Clinical remission per Partial Mayo Score (PMS) is defined as PMS <= 2 and no individual subscore > 1.

Cross reference: M11-290 Main-study CSR_Interim Table 14.2__1.2.3

表 2.7.3.6-90. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Overall	N=5	N=13	N=16	N=29	N=34
Yes	2 (40.0)	4 (30.8)	5 (31.3)	9 (31.0)	11 (32.4)
No	3 (60.0)	9 (69.2)	11 (68.8)	20 (69.0)	23 (67.6)
95% Confidence Interval [A]	(5.27, 85.34)	(9.09, 61.43)	(11.02, 58.66)	(15.28, 50.83)	(17.39, 50.53)
P-Value [B1]		0.573	0.502	0.381	
ADJ. P-Value [B2]		1.000	1.000	0.382	
P-Value [C]		0.978			
PMS Remission at Week 8 - Yes	N=5	N=8	N=11	N=19	N=24
Yes	2 (40.0)	4 (50.0)	5 (45.5)	9 (47.4)	11 (45.8)
No	3 (60.0)	4 (50.0)	6 (54.5)	10 (52.6)	13 (54.2)
95% Confidence Interval [A]	(5.27, 85.34)	(15.70, 84.30)	(16.75, 76.62)	(24.45, 71.14)	(25.55, 67.18)

表 2.7.3.6-90. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
PMS Remission at Week 8 - No	N=0	N=5	N=5	N=10	N=10
Yes	0	0	0	0	0
No	0	5 (100)	5 (100)	10 (100)	10 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 52.18)	(0.00, 52.18)	(0.00, 30.85)	(0.00, 30.85)
I-SD	N=0	N=5	N=3	N=8	N=8
Yes	0	0	0	0	0
No	0	5 (100)	3 (100)	8 (100)	8 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 52.18)	(0.00, 70.76)	(0.00, 36.94)	(0.00, 36.94)
I-HD/I-HD-OL	N=5	N=8	N=13	N=21	N=26
Yes	2 (40.0)	4 (50.0)	5 (38.5)	9 (42.9)	11 (42.3)
No	3 (60.0)	4 (50.0)	8 (61.5)	12 (57.1)	15 (57.7)
95% Confidence Interval [A]	(5.27, 85.34)	(15.70, 84.30)	(13.86, 68.42)	(21.82, 65.98)	(23.35, 63.08)

表 2.7.3.6-90. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
I-HD	N=5	N=5	N=8	N=13	N=18
Yes	2 (40.0)	3 (60.0)	3 (37.5)	6 (46.2)	8 (44.4)
No	3 (60.0)	2 (40.0)	5 (62.5)	7 (53.8)	10 (55.6)
95% Confidence Interval [A]	(5.27, 85.34)	(14.66, 94.73)	(8.52, 75.51)	(19.22, 74.87)	(21.53, 69.24)
I-HD-OL	N=0	N=3	N=5	N=8	N=8
Yes	0	1 (33.3)	2 (40.0)	3 (37.5)	3 (37.5)
No	0	2 (66.7)	3 (60.0)	5 (62.5)	5 (62.5)
95% Confidence Interval [A]	(NA, NA)	(0.84, 90.57)	(5.27, 85.34)	(8.52, 75.51)	(8.52, 75.51)
Sex - Male	N=4	N=5	N=7	N=12	N=16
Yes	1 (25.0)	1 (20.0)	3 (42.9)	4 (33.3)	5 (31.3)
No	3 (75.0)	4 (80.0)	4 (57.1)	8 (66.7)	11 (68.8)
95% Confidence Interval [A]	(0.63, 80.59)	(0.51, 71.64)	(9.90, 81.59)	(9.92, 65.11)	(11.02, 58.66)

表 2.7.3.6-90. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Sex - Female	N=1	N=8	N=9	N=17	N=18
Yes	1 (100)	3 (37.5)	2 (22.2)	5 (29.4)	6 (33.3)
No	0	5 (62.5)	7 (77.8)	12 (70.6)	12 (66.7)
95% Confidence Interval [A]	(2.50, 100.00)	(8.52, 75.51)	(2.81, 60.01)	(10.31, 55.96)	(13.34, 59.01)
Age < 13 Years	N=1	N=3	N=6	N=9	N=10
Yes	0	2 (66.7)	1 (16.7)	3 (33.3)	3 (30.0)
No	1 (100)	1 (33.3)	5 (83.3)	6 (66.7)	7 (70.0)
95% Confidence Interval [A]	(0.00, 97.50)	(9.43, 99.16)	(0.42, 64.12)	(7.49, 70.07)	(6.67, 65.25)
Age >= 13 Years	N=4	N=10	N=10	N=20	N=24
Yes	2 (50.0)	2 (20.0)	4 (40.0)	6 (30.0)	8 (33.3)
No	2 (50.0)	8 (80.0)	6 (60.0)	14 (70.0)	16 (66.7)
95% Confidence Interval [A]	(6.76, 93.24)	(2.52, 55.61)	(12.16, 73.76)	(11.89, 54.28)	(15.63, 55.32)

表 2.7.3.6-90. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Ethnicity - White	N=5	N=11	N=15	N=26	N=31
Yes	2 (40.0)	3 (27.3)	5 (33.3)	8 (30.8)	10 (32.3)
No	3 (60.0)	8 (72.7)	10 (66.7)	18 (69.2)	21 (67.7)
95% Confidence Interval [A]	(5.27, 85.34)	(6.02, 60.97)	(11.82, 61.62)	(14.33, 51.79)	(16.68, 51.37)
Ethnicity - Non-white	N=0	N=2	N=1	N=3	N=3
Yes	0	1 (50.0)	0	1 (33.3)	1 (33.3)
No	0	1 (50.0)	1 (100)	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(1.26, 98.74)	(0.00, 97.50)	(0.84, 90.57)	(0.84, 90.57)
Geographic Region - North America	N=0	N=5	N=2	N=7	N=7
Yes	0	1 (20.0)	0	1 (14.3)	1 (14.3)
No	0	4 (80.0)	2 (100)	6 (85.7)	6 (85.7)
95% Confidence Interval [A]	(NA, NA)	(0.51, 71.64)	(0.00, 84.19)	(0.36, 57.87)	(0.36, 57.87)

表 2.7.3.6-90. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Geographic Region - Western Europe	N=0	N=0	N=1	N=1	N=1
Yes	0	0	0	0	0
No	0	0	1 (100)	1 (100)	1 (100)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)	(0.00, 97.50)
Geographic Region - Eastern Europe	N=5	N=8	N=13	N=21	N=26
Yes	2 (40.0)	3 (37.5)	5 (38.5)	8 (38.1)	10 (38.5)
No	3 (60.0)	5 (62.5)	8 (61.5)	13 (61.9)	16 (61.5)
95% Confidence Interval [A]	(5.27, 85.34)	(8.52, 75.51)	(13.86, 68.42)	(18.11, 61.56)	(20.23, 59.43)
Baseline Mayo Score <= 9	N=4	N=11	N=15	N=26	N=30
Yes	2 (50.0)	3 (27.3)	4 (26.7)	7 (26.9)	9 (30.0)
No	2 (50.0)	8 (72.7)	11 (73.3)	19 (73.1)	21 (70.0)
95% Confidence Interval [A]	(6.76, 93.24)	(6.02, 60.97)	(7.79, 55.10)	(11.57, 47.79)	(14.73, 49.40)

表 2.7.3.6-90. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Baseline Mayo Score > 9	N=1	N=2	N=1	N=3	N=4
Yes	0	1 (50.0)	1 (100)	2 (66.7)	2 (50.0)
No	1 (100)	1 (50.0)	0	1 (33.3)	2 (50.0)
95% Confidence Interval [A]	(0.00, 97.50)	(1.26, 98.74)	(2.50, 100.00)	(9.43, 99.16)	(6.76, 93.24)
Prior Anti-TNF Use	N=0	N=0	N=4	N=4	N=4
Yes	0	0	0	0	0
No	0	0	4 (100)	4 (100)	4 (100)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.00, 60.24)	(0.00, 60.24)	(0.00, 60.24)
Prior Anti-TNF Naive	N=5	N=13	N=12	N=25	N=30
Yes	2 (40.0)	4 (30.8)	5 (41.7)	9 (36.0)	11 (36.7)
No	3 (60.0)	9 (69.2)	7 (58.3)	16 (64.0)	19 (63.3)
95% Confidence Interval [A]	(5.27, 85.34)	(9.09, 61.43)	(15.17, 72.33)	(17.97, 57.48)	(19.93, 56.14)

表 2.7.3.6-90. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Baseline Corticosteroid Use - Yes	N=5	N=13	N=16	N=29	N=34
Yes	2 (40.0)	4 (30.8)	5 (31.3)	9 (31.0)	11 (32.4)
No	3 (60.0)	9 (69.2)	11 (68.8)	20 (69.0)	23 (67.6)
95% Confidence Interval [A]	(5.27, 85.34)	(9.09, 61.43)	(11.02, 58.66)	(15.28, 50.83)	(17.39, 50.53)
Baseline Corticosteroid Use - No	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Baseline IMM Use - Yes	N=2	N=4	N=7	N=11	N=13
Yes	1 (50.0)	1 (25.0)	2 (28.6)	3 (27.3)	4 (30.8)
No	1 (50.0)	3 (75.0)	5 (71.4)	8 (72.7)	9 (69.2)
95% Confidence Interval [A]	(1.26, 98.74)	(0.63, 80.59)	(3.67, 70.96)	(6.02, 60.97)	(9.09, 61.43)

表 2.7.3.6-90. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Baseline IMM Use - No	N=3	N=9	N=9	N=18	N=21
Yes	1 (33.3)	3 (33.3)	3 (33.3)	6 (33.3)	7 (33.3)
No	2 (66.7)	6 (66.7)	6 (66.7)	12 (66.7)	14 (66.7)
95% Confidence Interval [A]	(0.84, 90.57)	(7.49, 70.07)	(7.49, 70.07)	(13.34, 59.01)	(14.59, 56.97)
Weight < 40 kg	N=0	N=2	N=5	N=7	N=7
Yes	0	1 (50.0)	1 (20.0)	2 (28.6)	2 (28.6)
No	0	1 (50.0)	4 (80.0)	5 (71.4)	5 (71.4)
95% Confidence Interval [A]	(NA, NA)	(1.26, 98.74)	(0.51, 71.64)	(3.67, 70.96)	(3.67, 70.96)
Weight >= 40 kg	N=5	N=11	N=11	N=22	N=27
Yes	2 (40.0)	3 (27.3)	4 (36.4)	7 (31.8)	9 (33.3)
No	3 (60.0)	8 (72.7)	7 (63.6)	15 (68.2)	18 (66.7)
95% Confidence Interval [A]	(5.27, 85.34)	(6.02, 60.97)	(10.93, 69.21)	(13.86, 54.87)	(16.52, 53.96)

表 2.7.3.6-90. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Pancolitis - Yes	N=1	N=10	N=6	N=16	N=17
Yes	0	3 (30.0)	3 (50.0)	6 (37.5)	6 (35.3)
No	1 (100)	7 (70.0)	3 (50.0)	10 (62.5)	11 (64.7)
95% Confidence Interval [A]	(0.00, 97.50)	(6.67, 65.25)	(11.81, 88.19)	(15.20, 64.57)	(14.21, 61.67)
Pancolitis - No	N=4	N=3	N=10	N=13	N=17
Yes	2 (50.0)	1 (33.3)	2 (20.0)	3 (23.1)	5 (29.4)
No	2 (50.0)	2 (66.7)	8 (80.0)	10 (76.9)	12 (70.6)
95% Confidence Interval [A]	(6.76, 93.24)	(0.84, 90.57)	(2.52, 55.61)	(5.04, 53.81)	(10.31, 55.96)
Disease Duration <= Baseline Median (19.1 Months)	N=1	N=11	N=10	N=21	N=22
Yes	0	3 (27.3)	3 (30.0)	6 (28.6)	6 (27.3)
No	1 (100)	8 (72.7)	7 (70.0)	15 (71.4)	16 (72.7)
95% Confidence Interval [A]	(0.00, 97.50)	(6.02, 60.97)	(6.67, 65.25)	(11.28, 52.18)	(10.73, 50.22)

表 2.7.3.6-90. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Disease Duration > Baseline Median (19.1 Months)	N=4	N=2	N=6	N=8	N=12
Yes	2 (50.0)	1 (50.0)	2 (33.3)	3 (37.5)	5 (41.7)
No	2 (50.0)	1 (50.0)	4 (66.7)	5 (62.5)	7 (58.3)
95% Confidence Interval [A]	(6.76, 93.24)	(1.26, 98.74)	(4.33, 77.72)	(8.52, 75.51)	(15.17, 72.33)
Baseline hs-CRP <= Baseline Median (1.29 mg/L)	N=4	N=8	N=10	N=18	N=22
Yes	2 (50.0)	1 (12.5)	4 (40.0)	5 (27.8)	7 (31.8)
No	2 (50.0)	7 (87.5)	6 (60.0)	13 (72.2)	15 (68.2)
95% Confidence Interval [A]	(6.76, 93.24)	(0.32, 52.65)	(12.16, 73.76)	(9.69, 53.48)	(13.86, 54.87)
Baseline hs-CRP > Baseline Median (1.29 mg/L)	N=1	N=4	N=5	N=9	N=10
Yes	0	2 (50.0)	1 (20.0)	3 (33.3)	3 (30.0)
No	1 (100)	2 (50.0)	4 (80.0)	6 (66.7)	7 (70.0)
95% Confidence Interval [A]	(0.00, 97.50)	(6.76, 93.24)	(0.51, 71.64)	(7.49, 70.07)	(6.67, 65.25)

表 2.7.3.6-90. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Baseline Fecal Calprotectin <= Baseline Median (2302.5 ug/g)	N=0	N=1	N=1	N=2	N=2
Yes	0	0	0	0	0
No	0	1 (100)	1 (100)	2 (100)	2 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)	(0.00, 84.19)	(0.00, 84.19)
Baseline Fecal Calprotectin > Baseline Median (2302.5 ug/g)	N=0	N=3	N=1	N=4	N=4
Yes	0	0	1 (100)	1 (25.0)	1 (25.0)
No	0	3 (100)	0	3 (75.0)	3 (75.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 70.76)	(2.50, 100.00)	(0.63, 80.59)	(0.63, 80.59)

表 2.7.3.6-90. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Note: M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
[A] Clopper-Pearson confidence interval for proportion in remission.
[B1] Nominal p-values from a one-sample two-sided chi-square test.
[B2] Adjusted p-values from a sequentially rejective multiple test procedure (details in SAP), testing co-primary and ranked secondary endpoints first for M-SD/M-HD combined (p-value in 'Total' column) and then for individual ADA dose groups (p-values in 'M-HD' column and in 'M-SD' column, respectively) against the respective external placebo rate (here: 24.08%).
[C] Nominal p-value for the exploratory comparison of M-SD vs. M-HD.
Non-responder imputation (NRI): missing data is imputed as not having met the endpoint. Subjects re-randomized due to disease flare are considered as not having met the endpoint at and after their 1st disease flare.
Corticosteroid-Free is defined as subjects receiving systemic corticosteroids (UC related or non-UC related) at baseline who have discontinued systemic corticosteroids prior to week 52.
Clinical remission per full Mayo Score (FMS) is defined as Mayo Score <= 2 and no individual subscore > 1.
Clinical response per Partial Mayo Score (PMS) is defined as decrease in PMS >= 2 points and >= 30% from baseline.
Clinical remission per Partial Mayo Score (PMS) is defined as PMS <= 2 and no individual subscore > 1.

Cross reference: M11-290 Main-study CSR_Interim Table 14.2__1.2.4

表 2.7.3.6-91. 維持療法期間中の投与 52 週時点でのその他の探索的な副次解析の結果（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）

	mITT				
		mITT-E			
Clinical Endpoint Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
PMS Remission at Week 52 in Week 8 PMS Responders	N=12	N=31	N=31	N=62	N=74
Yes	4 (33.3)	16 (51.6)	19 (61.3)	35 (56.5)	39 (52.7)
No	8 (66.7)	15 (48.4)	12 (38.7)	27 (43.5)	35 (47.3)
95% Confidence Interval [A]	(9.92, 65.11)	(33.06, 69.85)	(42.19, 78.15)	(43.26, 69.01)	(40.75, 64.43)
P-Value [B]		0.442			
PUCAI Remission at Week 52 in Week 8 PMS Responders	N=12	N=31	N=31	N=62	N=74
Yes	3 (25.0)	14 (45.2)	18 (58.1)	32 (51.6)	35 (47.3)
No	9 (75.0)	17 (54.8)	13 (41.9)	30 (48.4)	39 (52.7)
95% Confidence Interval [A]	(5.49, 57.19)	(27.32, 63.97)	(39.08, 75.45)	(38.56, 64.50)	(35.57, 59.25)
P-Value [B]		0.309			

表 2.7.3.6-91. 維持療法期間中の投与 52 週時点でのその他の探索的な副次解析の結果（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Clinical Endpoint Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
PUCAI Response at Week 52 in Week 8 PMS Responders	N=12	N=31	N=31	N=62	N=74
Yes	4 (33.3)	18 (58.1)	16 (51.6)	34 (54.8)	38 (51.4)
No	8 (66.7)	13 (41.9)	15 (48.4)	28 (45.2)	36 (48.6)
95% Confidence Interval [A]	(9.92, 65.11)	(39.08, 75.45)	(33.06, 69.85)	(41.68, 67.52)	(39.44, 63.15)
P-Value [B]		0.610			
CS-Free PUCAI Remission at Week 52 in Week 8 PMS Responders	N=5	N=13	N=16	N=29	N=34
Yes	2 (40.0)	5 (38.5)	7 (43.8)	12 (41.4)	14 (41.2)
No	3 (60.0)	8 (61.5)	9 (56.3)	17 (58.6)	20 (58.8)
95% Confidence Interval [A]	(5.27, 85.34)	(13.86, 68.42)	(19.75, 70.12)	(23.52, 61.06)	(24.65, 59.30)
P-Value [B]		0.774			

表 2.7.3.6-91. 維持療法期間中の投与 52 週時点でのその他の探索的な副次解析の結果（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Clinical Endpoint Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
Endoscopy Subscore 0 or 1 (w/o Friability)	N=12	N=31	N=31	N=62	N=74
Yes	4 (33.3)	11 (35.5)	13 (41.9)	24 (38.7)	28 (37.8)
No	8 (66.7)	20 (64.5)	18 (58.1)	38 (61.3)	46 (62.2)
95% Confidence Interval [A]	(9.92, 65.11)	(19.23, 54.63)	(24.55, 60.92)	(26.60, 51.93)	(26.81, 49.87)
9-Point Mayo (w/o SFS) Remission at Week 52 in Week 8 PMS Responders	N=12	N=31	N=31	N=62	N=74
Yes	4 (33.3)	11 (35.5)	15 (48.4)	26 (41.9)	30 (40.5)
No	8 (66.7)	20 (64.5)	16 (51.6)	36 (58.1)	44 (59.5)
95% Confidence Interval [A]	(9.92, 65.11)	(19.23, 54.63)	(30.15, 66.94)	(29.51, 55.15)	(29.27, 52.59)

表 2.7.3.6-91. 維持療法期間中の投与 52 週時点でのその他の探索的な副次解析の結果（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

	mITT				
		mITT-E			
Clinical Endpoint Endpoint Met	M-PL (N=12)	M-SD (N=31)	M-HD (N=31)	Total (N=62)	Total (N=74)
9-Point Mayo (w/o PGA) Remission at Week 52 in Week 8 PMS Responders	N=12	N=31	N=31	N=62	N=74
Yes	4 (33.3)	11 (35.5)	15 (48.4)	26 (41.9)	30 (40.5)
No	8 (66.7)	20 (64.5)	16 (51.6)	36 (58.1)	44 (59.5)
95% Confidence Interval [A]	(9.92, 65.11)	(19.23, 54.63)	(30.15, 66.94)	(29.51, 55.15)	(29.27, 52.59)
9-Point Mayo (w/o RBS) Remission at Week 52 in Week 8 PMS Responders	N=12	N=31	N=31	N=62	N=74
Yes	4 (33.3)	11 (35.5)	15 (48.4)	26 (41.9)	30 (40.5)
No	8 (66.7)	20 (64.5)	16 (51.6)	36 (58.1)	44 (59.5)
95% Confidence Interval [A]	(9.92, 65.11)	(19.23, 54.63)	(30.15, 66.94)	(29.51, 55.15)	(29.27, 52.59)

表 2.7.3.6-91. 維持療法期間中の投与 52 週時点でのその他の探索的な副次解析の結果（NRI）（mITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Note: M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
[A] Clopper-Pearson confidence interval for proportion in remission, response.
[B] Nominal p-value for the exploratory comparison of M-SD vs. M-HD.
Non-responder imputation (NRI): missing data is imputed as not having met the endpoint. Subjects re-randomized due to disease flare are considered as not having met the endpoint at and after their 1st disease flare.
Corticosteroid-Free is defined as subjects receiving systemic corticosteroids (UC related or non-UC related) at baseline who have discontinued systemic corticosteroids prior to week 52.
PMS = partial mayo score, CS = corticosteroid, SFS = stool frequency subscore, PGA = physician's global assessment subscore, RBS = rectal bleeding subscore.
Clinical remission per Partial Mayo Score (PMS) is defined as PMS <= 2 and no individual subscore > 1.
PUCAI = pediatric ulcerative colitis activity index.
PUCAI remission is defined as PUCAI < 10.
PUCAI response is defined as a decrease in PUCAI >= 20 points from baseline.
Clinical remission per 9 point Mayo Score is defined as the 9 point Mayo Score <=2 and no individual subscore > 1.

Cross reference: M11-290 Main-study CSR_Interim Table 14.2__1.3.2

表 2.7.3.6-92. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の ITT 集団，M11-290 試験の主試験）（中間 CSR）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Body						
Week 8						
I-SD	27	10.6	10.5	-0.1	(-0.82, 0.53)	0.33
I-SD/-	7	10.1	9.3	-0.9	(-2.41, 0.69)	0.63
I-SD/M-PL	4	12.0	12.3	0.3	(-1.75, 2.25)	0.63
I-SD/M-SD	7	10.0	10.6	0.6	(-1.34, 2.49)	0.78
I-SD/M-HD	9	10.9	10.6	-0.3	(-1.55, 0.88)	0.53
I-HD	43	9.9	10.1	0.2	(-0.30, 0.77)	0.27
I-HD/-	7	8.0	8.6	0.6	(-0.72, 1.86)	0.53
I-HD/M-PL	8	9.1	10.3	1.1	(-0.99, 3.24)	0.90
I-HD/M-SD	14	10.7	10.9	0.2	(-0.64, 1.07)	0.39
I-HD/M-HD	14	10.5	10.1	-0.4	(-1.30, 0.44)	0.40
I-SD + I-HD Total	70	10.2	10.3	0.1	(-0.33, 0.50)	0.21
I-HD-OL	15	9.3	9.8	0.5	(-0.37, 1.30)	0.39
I-HD-OL/-	2	8.5	9.5	1.0		0.00
I-HD-OL/M-SD	7	9.0	9.4	0.4	(-0.97, 1.83)	0.57
I-HD-OL/M-HD	6	10.0	10.3	0.3	(-1.62, 2.29)	0.76
M-SD Total	28	10.1	10.5	0.4	(-0.26, 0.97)	0.30
M-HD Total	29	10.5	10.3	-0.2	(-0.84, 0.36)	0.29
M-SD + M-HD Total	57	10.3	10.4	0.1	(-0.37, 0.48)	0.21

表 2.7.3.6-92. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Body (Cont.)						
Week 26						
I-SD	19	10.8	11.1	0.3	(-0.47, 1.00)	0.35
I-SD/M-PL	4	12.0	11.8	-0.3	(-2.97, 2.47)	0.85
I-SD/M-SD	7	10.0	10.1	0.1	(-1.58, 1.87)	0.70
I-SD/M-HD	8	10.9	11.5	0.6	(-0.37, 1.62)	0.42
I-HD	36	10.3	10.5	0.2	(-0.45, 0.89)	0.33
I-HD/M-PL	8	9.1	9.5	0.4	(-2.03, 2.78)	1.02
I-HD/M-SD	14	10.7	11.3	0.6	(-0.43, 1.58)	0.47
I-HD/M-HD	14	10.5	10.3	-0.2	(-1.18, 0.75)	0.45
I-SD + I-HD Total	55	10.5	10.7	0.2	(-0.26, 0.73)	0.25
I-HD-OL	13	9.5	9.8	0.3	(-0.66, 1.28)	0.44
I-HD-OL/M-SD	7	9.0	9.4	0.4	(-0.97, 1.83)	0.57
I-HD-OL/M-HD	6	10.0	10.2	0.2	(-1.76, 2.09)	0.75
M-SD Total	28	10.1	10.5	0.4	(-0.22, 1.07)	0.31
M-HD Total	28	10.5	10.6	0.1	(-0.50, 0.72)	0.30
M-SD + M-HD Total	56	10.3	10.6	0.3	(-0.16, 0.70)	0.22

表 2.7.3.6-92. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Body (Cont.)						
Week 52						
I-SD	19	10.8	11.4	0.6	(-0.31, 1.46)	0.42
I-SD/M-PL	4	12.0	11.5	-0.5	(-3.81, 2.81)	1.04
I-SD/M-SD	7	10.0	10.9	0.9	(-1.03, 2.74)	0.77
I-SD/M-HD	8	10.9	11.8	0.9	(-0.42, 2.17)	0.55
I-HD	36	10.3	10.7	0.4	(-0.28, 1.11)	0.34
I-HD/M-PL	8	9.1	9.9	0.8	(-1.47, 2.97)	0.94
I-HD/M-SD	14	10.7	11.5	0.8	(-0.13, 1.70)	0.42
I-HD/M-HD	14	10.5	10.4	-0.1	(-1.36, 1.07)	0.56
I-SD + I-HD Total	55	10.5	10.9	0.5	(-0.06, 1.00)	0.26
I-HD-OL	13	9.5	9.9	0.5	(-0.74, 1.66)	0.55
I-HD-OL/M-SD	7	9.0	9.6	0.6	(-1.55, 2.70)	0.87
I-HD-OL/M-HD	6	10.0	10.3	0.3	(-1.50, 2.17)	0.71
M-SD Total	28	10.1	10.9	0.8	(0.05, 1.45)	0.34
M-HD Total	28	10.5	10.8	0.3	(-0.48, 0.98)	0.35
M-SD + M-HD Total	56	10.3	10.8	0.5	(0.00, 1.00)	0.25

表 2.7.3.6-92. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Bowel						
Week 8						
I-SD	27	21.06	25.44	4.39	(1.995, 6.781)	1.164
I-SD/-	7	21.14	22.29	1.14	(-2.534, 4.820)	1.503
I-SD/M-PL	4	25.00	28.00	3.00	(0.402, 5.598)	0.816
I-SD/M-SD	7	20.71	27.00	6.29	(-0.334, 12.906)	2.705
I-SD/M-HD	9	19.50	25.56	6.05	(0.554, 11.551)	2.384
I-HD	43	20.35	25.84	5.49	(3.835, 7.142)	0.819
I-HD/-	7	16.71	15.86	-0.86	(-3.386, 1.672)	1.033
I-HD/M-PL	8	18.88	26.50	7.63	(1.548, 13.702)	2.570
I-HD/M-SD	14	20.00	27.14	7.14	(5.094, 9.192)	0.948
I-HD/M-HD	14	23.36	29.14	5.79	(3.124, 8.448)	1.232
I-SD + I-HD Total	70	20.62	25.69	5.06	(3.722, 6.405)	0.672
I-HD-OL	15	18.67	25.20	6.53	(2.055, 11.012)	2.088
I-HD-OL/-	2	18.50	11.50	-7.00	(-57.825, 43.825)	4.000
I-HD-OL/M-SD	7	19.14	25.86	6.71	(0.995, 12.433)	2.337
I-HD-OL/M-HD	6	18.17	29.00	10.83	(4.592, 17.074)	2.428
M-SD Total	28	19.96	26.79	6.82	(4.841, 8.802)	0.965
M-HD Total	29	21.09	28.00	6.91	(4.663, 9.162)	1.098
M-SD + M-HD Total	57	20.54	27.40	6.87	(5.413, 8.323)	0.726

表 2.7.3.6-92. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Bowel (Cont.)						
Week 26						
I-SD	19	21.24	28.32	7.08	(3.757, 10.398)	1.580
I-SD/M-PL	4	25.00	29.50	4.50	(-0.274, 9.274)	1.500
I-SD/M-SD	7	20.71	26.86	6.14	(-1.167, 13.453)	2.988
I-SD/M-HD	8	19.82	29.00	9.18	(2.990, 15.378)	2.619
I-HD	36	21.06	27.78	6.72	(4.666, 8.779)	1.013
I-HD/M-PL	8	18.88	25.75	6.88	(-0.054, 13.804)	2.930
I-HD/M-SD	14	20.00	26.64	6.64	(3.219, 10.067)	1.585
I-HD/M-HD	14	23.36	30.07	6.71	(3.698, 9.731)	1.396
I-SD + I-HD Total	55	21.12	27.96	6.84	(5.139, 8.550)	0.851
I-HD-OL	13	18.69	27.23	8.54	(3.491, 13.586)	2.317
I-HD-OL/M-SD	7	19.14	25.43	6.29	(-2.467, 15.039)	3.577
I-HD-OL/M-HD	6	18.17	29.33	11.17	(4.161, 18.173)	2.725
M-SD Total	28	19.96	26.39	6.43	(3.666, 9.192)	1.347
M-HD Total	28	21.23	29.61	8.37	(5.953, 10.795)	1.180
M-SD + M-HD Total	56	20.60	28.00	7.40	(5.604, 9.198)	0.897

表 2.7.3.6-92. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Bowel (Cont.)						
Week 52						
I-SD	19	21.24	27.55	6.32	(2.580, 10.052)	1.778
I-SD/M-PL	4	25.00	29.50	4.50	(-0.274, 9.274)	1.500
I-SD/M-SD	7	20.71	25.43	4.71	(-1.552, 10.980)	2.561
I-SD/M-HD	8	19.82	28.44	8.63	(0.234, 17.016)	3.548
I-HD	36	21.06	27.94	6.89	(4.810, 8.968)	1.024
I-HD/M-PL	8	18.88	26.63	7.75	(0.860, 14.640)	2.914
I-HD/M-SD	14	20.00	27.71	7.71	(4.344, 11.084)	1.560
I-HD/M-HD	14	23.36	28.93	5.57	(2.519, 8.624)	1.413
I-SD + I-HD Total	55	21.12	27.81	6.69	(4.886, 8.496)	0.900
I-HD-OL	13	18.69	27.77	9.08	(5.340, 12.814)	1.715
I-HD-OL/M-SD	7	19.14	26.29	7.14	(2.037, 12.248)	2.087
I-HD-OL/M-HD	6	18.17	29.50	11.33	(4.383, 18.284)	2.704
M-SD Total	28	19.96	26.79	6.82	(4.528, 9.114)	1.118
M-HD Total	28	21.23	28.91	7.68	(4.849, 10.508)	1.379
M-SD + M-HD Total	56	20.60	27.85	7.25	(5.484, 9.016)	0.881

表 2.7.3.6-92. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Emotional						
Week 8						
I-SD	27	20.4	23.6	3.1	(0.85, 5.37)	1.10
I-SD/-	7	19.1	19.6	0.4	(-5.70, 6.56)	2.51
I-SD/M-PL	4	23.0	27.8	4.8	(-0.51, 10.01)	1.65
I-SD/M-SD	7	20.9	24.3	3.4	(-3.30, 10.16)	2.75
I-SD/M-HD	9	20.0	24.2	4.2	(0.75, 7.70)	1.51
I-HD	43	21.0	24.0	3.1	(1.72, 4.42)	0.67
I-HD/-	7	16.1	14.6	-1.6	(-3.49, 0.34)	0.78
I-HD/M-PL	8	20.1	25.1	5.0	(-0.29, 10.29)	2.24
I-HD/M-SD	14	21.1	25.5	4.4	(2.37, 6.49)	0.95
I-HD/M-HD	14	23.8	26.7	2.9	(1.11, 4.75)	0.84
I-SD + I-HD Total	70	20.8	23.9	3.1	(1.92, 4.25)	0.59
I-HD-OL	15	19.4	23.8	4.4	(2.01, 6.79)	1.12
I-HD-OL/-	2	17.0	17.5	0.5	(-18.56, 19.56)	1.50
I-HD-OL/M-SD	7	20.4	24.4	4.0	(-0.98, 8.98)	2.04
I-HD-OL/M-HD	6	19.0	25.2	6.2	(3.48, 8.86)	1.05
M-SD Total	28	20.9	24.9	4.1	(2.15, 5.99)	0.94
M-HD Total	29	21.6	25.6	4.0	(2.62, 5.38)	0.68
M-SD + M-HD Total	57	21.2	25.3	4.0	(2.90, 5.17)	0.57

表 2.7.3.6-92. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Emotional (Cont.)						
Week 26						
I-SD	19	21.3	27.9	6.6	(3.29, 9.87)	1.57
I-SD/M-PL	4	23.0	29.8	6.8	(-3.83, 17.33)	3.33
I-SD/M-SD	7	20.9	25.7	4.9	(-3.03, 12.75)	3.23
I-SD/M-HD	8	20.9	28.9	8.0	(3.17, 12.83)	2.04
I-HD	36	21.9	26.6	4.7	(3.01, 6.43)	0.84
I-HD/M-PL	8	20.1	25.5	5.4	(-0.17, 10.92)	2.34
I-HD/M-SD	14	21.1	25.6	4.5	(1.70, 7.30)	1.30
I-HD/M-HD	14	23.8	28.4	4.6	(1.92, 7.22)	1.23
I-SD + I-HD Total	55	21.7	27.1	5.4	(3.81, 6.91)	0.77
I-HD-OL	13	19.8	25.9	6.2	(3.03, 9.28)	1.44
I-HD-OL/M-SD	7	20.4	25.9	5.4	(0.63, 10.23)	1.96
I-HD-OL/M-HD	6	19.0	26.0	7.0	(1.21, 12.79)	2.25
M-SD Total	28	20.9	25.7	4.8	(2.57, 7.07)	1.10
M-HD Total	28	21.9	28.0	6.1	(4.06, 8.08)	0.98
M-SD + M-HD Total	56	21.4	26.8	5.4	(3.98, 6.92)	0.73

表 2.7.3.6-92. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Emotional (Cont.)						
Week 52						
I-SD	19	21.3	27.8	6.5	(2.98, 10.08)	1.69
I-SD/M-PL	4	23.0	29.8	6.8	(-4.97, 18.47)	3.68
I-SD/M-SD	7	20.9	25.4	4.6	(-1.86, 11.00)	2.63
I-SD/M-HD	8	20.9	29.0	8.1	(1.22, 15.03)	2.92
I-HD	36	21.9	25.8	3.9	(1.98, 5.85)	0.95
I-HD/M-PL	8	20.1	25.0	4.9	(-0.40, 10.15)	2.23
I-HD/M-SD	14	21.1	26.9	5.8	(2.62, 8.95)	1.46
I-HD/M-HD	14	23.8	25.3	1.5	(-1.44, 4.44)	1.36
I-SD + I-HD Total	55	21.7	26.5	4.8	(3.09, 6.55)	0.86
I-HD-OL	13	19.8	25.8	6.0	(2.42, 9.58)	1.64
I-HD-OL/M-SD	7	20.4	26.9	6.4	(3.02, 9.84)	1.39
I-HD-OL/M-HD	6	19.0	24.5	5.5	(-3.12, 14.12)	3.35
M-SD Total	28	20.9	26.5	5.6	(3.57, 7.72)	1.01
M-HD Total	28	21.9	26.2	4.3	(1.47, 7.03)	1.35
M-SD + M-HD Total	56	21.4	26.3	4.9	(3.26, 6.64)	0.84

表 2.7.3.6-92. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Social						
Week 8						
I-SD	27	40.20	43.26	3.06	(0.387, 5.737)	1.301
I-SD/-	7	38.84	37.43	-1.41	(-5.852, 3.028)	1.815
I-SD/M-PL	4	43.00	46.00	3.00	(-1.684, 7.684)	1.472
I-SD/M-SD	7	43.00	47.71	4.71	(-4.295, 13.724)	3.682
I-SD/M-HD	9	37.83	43.11	5.28	(0.976, 9.592)	1.868
I-HD	43	40.90	46.32	5.42	(3.588, 7.259)	0.910
I-HD/-	7	36.29	35.43	-0.86	(-4.832, 3.118)	1.625
I-HD/M-PL	8	36.88	45.25	8.38	(1.439, 15.311)	2.933
I-HD/M-SD	14	42.25	49.63	7.37	(5.072, 9.672)	1.065
I-HD/M-HD	14	44.14	49.07	4.93	(2.188, 7.669)	1.269
I-SD + I-HD Total	70	40.63	45.14	4.51	(3.000, 6.025)	0.758
I-HD-OL	15	41.13	46.53	5.40	(2.269, 8.531)	1.460
I-HD-OL/-	2	41.50	36.50	-5.00		0.000
I-HD-OL/M-SD	7	44.00	49.86	5.86	(1.672, 10.042)	1.710
I-HD-OL/M-HD	6	37.67	46.00	8.33	(4.842, 11.824)	1.358
M-SD Total	28	42.88	49.21	6.33	(4.049, 8.609)	1.111
M-HD Total	29	40.84	46.59	5.74	(3.909, 7.578)	0.895
M-SD + M-HD Total	57	41.84	47.87	6.03	(4.617, 7.445)	0.706

表 2.7.3.6-92. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Social (Cont.)						
Week 26						
I-SD	19	41.26	48.68	7.42	(3.020, 11.822)	2.095
I-SD/M-PL	4	43.00	48.75	5.75	(-5.455, 16.955)	3.521
I-SD/M-SD	7	43.00	48.14	5.14	(-6.622, 16.907)	4.808
I-SD/M-HD	8	38.88	49.13	10.25	(5.063, 15.437)	2.194
I-HD	36	41.79	48.02	6.23	(4.043, 8.413)	1.076
I-HD/M-PL	8	36.88	44.75	7.88	(0.789, 14.961)	2.997
I-HD/M-SD	14	42.25	48.27	6.01	(2.911, 9.119)	1.437
I-HD/M-HD	14	44.14	49.64	5.50	(1.739, 9.261)	1.741
I-SD + I-HD Total	55	41.61	48.25	6.64	(4.632, 8.648)	1.001
I-HD-OL	13	41.08	48.85	7.77	(4.987, 10.551)	1.277
I-HD-OL/M-SD	7	44.00	50.57	6.57	(4.253, 8.890)	0.948
I-HD-OL/M-HD	6	37.67	46.83	9.17	(2.616, 15.718)	2.548
M-SD Total	28	42.88	48.81	5.94	(3.152, 8.720)	1.357
M-HD Total	28	41.25	48.89	7.64	(5.114, 10.172)	1.233
M-SD + M-HD Total	56	42.06	48.85	6.79	(4.955, 8.624)	0.915

表 2.7.3.6-92. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Social (Cont.)						
Week 52						
I-SD	19	41.26	50.00	8.74	(3.867, 13.607)	2.318
I-SD/M-PL	4	43.00	50.75	7.75	(-1.653, 17.153)	2.955
I-SD/M-SD	7	43.00	48.14	5.14	(-5.285, 15.571)	4.262
I-SD/M-HD	8	38.88	51.25	12.38	(3.607, 21.143)	3.708
I-HD	36	41.79	47.99	6.20	(4.067, 8.333)	1.051
I-HD/M-PL	8	36.88	45.00	8.13	(1.153, 15.097)	2.949
I-HD/M-SD	14	42.25	48.84	6.59	(3.239, 9.933)	1.549
I-HD/M-HD	14	44.14	48.86	4.71	(1.492, 7.936)	1.491
I-SD + I-HD Total	55	41.61	48.69	7.08	(4.960, 9.193)	1.056
I-HD-OL	13	41.08	48.69	7.62	(3.454, 11.777)	1.910
I-HD-OL/M-SD	7	44.00	49.86	5.86	(2.504, 9.210)	1.370
I-HD-OL/M-HD	6	37.67	47.33	9.67	(-0.215, 19.548)	3.844
M-SD Total	28	42.88	48.92	6.04	(3.364, 8.722)	1.306
M-HD Total	28	41.25	49.21	7.96	(4.678, 11.250)	1.601
M-SD + M-HD Total	56	42.06	49.07	7.00	(4.936, 9.072)	1.032

表 2.7.3.6-92. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Systemic						
Week 8						
I-SD	27	8.19	9.45	1.27	(-0.041, 2.579)	0.637
I-SD/-	7	6.86	6.29	-0.57	(-2.161, 1.018)	0.649
I-SD/M-PL	4	11.00	10.25	-0.75	(-3.468, 1.968)	0.854
I-SD/M-SD	7	7.86	10.89	3.04	(-0.402, 6.478)	1.406
I-SD/M-HD	9	8.22	10.44	2.22	(-0.570, 5.014)	1.211
I-HD	43	8.42	10.79	2.37	(1.479, 3.266)	0.443
I-HD/-	7	7.71	7.29	-0.43	(-3.196, 2.339)	1.131
I-HD/M-PL	8	8.38	11.25	2.88	(0.855, 4.895)	0.854
I-HD/M-SD	14	8.36	11.64	3.29	(1.938, 4.634)	0.624
I-HD/M-HD	14	8.86	11.43	2.57	(0.821, 4.321)	0.810
I-SD + I-HD Total	70	8.33	10.28	1.95	(1.210, 2.684)	0.369
I-HD-OL	15	8.40	10.40	2.00	(0.434, 3.566)	0.730
I-HD-OL/-	2	7.50	4.00	-3.50	(-9.853, 2.853)	0.500
I-HD-OL/M-SD	7	8.71	10.71	2.00	(0.311, 3.689)	0.690
I-HD-OL/M-HD	6	8.33	12.17	3.83	(2.289, 5.378)	0.601
M-SD Total	28	8.32	11.22	2.90	(1.896, 3.908)	0.490
M-HD Total	29	8.55	11.28	2.72	(1.597, 3.851)	0.550
M-SD + M-HD Total	57	8.44	11.25	2.81	(2.078, 3.545)	0.366

表 2.7.3.6-92. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Systemic (Cont.)						
Week 26						
I-SD	19	8.68	10.95	2.26	(0.855, 3.672)	0.670
I-SD/M-PL	4	11.00	11.00	0.00	(-3.898, 3.898)	1.225
I-SD/M-SD	7	7.86	10.14	2.29	(-1.079, 5.651)	1.375
I-SD/M-HD	8	8.25	11.63	3.38	(1.768, 4.982)	0.680
I-HD	36	8.56	11.28	2.72	(1.784, 3.661)	0.462
I-HD/M-PL	8	8.38	10.50	2.13	(0.056, 4.194)	0.875
I-HD/M-SD	14	8.36	11.71	3.36	(1.565, 5.149)	0.829
I-HD/M-HD	14	8.86	11.29	2.43	(0.897, 3.960)	0.709
I-SD + I-HD Total	55	8.60	11.16	2.56	(1.805, 3.323)	0.379
I-HD-OL	13	8.54	11.31	2.77	(0.971, 4.568)	0.826
I-HD-OL/M-SD	7	8.71	11.14	2.43	(-0.813, 5.670)	1.325
I-HD-OL/M-HD	6	8.33	11.50	3.17	(0.561, 5.773)	1.014
M-SD Total	28	8.32	11.18	2.86	(1.596, 4.118)	0.614
M-HD Total	28	8.57	11.43	2.86	(1.933, 3.781)	0.450
M-SD + M-HD Total	56	8.45	11.30	2.86	(2.101, 3.614)	0.377

表 2.7.3.6-92. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Systemic (Cont.)						
Week 52						
I-SD	19	8.68	11.21	2.53	(0.966, 4.087)	0.743
I-SD/M-PL	4	11.00	11.50	0.50	(-4.447, 5.447)	1.555
I-SD/M-SD	7	7.86	10.57	2.71	(-0.097, 5.525)	1.149
I-SD/M-HD	8	8.25	11.63	3.38	(0.516, 6.234)	1.209
I-HD	36	8.56	11.08	2.53	(1.566, 3.490)	0.474
I-HD/M-PL	8	8.38	10.75	2.38	(0.330, 4.420)	0.865
I-HD/M-SD	14	8.36	11.57	3.21	(1.457, 4.971)	0.813
I-HD/M-HD	14	8.86	10.79	1.93	(0.257, 3.600)	0.774
I-SD + I-HD Total	55	8.60	11.13	2.53	(1.728, 3.326)	0.399
I-HD-OL	13	8.54	10.92	2.38	(0.546, 4.223)	0.844
I-HD-OL/M-SD	7	8.71	11.14	2.43	(-0.179, 5.037)	1.066
I-HD-OL/M-HD	6	8.33	10.67	2.33	(-1.402, 6.068)	1.453
M-SD Total	28	8.32	11.21	2.89	(1.769, 4.016)	0.548
M-HD Total	28	8.57	11.00	2.43	(1.214, 3.643)	0.592
M-SD + M-HD Total	56	8.45	11.11	2.66	(1.858, 3.464)	0.401

表 2.7.3.6-92. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Treatment						
Week 8						
I-SD	27	10.4	11.1	0.7	(0.06, 1.42)	0.33
I-SD/-	7	9.1	9.6	0.4	(-1.49, 2.34)	0.78
I-SD/M-PL	4	12.5	11.8	-0.8	(-4.51, 3.01)	1.18
I-SD/M-SD	7	10.3	11.9	1.6	(0.67, 2.47)	0.37
I-SD/M-HD	9	10.4	11.4	1.0	(-0.02, 2.02)	0.44
I-HD	43	10.2	11.0	0.7	(-0.01, 1.45)	0.36
I-HD/-	7	8.3	7.4	-0.9	(-1.98, 0.27)	0.46
I-HD/M-PL	8	9.1	11.1	2.0	(-0.86, 4.86)	1.21
I-HD/M-SD	14	10.8	11.4	0.6	(-0.46, 1.74)	0.51
I-HD/M-HD	14	11.3	12.1	0.9	(-0.48, 2.19)	0.62
I-SD + I-HD Total	70	10.3	11.0	0.7	(0.22, 1.24)	0.26
I-HD-OL	15	10.5	11.3	0.9	(0.03, 1.70)	0.39
I-HD-OL/-	2	11.5	12.0	0.5	(-18.56, 19.56)	1.50
I-HD-OL/M-SD	7	10.7	11.1	0.4	(-1.16, 2.02)	0.65
I-HD-OL/M-HD	6	9.8	11.3	1.5	(0.40, 2.60)	0.43
M-SD Total	28	10.6	11.5	0.8	(0.17, 1.47)	0.32
M-HD Total	29	10.7	11.8	1.0	(0.35, 1.72)	0.33
M-SD + M-HD Total	57	10.7	11.6	0.9	(0.47, 1.39)	0.23

表 2.7.3.6-92. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Treatment (Cont.)						
Week 26						
I-SD	19	11.0	11.9	0.9	(0.03, 1.76)	0.41
I-SD/M-PL	4	12.5	13.3	0.8	(-0.77, 2.27)	0.48
I-SD/M-SD	7	10.3	11.0	0.7	(-1.26, 2.69)	0.81
I-SD/M-HD	8	10.9	12.0	1.1	(-0.51, 2.76)	0.69
I-HD	36	10.6	11.6	1.0	(0.08, 1.86)	0.44
I-HD/M-PL	8	9.1	11.3	2.1	(-1.02, 5.27)	1.33
I-HD/M-SD	14	10.8	11.6	0.8	(-0.48, 2.05)	0.59
I-HD/M-HD	14	11.3	11.8	0.5	(-0.80, 1.80)	0.60
I-SD + I-HD Total	55	10.7	11.7	0.9	(0.31, 1.58)	0.32
I-HD-OL	13	10.3	11.9	1.6	(0.19, 3.04)	0.66
I-HD-OL/M-SD	7	10.7	12.7	2.0	(-0.77, 4.77)	1.13
I-HD-OL/M-HD	6	9.8	11.0	1.2	(-0.38, 2.71)	0.60
M-SD Total	28	10.6	11.7	1.1	(0.15, 1.99)	0.45
M-HD Total	28	10.9	11.7	0.8	(0.05, 1.59)	0.37
M-SD + M-HD Total	56	10.8	11.7	0.9	(0.37, 1.53)	0.29

表 2.7.3.6-92. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Treatment (Cont.)						
Week 52						
I-SD	19	11.0	12.0	1.0	(0.02, 1.98)	0.47
I-SD/M-PL	4	12.5	13.5	1.0	(-1.25, 3.25)	0.71
I-SD/M-SD	7	10.3	10.9	0.6	(-1.02, 2.16)	0.65
I-SD/M-HD	8	10.9	12.3	1.4	(-0.81, 3.56)	0.92
I-HD	36	10.6	11.5	0.9	(0.07, 1.70)	0.40
I-HD/M-PL	8	9.1	10.9	1.8	(-0.77, 4.27)	1.06
I-HD/M-SD	14	10.8	11.7	0.9	(-0.26, 2.12)	0.55
I-HD/M-HD	14	11.3	11.6	0.4	(-1.03, 1.75)	0.64
I-SD + I-HD Total	55	10.7	11.7	0.9	(0.31, 1.54)	0.31
I-HD-OL	13	10.3	11.7	1.4	(0.02, 2.75)	0.63
I-HD-OL/M-SD	7	10.7	11.9	1.1	(-1.33, 3.61)	1.01
I-HD-OL/M-HD	6	9.8	11.5	1.7	(-0.29, 3.62)	0.76
M-SD Total	28	10.6	11.5	0.9	(0.09, 1.70)	0.39
M-HD Total	28	10.9	11.8	0.9	(0.02, 1.84)	0.45
M-SD + M-HD Total	56	10.8	11.7	0.9	(0.32, 1.50)	0.29

表 2.7.3.6-92. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III Total						
Week 8						
I-SD	27	110.88	123.31	12.42	(4.163, 20.682)	4.018
I-SD/-	7	105.27	104.43	-0.84	(-14.535, 12.854)	5.597
I-SD/M-PL	4	126.50	136.00	9.50	(1.232, 17.768)	2.598
I-SD/M-SD	7	112.71	132.32	19.61	(-6.687, 45.905)	10.747
I-SD/M-HD	9	106.89	125.33	18.45	(3.237, 33.658)	6.596
I-HD	43	110.78	128.09	17.31	(11.783, 22.831)	2.737
I-HD/-	7	93.14	89.14	-4.00	(-11.920, 3.920)	3.237
I-HD/M-PL	8	102.50	129.50	27.00	(6.352, 47.648)	8.732
I-HD/M-SD	14	113.18	136.27	23.09	(16.264, 29.908)	3.158
I-HD/M-HD	14	121.93	138.57	16.64	(8.472, 24.813)	3.782
I-SD + I-HD Total	70	110.82	126.24	15.42	(10.861, 19.985)	2.287
I-HD-OL	15	107.40	127.07	19.67	(8.846, 30.488)	5.045
I-HD-OL/-	2	104.50	91.00	-13.50	(-32.559, 5.559)	1.500
I-HD-OL/M-SD	7	112.00	131.43	19.43	(3.844, 35.013)	6.369
I-HD-OL/M-HD	6	103.00	134.00	31.00	(18.888, 43.112)	4.712
M-SD Total	28	112.77	134.07	21.30	(14.439, 28.166)	3.345
M-HD Total	29	113.34	133.52	20.17	(14.029, 26.318)	3.000
M-SD + M-HD Total	57	113.06	133.79	20.73	(16.274, 25.183)	2.224

表 2.7.3.6-92. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III Total (Cont.)						
Week 26						
I-SD	19	114.29	138.79	24.50	(12.122, 36.874)	5.891
I-SD/M-PL	4	126.50	144.00	17.50	(-10.920, 45.920)	8.930
I-SD/M-SD	7	112.71	132.00	19.29	(-13.784, 52.356)	13.515
I-SD/M-HD	8	109.57	142.13	32.56	(17.295, 47.823)	6.455
I-HD	36	114.21	135.80	21.59	(14.893, 28.285)	3.299
I-HD/M-PL	8	102.50	127.25	24.75	(2.772, 46.728)	9.294
I-HD/M-SD	14	113.18	135.05	21.87	(11.037, 32.707)	5.015
I-HD/M-HD	14	121.93	141.43	19.50	(9.182, 29.818)	4.776
I-SD + I-HD Total	55	114.24	136.83	22.59	(16.699, 28.490)	2.941
I-HD-OL	13	107.85	135.00	27.15	(16.155, 38.153)	5.048
I-HD-OL/M-SD	7	112.00	135.14	23.14	(7.905, 38.381)	6.228
I-HD-OL/M-HD	6	103.00	134.83	31.83	(10.312, 53.355)	8.372
M-SD Total	28	112.77	134.31	21.54	(12.734, 30.352)	4.293
M-HD Total	28	114.34	140.21	25.87	(18.514, 33.234)	3.587
M-SD + M-HD Total	56	113.56	137.26	23.71	(18.123, 29.294)	2.787

表 2.7.3.6-92. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III Total (Cont.)						
Week 52						
I-SD	19	114.29	139.98	25.68	(11.614, 39.754)	6.697
I-SD/M-PL	4	126.50	146.50	20.00	(-11.100, 51.100)	9.772
I-SD/M-SD	7	112.71	131.29	18.57	(-8.780, 45.923)	11.178
I-SD/M-HD	8	109.57	144.32	34.75	(6.836, 62.664)	11.805
I-HD	36	114.21	135.05	20.84	(13.875, 27.803)	3.430
I-HD/M-PL	8	102.50	128.13	25.63	(4.045, 47.205)	9.126
I-HD/M-SD	14	113.18	138.20	25.01	(14.016, 36.013)	5.091
I-HD/M-HD	14	121.93	135.86	13.93	(3.366, 24.491)	4.889
I-SD + I-HD Total	55	114.24	136.75	22.51	(16.092, 28.933)	3.202
I-HD-OL	13	107.85	134.77	26.92	(15.024, 38.822)	5.461
I-HD-OL/M-SD	7	112.00	135.57	23.57	(14.218, 32.925)	3.823
I-HD-OL/M-HD	6	103.00	133.83	30.83	(1.642, 60.025)	11.356
M-SD Total	28	112.77	135.81	23.04	(15.297, 30.789)	3.775
M-HD Total	28	114.34	137.84	23.50	(13.311, 33.689)	4.966
M-SD + M-HD Total	56	113.56	136.83	23.27	(17.078, 29.465)	3.091

Note: I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group, M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
Note: baseline is defined as the last non-missing value prior to the first dose of study drug. Subjects with non-missing baseline and at least one post-baseline value are included in the analyses.
Last observation carried forward (LOCF): missing data is imputed by carrying forward the last non-missing post-baseline observation. For subjects re-randomized due to disease flare, the last non-missing value before the re-randomization after the first disease flare are carried forward.

Cross reference: M11-290 Main-study CSR_Interim Table 14.2__1.3.7

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%)						
Week 1						
I-SD	30	42.0	30.7	-11.3	(-17.67, -5.00)	3.10
I-SD/-	8	45.0	42.5	-2.5	(-11.15, 6.15)	3.66
I-SD/M-PL	4	60.0	37.5	-22.5	(-55.30, 10.30)	10.31
I-SD/M-SD	8	25.0	18.8	-6.3	(-21.03, 8.53)	6.25
I-SD/M-HD	10	46.0	28.0	-18.0	(-29.58, -6.42)	5.12
I-HD	45	47.6	37.8	-9.8	(-15.73, -3.82)	2.96
I-HD/-	8	58.8	48.8	-10.0	(-25.48, 5.48)	6.55
I-HD/M-PL	7	52.9	42.9	-10.0	(-20.68, 0.68)	4.36
I-HD/M-SD	15	47.3	38.0	-9.3	(-24.92, 6.26)	7.27
I-HD/M-HD	15	39.3	29.3	-10.0	(-18.11, -1.89)	3.78
I-SD + I-HD Total	75	45.3	34.9	-10.4	(-14.69, -6.11)	2.15
I-HD-OL	14	53.6	45.7	-7.9	(-22.74, 7.02)	6.89
I-HD-OL/-	2	50.0	55.0	5.0	(-58.53, 68.53)	5.00
I-HD-OL/M-SD	6	40.0	43.3	3.3	(-24.56, 31.23)	10.85
I-HD-OL/M-HD	6	68.3	45.0	-23.3	(-46.96, 0.29)	9.19
M-SD Total	29	39.7	33.8	-5.9	(-15.37, 3.65)	4.64
M-HD Total	31	47.1	31.9	-15.2	(-21.43, -8.89)	3.07
M-SD + M-HD Total	60	43.5	32.8	-10.7	(-16.25, -5.08)	2.79

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 2						
I-SD	30	42.0	26.0	-16.0	(-24.64, -7.36)	4.22
I-SD/-	8	45.0	37.5	-7.5	(-19.94, 4.94)	5.26
I-SD/M-PL	4	60.0	40.0	-20.0	(-49.05, 9.05)	9.13
I-SD/M-SD	8	25.0	20.0	-5.0	(-19.82, 9.82)	6.27
I-SD/M-HD	10	46.0	16.0	-30.0	(-50.23, -9.77)	8.94
I-HD	46	48.0	30.4	-17.6	(-23.65, -11.57)	3.00
I-HD/-	8	58.8	41.3	-17.5	(-29.11, -5.89)	4.91
I-HD/M-PL	7	52.9	28.6	-24.3	(-48.08, -0.49)	9.72
I-HD/M-SD	16	48.8	33.1	-15.6	(-28.96, -2.29)	6.26
I-HD/M-HD	15	39.3	22.7	-16.7	(-25.46, -7.87)	4.10
I-SD + I-HD Total	76	45.7	28.7	-17.0	(-21.85, -12.09)	2.45
I-HD-OL	15	54.7	32.7	-22.0	(-40.74, -3.26)	8.74
I-HD-OL/-	2	50.0	45.0	-5.0	(-195.59, 185.59)	15.00
I-HD-OL/M-SD	6	40.0	28.3	-11.7	(-56.40, 33.06)	17.40
I-HD-OL/M-HD	7	68.6	32.9	-35.7	(-59.51, -11.92)	9.72
M-SD Total	30	40.7	28.7	-12.0	(-22.12, -1.88)	4.95
M-HD Total	32	47.8	22.8	-25.0	(-33.39, -16.61)	4.12
M-SD + M-HD Total	62	44.4	25.6	-18.7	(-25.27, -12.15)	3.28

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 4						
I-SD	30	42.0	27.7	-14.3	(-21.91, -6.76)	3.70
I-SD/-	8	45.0	42.5	-2.5	(-13.22, 8.22)	4.53
I-SD/M-PL	4	60.0	32.5	-27.5	(-62.78, 7.78)	11.09
I-SD/M-SD	8	25.0	18.8	-6.3	(-18.02, 5.52)	4.98
I-SD/M-HD	10	46.0	21.0	-25.0	(-40.91, -9.09)	7.03
I-HD	46	48.0	25.4	-22.6	(-29.04, -16.18)	3.19
I-HD/-	8	58.8	25.0	-33.8	(-49.82, -17.68)	6.80
I-HD/M-PL	7	52.9	28.6	-24.3	(-44.16, -4.41)	8.12
I-HD/M-SD	16	48.8	27.5	-21.3	(-34.57, -7.93)	6.25
I-HD/M-HD	15	39.3	22.0	-17.3	(-27.69, -6.98)	4.83
I-SD + I-HD Total	76	45.7	26.3	-19.3	(-24.23, -14.46)	2.45
I-HD-OL	16	53.1	32.5	-20.6	(-43.27, 2.02)	10.63
I-HD-OL/-	2	50.0	40.0	-10.0	(-518.25, 498.25)	40.00
I-HD-OL/M-SD	7	38.6	38.6	0.0	(-32.04, 32.04)	13.09
I-HD-OL/M-HD	7	68.6	24.3	-44.3	(-81.22, -7.35)	15.10
M-SD Total	31	40.3	27.7	-12.6	(-22.19, -2.97)	4.71
M-HD Total	32	47.8	22.2	-25.6	(-35.31, -15.94)	4.75
M-SD + M-HD Total	63	44.1	24.9	-19.2	(-26.04, -12.37)	3.42

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 8						
I-SD	30	42.0	31.7	-10.3	(-21.23, 0.56)	5.33
I-SD/-	8	45.0	55.0	10.0	(-2.64, 22.64)	5.35
I-SD/M-PL	4	60.0	25.0	-35.0	(-55.54, -14.46)	6.45
I-SD/M-SD	8	25.0	22.5	-2.5	(-28.07, 23.07)	10.82
I-SD/M-HD	10	46.0	23.0	-23.0	(-44.61, -1.39)	9.55
I-HD	46	48.0	25.4	-22.6	(-29.65, -15.57)	3.50
I-HD/-	8	58.8	50.0	-8.8	(-36.09, 18.59)	11.56
I-HD/M-PL	7	52.9	24.3	-28.6	(-43.12, -14.02)	5.95
I-HD/M-SD	16	48.8	24.4	-24.4	(-37.42, -11.33)	6.12
I-HD/M-HD	15	39.3	14.0	-25.3	(-36.18, -14.48)	5.06
I-SD + I-HD Total	76	45.7	27.9	-17.8	(-23.82, -11.70)	3.04
I-HD-OL	16	53.1	37.5	-15.6	(-37.29, 6.04)	10.16
I-HD-OL/-	2	50.0	85.0	35.0	(-28.53, 98.53)	5.00
I-HD-OL/M-SD	7	38.6	25.7	-12.9	(-50.88, 25.17)	15.54
I-HD-OL/M-HD	7	68.6	35.7	-32.9	(-65.21, -0.50)	13.22
M-SD Total	31	40.3	24.2	-16.1	(-27.40, -4.86)	5.52
M-HD Total	32	47.8	21.6	-26.3	(-35.71, -16.79)	4.64
M-SD + M-HD Total	63	44.1	22.9	-21.3	(-28.51, -14.03)	3.62

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 12						
I-SD	21	39.0	21.4	-17.6	(-32.22, -3.02)	7.00
I-SD/M-PL	4	60.0	37.5	-22.5	(-55.30, 10.30)	10.31
I-SD/M-SD	8	25.0	20.0	-5.0	(-32.91, 22.91)	11.80
I-SD/M-HD	9	42.2	15.6	-26.7	(-53.02, -0.32)	11.43
I-HD	39	44.6	19.2	-25.4	(-34.52, -16.25)	4.51
I-HD/M-PL	8	46.3	16.3	-30.0	(-49.98, -10.02)	8.45
I-HD/M-SD	16	48.8	25.6	-23.1	(-42.75, -3.50)	9.21
I-HD/M-HD	15	39.3	14.0	-25.3	(-36.38, -14.28)	5.15
I-SD + I-HD Total	60	42.7	20.0	-22.7	(-30.30, -15.03)	3.82
I-HD-OL	14	53.6	32.9	-20.7	(-45.05, 3.62)	11.26
I-HD-OL/M-SD	7	38.6	41.4	2.9	(-31.63, 37.34)	14.09
I-HD-OL/M-HD	7	68.6	24.3	-44.3	(-75.81, -12.76)	12.88
M-SD Total	31	40.3	27.7	-12.6	(-26.04, 0.88)	6.59
M-HD Total	31	46.8	16.8	-30.0	(-40.33, -19.67)	5.06
M-SD + M-HD Total	62	43.5	22.3	-21.3	(-29.82, -12.76)	4.27

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 18						
I-SD	21	39.0	18.1	-21.0	(-34.52, -7.38)	6.51
I-SD/M-PL	4	60.0	22.5	-37.5	(-61.37, -13.63)	7.50
I-SD/M-SD	8	25.0	21.3	-3.8	(-28.20, 20.70)	10.34
I-SD/M-HD	9	42.2	13.3	-28.9	(-51.77, -6.01)	9.92
I-HD	39	44.6	19.2	-25.4	(-33.04, -17.73)	3.78
I-HD/M-PL	8	46.3	23.8	-22.5	(-45.61, 0.61)	9.77
I-HD/M-SD	16	48.8	24.4	-24.4	(-38.54, -10.21)	6.64
I-HD/M-HD	15	39.3	11.3	-28.0	(-38.51, -17.49)	4.90
I-SD + I-HD Total	60	42.7	18.8	-23.8	(-30.49, -17.17)	3.33
I-HD-OL	14	53.6	27.1	-26.4	(-50.03, -2.83)	10.92
I-HD-OL/M-SD	7	38.6	28.6	-10.0	(-49.96, 29.96)	16.33
I-HD-OL/M-HD	7	68.6	25.7	-42.9	(-73.86, -11.85)	12.67
M-SD Total	31	40.3	24.5	-15.8	(-27.47, -4.14)	5.71
M-HD Total	31	46.8	15.2	-31.6	(-41.09, -22.14)	4.64
M-SD + M-HD Total	62	43.5	19.8	-23.7	(-31.28, -16.14)	3.79

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 26						
I-SD	21	39.0	16.7	-22.4	(-36.70, -8.07)	6.86
I-SD/M-PL	4	60.0	25.0	-35.0	(-55.54, -14.46)	6.45
I-SD/M-SD	8	25.0	25.0	0.0	(-24.06, 24.06)	10.18
I-SD/M-HD	9	42.2	5.6	-36.7	(-59.40, -13.93)	9.86
I-HD	39	44.6	19.5	-25.1	(-32.89, -17.37)	3.83
I-HD/M-PL	8	46.3	20.0	-26.3	(-50.70, -1.80)	10.34
I-HD/M-SD	16	48.8	26.3	-22.5	(-36.33, -8.67)	6.49
I-HD/M-HD	15	39.3	12.0	-27.3	(-38.30, -16.36)	5.11
I-SD + I-HD Total	60	42.7	18.5	-24.2	(-31.03, -17.30)	3.43
I-HD-OL	14	53.6	26.4	-27.1	(-52.81, -1.48)	11.88
I-HD-OL/M-SD	7	38.6	30.0	-8.6	(-51.10, 33.95)	17.38
I-HD-OL/M-HD	7	68.6	22.9	-45.7	(-79.84, -11.58)	13.95
M-SD Total	31	40.3	26.8	-13.5	(-25.44, -1.66)	5.82
M-HD Total	31	46.8	12.6	-34.2	(-44.21, -24.18)	4.90
M-SD + M-HD Total	62	43.5	19.7	-23.9	(-31.87, -15.88)	4.00

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 34						
I-SD	21	39.0	15.7	-23.3	(-36.47, -10.19)	6.30
I-SD/M-PL	4	60.0	25.0	-35.0	(-55.54, -14.46)	6.45
I-SD/M-SD	8	25.0	23.8	-1.3	(-17.63, 15.13)	6.93
I-SD/M-HD	9	42.2	4.4	-37.8	(-60.77, -14.79)	9.97
I-HD	39	44.6	18.5	-26.2	(-34.25, -18.05)	4.00
I-HD/M-PL	8	46.3	20.0	-26.3	(-50.70, -1.80)	10.34
I-HD/M-SD	16	48.8	23.8	-25.0	(-40.20, -9.80)	7.13
I-HD/M-HD	15	39.3	12.0	-27.3	(-38.30, -16.36)	5.11
I-SD + I-HD Total	60	42.7	17.5	-25.2	(-31.93, -18.40)	3.38
I-HD-OL	14	53.6	24.3	-29.3	(-54.24, -4.33)	11.55
I-HD-OL/M-SD	7	38.6	27.1	-11.4	(-51.18, 28.32)	16.25
I-HD-OL/M-HD	7	68.6	21.4	-47.1	(-82.45, -11.84)	14.43
M-SD Total	31	40.3	24.5	-15.8	(-27.24, -4.37)	5.60
M-HD Total	31	46.8	11.9	-34.8	(-45.08, -24.60)	5.01
M-SD + M-HD Total	62	43.5	18.2	-25.3	(-33.16, -17.48)	3.92

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 42						
I-SD	21	39.0	14.3	-24.8	(-39.56, -9.97)	7.09
I-SD/M-PL	4	60.0	12.5	-47.5	(-87.28, -7.72)	12.50
I-SD/M-SD	8	25.0	23.8	-1.3	(-17.63, 15.13)	6.93
I-SD/M-HD	9	42.2	6.7	-35.6	(-61.37, -9.74)	11.19
I-HD	39	44.6	17.7	-26.9	(-34.69, -19.15)	3.84
I-HD/M-PL	8	46.3	20.0	-26.3	(-50.70, -1.80)	10.34
I-HD/M-SD	16	48.8	22.5	-26.3	(-40.53, -11.97)	6.70
I-HD/M-HD	15	39.3	11.3	-28.0	(-38.51, -17.49)	4.90
I-SD + I-HD Total	60	42.7	16.5	-26.2	(-33.14, -19.19)	3.49
I-HD-OL	14	53.6	19.3	-34.3	(-53.99, -14.58)	9.12
I-HD-OL/M-SD	7	38.6	18.6	-20.0	(-48.25, 8.25)	11.55
I-HD-OL/M-HD	7	68.6	20.0	-48.6	(-79.44, -17.70)	12.62
M-SD Total	31	40.3	21.9	-18.4	(-28.41, -8.36)	4.91
M-HD Total	31	46.8	11.9	-34.8	(-44.95, -24.73)	4.95
M-SD + M-HD Total	62	43.5	16.9	-26.6	(-33.84, -19.39)	3.61

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 52						
I-SD	21	39.0	12.9	-26.2	(-41.04, -11.34)	7.12
I-SD/M-PL	4	60.0	10.0	-50.0	(-88.98, -11.02)	12.25
I-SD/M-SD	8	25.0	22.5	-2.5	(-21.85, 16.85)	8.18
I-SD/M-HD	9	42.2	5.6	-36.7	(-60.97, -12.36)	10.54
I-HD	39	44.6	19.0	-25.6	(-34.08, -17.20)	4.17
I-HD/M-PL	8	46.3	20.0	-26.3	(-50.70, -1.80)	10.34
I-HD/M-SD	16	48.8	20.6	-28.1	(-44.66, -11.59)	7.76
I-HD/M-HD	15	39.3	16.7	-22.7	(-33.23, -12.10)	4.92
I-SD + I-HD Total	60	42.7	16.8	-25.8	(-33.13, -18.54)	3.65
I-HD-OL	14	53.6	20.0	-33.6	(-55.60, -11.54)	10.20
I-HD-OL/M-SD	7	38.6	21.4	-17.1	(-49.93, 15.65)	13.40
I-HD-OL/M-HD	7	68.6	18.6	-50.0	(-82.92, -17.08)	13.45
M-SD Total	31	40.3	21.3	-19.0	(-30.49, -7.57)	5.61
M-HD Total	31	46.8	13.9	-32.9	(-43.37, -22.43)	5.13
M-SD + M-HD Total	62	43.5	17.6	-26.0	(-33.71, -18.23)	3.87

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%)						
Week 1						
I-SD	20	44.5	37.0	-7.5	(-16.47, 1.47)	4.28
I-SD/-	5	58.0	48.0	-10.0	(-22.42, 2.42)	4.47
I-SD/M-PL	3	53.3	43.3	-10.0	(-75.72, 55.72)	15.28
I-SD/M-SD	4	42.5	32.5	-10.0	(-44.37, 24.37)	10.80
I-SD/M-HD	8	33.8	30.0	-3.8	(-22.68, 15.18)	8.00
I-HD	28	44.6	31.1	-13.6	(-25.09, -2.05)	5.62
I-HD/-	4	60.0	45.0	-15.0	(-89.07, 59.07)	23.27
I-HD/M-PL	6	50.0	46.7	-3.3	(-8.75, 2.09)	2.11
I-HD/M-SD	10	47.0	25.0	-22.0	(-48.72, 4.72)	11.81
I-HD/M-HD	8	30.0	20.0	-10.0	(-27.87, 7.87)	7.56
I-SD + I-HD Total	48	44.6	33.5	-11.0	(-18.53, -3.55)	3.72
I-HD-OL	6	38.3	36.7	-1.7	(-13.94, 10.60)	4.77
I-HD-OL/-	1	50.0	60.0	10.0		0.00
I-HD-OL/M-SD	1	0.0	10.0	10.0		0.00
I-HD-OL/M-HD	4	45.0	37.5	-7.5	(-22.73, 7.73)	4.79
M-SD Total	15	42.7	26.0	-16.7	(-34.87, 1.54)	8.49
M-HD Total	20	34.5	27.5	-7.0	(-16.12, 2.12)	4.36
M-SD + M-HD Total	35	38.0	26.9	-11.1	(-20.11, -2.18)	4.41

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 2						
I-SD	20	44.5	29.5	-15.0	(-23.66, -6.34)	4.14
I-SD/-	5	58.0	42.0	-16.0	(-30.16, -1.84)	5.10
I-SD/M-PL	3	53.3	40.0	-13.3	(-70.70, 44.04)	13.33
I-SD/M-SD	4	42.5	25.0	-17.5	(-57.28, 22.28)	12.50
I-SD/M-HD	8	33.8	20.0	-13.8	(-31.02, 3.52)	7.30
I-HD	29	45.5	24.1	-21.4	(-30.85, -11.91)	4.62
I-HD/-	4	60.0	30.0	-30.0	(-48.37, -11.63)	5.77
I-HD/M-PL	6	50.0	28.3	-21.7	(-49.37, 6.03)	10.78
I-HD/M-SD	11	49.1	24.5	-24.5	(-45.87, -3.22)	9.57
I-HD/M-HD	8	30.0	17.5	-12.5	(-27.82, 2.82)	6.48
I-SD + I-HD Total	49	45.1	26.3	-18.8	(-25.24, -12.31)	3.22
I-HD-OL	6	38.3	33.3	-5.0	(-24.63, 14.63)	7.64
I-HD-OL/-	1	50.0	60.0	10.0		0.00
I-HD-OL/M-SD	1	0.0	20.0	20.0		0.00
I-HD-OL/M-HD	4	45.0	30.0	-15.0	(-35.54, 5.54)	6.45
M-SD Total	16	44.4	24.4	-20.0	(-36.16, -3.84)	7.58
M-HD Total	20	34.5	21.0	-13.5	(-21.72, -5.28)	3.93
M-SD + M-HD Total	36	38.9	22.5	-16.4	(-24.48, -8.29)	3.99

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 4						
I-SD	20	44.5	28.5	-16.0	(-27.50, -4.50)	5.50
I-SD/-	5	58.0	46.0	-12.0	(-28.19, 4.19)	5.83
I-SD/M-PL	3	53.3	43.3	-10.0	(-99.57, 79.57)	20.82
I-SD/M-SD	4	42.5	20.0	-22.5	(-52.62, 7.62)	9.46
I-SD/M-HD	8	33.8	16.3	-17.5	(-43.46, 8.46)	10.98
I-HD	29	45.5	21.4	-24.1	(-34.53, -13.74)	5.07
I-HD/-	4	60.0	25.0	-35.0	(-72.88, 2.88)	11.90
I-HD/M-PL	6	50.0	30.0	-20.0	(-51.13, 11.13)	12.11
I-HD/M-SD	11	49.1	19.1	-30.0	(-51.03, -8.97)	9.44
I-HD/M-HD	8	30.0	16.3	-13.8	(-31.59, 4.09)	7.54
I-SD + I-HD Total	49	45.1	24.3	-20.8	(-28.37, -13.27)	3.76
I-HD-OL	7	37.1	27.1	-10.0	(-32.02, 12.02)	9.00
I-HD-OL/-	1	50.0	80.0	30.0		0.00
I-HD-OL/M-SD	2	15.0	10.0	-5.0	(-195.59, 185.59)	15.00
I-HD-OL/M-HD	4	45.0	22.5	-22.5	(-46.37, 1.37)	7.50
M-SD Total	17	43.5	18.2	-25.3	(-39.62, -10.97)	6.76
M-HD Total	20	34.5	17.5	-17.0	(-28.17, -5.83)	5.34
M-SD + M-HD Total	37	38.6	17.8	-20.8	(-29.40, -12.22)	4.23

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 8						
I-SD	20	44.5	26.0	-18.5	(-29.58, -7.42)	5.30
I-SD/-	5	58.0	54.0	-4.0	(-15.11, 7.11)	4.00
I-SD/M-PL	3	53.3	26.7	-26.7	(-89.18, 35.85)	14.53
I-SD/M-SD	4	42.5	15.0	-27.5	(-75.02, 20.02)	14.93
I-SD/M-HD	8	33.8	13.8	-20.0	(-41.89, 1.89)	9.26
I-HD	29	45.5	18.6	-26.9	(-36.71, -17.09)	4.79
I-HD/-	4	60.0	35.0	-25.0	(-77.77, 27.77)	16.58
I-HD/M-PL	6	50.0	26.7	-23.3	(-51.23, 4.56)	10.85
I-HD/M-SD	11	49.1	13.6	-35.5	(-54.54, -16.37)	8.57
I-HD/M-HD	8	30.0	11.3	-18.8	(-33.86, -3.64)	6.39
I-SD + I-HD Total	49	45.1	21.6	-23.5	(-30.66, -16.28)	3.58
I-HD-OL	7	37.1	30.0	-7.1	(-27.63, 13.34)	8.37
I-HD-OL/-	1	50.0	80.0	30.0		0.00
I-HD-OL/M-SD	2	15.0	5.0	-10.0	(-264.12, 244.12)	20.00
I-HD-OL/M-HD	4	45.0	30.0	-15.0	(-35.54, 5.54)	6.45
M-SD Total	17	43.5	12.9	-30.6	(-45.07, -16.11)	6.83
M-HD Total	20	34.5	16.0	-18.5	(-27.89, -9.11)	4.49
M-SD + M-HD Total	37	38.6	14.6	-24.1	(-32.24, -15.87)	4.04

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 12						
I-SD	15	40.0	17.3	-22.7	(-39.60, -5.73)	7.90
I-SD/M-PL	3	53.3	36.7	-16.7	(-88.38, 55.04)	16.67
I-SD/M-SD	4	42.5	10.0	-32.5	(-74.35, 9.35)	13.15
I-SD/M-HD	8	33.8	13.8	-20.0	(-49.64, 9.64)	12.54
I-HD	26	41.5	17.3	-24.2	(-37.01, -11.45)	6.21
I-HD/M-PL	7	42.9	21.4	-21.4	(-47.82, 4.96)	10.79
I-HD/M-SD	11	49.1	17.3	-31.8	(-57.28, -6.36)	11.43
I-HD/M-HD	8	30.0	13.8	-16.3	(-37.65, 5.15)	9.05
I-SD + I-HD Total	41	41.0	17.3	-23.7	(-33.41, -13.91)	4.82
I-HD-OL	7	41.4	30.0	-11.4	(-23.87, 1.01)	5.08
I-HD-OL/M-SD	3	36.7	33.3	-3.3	(-41.28, 34.61)	8.82
I-HD-OL/M-HD	4	45.0	27.5	-17.5	(-32.73, -2.27)	4.79
M-SD Total	18	45.6	18.3	-27.2	(-43.83, -10.61)	7.87
M-HD Total	20	34.5	16.5	-18.0	(-30.58, -5.42)	6.01
M-SD + M-HD Total	38	39.7	17.4	-22.4	(-32.26, -12.48)	4.88

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 18						
I-SD	15	40.0	16.0	-24.0	(-42.46, -5.54)	8.61
I-SD/M-PL	3	53.3	20.0	-33.3	(-85.04, 18.38)	12.02
I-SD/M-SD	4	42.5	20.0	-22.5	(-87.95, 42.95)	20.56
I-SD/M-HD	8	33.8	12.5	-21.3	(-51.70, 9.20)	12.88
I-HD	26	41.5	15.8	-25.8	(-37.43, -14.11)	5.66
I-HD/M-PL	7	42.9	25.7	-17.1	(-45.76, 11.47)	11.69
I-HD/M-SD	11	49.1	14.5	-34.5	(-54.56, -14.53)	8.98
I-HD/M-HD	8	30.0	8.8	-21.3	(-42.88, 0.38)	9.15
I-SD + I-HD Total	41	41.0	15.9	-25.1	(-34.65, -15.60)	4.71
I-HD-OL	7	41.4	20.0	-21.4	(-49.39, 6.54)	11.43
I-HD-OL/M-SD	3	36.7	6.7	-30.0	(-143.84, 83.84)	26.46
I-HD-OL/M-HD	4	45.0	30.0	-15.0	(-42.56, 12.56)	8.66
M-SD Total	18	45.6	14.4	-31.1	(-47.55, -14.67)	7.79
M-HD Total	20	34.5	14.5	-20.0	(-33.15, -6.85)	6.28
M-SD + M-HD Total	38	39.7	14.5	-25.3	(-35.34, -15.19)	4.97

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 26						
I-SD	15	40.0	14.0	-26.0	(-43.86, -8.14)	8.33
I-SD/M-PL	3	53.3	20.0	-33.3	(-71.28, 4.61)	8.82
I-SD/M-SD	4	42.5	25.0	-17.5	(-82.95, 47.95)	20.56
I-SD/M-HD	8	33.8	6.3	-27.5	(-56.72, 1.72)	12.36
I-HD	26	41.5	17.3	-24.2	(-38.00, -10.47)	6.68
I-HD/M-PL	7	42.9	20.0	-22.9	(-48.31, 2.59)	10.40
I-HD/M-SD	11	49.1	21.8	-27.3	(-57.03, 2.48)	13.35
I-HD/M-HD	8	30.0	8.8	-21.3	(-42.88, 0.38)	9.15
I-SD + I-HD Total	41	41.0	16.1	-24.9	(-35.30, -14.45)	5.16
I-HD-OL	7	41.4	15.7	-25.7	(-55.38, 3.95)	12.12
I-HD-OL/M-SD	3	36.7	6.7	-30.0	(-143.84, 83.84)	26.46
I-HD-OL/M-HD	4	45.0	22.5	-22.5	(-62.28, 17.28)	12.50
M-SD Total	18	45.6	20.0	-25.6	(-46.18, -4.93)	9.78
M-HD Total	20	34.5	10.5	-24.0	(-37.27, -10.73)	6.34
M-SD + M-HD Total	38	39.7	15.0	-24.7	(-36.14, -13.33)	5.63

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 34						
I-SD	15	40.0	15.3	-24.7	(-43.02, -6.32)	8.56
I-SD/M-PL	3	53.3	20.0	-33.3	(-71.28, 4.61)	8.82
I-SD/M-SD	4	42.5	27.5	-15.0	(-80.61, 50.61)	20.62
I-SD/M-HD	8	33.8	7.5	-26.3	(-56.54, 4.04)	12.81
I-HD	26	41.5	17.3	-24.2	(-38.14, -10.32)	6.75
I-HD/M-PL	7	42.9	20.0	-22.9	(-48.31, 2.59)	10.40
I-HD/M-SD	11	49.1	21.8	-27.3	(-57.48, 2.93)	13.56
I-HD/M-HD	8	30.0	8.8	-21.3	(-42.88, 0.38)	9.15
I-SD + I-HD Total	41	41.0	16.6	-24.4	(-34.98, -13.80)	5.24
I-HD-OL	7	41.4	18.6	-22.9	(-44.02, -1.69)	8.65
I-HD-OL/M-SD	3	36.7	13.3	-23.3	(-110.57, 63.91)	20.28
I-HD-OL/M-HD	4	45.0	22.5	-22.5	(-46.37, 1.37)	7.50
M-SD Total	18	45.6	21.7	-23.9	(-44.15, -3.63)	9.60
M-HD Total	20	34.5	11.0	-23.5	(-36.50, -10.50)	6.21
M-SD + M-HD Total	38	39.7	16.1	-23.7	(-34.87, -12.49)	5.52

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 42						
I-SD	15	40.0	12.7	-27.3	(-47.13, -7.54)	9.23
I-SD/M-PL	3	53.3	6.7	-46.7	(-109.18, 15.85)	14.53
I-SD/M-SD	4	42.5	25.0	-17.5	(-82.95, 47.95)	20.56
I-SD/M-HD	8	33.8	8.8	-25.0	(-56.60, 6.60)	13.36
I-HD	26	41.5	17.3	-24.2	(-38.09, -10.37)	6.73
I-HD/M-PL	7	42.9	20.0	-22.9	(-48.31, 2.59)	10.40
I-HD/M-SD	11	49.1	21.8	-27.3	(-57.33, 2.79)	13.49
I-HD/M-HD	8	30.0	8.8	-21.3	(-42.88, 0.38)	9.15
I-SD + I-HD Total	41	41.0	15.6	-25.4	(-36.23, -14.50)	5.38
I-HD-OL	7	41.4	14.3	-27.1	(-48.97, -5.31)	8.92
I-HD-OL/M-SD	3	36.7	13.3	-23.3	(-110.57, 63.91)	20.28
I-HD-OL/M-HD	4	45.0	15.0	-30.0	(-55.98, -4.02)	8.16
M-SD Total	18	45.6	21.1	-24.4	(-44.57, -4.32)	9.54
M-HD Total	20	34.5	10.0	-24.5	(-37.95, -11.05)	6.43
M-SD + M-HD Total	38	39.7	15.3	-24.5	(-35.75, -13.20)	5.56

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 52						
I-SD	15	40.0	10.7	-29.3	(-49.02, -9.65)	9.18
I-SD/M-PL	3	53.3	3.3	-50.0	(-99.68, -0.32)	11.55
I-SD/M-SD	4	42.5	25.0	-17.5	(-82.95, 47.95)	20.56
I-SD/M-HD	8	33.8	6.3	-27.5	(-59.02, 4.02)	13.33
I-HD	26	41.5	16.9	-24.6	(-38.94, -10.29)	6.96
I-HD/M-PL	7	42.9	20.0	-22.9	(-48.31, 2.59)	10.40
I-HD/M-SD	11	49.1	20.0	-29.1	(-60.67, 2.48)	14.17
I-HD/M-HD	8	30.0	10.0	-20.0	(-40.96, 0.96)	8.86
I-SD + I-HD Total	41	41.0	14.6	-26.3	(-37.43, -15.25)	5.49
I-HD-OL	7	41.4	14.3	-27.1	(-50.24, -4.04)	9.44
I-HD-OL/M-SD	3	36.7	10.0	-26.7	(-127.06, 73.73)	23.33
I-HD-OL/M-HD	4	45.0	17.5	-27.5	(-47.52, -7.48)	6.29
M-SD Total	18	45.6	19.4	-26.1	(-47.29, -4.93)	10.04
M-HD Total	20	34.5	10.0	-24.5	(-37.69, -11.31)	6.30
M-SD + M-HD Total	38	39.7	14.5	-25.3	(-36.85, -13.68)	5.72

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%)						
Week 1						
I-SD	19	49.360	39.441	-9.920	(-21.5365, 1.6974)	5.5295
I-SD/-	4	72.500	51.682	-20.818	(-52.3135, 10.6771)	9.8966
I-SD/M-PL	3	53.333	46.667	-6.667	(-82.5583, 69.2250)	17.6383
I-SD/M-SD	4	47.962	34.604	-13.357	(-56.2986, 29.5836)	13.4931
I-SD/M-HD	8	37.000	33.029	-3.971	(-24.9138, 16.9715)	8.8567
I-HD	27	48.515	35.781	-12.733	(-24.0531, -1.4135)	5.5070
I-HD/-	4	64.063	50.714	-13.348	(-84.7354, 58.0390)	22.4316
I-HD/M-PL	6	54.720	47.599	-7.121	(-16.2301, 1.9880)	3.5436
I-HD/M-SD	9	49.096	32.500	-16.596	(-45.5790, 12.3873)	12.5686
I-HD/M-HD	8	35.432	23.142	-12.290	(-30.0935, 5.5140)	7.5292
I-SD + I-HD Total	46	48.864	37.293	-11.571	(-19.4696, -3.6726)	3.9216
I-HD-OL	6	47.093	47.343	0.250	(-20.7508, 21.2511)	8.1697
I-HD-OL/-	1	57.143	62.353	5.210		0.0000
I-HD-OL/M-SD	1	0.000	10.000	10.000		0.0000
I-HD-OL/M-HD	4	56.354	52.927	-3.427	(-42.7123, 35.8578)	12.3443
M-SD Total	14	45.265	31.494	-13.771	(-32.8508, 5.3090)	8.8318
M-HD Total	20	40.244	33.054	-7.190	(-17.7882, 3.4085)	5.0637
M-SD + M-HD Total	34	42.311	32.412	-9.900	(-19.3671, -0.4322)	4.6534

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 2						
I-SD	20	49.670	32.926	-16.744	(-28.1413, -5.3472)	5.4452
I-SD/-	5	69.111	46.000	-23.111	(-45.0024, -1.2198)	7.8847
I-SD/M-PL	3	53.333	40.000	-13.333	(-70.7020, 44.0354)	13.3333
I-SD/M-SD	4	47.962	28.879	-19.082	(-71.7865, 33.6218)	16.5609
I-SD/M-HD	8	37.000	24.125	-12.875	(-35.8506, 10.1006)	9.7164
I-HD	29	50.356	27.064	-23.291	(-32.9739, -13.6090)	4.7268
I-HD/-	4	64.063	39.000	-25.063	(-55.5674, 5.4424)	9.5853
I-HD/M-PL	6	54.720	29.736	-24.984	(-52.5054, 2.5369)	10.7062
I-HD/M-SD	11	53.845	26.205	-27.640	(-48.5377, -6.7425)	9.3790
I-HD/M-HD	8	35.432	20.275	-15.157	(-32.9142, 2.6004)	7.5096
I-SD + I-HD Total	49	50.076	29.457	-20.619	(-27.7900, -13.4482)	3.5665
I-HD-OL	6	47.093	36.841	-10.252	(-31.6227, 11.1182)	8.3135
I-HD-OL/-	1	57.143	61.379	4.236		0.0000
I-HD-OL/M-SD	1	0.000	20.000	20.000		0.0000
I-HD-OL/M-HD	4	56.354	34.917	-21.438	(-40.8794, -1.9956)	6.1091
M-SD Total	16	49.009	26.485	-22.523	(-39.4359, -5.6104)	7.9349
M-HD Total	20	40.244	24.743	-15.500	(-25.7370, -5.2636)	4.8909
M-SD + M-HD Total	36	44.139	25.518	-18.622	(-27.5989, -9.6442)	4.4221

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 4						
I-SD	20	49.670	30.264	-19.406	(-32.5564, -6.2552)	6.2831
I-SD/-	5	69.111	51.629	-17.483	(-41.2258, 6.2607)	8.5517
I-SD/M-PL	3	53.333	43.333	-10.000	(-99.5669, 79.5669)	20.8167
I-SD/M-SD	4	47.962	20.000	-27.962	(-66.2793, 10.3560)	12.0403
I-SD/M-HD	8	37.000	17.143	-19.857	(-49.1955, 9.4812)	12.4072
I-HD	29	50.356	27.681	-22.675	(-34.3391, -11.0109)	5.6942
I-HD/-	4	64.063	39.000	-25.063	(-62.1252, 12.0002)	11.6460
I-HD/M-PL	6	54.720	33.179	-21.541	(-52.8604, 9.7777)	12.1837
I-HD/M-SD	11	53.845	27.743	-26.102	(-53.2193, 1.0156)	12.1705
I-HD/M-HD	8	35.432	17.813	-17.620	(-36.5534, 1.3140)	8.0071
I-SD + I-HD Total	49	50.076	28.735	-21.341	(-29.7820, -12.8994)	4.1983
I-HD-OL	6	47.093	32.417	-14.677	(-49.6736, 20.3204)	13.6144
I-HD-OL/-	1	57.143	82.500	25.357		0.0000
I-HD-OL/M-SD	1	0.000	10.000	10.000		0.0000
I-HD-OL/M-HD	4	56.354	25.500	-30.854	(-74.9331, 13.2248)	13.8507
M-SD Total	16	49.009	24.698	-24.310	(-43.4236, -5.1972)	8.9672
M-HD Total	20	40.244	19.082	-21.162	(-34.3129, -8.0103)	6.2834
M-SD + M-HD Total	36	44.139	21.578	-22.561	(-33.1670, -11.9552)	5.2243

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 8						
I-SD	20	49.670	28.653	-21.017	(-33.0486, -8.9862)	5.7482
I-SD/-	5	69.111	60.611	-8.500	(-27.3513, 10.3507)	6.7896
I-SD/M-PL	3	53.333	26.667	-26.667	(-89.1828, 35.8494)	14.5297
I-SD/M-SD	4	47.962	15.000	-32.962	(-87.7571, 21.8338)	17.2180
I-SD/M-HD	8	37.000	16.250	-20.750	(-43.8829, 2.3829)	9.7829
I-HD	29	50.356	20.246	-30.110	(-40.2037, -20.0167)	4.9275
I-HD/-	4	64.063	40.000	-24.063	(-78.0082, 29.8832)	16.9510
I-HD/M-PL	6	54.720	28.750	-25.970	(-54.9021, 2.9613)	11.2549
I-HD/M-SD	11	53.845	14.834	-39.011	(-57.6857, -20.3362)	8.3813
I-HD/M-HD	8	35.432	11.432	-24.000	(-42.2100, -5.7908)	7.7009
I-SD + I-HD Total	49	50.076	23.677	-26.399	(-33.9587, -18.8390)	3.7599
I-HD-OL	7	44.651	30.136	-14.515	(-36.6539, 7.6232)	9.0475
I-HD-OL/-	1	57.143	80.952	23.810		0.0000
I-HD-OL/M-SD	2	15.000	5.000	-10.000	(-264.1241, 244.1241)	20.0000
I-HD-OL/M-HD	4	56.354	30.000	-26.354	(-48.2460, -4.4623)	6.8789
M-SD Total	17	47.890	13.716	-34.175	(-49.1185, -19.2305)	7.0494
M-HD Total	20	40.244	17.073	-23.171	(-33.5483, -12.7937)	4.9580
M-SD + M-HD Total	37	43.757	15.530	-28.227	(-36.8302, -19.6232)	4.2422

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 12						
I-SD	15	43.190	20.000	-23.190	(-41.5453, -4.8343)	8.5582
I-SD/M-PL	3	53.333	36.667	-16.667	(-88.3775, 55.0442)	16.6667
I-SD/M-SD	4	47.962	17.500	-30.462	(-87.7734, 26.8501)	18.0087
I-SD/M-HD	8	37.000	15.000	-22.000	(-52.7531, 8.7531)	13.0055
I-HD	25	48.163	20.384	-27.779	(-40.9092, -14.6486)	6.3619
I-HD/M-PL	6	54.720	25.079	-29.641	(-60.0787, 0.7966)	11.8408
I-HD/M-SD	11	53.845	19.636	-34.208	(-59.4267, -8.9898)	11.3182
I-HD/M-HD	8	35.432	17.890	-17.542	(-39.1430, 4.0589)	9.1350
I-SD + I-HD Total	40	46.298	20.240	-26.058	(-36.2827, -15.8333)	5.0550
I-HD-OL	7	49.947	32.071	-17.875	(-32.5706, -3.1801)	6.0056
I-HD-OL/M-SD	3	41.404	30.000	-11.404	(-61.4519, 38.6449)	11.6320
I-HD-OL/M-HD	4	56.354	33.625	-22.729	(-42.9222, -2.5361)	6.3451
M-SD Total	18	50.464	20.889	-29.575	(-46.6422, -12.5076)	8.0895
M-HD Total	20	40.244	19.881	-20.363	(-33.3964, -7.3289)	6.2272
M-SD + M-HD Total	38	45.085	20.358	-24.726	(-34.9168, -14.5359)	5.0294

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 18						
I-SD	15	43.190	19.000	-24.190	(-45.5200, -2.8595)	9.9452
I-SD/M-PL	3	53.333	20.000	-33.333	(-85.0448, 18.3781)	12.0185
I-SD/M-SD	4	47.962	31.250	-16.712	(-99.5288, 66.1055)	26.0231
I-SD/M-HD	8	37.000	12.500	-24.500	(-58.0928, 9.0928)	14.2064
I-HD	25	48.163	20.511	-27.652	(-40.1404, -15.1641)	6.0508
I-HD/M-PL	6	54.720	31.052	-23.669	(-59.8295, 12.4919)	14.0671
I-HD/M-SD	11	53.845	21.364	-32.481	(-54.6112, -10.3508)	9.9321
I-HD/M-HD	8	35.432	11.432	-24.000	(-45.7116, -2.2892)	9.1817
I-SD + I-HD Total	40	46.298	19.944	-26.354	(-36.9547, -15.7530)	5.2410
I-HD-OL	7	49.947	30.429	-19.518	(-34.2557, -4.7807)	6.0229
I-HD-OL/M-SD	3	41.404	30.000	-11.404	(-61.4519, 38.6449)	11.6320
I-HD-OL/M-HD	4	56.354	30.750	-25.604	(-43.1809, -8.0274)	5.5230
M-SD Total	18	50.464	25.000	-25.464	(-43.0375, -7.8900)	8.3295
M-HD Total	20	40.244	15.723	-24.521	(-38.2693, -10.7727)	6.5686
M-SD + M-HD Total	38	45.085	20.117	-24.968	(-35.4505, -14.4846)	5.1737

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 26						
I-SD	15	43.190	15.067	-28.123	(-48.9806, -7.2656)	9.7247
I-SD/M-PL	3	53.333	20.000	-33.333	(-71.2792, 4.6125)	8.8192
I-SD/M-SD	4	47.962	29.000	-18.962	(-102.5639, 64.6406)	26.2698
I-SD/M-HD	8	37.000	6.250	-30.750	(-63.3433, 1.8433)	13.7837
I-HD	25	48.163	20.848	-27.315	(-41.2990, -13.3313)	6.7755
I-HD/M-PL	6	54.720	23.413	-31.308	(-59.8424, -2.7730)	11.1005
I-HD/M-SD	11	53.845	26.212	-27.633	(-56.8457, 1.5807)	13.1110
I-HD/M-HD	8	35.432	11.548	-23.884	(-45.6570, -2.1118)	9.2076
I-SD + I-HD Total	40	46.298	18.680	-27.618	(-38.7688, -16.4674)	5.5128
I-HD-OL	7	49.947	27.568	-22.379	(-43.7754, -0.9829)	8.7442
I-HD-OL/M-SD	3	41.404	30.000	-11.404	(-61.4519, 38.6449)	11.6320
I-HD-OL/M-HD	4	56.354	25.743	-30.611	(-69.2298, 8.0080)	12.1350
M-SD Total	18	50.464	27.463	-23.001	(-43.4358, -2.5658)	9.6857
M-HD Total	20	40.244	12.268	-27.976	(-42.1299, -13.8220)	6.7624
M-SD + M-HD Total	38	45.085	19.465	-25.619	(-37.2490, -13.9897)	5.7397

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 34						
I-SD	15	43.190	16.768	-26.422	(-47.6812, -5.1627)	9.9121
I-SD/M-PL	3	53.333	20.000	-33.333	(-71.2792, 4.6125)	8.8192
I-SD/M-SD	4	47.962	32.879	-15.082	(-97.7145, 67.5498)	25.9650
I-SD/M-HD	8	37.000	7.500	-29.500	(-63.1522, 4.1522)	14.2315
I-HD	25	48.163	20.811	-27.352	(-41.4356, -13.2690)	6.8236
I-HD/M-PL	6	54.720	23.413	-31.308	(-59.8424, -2.7730)	11.1005
I-HD/M-SD	11	53.845	26.212	-27.633	(-57.1730, 1.9080)	13.2579
I-HD/M-HD	8	35.432	11.432	-24.000	(-45.7116, -2.2892)	9.1817
I-SD + I-HD Total	40	46.298	19.295	-27.003	(-38.2906, -15.7162)	5.5803
I-HD-OL	7	49.947	20.238	-29.709	(-56.5250, -2.8923)	10.9593
I-HD-OL/M-SD	3	41.404	10.000	-31.404	(-136.0424, 73.2353)	24.3196
I-HD-OL/M-HD	4	56.354	27.917	-28.438	(-63.7885, 6.9135)	11.1081
M-SD Total	18	50.464	24.992	-25.472	(-46.8995, -4.0447)	10.1560
M-HD Total	20	40.244	13.156	-27.088	(-41.3617, -12.8136)	6.8198
M-SD + M-HD Total	38	45.085	18.762	-26.322	(-38.3157, -14.3291)	5.9191

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 42						
I-SD	15	43.190	14.101	-29.089	(-51.5404, -6.6369)	10.4681
I-SD/M-PL	3	53.333	6.667	-46.667	(-109.1828, 15.8494)	14.5297
I-SD/M-SD	4	47.962	30.379	-17.582	(-100.0783, 64.9136)	25.9222
I-SD/M-HD	8	37.000	8.750	-28.250	(-63.1797, 6.6797)	14.7718
I-HD	25	48.163	21.451	-26.712	(-40.5963, -12.8283)	6.7271
I-HD/M-PL	6	54.720	23.413	-31.308	(-59.8424, -2.7730)	11.1005
I-HD/M-SD	11	53.845	26.212	-27.633	(-56.9382, 1.6732)	13.1526
I-HD/M-HD	8	35.432	13.432	-22.000	(-42.2654, -1.7354)	8.5701
I-SD + I-HD Total	40	46.298	18.695	-27.603	(-39.0795, -16.1274)	5.6737
I-HD-OL	7	49.947	14.286	-35.661	(-60.4712, -10.8508)	10.1394
I-HD-OL/M-SD	3	41.404	10.000	-31.404	(-136.0424, 73.2353)	24.3196
I-HD-OL/M-HD	4	56.354	17.500	-38.854	(-62.7064, -15.0019)	7.4949
M-SD Total	18	50.464	24.436	-26.028	(-47.2774, -4.7779)	10.0719
M-HD Total	20	40.244	12.373	-27.871	(-42.1822, -13.5598)	6.8376
M-SD + M-HD Total	38	45.085	18.087	-26.998	(-38.9397, -15.0559)	5.8938

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 52						
I-SD	15	43.190	19.071	-24.119	(-44.9224, -3.3155)	9.6996
I-SD/M-PL	3	53.333	21.515	-31.818	(-74.9039, 11.2676)	10.0138
I-SD/M-SD	4	47.962	30.379	-17.582	(-100.0783, 64.9136)	25.9222
I-SD/M-HD	8	37.000	12.500	-24.500	(-57.2500, 8.2500)	13.8500
I-HD	25	48.163	20.877	-27.286	(-41.6681, -12.9031)	6.9686
I-HD/M-PL	6	54.720	23.413	-31.308	(-59.8424, -2.7730)	11.1005
I-HD/M-SD	11	53.845	24.394	-29.451	(-60.2361, 1.3348)	13.8167
I-HD/M-HD	8	35.432	14.140	-21.292	(-41.2895, -1.2946)	8.4569
I-SD + I-HD Total	40	46.298	20.200	-26.098	(-37.4328, -14.7634)	5.6038
I-HD-OL	7	49.947	16.429	-33.518	(-59.0279, -8.0085)	10.4253
I-HD-OL/M-SD	3	41.404	6.667	-34.737	(-152.1957, 82.7220)	27.2992
I-HD-OL/M-HD	4	56.354	23.750	-32.604	(-41.1013, -24.1070)	2.6700
M-SD Total	18	50.464	22.769	-27.694	(-49.9748, -5.4138)	10.5604
M-HD Total	20	40.244	15.406	-24.838	(-38.0644, -11.6109)	6.3194
M-SD + M-HD Total	38	45.085	18.894	-26.191	(-38.1984, -14.1832)	5.9262

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%)						
Week 1						
I-SD	19	12.912	5.097	-7.814	(-16.3855, 0.7566)	4.0797
I-SD/-	4	25.833	7.273	-18.561	(-56.5473, 19.4261)	11.9363
I-SD/M-PL	3	0.000	5.556	5.556	(-18.3481, 29.4592)	5.5556
I-SD/M-SD	4	12.997	2.708	-10.289	(-38.7282, 18.1505)	8.9363
I-SD/M-HD	8	11.250	5.032	-6.218	(-19.6088, 7.1729)	5.6630
I-HD	28	11.846	8.616	-3.230	(-7.2571, 0.7976)	1.9628
I-HD/-	4	31.696	28.571	-3.125	(-13.0701, 6.8201)	3.1250
I-HD/M-PL	6	8.191	1.699	-6.492	(-17.1682, 4.1841)	4.1532
I-HD/M-SD	10	8.146	7.847	-0.300	(-10.8776, 10.2777)	4.6759
I-HD/M-HD	8	9.287	4.789	-4.498	(-8.3361, -0.6592)	1.6233
I-SD + I-HD Total	47	12.277	7.194	-5.083	(-9.1540, -1.0123)	2.0224
I-HD-OL	6	18.909	17.750	-1.159	(-34.2100, 31.8918)	12.8574
I-HD-OL/-	1	14.286	5.882	-8.403		0.0000
I-HD-OL/M-SD	1	0.000	0.000	0.000		
I-HD-OL/M-HD	4	24.792	25.154	0.362	(-63.9219, 64.6462)	20.1996
M-SD Total	15	8.897	5.953	-2.944	(-11.3427, 5.4554)	3.9160
M-HD Total	20	13.173	8.959	-4.214	(-13.1689, 4.7413)	4.2785
M-SD + M-HD Total	35	11.340	7.671	-3.669	(-9.6165, 2.2776)	2.9263

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 2						
I-SD	20	12.822	5.845	-6.977	(-15.3118, 1.3582)	3.9823
I-SD/-	5	22.889	8.000	-14.889	(-40.4325, 10.6547)	9.2001
I-SD/M-PL	3	0.000	0.000	0.000		
I-SD/M-SD	4	12.997	6.724	-6.273	(-43.4897, 30.9437)	11.6944
I-SD/M-HD	8	11.250	6.250	-5.000	(-19.8211, 9.8211)	6.2678
I-HD	29	12.472	6.430	-6.042	(-10.2853, -1.7991)	2.0714
I-HD/-	4	31.696	30.000	-1.696	(-26.8361, 23.4432)	7.8995
I-HD/M-PL	6	8.191	2.269	-5.922	(-17.1293, 5.2848)	4.3597
I-HD/M-SD	11	10.133	1.721	-8.412	(-15.9195, -0.9053)	3.3692
I-HD/M-HD	8	9.287	4.241	-5.046	(-13.8196, 3.7276)	3.7104
I-SD + I-HD Total	49	12.615	6.191	-6.424	(-10.4689, -2.3784)	2.0119
I-HD-OL	6	18.909	6.686	-12.223	(-30.7964, 6.3506)	7.2254
I-HD-OL/-	1	14.286	3.448	-10.837		0.0000
I-HD-OL/M-SD	1	0.000	0.000	0.000		
I-HD-OL/M-HD	4	24.792	9.167	-15.625	(-49.6114, 18.3614)	10.6793
M-SD Total	16	10.216	2.864	-7.352	(-14.8383, 0.1347)	3.5124
M-HD Total	20	13.173	6.030	-7.143	(-14.5037, 0.2169)	3.5166
M-SD + M-HD Total	36	11.859	4.623	-7.236	(-12.2417, -2.2303)	2.4657

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 4						
I-SD	20	12.822	4.214	-8.607	(-18.7054, 1.4906)	4.8246
I-SD/-	5	22.889	15.429	-7.460	(-53.6325, 38.7119)	16.6300
I-SD/M-PL	3	0.000	0.000	0.000		
I-SD/M-SD	4	12.997	0.000	-12.997	(-40.4160, 14.4216)	8.6156
I-SD/M-HD	8	11.250	0.893	-10.357	(-24.8128, 4.0985)	6.1133
I-HD	29	12.472	9.613	-2.859	(-8.8152, 3.0978)	2.9079
I-HD/-	4	31.696	30.000	-1.696	(-26.8361, 23.4432)	7.8995
I-HD/M-PL	6	8.191	5.693	-2.498	(-15.5414, 10.5449)	5.0740
I-HD/M-SD	11	10.133	9.058	-1.076	(-15.6388, 13.4878)	6.5361
I-HD/M-HD	8	9.287	3.125	-6.162	(-13.3482, 1.0241)	3.0390
I-SD + I-HD Total	49	12.615	7.410	-5.205	(-10.4660, 0.0558)	2.6165
I-HD-OL	6	18.909	5.417	-13.492	(-41.3038, 14.3196)	10.8192
I-HD-OL/-	1	14.286	12.500	-1.786		0.0000
I-HD-OL/M-SD	1	0.000	0.000	0.000		
I-HD-OL/M-HD	4	24.792	5.000	-19.792	(-70.3937, 30.8103)	15.9004
M-SD Total	16	10.216	6.227	-3.989	(-14.6671, 6.6897)	5.0099
M-HD Total	20	13.173	2.607	-10.566	(-18.9792, -2.1528)	4.0196
M-SD + M-HD Total	36	11.859	4.216	-7.643	(-14.0493, -1.2362)	3.1558

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 8						
I-SD	20	12.822	5.739	-7.083	(-16.4123, 2.2465)	4.4574
I-SD/-	5	22.889	18.955	-3.934	(-48.7433, 40.8754)	16.1391
I-SD/M-PL	3	0.000	0.000	0.000		
I-SD/M-SD	4	12.997	0.000	-12.997	(-40.4160, 14.4216)	8.6156
I-SD/M-HD	8	11.250	2.500	-8.750	(-19.1704, 1.6704)	4.4068
I-HD	29	12.472	4.878	-7.594	(-11.9137, -3.2752)	2.1086
I-HD/-	4	31.696	25.000	-6.696	(-19.0549, 5.6621)	3.8833
I-HD/M-PL	6	8.191	4.167	-4.024	(-19.2553, 11.2071)	5.9252
I-HD/M-SD	11	10.133	1.330	-8.803	(-16.9884, -0.6172)	3.6737
I-HD/M-HD	8	9.287	0.227	-9.060	(-17.8761, -0.2435)	3.7284
I-SD + I-HD Total	49	12.615	5.229	-7.386	(-11.7660, -3.0053)	2.1786
I-HD-OL	7	16.207	0.680	-15.527	(-37.5550, 6.5006)	9.0023
I-HD-OL/-	1	14.286	4.762	-9.524		0.0000
I-HD-OL/M-SD	2	0.000	0.000	0.000		
I-HD-OL/M-HD	4	24.792	0.000	-24.792	(-71.1123, 21.5289)	14.5550
M-SD Total	17	9.615	0.861	-8.754	(-15.3091, -2.1991)	3.0921
M-HD Total	20	13.173	1.091	-12.082	(-19.8368, -4.3277)	3.7050
M-SD + M-HD Total	37	11.538	0.985	-10.553	(-15.4980, -5.6082)	2.4382

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 12						
I-SD	15	9.466	0.000	-9.466	(-17.7362, -1.1957)	3.8560
I-SD/M-PL	3	0.000	0.000	0.000		
I-SD/M-SD	4	12.997	0.000	-12.997	(-40.4160, 14.4216)	8.6156
I-SD/M-HD	8	11.250	0.000	-11.250	(-24.9781, 2.4781)	5.8056
I-HD	25	9.396	2.174	-7.222	(-11.9332, -2.5107)	2.2827
I-HD/M-PL	6	8.191	2.646	-5.545	(-16.3270, 5.2365)	4.1943
I-HD/M-SD	11	10.133	1.818	-8.315	(-16.6726, 0.0426)	3.7509
I-HD/M-HD	8	9.287	2.311	-6.976	(-17.0707, 3.1177)	4.2688
I-SD + I-HD Total	40	9.422	1.359	-8.063	(-12.1269, -3.9999)	2.0090
I-HD-OL	7	24.317	6.429	-17.888	(-43.7755, 7.9986)	10.5795
I-HD-OL/M-SD	3	23.684	0.000	-23.684	(-125.5891, 78.2207)	23.6842
I-HD-OL/M-HD	4	24.792	11.250	-13.542	(-44.8158, 17.7324)	9.8271
M-SD Total	18	13.028	1.111	-11.917	(-21.5408, -2.2932)	4.5614
M-HD Total	20	13.173	3.174	-9.999	(-16.9595, -3.0384)	3.3256
M-SD + M-HD Total	38	13.104	2.197	-10.907	(-16.4720, -5.3429)	2.7463

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 18						
I-SD	15	9.466	3.333	-6.133	(-16.8971, 4.6320)	5.0189
I-SD/M-PL	3	0.000	0.000	0.000		
I-SD/M-SD	4	12.997	12.500	-0.497	(-50.4200, 49.4257)	15.6870
I-SD/M-HD	8	11.250	0.000	-11.250	(-24.9781, 2.4781)	5.8056
I-HD	25	9.396	4.263	-5.133	(-10.6484, 0.3823)	2.6723
I-HD/M-PL	6	8.191	4.960	-3.230	(-17.5574, 11.0965)	5.5734
I-HD/M-SD	11	10.133	6.818	-3.315	(-13.7071, 7.0771)	4.6640
I-HD/M-HD	8	9.287	0.227	-9.060	(-17.8761, -0.2435)	3.7284
I-SD + I-HD Total	40	9.422	3.915	-5.508	(-10.5213, -0.4944)	2.4786
I-HD-OL	7	24.317	1.429	-22.888	(-49.9805, 4.2035)	11.0719
I-HD-OL/M-SD	3	23.684	0.000	-23.684	(-125.5891, 78.2207)	23.6842
I-HD-OL/M-HD	4	24.792	2.500	-22.292	(-61.0480, 16.4646)	12.1781
M-SD Total	18	13.028	6.944	-6.084	(-18.0539, 5.8865)	5.6736
M-HD Total	20	13.173	0.591	-12.582	(-20.1259, -5.0386)	3.6042
M-SD + M-HD Total	38	13.104	3.600	-9.504	(-16.1630, -2.8449)	3.2865

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 26						
I-SD	15	9.466	2.667	-6.799	(-17.6481, 4.0496)	5.0582
I-SD/M-PL	3	0.000	0.000	0.000		
I-SD/M-SD	4	12.997	10.000	-2.997	(-54.3990, 48.4047)	16.1517
I-SD/M-HD	8	11.250	0.000	-11.250	(-24.9781, 2.4781)	5.8056
I-HD	25	9.396	4.082	-5.314	(-10.9736, 0.3456)	2.7422
I-HD/M-PL	6	8.191	2.646	-5.545	(-16.3270, 5.2365)	4.1943
I-HD/M-SD	11	10.133	7.576	-2.557	(-14.1883, 9.0735)	5.2200
I-HD/M-HD	8	9.287	0.356	-8.931	(-17.8576, -0.0042)	3.7751
I-SD + I-HD Total	40	9.422	3.551	-5.871	(-10.9679, -0.7741)	2.5198
I-HD-OL	7	24.317	6.178	-18.139	(-41.5672, 5.2883)	9.5744
I-HD-OL/M-SD	3	23.684	0.000	-23.684	(-125.5891, 78.2207)	23.6842
I-HD-OL/M-HD	4	24.792	10.811	-13.981	(-30.4931, 2.5313)	5.1885
M-SD Total	18	13.028	6.852	-6.176	(-18.5924, 6.2399)	5.8850
M-HD Total	20	13.173	2.305	-10.869	(-16.8259, -4.9111)	2.8463
M-SD + M-HD Total	38	13.104	4.459	-8.646	(-15.0132, -2.2786)	3.1425

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 34						
I-SD	15	9.466	3.126	-6.339	(-17.1099, 4.4310)	5.0217
I-SD/M-PL	3	0.000	0.000	0.000		
I-SD/M-SD	4	12.997	11.724	-1.273	(-51.5249, 48.9789)	15.7903
I-SD/M-HD	8	11.250	0.000	-11.250	(-24.9781, 2.4781)	5.8056
I-HD	25	9.396	4.041	-5.355	(-11.0073, 0.2968)	2.7385
I-HD/M-PL	6	8.191	2.646	-5.545	(-16.3270, 5.2365)	4.1943
I-HD/M-SD	11	10.133	7.576	-2.557	(-14.1883, 9.0735)	5.2200
I-HD/M-HD	8	9.287	0.227	-9.060	(-17.8761, -0.2435)	3.7284
I-SD + I-HD Total	40	9.422	3.698	-5.724	(-10.7952, -0.6535)	2.5070
I-HD-OL	7	24.317	5.238	-19.079	(-47.1112, 8.9533)	11.4562
I-HD-OL/M-SD	3	23.684	0.000	-23.684	(-125.5891, 78.2207)	23.6842
I-HD-OL/M-HD	4	24.792	9.167	-15.625	(-57.0706, 25.8206)	13.0232
M-SD Total	18	13.028	7.235	-5.793	(-18.1592, 6.5729)	5.8612
M-HD Total	20	13.173	1.924	-11.249	(-18.7002, -3.7976)	3.5601
M-SD + M-HD Total	38	13.104	4.440	-8.665	(-15.4160, -1.9132)	3.3321

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 42						
I-SD	15	9.466	3.126	-6.339	(-17.1099, 4.4310)	5.0217
I-SD/M-PL	3	0.000	0.000	0.000		
I-SD/M-SD	4	12.997	11.724	-1.273	(-51.5249, 48.9789)	15.7903
I-SD/M-HD	8	11.250	0.000	-11.250	(-24.9781, 2.4781)	5.8056
I-HD	25	9.396	4.841	-4.555	(-9.9490, 0.8385)	2.6134
I-HD/M-PL	6	8.191	2.646	-5.545	(-16.3270, 5.2365)	4.1943
I-HD/M-SD	11	10.133	7.576	-2.557	(-14.1883, 9.0735)	5.2200
I-HD/M-HD	8	9.287	2.727	-6.560	(-13.5606, 0.4410)	2.9606
I-SD + I-HD Total	40	9.422	4.198	-5.224	(-10.1957, -0.2530)	2.4578
I-HD-OL	7	24.317	2.857	-21.460	(-46.9528, 4.0330)	10.4184
I-HD-OL/M-SD	3	23.684	0.000	-23.684	(-125.5891, 78.2207)	23.6842
I-HD-OL/M-HD	4	24.792	5.000	-19.792	(-51.1780, 11.5947)	9.8623
M-SD Total	18	13.028	7.235	-5.793	(-18.1592, 6.5729)	5.8612
M-HD Total	20	13.173	2.091	-11.082	(-17.8838, -4.2807)	3.2496
M-SD + M-HD Total	38	13.104	4.528	-8.577	(-15.1485, -2.0053)	3.2433

表 2.7.3.6-93. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 52						
I-SD	15	9.466	10.096	0.630	(-13.6947, 14.9551)	6.6789
I-SD/M-PL	3	0.000	18.182	18.182	(-60.0482, 96.4119)	18.1818
I-SD/M-SD	4	12.997	11.724	-1.273	(-51.5249, 48.9789)	15.7903
I-SD/M-HD	8	11.250	6.250	-5.000	(-22.8749, 12.8749)	7.5593
I-HD	25	9.396	4.708	-4.689	(-10.0913, 0.7142)	2.6177
I-HD/M-PL	6	8.191	2.646	-5.545	(-16.3270, 5.2365)	4.1943
I-HD/M-SD	11	10.133	7.576	-2.557	(-14.1883, 9.0735)	5.2200
I-HD/M-HD	8	9.287	2.311	-6.976	(-13.9724, 0.0195)	2.9586
I-SD + I-HD Total	40	9.422	6.728	-2.694	(-8.6979, 3.3098)	2.9683
I-HD-OL	7	24.317	5.238	-19.079	(-45.3614, 7.2035)	10.7411
I-HD-OL/M-SD	3	23.684	0.000	-23.684	(-125.5891, 78.2207)	23.6842
I-HD-OL/M-HD	4	24.792	9.167	-15.625	(-49.6114, 18.3614)	10.6793
M-SD Total	18	13.028	7.235	-5.793	(-18.1592, 6.5729)	5.8612
M-HD Total	20	13.173	5.258	-7.916	(-15.7848, -0.0463)	3.7597
M-SD + M-HD Total	38	13.104	6.194	-6.910	(-13.7296, -0.0908)	3.3656

Note: I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group, M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
Note: baseline is defined as the last non-missing value prior to the first dose of study drug. Subjects with non-missing baseline and at least one post-baseline value are included in the analyses.
Last observation carried forward (LOCF): missing data is imputed by carrying forward the last non-missing post-baseline observation. For subjects re-randomized due to disease flare, the last non-missing value before the re-randomization after the first disease flare are carried forward.
WPAI = work productivity and activity impairment.

Cross reference: M11-290 Main-study CSR_Interim Table 14.2__1.3.8

表 2.7.3.6-94.　　治験期間中に入院した，又は結腸切除を行った被験者の割合（OC）（ITT 集団，M11-290 試験の主試験）（中間 CSR）

Parameter Timepoint Treatment Group	N	---------- Endpoint Met ---------- n (%)	95% CI $
Hospitalized (All Cause)			
During Induction	93	22 (23.7)	(15.46, 33.60)
I-SD	30	9 (30.0)	(14.73, 49.40)
I-HD	47	10 (21.3)	(10.70, 35.66)
I-HD-OL	16	3 (18.8)	(4.05, 45.65)
During Maintenance	74	13 (17.6)	(9.70, 28.17)
M-PL	12	1 (8.3)	(0.21, 38.48)
I-SD	4	0	(0.00, 60.24)
I-HD	8	1 (12.5)	(0.32, 52.65)
M-SD	31	6 (19.4)	(7.45, 37.47)
I-SD	8	2 (25.0)	(3.19, 65.09)
I-HD/I-HD-OL	23	4 (17.4)	(4.95, 38.78)
M-HD	31	6 (19.4)	(7.45, 37.47)
I-SD	9	2 (22.2)	(2.81, 60.01)
I-HD/I-HD-OL	22	4 (18.2)	(5.19, 40.28)

表 2.7.3.6-94. 治験期間中に入院した，又は結腸切除を行った被験者の割合（OC）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Endpoint Met n (%)	Endpoint Met 95% CI $
Hospitalized (UC-Related)			
During Induction	93	13 (14.0)	(7.66, 22.72)
I-SD	30	5 (16.7)	(5.64, 34.72)
I-HD	47	6 (12.8)	(4.83, 25.74)
I-HD-OL	16	2 (12.5)	(1.55, 38.35)
During Maintenance	74	6 (8.1)	(3.03, 16.82)
M-PL	12	0	(0.00, 26.46)
I-SD	4	0	(0.00, 60.24)
I-HD	8	0	(0.00, 36.94)
M-SD	31	5 (16.1)	(5.45, 33.73)
I-SD	8	1 (12.5)	(0.32, 52.65)
I-HD/I-HD-OL	23	4 (17.4)	(4.95, 38.78)
M-HD	31	1 (3.2)	(0.08, 16.70)
I-SD	9	1 (11.1)	(0.28, 48.25)
I-HD/I-HD-OL	22	0	(0.00, 15.44)

表 2.7.3.6-94. 治験期間中に入院した，又は結腸切除を行った被験者の割合（OC）（ITT 集団，M11-290 試験の主試験）（中間 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Endpoint Met n (%)	Endpoint Met 95% CI $
Underwent Colectomy			
During Induction	93	1 (1.1)	(0.03, 5.85)
I-SD	30	0	(0.00, 11.57)
I-HD	47	1 (2.1)	(0.05, 11.29)
I-HD-OL	16	0	(0.00, 20.59)
During Maintenance	74	0	(0.00, 4.86)
M-PL	12	0	(0.00, 26.46)
I-SD	4	0	(0.00, 60.24)
I-HD	8	0	(0.00, 36.94)
M-SD	31	0	(0.00, 11.22)
I-SD	8	0	(0.00, 36.94)
I-HD/I-HD-OL	23	0	(0.00, 14.82)
M-HD	31	0	(0.00, 11.22)
I-SD	9	0	(0.00, 33.63)
I-HD/I-HD-OL	22	0	(0.00, 15.44)

Note: I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group, M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
$ Clopper-Pearson confidence interval for proportion of patients with adjudicated event.
Observed cases (OC): missing values are not imputed for the observed case analysis. For subjects re-randomized due to disease flare, only non-missing data up to before the first disease flare is used.

Cross reference: M11-290 Main-study CSR_Interim Table 14.2__1.3.28

表 2.7.3.6-95. 治験期間中に Mayo 内視鏡所見サブスコアにより粘膜治癒を達成した被験者の割合（LOCF）（FAS 集団，M10-870 試験の主試験）（中間 CSR）

	Adalimumab		
		Endpoint Met	
Timepoint	N	n (%)	95% CI $
Baseline	55	35 (63.6)	(49.56, 76.19)
Week 48	3	1 (33.3)	(0.84, 90.57)
Week 96	13	8 (61.5)	(31.58, 86.14)
Week 192	1	1 (100)	(2.50, 100.00)

$ Clopper-Pearson confidence interval for proportion of subjects with mucosal healing.
Note: baseline is defined as the last non-missing value before the baseline visit date (i.e., at or before the Week 52 visit from the Study M11-290) and prior to first dose of M10-870.
Last observation carried forward (LOCF): missing data will be imputed by carrying forward the last non-missing post-baseline observation.
For interim analyses, missing values will only be imputed up to the timepoint a patient could have potentially reached at the data cutoff for analyses.
Mucosal healing is defined as endoscopy subscore of 0 or 1.

Cross reference: M10-870 Main-study CSR_Interim Table 14.2__4.3

表 2.7.3.6-96.　治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験）（最終 CSR）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
All Sites	101	101	83	80	68	83	62	101	25	68
I-SD	32	32	32	21	17	32	15	32	5	18
I-SD/-	10	10	10	--	--	10	--	10	--	--
I-SD/M-PL	4	4	4	4	--	4	0	4	2	4
I-SD/M-SD	8	8	8	8	8	8	8	8	0	5
I-SD/M-HD	10	10	10	9	9	10	7	10	3	9
I-HD	51	51	51	43	35	51	31	51	16	38
I-HD/-	8	8	8	--	--	8	--	8	--	--
I-HD/M-PL	8	8	8	8	--	8	0	8	5	7
I-HD/M-SD	17	17	17	17	17	17	15	17	5	14
I-HD/M-HD	18	18	18	18	18	18	16	18	6	17
I-HD-OL	18	18	--	16	16	0	16	18	4	12
I-HD-OL/-	2	2	--	--	--	0	--	2	--	--
I-HD-OL/M-SD	8	8	--	8	8	0	8	8	3	6
I-HD-OL/M-HD	8	8	--	8	8	0	8	8	1	6
M-SD + M-HD total	69	69	53	68	68	53	62	69	18	57
M-SD total	33	33	25	33	33	25	31	33	8	25
M-HD total	36	36	28	35	35	28	31	36	10	32

表 2.7.3.6-96. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験）（最終 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	8	8	8	8	7	8	6	8	1	8
I-SD	3	3	3	3	3	3	2	3	1	3
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	1	1	1	1	1	1	1	1	0	1
I-SD/M-HD	2	2	2	2	2	2	1	2	1	2
I-HD	5	5	5	5	4	5	4	5	0	5
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	1	1	1	1	--	1	0	1	0	1
I-HD/M-SD	1	1	1	1	1	1	1	1	0	1
I-HD/M-HD	3	3	3	3	3	3	3	3	0	3
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	7	7	7	7	7	7	6	7	1	7
M-SD total	2	2	2	2	2	2	2	2	0	2
M-HD total	5	5	5	5	5	5	4	5	1	5

表 2.7.3.6-96. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験）（最終 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	13	13	9	9	7	9	7	13	3	9
I-SD	3	3	3	1	1	3	1	3	0	1
I-SD/-	2	2	2	--	--	2	--	2	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	1	1	1	1	1	1	1	1	0	1
I-HD	6	6	6	5	3	6	3	6	3	5
I-HD/-	1	1	1	--	--	1	--	1	--	--
I-HD/M-PL	2	2	2	2	--	2	0	2	2	2
I-HD/M-SD	1	1	1	1	1	1	1	1	0	1
I-HD/M-HD	2	2	2	2	2	2	2	2	1	2
I-HD-OL	4	4	--	3	3	0	3	4	0	3
I-HD-OL/-	1	1	--	--	--	0	--	1	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	3	3	--	3	3	0	3	3	0	3
M-SD + M-HD total	7	7	4	7	7	4	7	7	1	7
M-SD total	1	1	1	1	1	1	1	1	0	1
M-HD total	6	6	3	6	6	3	6	6	1	6

表 2.7.3.6-96. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験）（最終 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	1	1	1	0	0	1	0	1	0	0
I-SD	0	0	0	0	0	0	0	0	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	1	1	1	0	0	1	0	1	0	0
I-HD/-	1	1	1	--	--	1	--	1	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	0	0	0	0	0	0	0	0	0	0
M-SD total	0	0	0	0	0	0	0	0	0	0
M-HD total	0	0	0	0	0	0	0	0	0	0

表 2.7.3.6-96. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験）（最終 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	4	4	2	4	3	2	2	4	0	3
I-SD	0	0	0	0	0	0	0	0	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	2	2	2	2	1	2	0	2	0	2
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	1	1	1	1	--	1	0	1	0	1
I-HD/M-SD	1	1	1	1	1	1	0	1	0	1
I-HD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD-OL	2	2	--	2	2	0	2	2	0	1
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	1	1	--	1	1	0	1	1	0	1
I-HD-OL/M-HD	1	1	--	1	1	0	1	1	0	0
M-SD + M-HD total	3	3	1	3	3	1	2	3	0	2
M-SD total	2	2	1	2	2	1	1	2	0	2
M-HD total	1	1	0	1	1	0	1	1	0	0

表 2.7.3.6-96. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験）（最終 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	2	2	2	0	0	2	0	2	0	0
I-SD	0	0	0	0	0	0	0	0	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	2	2	2	0	0	2	0	2	0	0
I-HD/-	2	2	2	--	--	2	--	2	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	0	0	0	0	0	0	0	0	0	0
M-SD total	0	0	0	0	0	0	0	0	0	0
M-HD total	0	0	0	0	0	0	0	0	0	0

表 2.7.3.6-96. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験）（最終 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	2	2	1	1	1	1	1	2	0	0
I-SD	1	1	1	0	0	1	0	1	0	0
I-SD/-	1	1	1	--	--	1	--	1	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	0	0	0	0	0	0	0	0	0	0
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD-OL	1	1	--	1	1	0	1	1	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	1	1	--	1	1	0	1	1	0	0
M-SD + M-HD total	1	1	0	1	1	0	1	1	0	0
M-SD total	0	0	0	0	0	0	0	0	0	0
M-HD total	1	1	0	1	1	0	1	1	0	0

表 2.7.3.6-96. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験）（最終 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	2	2	2	2	2	2	2	2	0	0
I-SD	1	1	1	1	1	1	1	1	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	1	1	1	1	1	1	1	1	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	1	1	1	1	1	1	1	1	0	0
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	1	1	1	1	1	1	1	1	0	0
I-HD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	2	2	2	2	2	2	2	2	0	0
M-SD total	2	2	2	2	2	2	2	2	0	0
M-HD total	0	0	0	0	0	0	0	0	0	0

表 2.7.3.6-96. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験）（最終 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	39	39	35	30	24	35	22	39	12	28
I-SD	17	17	17	11	8	17	7	17	4	11
I-SD/-	6	6	6	--	--	6	--	6	--	--
I-SD/M-PL	3	3	3	3	--	3	0	3	2	3
I-SD/M-SD	3	3	3	3	3	3	3	3	0	3
I-SD/M-HD	5	5	5	5	5	5	4	5	2	5
I-HD	18	18	18	15	12	18	11	18	7	13
I-HD/-	3	3	3	--	--	3	--	3	--	--
I-HD/M-PL	3	3	3	3	--	3	0	3	2	3
I-HD/M-SD	7	7	7	7	7	7	7	7	3	6
I-HD/M-HD	5	5	5	5	5	5	4	5	2	4
I-HD-OL	4	4	--	4	4	0	4	4	1	4
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	3	3	--	3	3	0	3	3	1	3
I-HD-OL/M-HD	1	1	--	1	1	0	1	1	0	1
M-SD + M-HD total	24	24	20	24	24	20	22	24	8	22
M-SD total	13	13	10	13	13	10	13	13	4	12
M-HD total	11	11	10	11	11	10	9	11	4	10

表 2.7.3.6-96. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験）（最終 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	1	1	1	1	1	1	1	1	1	1
I-SD	0	0	0	0	0	0	0	0	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	1	1	1	1	1	1	1	1	1	1
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	1	1	1	1	1	1	1	1	1	1
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	1	1	1	1	1	1	1	1	1	1
M-SD total	0	0	0	0	0	0	0	0	0	0
M-HD total	1	1	1	1	1	1	1	1	1	1

表 2.7.3.6-96. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験）（最終 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	1	1	1	1	1	1	1	1	0	1
I-SD	0	0	0	0	0	0	0	0	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	1	1	1	1	1	1	1	1	0	1
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	1	1	1	1	1	1	1	1	0	1
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	1	1	1	1	1	1	1	1	0	1
M-SD total	0	0	0	0	0	0	0	0	0	0
M-HD total	1	1	1	1	1	1	1	1	0	1

表 2.7.3.6-96. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験）（最終 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	1	1	0	0	0	0	0	1	0	0
I-SD	0	0	0	0	0	0	0	0	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	0	0	0	0	0	0	0	0	0	0
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD-OL	1	1	--	0	0	0	0	1	0	0
I-HD-OL/-	1	1	--	--	--	0	--	1	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	0	0	0	0	0	0	0	0	0	0
M-SD total	0	0	0	0	0	0	0	0	0	0
M-HD total	0	0	0	0	0	0	0	0	0	0

表 2.7.3.6-96. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験）（最終 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted]	2	2	0	2	2	0	2	2	0	2
I-SD	0	0	0	0	0	0	0	0	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	0	0	0	0	0	0	0	0	0	0
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD-OL	2	2	--	2	2	0	2	2	0	2
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	1	1	--	1	1	0	1	1	0	1
I-HD-OL/M-HD	1	1	--	1	1	0	1	1	0	1
M-SD + M-HD total	2	2	0	2	2	0	2	2	0	2
M-SD total	1	1	0	1	1	0	1	1	0	1
M-HD total	1	1	0	1	1	0	1	1	0	1

表 2.7.3.6-96. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験）（最終 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted]	1	1	1	1	0	1	0	1	0	1
I-SD	1	1	1	1	0	1	0	1	0	1
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	1	1	1	1	--	1	0	1	0	1
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	0	0	0	0	0	0	0	0	0	0
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	0	0	0	0	0	0	0	0	0	0
M-SD total	0	0	0	0	0	0	0	0	0	0
M-HD total	0	0	0	0	0	0	0	0	0	0

表 2.7.3.6-96. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験）（最終 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	2	2	2	1	1	2	0	2	0	1
I-SD	0	0	0	0	0	0	0	0	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	2	2	2	1	1	2	0	2	0	1
I-HD/-	1	1	1	--	--	1	--	1	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	1	1	1	1	1	1	0	1	0	1
I-HD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	1	1	1	1	1	1	0	1	0	1
M-SD total	1	1	1	1	1	1	0	1	0	1
M-HD total	0	0	0	0	0	0	0	0	0	0

表 2.7.3.6-96. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験）（最終 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	2	2	1	2	2	1	2	2	1	2
I-SD	1	1	1	1	1	1	1	1	0	1
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	1	1	1	1	1	1	1	1	0	1
I-HD	0	0	0	0	0	0	0	0	0	0
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD-OL	1	1	--	1	1	0	1	1	1	1
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	1	1	--	1	1	0	1	1	1	1
M-SD + M-HD total	2	2	1	2	2	1	2	2	1	2
M-SD total	0	0	0	0	0	0	0	0	0	0
M-HD total	2	2	1	2	2	1	2	2	1	2

表 2.7.3.6-96. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験）（最終 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted]	1	1	1	1	1	1	1	1	0	1
I-SD	0	0	0	0	0	0	0	0	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	1	1	1	1	1	1	1	1	0	1
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	1	1	1	1	1	1	1	1	0	1
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	1	1	1	1	1	1	1	1	0	1
M-SD total	0	0	0	0	0	0	0	0	0	0
M-HD total	1	1	1	1	1	1	1	1	0	1

表 2.7.3.6-96. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験）（最終 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	4	4	2	4	4	2	4	4	2	3
I-SD	0	0	0	0	0	0	0	0	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	2	2	2	2	2	2	2	2	1	2
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	1	1	1	1	1	1	1	1	0	1
I-HD/M-HD	1	1	1	1	1	1	1	1	1	1
I-HD-OL	2	2	--	2	2	0	2	2	1	1
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	2	2	--	2	2	0	2	2	1	1
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	4	4	2	4	4	2	4	4	2	3
M-SD total	3	3	1	3	3	1	3	3	1	2
M-HD total	1	1	1	1	1	1	1	1	1	1

表 2.7.3.6-96. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験）（最終 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	4	4	4	4	4	4	4	4	1	4
I-SD	1	1	1	1	1	1	1	1	0	1
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	1	1	1	1	1	1	1	1	0	1
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	3	3	3	3	3	3	3	3	1	3
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	2	2	2	2	2	2	2	2	1	2
I-HD/M-HD	1	1	1	1	1	1	1	1	0	1
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	4	4	4	4	4	4	4	4	1	4
M-SD total	3	3	3	3	3	3	3	3	1	3
M-HD total	1	1	1	1	1	1	1	1	0	1

表 2.7.3.6-96. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験）（最終 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted]	1	1	1	0	0	1	0	1	0	0
I-SD	1	1	1	0	0	1	0	1	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	1	1	1	0	0	1	0	1	0	0
I-HD	0	0	0	0	0	0	0	0	0	0
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	1	1	1	0	0	1	0	1	0	0
M-SD total	0	0	0	0	0	0	0	0	0	0
M-HD total	1	1	1	0	0	1	0	1	0	0

表 2.7.3.6-96. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験）（最終 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	1	1	0	1	1	0	1	1	1	0
I-SD	0	0	0	0	0	0	0	0	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	0	0	0	0	0	0	0	0	0	0
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD-OL	1	1	--	1	1	0	1	1	1	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	1	1	--	1	1	0	1	1	1	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	1	1	0	1	1	0	1	1	1	0
M-SD total	1	1	0	1	1	0	1	1	1	0
M-HD total	0	0	0	0	0	0	0	0	0	0

表 2.7.3.6-96. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験）（最終 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	1	1	1	1	1	1	1	1	0	0
I-SD	1	1	1	1	1	1	1	1	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	1	1	1	1	1	1	1	1	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	0	0	0	0	0	0	0	0	0	0
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	1	1	1	1	1	1	1	1	0	0
M-SD total	1	1	1	1	1	1	1	1	0	0
M-HD total	0	0	0	0	0	0	0	0	0	0

表 2.7.3.6-96. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験）（最終 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	2	2	2	1	1	2	1	2	0	1
I-SD	1	1	1	0	0	1	0	1	0	0
I-SD/-	1	1	1	--	--	1	--	1	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	1	1	1	1	1	1	1	1	0	1
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	1	1	1	1	1	1	1	1	0	1
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	1	1	1	1	1	1	1	1	0	1
M-SD total	0	0	0	0	0	0	0	0	0	0
M-HD total	1	1	1	1	1	1	1	1	0	1

表 2.7.3.6-96. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験）（最終 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	2	2	2	2	2	2	2	2	2	2
I-SD	0	0	0	0	0	0	0	0	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	2	2	2	2	2	2	2	2	2	2
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	1	1	1	1	1	1	1	1	1	1
I-HD/M-HD	1	1	1	1	1	1	1	1	1	1
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	2	2	2	2	2	2	2	2	2	2
M-SD total	1	1	1	1	1	1	1	1	1	1
M-HD total	1	1	1	1	1	1	1	1	1	1

表 2.7.3.6-96. 治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験）（最終 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	4	4	4	4	3	4	2	4	1	1
I-SD	1	1	1	1	1	1	1	1	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	1	1	1	1	1	1	1	1	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	3	3	3	3	2	3	1	3	1	1
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	1	1	1	1	--	1	0	1	1	0
I-HD/M-SD	1	1	1	1	1	1	1	1	0	0
I-HD/M-HD	1	1	1	1	1	1	0	1	0	1
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	3	3	3	3	3	3	2	3	0	1
M-SD total	2	2	2	2	2	2	2	2	0	0
M-HD total	1	1	1	1	1	1	0	1	0	1

表 2.7.3.6-96.　　治験責任医師別の被験者の内訳（無作為化した統合被験者集団，M11-290 試験）（最終 CSR）（続き）

I-SD = induction standard dose group; I-HD = induction high dose group; I-HD-OL = induction high dose open-label group;
M-PL = maintenance placebo group; M-SD = maintenance standard dose group; M-HD = maintenance high dose group.
Note: 'randomized' group includes all patients randomized to a treatment or enrolled under amendment 4 into the OL
treatment group. Screening Failures are excluded.

Cross reference: M11-290 CSR_Final Table 14.1__1.1_A

表 2.7.3.6-97.　　治験責任医師別の被験者の内訳（無作為化した日本人被験者集団，M11-290 試験）（最終 CSR）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
All Sites	8	8	6	6	6	6	6	8	3	4
I-SD	2	2	2	0	0	2	0	2	0	0
I-SD/-	2	2	2	--	--	2	--	2	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	4	4	4	4	4	4	4	4	2	4
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	1	1	1	1	1	1	1	1	1	1
I-HD/M-HD	3	3	3	3	3	3	3	3	1	3
I-HD-OL	2	2	--	2	2	0	2	2	1	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	1	1	--	1	1	0	1	1	1	0
I-HD-OL/M-HD	1	1	--	1	1	0	1	1	0	0
M-SD + M-HD total	6	6	4	6	6	4	6	6	3	4
M-SD total	2	2	1	2	2	1	2	2	2	1
M-HD total	4	4	3	4	4	3	4	4	1	3

表 2.7.3.6-97. 治験責任医師別の被験者の内訳（無作為化した日本人被験者集団，M11-290 試験）（最終 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	2	2	1	1	1	1	1	2	0	0
I-SD	1	1	1	0	0	1	0	1	0	0
I-SD/-	1	1	1	--	--	1	--	1	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	0	0	0	0	0	0	0	0	0	0
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD-OL	1	1	--	1	1	0	1	1	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	1	1	--	1	1	0	1	1	0	0
M-SD + M-HD total	1	1	0	1	1	0	1	1	0	0
M-SD total	0	0	0	0	0	0	0	0	0	0
M-HD total	1	1	0	1	1	0	1	1	0	0

表 2.7.3.6-97. 治験責任医師別の被験者の内訳（無作為化した日本人被験者集団，M11-290 試験）（最終 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted]	1	1	1	1	1	1	1	1	0	1
I-SD	0	0	0	0	0	0	0	0	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	1	1	1	1	1	1	1	1	0	1
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	1	1	1	1	1	1	1	1	0	1
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	1	1	1	1	1	1	1	1	0	1
M-SD total	0	0	0	0	0	0	0	0	0	0
M-HD total	1	1	1	1	1	1	1	1	0	1

表 2.7.3.6-97. 治験責任医師別の被験者の内訳（無作為化した日本人被験者集団，M11-290 試験）（最終 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted]	1	1	0	1	1	0	1	1	1	0
I-SD	0	0	0	0	0	0	0	0	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	0	0	0	0	0	0	0	0	0	0
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD-OL	1	1	--	1	1	0	1	1	1	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	1	1	--	1	1	0	1	1	1	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	1	1	0	1	1	0	1	1	1	0
M-SD total	1	1	0	1	1	0	1	1	1	0
M-HD total	0	0	0	0	0	0	0	0	0	0

表 2.7.3.6-97. 治験責任医師別の被験者の内訳（無作為化した日本人被験者集団，M11-290 試験）（最終 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	2	2	2	1	1	2	1	2	0	1
I-SD	1	1	1	0	0	1	0	1	0	0
I-SD/-	1	1	1	--	--	1	--	1	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	1	1	1	1	1	1	1	1	0	1
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	0	0	0	0	0	0	0	0	0	0
I-HD/M-HD	1	1	1	1	1	1	1	1	0	1
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	1	1	1	1	1	1	1	1	0	1
M-SD total	0	0	0	0	0	0	0	0	0	0
M-HD total	1	1	1	1	1	1	1	1	0	1

表 2.7.3.6-97. 治験責任医師別の被験者の内訳（無作為化した日本人被験者集団，M11-290 試験）（最終 CSR）（続き）

Current Investigator (Site Number) Treatment	Randomized n	ITT n	ITT-E n	mITT n	mITT-E n	I-PP n	M-PP n	Safety n	RR n	Completed Week 52 n
[redacted] ([redacted])	2	2	2	2	2	2	2	2	2	2
I-SD	0	0	0	0	0	0	0	0	0	0
I-SD/-	0	0	0	--	--	0	--	0	--	--
I-SD/M-PL	0	0	0	0	--	0	0	0	0	0
I-SD/M-SD	0	0	0	0	0	0	0	0	0	0
I-SD/M-HD	0	0	0	0	0	0	0	0	0	0
I-HD	2	2	2	2	2	2	2	2	2	2
I-HD/-	0	0	0	--	--	0	--	0	--	--
I-HD/M-PL	0	0	0	0	--	0	0	0	0	0
I-HD/M-SD	1	1	1	1	1	1	1	1	1	1
I-HD/M-HD	1	1	1	1	1	1	1	1	1	1
I-HD-OL	0	0	--	0	0	0	0	0	0	0
I-HD-OL/-	0	0	--	--	--	0	--	0	--	--
I-HD-OL/M-SD	0	0	--	0	0	0	0	0	0	0
I-HD-OL/M-HD	0	0	--	0	0	0	0	0	0	0
M-SD + M-HD total	2	2	2	2	2	2	2	2	2	2
M-SD total	1	1	1	1	1	1	1	1	1	1
M-HD total	1	1	1	1	1	1	1	1	1	1

表 2.7.3.6-97.　　治験責任医師別の被験者の内訳（無作為化した日本人被験者集団，M11-290 試験）（最終 CSR）（続き）

I-SD = induction standard dose group; I-HD = induction high dose group; I-HD-OL = induction high dose open-label group;
M-PL = maintenance placebo group; M-SD = maintenance standard dose group; M-HD = maintenance high dose group.
Note: 'randomized' group includes all patients randomized to a treatment or enrolled under amendment 4 into the OL treatment group. Screening Failures are excluded.

Cross reference: M11-290 CSR_Final Table 14.1__1.1_J

表 2.7.3.6-98. 被験者の最終状況（統合集団，M11-290 試験）（最終 CSR）

Category Treatment	ITT (N=101) n	ITT-E (N=83) n	mITT (N=80) n	mITT-E (N=68) n	RR (N=25) n	Safety (N=101) n
Disc. in induction period	20	18	--	--	--	20
I-SD	10	10	--	--	--	10
I-HD	8	8	--	--	--	8
I-HD-OL	2	0	--	--	--	2
Disc. in maintenance period	--	--	12	11	5	13
M-PL	--	--	1	0	1	1
M-SD	--	--	8	8	3	8
M-HD	--	--	3	3	1	4
On DB TRT w/o re-rand. due to disease flare	--	--	7	7	--	8
M-PL	--	--	0	0	--	0
M-SD	--	--	5	5	--	5
M-HD	--	--	2	2	--	3
On DB TRT after re-rand. due to disease flare	--	--	4	3	4	4
M-PL	--	--	1	0	1	1
M-SD	--	--	2	2	2	2
M-HD	--	--	1	1	1	1
On OL TRT after re-rand. due to disease flare	--	--	1	1	1	1
M-PL	--	--	0	0	0	0
M-SD	--	--	1	1	1	1
M-HD	--	--	0	0	0	0

表 2.7.3.6-98. 被験者の最終状況（統合集団，M11-290 試験）（最終 CSR）（続き）

Category Treatment	ITT (N=101) n	ITT-E (N=83) n	mITT (N=80) n	mITT-E (N=68) n	RR (N=25) n	Safety (N=101) n
Completed week 52	--	--	68	57	20	68
M-PL	--	--	11	0	6	11
I-SD	--	--	4	0	2	4
I-HD	--	--	7	0	4	7
M-SD	--	--	25	25	5	25
I-SD	--	--	5	5	0	5
I-HD/I-HD-OL	--	--	20	20	5	20
I-HD	--	--	14	14	4	14
I-HD-OL	--	--	6	6	1	6
M-HD	--	--	32	32	9	32
I-SD	--	--	9	9	3	9
I-HD/I-HD-OL	--	--	23	23	6	23
I-HD	--	--	17	17	5	17
I-HD-OL	--	--	6	6	1	6
On DB TRT w/o disease flare	--	--	48	43	--	48
M-PL	--	--	5	0	--	5
I-SD	--	--	2	0	--	2
I-HD	--	--	3	0	--	3
M-SD	--	--	20	20	--	20
I-SD	--	--	5	5	--	5
I-HD/I-HD-OL	--	--	15	15	--	15
I-HD	--	--	10	10	--	10
I-HD-OL	--	--	5	5	--	5
M-HD	--	--	23	23	--	23
I-SD	--	--	6	6	--	6
I-HD/I-HD-OL	--	--	17	17	--	17
I-HD	--	--	12	12	--	12
I-HD-OL	--	--	5	5	--	5

表 2.7.3.6-98. 被験者の最終状況（統合集団，M11-290 試験）（最終 CSR）（続き）

Category Treatment	ITT (N=101) n	ITT-E (N=83) n	mITT (N=80) n	mITT-E (N=68) n	RR (N=25) n	Safety (N=101) n
On DB TRT after re-rand. due to disease flare	--	--	11	8	11	11
M-PL	--	--	3	0	3	3
I-SD	--	--	2	0	2	2
I-HD	--	--	1	0	1	1
M-SD	--	--	3	3	3	3
I-SD	--	--	0	0	0	0
I-HD/I-HD-OL	--	--	3	3	3	3
I-HD	--	--	3	3	3	3
I-HD-OL	--	--	0	0	0	0
M-HD	--	--	5	5	5	5
I-SD	--	--	2	2	2	2
I-HD/I-HD-OL	--	--	3	3	3	3
I-HD	--	--	3	3	3	3
I-HD-OL	--	--	0	0	0	0
On OL TRT after re-rand. due to disease flare	--	--	9	6	9	9
M-PL	--	--	3	0	3	3
I-SD	--	--	0	0	0	0
I-HD	--	--	3	0	3	3
M-SD	--	--	2	2	2	2
I-SD	--	--	0	0	0	0
I-HD/I-HD-OL	--	--	2	2	2	2
I-HD	--	--	1	1	1	1
I-HD-OL	--	--	1	1	1	1
M-HD	--	--	4	4	4	4
I-SD	--	--	1	1	1	1
I-HD/I-HD-OL	--	--	3	3	3	3
I-HD	--	--	2	2	2	2
I-HD-OL	--	--	1	1	1	1

表 2.7.3.6-98.　　被験者の最終状況（統合集団，M11-290 試験）（最終 CSR）（続き）

I-SD = induction standard dose group; I-HD = induction high dose group; I-HD-OL = induction high dose open-label group;
M-PL = maintenance placebo group; M-SD = maintenance standard dose group; M-HD = maintenance high dose group.

Cross reference: M11-290 CSR_Final Table 14.1__2.1_A

表 2.7.3.6-99.　被験者の最終状況（日本人被験者集団，M11-290 試験）（最終 CSR）

Category Treatment	ITT (N=8) n	ITT-E (N=6) n	mITT (N=6) n	mITT-E (N=6) n	RR (N=3) n	Safety (N=8) n
Disc. in induction period	2	2	--	--	--	2
I-SD	2	2	--	--	--	2
I-HD	0	0	--	--	--	0
I-HD-OL	0	0	--	--	--	0
Disc. in maintenance period	--	--	2	2	1	2
M-PL	--	--	0	0	0	0
M-SD	--	--	1	1	1	1
M-HD	--	--	1	1	0	1
On DB TRT w/o re-rand. due to disease flare	--	--	1	1	--	1
M-PL	--	--	0	0	--	0
M-SD	--	--	0	0	--	0
M-HD	--	--	1	1	--	1
On DB TRT after re-rand. due to disease flare	--	--	0	0	0	0
M-PL	--	--	0	0	0	0
M-SD	--	--	0	0	0	0
M-HD	--	--	0	0	0	0
On OL TRT after re-rand. due to disease flare	--	--	1	1	1	1
M-PL	--	--	0	0	0	0
M-SD	--	--	1	1	1	1
M-HD	--	--	0	0	0	0

表 2.7.3.6-99. 被験者の最終状況（日本人被験者集団，M11-290 試験）（最終 CSR）（続き）

Category Treatment	ITT (N=8) n	ITT-E (N=6) n	mITT (N=6) n	mITT-E (N=6) n	RR (N=3) n	Safety (N=8) n
Completed week 52	--	--	4	4	2	4
M-PL	--	--	0	0	0	0
I-SD	--	--	0	0	0	0
I-HD	--	--	0	0	0	0
M-SD	--	--	1	1	1	1
I-SD	--	--	0	0	0	0
I-HD/I-HD-OL	--	--	1	1	1	1
I-HD	--	--	1	1	1	1
I-HD-OL	--	--	0	0	0	0
M-HD	--	--	3	3	1	3
I-SD	--	--	0	0	0	0
I-HD/I-HD-OL	--	--	3	3	1	3
I-HD	--	--	3	3	1	3
I-HD-OL	--	--	0	0	0	0
On DB TRT w/o disease flare	--	--	2	2	--	2
M-PL	--	--	0	0	--	0
I-SD	--	--	0	0	--	0
I-HD	--	--	0	0	--	0
M-SD	--	--	0	0	--	0
I-SD	--	--	0	0	--	0
I-HD/I-HD-OL	--	--	0	0	--	0
I-HD	--	--	0	0	--	0
I-HD-OL	--	--	0	0	--	0
M-HD	--	--	2	2	--	2
I-SD	--	--	0	0	--	0
I-HD/I-HD-OL	--	--	2	2	--	2
I-HD	--	--	2	2	--	2
I-HD-OL	--	--	0	0	--	0

表 2.7.3.6-99. 被験者の最終状況（日本人被験者集団，M11-290 試験）（最終 CSR）（続き）

Category Treatment	ITT (N=8) n	ITT-E (N=6) n	mITT (N=6) n	mITT-E (N=6) n	RR (N=3) n	Safety (N=8) n
On DB TRT after re-rand. due to disease flare	--	--	0	0	0	0
M-PL	--	--	0	0	0	0
I-SD	--	--	0	0	0	0
I-HD	--	--	0	0	0	0
M-SD	--	--	0	0	0	0
I-SD	--	--	0	0	0	0
I-HD/I-HD-OL	--	--	0	0	0	0
I-HD	--	--	0	0	0	0
I-HD-OL	--	--	0	0	0	0
M-HD	--	--	0	0	0	0
I-SD	--	--	0	0	0	0
I-HD/I-HD-OL	--	--	0	0	0	0
I-HD	--	--	0	0	0	0
I-HD-OL	--	--	0	0	0	0
On OL TRT after re-rand. due to disease flare	--	--	2	2	2	2
M-PL	--	--	0	0	0	0
I-SD	--	--	0	0	0	0
I-HD	--	--	0	0	0	0
M-SD	--	--	1	1	1	1
I-SD	--	--	0	0	0	0
I-HD/I-HD-OL	--	--	1	1	1	1
I-HD	--	--	1	1	1	1
I-HD-OL	--	--	0	0	0	0
M-HD	--	--	1	1	1	1
I-SD	--	--	0	0	0	0
I-HD/I-HD-OL	--	--	1	1	1	1
I-HD	--	--	1	1	1	1
I-HD-OL	--	--	0	0	0	0

表 2.7.3.6-99.　　被験者の最終状況（日本人被験者集団，M11-290 試験）（最終 CSR）（続き）

I-SD = induction standard dose group; I-HD = induction high dose group; I-HD-OL = induction high dose open-label group;
M-PL = maintenance placebo group; M-SD = maintenance standard dose group; M-HD = maintenance high dose group.

Cross reference: M11-290 CSR_Final Table 14.1__2.1_J

表 2.7.3.6-100.　被験者の中止理由（統合被験者集団，M11-290 試験）（最終 CSR）

Study Period Treatment Discontinuation due to	ITT (N=101) n (%)	ITT-E (N=83) n (%)	mITT (N=80) n (%)	mITT-E (N=68) n (%)	RR (N=25) n (%)	Safety (N=101) n (%)
Disc. in induction period	20 (19.8)	18 (21.7)	--	--	--	20 (19.8)
I-SD						
All reasons$	10 (9.9)	10 (12.0)	--	--	--	10 (9.9)
Adverse event	3 (3.0)	3 (3.6)	--	--	--	3 (3.0)
Withdrew consent	3 (3.0)	3 (3.6)	--	--	--	3 (3.0)
Lost to follow-up	0	0	--	--	--	0
Lack of efficacy	2 (2.0)	2 (2.4)	--	--	--	2 (2.0)
Requires alternative (or prohibited) therapy	1 (1.0)	1 (1.2)	--	--	--	1 (1.0)
Subject non-compliance	0	0	--	--	--	0
Non-Responder at week 8	4 (4.0)	4 (4.8)	--	--	--	4 (4.0)
Other	0	0	--	--	--	0
Primary reason	10 (9.9)	10 (12.0)	--	--	--	10 (9.9)
Adverse event	1 (1.0)	1 (1.2)	--	--	--	1 (1.0)
Withdrew consent	2 (2.0)	2 (2.4)	--	--	--	2 (2.0)
Lost to follow-up	0	0	--	--	--	0
Lack of efficacy	2 (2.0)	2 (2.4)	--	--	--	2 (2.0)
Requires alternative (or prohibited) therapy	1 (1.0)	1 (1.2)	--	--	--	1 (1.0)
Subject non-compliance	0	0	--	--	--	0
Non-Responder at week 8	4 (4.0)	4 (4.8)	--	--	--	4 (4.0)
Other	0	0	--	--	--	0

表 2.7.3.6-100.　被験者の中止理由（統合被験者集団，M11-290 試験）（最終 CSR）（続き）

Study Period Treatment Discontinuation due to	ITT (N=101) n (%)	ITT-E (N=83) n (%)	mITT (N=80) n (%)	mITT-E (N=68) n (%)	RR (N=25) n (%)	Safety (N=101) n (%)
I-HD						
All reasons$	8 (7.9)	8 (9.6)	--	--	--	8 (7.9)
Adverse event	1 (1.0)	1 (1.2)	--	--	--	1 (1.0)
Withdrew consent	1 (1.0)	1 (1.2)	--	--	--	1 (1.0)
Lost to follow-up	0	0	--	--	--	0
Lack of efficacy	2 (2.0)	2 (2.4)	--	--	--	2 (2.0)
Requires alternative (or prohibited) therapy	1 (1.0)	1 (1.2)	--	--	--	1 (1.0)
Subject non-compliance	0	0	--	--	--	0
Non-Responder at week 8	6 (5.9)	6 (7.2)	--	--	--	6 (5.9)
Other	0	0	--	--	--	0
Primary reason	8 (7.9)	8 (9.6)	--	--	--	8 (7.9)
Adverse event	1 (1.0)	1 (1.2)	--	--	--	1 (1.0)
Withdrew consent	1 (1.0)	1 (1.2)	--	--	--	1 (1.0)
Lost to follow-up	0	0	--	--	--	0
Lack of efficacy	1 (1.0)	1 (1.2)	--	--	--	1 (1.0)
Requires alternative (or prohibited) therapy	1 (1.0)	1 (1.2)	--	--	--	1 (1.0)
Subject non-compliance	0	0	--	--	--	0
Non-Responder at week 8	4 (4.0)	4 (4.8)	--	--	--	4 (4.0)
Other	0	0	--	--	--	0

表 2.7.3.6-100.　被験者の中止理由（統合被験者集団，M11-290 試験）（最終 CSR）（続き）

Study Period Treatment Discontinuation due to	ITT (N=101) n (%)	ITT-E (N=83) n (%)	mITT (N=80) n (%)	mITT-E (N=68) n (%)	RR (N=25) n (%)	Safety (N=101) n (%)
I-HD-OL						
All reasons$	2 (2.0)	--	--	--	--	2 (2.0)
Adverse event	0	--	--	--	--	0
Withdrew consent	0	--	--	--	--	0
Lost to follow-up	0	--	--	--	--	0
Lack of efficacy	2 (2.0)	--	--	--	--	2 (2.0)
Requires alternative (or prohibited) therapy	2 (2.0)	--	--	--	--	2 (2.0)
Subject non-compliance	0	--	--	--	--	0
Non-Responder at week 8	0	--	--	--	--	0
Other	0	--	--	--	--	0
Primary reason	2 (2.0)	--	--	--	--	2 (2.0)
Adverse event	0	--	--	--	--	0
Withdrew consent	0	--	--	--	--	0
Lost to follow-up	0	--	--	--	--	0
Lack of efficacy	1 (1.0)	--	--	--	--	1 (1.0)
Requires alternative (or prohibited) therapy	1 (1.0)	--	--	--	--	1 (1.0)
Subject non-compliance	0	--	--	--	--	0
Non-Responder at week 8	0	--	--	--	--	0
Other	0	--	--	--	--	0

表 2.7.3.6-100.　被験者の中止理由（統合被験者集団，M11-290 試験）（最終 CSR）（続き）

Study Period Treatment Discontinuation due to	ITT (N=101) n (%)	ITT-E (N=83) n (%)	mITT (N=80) n (%)	mITT-E (N=68) n (%)	RR (N=25) n (%)	Safety (N=101) n (%)
Disc. in maintenance period	--	--	12 (15.0)	11 (16.2)	5 (20.0)	13 (12.9)
M-PL						
All reasons$	--	--	1 (1.3)	0	1 (4.0)	1 (1.0)
Adverse event	--	--	0	0	0	0
Withdrew consent	--	--	0	0	0	0
Lost to follow-up	--	--	0	0	0	0
Lack of efficacy	--	--	0	0	0	0
Requires alternative (or prohibited) therapy	--	--	1 (1.3)	0	1 (4.0)	1 (1.0)
Subject non-compliance	--	--	0	0	0	0
Non-Responder at week 8	--	--	0	0	0	0
Other	--	--	0	0	0	0
Primary reason	--	--	1 (1.3)	0	1 (4.0)	1 (1.0)
Adverse event	--	--	0	0	0	0
Withdrew consent	--	--	0	0	0	0
Lost to follow-up	--	--	0	0	0	0
Lack of efficacy	--	--	0	0	0	0
Requires alternative (or prohibited) therapy	--	--	1 (1.3)	0	1 (4.0)	1 (1.0)
Subject non-compliance	--	--	0	0	0	0
Non-Responder at week 8	--	--	0	0	0	0
Other	--	--	0	0	0	0

表 2.7.3.6-100.　被験者の中止理由（統合被験者集団，M11-290 試験）（最終 CSR）（続き）

Study Period Treatment Discontinuation due to	ITT (N=101) n (%)	ITT-E (N=83) n (%)	mITT (N=80) n (%)	mITT-E (N=68) n (%)	RR (N=25) n (%)	Safety (N=101) n (%)
M-SD + M-HD total	--	--	11 (13.8)	11 (16.2)	4 (16.0)	12 (11.9)
M-SD						
All reasons$	--	--	8 (10.0)	8 (11.8)	3 (12.0)	8 (7.9)
Adverse event	--	--	2 (2.5)	2 (2.9)	0	2 (2.0)
Withdrew consent	--	--	2 (2.5)	2 (2.9)	0	2 (2.0)
Lost to follow-up	--	--	0	0	0	0
Lack of efficacy	--	--	5 (6.3)	5 (7.4)	2 (8.0)	5 (5.0)
Requires alternative (or prohibited) therapy	--	--	2 (2.5)	2 (2.9)	2 (8.0)	2 (2.0)
Subject non-compliance	--	--	0	0	0	0
Non-Responder at week 8	--	--	0	0	0	0
Other	--	--	0	0	0	0
Primary reason	--	--	8 (10.0)	8 (11.8)	3 (12.0)	8 (7.9)
Adverse event	--	--	0	0	0	0
Withdrew consent	--	--	2 (2.5)	2 (2.9)	0	2 (2.0)
Lost to follow-up	--	--	0	0	0	0
Lack of efficacy	--	--	5 (6.3)	5 (7.4)	2 (8.0)	5 (5.0)
Requires alternative (or prohibited) therapy	--	--	1 (1.3)	1 (1.5)	1 (4.0)	1 (1.0)
Subject non-compliance	--	--	0	0	0	0
Non-Responder at week 8	--	--	0	0	0	0
Other	--	--	0	0	0	0

表 2.7.3.6-100.　被験者の中止理由（統合被験者集団，M11-290 試験）（最終 CSR）（続き）

Study Period Treatment Discontinuation due to	ITT (N=101) n (%)	ITT-E (N=83) n (%)	mITT (N=80) n (%)	mITT-E (N=68) n (%)	RR (N=25) n (%)	Safety (N=101) n (%)
M-HD						
All reasons$	--	--	3 (3.8)	3 (4.4)	1 (4.0)	4 (4.0)
Adverse event	--	--	0	0	0	0
Withdrew consent	--	--	1 (1.3)	1 (1.5)	0	1 (1.0)
Lost to follow-up	--	--	1 (1.3)	1 (1.5)	0	1 (1.0)
Lack of efficacy	--	--	1 (1.3)	1 (1.5)	0	2 (2.0)
Requires alternative (or prohibited) therapy	--	--	2 (2.5)	2 (2.9)	0	2 (2.0)
Subject non-compliance	--	--	1 (1.3)	1 (1.5)	1 (4.0)	1 (1.0)
Non-Responder at week 8	--	--	0	0	0	0
Other	--	--	0	0	0	0
Primary reason	--	--	3 (3.8)	3 (4.4)	1 (4.0)	4 (4.0)
Adverse event	--	--	0	0	0	0
Withdrew consent	--	--	1 (1.3)	1 (1.5)	0	1 (1.0)
Lost to follow-up	--	--	0	0	0	0
Lack of efficacy	--	--	1 (1.3)	1 (1.5)	0	2 (2.0)
Requires alternative (or prohibited) therapy	--	--	0	0	0	0
Subject non-compliance	--	--	1 (1.3)	1 (1.5)	1 (4.0)	1 (1.0)
Non-Responder at week 8	--	--	0	0	0	0
Other	--	--	0	0	0	0

I-SD = induction standard dose group; I-HD = induction high dose group; I-HD-OL = induction high dose open-label group;
M-PL = maintenance placebo group; M-SD = maintenance standard dose group; M-HD = maintenance high dose group.
$ Subjects who discontinued study drug are counted under each reason given for discontinuation, therefore,
the sum of the counts given for the reasons may be greater than the overall number of discontinuations.

Cross reference: M11-290 CSR_Final Table 14.1__2.2_A

表 2.7.3.6-101.　被験者の中止理由（日本人被験者，M11-290 試験）（最終 CSR）

Study Period Treatment Discontinuation due to	ITT (N=8) n (%)	ITT-E (N=6) n (%)	mITT (N=6) n (%)	mITT-E (N=6) n (%)	RR (N=3) n (%)	Safety (N=8) n (%)
Disc. in induction period	2 (25.0)	2 (33.3)	--	--	--	2 (25.0)
I-SD						
All reasons$	2 (25.0)	2 (33.3)	--	--	--	2 (25.0)
Adverse event	1 (12.5)	1 (16.7)	--	--	--	1 (12.5)
Withdrew consent	1 (12.5)	1 (16.7)	--	--	--	1 (12.5)
Lost to follow-up	0	0	--	--	--	0
Lack of efficacy	0	0	--	--	--	0
Requires alternative (or prohibited) therapy	0	0	--	--	--	0
Subject non-compliance	0	0	--	--	--	0
Non-Responder at week 8	1 (12.5)	1 (16.7)	--	--	--	1 (12.5)
Other	0	0	--	--	--	0
Primary reason	2 (25.0)	2 (33.3)	--	--	--	2 (25.0)
Adverse event	1 (12.5)	1 (16.7)	--	--	--	1 (12.5)
Withdrew consent	0	0	--	--	--	0
Lost to follow-up	0	0	--	--	--	0
Lack of efficacy	0	0	--	--	--	0
Requires alternative (or prohibited) therapy	0	0	--	--	--	0
Subject non-compliance	0	0	--	--	--	0
Non-Responder at week 8	1 (12.5)	1 (16.7)	--	--	--	1 (12.5)
Other	0	0	--	--	--	0

表 2.7.3.6-101.　被験者の中止理由（日本人被験者，M11-290 試験）（最終 CSR）（続き）

Study Period Treatment Discontinuation due to	ITT (N=8) n (%)	ITT-E (N=6) n (%)	mITT (N=6) n (%)	mITT-E (N=6) n (%)	RR (N=3) n (%)	Safety (N=8) n (%)
I-HD						
All reasons$	0	0	--	--	--	0
Adverse event	0	0	--	--	--	0
Withdrew consent	0	0	--	--	--	0
Lost to follow-up	0	0	--	--	--	0
Lack of efficacy	0	0	--	--	--	0
Requires alternative (or prohibited) therapy	0	0	--	--	--	0
Subject non-compliance	0	0	--	--	--	0
Non-Responder at week 8	0	0	--	--	--	0
Other	0	0	--	--	--	0
Primary reason	0	0	--	--	--	0
Adverse event	0	0	--	--	--	0
Withdrew consent	0	0	--	--	--	0
Lost to follow-up	0	0	--	--	--	0
Lack of efficacy	0	0	--	--	--	0
Requires alternative (or prohibited) therapy	0	0	--	--	--	0
Subject non-compliance	0	0	--	--	--	0
Non-Responder at week 8	0	0	--	--	--	0
Other	0	0	--	--	--	0

表 2.7.3.6-101.　被験者の中止理由（日本人被験者，M11-290 試験）（最終 CSR）（続き）

Study Period Treatment Discontinuation due to	ITT (N=8) n (%)	ITT-E (N=6) n (%)	mITT (N=6) n (%)	mITT-E (N=6) n (%)	RR (N=3) n (%)	Safety (N=8) n (%)
I-HD-OL						
All reasons$	0	--	--	--	--	0
Adverse event	0	--	--	--	--	0
Withdrew consent	0	--	--	--	--	0
Lost to follow-up	0	--	--	--	--	0
Lack of efficacy	0	--	--	--	--	0
Requires alternative (or prohibited) therapy	0	--	--	--	--	0
Subject non-compliance	0	--	--	--	--	0
Non-Responder at week 8	0	--	--	--	--	0
Other	0	--	--	--	--	0
Primary reason	0	--	--	--	--	0
Adverse event	0	--	--	--	--	0
Withdrew consent	0	--	--	--	--	0
Lost to follow-up	0	--	--	--	--	0
Lack of efficacy	0	--	--	--	--	0
Requires alternative (or prohibited) therapy	0	--	--	--	--	0
Subject non-compliance	0	--	--	--	--	0
Non-Responder at week 8	0	--	--	--	--	0
Other	0	--	--	--	--	0

表 2.7.3.6-101.　被験者の中止理由（日本人被験者，M11-290 試験）（最終 CSR）（続き）

Study Period Treatment Discontinuation due to	ITT (N=8) n (%)	ITT-E (N=6) n (%)	mITT (N=6) n (%)	mITT-E (N=6) n (%)	RR (N=3) n (%)	Safety (N=8) n (%)
Disc. in maintenance period	--	--	2 (33.3)	2 (33.3)	1 (33.3)	2 (25.0)
M-PL						
All reasons$	--	--	0	0	0	0
Adverse event	--	--	0	0	0	0
Withdrew consent	--	--	0	0	0	0
Lost to follow-up	--	--	0	0	0	0
Lack of efficacy	--	--	0	0	0	0
Requires alternative (or prohibited) therapy	--	--	0	0	0	0
Subject non-compliance	--	--	0	0	0	0
Non-Responder at week 8	--	--	0	0	0	0
Other	--	--	0	0	0	0
Primary reason	--	--	0	0	0	0
Adverse event	--	--	0	0	0	0
Withdrew consent	--	--	0	0	0	0
Lost to follow-up	--	--	0	0	0	0
Lack of efficacy	--	--	0	0	0	0
Requires alternative (or prohibited) therapy	--	--	0	0	0	0
Subject non-compliance	--	--	0	0	0	0
Non-Responder at week 8	--	--	0	0	0	0
Other	--	--	0	0	0	0

表 2.7.3.6-101.　被験者の中止理由（日本人被験者，M11-290 試験）（最終 CSR）（続き）

Study Period Treatment Discontinuation due to	ITT (N=8) n (%)	ITT-E (N=6) n (%)	mITT (N=6) n (%)	mITT-E (N=6) n (%)	RR (N=3) n (%)	Safety (N=8) n (%)
M-SD + M-HD total	--	--	2 (33.3)	2 (33.3)	1 (33.3)	2 (25.0)
M-SD						
All reasons$	--	--	1 (16.7)	1 (16.7)	1 (33.3)	1 (12.5)
Adverse event	--	--	0	0	0	0
Withdrew consent	--	--	0	0	0	0
Lost to follow-up	--	--	0	0	0	0
Lack of efficacy	--	--	1 (16.7)	1 (16.7)	1 (33.3)	1 (12.5)
Requires alternative (or prohibited) therapy	--	--	1 (16.7)	1 (16.7)	1 (33.3)	1 (12.5)
Subject non-compliance	--	--	0	0	0	0
Non-Responder at week 8	--	--	0	0	0	0
Other	--	--	0	0	0	0
Primary reason	--	--	1 (16.7)	1 (16.7)	1 (33.3)	1 (12.5)
Adverse event	--	--	0	0	0	0
Withdrew consent	--	--	0	0	0	0
Lost to follow-up	--	--	0	0	0	0
Lack of efficacy	--	--	1 (16.7)	1 (16.7)	1 (33.3)	1 (12.5)
Requires alternative (or prohibited) therapy	--	--	0	0	0	0
Subject non-compliance	--	--	0	0	0	0
Non-Responder at week 8	--	--	0	0	0	0
Other	--	--	0	0	0	0

表 2.7.3.6-101.　被験者の中止理由（日本人被験者，M11-290 試験）（最終 CSR）（続き）

Study Period Treatment Discontinuation due to	ITT (N=8) n (%)	ITT-E (N=6) n (%)	mITT (N=6) n (%)	mITT-E (N=6) n (%)	RR (N=3) n (%)	Safety (N=8) n (%)
M-HD						
All reasons$	--	--	1 (16.7)	1 (16.7)	0	1 (12.5)
Adverse event	--	--	0	0	0	0
Withdrew consent	--	--	0	0	0	0
Lost to follow-up	--	--	0	0	0	0
Lack of efficacy	--	--	1 (16.7)	1 (16.7)	0	1 (12.5)
Requires alternative (or prohibited) therapy	--	--	1 (16.7)	1 (16.7)	0	1 (12.5)
Subject non-compliance	--	--	0	0	0	0
Non-Responder at week 8	--	--	0	0	0	0
Other	--	--	0	0	0	0
Primary reason	--	--	1 (16.7)	1 (16.7)	0	1 (12.5)
Adverse event	--	--	0	0	0	0
Withdrew consent	--	--	0	0	0	0
Lost to follow-up	--	--	0	0	0	0
Lack of efficacy	--	--	1 (16.7)	1 (16.7)	0	1 (12.5)
Requires alternative (or prohibited) therapy	--	--	0	0	0	0
Subject non-compliance	--	--	0	0	0	0
Non-Responder at week 8	--	--	0	0	0	0
Other	--	--	0	0	0	0

I-SD = induction standard dose group; I-HD = induction high dose group; I-HD-OL = induction high dose open-label group;
M-PL = maintenance placebo group; M-SD = maintenance standard dose group; M-HD = maintenance high dose group.
$ Subjects who discontinued study drug are counted under each reason given for discontinuation, therefore,
the sum of the counts given for the reasons may be greater than the overall number of discontinuations.

Cross reference: M11-290 CSR_Final Table 14.1__2.2_J

表 2.7.3.6-102. 治験実施計画書からの逸脱（無作為化した統合被験者集団，M11-290 試験）（最終 CSR）

		I-SD				I-HD/HD-OL				
		--$ (N=10)	M-PL (N=4)	M-SD (N=8)	M-HD (N=10)	--$ (N=10)	M-PL (N=8)	M-SD (N=25)	M-HD (N=26)	Total (N=101)
Subjects who had at least one protocol deviation		0	1 (25.0)	0	4 (40.0)	1 (10.0)	3 (37.5)	8 (32.0)	5 (19.2)	22 (21.8)
Subject entered into the study even though did not satisfy entry criteria		0	0	0	1 (10.0)	0	1 (12.5)	2 (8.0)	1 (3.8)	5 (5.0)
Inclusion criteria violated	6	0	0	0	1 (10.0)	0	1 (12.5)	0	1 (3.8)	3 (3.0)
Exclusion criteria violated	24	0	0	0	0	0	0	1 (4.0)	0	1 (1.0)
	27	0	0	0	0	0	0	1 (4.0)	0	1 (1.0)
Subject received wrong treatment or incorrect dose		0	1 (25.0)	0	2 (20.0)	1 (10.0)	2 (25.0)	4 (16.0)	4 (15.4)	14 (13.9)
Subject received excluded concomitant treatment		0	0	0	0	0	0	2 (8.0)	0	2 (2.0)
Subject developed withdrawal criteria during the study and was not withdrawn		0	0	0	1 (10.0)	0	0	0	0	1 (1.0)

表 2.7.3.6-102.　治験実施計画書からの逸脱（無作為化した統合被験者集団，M11-290 試験）（最終 CSR）（続き）

	I-SD				I-HD/HD-OL				
	--$ (N=10)	M-PL (N=4)	M-SD (N=8)	M-HD (N=10)	--$ (N=10)	M-PL (N=8)	M-SD (N=25)	M-HD (N=26)	Total (N=101)

Inclusion Criteria Violated

6: Subject has a neg TB Screening Assessment. If a subject has a pos (>= 5 mm induration) PPD test and/or IGRA test at Screening, a CXR (PA and lateral view) for evaluation of active TB disease.

表 2.7.3.6-102.　治験実施計画書からの逸脱（無作為化した統合被験者集団，M11-290 試験）（最終 CSR）（続き）

	I-SD				I-HD/HD-OL				
	--$ (N=10)	M-PL (N=4)	M-SD (N=8)	M-HD (N=10)	--$ (N=10)	M-PL (N=8)	M-SD (N=25)	M-HD (N=26)	Total (N=101)

Exclusion Criteria Violated

24: Subject with a positive result for the Hepatitis B surface antigen (HBs Ag) or any HBV DNA PCR result that meets or exceeds detection sensitivity will be excluded.

27: Infection(s) requiring treatment with intravenous (IV) anti-infectives within 30 days prior to the Baseline Visit or oral anti-infectives within 14 days prior to the Baseline Visit.

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group,
M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
NOTE: All Randomized = includes all patients randomized to a treatment or enrolled under amendment 4 into the OL treatment group.
Screening Failures are excluded.
$ patients who discontinued as non-responders from the study at week 8.

Cross reference: M11-290 CSR_Final Table 14.1__9_A

表 2.7.3.6-103.　治験実施計画書からの逸脱（無作為化した日本人被験者集団，M11-290 試験）（最終 CSR）

		I-SD				I-HD/HD-OL				
		--$ (N=2)	M-PL (N=0)	M-SD (N=0)	M-HD (N=0)	--$ (N=0)	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=8)
Subjects who had at least one protocol deviation		0	0	0	0	0	0	2 (100)	0	2 (25.0)
Subject entered into the study even though did not satisfy entry criteria		0	0	0	0	0	0	1 (50.0)	0	1 (12.5)
Exclusion criteria violated	27	0	0	0	0	0	0	1 (50.0)	0	1 (12.5)
Subject received wrong treatment or incorrect dose		0	0	0	0	0	0	0	0	0
Subject received excluded concomitant treatment		0	0	0	0	0	0	1 (50.0)	0	1 (12.5)
Subject developed withdrawal criteria during the study and was not withdrawn		0	0	0	0	0	0	0	0	0

表 2.7.3.6-103.　治験実施計画書からの逸脱（無作為化した日本人被験者集団，M11-290 試験）（最終 CSR）（続き）

	I-SD				I-HD/HD-OL				
	--$ (N=2)	M-PL (N=0)	M-SD (N=0)	M-HD (N=0)	--$ (N=0)	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=8)

Inclusion Criteria Violated

No subject has inclusion criteria violated

表 2.7.3.6-103.　治験実施計画書からの逸脱（無作為化した日本人被験者集団，M11-290 試験）（最終 CSR）（続き）

	I-SD				I-HD/HD-OL				
	--$ (N=2)	M-PL (N=0)	M-SD (N=0)	M-HD (N=0)	--$ (N=0)	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=8)

Exclusion Criteria Violated

27: Infection(s) requiring treatment with intravenous (IV) anti-infectives within 30 days prior to the Baseline Visit or oral anti-infectives within 14 days prior to the Baseline Visit.

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group,
M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
NOTE: All Randomized = includes all patients randomized to a treatment or enrolled under amendment 4 into the OL treatment group.
Screening Failures are excluded.
$ patients who discontinued as non-responders from the study at week 8.

Cross reference: M11-290 CSR_Final Table 14.1__9_J

表 2.7.3.6-104.　人口統計学的特性（統合 ITT 集団，M11-290 試験）（最終 CSR）

	ITT					
	ITT-E					
	I-SD (N=32)	I-HD (N=51)	Total (N=83)	I-HD-OL (N=18)	Total (N=101)	P-Value@
Sex - n (%)						
Female	15 (46.9)	23 (45.1)	38 (45.8)	13 (72.2)	51 (50.5)	0.874
Male	17 (53.1)	28 (54.9)	45 (54.2)	5 (27.8)	50 (49.5)	
Age (year)						
n	32	51	83	18	101	0.182
Mean (SD)	14.7 (2.66)	13.8 (3.06)	14.1 (2.93)	13.8 (2.82)	14.1 (2.90)	
Median	15.5	15.0	15.0	14.0	15.0	
Min, Max	6, 17	5, 17	5, 17	7, 17	5, 17	
Age group 1 (year) - n (%)						
< 13	4 (12.5)	17 (33.3)	21 (25.3)	5 (27.8)	26 (25.7)	0.040*
>= 13	28 (87.5)	34 (66.7)	62 (74.7)	13 (72.2)	75 (74.3)	
Age group 2 (year) - n (%)						
< 12	3 (9.4)	12 (23.5)	15 (18.1)	4 (22.2)	19 (18.8)	0.145
>= 12	29 (90.6)	39 (76.5)	68 (81.9)	14 (77.8)	82 (81.2)	
Race - n (%)						
White	28 (87.5)	45 (88.2)	73 (88.0)	15 (83.3)	88 (87.1)	1.000
Black	1 (3.1)	2 (3.9)	3 (3.6)	0	3 (3.0)	
Asian	3 (9.4)	4 (7.8)	7 (8.4)	2 (11.1)	9 (8.9)	
American Indian/Alaska Native	0	0	0	0	0	
Other	0	0	0	0	0	
Multiple	0	0	0	1 (5.6)	1 (1.0)	

表 2.7.3.6-104. 人口統計学的特性（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=32)	I-HD (N=51)	Total (N=83)	I-HD-OL (N=18)	Total (N=101)	P-Value@
Ethnicity - n (%)						
Hispanic or Latino	1 (3.1)	2 (3.9)	3 (3.6)	1 (5.6)	4 (4.0)	1.000
Japanese	2 (6.3)	4 (7.8)	6 (7.2)	2 (11.1)	8 (7.9)	
No ethnicity	29 (90.6)	45 (88.2)	74 (89.2)	15 (83.3)	89 (88.1)	
Geographic region - n (%)						
North America	2 (6.3)	8 (15.7)	10 (12.0)	3 (16.7)	13 (12.9)	0.666
Western Europe	3 (9.4)	4 (7.8)	7 (8.4)	1 (5.6)	8 (7.9)	
Eastern Europe	25 (78.1)	35 (68.6)	60 (72.3)	12 (66.7)	72 (71.3)	
Japan	2 (6.3)	4 (7.8)	6 (7.2)	2 (11.1)	8 (7.9)	
Disease severity per baseline Mayo Score& - n (%)						
<= 9	27 (84.4)	42 (82.4)	69 (83.1)	15 (83.3)	84 (83.2)	0.811
> 9	5 (15.6)	9 (17.6)	14 (16.9)	3 (16.7)	17 (16.8)	
Prior exposure to anti-TNF - n (%)						
Yes	7 (21.9)	8 (15.7)	15 (18.1)	1 (5.6)	16 (15.8)	0.476
No	25 (78.1)	43 (84.3)	68 (81.9)	17 (94.4)	85 (84.2)	
Baseline systemic corticosteroid use# - n (%)						
Yes	15 (46.9)	24 (47.1)	39 (47.0)	10 (55.6)	49 (48.5)	0.987
No	17 (53.1)	27 (52.9)	44 (53.0)	8 (44.4)	52 (51.5)	

表 2.7.3.6-104. 人口統計学的特性（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=32)	I-HD (N=51)	Total (N=83)	I-HD-OL (N=18)	Total (N=101)	P-Value@
Baseline immunosuppressants (IMM) use - n (%)						
Yes	23 (71.9)	33 (64.7)	56 (67.5)	7 (38.9)	63 (62.4)	0.497
No	9 (28.1)	18 (35.3)	27 (32.5)	11 (61.1)	38 (37.6)	
Weight (kg)						
n	32	51	83	18	101	0.817
Mean (SD)	56.6 (15.07)	55.7 (19.17)	56.0 (17.61)	52.2 (17.49)	55.4 (17.56)	
Median	57.0	53.0	55.0	52.6	53.5	
Min, Max	22.2, 92.9	15.0, 110.0	15.0, 110.0	20.0, 97.4	15.0, 110.0	
Weight (kg) by sex						
Female						
n	15	23	38	13	51	0.597
Mean (SD)	53.4 (12.78)	51.0 (13.93)	52.0 (13.36)	48.8 (15.80)	51.2 (13.93)	
Median	57.0	51.0	52.5	50.1	52.0	
Min, Max	22.2, 76.0	21.5, 89.0	21.5, 89.0	20.0, 76.5	20.0, 89.0	
Male						
n	17	28	45	5	50	0.990
Mean (SD)	59.4 (16.69)	59.5 (22.10)	59.5 (20.03)	61.0 (20.44)	59.6 (19.86)	
Median	57.0	59.0	58.0	52.8	56.7	
Min, Max	22.9, 92.9	15.0, 110.0	15.0, 110.0	48.8, 97.4	15.0, 110.0	
Weight (kg) - n (%)						
< 40	3 (9.4)	10 (19.6)	13 (15.7)	3 (16.7)	16 (15.8)	0.345
40 - < 60	19 (59.4)	23 (45.1)	42 (50.6)	11 (61.1)	53 (52.5)	
>= 60	10 (31.3)	18 (35.3)	28 (33.7)	4 (22.2)	32 (31.7)	

表 2.7.3.6-104. 人口統計学的特性（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=32)	I-HD (N=51)	Total (N=83)	I-HD-OL (N=18)	Total (N=101)	P-Value@
Height (cm)						
n	32	51	83	18	101	0.077
Mean (SD)	166.9 (14.95)	160.1 (18.09)	162.7 (17.19)	160.1 (13.68)	162.3 (16.58)	
Median	169.5	160.0	162.0	162.1	162.0	
Min, Max	120.1, 190.5	104.5, 193.0	104.5, 193.0	119.0, 182.4	104.5, 193.0	
Body mass index (kg/m^2)						
n	32	51	83	18	101	0.236
Mean (SD)	20.0 (3.60)	21.0 (4.00)	20.6 (3.86)	19.9 (4.57)	20.5 (3.98)	
Median	19.5	20.3	20.1	19.2	20.0	
Min, Max	14.7, 32.1	13.7, 32.7	13.7, 32.7	12.1, 29.3	12.1, 32.7	
Tobacco/Nicotine$ - n (%)						
Current	0	0	0	0	0	
Former	0	0	0	0	0	
Never	32 (100)	51 (100)	83 (100)	18 (100)	101 (100)	
Unknown	0	0	0	0	0	

表 2.7.3.6-104.　人口統計学的特性（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=32)	I-HD (N=51)	Total (N=83)	I-HD-OL (N=18)	Total (N=101)	P-Value@
Alcohol$ - n (%)						
Current	0	0	0	0	0	
Former	0	0	0	0	0	
Never	32 (100)	50 (100)	82 (100)	18 (100)	100 (100)	
Unknown	0	1	1	0	1	

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
Note: percentages calculated on non-missing values.
$ percentages calculated on non-unknown values. A subject may be a current user of one type of tobacco, A former user of another type of tobacco and never used another type of tobacco.
A subject will be counted in the category closest to user.
@ p-value for differences between the treatment groups I-SD and I-HD from chi-square test (or fisher's exact test if expected number of counts in a cell is < 5) for categorical variables or from one-way anova for continuous variables.
& true baseline Mayo Score is displayed. Subject [redacted] was randomized in the stratum '> 9', but actually had a baseline Mayo Score of 8.8 (corrected by the site from 9.8 to 8.8 after randomization).
# true baseline systemic corticosteroid use is displayed. Subject [redacted] was randomized in the stratum 'No', but actually has baseline systemic corticosteroid use documented.
***, **, * Statistically significant at 0.001, 0.01, and 0.05 level, respectively.

Cross reference: M11-290 CSR_Final Table 14.1__3.1_A

表 2.7.3.6-105. 人口統計学的特性（日本人 ITT 集団，M11-290 試験）（最終 CSR）

	ITT					
	ITT-E					
	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=2)	Total (N=8)	P-Value@
Sex - n (%)						
Female	0	0	0	0	0	
Male	2 (100)	4 (100)	6 (100)	2 (100)	8 (100)	
Age (year)						
n	2	4	6	2	8	0.428
Mean (SD)	15.0 (1.41)	13.8 (1.71)	14.2 (1.60)	15.0 (0.00)	14.4 (1.41)	
Median	15.0	13.5	14.0	15.0	14.5	
Min, Max	14, 16	12, 16	12, 16	15, 15	12, 16	
Age group 1 (year) - n (%)						
< 13	0	1 (25.0)	1 (16.7)	0	1 (12.5)	1.000
>= 13	2 (100)	3 (75.0)	5 (83.3)	2 (100)	7 (87.5)	
Age group 2 (year) - n (%)						
< 12	0	0	0	0	0	
>= 12	2 (100)	4 (100)	6 (100)	2 (100)	8 (100)	
Race - n (%)						
White	0	0	0	0	0	
Black	0	0	0	0	0	
Asian	2 (100)	4 (100)	6 (100)	2 (100)	8 (100)	
American Indian/Alaska Native	0	0	0	0	0	
Other	0	0	0	0	0	
Multiple	0	0	0	0	0	

表 2.7.3.6-105. 人口統計学的特性（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=2)	Total (N=8)	P-Value@
Ethnicity - n (%)						
Hispanic or Latino	0	0	0	0	0	
Japanese	2 (100)	4 (100)	6 (100)	2 (100)	8 (100)	
No ethnicity	0	0	0	0	0	
Geographic region - n (%)						
Japan	2 (100)	4 (100)	6 (100)	2 (100)	8 (100)	
Disease severity per baseline Mayo Score - n (%)						
<= 9	2 (100)	4 (100)	6 (100)	2 (100)	8 (100)	
> 9	0	0	0	0	0	
Prior exposure to anti-TNF - n (%)						
Yes	1 (50.0)	0	1 (16.7)	0	1 (12.5)	0.333
No	1 (50.0)	4 (100)	5 (83.3)	2 (100)	7 (87.5)	
Baseline systemic corticosteroid use - n (%)						
Yes	2 (100)	2 (50.0)	4 (66.7)	1 (50.0)	5 (62.5)	0.467
No	0	2 (50.0)	2 (33.3)	1 (50.0)	3 (37.5)	

表 2.7.3.6-105. 人口統計学的特性（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=2)	Total (N=8)	P-Value@
Baseline immunosuppressants (IMM) use - n (%)						
Yes	2 (100)	4 (100)	6 (100)	2 (100)	8 (100)	
No	0	0	0	0	0	
Weight (kg)						
n	2	4	6	2	8	0.980
Mean (SD)	47.2 (3.32)	47.0 (6.00)	47.1 (4.88)	53.0 (0.78)	48.5 (4.95)	
Median	47.2	48.9	48.1	53.0	50.4	
Min, Max	44.8, 49.5	38.7, 51.6	38.7, 51.6	52.4, 53.5	38.7, 53.5	
Weight (kg) by sex						
Female						
n	0	0	0	0	0	
Mean (SD)						
Median						
Min, Max						
Male						
n	2	4	6	2	8	0.980
Mean (SD)	47.2 (3.32)	47.0 (6.00)	47.1 (4.88)	53.0 (0.78)	48.5 (4.95)	
Median	47.2	48.9	48.1	53.0	50.4	
Min, Max	44.8, 49.5	38.7, 51.6	38.7, 51.6	52.4, 53.5	38.7, 53.5	
Weight (kg) - n (%)						
< 40	0	1 (25.0)	1 (16.7)	0	1 (12.5)	1.000
40 - < 60	2 (100)	3 (75.0)	5 (83.3)	2 (100)	7 (87.5)	
>= 60	0	0	0	0	0	

表 2.7.3.6-105. 人口統計学的特性（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=2)	Total (N=8)	P-Value@
Height (cm)						
n	2	4	6	2	8	0.639
Mean (SD)	158.2 (5.02)	154.8 (8.38)	155.9 (7.09)	167.3 (7.28)	158.7 (8.43)	
Median	158.2	158.3	158.3	167.3	159.6	
Min, Max	154.6, 161.7	142.3, 160.2	142.3, 161.7	162.1, 172.4	142.3, 172.4	
Body mass index (kg/m^2)						
n	2	4	6	2	8	0.631
Mean (SD)	18.9 (2.53)	19.6 (0.73)	19.3 (1.31)	19.0 (1.37)	19.3 (1.23)	
Median	18.9	19.6	19.6	19.0	19.5	
Min, Max	17.1, 20.7	18.8, 20.3	17.1, 20.7	18.0, 19.9	17.1, 20.7	
Tobacco/Nicotine$ - n (%)						
Current	0	0	0	0	0	
Former	0	0	0	0	0	
Never	2 (100)	4 (100)	6 (100)	2 (100)	8 (100)	
Unknown	0	0	0	0	0	

表 2.7.3.6-105.　人口統計学的特性（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=2)	Total (N=8)	P-Value@
Alcohol$ - n (%)						
Current	0	0	0	0	0	
Former	0	0	0	0	0	
Never	2 (100)	4 (100)	6 (100)	2 (100)	8 (100)	
Unknown	0	0	0	0	0	

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
Note: percentages calculated on non-missing values.
$ percentages calculated on non-unknown values. A subject may be a current user of one type of tobacco, A former user of another type of tobacco and never used another type of tobacco.
A subject will be counted in the category closest to user.
@ p-value for differences between the treatment groups I-SD and I-HD from chi-square test (or fisher's exact test if expected number of counts in a cell is < 5) for categorical variables or from one-way anova for continuous variables.

Cross reference: M11-290 CSR_Final Table 14.1__3.1_J

表 2.7.3.6-106. 人口統計学的特性（統合 mITT 集団，M11-290 試験）（最終 CSR）

	mITT					
	mITT-E					
	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)	P-Value@
Sex - n (%)						
Female	3 (25.0)	18 (54.5)	18 (51.4)	36 (52.9)	39 (48.8)	0.797
Male	9 (75.0)	15 (45.5)	17 (48.6)	32 (47.1)	41 (51.3)	
Age (year)						
n	12	33	35	68	80	0.217
Mean (SD)	14.9 (2.54)	13.2 (3.04)	14.2 (3.29)	13.7 (3.19)	13.9 (3.11)	
Median	15.5	14.0	16.0	14.0	15.0	
Min, Max	9, 17	6, 17	5, 17	5, 17	5, 17	
Age group 1 (year) - n (%)						
< 13	2 (16.7)	12 (36.4)	9 (25.7)	21 (30.9)	23 (28.8)	0.342
>= 13	10 (83.3)	21 (63.6)	26 (74.3)	47 (69.1)	57 (71.3)	
Age group 2 (year) - n (%)						
< 12	2 (16.7)	10 (30.3)	7 (20.0)	17 (25.0)	19 (23.8)	0.327
>= 12	10 (83.3)	23 (69.7)	28 (80.0)	51 (75.0)	61 (76.3)	
Race - n (%)						
White	11 (91.7)	29 (87.9)	30 (85.7)	59 (86.8)	70 (87.5)	0.752
Black	0	2 (6.1)	1 (2.9)	3 (4.4)	3 (3.8)	
Asian	1 (8.3)	2 (6.1)	4 (11.4)	6 (8.8)	7 (8.8)	
American Indian/Alaska Native	0	0	0	0	0	
Other	0	0	0	0	0	
Multiple	0	0	0	0	0	

表 2.7.3.6-106. 人口統計学的特性（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT					
	mITT-E					
	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)	P-Value@
Ethnicity - n (%)						
Hispanic or Latino	0	3 (9.1)	1 (2.9)	4 (5.9)	4 (5.0)	0.527
Japanese	0	2 (6.1)	4 (11.4)	6 (8.8)	6 (7.5)	
No ethnicity	12 (100)	28 (84.8)	30 (85.7)	58 (85.3)	70 (87.5)	
Geographic region - n (%)						
North America	1 (8.3)	7 (21.2)	3 (8.6)	10 (14.7)	11 (13.8)	0.172
Western Europe	1 (8.3)	0	3 (8.6)	3 (4.4)	4 (5.0)	
Eastern Europe	10 (83.3)	24 (72.7)	25 (71.4)	49 (72.1)	59 (73.8)	
Japan	0	2 (6.1)	4 (11.4)	6 (8.8)	6 (7.5)	
Disease severity per baseline Mayo Score - n (%)						
<= 9	11 (91.7)	27 (81.8)	30 (85.7)	57 (83.8)	68 (85.0)	0.663
> 9	1 (8.3)	6 (18.2)	5 (14.3)	11 (16.2)	12 (15.0)	
Prior exposure to anti-TNF - n (%)						
Yes	2 (16.7)	2 (6.1)	6 (17.1)	8 (11.8)	10 (12.5)	0.260
No	10 (83.3)	31 (93.9)	29 (82.9)	60 (88.2)	70 (87.5)	
Baseline systemic corticosteroid use - n (%)						
Yes	5 (41.7)	15 (45.5)	17 (48.6)	32 (47.1)	37 (46.3)	0.797
No	7 (58.3)	18 (54.5)	18 (51.4)	36 (52.9)	43 (53.8)	

表 2.7.3.6-106. 人口統計学的特性（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT					
	mITT-E					
	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)	P-Value@
Baseline immunosuppressants (IMM) use - n (%)						
Yes	8 (66.7)	19 (57.6)	25 (71.4)	44 (64.7)	52 (65.0)	0.232
No	4 (33.3)	14 (42.4)	10 (28.6)	24 (35.3)	28 (35.0)	
Weight (kg)						
n	12	33	35	68	80	0.435
Mean (SD)	61.7 (14.55)	53.1 (15.26)	56.7 (21.86)	54.9 (18.90)	55.9 (18.40)	
Median	58.5	53.5	57.0	53.9	55.7	
Min, Max	43.0, 92.9	21.5, 91.6	15.0, 110.0	15.0, 110.0	15.0, 110.0	
Weight (kg) by sex						
Female						
n	3	18	18	36	39	0.220
Mean (SD)	51.9 (7.05)	48.1 (14.85)	54.9 (17.35)	51.5 (16.28)	51.5 (15.70)	
Median	48.1	50.6	56.1	53.3	53.0	
Min, Max	47.5, 60.0	21.5, 76.5	20.0, 89.0	20.0, 89.0	20.0, 89.0	
Male						
n	9	15	17	32	41	0.960
Mean (SD)	65.0 (15.17)	59.0 (14.01)	58.6 (26.24)	58.8 (21.07)	60.1 (19.92)	
Median	59.0	56.3	57.0	56.7	58.0	
Min, Max	43.0, 92.9	31.5, 91.6	15.0, 110.0	15.0, 110.0	15.0, 110.0	
Weight (kg) - n (%)						
< 40	0	7 (21.2)	8 (22.9)	15 (22.1)	15 (18.8)	0.454
40 - < 60	7 (58.3)	16 (48.5)	12 (34.3)	28 (41.2)	35 (43.8)	
>= 60	5 (41.7)	10 (30.3)	15 (42.9)	25 (36.8)	30 (37.5)	

表 2.7.3.6-106. 人口統計学的特性（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT					
	mITT-E					
	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)	P-Value@
Height (cm)						
n	12	33	35	68	80	0.912
Mean (SD)	170.9 (13.13)	159.8 (16.39)	160.3 (19.22)	160.0 (17.77)	161.6 (17.52)	
Median	172.0	162.0	162.0	162.0	162.1	
Min, Max	149.0, 190.5	120.0, 184.0	104.5, 193.0	104.5, 193.0	104.5, 193.0	
Body mass index (kg/m^2)						
n	12	33	35	68	80	0.460
Mean (SD)	20.9 (2.54)	20.3 (3.51)	21.1 (4.94)	20.7 (4.29)	20.8 (4.07)	
Median	20.4	20.0	20.3	20.2	20.2	
Min, Max	17.8, 25.6	14.7, 32.1	12.1, 30.4	12.1, 32.1	12.1, 32.1	
Tobacco/Nicotine$ - n (%)						
Current	0	0	0	0	0	
Former	0	0	0	0	0	
Never	12 (100)	33 (100)	35 (100)	68 (100)	80 (100)	
Unknown	0	0	0	0	0	

表 2.7.3.6-106. 人口統計学的特性（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT					
			mITT-E			
	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)	P-Value@
Alcohol$ - n (%)						
Current	0	0	0	0	0	
Former	0	0	0	0	0	
Never	12 (100)	33 (100)	35 (100)	68 (100)	80 (100)	
Unknown	0	0	0	0	0	

M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
Note: percentages calculated on non-missing values.
$ percentages calculated on non-unknown values. A subject may be a current user of one type of tobacco, A former user of another type of tobacco and never used another type of tobacco.
A subject will be counted in the category closest to user.
@ p-value for differences between the treatment groups M-SD and M-HD from chi-square test (or fisher's exact test if expected number of counts in a cell is < 5) for categorical variables or from one-way anova for continuous variables.

Cross reference: M11-290 CSR_Final Table 14.1__3.2_A

表 2.7.3.6-107.　人口統計学的特性（日本人 mITT 集団，M11-290 試験）（最終 CSR）

	mITT					
		mITT-E				
	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)	P-Value@
Sex - n (%)						
Female	0	0	0	0	0	
Male	0	2 (100)	4 (100)	6 (100)	6 (100)	
Age (year)						
n	0	2	4	6	6	0.869
Mean (SD)		14.0 (1.41)	14.3 (1.71)	14.2 (1.47)	14.2 (1.47)	
Median		14.0	14.5	14.5	14.5	
Min, Max		13, 15	12, 16	12, 16	12, 16	
Age group 1 (year) - n (%)						
< 13	0	0	1 (25.0)	1 (16.7)	1 (16.7)	1.000
>= 13	0	2 (100)	3 (75.0)	5 (83.3)	5 (83.3)	
Age group 2 (year) - n (%)						
< 12	0	0	0	0	0	
>= 12	0	2 (100)	4 (100)	6 (100)	6 (100)	
Race - n (%)						
White	0	0	0	0	0	
Black	0	0	0	0	0	
Asian	0	2 (100)	4 (100)	6 (100)	6 (100)	
American Indian/Alaska Native	0	0	0	0	0	
Other	0	0	0	0	0	
Multiple	0	0	0	0	0	

表 2.7.3.6-107. 人口統計学的特性（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT					
		mITT-E				
	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)	P-Value@
Ethnicity - n (%)						
Hispanic or Latino	0	0	0	0	0	
Japanese	0	2 (100)	4 (100)	6 (100)	6 (100)	
No ethnicity	0	0	0	0	0	
Geographic region - n (%)						
Japan	0	2 (100)	4 (100)	6 (100)	6 (100)	
Disease severity per baseline Mayo Score - n (%)						
<= 9	0	2 (100)	4 (100)	6 (100)	6 (100)	
> 9	0	0	0	0	0	
Prior exposure to anti-TNF - n (%)						
Yes	0	0	0	0	0	
No	0	2 (100)	4 (100)	6 (100)	6 (100)	
Baseline systemic corticosteroid use - n (%)						
Yes	0	2 (100)	1 (25.0)	3 (50.0)	3 (50.0)	0.400
No	0	0	3 (75.0)	3 (50.0)	3 (50.0)	

表 2.7.3.6-107. 人口統計学的特性（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT					
		mITT-E				
	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)	P-Value@
Baseline immunosuppressants (IMM) use - n (%)						
Yes	0	2 (100)	4 (100)	6 (100)	6 (100)	
No	0	0	0	0	0	
Weight (kg)						
n	0	2	4	6	6	0.320
Mean (SD)		52.6 (1.34)	47.2 (6.21)	49.0 (5.57)	49.0 (5.57)	
Median		52.6	48.9	51.4	51.4	
Min, Max		51.6, 53.5	38.7, 52.4	38.7, 53.5	38.7, 53.5	
Weight (kg) by sex						
Female						
n	0	0	0	0	0	
Mean (SD)						
Median						
Min, Max						
Male						
n	0	2	4	6	6	0.320
Mean (SD)		52.6 (1.34)	47.2 (6.21)	49.0 (5.57)	49.0 (5.57)	
Median		52.6	48.9	51.4	51.4	
Min, Max		51.6, 53.5	38.7, 52.4	38.7, 53.5	38.7, 53.5	
Weight (kg) - n (%)						
< 40	0	0	1 (25.0)	1 (16.7)	1 (16.7)	1.000
40 - < 60	0	2 (100)	3 (75.0)	5 (83.3)	5 (83.3)	
>= 60	0	0	0	0	0	

表 2.7.3.6-107.　人口統計学的特性（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT					
		mITT-E				
	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)	P-Value@
Height (cm)						
n	0	2	4	6	6	0.220
Mean (SD)		166.3 (8.63)	155.3 (8.84)	158.9 (9.71)	158.9 (9.71)	
Median		166.3	158.3	159.6	159.6	
Min, Max		160.2, 172.4	142.3, 162.1	142.3, 172.4	142.3, 172.4	
Body mass index (kg/m^2)						
n	0	2	4	6	6	0.606
Mean (SD)		19.1 (1.49)	19.5 (0.70)	19.4 (0.89)	19.4 (0.89)	
Median		19.1	19.5	19.5	19.5	
Min, Max		18.0, 20.1	18.8, 20.3	18.0, 20.3	18.0, 20.3	
Tobacco/Nicotine$ - n (%)						
Current	0	0	0	0	0	
Former	0	0	0	0	0	
Never	0	2 (100)	4 (100)	6 (100)	6 (100)	
Unknown	0	0	0	0	0	

表 2.7.3.6-107.　人口統計学的特性（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT					
		mITT-E				
	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)	P-Value@
Alcohol$ - n (%)						
Current	0	0	0	0	0	
Former	0	0	0	0	0	
Never	0	2 (100)	4 (100)	6 (100)	6 (100)	
Unknown	0	0	0	0	0	

M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
Note: percentages calculated on non-missing values.
$ percentages calculated on non-unknown values. A subject may be a current user of one type of tobacco, A former user of another type of tobacco and never used another type of tobacco.
A subject will be counted in the category closest to user.
@ p-value for differences between the treatment groups M-SD and M-HD from chi-square test (or fisher's exact test if expected number of counts in a cell is < 5) for categorical variables or from one-way anova for continuous variables.

Cross reference: M11-290 CSR_Final Table 14.1__3.2_J

表 2.7.3.6-108.　疾患特性（統合 ITT 集団，M11-290 試験）（最終 CSR）

	ITT					
	ITT-E					
	I-SD (N=32)	I-HD (N=51)	Total (N=83)	I-HD-OL (N=18)	Total (N=101)	P-Value@
Duration of UC (month)						
n	32	51	83	18	101	0.118
Mean (SD)	23.6 (19.77)	33.4 (31.58)	29.6 (27.92)	22.1 (24.49)	28.3 (27.38)	
Median	13.8	22.8	20.0	13.4	18.9	
Min, Max	3.7, 63.9	4.5, 136.9	3.7, 136.9	3.9, 108.0	3.7, 136.9	
Duration of UC (year)						
n	32	51	83	18	101	0.118
Mean (SD)	2.0 (1.65)	2.8 (2.63)	2.5 (2.33)	1.8 (2.04)	2.4 (2.28)	
Median	1.1	1.9	1.7	1.1	1.6	
Min, Max	0.3, 5.3	0.4, 11.4	0.3, 11.4	0.3, 9.0	0.3, 11.4	
Site of UC - n (%)						
Left sided UC	11 (34.4)	22 (43.1)	33 (39.8)	5 (27.8)	38 (37.6)	0.427
Extensive UC/pancolitis	21 (65.6)	29 (56.9)	50 (60.2)	13 (72.2)	63 (62.4)	
Mayo Score						
n	32	51	83	18	101	0.858
Mean (SD)	7.8 (1.22)	7.7 (1.25)	7.8 (1.23)	7.7 (1.09)	7.8 (1.20)	
Median	7.8	7.4	7.6	7.4	7.6	
Min, Max	6.0, 10.0	6.0, 10.8	6.0, 10.8	6.0, 9.6	6.0, 10.8	

表 2.7.3.6-108. 疾患特性（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=32)	I-HD (N=51)	Total (N=83)	I-HD-OL (N=18)	Total (N=101)	P-Value@
Partial Mayo Score						
n	32	51	83	18	101	0.656
Mean (SD)	5.7 (1.14)	5.5 (1.24)	5.6 (1.20)	5.5 (1.06)	5.6 (1.17)	
Median	5.8	5.2	5.4	5.3	5.4	
Min, Max	4.0, 8.0	3.4, 8.8	3.4, 8.8	4.0, 7.6	3.4, 8.8	
Endoscopy Subscore						
n	32	51	83	18	101	0.406
Mean (SD)	2.1 (0.34)	2.2 (0.40)	2.2 (0.38)	2.2 (0.43)	2.2 (0.38)	
Median	2.0	2.0	2.0	2.0	2.0	
Min, Max	2.0, 3.0	2.0, 3.0	2.0, 3.0	2.0, 3.0	2.0, 3.0	
Rectal Bleeding Subscore						
n	32	51	83	18	101	0.391
Mean (SD)	1.4 (0.93)	1.5 (0.88)	1.5 (0.90)	1.4 (0.97)	1.5 (0.91)	
Median	1.5	1.2	1.4	1.1	1.3	
Min, Max	0.0, 3.0	0.0, 3.0	0.0, 3.0	0.0, 3.0	0.0, 3.0	
PGA Subscore						
n	32	51	83	18	101	0.612
Mean (SD)	2.2 (0.40)	2.2 (0.43)	2.2 (0.41)	2.2 (0.38)	2.2 (0.41)	
Median	2.0	2.0	2.0	2.0	2.0	
Min, Max	2.0, 3.0	2.0, 3.0	2.0, 3.0	2.0, 3.0	2.0, 3.0	

表 2.7.3.6-108. 疾患特性（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=32)	I-HD (N=51)	Total (N=83)	I-HD-OL (N=18)	Total (N=101)	P-Value@
Stool Frequency Subscore						
n	32	51	83	18	101	0.074
Mean (SD)	2.1 (0.78)	1.8 (0.88)	1.9 (0.85)	1.9 (0.73)	1.9 (0.83)	
Median	2.1	1.6	2.0	2.0	2.0	
Min, Max	0.6, 3.0	0.0, 3.0	0.0, 3.0	0.0, 3.0	0.0, 3.0	
Number of stools in the last 24 hours prior to baseline						
n	32	51	83	18	101	0.849
Mean (SD)	3.9 (2.15)	4.0 (2.47)	4.0 (2.34)	4.4 (2.36)	4.1 (2.34)	
Median	4.0	4.0	4.0	4.0	4.0	
Min, Max	0.0, 9.0	0.0, 13.0	0.0, 13.0	2.0, 13.0	0.0, 13.0	
PUCAI total score						
n	32	51	83	18	101	0.775
Mean (SD)	39.8 (18.00)	40.9 (16.78)	40.5 (17.16)	41.8 (14.65)	40.7 (16.68)	
Median	38.8	40.0	40.0	43.8	42.5	
Min, Max	0.0, 72.5	5.0, 80.0	0.0, 80.0	15.0, 72.5	0.0, 80.0	
IMPACT III total score						
n	29	48	77	17	94	0.883
Mean (SD)	110.0 (21.71)	110.8 (23.57)	110.5 (22.74)	109.6 (19.19)	110.4 (22.05)	
Median	103.0	114.0	112.0	118.0	112.0	
Min, Max	78.0, 155.0	63.0, 159.0	63.0, 159.0	76.0, 144.0	63.0, 159.0	

表 2.7.3.6-108. 疾患特性（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=32)	I-HD (N=51)	Total (N=83)	I-HD-OL (N=18)	Total (N=101)	P-Value@
IMPACT III - body image						
n	29	48	77	17	94	0.170
Mean (SD)	10.4 (2.03)	9.7 (2.30)	10.0 (2.22)	9.5 (2.40)	9.9 (2.25)	
Median	11.0	10.0	10.0	10.0	10.0	
Min, Max	7.0, 15.0	4.0, 14.0	4.0, 15.0	4.0, 12.0	4.0, 15.0	
IMPACT III - bowel symptoms						
n	29	48	77	17	94	0.689
Mean (SD)	21.1 (5.28)	20.6 (5.12)	20.7 (5.15)	19.0 (4.15)	20.4 (5.01)	
Median	21.0	20.0	20.0	19.0	20.0	
Min, Max	10.5, 32.0	11.0, 30.0	10.5, 32.0	12.0, 28.0	10.5, 32.0	
IMPACT III - emotional functioning						
n	29	48	77	17	94	0.603
Mean (SD)	20.1 (6.68)	20.9 (6.87)	20.6 (6.76)	20.0 (5.62)	20.5 (6.55)	
Median	18.0	22.0	21.0	19.0	21.0	
Min, Max	11.0, 34.0	8.0, 35.0	8.0, 35.0	13.0, 29.0	8.0, 35.0	
IMPACT III - social functioning						
n	29	48	77	17	94	0.644
Mean (SD)	40.0 (7.65)	40.9 (8.53)	40.6 (8.17)	41.9 (7.25)	40.8 (7.99)	
Median	40.0	42.0	41.0	43.0	41.0	
Min, Max	27.0, 55.0	22.0, 57.0	22.0, 57.0	24.0, 52.0	22.0, 57.0	

表 2.7.3.6-108. 疾患特性（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=32)	I-HD (N=51)	Total (N=83)	I-HD-OL (N=18)	Total (N=101)	P-Value@
IMPACT III - systemic symptoms						
n	29	48	77	17	94	0.692
Mean (SD)	8.2 (2.83)	8.4 (2.21)	8.4 (2.45)	8.5 (2.12)	8.4 (2.38)	
Median	8.0	9.0	8.0	8.0	8.0	
Min, Max	3.0, 14.0	4.0, 12.0	3.0, 14.0	3.0, 12.0	3.0, 14.0	
IMPACT III - treatment/interventions						
n	29	48	77	17	94	0.946
Mean (SD)	10.2 (2.47)	10.3 (2.85)	10.2 (2.70)	10.8 (2.19)	10.3 (2.61)	
Median	11.0	11.0	11.0	11.0	11.0	
Min, Max	5.0, 14.0	4.0, 15.0	4.0, 15.0	7.0, 15.0	4.0, 15.0	
WPAI - absenteeism (%)						
n	22	33	55	8	63	0.754
Mean (SD)	11.7 (16.35)	13.3 (20.53)	12.6 (18.83)	23.1 (29.27)	14.0 (20.44)	
Median	0.0	7.9	3.9	13.4	4.8	
Min, Max	0.0, 50.0	0.0, 100.0	0.0, 100.0	0.0, 71.1	0.0, 100.0	
WPAI - presenteeism (%)						
n	22	34	56	8	64	0.889
Mean (SD)	42.3 (26.54)	41.2 (29.62)	41.6 (28.21)	42.5 (23.75)	41.7 (27.52)	
Median	40.0	35.0	40.0	45.0	40.0	
Min, Max	0.0, 80.0	0.0, 100.0	0.0, 100.0	0.0, 80.0	0.0, 100.0	

表 2.7.3.6-108. 疾患特性（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=32)	I-HD (N=51)	Total (N=83)	I-HD-OL (N=18)	Total (N=101)	P-Value@
WPAI - work impairment (%)						
n	22	33	55	8	63	0.929
Mean (SD)	47.0 (29.53)	47.7 (28.94)	47.4 (28.91)	50.8 (30.64)	47.8 (28.90)	
Median	48.2	53.9	53.9	48.6	53.9	
Min, Max	0.0, 86.0	0.0, 100.0	0.0, 100.0	0.0, 94.2	0.0, 100.0	
WPAI - activity impairment (%)						
n	32	51	83	18	101	0.432
Mean (SD)	41.6 (25.79)	46.3 (26.83)	44.5 (26.38)	50.6 (29.60)	45.5 (26.92)	
Median	45.0	40.0	40.0	50.0	50.0	
Min, Max	0.0, 80.0	0.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0	
hs-CRP [mg/l]						
n	30	45	75	18	93	0.538
Mean (SD)	7.2 (25.86)	4.7 (8.33)	5.7 (17.46)	7.6 (14.06)	6.1 (16.81)	
Median	1.2	1.2	1.2	1.7	1.3	
Min, Max	0.1, 142.6	0.1, 35.2	0.1, 142.6	0.1, 40.4	0.1, 142.6	
Tuberculin PPD skin test - n (%)						
Negative	2 (100)	4 (100)	6 (100)	1 (100)	7 (100)	
Positive&	0	0	0	0	0	
Missing	30	47	77	17	94	

表 2.7.3.6-108. 疾患特性（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=32)	I-HD (N=51)	Total (N=83)	I-HD-OL (N=18)	Total (N=101)	P-Value@
QuantiFERON-TB Gold test - n (%)						
Negative	29 (93.5)	44 (89.8)	73 (91.3)	17 (100)	90 (92.8)	0.829
Positive	0	2 (4.1)	2 (2.5)	0	2 (2.1)	
Indeterminate	2 (6.5)	3 (6.1)	5 (6.3)	0	5 (5.2)	
Missing	1	2	3	1	4	
Tuberculin positive - n (%)						
Yes$	0	2 (3.9)	2 (2.4)	0	2 (2.0)	0.520
No	32 (100)	49 (96.1)	81 (97.6)	18 (100)	99 (98.0)	
Enrollment under TB prophylaxis - n (%)						
Yes	0	2 (3.9)	2 (2.4)	0	2 (2.0)	0.520
No	32 (100)	49 (96.1)	81 (97.6)	18 (100)	99 (98.0)	

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
Note: percentages calculated on non-missing values.
& positive defined as >= 5 mm.
$ tuberculin PPD skin test >= 5 mm or QuantiFERON-TB Gold test is positive.
@ p-value for differences between the treatment groups I-SD and I-HD from chi-square test (or fisher's exact test if expected number of counts in a cell is < 5) for categorical variables or from one-way anova for continuous variables.
Duration of UC in months: (baseline date - date of diagnosis of UC + 1) / (365.25/12).
Duration of UC in years: (baseline date - date of diagnosis of UC + 1) / 365.25.

Cross reference: M11-290 CSR_Final Table 14.1__4.1_A

表 2.7.3.6-109.　疾患特性（日本人 ITT 集団，M11-290 試験）（最終 CSR）

	ITT					
	ITT-E					
	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=2)	Total (N=8)	P-Value@
Duration of UC (month)						
n	2	4	6	2	8	0.459
Mean (SD)	40.1 (10.85)	58.9 (29.99)	52.7 (25.64)	9.4 (7.88)	41.9 (29.64)	
Median	40.1	55.2	45.5	9.4	37.9	
Min, Max	32.5, 47.8	28.3, 97.0	28.3, 97.0	3.9, 15.0	3.9, 97.0	
Duration of UC (year)						
n	2	4	6	2	8	0.459
Mean (SD)	3.3 (0.90)	4.9 (2.50)	4.4 (2.14)	0.8 (0.66)	3.5 (2.47)	
Median	3.3	4.6	3.8	0.8	3.2	
Min, Max	2.7, 4.0	2.4, 8.1	2.4, 8.1	0.3, 1.3	0.3, 8.1	
Site of UC - n (%)						
Left sided UC	1 (50.0)	0	1 (16.7)	0	1 (12.5)	0.333
Extensive UC/pancolitis	1 (50.0)	4 (100)	5 (83.3)	2 (100)	7 (87.5)	
Mayo Score						
n	2	4	6	2	8	0.478
Mean (SD)	6.6 (0.57)	7.0 (0.50)	6.8 (0.50)	7.3 (1.51)	6.9 (0.74)	
Median	6.6	6.9	6.9	7.3	6.9	
Min, Max	6.2, 7.0	6.4, 7.6	6.2, 7.6	6.2, 8.3	6.2, 8.3	

表 2.7.3.6-109.　疾患特性（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=2)	Total (N=8)	P-Value@
Partial Mayo Score						
n	2	4	6	2	8	0.899
Mean (SD)	4.6 (0.57)	4.7 (0.93)	4.7 (0.77)	5.3 (1.51)	4.8 (0.91)	
Median	4.6	4.9	4.9	5.3	4.9	
Min, Max	4.2, 5.0	3.4, 5.6	3.4, 5.6	4.2, 6.3	3.4, 6.3	
Endoscopy Subscore						
n	2	4	6	2	8	0.541
Mean (SD)	2.0 (0.00)	2.3 (0.50)	2.2 (0.41)	2.0 (0.00)	2.1 (0.35)	
Median	2.0	2.0	2.0	2.0	2.0	
Min, Max	2.0, 2.0	2.0, 3.0	2.0, 3.0	2.0, 2.0	2.0, 3.0	
Rectal Bleeding Subscore						
n	2	4	6	2	8	0.498
Mean (SD)	1.8 (0.28)	1.4 (0.79)	1.5 (0.67)	0.8 (0.80)	1.3 (0.72)	
Median	1.8	1.5	1.8	0.8	1.5	
Min, Max	1.6, 2.0	0.4, 2.0	0.4, 2.0	0.2, 1.3	0.2, 2.0	
PGA Subscore						
n	2	4	6	2	8	0.541
Mean (SD)	2.0 (0.00)	2.3 (0.50)	2.2 (0.41)	2.0 (0.00)	2.1 (0.35)	
Median	2.0	2.0	2.0	2.0	2.0	
Min, Max	2.0, 2.0	2.0, 3.0	2.0, 3.0	2.0, 2.0	2.0, 3.0	

表 2.7.3.6-109. 疾患特性（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=2)	Total (N=8)	P-Value@
Stool Frequency Subscore						
n	2	4	6	2	8	0.653
Mean (SD)	0.8 (0.28)	1.1 (0.81)	1.0 (0.66)	2.5 (0.71)	1.4 (0.93)	
Median	0.8	1.3	1.0	2.5	1.3	
Min, Max	0.6, 1.0	0.0, 1.8	0.0, 1.8	2.0, 3.0	0.0, 3.0	
Number of stools in the last 24 hours prior to baseline						
n	2	4	6	2	8	0.506
Mean (SD)	2.5 (0.71)	3.0 (0.82)	2.8 (0.75)	4.0 (0.00)	3.1 (0.83)	
Median	2.5	3.0	3.0	4.0	3.0	
Min, Max	2.0, 3.0	2.0, 4.0	2.0, 4.0	4.0, 4.0	2.0, 4.0	
PUCAI total score						
n	2	4	6	2	8	0.719
Mean (SD)	38.8 (5.30)	31.9 (23.57)	34.2 (18.75)	28.8 (19.45)	32.8 (17.65)	
Median	38.8	30.0	32.5	28.8	32.5	
Min, Max	35.0, 42.5	5.0, 62.5	5.0, 62.5	15.0, 42.5	5.0, 62.5	
IMPACT III total score						
n	2	4	6	2	8	0.186
Mean (SD)	98.5 (3.54)	119.8 (17.63)	112.7 (17.59)	126.5 (7.78)	116.1 (16.45)	
Median	98.5	121.0	110.5	126.5	120.5	
Min, Max	96.0, 101.0	97.0, 140.0	96.0, 140.0	121.0, 132.0	96.0, 140.0	

表 2.7.3.6-109. 疾患特性（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=2)	Total (N=8)	P-Value@
IMPACT III - body image						
n	2	4	6	2	8	0.685
Mean (SD)	8.0 (1.41)	8.5 (1.29)	8.3 (1.21)	10.5 (0.71)	8.9 (1.46)	
Median	8.0	8.5	8.5	10.5	9.0	
Min, Max	7.0, 9.0	7.0, 10.0	7.0, 10.0	10.0, 11.0	7.0, 11.0	
IMPACT III - bowel symptoms						
n	2	4	6	2	8	0.460
Mean (SD)	21.0 (1.41)	24.0 (4.83)	23.0 (4.10)	21.5 (2.12)	22.6 (3.62)	
Median	21.0	25.5	23.5	21.5	22.5	
Min, Max	20.0, 22.0	17.0, 28.0	17.0, 28.0	20.0, 23.0	17.0, 28.0	
IMPACT III - emotional functioning						
n	2	4	6	2	8	0.179
Mean (SD)	15.5 (2.12)	23.3 (6.24)	20.7 (6.35)	24.5 (0.71)	21.6 (5.66)	
Median	15.5	24.0	20.0	24.5	23.5	
Min, Max	14.0, 17.0	15.0, 30.0	14.0, 30.0	24.0, 25.0	14.0, 30.0	
IMPACT III - social functioning						
n	2	4	6	2	8	0.139
Mean (SD)	37.5 (2.12)	44.3 (4.72)	42.0 (5.14)	47.5 (6.36)	43.4 (5.58)	
Median	37.5	42.5	41.0	47.5	42.0	
Min, Max	36.0, 39.0	41.0, 51.0	36.0, 51.0	43.0, 52.0	36.0, 52.0	

表 2.7.3.6-109.　疾患特性（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=2)	Total (N=8)	P-Value@
IMPACT III - systemic symptoms						
n	2	4	6	2	8	0.896
Mean (SD)	8.5 (2.12)	8.3 (2.06)	8.3 (1.86)	9.0 (1.41)	8.5 (1.69)	
Median	8.5	8.0	8.0	9.0	8.0	
Min, Max	7.0, 10.0	6.0, 11.0	6.0, 11.0	8.0, 10.0	6.0, 11.0	
IMPACT III - treatment/interventions						
n	2	4	6	2	8	0.054
Mean (SD)	8.0 (2.83)	11.5 (0.58)	10.3 (2.25)	13.5 (2.12)	11.1 (2.53)	
Median	8.0	11.5	11.0	13.5	11.5	
Min, Max	6.0, 10.0	11.0, 12.0	6.0, 12.0	12.0, 15.0	6.0, 15.0	
WPAI - absenteeism (%)						
n	2	4	6	0	6	0.415
Mean (SD)	0.0 (0.00)	19.3 (28.32)	12.9 (24.10)		12.9 (24.10)	
Median	0.0	8.6	0.0		0.0	
Min, Max	0.0, 0.0	0.0, 60.0	0.0, 60.0		0.0, 60.0	
WPAI - presenteeism (%)						
n	2	4	6	0	6	1.000
Mean (SD)	20.0 (28.28)	20.0 (33.67)	20.0 (28.98)		20.0 (28.98)	
Median	20.0	5.0	5.0		5.0	
Min, Max	0.0, 40.0	0.0, 70.0	0.0, 70.0		0.0, 70.0	

表 2.7.3.6-109. 疾患特性（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=2)	Total (N=8)	P-Value@
WPAI - work impairment (%)						
n	2	4	6	0	6	0.815
Mean (SD)	20.0 (28.28)	28.4 (41.53)	25.6 (34.83)		25.6 (34.83)	
Median	20.0	12.8	12.8		12.8	
Min, Max	0.0, 40.0	0.0, 88.0	0.0, 88.0		0.0, 88.0	
WPAI - activity impairment (%)						
n	2	4	6	2	8	0.923
Mean (SD)	35.0 (7.07)	37.5 (32.02)	36.7 (25.03)	30.0 (28.28)	35.0 (23.90)	
Median	35.0	35.0	35.0	30.0	35.0	
Min, Max	30.0, 40.0	10.0, 70.0	10.0, 70.0	10.0, 50.0	10.0, 70.0	
hs-CRP [mg/l]						
n	2	4	6	2	8	0.774
Mean (SD)	1.7 (1.27)	2.5 (3.29)	2.2 (2.65)	39.1 (1.85)	11.4 (17.22)	
Median	1.7	1.1	1.1	39.1	1.9	
Min, Max	0.8, 2.6	0.3, 7.4	0.3, 7.4	37.8, 40.4	0.3, 40.4	
Tuberculin PPD skin test - n (%)						
Negative	1 (100)	0	1 (100)	0	1 (100)	
Positive&	0	0	0	0	0	
Missing	1	4	5	2	7	

表 2.7.3.6-109.　疾患特性（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

	ITT					
	ITT-E					
	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=2)	Total (N=8)	P-Value@
QuantiFERON-TB Gold test - n (%)						
Negative	1 (50.0)	4 (100)	5 (83.3)	2 (100)	7 (87.5)	0.333
Positive	0	0	0	0	0	
Indeterminate	1 (50.0)	0	1 (16.7)	0	1 (12.5)	
Tuberculin positive - n (%)						
Yes$	0	0	0	0	0	
No	2 (100)	4 (100)	6 (100)	2 (100)	8 (100)	
Enrollment under TB prophylaxis - n (%)						
Yes	0	0	0	0	0	
No	2 (100)	4 (100)	6 (100)	2 (100)	8 (100)	

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
Note: percentages calculated on non-missing values.
Duration of UC in months: (baseline date - date of diagnosis of UC + 1) / (365.25/12).
Duration of UC in years: (baseline date - date of diagnosis of UC + 1) / 365.25.
& positive defined as >= 5 mm.
$ tuberculin PPD skin test >= 5 mm or QuantiFERON-TB Gold test is positive.
@ p-value for differences between the treatment groups I-SD and I-HD from chi-square test (or fisher's exact test if expected number of counts in a cell is < 5) for categorical variables or from one-way anova for continuous variables.

Cross reference: M11-290 CSR_Final Table 14.1__4.1_J

表 2.7.3.6-110.　疾患特性（統合 mITT 集団，M11-290 試験）（最終 CSR）

	mITT					
	mITT-E					
	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)	P-Value@
Duration of UC (month)						
n	12	33	35	68	80	0.063
Mean (SD)	38.0 (35.55)	22.5 (16.75)	33.9 (30.48)	28.3 (25.27)	29.8 (27.01)	
Median	29.8	16.1	27.4	18.7	19.1	
Min, Max	6.2, 131.9	3.9, 67.2	5.3, 123.4	3.9, 123.4	3.9, 131.9	
Duration of UC (year)						
n	12	33	35	68	80	0.063
Mean (SD)	3.2 (2.96)	1.9 (1.40)	2.8 (2.54)	2.4 (2.11)	2.5 (2.25)	
Median	2.5	1.3	2.3	1.6	1.6	
Min, Max	0.5, 11.0	0.3, 5.6	0.4, 10.3	0.3, 10.3	0.3, 11.0	
Site of UC - n (%)						
Left sided UC	5 (41.7)	11 (33.3)	14 (40.0)	25 (36.8)	30 (37.5)	0.569
Extensive UC/pancolitis	7 (58.3)	22 (66.7)	21 (60.0)	43 (63.2)	50 (62.5)	
Mayo Score						
n	12	33	35	68	80	0.207
Mean (SD)	7.4 (0.91)	7.9 (1.19)	7.6 (1.11)	7.8 (1.16)	7.7 (1.13)	
Median	7.2	7.8	7.4	7.6	7.6	
Min, Max	6.0, 9.2	6.0, 10.8	6.0, 9.8	6.0, 10.8	6.0, 10.8	

表 2.7.3.6-110.　疾患特性（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT					
	mITT-E					
	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)	P-Value@
Partial Mayo Score						
n	12	33	35	68	80	0.077
Mean (SD)	5.3 (0.77)	5.9 (1.21)	5.4 (1.05)	5.6 (1.15)	5.6 (1.11)	
Median	5.2	5.8	5.4	5.5	5.4	
Min, Max	4.0, 6.6	4.0, 8.8	3.4, 7.8	3.4, 8.8	3.4, 8.8	
Endoscopy Subscore						
n	12	33	35	68	80	0.093
Mean (SD)	2.1 (0.29)	2.1 (0.24)	2.2 (0.41)	2.1 (0.34)	2.1 (0.33)	
Median	2.0	2.0	2.0	2.0	2.0	
Min, Max	2.0, 3.0	2.0, 3.0	2.0, 3.0	2.0, 3.0	2.0, 3.0	
Rectal Bleeding Subscore						
n	12	33	35	68	80	0.276
Mean (SD)	1.2 (0.78)	1.6 (0.94)	1.4 (0.90)	1.5 (0.92)	1.5 (0.91)	
Median	1.0	1.8	1.0	1.4	1.3	
Min, Max	0.0, 2.6	0.0, 3.0	0.0, 3.0	0.0, 3.0	0.0, 3.0	
PGA Subscore						
n	12	33	35	68	80	0.082
Mean (SD)	2.2 (0.39)	2.2 (0.44)	2.1 (0.28)	2.2 (0.37)	2.2 (0.37)	
Median	2.0	2.0	2.0	2.0	2.0	
Min, Max	2.0, 3.0	2.0, 3.0	2.0, 3.0	2.0, 3.0	2.0, 3.0	

表 2.7.3.6-110.　疾患特性（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT					
		mITT-E				
	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)	P-Value@
Stool Frequency Subscore						
n	12	33	35	68	80	0.632
Mean (SD)	2.0 (0.89)	2.0 (0.75)	1.9 (0.83)	2.0 (0.79)	2.0 (0.80)	
Median	2.2	2.0	1.8	2.0	2.0	
Min, Max	0.0, 3.0	0.6, 3.0	0.0, 3.0	0.0, 3.0	0.0, 3.0	
Number of stools in the last 24 hours prior to baseline						
n	12	33	35	68	80	0.668
Mean (SD)	3.6 (1.93)	4.5 (3.10)	4.2 (1.57)	4.3 (2.42)	4.2 (2.36)	
Median	3.5	3.0	4.0	4.0	4.0	
Min, Max	1.0, 7.0	1.0, 13.0	1.0, 7.0	1.0, 13.0	1.0, 13.0	
PUCAI total score						
n	12	33	35	68	80	0.230
Mean (SD)	40.0 (13.98)	43.3 (14.52)	38.6 (17.17)	40.9 (16.00)	40.8 (15.63)	
Median	42.5	42.5	35.0	41.3	41.3	
Min, Max	10.0, 55.0	20.0, 72.5	5.0, 72.5	5.0, 72.5	5.0, 72.5	
IMPACT III total score						
n	12	31	32	63	75	0.574
Mean (SD)	110.5 (22.75)	112.2 (20.19)	115.3 (23.84)	113.8 (22.00)	113.3 (22.00)	
Median	112.5	116.0	117.5	117.0	116.0	
Min, Max	69.0, 154.0	77.0, 144.0	71.0, 159.0	71.0, 159.0	69.0, 159.0	

表 2.7.3.6-110.　疾患特性（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT					
	mITT-E					
	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)	P-Value@
IMPACT III - body image						
n	12	31	32	63	75	0.527
Mean (SD)	10.1 (2.07)	10.0 (2.15)	10.3 (2.15)	10.1 (2.14)	10.1 (2.11)	
Median	9.0	10.0	11.0	10.0	10.0	
Min, Max	8.0, 15.0	4.0, 14.0	6.0, 14.0	4.0, 14.0	4.0, 15.0	
IMPACT III - bowel symptoms						
n	12	31	32	63	75	0.247
Mean (SD)	20.9 (6.19)	20.0 (4.91)	21.5 (5.38)	20.8 (5.17)	20.8 (5.30)	
Median	20.5	19.0	21.0	20.0	20.0	
Min, Max	11.0, 29.0	12.0, 30.0	10.5, 32.0	10.5, 32.0	10.5, 32.0	
IMPACT III - emotional functioning						
n	12	31	32	63	75	0.445
Mean (SD)	21.1 (6.75)	20.8 (6.31)	22.1 (6.97)	21.4 (6.63)	21.4 (6.60)	
Median	22.0	21.0	23.5	22.0	22.0	
Min, Max	11.0, 34.0	10.0, 31.0	10.0, 35.0	10.0, 35.0	10.0, 35.0	
IMPACT III - social functioning						
n	12	31	32	63	75	0.781
Mean (SD)	38.9 (7.03)	42.4 (6.99)	41.9 (8.88)	42.2 (7.94)	41.6 (7.85)	
Median	40.0	45.0	41.5	43.0	43.0	
Min, Max	24.0, 48.0	27.0, 54.0	22.0, 57.0	22.0, 57.0	22.0, 57.0	

表 2.7.3.6-110. 疾患特性（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT					
	mITT-E					
	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)	P-Value@
IMPACT III - systemic symptoms						
n	12	31	32	63	75	0.687
Mean (SD)	9.3 (2.60)	8.4 (2.33)	8.6 (2.35)	8.5 (2.33)	8.6 (2.37)	
Median	8.5	9.0	8.5	9.0	9.0	
Min, Max	6.0, 14.0	3.0, 12.0	4.0, 12.0	3.0, 12.0	3.0, 14.0	
IMPACT III - treatment/interventions						
n	12	31	32	63	75	0.572
Mean (SD)	10.3 (3.33)	10.6 (2.35)	11.0 (2.18)	10.8 (2.25)	10.7 (2.44)	
Median	11.5	11.0	11.0	11.0	11.0	
Min, Max	4.0, 14.0	6.0, 15.0	5.0, 15.0	5.0, 15.0	4.0, 15.0	
WPAI - absenteeism (%)						
n	9	19	23	42	51	0.581
Mean (SD)	5.5 (9.03)	15.5 (21.55)	12.2 (16.81)	13.7 (18.93)	12.2 (17.80)	
Median	0.0	4.8	3.9	4.3	0.0	
Min, Max	0.0, 22.5	0.0, 71.1	0.0, 66.7	0.0, 71.1	0.0, 71.1	
WPAI - presenteeism (%)						
n	10	19	23	42	52	0.061
Mean (SD)	46.0 (25.47)	46.8 (29.07)	30.4 (26.02)	37.9 (28.33)	39.4 (27.75)	
Median	50.0	40.0	30.0	30.0	35.0	
Min, Max	0.0, 80.0	0.0, 90.0	0.0, 80.0	0.0, 90.0	0.0, 90.0	

表 2.7.3.6-110.　疾患特性（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT					
	mITT-E					
	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)	P-Value@
WPAI - work impairment (%)						
n	9	19	23	42	51	0.089
Mean (SD)	54.3 (19.77)	52.4 (30.43)	36.1 (30.03)	43.5 (30.95)	45.4 (29.42)	
Median	60.0	44.0	36.4	40.0	40.9	
Min, Max	20.0, 80.0	0.0, 94.2	0.0, 86.7	0.0, 94.2	0.0, 94.2	
WPAI - activity impairment (%)						
n	12	33	35	68	80	0.724
Mean (SD)	50.8 (22.75)	41.5 (27.96)	44.0 (29.63)	42.8 (28.64)	44.0 (27.86)	
Median	50.0	40.0	40.0	40.0	40.0	
Min, Max	0.0, 80.0	0.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0	
hs-CRP [mg/l]						
n	11	30	33	63	74	0.801
Mean (SD)	2.2 (3.10)	4.9 (8.50)	4.3 (9.08)	4.6 (8.74)	4.2 (8.18)	
Median	0.9	1.8	1.1	1.5	1.3	
Min, Max	0.1, 9.9	0.1, 37.8	0.1, 40.4	0.1, 40.4	0.1, 40.4	
Tuberculin PPD skin test - n (%)						
Negative	0	0	1 (100)	1 (100)	1 (100)	
Positive&	0	0	0	0	0	
Missing	12	33	34	67	79	

表 2.7.3.6-110.　疾患特性（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT					
	mITT-E					
	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)	P-Value@
QuantiFERON-TB Gold test - n (%)						
Negative	10 (83.3)	33 (100)	32 (91.4)	65 (95.6)	75 (93.8)	0.493
Positive	1 (8.3)	0	1 (2.9)	1 (1.5)	2 (2.5)	
Indeterminate	1 (8.3)	0	2 (5.7)	2 (2.9)	3 (3.8)	
Tuberculin positive - n (%)						
Yes$	1 (8.3)	0	1 (2.9)	1 (1.5)	2 (2.5)	1.000
No	11 (91.7)	33 (100)	34 (97.1)	67 (98.5)	78 (97.5)	
Enrollment under TB prophylaxis - n (%)						
Yes	1 (8.3)	0	1 (2.9)	1 (1.5)	2 (2.5)	1.000
No	11 (91.7)	33 (100)	34 (97.1)	67 (98.5)	78 (97.5)	

M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
Note: percentages calculated on non-missing values.
Duration of UC in months: (baseline date - date of diagnosis of UC + 1) / (365.25/12).
Duration of UC in years: (baseline date - date of diagnosis of UC + 1) / 365.25.
& positive defined as >= 5 mm.
$ tuberculin PPD skin test >= 5 mm or QuantiFERON-TB Gold test is positive.
@ p-value for differences between the treatment groups M-SD and M-HD from chi-square test (or fisher's exact test if expected number of counts in a cell is < 5) for categorical variables or from one-way anova for continuous variables.

Cross reference: M11-290 CSR_Final_ Table 14.1__4.2_A

表 2.7.3.6-111.　疾患特性（日本人 mITT 集団，M11-290 試験）（最終 CSR）

	mITT					
		mITT-E				
	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)	P-Value@
Duration of UC (month)						
n	0	2	4	6	6	0.771
Mean (SD)		35.5 (44.77)	45.9 (35.95)	42.4 (34.71)	42.4 (34.71)	
Median		35.5	35.8	35.8	35.8	
Min, Max		3.9, 67.2	15.0, 97.0	3.9, 97.0	3.9, 97.0	
Duration of UC (year)						
n	0	2	4	6	6	0.771
Mean (SD)		3.0 (3.73)	3.8 (3.00)	3.5 (2.89)	3.5 (2.89)	
Median		3.0	3.0	3.0	3.0	
Min, Max		0.3, 5.6	1.3, 8.1	0.3, 8.1	0.3, 8.1	
Site of UC - n (%)						
Left sided UC	0	0	0	0	0	
Extensive UC/pancolitis	0	2 (100)	4 (100)	6 (100)	6 (100)	
Mayo Score						
n	0	2	4	6	6	0.315
Mean (SD)		7.6 (1.08)	6.8 (0.63)	7.1 (0.79)	7.1 (0.79)	
Median		7.6	6.7	6.9	6.9	
Min, Max		6.8, 8.3	6.2, 7.6	6.2, 8.3	6.2, 8.3	

表 2.7.3.6-111. 疾患特性（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT					
		mITT-E				
	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)	P-Value@
Partial Mayo Score						
n	0	2	4	6	6	0.302
Mean (SD)		5.6 (1.08)	4.6 (0.96)	4.9 (1.03)	4.9 (1.03)	
Median		5.6	4.6	4.9	4.9	
Min, Max		4.8, 6.3	3.4, 5.6	3.4, 6.3	3.4, 6.3	
Endoscopy Subscore						
n	0	2	4	6	6	0.541
Mean (SD)		2.0 (0.00)	2.3 (0.50)	2.2 (0.41)	2.2 (0.41)	
Median		2.0	2.0	2.0	2.0	
Min, Max		2.0, 2.0	2.0, 3.0	2.0, 3.0	2.0, 3.0	
Rectal Bleeding Subscore						
n	0	2	4	6	6	0.983
Mean (SD)		1.2 (0.24)	1.2 (0.98)	1.2 (0.77)	1.2 (0.77)	
Median		1.2	1.2	1.2	1.2	
Min, Max		1.0, 1.3	0.2, 2.0	0.2, 2.0	0.2, 2.0	
PGA Subscore						
n	0	2	4	6	6	0.541
Mean (SD)		2.0 (0.00)	2.3 (0.50)	2.2 (0.41)	2.2 (0.41)	
Median		2.0	2.0	2.0	2.0	
Min, Max		2.0, 2.0	2.0, 3.0	2.0, 3.0	2.0, 3.0	

表 2.7.3.6-111. 疾患特性（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT					
		mITT-E				
	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)	P-Value@
Stool Frequency Subscore						
n	0	2	4	6	6	0.170
Mean (SD)		2.4 (0.85)	1.2 (0.87)	1.6 (1.01)	1.6 (1.01)	
Median		2.4	1.3	1.7	1.7	
Min, Max		1.8, 3.0	0.0, 2.0	0.0, 3.0	0.0, 3.0	
Number of stools in the last 24 hours prior to baseline						
n	0	2	4	6	6	0.765
Mean (SD)		3.5 (0.71)	3.3 (0.96)	3.3 (0.82)	3.3 (0.82)	
Median		3.5	3.5	3.5	3.5	
Min, Max		3.0, 4.0	2.0, 4.0	2.0, 4.0	2.0, 4.0	
PUCAI total score						
n	0	2	4	6	6	0.694
Mean (SD)		36.3 (8.84)	28.1 (25.11)	30.8 (20.29)	30.8 (20.29)	
Median		36.3	22.5	30.0	30.0	
Min, Max		30.0, 42.5	5.0, 62.5	5.0, 62.5	5.0, 62.5	
IMPACT III total score						
n	0	2	4	6	6	0.960
Mean (SD)		121.5 (0.71)	122.3 (18.73)	122.0 (14.52)	122.0 (14.52)	
Median		121.5	126.0	121.5	121.5	
Min, Max		121.0, 122.0	97.0, 140.0	97.0, 140.0	97.0, 140.0	

表 2.7.3.6-111. 疾患特性（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT					
		mITT-E				
	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)	P-Value@
IMPACT III - body image						
n	0	2	4	6	6	0.740
Mean (SD)		9.5 (0.71)	9.0 (1.83)	9.2 (1.47)	9.2 (1.47)	
Median		9.5	9.0	9.5	9.5	
Min, Max		9.0, 10.0	7.0, 11.0	7.0, 11.0	7.0, 11.0	
IMPACT III - bowel symptoms						
n	0	2	4	6	6	0.811
Mean (SD)		22.5 (3.54)	23.5 (4.80)	23.2 (4.07)	23.2 (4.07)	
Median		22.5	24.5	24.0	24.0	
Min, Max		20.0, 25.0	17.0, 28.0	17.0, 28.0	17.0, 28.0	
IMPACT III - emotional functioning						
n	0	2	4	6	6	0.688
Mean (SD)		25.0 (0.00)	23.0 (6.16)	23.7 (4.89)	23.7 (4.89)	
Median		25.0	23.5	24.5	24.5	
Min, Max		25.0, 25.0	15.0, 30.0	15.0, 30.0	15.0, 30.0	
IMPACT III - social functioning						
n	0	2	4	6	6	0.580
Mean (SD)		43.5 (0.71)	46.3 (6.08)	45.3 (4.93)	45.3 (4.93)	
Median		43.5	46.0	43.5	43.5	
Min, Max		43.0, 44.0	41.0, 52.0	41.0, 52.0	41.0, 52.0	

表 2.7.3.6-111. 疾患特性（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT					
		mITT-E				
	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)	P-Value@
IMPACT III - systemic symptoms						
n	0	2	4	6	6	0.675
Mean (SD)		8.0 (0.00)	8.8 (2.22)	8.5 (1.76)	8.5 (1.76)	
Median		8.0	9.0	8.0	8.0	
Min, Max		8.0, 8.0	6.0, 11.0	6.0, 11.0	6.0, 11.0	
IMPACT III - treatment/interventions						
n	0	2	4	6	6	0.384
Mean (SD)		13.0 (2.83)	11.8 (0.50)	12.2 (1.47)	12.2 (1.47)	
Median		13.0	12.0	12.0	12.0	
Min, Max		11.0, 15.0	11.0, 12.0	11.0, 15.0	11.0, 15.0	
WPAI - absenteeism (%)						
n	0	1	3	4	4	0.042*
Mean (SD)		60.0 (NA)	5.7 (9.95)	19.3 (28.32)	19.3 (28.32)	
Median		60.0	0.0	8.6	8.6	
Min, Max		60.0, 60.0	0.0, 17.2	0.0, 60.0	0.0, 60.0	
WPAI - presenteeism (%)						
n	0	1	3	4	4	0.010**
Mean (SD)		70.0 (NA)	3.3 (5.77)	20.0 (33.67)	20.0 (33.67)	
Median		70.0	0.0	5.0	5.0	
Min, Max		70.0, 70.0	0.0, 10.0	0.0, 70.0	0.0, 70.0	

表 2.7.3.6-111. 疾患特性（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT					
		mITT-E				
	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)	P-Value@
WPAI - work impairment (%)						
n	0	1	3	4	4	0.043*
Mean (SD)		88.0 (NA)	8.5 (14.73)	28.4 (41.53)	28.4 (41.53)	
Median		88.0	0.0	12.8	12.8	
Min, Max		88.0, 88.0	0.0, 25.5	0.0, 88.0	0.0, 88.0	
WPAI - activity impairment (%)						
n	0	2	4	6	6	0.130
Mean (SD)		60.0 (14.14)	22.5 (25.00)	35.0 (28.11)	35.0 (28.11)	
Median		60.0	10.0	30.0	30.0	
Min, Max		50.0, 70.0	10.0, 60.0	10.0, 70.0	10.0, 70.0	
hs-CRP [mg/l]						
n	0	2	4	6	6	0.536
Mean (SD)		22.6 (21.47)	10.7 (19.77)	14.7 (19.09)	14.7 (19.09)	
Median		22.6	1.1	4.3	4.3	
Min, Max		7.4, 37.8	0.3, 40.4	0.3, 40.4	0.3, 40.4	
Tuberculin PPD skin test - n (%)						
Negative	0	0	0	0	0	
Positive&	0	0	0	0	0	
Missing		2	4	6	6	

表 2.7.3.6-111.　疾患特性（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT					
		mITT-E				
	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)	P-Value@
QuantiFERON-TB Gold test - n (%)						
Negative	0	2 (100)	4 (100)	6 (100)	6 (100)	
Positive	0	0	0	0	0	
Indeterminate	0	0	0	0	0	
Tuberculin positive - n (%)						
Yes$	0	0	0	0	0	
No	0	2 (100)	4 (100)	6 (100)	6 (100)	
Enrollment under TB prophylaxis - n (%)						
Yes	0	0	0	0	0	
No	0	2 (100)	4 (100)	6 (100)	6 (100)	

M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
Note: percentages calculated on non-missing values.
Duration of UC in months: (baseline date - date of diagnosis of UC + 1) / (365.25/12).
Duration of UC in years: (baseline date - date of diagnosis of UC + 1) / 365.25.
& positive defined as >= 5 mm.
$ tuberculin PPD skin test >= 5 mm or QuantiFERON-TB Gold test is positive.
@ p-value for differences between the treatment groups M-SD and M-HD from chi-square test (or fisher's exact test if expected number of counts in a cell is < 5) for categorical variables or from one-way anova for continuous variables.
***, **, * Statistically significant at 0.001, 0.01, and 0.05 level, respectively.

Cross reference: M11-290 CSR_Final Table 14.1__4.2_J

表 2.7.3.6-112.　UC に関連した前治療薬（一般名）（統合 ITT 集団，M11-290 試験）（最終 CSR）

Generic Name (WHO Q1 2018)	ITT / ITT-E: I-SD (N=32) n (%)	I-HD (N=51) n (%)	Total (N=83) n (%)	I-HD-OL (N=18) n (%)	Total (N=101) n (%)
Any prior UC-related medication	32 (100)	51 (100)	83 (100)	18 (100)	101 (100)
AZATHIOPRINE	26 (81.3)	39 (76.5)	65 (78.3)	7 (38.9)	72 (71.3)
BALSALAZIDE	0	2 (3.9)	2 (2.4)	1 (5.6)	3 (3.0)
BECLOMETASONE	0	1 (2.0)	1 (1.2)	0	1 (1.0)
BUDESONIDE	4 (12.5)	10 (19.6)	14 (16.9)	6 (33.3)	20 (19.8)
CICLOSPORIN	4 (12.5)	4 (7.8)	8 (9.6)	0	8 (7.9)
CIPROFLOXACIN	2 (6.3)	0	2 (2.4)	1 (5.6)	3 (3.0)
HYDROCORTISONE	2 (6.3)	1 (2.0)	3 (3.6)	1 (5.6)	4 (4.0)
IMIPENEM	0	0	0	1 (5.6)	1 (1.0)
INFLIXIMAB	7 (21.9)	8 (15.7)	15 (18.1)	1 (5.6)	16 (15.8)
LOPERAMIDE	0	1 (2.0)	1 (1.2)	0	1 (1.0)
MERCAPTOPURINE	2 (6.3)	2 (3.9)	4 (4.8)	0	4 (4.0)
MESALAZINE	28 (87.5)	42 (82.4)	70 (84.3)	14 (77.8)	84 (83.2)
METHOTREXATE	0	1 (2.0)	1 (1.2)	0	1 (1.0)
METHYLPREDNISOLONE	2 (6.3)	6 (11.8)	8 (9.6)	2 (11.1)	10 (9.9)
METRONIDAZOLE	3 (9.4)	3 (5.9)	6 (7.2)	1 (5.6)	7 (6.9)
MYCOPHENOLIC ACID	1 (3.1)	0	1 (1.2)	0	1 (1.0)
PREDNISOLONE	4 (12.5)	4 (7.8)	8 (9.6)	1 (5.6)	9 (8.9)

表 2.7.3.6-112.　UC に関連した前治療薬（一般名）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

	ITT				
	ITT-E				
Generic Name (WHO Q1 2018)	I-SD (N=32) n (%)	I-HD (N=51) n (%)	Total (N=83) n (%)	I-HD-OL (N=18) n (%)	Total (N=101) n (%)
PREDNISONE	14 (43.8)	23 (45.1)	37 (44.6)	11 (61.1)	48 (47.5)
SULFASALAZINE	3 (9.4)	2 (3.9)	5 (6.0)	1 (5.6)	6 (5.9)
VANCOMYCIN	1 (3.1)	0	1 (1.2)	0	1 (1.0)

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
Note: all medications with a start date prior to the first study drug dose are included. Subjects are counted once in each row, regardless of the number of medications they may have taken.

Cross reference: M11-290 CSR_Final Table 14.1__6.1.2_A

表 2.7.3.6-113.　UC に関連した前治療薬（一般名）（日本人 ITT 集団，M11-290 試験）（最終 CSR）

	ITT				
	ITT-E				
Generic Name (WHO Q1 2018)	I-SD (N=2) n (%)	I-HD (N=4) n (%)	Total (N=6) n (%)	I-HD-OL (N=2) n (%)	Total (N=8) n (%)
Any prior UC-related medication	2 (100)	4 (100)	6 (100)	2 (100)	8 (100)
AZATHIOPRINE	1 (50.0)	3 (75.0)	4 (66.7)	2 (100)	6 (75.0)
INFLIXIMAB	1 (50.0)	0	1 (16.7)	0	1 (12.5)
MERCAPTOPURINE	1 (50.0)	1 (25.0)	2 (33.3)	0	2 (25.0)
MESALAZINE	2 (100)	4 (100)	6 (100)	1 (50.0)	7 (87.5)
PREDNISOLONE	2 (100)	2 (50.0)	4 (66.7)	1 (50.0)	5 (62.5)

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
Note: all medications with a start date prior to the first study drug dose are included. Subjects are counted once in each row, regardless of the number of medications they may have taken.

Cross reference: M11-290 CSR_Final Table 14.1__6.1.2_J

表 2.7.3.6-114.　ベースラインの UC に関連した治療薬（一般名）（統合 ITT 集団，M11-290 試験）（最終 CSR）

	ITT				
	ITT-E				
Generic Name (WHO Q1 2018)	I-SD (N=32) n (%)	I-HD (N=51) n (%)	Total (N=83) n (%)	I-HD-OL (N=18) n (%)	Total (N=101) n (%)
Any baseline UC-related medication	31 (96.9)	47 (92.2)	78 (94.0)	18 (100)	96 (95.0)
AZATHIOPRINE	22 (68.8)	31 (60.8)	53 (63.9)	7 (38.9)	60 (59.4)
BALSALAZIDE	0	1 (2.0)	1 (1.2)	1 (5.6)	2 (2.0)
BECLOMETASONE	0	1 (2.0)	1 (1.2)	0	1 (1.0)
BUDESONIDE	1 (3.1)	4 (7.8)	5 (6.0)	4 (22.2)	9 (8.9)
LOPERAMIDE	0	1 (2.0)	1 (1.2)	0	1 (1.0)
MERCAPTOPURINE	1 (3.1)	1 (2.0)	2 (2.4)	0	2 (2.0)
MESALAZINE	26 (81.3)	38 (74.5)	64 (77.1)	14 (77.8)	78 (77.2)
METHYLPREDNISOLONE	2 (6.3)	3 (5.9)	5 (6.0)	0	5 (5.0)
PREDNISOLONE	3 (9.4)	2 (3.9)	5 (6.0)	1 (5.6)	6 (5.9)
PREDNISONE	9 (28.1)	13 (25.5)	22 (26.5)	5 (27.8)	27 (26.7)
SULFASALAZINE	2 (6.3)	1 (2.0)	3 (3.6)	1 (5.6)	4 (4.0)

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
Note: all medications with started prior to the first dose of study drug and continued after the first dose of study drug or ended at the time of the first dose of study drug, including medications taken on the day of the first dose of study drug. Subjects are counted once in each row regardless of the number of medications they may have taken.

Cross reference: M11-290 CSR_Final Table 14.1__6.2.2_A

表 2.7.3.6-115.　ベースラインの UC に関連した治療薬（一般名）（日本人 ITT 集団，M11-290 試験）（最終 CSR）

Generic Name (WHO Q1 2018)	ITT / ITT-E: I-SD (N=2) n (%)	I-HD (N=4) n (%)	Total (N=6) n (%)	I-HD-OL (N=2) n (%)	Total (N=8) n (%)
Any baseline UC-related medication	2 (100)	4 (100)	6 (100)	2 (100)	8 (100)
AZATHIOPRINE	1 (50.0)	3 (75.0)	4 (66.7)	2 (100)	6 (75.0)
MERCAPTOPURINE	1 (50.0)	1 (25.0)	2 (33.3)	0	2 (25.0)
MESALAZINE	2 (100)	4 (100)	6 (100)	1 (50.0)	7 (87.5)
PREDNISOLONE	2 (100)	2 (50.0)	4 (66.7)	1 (50.0)	5 (62.5)

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
Note: all medications with started prior to the first dose of study drug and continued after the first dose of study drug or ended at the time of the first dose of study drug, including medications taken on the day of the first dose of study drug. Subjects are counted once in each row regardless of the number of medications they may have taken.

Cross reference: M11-290 CSR_Final Table 14.1__6.2.2_J

表 2.7.3.6-116. 導入療法期間中の UC に関連した併用薬（一般名）（統合 ITT 集団，M11-290 試験）（最終 CSR）

	ITT				
	ITT-E				
Generic Name (WHO Q1 2018)	I-SD (N=32) n (%)	I-HD (N=51) n (%)	Total (N=83) n (%)	I-HD-OL (N=18) n (%)	Total (N=101) n (%)
Any concomitant UC-related medication during induction period	31 (96.9)	47 (92.2)	78 (94.0)	18 (100)	96 (95.0)
AZATHIOPRINE	22 (68.8)	31 (60.8)	53 (63.9)	7 (38.9)	60 (59.4)
BALSALAZIDE	0	1 (2.0)	1 (1.2)	1 (5.6)	2 (2.0)
BECLOMETASONE	0	1 (2.0)	1 (1.2)	0	1 (1.0)
BUDESONIDE	1 (3.1)	4 (7.8)	5 (6.0)	4 (22.2)	9 (8.9)
CICLOSPORIN	0	1 (2.0)	1 (1.2)	0	1 (1.0)
CIPROFLOXACIN	0	1 (2.0)	1 (1.2)	0	1 (1.0)
HYDROCORTISONE	1 (3.1)	0	1 (1.2)	0	1 (1.0)
LOPERAMIDE	0	1 (2.0)	1 (1.2)	0	1 (1.0)
MERCAPTOPURINE	1 (3.1)	1 (2.0)	2 (2.4)	0	2 (2.0)
MESALAZINE	26 (81.3)	38 (74.5)	64 (77.1)	14 (77.8)	78 (77.2)
METHYLPREDNISOLONE	2 (6.3)	3 (5.9)	5 (6.0)	1 (5.6)	6 (5.9)
PREDNISOLONE	3 (9.4)	2 (3.9)	5 (6.0)	1 (5.6)	6 (5.9)
PREDNISONE	10 (31.3)	13 (25.5)	23 (27.7)	5 (27.8)	28 (27.7)
SULFASALAZINE	2 (6.3)	1 (2.0)	3 (3.6)	1 (5.6)	4 (4.0)

表 2.7.3.6-116.　導入療法期間中の UC に関連した併用薬（一般名）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
Note: this table includes all medications with a start date between first study drug in induction period and last study drug in induction period + (max.*) 14 days, including medications with a start date prior to first dose date of study drug in induction period and which are ongoing after first dose date of study drug in induction period and taken on the day of the first dose date of study drug in induction period.
* cutting before first dose of study drug in the maintenance period.
Subjects are counted once in each row, regardless of the number of medications they may have taken.

Cross reference: M11-290 CSR_Final Table 14.1__6.3.2_A

表 2.7.3.6-117.　導入療法期間中の UC に関連した併用薬（一般名）（日本人 ITT 集団，M11-290 試験）（最終 CSR）

	ITT				
	ITT-E				
Generic Name (WHO Q1 2018)	I-SD (N=2) n (%)	I-HD (N=4) n (%)	Total (N=6) n (%)	I-HD-OL (N=2) n (%)	Total (N=8) n (%)
Any concomitant UC-related medication during induction period	2 (100)	4 (100)	6 (100)	2 (100)	8 (100)
AZATHIOPRINE	1 (50.0)	3 (75.0)	4 (66.7)	2 (100)	6 (75.0)
MERCAPTOPURINE	1 (50.0)	1 (25.0)	2 (33.3)	0	2 (25.0)
MESALAZINE	2 (100)	4 (100)	6 (100)	1 (50.0)	7 (87.5)
PREDNISOLONE	2 (100)	2 (50.0)	4 (66.7)	1 (50.0)	5 (62.5)

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
Note: this table includes all medications with a start date between first study drug in induction period and last study drug in induction period + (max.*) 14 days, including medications with a start date prior to first dose date of study drug in induction period and which are ongoing after first dose date of study drug in induction period and taken on the day of the first dose date of study drug in induction period.
* cutting before first dose of study drug in the maintenance period.
Subjects are counted once in each row, regardless of the number of medications they may have taken.

Cross reference: M11-290 CSR_Final Table 14.1__6.3.2_J

表 2.7.3.6-118.　維持療法期間中の UC に関連した併用薬（一般名）（統合 mITT 集団，M11-290 試験）（最終 CSR）

Generic Name (WHO Q1 2018)	mITT / mITT-E: M-PL (N=12) n (%)	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total (N=68) n (%)	Total (N=80) n (%)
Any concomitant UC-related medication during maintenance period	12 (100)	31 (93.9)	34 (97.1)	65 (95.6)	77 (96.3)
ADALIMUMAB	0	1 (3.0)	0	1 (1.5)	1 (1.3)
AZATHIOPRINE	9 (75.0)	19 (57.6)	23 (65.7)	42 (61.8)	51 (63.8)
BALSALAZIDE	0	2 (6.1)	0	2 (2.9)	2 (2.5)
BECLOMETASONE	0	0	1 (2.9)	1 (1.5)	1 (1.3)
BUDESONIDE	4 (33.3)	2 (6.1)	3 (8.6)	5 (7.4)	9 (11.3)
CIPROFLOXACIN	2 (16.7)	1 (3.0)	2 (5.7)	3 (4.4)	5 (6.3)
LOPERAMIDE	0	1 (3.0)	2 (5.7)	3 (4.4)	3 (3.8)
MERCAPTOPURINE	0	0	1 (2.9)	1 (1.5)	1 (1.3)
MESALAZINE	10 (83.3)	25 (75.8)	31 (88.6)	56 (82.4)	66 (82.5)
METHYLPREDNISOLONE	0	3 (9.1)	3 (8.6)	6 (8.8)	6 (7.5)
METRONIDAZOLE	2 (16.7)	2 (6.1)	0	2 (2.9)	4 (5.0)
PREDNISOLONE	0	3 (9.1)	2 (5.7)	5 (7.4)	5 (6.3)
PREDNISONE	3 (25.0)	9 (27.3)	8 (22.9)	17 (25.0)	20 (25.0)
SULFASALAZINE	1 (8.3)	2 (6.1)	0	2 (2.9)	3 (3.8)

表 2.7.3.6-118.　維持療法期間中の UC に関連した併用薬（一般名）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
Note: this table includes all medications with a start date between first study drug in maintenance period and last study drug in maintenance period + (max.*) 14 days, including medications with a start date prior to first dose date of study drug in maintenance period and which are ongoing after first dose date of study drug in maintenance period and taken on the day of the first dose date of study drug in maintenance period.
* cutting before first dose of study drug in M10-870, if applicable.
Subjects are counted once in each row, regardless of the number of medications they may have taken.

Cross reference: M11-290 CSR_Final Table 14.1__6.3.4_A

表 2.7.3.6-119.　維持療法期間中の UC に関連した併用薬（一般名）（日本人 mITT 集団，M11-290 試験）（最終 CSR）

	mITT				
		mITT-E			
Generic Name (WHO Q1 2018)	M-PL (N=0) n (%)	M-SD (N=2) n (%)	M-HD (N=4) n (%)	Total (N=6) n (%)	Total (N=6) n (%)
Any concomitant UC-related medication during maintenance period	0	2 (100)	4 (100)	6 (100)	6 (100)
AZATHIOPRINE	0	2 (100)	3 (75.0)	5 (83.3)	5 (83.3)
MERCAPTOPURINE	0	0	1 (25.0)	1 (16.7)	1 (16.7)
MESALAZINE	0	1 (50.0)	4 (100)	5 (83.3)	5 (83.3)
PREDNISOLONE	0	2 (100)	2 (50.0)	4 (66.7)	4 (66.7)

M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
Note: this table includes all medications with a start date between first study drug in maintenance period and last study drug in maintenance period + (max.*) 14 days, including medications with a start date prior to first dose date of study drug in maintenance period and which are ongoing after first dose date of study drug in maintenance period and taken on the day of the first dose date of study drug in maintenance period.
* cutting before first dose of study drug in M10-870, if applicable.
Subjects are counted once in each row, regardless of the number of medications they may have taken.

Cross reference: M11-290 CSR_Final Table 14.1__6.3.4_J

表 2.7.3.6-120.　治験薬の服薬順守率（統合安全性解析対象集団，M11-290 試験）（最終 CSR）

Treatment	N	Mean	SD	Min	Q1	Median	Q3	Max
Treatment Compliance (%)								
I-SD + I-HD Total	83	97.93	8.733	25.0	99.15	100.00	100.00	103.6
I-SD	32	96.50	13.267	25.0	98.21	100.00	100.00	100.0
I-SD/-	10	90.76	23.388	25.0	91.67	100.00	100.00	100.0
I-SD/M-PL	4	100.00	0.000	100.0	100.00	100.00	100.00	100.0
I-SD/M-SD	8	98.67	2.018	95.5	96.93	100.00	100.00	100.0
I-SD/M-HD	10	99.13	1.483	96.4	98.21	100.00	100.00	100.0
I-HD	51	98.82	3.721	82.1	100.00	100.00	100.00	103.6
I-HD/-	8	100.00	0.000	100.0	100.00	100.00	100.00	100.0
I-HD/M-PL	8	99.30	3.359	91.7	99.58	100.00	100.00	103.6
I-HD/M-SD	17	98.49	4.275	83.9	100.00	100.00	100.00	101.8
I-HD/M-HD	18	98.38	4.219	82.1	98.31	100.00	100.00	100.0
I-HD-OL	18	98.56	5.958	78.0	98.21	100.00	100.00	106.8
I-HD-OL/-	2	95.83	5.893	91.7	91.67	95.83	100.00	100.0
I-HD-OL/M-SD	8	97.79	8.202	78.0	99.11	100.00	100.85	104.4
I-HD-OL/M-HD	8	100.00	2.968	97.4	97.89	100.00	100.00	106.8

Note: I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.

Cross reference: M11-290 CSR_Final Table 14.1__8_A

表 2.7.3.6-121.　治験薬の服薬順守率（日本人安全性解析対象集団，M11-290 試験）（最終 CSR）

Treatment	N	Mean	SD	Min	Q1	Median	Q3	Max
Treatment Compliance (%)								
I-SD + I-HD Total	6	87.50	30.619	25.0	100.00	100.00	100.00	100.0
I-SD	2	62.50	53.033	25.0	25.00	62.50	100.00	100.0
I-SD/-	2	62.50	53.033	25.0	25.00	62.50	100.00	100.0
I-SD/M-PL	0							
I-SD/M-SD	0							
I-SD/M-HD	0							
I-HD	4	100.00	0.000	100.0	100.00	100.00	100.00	100.0
I-HD/-	0							
I-HD/M-PL	0							
I-HD/M-SD	1	100.00		100.0	100.00	100.00	100.00	100.0
I-HD/M-HD	3	100.00	0.000	100.0	100.00	100.00	100.00	100.0
I-HD-OL	2	101.00	4.867	97.6	97.56	101.00	104.44	104.4
I-HD-OL/-	0							
I-HD-OL/M-SD	1	104.44		104.4	104.44	104.44	104.44	104.4
I-HD-OL/M-HD	1	97.56		97.6	97.56	97.56	97.56	97.6

Note: I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.

Cross reference: M11-290 CSR_Final Table 14.1__8_J

表 2.7.3.6-122.　導入療法期における治験薬の曝露期間（統合安全性解析対象集団，M11-290 試験）（最終 CSR）

	I-SD (N=32)	I-HD (N=51)	I-HD-OL (N=18)	Total (N=101)
Duration (day)				
n	32	51	18	101
Mean (SD)	52.8(9.30)	55.4(2.22)	53.8(4.92)	54.3(5.90)
Median	56.0	56.0	56.0	56.0
Min, Max	14, 59	42, 58	41, 58	14, 59
Patient-Years of exposure	4.6	7.7	2.7	15.0

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
Note: duration of induction-exposure = last induction dose date - first induction dose date + (max.*) 14 days.
* cutting before first dose of study drug in the maintenance period.

Cross reference: M11-290 CSR_Final Table 14.1__7.1_A

表 2.7.3.6-123.　維持療法期における治験薬の曝露期間（統合安全性解析対象集団，M11-290 試験）（最終 CSR）

	M-PL (N=12)	M-SD (N=33)	M-HD (N=36)	ADA-Total (N=69)	Total (N=81)
Duration (day)					
n	12	33	36	69	81
Mean (SD)	184.2(123.02)	226.8(110.20)	241.0(103.25)	234.2(106.08)	226.8(109.39)
Median	196.5	307.0	308.0	308.0	307.0
Min, Max	26, 310	30, 316	28, 316	28, 316	26, 316
Patient-Years of exposure	6.1	20.5	23.8	44.2	50.3

M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
Note: duration of maintenance-exposure = last maintenance dose date (prior to potential re-randomization due to 1st disease flare) - first maintenance dose date + (max.*) 14 days. * cutting before first dose of study drug after re-randomization due to 1st disease flare, if applicable, or the first dose of study drug in M10-870, if applicable.

Cross reference: M11-290 CSR_Final Table 14.1__7.3_A

表 2.7.3.6-124.　治験期間を通したアダリムマブの曝露期間（統合安全性解析対象集団，M11-290 試験）（最終 CSR）

	Any ADA								
	I-SD				I-HD/HD-OL				
	--$ (N=10)	M-PL (N=4)	M-SD (N=8)	M-HD (N=10)	--$ (N=10)	M-PL (N=8)	M-SD (N=25)	M-HD (N=26)	Total (N=101)
Duration (day)									
n	10	4	8	10	10	8	25	26	101
Mean (SD)	45.7(14.60)	145.3(133.98)	278.9(121.10)	343.2(73.94)	51.9(7.13)	168.5(118.84)	330.7(74.56)	348.3(54.90)	256.3(138.77)
Median	54.0	93.5	364.5	364.5	55.5	145.5	364.0	364.0	363.0
Min, Max	14, 56	55, 339	132, 372	133, 372	41, 58	55, 329	134, 371	112, 371	14, 372
Patient-Years of exposure	1.3	1.6	6.1	9.4	1.4	3.7	22.6	24.8	70.9

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group,
M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
Note: subjects who are randomized to placebo at week 8 and who have not been re-randomized due to a disease flare:
Overall ADA exposure = duration of induction-exposure.

Subjects who are randomized to placebo at week 8 and are re-randomized due to at least one disease flare during maintenance:
Overall ADA exposure = duration of induction-exposure + (last adalimumab dose date in the study after re-randomization due to 1st disease flare - first dose date of adalimumab after re-randomization due to 1st disease flare + (max.*) 14 days).

Subjects who are not randomized to placebo:
Overall ADA exposure = last adalimumab dose date in the study - first dose of adalimumab + (max.*) 14 days.
* cutting before first dose of study drug in M10-870, if applicable.

$ patients who discontinued as non-responders from the study at week 8.

Cross reference: M11-290 CSR_Final Table 14.1__7.5_A

表 2.7.3.6-125.　投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（統合 ITT 集団，M11-290 試験）（最終 CSR）

	ITT				
	ITT-E				
Category Endpoint Met	I-SD (N=32)	I-HD (N=51)	Total (N=83)	I-HD-OL (N=18)	Total (N=101)
Overall	N=32	N=51	N=83	N=18	N=101
Yes	13 (40.6)	30 (58.8)	43 (51.8)	12 (66.7)	55 (54.5)
No	19 (59.4)	21 (41.2)	40 (48.2)	6 (33.3)	46 (45.5)
95% Confidence Interval [A]	(23.70, 59.36)	(44.17, 72.42)	(40.56, 62.92)	(40.99, 86.66)	(44.24, 64.40)
P-Value [B1]	0.003	<0.001	<0.001		
ADJ. P-Value [B2]	0.344	<0.001	<0.001		
P-Value [C]	0.106				
Baseline Mayo Score <= 9 &	N=27	N=42	N=69	N=15	N=84
Yes	11 (40.7)	26 (61.9)	37 (53.6)	10 (66.7)	47 (56.0)
No	16 (59.3)	16 (38.1)	32 (46.4)	5 (33.3)	37 (44.0)
95% Confidence Interval [A]	(22.39, 61.20)	(45.64, 76.43)	(41.20, 65.72)	(38.38, 88.18)	(44.70, 66.78)
Baseline Mayo Score > 9 &	N=5	N=9	N=14	N=3	N=17
Yes	2 (40.0)	4 (44.4)	6 (42.9)	2 (66.7)	8 (47.1)
No	3 (60.0)	5 (55.6)	8 (57.1)	1 (33.3)	9 (52.9)
95% Confidence Interval [A]	(5.27, 85.34)	(13.70, 78.80)	(17.66, 71.14)	(9.43, 99.16)	(22.98, 72.19)

表 2.7.3.6-125. 投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

	ITT				
	ITT-E				
Category Endpoint Met	I-SD (N=32)	I-HD (N=51)	Total (N=83)	I-HD-OL (N=18)	Total (N=101)
Prior Anti-TNF Use	N=7	N=8	N=15	N=1	N=16
Yes	1 (14.3)	3 (37.5)	4 (26.7)	1 (100)	5 (31.3)
No	6 (85.7)	5 (62.5)	11 (73.3)	0	11 (68.8)
95% Confidence Interval [A]	(0.36, 57.87)	(8.52, 75.51)	(7.79, 55.10)	(2.50, 100.00)	(11.02, 58.66)
Prior Anti-TNF Naive	N=25	N=43	N=68	N=17	N=85
Yes	12 (48.0)	27 (62.8)	39 (57.4)	11 (64.7)	50 (58.8)
No	13 (52.0)	16 (37.2)	29 (42.6)	6 (35.3)	35 (41.2)
95% Confidence Interval [A]	(27.80, 68.69)	(46.73, 77.02)	(44.77, 69.28)	(38.33, 85.79)	(47.62, 69.39)
Baseline Corticosteroid Use - Yes #	N=15	N=24	N=39	N=10	N=49
Yes	4 (26.7)	15 (62.5)	19 (48.7)	6 (60.0)	25 (51.0)
No	11 (73.3)	9 (37.5)	20 (51.3)	4 (40.0)	24 (49.0)
95% Confidence Interval [A]	(7.79, 55.10)	(40.59, 81.20)	(32.42, 65.22)	(26.24, 87.84)	(36.34, 65.58)
Baseline Corticosteroid Use - No #	N=17	N=27	N=44	N=8	N=52
Yes	9 (52.9)	15 (55.6)	24 (54.5)	6 (75.0)	30 (57.7)
No	8 (47.1)	12 (44.4)	20 (45.5)	2 (25.0)	22 (42.3)
95% Confidence Interval [A]	(27.81, 77.02)	(35.33, 74.52)	(38.85, 69.61)	(34.91, 96.81)	(43.20, 71.27)

表 2.7.3.6-125. 投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Category Endpoint Met	ITT ITT-E I-SD (N=32)	ITT ITT-E I-HD (N=51)	ITT ITT-E Total (N=83)	ITT I-HD-OL (N=18)	ITT Total (N=101)
Sex - Male	N=17	N=28	N=45	N=5	N=50
Yes	4 (23.5)	18 (64.3)	22 (48.9)	4 (80.0)	26 (52.0)
No	13 (76.5)	10 (35.7)	23 (51.1)	1 (20.0)	24 (48.0)
95% Confidence Interval [A]	(6.81, 49.90)	(44.07, 81.36)	(33.70, 64.23)	(28.36, 99.49)	(37.42, 66.34)
Sex - Female	N=15	N=23	N=38	N=13	N=51
Yes	9 (60.0)	12 (52.2)	21 (55.3)	8 (61.5)	29 (56.9)
No	6 (40.0)	11 (47.8)	17 (44.7)	5 (38.5)	22 (43.1)
95% Confidence Interval [A]	(32.29, 83.66)	(30.59, 73.18)	(38.30, 71.38)	(31.58, 86.14)	(42.25, 70.65)
Age < 13 Years	N=4	N=17	N=21	N=5	N=26
Yes	2 (50.0)	11 (64.7)	13 (61.9)	3 (60.0)	16 (61.5)
No	2 (50.0)	6 (35.3)	8 (38.1)	2 (40.0)	10 (38.5)
95% Confidence Interval [A]	(6.76, 93.24)	(38.33, 85.79)	(38.44, 81.89)	(14.66, 94.73)	(40.57, 79.77)
Age >= 13 Years	N=28	N=34	N=62	N=13	N=75
Yes	11 (39.3)	19 (55.9)	30 (48.4)	9 (69.2)	39 (52.0)
No	17 (60.7)	15 (44.1)	32 (51.6)	4 (30.8)	36 (48.0)
95% Confidence Interval [A]	(21.50, 59.42)	(37.89, 72.81)	(35.50, 61.44)	(38.57, 90.91)	(40.15, 63.69)

表 2.7.3.6-125. 投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

	ITT				
	ITT-E				
Category Endpoint Met	I-SD (N=32)	I-HD (N=51)	Total (N=83)	I-HD-OL (N=18)	Total (N=101)
Ethnicity - White	N=28	N=45	N=73	N=15	N=88
Yes	11 (39.3)	27 (60.0)	38 (52.1)	11 (73.3)	49 (55.7)
No	17 (60.7)	18 (40.0)	35 (47.9)	4 (26.7)	39 (44.3)
95% Confidence Interval [A]	(21.50, 59.42)	(44.33, 74.30)	(40.04, 63.90)	(44.90, 92.21)	(44.70, 66.27)
Ethnicity - Non-white	N=4	N=6	N=10	N=3	N=13
Yes	2 (50.0)	3 (50.0)	5 (50.0)	1 (33.3)	6 (46.2)
No	2 (50.0)	3 (50.0)	5 (50.0)	2 (66.7)	7 (53.8)
95% Confidence Interval [A]	(6.76, 93.24)	(11.81, 88.19)	(18.71, 81.29)	(0.84, 90.57)	(19.22, 74.87)
Geographic Region - North America	N=2	N=8	N=10	N=3	N=13
Yes	1 (50.0)	3 (37.5)	4 (40.0)	2 (66.7)	6 (46.2)
No	1 (50.0)	5 (62.5)	6 (60.0)	1 (33.3)	7 (53.8)
95% Confidence Interval [A]	(1.26, 98.74)	(8.52, 75.51)	(12.16, 73.76)	(9.43, 99.16)	(19.22, 74.87)
Geographic Region - Western Europe	N=3	N=4	N=7	N=1	N=8
Yes	1 (33.3)	1 (25.0)	2 (28.6)	1 (100)	3 (37.5)
No	2 (66.7)	3 (75.0)	5 (71.4)	0	5 (62.5)
95% Confidence Interval [A]	(0.84, 90.57)	(0.63, 80.59)	(3.67, 70.96)	(2.50, 100.00)	(8.52, 75.51)

表 2.7.3.6-125. 投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Category Endpoint Met	ITT ITT-E I-SD (N=32)	ITT ITT-E I-HD (N=51)	ITT ITT-E Total (N=83)	ITT I-HD-OL (N=18)	ITT Total (N=101)
Geographic Region - Eastern Europe	N=25	N=35	N=60	N=12	N=72
Yes	11 (44.0)	24 (68.6)	35 (58.3)	8 (66.7)	43 (59.7)
No	14 (56.0)	11 (31.4)	25 (41.7)	4 (33.3)	29 (40.3)
95% Confidence Interval [A]	(24.40, 65.07)	(50.71, 83.15)	(44.88, 70.93)	(34.89, 90.08)	(47.50, 71.12)
Geographic Region - Japan	N=2	N=4	N=6	N=2	N=8
Yes	0	2 (50.0)	2 (33.3)	1 (50.0)	3 (37.5)
No	2 (100)	2 (50.0)	4 (66.7)	1 (50.0)	5 (62.5)
95% Confidence Interval [A]	(0.00, 84.19)	(6.76, 93.24)	(4.33, 77.72)	(1.26, 98.74)	(8.52, 75.51)
Baseline IMM Use - Yes	N=23	N=33	N=56	N=7	N=63
Yes	11 (47.8)	20 (60.6)	31 (55.4)	5 (71.4)	36 (57.1)
No	12 (52.2)	13 (39.4)	25 (44.6)	2 (28.6)	27 (42.9)
95% Confidence Interval [A]	(26.82, 69.41)	(42.14, 77.09)	(41.47, 68.66)	(29.04, 96.33)	(44.05, 69.54)
Baseline IMM Use - No	N=9	N=18	N=27	N=11	N=38
Yes	2 (22.2)	10 (55.6)	12 (44.4)	7 (63.6)	19 (50.0)
No	7 (77.8)	8 (44.4)	15 (55.6)	4 (36.4)	19 (50.0)
95% Confidence Interval [A]	(2.81, 60.01)	(30.76, 78.47)	(25.48, 64.67)	(30.79, 89.07)	(33.38, 66.62)

表 2.7.3.6-125. 投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

	ITT				
	ITT-E				
Category Endpoint Met	I-SD (N=32)	I-HD (N=51)	Total (N=83)	I-HD-OL (N=18)	Total (N=101)
Weight < 40 kg	N=3	N=10	N=13	N=3	N=16
Yes	2 (66.7)	5 (50.0)	7 (53.8)	2 (66.7)	9 (56.3)
No	1 (33.3)	5 (50.0)	6 (46.2)	1 (33.3)	7 (43.8)
95% Confidence Interval [A]	(9.43, 99.16)	(18.71, 81.29)	(25.13, 80.78)	(9.43, 99.16)	(29.88, 80.25)
Weight >= 40 kg	N=29	N=41	N=70	N=15	N=85
Yes	11 (37.9)	25 (61.0)	36 (51.4)	10 (66.7)	46 (54.1)
No	18 (62.1)	16 (39.0)	34 (48.6)	5 (33.3)	39 (45.9)
95% Confidence Interval [A]	(20.69, 57.74)	(44.50, 75.80)	(39.17, 63.56)	(38.38, 88.18)	(42.96, 64.98)
Pancolitis - Yes	N=21	N=29	N=50	N=13	N=63
Yes	7 (33.3)	15 (51.7)	22 (44.0)	10 (76.9)	32 (50.8)
No	14 (66.7)	14 (48.3)	28 (56.0)	3 (23.1)	31 (49.2)
95% Confidence Interval [A]	(14.59, 56.97)	(32.53, 70.55)	(29.99, 58.75)	(46.19, 94.96)	(37.89, 63.62)
Pancolitis - No	N=11	N=22	N=33	N=5	N=38
Yes	6 (54.5)	15 (68.2)	21 (63.6)	2 (40.0)	23 (60.5)
No	5 (45.5)	7 (31.8)	12 (36.4)	3 (60.0)	15 (39.5)
95% Confidence Interval [A]	(23.38, 83.25)	(45.13, 86.14)	(45.12, 79.60)	(5.27, 85.34)	(43.39, 75.96)

表 2.7.3.6-125. 投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Category Endpoint Met	ITT ITT-E I-SD (N=32)	ITT ITT-E I-HD (N=51)	ITT ITT-E Total (N=83)	ITT I-HD-OL (N=18)	ITT Total (N=101)
Disease Duration <= Baseline Median (18.9 Months)	N=19	N=21	N=40	N=11	N=51
Yes	7 (36.8)	9 (42.9)	16 (40.0)	7 (63.6)	23 (45.1)
No	12 (63.2)	12 (57.1)	24 (60.0)	4 (36.4)	28 (54.9)
95% Confidence Interval [A]	(16.29, 61.64)	(21.82, 65.98)	(24.86, 56.67)	(30.79, 89.07)	(31.13, 59.66)
Disease Duration > Baseline Median (18.9 Months)	N=13	N=30	N=43	N=7	N=50
Yes	6 (46.2)	21 (70.0)	27 (62.8)	5 (71.4)	32 (64.0)
No	7 (53.8)	9 (30.0)	16 (37.2)	2 (28.6)	18 (36.0)
95% Confidence Interval [A]	(19.22, 74.87)	(50.60, 85.27)	(46.73, 77.02)	(29.04, 96.33)	(49.19, 77.08)
Baseline hs-CRP <= Baseline Median (1.34 mg/L)	N=16	N=23	N=39	N=8	N=47
Yes	8 (50.0)	15 (65.2)	23 (59.0)	5 (62.5)	28 (59.6)
No	8 (50.0)	8 (34.8)	16 (41.0)	3 (37.5)	19 (40.4)
95% Confidence Interval [A]	(24.65, 75.35)	(42.73, 83.62)	(42.10, 74.43)	(24.49, 91.48)	(44.27, 73.63)
Baseline hs-CRP > Baseline Median (1.34 mg/L)	N=14	N=22	N=36	N=10	N=46
Yes	4 (28.6)	12 (54.5)	16 (44.4)	7 (70.0)	23 (50.0)
No	10 (71.4)	10 (45.5)	20 (55.6)	3 (30.0)	23 (50.0)
95% Confidence Interval [A]	(8.39, 58.10)	(32.21, 75.61)	(27.94, 61.90)	(34.75, 93.33)	(34.90, 65.10)

表 2.7.3.6-125. 投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Category Endpoint Met	ITT ITT-E I-SD (N=32)	ITT ITT-E I-HD (N=51)	ITT ITT-E Total (N=83)	ITT I-HD-OL (N=18)	ITT Total (N=101)
Baseline Fecal Calprotectin <= Baseline Median (2302.5 ug/g)	N=7	N=7	N=14	N=0	N=14
Yes	2 (28.6)	3 (42.9)	5 (35.7)	0	5 (35.7)
No	5 (71.4)	4 (57.1)	9 (64.3)	0	9 (64.3)
95% Confidence Interval [A]	(3.67, 70.96)	(9.90, 81.59)	(12.76, 64.86)	(NA, NA)	(12.76, 64.86)
Baseline Fecal Calprotectin > Baseline Median (2302.5 ug/g)	N=6	N=8	N=14	N=0	N=14
Yes	2 (33.3)	3 (37.5)	5 (35.7)	0	5 (35.7)
No	4 (66.7)	5 (62.5)	9 (64.3)	0	9 (64.3)
95% Confidence Interval [A]	(4.33, 77.72)	(8.52, 75.51)	(12.76, 64.86)	(NA, NA)	(12.76, 64.86)

表 2.7.3.6-125.　投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Note: I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
[A] Clopper-Pearson confidence interval for proportion in remission.
[B1] Nominal p-values from a one-sample two-sided chi-square test.
[B2] Adjusted p-values from a sequentially rejective multiple test procedure (details in SAP), testing co-primary and ranked secondary endpoints first for I-SD/I-HD combined (p-value in 'Total' column) and then for individual ADA dose groups (p-values in 'I-HD' column and in 'I-SD' column, respectively) against the respective external placebo rate (here: 19.83%).
[C] Nominal p-value for the exploratory comparison of I-SD vs. I-HD.
Non-responder imputation (NRI): missing data is imputed as not having met the endpoint. Subjects re-randomized due to disease flare are considered as not having met the endpoint at and after their 1st disease flare.
Clinical remission per Partial Mayo Score (PMS) is defined as PMS <= 2 and no individual subscore > 1.
& True baseline Mayo Score is displayed. Subject [redacted] was randomized in the stratum '> 9', but actually had a baseline Mayo Score of 8.8 (corrected by the site from 9.8 to 8.8 after randomization).
# True baseline systemic corticosteroid use is displayed. Subject [redacted] was randomized in the stratum 'No', but actually has baseline systemic corticosteroid use documented.

Cross reference: M11-290 CSR_Final Table 14.2__1.1.1_A

表 2.7.3.6-126.　投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（日本人 ITT 集団，M11-290 試験）（最終 CSR）

	ITT				
	ITT-E				
Category Endpoint Met	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=2)	Total (N=8)
Overall	N=2	N=4	N=6	N=2	N=8
Yes	0	2 (50.0)	2 (33.3)	1 (50.0)	3 (37.5)
No	2 (100)	2 (50.0)	4 (66.7)	1 (50.0)	5 (62.5)
95% Confidence Interval [A]	(0.00, 84.19)	(6.76, 93.24)	(4.33, 77.72)	(1.26, 98.74)	(8.52, 75.51)
P-Value [B1]	0.482	0.130	0.407		
P-Value [C]	0.221				
Baseline Mayo Score <= 9	N=2	N=4	N=6	N=2	N=8
Yes	0	2 (50.0)	2 (33.3)	1 (50.0)	3 (37.5)
No	2 (100)	2 (50.0)	4 (66.7)	1 (50.0)	5 (62.5)
95% Confidence Interval [A]	(0.00, 84.19)	(6.76, 93.24)	(4.33, 77.72)	(1.26, 98.74)	(8.52, 75.51)
Baseline Mayo Score > 9	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)

表 2.7.3.6-126. 投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

	ITT				
	ITT-E				
Category Endpoint Met	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=2)	Total (N=8)
Prior Anti-TNF Use	N=1	N=0	N=1	N=0	N=1
Yes	0	0	0	0	0
No	1 (100)	0	1 (100)	0	1 (100)
95% Confidence Interval [A]	(0.00, 97.50)	(NA, NA)	(0.00, 97.50)	(NA, NA)	(0.00, 97.50)
Prior Anti-TNF Naive	N=1	N=4	N=5	N=2	N=7
Yes	0	2 (50.0)	2 (40.0)	1 (50.0)	3 (42.9)
No	1 (100)	2 (50.0)	3 (60.0)	1 (50.0)	4 (57.1)
95% Confidence Interval [A]	(0.00, 97.50)	(6.76, 93.24)	(5.27, 85.34)	(1.26, 98.74)	(9.90, 81.59)
Baseline Corticosteroid Use - Yes	N=2	N=2	N=4	N=1	N=5
Yes	0	1 (50.0)	1 (25.0)	0	1 (20.0)
No	2 (100)	1 (50.0)	3 (75.0)	1 (100)	4 (80.0)
95% Confidence Interval [A]	(0.00, 84.19)	(1.26, 98.74)	(0.63, 80.59)	(0.00, 97.50)	(0.51, 71.64)
Baseline Corticosteroid Use - No	N=0	N=2	N=2	N=1	N=3
Yes	0	1 (50.0)	1 (50.0)	1 (100)	2 (66.7)
No	0	1 (50.0)	1 (50.0)	0	1 (33.3)
95% Confidence Interval [A]	(NA, NA)	(1.26, 98.74)	(1.26, 98.74)	(2.50, 100.00)	(9.43, 99.16)

表 2.7.3.6-126. 投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

	ITT				
	ITT-E				
Category Endpoint Met	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=2)	Total (N=8)
Sex - Male	N=2	N=4	N=6	N=2	N=8
Yes	0	2 (50.0)	2 (33.3)	1 (50.0)	3 (37.5)
No	2 (100)	2 (50.0)	4 (66.7)	1 (50.0)	5 (62.5)
95% Confidence Interval [A]	(0.00, 84.19)	(6.76, 93.24)	(4.33, 77.72)	(1.26, 98.74)	(8.52, 75.51)
Sex - Female	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Age < 13 Years	N=0	N=1	N=1	N=0	N=1
Yes	0	1 (100)	1 (100)	0	1 (100)
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(2.50, 100.00)	(2.50, 100.00)	(NA, NA)	(2.50, 100.00)
Age >= 13 Years	N=2	N=3	N=5	N=2	N=7
Yes	0	1 (33.3)	1 (20.0)	1 (50.0)	2 (28.6)
No	2 (100)	2 (66.7)	4 (80.0)	1 (50.0)	5 (71.4)
95% Confidence Interval [A]	(0.00, 84.19)	(0.84, 90.57)	(0.51, 71.64)	(1.26, 98.74)	(3.67, 70.96)

表 2.7.3.6-126. 投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

	ITT				
	ITT-E				
Category Endpoint Met	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=2)	Total (N=8)
Ethnicity - White	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Ethnicity - Non-white	N=2	N=4	N=6	N=2	N=8
Yes	0	2 (50.0)	2 (33.3)	1 (50.0)	3 (37.5)
No	2 (100)	2 (50.0)	4 (66.7)	1 (50.0)	5 (62.5)
95% Confidence Interval [A]	(0.00, 84.19)	(6.76, 93.24)	(4.33, 77.72)	(1.26, 98.74)	(8.52, 75.51)
Geographic Region - Japan	N=2	N=4	N=6	N=2	N=8
Yes	0	2 (50.0)	2 (33.3)	1 (50.0)	3 (37.5)
No	2 (100)	2 (50.0)	4 (66.7)	1 (50.0)	5 (62.5)
95% Confidence Interval [A]	(0.00, 84.19)	(6.76, 93.24)	(4.33, 77.72)	(1.26, 98.74)	(8.52, 75.51)

表 2.7.3.6-126. 投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Category Endpoint Met	ITT ITT-E I-SD (N=2)	ITT ITT-E I-HD (N=4)	ITT ITT-E Total (N=6)	ITT I-HD-OL (N=2)	ITT Total (N=8)
Baseline IMM Use - Yes	N=2	N=4	N=6	N=2	N=8
Yes	0	2 (50.0)	2 (33.3)	1 (50.0)	3 (37.5)
No	2 (100)	2 (50.0)	4 (66.7)	1 (50.0)	5 (62.5)
95% Confidence Interval [A]	(0.00, 84.19)	(6.76, 93.24)	(4.33, 77.72)	(1.26, 98.74)	(8.52, 75.51)
Baseline IMM Use - No	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Weight < 40 kg	N=0	N=1	N=1	N=0	N=1
Yes	0	1 (100)	1 (100)	0	1 (100)
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(2.50, 100.00)	(2.50, 100.00)	(NA, NA)	(2.50, 100.00)

表 2.7.3.6-126. 投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

	ITT				
	ITT-E				
Category Endpoint Met	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=2)	Total (N=8)
Weight >= 40 kg	N=2	N=3	N=5	N=2	N=7
Yes	0	1 (33.3)	1 (20.0)	1 (50.0)	2 (28.6)
No	2 (100)	2 (66.7)	4 (80.0)	1 (50.0)	5 (71.4)
95% Confidence Interval [A]	(0.00, 84.19)	(0.84, 90.57)	(0.51, 71.64)	(1.26, 98.74)	(3.67, 70.96)
Pancolitis - Yes	N=1	N=4	N=5	N=2	N=7
Yes	0	2 (50.0)	2 (40.0)	1 (50.0)	3 (42.9)
No	1 (100)	2 (50.0)	3 (60.0)	1 (50.0)	4 (57.1)
95% Confidence Interval [A]	(0.00, 97.50)	(6.76, 93.24)	(5.27, 85.34)	(1.26, 98.74)	(9.90, 81.59)
Pancolitis - No	N=1	N=0	N=1	N=0	N=1
Yes	0	0	0	0	0
No	1 (100)	0	1 (100)	0	1 (100)
95% Confidence Interval [A]	(0.00, 97.50)	(NA, NA)	(0.00, 97.50)	(NA, NA)	(0.00, 97.50)
Disease Duration <= Baseline Median (18.9 Months)	N=0	N=0	N=0	N=2	N=2
Yes	0	0	0	1 (50.0)	1 (50.0)
No	0	0	0	1 (50.0)	1 (50.0)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(1.26, 98.74)	(1.26, 98.74)

表 2.7.3.6-126. 投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

	ITT				
	ITT-E				
Category Endpoint Met	I-SD (N=2)	I-HD (N=4)	Total (N=6)	I-HD-OL (N=2)	Total (N=8)
Disease Duration > Baseline Median (18.9 Months)	N=2	N=4	N=6	N=0	N=6
Yes	0	2 (50.0)	2 (33.3)	0	2 (33.3)
No	2 (100)	2 (50.0)	4 (66.7)	0	4 (66.7)
95% Confidence Interval [A]	(0.00, 84.19)	(6.76, 93.24)	(4.33, 77.72)	(NA, NA)	(4.33, 77.72)
Baseline hs-CRP <= Baseline Median (1.34 mg/L)	N=1	N=3	N=4	N=0	N=4
Yes	0	2 (66.7)	2 (50.0)	0	2 (50.0)
No	1 (100)	1 (33.3)	2 (50.0)	0	2 (50.0)
95% Confidence Interval [A]	(0.00, 97.50)	(9.43, 99.16)	(6.76, 93.24)	(NA, NA)	(6.76, 93.24)
Baseline hs-CRP > Baseline Median (1.34 mg/L)	N=1	N=1	N=2	N=2	N=4
Yes	0	0	0	1 (50.0)	1 (25.0)
No	1 (100)	1 (100)	2 (100)	1 (50.0)	3 (75.0)
95% Confidence Interval [A]	(0.00, 97.50)	(0.00, 97.50)	(0.00, 84.19)	(1.26, 98.74)	(0.63, 80.59)
Baseline Fecal Calprotectin <= Baseline Median (2302.5 ug/g)	N=1	N=0	N=1	N=0	N=1
Yes	0	0	0	0	0
No	1 (100)	0	1 (100)	0	1 (100)
95% Confidence Interval [A]	(0.00, 97.50)	(NA, NA)	(0.00, 97.50)	(NA, NA)	(0.00, 97.50)

表 2.7.3.6-126.　投与 8 週時に PMS により寛解を達成した被験者の割合（NRI）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Category Endpoint Met	ITT ITT-E I-SD (N=2)	ITT ITT-E I-HD (N=4)	ITT ITT-E Total (N=6)	ITT I-HD-OL (N=2)	ITT Total (N=8)
Baseline Fecal Calprotectin > Baseline Median (2302.5 ug/g)	N=1	N=1	N=2	N=0	N=2
Yes	0	1 (100)	1 (50.0)	0	1 (50.0)
No	1 (100)	0	1 (50.0)	0	1 (50.0)
95% Confidence Interval [A]	(0.00, 97.50)	(2.50, 100.00)	(1.26, 98.74)	(NA, NA)	(1.26, 98.74)

Note: I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
[A] Clopper-Pearson confidence interval for proportion in remission.
[B1] Nominal p-values from a one-sample two-sided chi-square test.
[C] Nominal p-value for the exploratory comparison of I-SD vs. I-HD.
Non-responder imputation (NRI): missing data is imputed as not having met the endpoint. Subjects re-randomized due to disease flare are considered as not having met the endpoint at and after their 1st disease flare.
Clinical remission per Partial Mayo Score (PMS) is defined as PMS <= 2 and no individual subscore > 1.

Cross reference: M11-290 CSR_Final Table 14.2__1.1.1_J

表 2.7.3.6-127. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Overall	N=12	N=33	N=35	N=68	N=80
Yes	4 (33.3)	9 (27.3)	15 (42.9)	24 (35.3)	28 (35.0)
No	8 (66.7)	24 (72.7)	20 (57.1)	44 (64.7)	52 (65.0)
95% Confidence Interval [A]	(9.92, 65.11)	(13.30, 45.52)	(26.32, 60.65)	(24.08, 47.83)	(24.67, 46.48)
P-Value [B1]		0.187	<0.001	<0.001	
ADJ. P-Value [B2]		0.344	<0.001	<0.001	
P-Value [C]		0.179			
PMS Remission at Week 8 - Yes	N=8	N=21	N=25	N=46	N=54
Yes	3 (37.5)	9 (42.9)	11 (44.0)	20 (43.5)	23 (42.6)
No	5 (62.5)	12 (57.1)	14 (56.0)	26 (56.5)	31 (57.4)
95% Confidence Interval [A]	(8.52, 75.51)	(21.82, 65.98)	(24.40, 65.07)	(28.93, 58.89)	(29.23, 56.79)

表 2.7.3.6-127. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
PMS Remission at Week 8 - No	N=4	N=12	N=10	N=22	N=26
Yes	1 (25.0)	0	4 (40.0)	4 (18.2)	5 (19.2)
No	3 (75.0)	12 (100)	6 (60.0)	18 (81.8)	21 (80.8)
95% Confidence Interval [A]	(0.63, 80.59)	(0.00, 26.46)	(12.16, 73.76)	(5.19, 40.28)	(6.55, 39.35)
I-SD	N=4	N=8	N=9	N=17	N=21
Yes	1 (25.0)	0	4 (44.4)	4 (23.5)	5 (23.8)
No	3 (75.0)	8 (100)	5 (55.6)	13 (76.5)	16 (76.2)
95% Confidence Interval [A]	(0.63, 80.59)	(0.00, 36.94)	(13.70, 78.80)	(6.81, 49.90)	(8.22, 47.17)
I-HD/I-HD-OL	N=8	N=25	N=26	N=51	N=59
Yes	3 (37.5)	9 (36.0)	11 (42.3)	20 (39.2)	23 (39.0)
No	5 (62.5)	16 (64.0)	15 (57.7)	31 (60.8)	36 (61.0)
95% Confidence Interval [A]	(8.52, 75.51)	(17.97, 57.48)	(23.35, 63.08)	(25.84, 53.89)	(26.55, 52.56)

表 2.7.3.6-127. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
I-HD	N=8	N=17	N=18	N=35	N=43
Yes	3 (37.5)	7 (41.2)	8 (44.4)	15 (42.9)	18 (41.9)
No	5 (62.5)	10 (58.8)	10 (55.6)	20 (57.1)	25 (58.1)
95% Confidence Interval [A]	(8.52, 75.51)	(18.44, 67.08)	(21.53, 69.24)	(26.32, 60.65)	(27.01, 57.87)
I-HD-OL	N=0	N=8	N=8	N=16	N=16
Yes	0	2 (25.0)	3 (37.5)	5 (31.3)	5 (31.3)
No	0	6 (75.0)	5 (62.5)	11 (68.8)	11 (68.8)
95% Confidence Interval [A]	(NA, NA)	(3.19, 65.09)	(8.52, 75.51)	(11.02, 58.66)	(11.02, 58.66)
Sex - Male	N=9	N=15	N=17	N=32	N=41
Yes	2 (22.2)	4 (26.7)	7 (41.2)	11 (34.4)	13 (31.7)
No	7 (77.8)	11 (73.3)	10 (58.8)	21 (65.6)	28 (68.3)
95% Confidence Interval [A]	(2.81, 60.01)	(7.79, 55.10)	(18.44, 67.08)	(18.57, 53.19)	(18.08, 48.09)

表 2.7.3.6-127. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Sex - Female	N=3	N=18	N=18	N=36	N=39
Yes	2 (66.7)	5 (27.8)	8 (44.4)	13 (36.1)	15 (38.5)
No	1 (33.3)	13 (72.2)	10 (55.6)	23 (63.9)	24 (61.5)
95% Confidence Interval [A]	(9.43, 99.16)	(9.69, 53.48)	(21.53, 69.24)	(20.82, 53.78)	(23.36, 55.38)
Age < 13 Years	N=2	N=12	N=9	N=21	N=23
Yes	1 (50.0)	5 (41.7)	4 (44.4)	9 (42.9)	10 (43.5)
No	1 (50.0)	7 (58.3)	5 (55.6)	12 (57.1)	13 (56.5)
95% Confidence Interval [A]	(1.26, 98.74)	(15.17, 72.33)	(13.70, 78.80)	(21.82, 65.98)	(23.19, 65.51)
Age >= 13 Years	N=10	N=21	N=26	N=47	N=57
Yes	3 (30.0)	4 (19.0)	11 (42.3)	15 (31.9)	18 (31.6)
No	7 (70.0)	17 (81.0)	15 (57.7)	32 (68.1)	39 (68.4)
95% Confidence Interval [A]	(6.67, 65.25)	(5.45, 41.91)	(23.35, 63.08)	(19.09, 47.12)	(19.91, 45.24)

表 2.7.3.6-127. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Ethnicity - White	N=11	N=29	N=30	N=59	N=70
Yes	4 (36.4)	8 (27.6)	14 (46.7)	22 (37.3)	26 (37.1)
No	7 (63.6)	21 (72.4)	16 (53.3)	37 (62.7)	44 (62.9)
95% Confidence Interval [A]	(10.93, 69.21)	(12.73, 47.24)	(28.34, 65.67)	(25.04, 50.85)	(25.89, 49.52)
Ethnicity - Non-white	N=1	N=4	N=5	N=9	N=10
Yes	0	1 (25.0)	1 (20.0)	2 (22.2)	2 (20.0)
No	1 (100)	3 (75.0)	4 (80.0)	7 (77.8)	8 (80.0)
95% Confidence Interval [A]	(0.00, 97.50)	(0.63, 80.59)	(0.51, 71.64)	(2.81, 60.01)	(2.52, 55.61)
Geographic Region - North America	N=1	N=7	N=3	N=10	N=11
Yes	0	2 (28.6)	1 (33.3)	3 (30.0)	3 (27.3)
No	1 (100)	5 (71.4)	2 (66.7)	7 (70.0)	8 (72.7)
95% Confidence Interval [A]	(0.00, 97.50)	(3.67, 70.96)	(0.84, 90.57)	(6.67, 65.25)	(6.02, 60.97)

表 2.7.3.6-127. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Geographic Region - Western Europe	N=1	N=0	N=3	N=3	N=4
Yes	0	0	1 (33.3)	1 (33.3)	1 (25.0)
No	1 (100)	0	2 (66.7)	2 (66.7)	3 (75.0)
95% Confidence Interval [A]	(0.00, 97.50)	(NA, NA)	(0.84, 90.57)	(0.84, 90.57)	(0.63, 80.59)
Geographic Region - Eastern Europe	N=10	N=24	N=25	N=49	N=59
Yes	4 (40.0)	7 (29.2)	12 (48.0)	19 (38.8)	23 (39.0)
No	6 (60.0)	17 (70.8)	13 (52.0)	30 (61.2)	36 (61.0)
95% Confidence Interval [A]	(12.16, 73.76)	(12.62, 51.09)	(27.80, 68.69)	(25.20, 53.76)	(26.55, 52.56)
Geographic Region - Japan	N=0	N=2	N=4	N=6	N=6
Yes	0	0	1 (25.0)	1 (16.7)	1 (16.7)
No	0	2 (100)	3 (75.0)	5 (83.3)	5 (83.3)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.63, 80.59)	(0.42, 64.12)	(0.42, 64.12)

表 2.7.3.6-127. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Baseline Mayo Score <= 9	N=11	N=27	N=30	N=57	N=68
Yes	4 (36.4)	8 (29.6)	11 (36.7)	19 (33.3)	23 (33.8)
No	7 (63.6)	19 (70.4)	19 (63.3)	38 (66.7)	45 (66.2)
95% Confidence Interval [A]	(10.93, 69.21)	(13.75, 50.18)	(19.93, 56.14)	(21.40, 47.06)	(22.79, 46.32)
Baseline Mayo Score > 9	N=1	N=6	N=5	N=11	N=12
Yes	0	1 (16.7)	4 (80.0)	5 (45.5)	5 (41.7)
No	1 (100)	5 (83.3)	1 (20.0)	6 (54.5)	7 (58.3)
95% Confidence Interval [A]	(0.00, 97.50)	(0.42, 64.12)	(28.36, 99.49)	(16.75, 76.62)	(15.17, 72.33)
Prior Anti-TNF Use	N=2	N=2	N=6	N=8	N=10
Yes	1 (50.0)	0	2 (33.3)	2 (25.0)	3 (30.0)
No	1 (50.0)	2 (100)	4 (66.7)	6 (75.0)	7 (70.0)
95% Confidence Interval [A]	(1.26, 98.74)	(0.00, 84.19)	(4.33, 77.72)	(3.19, 65.09)	(6.67, 65.25)

表 2.7.3.6-127. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Prior Anti-TNF Naive	N=10	N=31	N=29	N=60	N=70
Yes	3 (30.0)	9 (29.0)	13 (44.8)	22 (36.7)	25 (35.7)
No	7 (70.0)	22 (71.0)	16 (55.2)	38 (63.3)	45 (64.3)
95% Confidence Interval [A]	(6.67, 65.25)	(14.22, 48.04)	(26.45, 64.31)	(24.59, 50.10)	(24.61, 48.07)
Baseline Corticosteroid Use - Yes	N=5	N=15	N=17	N=32	N=37
Yes	2 (40.0)	4 (26.7)	6 (35.3)	10 (31.3)	12 (32.4)
No	3 (60.0)	11 (73.3)	11 (64.7)	22 (68.8)	25 (67.6)
95% Confidence Interval [A]	(5.27, 85.34)	(7.79, 55.10)	(14.21, 61.67)	(16.12, 50.01)	(18.01, 49.79)
Baseline Corticosteroid Use - No	N=7	N=18	N=18	N=36	N=43
Yes	2 (28.6)	5 (27.8)	9 (50.0)	14 (38.9)	16 (37.2)
No	5 (71.4)	13 (72.2)	9 (50.0)	22 (61.1)	27 (62.8)
95% Confidence Interval [A]	(3.67, 70.96)	(9.69, 53.48)	(26.02, 73.98)	(23.14, 56.54)	(22.98, 53.27)

表 2.7.3.6-127. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Baseline IMM Use - Yes	N=8	N=19	N=25	N=44	N=52
Yes	3 (37.5)	4 (21.1)	11 (44.0)	15 (34.1)	18 (34.6)
No	5 (62.5)	15 (78.9)	14 (56.0)	29 (65.9)	34 (65.4)
95% Confidence Interval [A]	(8.52, 75.51)	(6.05, 45.57)	(24.40, 65.07)	(20.49, 49.92)	(21.97, 49.09)
Baseline IMM Use - No	N=4	N=14	N=10	N=24	N=28
Yes	1 (25.0)	5 (35.7)	4 (40.0)	9 (37.5)	10 (35.7)
No	3 (75.0)	9 (64.3)	6 (60.0)	15 (62.5)	18 (64.3)
95% Confidence Interval [A]	(0.63, 80.59)	(12.76, 64.86)	(12.16, 73.76)	(18.80, 59.41)	(18.64, 55.93)
Weight < 40 kg	N=0	N=7	N=8	N=15	N=15
Yes	0	3 (42.9)	4 (50.0)	7 (46.7)	7 (46.7)
No	0	4 (57.1)	4 (50.0)	8 (53.3)	8 (53.3)
95% Confidence Interval [A]	(NA, NA)	(9.90, 81.59)	(15.70, 84.30)	(21.27, 73.41)	(21.27, 73.41)

表 2.7.3.6-127. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Weight >= 40 kg	N=12	N=26	N=27	N=53	N=65
Yes	4 (33.3)	6 (23.1)	11 (40.7)	17 (32.1)	21 (32.3)
No	8 (66.7)	20 (76.9)	16 (59.3)	36 (67.9)	44 (67.7)
95% Confidence Interval [A]	(9.92, 65.11)	(8.97, 43.65)	(22.39, 61.20)	(19.92, 46.32)	(21.23, 45.05)
Pancolitis - Yes	N=7	N=22	N=21	N=43	N=50
Yes	2 (28.6)	5 (22.7)	11 (52.4)	16 (37.2)	18 (36.0)
No	5 (71.4)	17 (77.3)	10 (47.6)	27 (62.8)	32 (64.0)
95% Confidence Interval [A]	(3.67, 70.96)	(7.82, 45.37)	(29.78, 74.29)	(22.98, 53.27)	(22.92, 50.81)
Pancolitis - No	N=5	N=11	N=14	N=25	N=30
Yes	2 (40.0)	4 (36.4)	4 (28.6)	8 (32.0)	10 (33.3)
No	3 (60.0)	7 (63.6)	10 (71.4)	17 (68.0)	20 (66.7)
95% Confidence Interval [A]	(5.27, 85.34)	(10.93, 69.21)	(8.39, 58.10)	(14.95, 53.50)	(17.29, 52.81)

表 2.7.3.6-127. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Disease Duration <= Baseline Median (18.9 Months)	N=5	N=19	N=16	N=35	N=40
Yes	0	3 (15.8)	7 (43.8)	10 (28.6)	10 (25.0)
No	5 (100)	16 (84.2)	9 (56.3)	25 (71.4)	30 (75.0)
95% Confidence Interval [A]	(0.00, 52.18)	(3.38, 39.58)	(19.75, 70.12)	(14.64, 46.30)	(12.69, 41.20)
Disease Duration > Baseline Median (18.9 Months)	N=7	N=14	N=19	N=33	N=40
Yes	4 (57.1)	6 (42.9)	8 (42.1)	14 (42.4)	18 (45.0)
No	3 (42.9)	8 (57.1)	11 (57.9)	19 (57.6)	22 (55.0)
95% Confidence Interval [A]	(18.41, 90.10)	(17.66, 71.14)	(20.25, 66.50)	(25.48, 60.78)	(29.26, 61.51)
Baseline hs-CRP <= Baseline Median (1.34 mg/L)	N=8	N=12	N=18	N=30	N=38
Yes	3 (37.5)	3 (25.0)	9 (50.0)	12 (40.0)	15 (39.5)
No	5 (62.5)	9 (75.0)	9 (50.0)	18 (60.0)	23 (60.5)
95% Confidence Interval [A]	(8.52, 75.51)	(5.49, 57.19)	(26.02, 73.98)	(22.66, 59.40)	(24.04, 56.61)

表 2.7.3.6-127. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Baseline hs-CRP > Baseline Median (1.34 mg/L)	N=3	N=18	N=15	N=33	N=36
Yes	0	4 (22.2)	5 (33.3)	9 (27.3)	9 (25.0)
No	3 (100)	14 (77.8)	10 (66.7)	24 (72.7)	27 (75.0)
95% Confidence Interval [A]	(0.00, 70.76)	(6.41, 47.64)	(11.82, 61.62)	(13.30, 45.52)	(12.12, 42.20)
Baseline Fecal Calprotectin <= Baseline Median (2302.5 ug/g)	N=3	N=5	N=2	N=7	N=10
Yes	1 (33.3)	1 (20.0)	1 (50.0)	2 (28.6)	3 (30.0)
No	2 (66.7)	4 (80.0)	1 (50.0)	5 (71.4)	7 (70.0)
95% Confidence Interval [A]	(0.84, 90.57)	(0.51, 71.64)	(1.26, 98.74)	(3.67, 70.96)	(6.67, 65.25)
Baseline Fecal Calprotectin > Baseline Median (2302.5 ug/g)	N=1	N=4	N=5	N=9	N=10
Yes	0	0	4 (80.0)	4 (44.4)	4 (40.0)
No	1 (100)	4 (100)	1 (20.0)	5 (55.6)	6 (60.0)
95% Confidence Interval [A]	(0.00, 97.50)	(0.00, 60.24)	(28.36, 99.49)	(13.70, 78.80)	(12.16, 73.76)

表 2.7.3.6-127.　投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

Note: M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
[A] Clopper-Pearson confidence interval for proportion in remission.
[B1] Nominal p-values from a one-sample two-sided chi-square test.
[B2] Adjusted p-values from a sequentially rejective multiple test procedure (details in SAP), testing co-primary and ranked secondary endpoints first for M-SD/M-HD combined (p-value in 'Total' column) and then for individual ADA dose groups (p-values in 'M-HD' column and in 'M-SD' column, respectively) against the respective external placebo rate (here: 18.37%).
[C] Nominal p-value for the exploratory comparison of M-SD vs. M-HD.
Non-responder imputation (NRI): missing data is imputed as not having met the endpoint. Subjects re-randomized due to disease flare are considered as not having met the endpoint at and after their 1st disease flare.
Clinical remission per Full Mayo Score (FMS) is defined as Mayo Score <= 2 and no individual subscore > 1.
Clinical response per Partial Mayo Score (PMS) is defined as decrease in PMS >= 2 points and >= 30% from baseline.
Clinical remission per Partial Mayo Score (PMS) is defined as PMS <= 2 and no individual subscore > 1.

Cross reference: M11-290 CSR_Final Table 14.2__1.1.2_A

表 2.7.3.6-128. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Overall	N=0	N=2	N=4	N=6	N=6
Yes	0	0	1 (25.0)	1 (16.7)	1 (16.7)
No	0	2 (100)	3 (75.0)	5 (83.3)	5 (83.3)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.63, 80.59)	(0.42, 64.12)	(0.42, 64.12)
P-Value [B1]		0.502	0.732	0.914	
P-Value [C]		0.439			
PMS Remission at Week 8 - Yes	N=0	N=0	N=3	N=3	N=3
Yes	0	0	1 (33.3)	1 (33.3)	1 (33.3)
No	0	0	2 (66.7)	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.84, 90.57)	(0.84, 90.57)	(0.84, 90.57)

表 2.7.3.6-128. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
PMS Remission at Week 8 - No	N=0	N=2	N=1	N=3	N=3
Yes	0	0	0	0	0
No	0	2 (100)	1 (100)	3 (100)	3 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.00, 97.50)	(0.00, 70.76)	(0.00, 70.76)
I-SD	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
I-HD/I-HD-OL	N=0	N=2	N=4	N=6	N=6
Yes	0	0	1 (25.0)	1 (16.7)	1 (16.7)
No	0	2 (100)	3 (75.0)	5 (83.3)	5 (83.3)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.63, 80.59)	(0.42, 64.12)	(0.42, 64.12)

表 2.7.3.6-128. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
I-HD	N=0	N=1	N=3	N=4	N=4
Yes	0	0	1 (33.3)	1 (25.0)	1 (25.0)
No	0	1 (100)	2 (66.7)	3 (75.0)	3 (75.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 97.50)	(0.84, 90.57)	(0.63, 80.59)	(0.63, 80.59)
I-HD-OL	N=0	N=1	N=1	N=2	N=2
Yes	0	0	0	0	0
No	0	1 (100)	1 (100)	2 (100)	2 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)	(0.00, 84.19)	(0.00, 84.19)
Sex - Male	N=0	N=2	N=4	N=6	N=6
Yes	0	0	1 (25.0)	1 (16.7)	1 (16.7)
No	0	2 (100)	3 (75.0)	5 (83.3)	5 (83.3)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.63, 80.59)	(0.42, 64.12)	(0.42, 64.12)

表 2.7.3.6-128. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Sex - Female	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Age < 13 Years	N=0	N=0	N=1	N=1	N=1
Yes	0	0	1 (100)	1 (100)	1 (100)
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(2.50, 100.00)	(2.50, 100.00)	(2.50, 100.00)
Age >= 13 Years	N=0	N=2	N=3	N=5	N=5
Yes	0	0	0	0	0
No	0	2 (100)	3 (100)	5 (100)	5 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.00, 70.76)	(0.00, 52.18)	(0.00, 52.18)

表 2.7.3.6-128. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Ethnicity - White	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Ethnicity - Non-white	N=0	N=2	N=4	N=6	N=6
Yes	0	0	1 (25.0)	1 (16.7)	1 (16.7)
No	0	2 (100)	3 (75.0)	5 (83.3)	5 (83.3)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.63, 80.59)	(0.42, 64.12)	(0.42, 64.12)
Geographic Region - Japan	N=0	N=2	N=4	N=6	N=6
Yes	0	0	1 (25.0)	1 (16.7)	1 (16.7)
No	0	2 (100)	3 (75.0)	5 (83.3)	5 (83.3)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.63, 80.59)	(0.42, 64.12)	(0.42, 64.12)

表 2.7.3.6-128. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Baseline Mayo Score <= 9	N=0	N=2	N=4	N=6	N=6
Yes	0	0	1 (25.0)	1 (16.7)	1 (16.7)
No	0	2 (100)	3 (75.0)	5 (83.3)	5 (83.3)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.63, 80.59)	(0.42, 64.12)	(0.42, 64.12)
Baseline Mayo Score > 9	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Prior Anti-TNF Use	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)

表 2.7.3.6-128. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Prior Anti-TNF Naive	N=0	N=2	N=4	N=6	N=6
Yes	0	0	1 (25.0)	1 (16.7)	1 (16.7)
No	0	2 (100)	3 (75.0)	5 (83.3)	5 (83.3)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.63, 80.59)	(0.42, 64.12)	(0.42, 64.12)
Baseline Corticosteroid Use - Yes	N=0	N=2	N=1	N=3	N=3
Yes	0	0	1 (100)	1 (33.3)	1 (33.3)
No	0	2 (100)	0	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(2.50, 100.00)	(0.84, 90.57)	(0.84, 90.57)
Baseline Corticosteroid Use - No	N=0	N=0	N=3	N=3	N=3
Yes	0	0	0	0	0
No	0	0	3 (100)	3 (100)	3 (100)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.00, 70.76)	(0.00, 70.76)	(0.00, 70.76)

表 2.7.3.6-128. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Baseline IMM Use - Yes	N=0	N=2	N=4	N=6	N=6
Yes	0	0	1 (25.0)	1 (16.7)	1 (16.7)
No	0	2 (100)	3 (75.0)	5 (83.3)	5 (83.3)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.63, 80.59)	(0.42, 64.12)	(0.42, 64.12)
Baseline IMM Use - No	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Weight < 40 kg	N=0	N=0	N=1	N=1	N=1
Yes	0	0	1 (100)	1 (100)	1 (100)
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(2.50, 100.00)	(2.50, 100.00)	(2.50, 100.00)

表 2.7.3.6-128. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Weight >= 40 kg	N=0	N=2	N=3	N=5	N=5
Yes	0	0	0	0	0
No	0	2 (100)	3 (100)	5 (100)	5 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.00, 70.76)	(0.00, 52.18)	(0.00, 52.18)
Pancolitis - Yes	N=0	N=2	N=4	N=6	N=6
Yes	0	0	1 (25.0)	1 (16.7)	1 (16.7)
No	0	2 (100)	3 (75.0)	5 (83.3)	5 (83.3)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.63, 80.59)	(0.42, 64.12)	(0.42, 64.12)
Pancolitis - No	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)

表 2.7.3.6-128. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Disease Duration <= Baseline Median (18.9 Months)	N=0	N=1	N=1	N=2	N=2
Yes	0	0	0	0	0
No	0	1 (100)	1 (100)	2 (100)	2 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)	(0.00, 84.19)	(0.00, 84.19)
Disease Duration > Baseline Median (18.9 Months)	N=0	N=1	N=3	N=4	N=4
Yes	0	0	1 (33.3)	1 (25.0)	1 (25.0)
No	0	1 (100)	2 (66.7)	3 (75.0)	3 (75.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 97.50)	(0.84, 90.57)	(0.63, 80.59)	(0.63, 80.59)
Baseline hs-CRP <= Baseline Median (1.34 mg/L)	N=0	N=0	N=3	N=3	N=3
Yes	0	0	1 (33.3)	1 (33.3)	1 (33.3)
No	0	0	2 (66.7)	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.84, 90.57)	(0.84, 90.57)	(0.84, 90.57)

表 2.7.3.6-128. 投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

Category Endpoint Met	mITT mITT-E M-PL (N=0)	mITT mITT-E M-SD (N=2)	mITT mITT-E M-HD (N=4)	mITT mITT-E Total (N=6)	mITT Total (N=6)
Baseline hs-CRP > Baseline Median (1.34 mg/L)	N=0	N=2	N=1	N=3	N=3
Yes	0	0	0	0	0
No	0	2 (100)	1 (100)	3 (100)	3 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.00, 97.50)	(0.00, 70.76)	(0.00, 70.76)
Baseline Fecal Calprotectin <= Baseline Median (2302.5 ug/g)	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Baseline Fecal Calprotectin > Baseline Median (2302.5 ug/g)	N=0	N=0	N=1	N=1	N=1
Yes	0	0	0	0	0
No	0	0	1 (100)	1 (100)	1 (100)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)	(0.00, 97.50)

表 2.7.3.6-128.　投与 8 週時に PMS により改善し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

Note: M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
[A] Clopper-Pearson confidence interval for proportion in remission.
[B1] Nominal p-values from a one-sample two-sided chi-square test.
[C] Nominal p-value for the exploratory comparison of M-SD vs. M-HD.
Non-responder imputation (NRI): missing data is imputed as not having met the endpoint. Subjects re-randomized due to disease flare are considered as not having met the endpoint at and after their 1st disease flare.
Clinical remission per Full Mayo Score (FMS) is defined as Mayo Score <= 2 and no individual subscore > 1.
Clinical response per Partial Mayo Score (PMS) is defined as decrease in PMS >= 2 points and >= 30% from baseline.
Clinical remission per Partial Mayo Score (PMS) is defined as PMS <= 2 and no individual subscore > 1.

Cross reference: M11-290 CSR_Final Table 14.2__1.1.2_J

表 2.7.3.6-129. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Overall	N=12	N=33	N=35	N=68	N=80
Yes	4 (33.3)	19 (57.6)	23 (65.7)	42 (61.8)	46 (57.5)
No	8 (66.7)	14 (42.4)	12 (34.3)	26 (38.2)	34 (42.5)
95% Confidence Interval [A]	(9.92, 65.11)	(39.22, 74.52)	(47.79, 80.87)	(49.18, 73.29)	(45.94, 68.49)
P-Value [B1]		<0.001	<0.001	<0.001	
ADJ. P-Value [B2]		0.038	<0.001	<0.001	
P-Value [C]		0.490			
PMS Remission at Week 8 - Yes	N=8	N=21	N=25	N=46	N=54
Yes	3 (37.5)	16 (76.2)	17 (68.0)	33 (71.7)	36 (66.7)
No	5 (62.5)	5 (23.8)	8 (32.0)	13 (28.3)	18 (33.3)
95% Confidence Interval [A]	(8.52, 75.51)	(52.83, 91.78)	(46.50, 85.05)	(56.54, 84.01)	(52.53, 78.91)

表 2.7.3.6-129. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
PMS Remission at Week 8 - No	N=4	N=12	N=10	N=22	N=26
Yes	1 (25.0)	3 (25.0)	6 (60.0)	9 (40.9)	10 (38.5)
No	3 (75.0)	9 (75.0)	4 (40.0)	13 (59.1)	16 (61.5)
95% Confidence Interval [A]	(0.63, 80.59)	(5.49, 57.19)	(26.24, 87.84)	(20.71, 63.65)	(20.23, 59.43)
I-SD	N=4	N=8	N=9	N=17	N=21
Yes	1 (25.0)	5 (62.5)	6 (66.7)	11 (64.7)	12 (57.1)
No	3 (75.0)	3 (37.5)	3 (33.3)	6 (35.3)	9 (42.9)
95% Confidence Interval [A]	(0.63, 80.59)	(24.49, 91.48)	(29.93, 92.51)	(38.33, 85.79)	(34.02, 78.18)
I-HD/I-HD-OL	N=8	N=25	N=26	N=51	N=59
Yes	3 (37.5)	14 (56.0)	17 (65.4)	31 (60.8)	34 (57.6)
No	5 (62.5)	11 (44.0)	9 (34.6)	20 (39.2)	25 (42.4)
95% Confidence Interval [A]	(8.52, 75.51)	(34.93, 75.60)	(44.33, 82.79)	(46.11, 74.16)	(44.07, 70.39)

表 2.7.3.6-129. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
I-HD	N=8	N=17	N=18	N=35	N=43
Yes	3 (37.5)	10 (58.8)	12 (66.7)	22 (62.9)	25 (58.1)
No	5 (62.5)	7 (41.2)	6 (33.3)	13 (37.1)	18 (41.9)
95% Confidence Interval [A]	(8.52, 75.51)	(32.92, 81.56)	(40.99, 86.66)	(44.92, 78.53)	(42.13, 72.99)
I-HD-OL	N=0	N=8	N=8	N=16	N=16
Yes	0	4 (50.0)	5 (62.5)	9 (56.3)	9 (56.3)
No	0	4 (50.0)	3 (37.5)	7 (43.8)	7 (43.8)
95% Confidence Interval [A]	(NA, NA)	(15.70, 84.30)	(24.49, 91.48)	(29.88, 80.25)	(29.88, 80.25)
Sex - Male	N=9	N=15	N=17	N=32	N=41
Yes	2 (22.2)	8 (53.3)	9 (52.9)	17 (53.1)	19 (46.3)
No	7 (77.8)	7 (46.7)	8 (47.1)	15 (46.9)	22 (53.7)
95% Confidence Interval [A]	(2.81, 60.01)	(26.59, 78.73)	(27.81, 77.02)	(34.74, 70.91)	(30.66, 62.58)

表 2.7.3.6-129. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Sex - Female	N=3	N=18	N=18	N=36	N=39
Yes	2 (66.7)	11 (61.1)	14 (77.8)	25 (69.4)	27 (69.2)
No	1 (33.3)	7 (38.9)	4 (22.2)	11 (30.6)	12 (30.8)
95% Confidence Interval [A]	(9.43, 99.16)	(35.75, 82.70)	(52.36, 93.59)	(51.89, 83.65)	(52.43, 82.98)
Age < 13 Years	N=2	N=12	N=9	N=21	N=23
Yes	1 (50.0)	8 (66.7)	8 (88.9)	16 (76.2)	17 (73.9)
No	1 (50.0)	4 (33.3)	1 (11.1)	5 (23.8)	6 (26.1)
95% Confidence Interval [A]	(1.26, 98.74)	(34.89, 90.08)	(51.75, 99.72)	(52.83, 91.78)	(51.59, 89.77)
Age >= 13 Years	N=10	N=21	N=26	N=47	N=57
Yes	3 (30.0)	11 (52.4)	15 (57.7)	26 (55.3)	29 (50.9)
No	7 (70.0)	10 (47.6)	11 (42.3)	21 (44.7)	28 (49.1)
95% Confidence Interval [A]	(6.67, 65.25)	(29.78, 74.29)	(36.92, 76.65)	(40.12, 69.83)	(37.29, 64.37)

表 2.7.3.6-129. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Ethnicity - White	N=11	N=29	N=30	N=59	N=70
Yes	4 (36.4)	18 (62.1)	21 (70.0)	39 (66.1)	43 (61.4)
No	7 (63.6)	11 (37.9)	9 (30.0)	20 (33.9)	27 (38.6)
95% Confidence Interval [A]	(10.93, 69.21)	(42.26, 79.31)	(50.60, 85.27)	(52.61, 77.92)	(49.03, 72.83)
Ethnicity - Non-white	N=1	N=4	N=5	N=9	N=10
Yes	0	1 (25.0)	2 (40.0)	3 (33.3)	3 (30.0)
No	1 (100)	3 (75.0)	3 (60.0)	6 (66.7)	7 (70.0)
95% Confidence Interval [A]	(0.00, 97.50)	(0.63, 80.59)	(5.27, 85.34)	(7.49, 70.07)	(6.67, 65.25)
Geographic Region - North America	N=1	N=7	N=3	N=10	N=11
Yes	0	3 (42.9)	1 (33.3)	4 (40.0)	4 (36.4)
No	1 (100)	4 (57.1)	2 (66.7)	6 (60.0)	7 (63.6)
95% Confidence Interval [A]	(0.00, 97.50)	(9.90, 81.59)	(0.84, 90.57)	(12.16, 73.76)	(10.93, 69.21)

表 2.7.3.6-129. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Geographic Region - Western Europe	N=1	N=0	N=3	N=3	N=4
Yes	0	0	2 (66.7)	2 (66.7)	2 (50.0)
No	1 (100)	0	1 (33.3)	1 (33.3)	2 (50.0)
95% Confidence Interval [A]	(0.00, 97.50)	(NA, NA)	(9.43, 99.16)	(9.43, 99.16)	(6.76, 93.24)
Geographic Region - Eastern Europe	N=10	N=24	N=25	N=49	N=59
Yes	4 (40.0)	16 (66.7)	18 (72.0)	34 (69.4)	38 (64.4)
No	6 (60.0)	8 (33.3)	7 (28.0)	15 (30.6)	21 (35.6)
95% Confidence Interval [A]	(12.16, 73.76)	(44.68, 84.37)	(50.61, 87.93)	(54.58, 81.75)	(50.87, 76.45)
Geographic Region - Japan	N=0	N=2	N=4	N=6	N=6
Yes	0	0	2 (50.0)	2 (33.3)	2 (33.3)
No	0	2 (100)	2 (50.0)	4 (66.7)	4 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(6.76, 93.24)	(4.33, 77.72)	(4.33, 77.72)

表 2.7.3.6-129. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Baseline Mayo Score <= 9	N=11	N=27	N=30	N=57	N=68
Yes	4 (36.4)	17 (63.0)	19 (63.3)	36 (63.2)	40 (58.8)
No	7 (63.6)	10 (37.0)	11 (36.7)	21 (36.8)	28 (41.2)
95% Confidence Interval [A]	(10.93, 69.21)	(42.37, 80.60)	(43.86, 80.07)	(49.34, 75.55)	(46.23, 70.63)
Baseline Mayo Score > 9	N=1	N=6	N=5	N=11	N=12
Yes	0	2 (33.3)	4 (80.0)	6 (54.5)	6 (50.0)
No	1 (100)	4 (66.7)	1 (20.0)	5 (45.5)	6 (50.0)
95% Confidence Interval [A]	(0.00, 97.50)	(4.33, 77.72)	(28.36, 99.49)	(23.38, 83.25)	(21.09, 78.91)
Prior Anti-TNF Use	N=2	N=2	N=6	N=8	N=10
Yes	1 (50.0)	1 (50.0)	3 (50.0)	4 (50.0)	5 (50.0)
No	1 (50.0)	1 (50.0)	3 (50.0)	4 (50.0)	5 (50.0)
95% Confidence Interval [A]	(1.26, 98.74)	(1.26, 98.74)	(11.81, 88.19)	(15.70, 84.30)	(18.71, 81.29)

表 2.7.3.6-129. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Prior Anti-TNF Naive	N=10	N=31	N=29	N=60	N=70
Yes	3 (30.0)	18 (58.1)	20 (69.0)	38 (63.3)	41 (58.6)
No	7 (70.0)	13 (41.9)	9 (31.0)	22 (36.7)	29 (41.4)
95% Confidence Interval [A]	(6.67, 65.25)	(39.08, 75.45)	(49.17, 84.72)	(49.90, 75.41)	(46.17, 70.23)
Baseline Corticosteroid Use - Yes	N=5	N=15	N=17	N=32	N=37
Yes	2 (40.0)	7 (46.7)	11 (64.7)	18 (56.3)	20 (54.1)
No	3 (60.0)	8 (53.3)	6 (35.3)	14 (43.8)	17 (45.9)
95% Confidence Interval [A]	(5.27, 85.34)	(21.27, 73.41)	(38.33, 85.79)	(37.66, 73.64)	(36.92, 70.51)
Baseline Corticosteroid Use - No	N=7	N=18	N=18	N=36	N=43
Yes	2 (28.6)	12 (66.7)	12 (66.7)	24 (66.7)	26 (60.5)
No	5 (71.4)	6 (33.3)	6 (33.3)	12 (33.3)	17 (39.5)
95% Confidence Interval [A]	(3.67, 70.96)	(40.99, 86.66)	(40.99, 86.66)	(49.03, 81.44)	(44.41, 75.02)

表 2.7.3.6-129. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Baseline IMM Use - Yes	N=8	N=19	N=25	N=44	N=52
Yes	3 (37.5)	11 (57.9)	16 (64.0)	27 (61.4)	30 (57.7)
No	5 (62.5)	8 (42.1)	9 (36.0)	17 (38.6)	22 (42.3)
95% Confidence Interval [A]	(8.52, 75.51)	(33.50, 79.75)	(42.52, 82.03)	(45.50, 75.64)	(43.20, 71.27)
Baseline IMM Use - No	N=4	N=14	N=10	N=24	N=28
Yes	1 (25.0)	8 (57.1)	7 (70.0)	15 (62.5)	16 (57.1)
No	3 (75.0)	6 (42.9)	3 (30.0)	9 (37.5)	12 (42.9)
95% Confidence Interval [A]	(0.63, 80.59)	(28.86, 82.34)	(34.75, 93.33)	(40.59, 81.20)	(37.18, 75.54)
Weight < 40 kg	N=0	N=7	N=8	N=15	N=15
Yes	0	4 (57.1)	6 (75.0)	10 (66.7)	10 (66.7)
No	0	3 (42.9)	2 (25.0)	5 (33.3)	5 (33.3)
95% Confidence Interval [A]	(NA, NA)	(18.41, 90.10)	(34.91, 96.81)	(38.38, 88.18)	(38.38, 88.18)

表 2.7.3.6-129. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Weight >= 40 kg	N=12	N=26	N=27	N=53	N=65
Yes	4 (33.3)	15 (57.7)	17 (63.0)	32 (60.4)	36 (55.4)
No	8 (66.7)	11 (42.3)	10 (37.0)	21 (39.6)	29 (44.6)
95% Confidence Interval [A]	(9.92, 65.11)	(36.92, 76.65)	(42.37, 80.60)	(46.00, 73.55)	(42.53, 67.73)
Pancolitis - Yes	N=7	N=22	N=21	N=43	N=50
Yes	2 (28.6)	12 (54.5)	14 (66.7)	26 (60.5)	28 (56.0)
No	5 (71.4)	10 (45.5)	7 (33.3)	17 (39.5)	22 (44.0)
95% Confidence Interval [A]	(3.67, 70.96)	(32.21, 75.61)	(43.03, 85.41)	(44.41, 75.02)	(41.25, 70.01)
Pancolitis - No	N=5	N=11	N=14	N=25	N=30
Yes	2 (40.0)	7 (63.6)	9 (64.3)	16 (64.0)	18 (60.0)
No	3 (60.0)	4 (36.4)	5 (35.7)	9 (36.0)	12 (40.0)
95% Confidence Interval [A]	(5.27, 85.34)	(30.79, 89.07)	(35.14, 87.24)	(42.52, 82.03)	(40.60, 77.34)

表 2.7.3.6-129. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Disease Duration <= Baseline Median (18.9 Months)	N=5	N=19	N=16	N=35	N=40
Yes	0	10 (52.6)	9 (56.3)	19 (54.3)	19 (47.5)
No	5 (100)	9 (47.4)	7 (43.8)	16 (45.7)	21 (52.5)
95% Confidence Interval [A]	(0.00, 52.18)	(28.86, 75.55)	(29.88, 80.25)	(36.65, 71.17)	(31.51, 63.87)
Disease Duration > Baseline Median (18.9 Months)	N=7	N=14	N=19	N=33	N=40
Yes	4 (57.1)	9 (64.3)	14 (73.7)	23 (69.7)	27 (67.5)
No	3 (42.9)	5 (35.7)	5 (26.3)	10 (30.3)	13 (32.5)
95% Confidence Interval [A]	(18.41, 90.10)	(35.14, 87.24)	(48.80, 90.85)	(51.29, 84.41)	(50.87, 81.43)
Baseline hs-CRP <= Baseline Median (1.34 mg/L)	N=8	N=12	N=18	N=30	N=38
Yes	3 (37.5)	6 (50.0)	14 (77.8)	20 (66.7)	23 (60.5)
No	5 (62.5)	6 (50.0)	4 (22.2)	10 (33.3)	15 (39.5)
95% Confidence Interval [A]	(8.52, 75.51)	(21.09, 78.91)	(52.36, 93.59)	(47.19, 82.71)	(43.39, 75.96)

表 2.7.3.6-129. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

Category Endpoint Met	mITT M-PL (N=12)	mITT-E M-SD (N=33)	mITT-E M-HD (N=35)	mITT-E Total (N=68)	mITT Total (N=80)
Baseline hs-CRP > Baseline Median (1.34 mg/L)	N=3	N=18	N=15	N=33	N=36
Yes	0	11 (61.1)	8 (53.3)	19 (57.6)	19 (52.8)
No	3 (100)	7 (38.9)	7 (46.7)	14 (42.4)	17 (47.2)
95% Confidence Interval [A]	(0.00, 70.76)	(35.75, 82.70)	(26.59, 78.73)	(39.22, 74.52)	(35.49, 69.59)
Baseline Fecal Calprotectin <= Baseline Median (2302.5 ug/g)	N=3	N=5	N=2	N=7	N=10
Yes	1 (33.3)	3 (60.0)	1 (50.0)	4 (57.1)	5 (50.0)
No	2 (66.7)	2 (40.0)	1 (50.0)	3 (42.9)	5 (50.0)
95% Confidence Interval [A]	(0.84, 90.57)	(14.66, 94.73)	(1.26, 98.74)	(18.41, 90.10)	(18.71, 81.29)
Baseline Fecal Calprotectin > Baseline Median (2302.5 ug/g)	N=1	N=4	N=5	N=9	N=10
Yes	0	1 (25.0)	4 (80.0)	5 (55.6)	5 (50.0)
No	1 (100)	3 (75.0)	1 (20.0)	4 (44.4)	5 (50.0)
95% Confidence Interval [A]	(0.00, 97.50)	(0.63, 80.59)	(28.36, 99.49)	(21.20, 86.30)	(18.71, 81.29)

表 2.7.3.6-129.　投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

Note: M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
[A] Clopper-Pearson confidence interval for proportion in response.
[B1] Nominal p-values from a one-sample two-sided chi-square test.
[B2] Adjusted p-values from a sequentially rejective multiple test procedure (details in SAP), testing co-primary and ranked secondary endpoints first for M-SD/M-HD combined (p-value in 'Total' column) and then for individual ADA dose groups (p-values in 'M-HD' column and in 'M-SD' column, respectively) against the respective external placebo rate (here: 26.10%).
[C] Nominal p-value for the exploratory comparison of M-SD vs. M-HD.
Non-responder imputation (NRI): missing data is imputed as not having met the endpoint. Subjects re-randomized due to disease flare are considered as not having met the endpoint at and after their 1st disease flare.
Clinical response per Full Mayo Score (FMS) is defined as decrease in Mayo Score >= 3 points and >= 30% from baseline.
Clinical response per Partial Mayo Score (PMS) is defined as decrease in PMS >= 2 points and >= 30% from baseline.
Clinical remission per Partial Mayo Score (PMS) is defined as PMS <= 2 and no individual subscore > 1.

Cross reference: M11-290 CSR_Final Table 14.2__1.2.1_A

表 2.7.3.6-130. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Overall	N=0	N=2	N=4	N=6	N=6
Yes	0	0	2 (50.0)	2 (33.3)	2 (33.3)
No	0	2 (100)	2 (50.0)	4 (66.7)	4 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(6.76, 93.24)	(4.33, 77.72)	(4.33, 77.72)
P-Value [B1]		0.401	0.276	0.687	
P-Value [C]		0.221			
PMS Remission at Week 8 - Yes	N=0	N=0	N=3	N=3	N=3
Yes	0	0	1 (33.3)	1 (33.3)	1 (33.3)
No	0	0	2 (66.7)	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.84, 90.57)	(0.84, 90.57)	(0.84, 90.57)

表 2.7.3.6-130. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

Category Endpoint Met	mITT M-PL (N=0)	mITT-E M-SD (N=2)	mITT-E M-HD (N=4)	mITT-E Total (N=6)	mITT Total (N=6)
PMS Remission at Week 8 - No	N=0	N=2	N=1	N=3	N=3
Yes	0	0	1 (100)	1 (33.3)	1 (33.3)
No	0	2 (100)	0	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(2.50, 100.00)	(0.84, 90.57)	(0.84, 90.57)
I-SD	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
I-HD/I-HD-OL	N=0	N=2	N=4	N=6	N=6
Yes	0	0	2 (50.0)	2 (33.3)	2 (33.3)
No	0	2 (100)	2 (50.0)	4 (66.7)	4 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(6.76, 93.24)	(4.33, 77.72)	(4.33, 77.72)

表 2.7.3.6-130. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

Category Endpoint Met	mITT M-PL (N=0)	mITT-E M-SD (N=2)	mITT-E M-HD (N=4)	mITT-E Total (N=6)	mITT Total (N=6)
I-HD	N=0	N=1	N=3	N=4	N=4
Yes	0	0	2 (66.7)	2 (50.0)	2 (50.0)
No	0	1 (100)	1 (33.3)	2 (50.0)	2 (50.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 97.50)	(9.43, 99.16)	(6.76, 93.24)	(6.76, 93.24)
I-HD-OL	N=0	N=1	N=1	N=2	N=2
Yes	0	0	0	0	0
No	0	1 (100)	1 (100)	2 (100)	2 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)	(0.00, 84.19)	(0.00, 84.19)
Sex - Male	N=0	N=2	N=4	N=6	N=6
Yes	0	0	2 (50.0)	2 (33.3)	2 (33.3)
No	0	2 (100)	2 (50.0)	4 (66.7)	4 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(6.76, 93.24)	(4.33, 77.72)	(4.33, 77.72)

表 2.7.3.6-130. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

Category Endpoint Met	mITT M-PL (N=0)	mITT-E M-SD (N=2)	mITT-E M-HD (N=4)	mITT-E Total (N=6)	mITT Total (N=6)
Sex - Female	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Age < 13 Years	N=0	N=0	N=1	N=1	N=1
Yes	0	0	1 (100)	1 (100)	1 (100)
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(2.50, 100.00)	(2.50, 100.00)	(2.50, 100.00)
Age >= 13 Years	N=0	N=2	N=3	N=5	N=5
Yes	0	0	1 (33.3)	1 (20.0)	1 (20.0)
No	0	2 (100)	2 (66.7)	4 (80.0)	4 (80.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.84, 90.57)	(0.51, 71.64)	(0.51, 71.64)

表 2.7.3.6-130. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Ethnicity - White	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Ethnicity - Non-white	N=0	N=2	N=4	N=6	N=6
Yes	0	0	2 (50.0)	2 (33.3)	2 (33.3)
No	0	2 (100)	2 (50.0)	4 (66.7)	4 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(6.76, 93.24)	(4.33, 77.72)	(4.33, 77.72)
Geographic Region - Japan	N=0	N=2	N=4	N=6	N=6
Yes	0	0	2 (50.0)	2 (33.3)	2 (33.3)
No	0	2 (100)	2 (50.0)	4 (66.7)	4 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(6.76, 93.24)	(4.33, 77.72)	(4.33, 77.72)

表 2.7.3.6-130. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Baseline Mayo Score <= 9	N=0	N=2	N=4	N=6	N=6
Yes	0	0	2 (50.0)	2 (33.3)	2 (33.3)
No	0	2 (100)	2 (50.0)	4 (66.7)	4 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(6.76, 93.24)	(4.33, 77.72)	(4.33, 77.72)
Baseline Mayo Score > 9	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Prior Anti-TNF Use	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)

表 2.7.3.6-130. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Prior Anti-TNF Naive	N=0	N=2	N=4	N=6	N=6
Yes	0	0	2 (50.0)	2 (33.3)	2 (33.3)
No	0	2 (100)	2 (50.0)	4 (66.7)	4 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(6.76, 93.24)	(4.33, 77.72)	(4.33, 77.72)
Baseline Corticosteroid Use - Yes	N=0	N=2	N=1	N=3	N=3
Yes	0	0	1 (100)	1 (33.3)	1 (33.3)
No	0	2 (100)	0	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(2.50, 100.00)	(0.84, 90.57)	(0.84, 90.57)
Baseline Corticosteroid Use - No	N=0	N=0	N=3	N=3	N=3
Yes	0	0	1 (33.3)	1 (33.3)	1 (33.3)
No	0	0	2 (66.7)	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.84, 90.57)	(0.84, 90.57)	(0.84, 90.57)

表 2.7.3.6-130. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Baseline IMM Use - Yes	N=0	N=2	N=4	N=6	N=6
Yes	0	0	2 (50.0)	2 (33.3)	2 (33.3)
No	0	2 (100)	2 (50.0)	4 (66.7)	4 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(6.76, 93.24)	(4.33, 77.72)	(4.33, 77.72)
Baseline IMM Use - No	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Weight < 40 kg	N=0	N=0	N=1	N=1	N=1
Yes	0	0	1 (100)	1 (100)	1 (100)
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(2.50, 100.00)	(2.50, 100.00)	(2.50, 100.00)

表 2.7.3.6-130. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Weight >= 40 kg	N=0	N=2	N=3	N=5	N=5
Yes	0	0	1 (33.3)	1 (20.0)	1 (20.0)
No	0	2 (100)	2 (66.7)	4 (80.0)	4 (80.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.84, 90.57)	(0.51, 71.64)	(0.51, 71.64)
Pancolitis - Yes	N=0	N=2	N=4	N=6	N=6
Yes	0	0	2 (50.0)	2 (33.3)	2 (33.3)
No	0	2 (100)	2 (50.0)	4 (66.7)	4 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(6.76, 93.24)	(4.33, 77.72)	(4.33, 77.72)
Pancolitis - No	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)

表 2.7.3.6-130. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

Category Endpoint Met	mITT M-PL (N=0)	mITT-E M-SD (N=2)	mITT-E M-HD (N=4)	mITT-E Total (N=6)	mITT Total (N=6)
Disease Duration <= Baseline Median (18.9 Months)	N=0	N=1	N=1	N=2	N=2
Yes	0	0	0	0	0
No	0	1 (100)	1 (100)	2 (100)	2 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)	(0.00, 84.19)	(0.00, 84.19)
Disease Duration > Baseline Median (18.9 Months)	N=0	N=1	N=3	N=4	N=4
Yes	0	0	2 (66.7)	2 (50.0)	2 (50.0)
No	0	1 (100)	1 (33.3)	2 (50.0)	2 (50.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 97.50)	(9.43, 99.16)	(6.76, 93.24)	(6.76, 93.24)
Baseline hs-CRP <= Baseline Median (1.34 mg/L)	N=0	N=0	N=3	N=3	N=3
Yes	0	0	2 (66.7)	2 (66.7)	2 (66.7)
No	0	0	1 (33.3)	1 (33.3)	1 (33.3)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(9.43, 99.16)	(9.43, 99.16)	(9.43, 99.16)

表 2.7.3.6-130. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

Category Endpoint Met	mITT mITT-E M-PL (N=0)	mITT mITT-E M-SD (N=2)	mITT mITT-E M-HD (N=4)	mITT mITT-E Total (N=6)	mITT Total (N=6)
Baseline hs-CRP > Baseline Median (1.34 mg/L)	N=0	N=2	N=1	N=3	N=3
Yes	0	0	0	0	0
No	0	2 (100)	1 (100)	3 (100)	3 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.00, 97.50)	(0.00, 70.76)	(0.00, 70.76)
Baseline Fecal Calprotectin <= Baseline Median (2302.5 ug/g)	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Baseline Fecal Calprotectin > Baseline Median (2302.5 ug/g)	N=0	N=0	N=1	N=1	N=1
Yes	0	0	0	0	0
No	0	0	1 (100)	1 (100)	1 (100)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)	(0.00, 97.50)

表 2.7.3.6-130. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

Note: M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
[A] Clopper-Pearson confidence interval for proportion in response.
[B1] Nominal p-values from a one-sample two-sided chi-square test.
[C] Nominal p-value for the exploratory comparison of M-SD vs. M-HD.
Non-responder imputation (NRI): missing data is imputed as not having met the endpoint. Subjects re-randomized due to disease flare are considered as not having met the endpoint at and after their 1st disease flare.
Clinical response per Full Mayo Score (FMS) is defined as decrease in Mayo Score >= 3 points and >= 30% from baseline.
Clinical response per Partial Mayo Score (PMS) is defined as decrease in PMS >= 2 points and >= 30% from baseline.
Clinical remission per Partial Mayo Score (PMS) is defined as PMS <= 2 and no individual subscore > 1.

Cross reference: M11-290 CSR_Final Table 14.2__1.2.1_J

表 2.7.3.6-131. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Overall	N=12	N=33	N=35	N=68	N=80
Yes	4 (33.3)	12 (36.4)	17 (48.6)	29 (42.6)	33 (41.3)
No	8 (66.7)	21 (63.6)	18 (51.4)	39 (57.4)	47 (58.8)
95% Confidence Interval [A]	(9.92, 65.11)	(20.40, 54.88)	(31.38, 66.01)	(30.72, 55.23)	(30.35, 52.82)
P-Value [B1]		0.047	<0.001	<0.001	
ADJ. P-Value [B2]		0.344	<0.001	<0.001	
P-Value [C]		0.309			
PMS Remission at Week 8 - Yes	N=8	N=21	N=25	N=46	N=54
Yes	3 (37.5)	11 (52.4)	13 (52.0)	24 (52.2)	27 (50.0)
No	5 (62.5)	10 (47.6)	12 (48.0)	22 (47.8)	27 (50.0)
95% Confidence Interval [A]	(8.52, 75.51)	(29.78, 74.29)	(31.31, 72.20)	(36.95, 67.11)	(36.08, 63.92)

表 2.7.3.6-131. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
PMS Remission at Week 8 - No	N=4	N=12	N=10	N=22	N=26
Yes	1 (25.0)	1 (8.3)	4 (40.0)	5 (22.7)	6 (23.1)
No	3 (75.0)	11 (91.7)	6 (60.0)	17 (77.3)	20 (76.9)
95% Confidence Interval [A]	(0.63, 80.59)	(0.21, 38.48)	(12.16, 73.76)	(7.82, 45.37)	(8.97, 43.65)
I-SD	N=4	N=8	N=9	N=17	N=21
Yes	1 (25.0)	2 (25.0)	5 (55.6)	7 (41.2)	8 (38.1)
No	3 (75.0)	6 (75.0)	4 (44.4)	10 (58.8)	13 (61.9)
95% Confidence Interval [A]	(0.63, 80.59)	(3.19, 65.09)	(21.20, 86.30)	(18.44, 67.08)	(18.11, 61.56)
I-HD/I-HD-OL	N=8	N=25	N=26	N=51	N=59
Yes	3 (37.5)	10 (40.0)	12 (46.2)	22 (43.1)	25 (42.4)
No	5 (62.5)	15 (60.0)	14 (53.8)	29 (56.9)	34 (57.6)
95% Confidence Interval [A]	(8.52, 75.51)	(21.13, 61.33)	(26.59, 66.63)	(29.35, 57.75)	(29.61, 55.93)

表 2.7.3.6-131. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
I-HD	N=8	N=17	N=18	N=35	N=43
Yes	3 (37.5)	8 (47.1)	9 (50.0)	17 (48.6)	20 (46.5)
No	5 (62.5)	9 (52.9)	9 (50.0)	18 (51.4)	23 (53.5)
95% Confidence Interval [A]	(8.52, 75.51)	(22.98, 72.19)	(26.02, 73.98)	(31.38, 66.01)	(31.18, 62.35)
I-HD-OL	N=0	N=8	N=8	N=16	N=16
Yes	0	2 (25.0)	3 (37.5)	5 (31.3)	5 (31.3)
No	0	6 (75.0)	5 (62.5)	11 (68.8)	11 (68.8)
95% Confidence Interval [A]	(NA, NA)	(3.19, 65.09)	(8.52, 75.51)	(11.02, 58.66)	(11.02, 58.66)
Sex - Male	N=9	N=15	N=17	N=32	N=41
Yes	2 (22.2)	5 (33.3)	7 (41.2)	12 (37.5)	14 (34.1)
No	7 (77.8)	10 (66.7)	10 (58.8)	20 (62.5)	27 (65.9)
95% Confidence Interval [A]	(2.81, 60.01)	(11.82, 61.62)	(18.44, 67.08)	(21.10, 56.31)	(20.08, 50.59)

表 2.7.3.6-131. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Sex - Female	N=3	N=18	N=18	N=36	N=39
Yes	2 (66.7)	7 (38.9)	10 (55.6)	17 (47.2)	19 (48.7)
No	1 (33.3)	11 (61.1)	8 (44.4)	19 (52.8)	20 (51.3)
95% Confidence Interval [A]	(9.43, 99.16)	(17.30, 64.25)	(30.76, 78.47)	(30.41, 64.51)	(32.42, 65.22)
Age < 13 Years	N=2	N=12	N=9	N=21	N=23
Yes	1 (50.0)	6 (50.0)	5 (55.6)	11 (52.4)	12 (52.2)
No	1 (50.0)	6 (50.0)	4 (44.4)	10 (47.6)	11 (47.8)
95% Confidence Interval [A]	(1.26, 98.74)	(21.09, 78.91)	(21.20, 86.30)	(29.78, 74.29)	(30.59, 73.18)
Age >= 13 Years	N=10	N=21	N=26	N=47	N=57
Yes	3 (30.0)	6 (28.6)	12 (46.2)	18 (38.3)	21 (36.8)
No	7 (70.0)	15 (71.4)	14 (53.8)	29 (61.7)	36 (63.2)
95% Confidence Interval [A]	(6.67, 65.25)	(11.28, 52.18)	(26.59, 66.63)	(24.51, 53.62)	(24.45, 50.66)

表 2.7.3.6-131. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Ethnicity - White	N=11	N=29	N=30	N=59	N=70
Yes	4 (36.4)	11 (37.9)	16 (53.3)	27 (45.8)	31 (44.3)
No	7 (63.6)	18 (62.1)	14 (46.7)	32 (54.2)	39 (55.7)
95% Confidence Interval [A]	(10.93, 69.21)	(20.69, 57.74)	(34.33, 71.66)	(32.72, 59.25)	(32.41, 56.66)
Ethnicity - Non-white	N=1	N=4	N=5	N=9	N=10
Yes	0	1 (25.0)	1 (20.0)	2 (22.2)	2 (20.0)
No	1 (100)	3 (75.0)	4 (80.0)	7 (77.8)	8 (80.0)
95% Confidence Interval [A]	(0.00, 97.50)	(0.63, 80.59)	(0.51, 71.64)	(2.81, 60.01)	(2.52, 55.61)
Geographic Region - North America	N=1	N=7	N=3	N=10	N=11
Yes	0	2 (28.6)	1 (33.3)	3 (30.0)	3 (27.3)
No	1 (100)	5 (71.4)	2 (66.7)	7 (70.0)	8 (72.7)
95% Confidence Interval [A]	(0.00, 97.50)	(3.67, 70.96)	(0.84, 90.57)	(6.67, 65.25)	(6.02, 60.97)

表 2.7.3.6-131. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Geographic Region - Western Europe	N=1	N=0	N=3	N=3	N=4
Yes	0	0	2 (66.7)	2 (66.7)	2 (50.0)
No	1 (100)	0	1 (33.3)	1 (33.3)	2 (50.0)
95% Confidence Interval [A]	(0.00, 97.50)	(NA, NA)	(9.43, 99.16)	(9.43, 99.16)	(6.76, 93.24)
Geographic Region - Eastern Europe	N=10	N=24	N=25	N=49	N=59
Yes	4 (40.0)	10 (41.7)	13 (52.0)	23 (46.9)	27 (45.8)
No	6 (60.0)	14 (58.3)	12 (48.0)	26 (53.1)	32 (54.2)
95% Confidence Interval [A]	(12.16, 73.76)	(22.11, 63.36)	(31.31, 72.20)	(32.53, 61.73)	(32.72, 59.25)
Geographic Region - Japan	N=0	N=2	N=4	N=6	N=6
Yes	0	0	1 (25.0)	1 (16.7)	1 (16.7)
No	0	2 (100)	3 (75.0)	5 (83.3)	5 (83.3)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.63, 80.59)	(0.42, 64.12)	(0.42, 64.12)

表 2.7.3.6-131. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Baseline Mayo Score <= 9	N=11	N=27	N=30	N=57	N=68
Yes	4 (36.4)	11 (40.7)	13 (43.3)	24 (42.1)	28 (41.2)
No	7 (63.6)	16 (59.3)	17 (56.7)	33 (57.9)	40 (58.8)
95% Confidence Interval [A]	(10.93, 69.21)	(22.39, 61.20)	(25.46, 62.57)	(29.14, 55.92)	(29.37, 53.77)
Baseline Mayo Score > 9	N=1	N=6	N=5	N=11	N=12
Yes	0	1 (16.7)	4 (80.0)	5 (45.5)	5 (41.7)
No	1 (100)	5 (83.3)	1 (20.0)	6 (54.5)	7 (58.3)
95% Confidence Interval [A]	(0.00, 97.50)	(0.42, 64.12)	(28.36, 99.49)	(16.75, 76.62)	(15.17, 72.33)
Prior Anti-TNF Use	N=2	N=2	N=6	N=8	N=10
Yes	1 (50.0)	0	3 (50.0)	3 (37.5)	4 (40.0)
No	1 (50.0)	2 (100)	3 (50.0)	5 (62.5)	6 (60.0)
95% Confidence Interval [A]	(1.26, 98.74)	(0.00, 84.19)	(11.81, 88.19)	(8.52, 75.51)	(12.16, 73.76)

表 2.7.3.6-131. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Prior Anti-TNF Naive	N=10	N=31	N=29	N=60	N=70
Yes	3 (30.0)	12 (38.7)	14 (48.3)	26 (43.3)	29 (41.4)
No	7 (70.0)	19 (61.3)	15 (51.7)	34 (56.7)	41 (58.6)
95% Confidence Interval [A]	(6.67, 65.25)	(21.85, 57.81)	(29.45, 67.47)	(30.59, 56.76)	(29.77, 53.83)
Baseline Corticosteroid Use - Yes	N=5	N=15	N=17	N=32	N=37
Yes	2 (40.0)	5 (33.3)	7 (41.2)	12 (37.5)	14 (37.8)
No	3 (60.0)	10 (66.7)	10 (58.8)	20 (62.5)	23 (62.2)
95% Confidence Interval [A]	(5.27, 85.34)	(11.82, 61.62)	(18.44, 67.08)	(21.10, 56.31)	(22.46, 55.24)
Baseline Corticosteroid Use - No	N=7	N=18	N=18	N=36	N=43
Yes	2 (28.6)	7 (38.9)	10 (55.6)	17 (47.2)	19 (44.2)
No	5 (71.4)	11 (61.1)	8 (44.4)	19 (52.8)	24 (55.8)
95% Confidence Interval [A]	(3.67, 70.96)	(17.30, 64.25)	(30.76, 78.47)	(30.41, 64.51)	(29.08, 60.12)

表 2.7.3.6-131. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Baseline IMM Use - Yes	N=8	N=19	N=25	N=44	N=52
Yes	3 (37.5)	7 (36.8)	12 (48.0)	19 (43.2)	22 (42.3)
No	5 (62.5)	12 (63.2)	13 (52.0)	25 (56.8)	30 (57.7)
95% Confidence Interval [A]	(8.52, 75.51)	(16.29, 61.64)	(27.80, 68.69)	(28.35, 58.97)	(28.73, 56.80)
Baseline IMM Use - No	N=4	N=14	N=10	N=24	N=28
Yes	1 (25.0)	5 (35.7)	5 (50.0)	10 (41.7)	11 (39.3)
No	3 (75.0)	9 (64.3)	5 (50.0)	14 (58.3)	17 (60.7)
95% Confidence Interval [A]	(0.63, 80.59)	(12.76, 64.86)	(18.71, 81.29)	(22.11, 63.36)	(21.50, 59.42)
Weight < 40 kg	N=0	N=7	N=8	N=15	N=15
Yes	0	3 (42.9)	4 (50.0)	7 (46.7)	7 (46.7)
No	0	4 (57.1)	4 (50.0)	8 (53.3)	8 (53.3)
95% Confidence Interval [A]	(NA, NA)	(9.90, 81.59)	(15.70, 84.30)	(21.27, 73.41)	(21.27, 73.41)

表 2.7.3.6-131. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Weight >= 40 kg	N=12	N=26	N=27	N=53	N=65
Yes	4 (33.3)	9 (34.6)	13 (48.1)	22 (41.5)	26 (40.0)
No	8 (66.7)	17 (65.4)	14 (51.9)	31 (58.5)	39 (60.0)
95% Confidence Interval [A]	(9.92, 65.11)	(17.21, 55.67)	(28.67, 68.05)	(28.14, 55.87)	(28.04, 52.90)
Pancolitis - Yes	N=7	N=22	N=21	N=43	N=50
Yes	2 (28.6)	7 (31.8)	11 (52.4)	18 (41.9)	20 (40.0)
No	5 (71.4)	15 (68.2)	10 (47.6)	25 (58.1)	30 (60.0)
95% Confidence Interval [A]	(3.67, 70.96)	(13.86, 54.87)	(29.78, 74.29)	(27.01, 57.87)	(26.41, 54.82)
Pancolitis - No	N=5	N=11	N=14	N=25	N=30
Yes	2 (40.0)	5 (45.5)	6 (42.9)	11 (44.0)	13 (43.3)
No	3 (60.0)	6 (54.5)	8 (57.1)	14 (56.0)	17 (56.7)
95% Confidence Interval [A]	(5.27, 85.34)	(16.75, 76.62)	(17.66, 71.14)	(24.40, 65.07)	(25.46, 62.57)

表 2.7.3.6-131. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Disease Duration <= Baseline Median (18.9 Months)	N=5	N=19	N=16	N=35	N=40
Yes	0	6 (31.6)	7 (43.8)	13 (37.1)	13 (32.5)
No	5 (100)	13 (68.4)	9 (56.3)	22 (62.9)	27 (67.5)
95% Confidence Interval [A]	(0.00, 52.18)	(12.58, 56.55)	(19.75, 70.12)	(21.47, 55.08)	(18.57, 49.13)
Disease Duration > Baseline Median (18.9 Months)	N=7	N=14	N=19	N=33	N=40
Yes	4 (57.1)	6 (42.9)	10 (52.6)	16 (48.5)	20 (50.0)
No	3 (42.9)	8 (57.1)	9 (47.4)	17 (51.5)	20 (50.0)
95% Confidence Interval [A]	(18.41, 90.10)	(17.66, 71.14)	(28.86, 75.55)	(30.80, 66.46)	(33.80, 66.20)
Baseline hs-CRP <= Baseline Median (1.34 mg/L)	N=8	N=12	N=18	N=30	N=38
Yes	3 (37.5)	4 (33.3)	9 (50.0)	13 (43.3)	16 (42.1)
No	5 (62.5)	8 (66.7)	9 (50.0)	17 (56.7)	22 (57.9)
95% Confidence Interval [A]	(8.52, 75.51)	(9.92, 65.11)	(26.02, 73.98)	(25.46, 62.57)	(26.31, 59.18)

表 2.7.3.6-131. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Baseline hs-CRP > Baseline Median (1.34 mg/L)	N=3	N=18	N=15	N=33	N=36
Yes	0	6 (33.3)	7 (46.7)	13 (39.4)	13 (36.1)
No	3 (100)	12 (66.7)	8 (53.3)	20 (60.6)	23 (63.9)
95% Confidence Interval [A]	(0.00, 70.76)	(13.34, 59.01)	(21.27, 73.41)	(22.91, 57.86)	(20.82, 53.78)
Baseline Fecal Calprotectin <= Baseline Median (2302.5 ug/g)	N=3	N=5	N=2	N=7	N=10
Yes	1 (33.3)	1 (20.0)	1 (50.0)	2 (28.6)	3 (30.0)
No	2 (66.7)	4 (80.0)	1 (50.0)	5 (71.4)	7 (70.0)
95% Confidence Interval [A]	(0.84, 90.57)	(0.51, 71.64)	(1.26, 98.74)	(3.67, 70.96)	(6.67, 65.25)
Baseline Fecal Calprotectin > Baseline Median (2302.5 ug/g)	N=1	N=4	N=5	N=9	N=10
Yes	0	0	4 (80.0)	4 (44.4)	4 (40.0)
No	1 (100)	4 (100)	1 (20.0)	5 (55.6)	6 (60.0)
95% Confidence Interval [A]	(0.00, 97.50)	(0.00, 60.24)	(28.36, 99.49)	(13.70, 78.80)	(12.16, 73.76)

表 2.7.3.6-131. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

Note: M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
[A] Clopper-Pearson confidence interval for proportion in mucosal healing.
[B1] Nominal p-values from a one-sample two-sided chi-square test.
[B2] Adjusted p-values from a sequentially rejective multiple test procedure (details in SAP), testing co-primary and ranked secondary endpoints first for M-SD/M-HD combined (p-value in 'Total' column) and then for individual ADA dose groups (p-values in 'M-HD' column and in 'M-SD' column, respectively) against the respective external placebo rate (here: 22.03%).
[C] Nominal p-value for the exploratory comparison of M-SD vs. M-HD.
Non-responder imputation (NRI): missing data is imputed as not having met the endpoint. Subjects re-randomized due to disease flare are considered as not having met the endpoint at and after their 1st disease flare.
Clinical response per Partial Mayo Score (PMS) is defined as decrease in PMS >= 2 points and >= 30% from baseline.
Clinical remission per Partial Mayo Score (PMS) is defined as PMS <= 2 and no individual subscore > 1.
Mucosal healing is defined as endoscopy subscore of 0 or 1.

Cross reference: M11-290 CSR_Final Table 14.2__1.2.2_A

表 2.7.3.6-132. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Overall	N=0	N=2	N=4	N=6	N=6
Yes	0	0	1 (25.0)	1 (16.7)	1 (16.7)
No	0	2 (100)	3 (75.0)	5 (83.3)	5 (83.3)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.63, 80.59)	(0.42, 64.12)	(0.42, 64.12)
P-Value [B1]		0.452	0.886	0.751	
P-Value [C]		0.439			
PMS Remission at Week 8 - Yes	N=0	N=0	N=3	N=3	N=3
Yes	0	0	1 (33.3)	1 (33.3)	1 (33.3)
No	0	0	2 (66.7)	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.84, 90.57)	(0.84, 90.57)	(0.84, 90.57)

表 2.7.3.6-132. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
PMS Remission at Week 8 - No	N=0	N=2	N=1	N=3	N=3
Yes	0	0	0	0	0
No	0	2 (100)	1 (100)	3 (100)	3 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.00, 97.50)	(0.00, 70.76)	(0.00, 70.76)
I-SD	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
I-HD/I-HD-OL	N=0	N=2	N=4	N=6	N=6
Yes	0	0	1 (25.0)	1 (16.7)	1 (16.7)
No	0	2 (100)	3 (75.0)	5 (83.3)	5 (83.3)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.63, 80.59)	(0.42, 64.12)	(0.42, 64.12)

表 2.7.3.6-132. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
I-HD	N=0	N=1	N=3	N=4	N=4
Yes	0	0	1 (33.3)	1 (25.0)	1 (25.0)
No	0	1 (100)	2 (66.7)	3 (75.0)	3 (75.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 97.50)	(0.84, 90.57)	(0.63, 80.59)	(0.63, 80.59)
I-HD-OL	N=0	N=1	N=1	N=2	N=2
Yes	0	0	0	0	0
No	0	1 (100)	1 (100)	2 (100)	2 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)	(0.00, 84.19)	(0.00, 84.19)
Sex - Male	N=0	N=2	N=4	N=6	N=6
Yes	0	0	1 (25.0)	1 (16.7)	1 (16.7)
No	0	2 (100)	3 (75.0)	5 (83.3)	5 (83.3)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.63, 80.59)	(0.42, 64.12)	(0.42, 64.12)

表 2.7.3.6-132. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Sex - Female	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Age < 13 Years	N=0	N=0	N=1	N=1	N=1
Yes	0	0	1 (100)	1 (100)	1 (100)
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(2.50, 100.00)	(2.50, 100.00)	(2.50, 100.00)
Age >= 13 Years	N=0	N=2	N=3	N=5	N=5
Yes	0	0	0	0	0
No	0	2 (100)	3 (100)	5 (100)	5 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.00, 70.76)	(0.00, 52.18)	(0.00, 52.18)

表 2.7.3.6-132. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Ethnicity - White	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Ethnicity - Non-white	N=0	N=2	N=4	N=6	N=6
Yes	0	0	1 (25.0)	1 (16.7)	1 (16.7)
No	0	2 (100)	3 (75.0)	5 (83.3)	5 (83.3)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.63, 80.59)	(0.42, 64.12)	(0.42, 64.12)
Geographic Region - Japan	N=0	N=2	N=4	N=6	N=6
Yes	0	0	1 (25.0)	1 (16.7)	1 (16.7)
No	0	2 (100)	3 (75.0)	5 (83.3)	5 (83.3)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.63, 80.59)	(0.42, 64.12)	(0.42, 64.12)

表 2.7.3.6-132. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Baseline Mayo Score <= 9	N=0	N=2	N=4	N=6	N=6
Yes	0	0	1 (25.0)	1 (16.7)	1 (16.7)
No	0	2 (100)	3 (75.0)	5 (83.3)	5 (83.3)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.63, 80.59)	(0.42, 64.12)	(0.42, 64.12)
Baseline Mayo Score > 9	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Prior Anti-TNF Use	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)

表 2.7.3.6-132. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Prior Anti-TNF Naive	N=0	N=2	N=4	N=6	N=6
Yes	0	0	1 (25.0)	1 (16.7)	1 (16.7)
No	0	2 (100)	3 (75.0)	5 (83.3)	5 (83.3)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.63, 80.59)	(0.42, 64.12)	(0.42, 64.12)
Baseline Corticosteroid Use - Yes	N=0	N=2	N=1	N=3	N=3
Yes	0	0	1 (100)	1 (33.3)	1 (33.3)
No	0	2 (100)	0	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(2.50, 100.00)	(0.84, 90.57)	(0.84, 90.57)
Baseline Corticosteroid Use - No	N=0	N=0	N=3	N=3	N=3
Yes	0	0	0	0	0
No	0	0	3 (100)	3 (100)	3 (100)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.00, 70.76)	(0.00, 70.76)	(0.00, 70.76)

表 2.7.3.6-132. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Baseline IMM Use - Yes	N=0	N=2	N=4	N=6	N=6
Yes	0	0	1 (25.0)	1 (16.7)	1 (16.7)
No	0	2 (100)	3 (75.0)	5 (83.3)	5 (83.3)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.63, 80.59)	(0.42, 64.12)	(0.42, 64.12)
Baseline IMM Use - No	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Weight < 40 kg	N=0	N=0	N=1	N=1	N=1
Yes	0	0	1 (100)	1 (100)	1 (100)
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(2.50, 100.00)	(2.50, 100.00)	(2.50, 100.00)

表 2.7.3.6-132. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Weight >= 40 kg	N=0	N=2	N=3	N=5	N=5
Yes	0	0	0	0	0
No	0	2 (100)	3 (100)	5 (100)	5 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.00, 70.76)	(0.00, 52.18)	(0.00, 52.18)
Pancolitis - Yes	N=0	N=2	N=4	N=6	N=6
Yes	0	0	1 (25.0)	1 (16.7)	1 (16.7)
No	0	2 (100)	3 (75.0)	5 (83.3)	5 (83.3)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.63, 80.59)	(0.42, 64.12)	(0.42, 64.12)
Pancolitis - No	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)

表 2.7.3.6-132. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Disease Duration <= Baseline Median (18.9 Months)	N=0	N=1	N=1	N=2	N=2
Yes	0	0	0	0	0
No	0	1 (100)	1 (100)	2 (100)	2 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)	(0.00, 84.19)	(0.00, 84.19)
Disease Duration > Baseline Median (18.9 Months)	N=0	N=1	N=3	N=4	N=4
Yes	0	0	1 (33.3)	1 (25.0)	1 (25.0)
No	0	1 (100)	2 (66.7)	3 (75.0)	3 (75.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 97.50)	(0.84, 90.57)	(0.63, 80.59)	(0.63, 80.59)
Baseline hs-CRP <= Baseline Median (1.34 mg/L)	N=0	N=0	N=3	N=3	N=3
Yes	0	0	1 (33.3)	1 (33.3)	1 (33.3)
No	0	0	2 (66.7)	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.84, 90.57)	(0.84, 90.57)	(0.84, 90.57)

表 2.7.3.6-132. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Baseline hs-CRP > Baseline Median (1.34 mg/L)	N=0	N=2	N=1	N=3	N=3
Yes	0	0	0	0	0
No	0	2 (100)	1 (100)	3 (100)	3 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.00, 97.50)	(0.00, 70.76)	(0.00, 70.76)
Baseline Fecal Calprotectin <= Baseline Median (2302.5 ug/g)	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Baseline Fecal Calprotectin > Baseline Median (2302.5 ug/g)	N=0	N=0	N=1	N=1	N=1
Yes	0	0	0	0	0
No	0	0	1 (100)	1 (100)	1 (100)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)	(0.00, 97.50)

表 2.7.3.6-132. 投与 8 週時の PMS 改善例のうち，投与 52 週時に Mayo 内視鏡所見サブスコアにより粘膜治癒が認められた被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

Note: M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
[A] Clopper-Pearson confidence interval for proportion in mucosal healing.
[B1] Nominal p-values from a one-sample two-sided chi-square test.
[C] Nominal p-value for the exploratory comparison of M-SD vs. M-HD.
Non-responder imputation (NRI): missing data is imputed as not having met the endpoint. Subjects re-randomized due to disease flare are considered as not having met the endpoint at and after their 1st disease flare.
Clinical response per Partial Mayo Score (PMS) is defined as decrease in PMS >= 2 points and >= 30% from baseline.
Clinical remission per Partial Mayo Score (PMS) is defined as PMS <= 2 and no individual subscore > 1.
Mucosal healing is defined as endoscopy subscore of 0 or 1.

Cross reference: M11-290 CSR_Final Table 14.2__1.2.2_J

表 2.7.3.6-133. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Overall	N=8	N=21	N=25	N=46	N=54
Yes	3 (37.5)	9 (42.9)	11 (44.0)	20 (43.5)	23 (42.6)
No	5 (62.5)	12 (57.1)	14 (56.0)	26 (56.5)	31 (57.4)
95% Confidence Interval [A]	(8.52, 75.51)	(21.82, 65.98)	(24.40, 65.07)	(28.93, 58.89)	(29.23, 56.79)
P-Value [B1]		<0.001	<0.001	<0.001	
ADJ. P-Value [B2]		0.292	<0.001	<0.001	
PMS Remission at Week 8 - Yes	N=8	N=21	N=25	N=46	N=54
Yes	3 (37.5)	9 (42.9)	11 (44.0)	20 (43.5)	23 (42.6)
No	5 (62.5)	12 (57.1)	14 (56.0)	26 (56.5)	31 (57.4)
95% Confidence Interval [A]	(8.52, 75.51)	(21.82, 65.98)	(24.40, 65.07)	(28.93, 58.89)	(29.23, 56.79)

表 2.7.3.6-133. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
PMS Remission at Week 8 - No	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
I-SD	N=2	N=4	N=6	N=10	N=12
Yes	0	0	2 (33.3)	2 (20.0)	2 (16.7)
No	2 (100)	4 (100)	4 (66.7)	8 (80.0)	10 (83.3)
95% Confidence Interval [A]	(0.00, 84.19)	(0.00, 60.24)	(4.33, 77.72)	(2.52, 55.61)	(2.09, 48.41)
I-HD/I-HD-OL	N=6	N=17	N=19	N=36	N=42
Yes	3 (50.0)	9 (52.9)	9 (47.4)	18 (50.0)	21 (50.0)
No	3 (50.0)	8 (47.1)	10 (52.6)	18 (50.0)	21 (50.0)
95% Confidence Interval [A]	(11.81, 88.19)	(27.81, 77.02)	(24.45, 71.14)	(32.92, 67.08)	(34.19, 65.81)

表 2.7.3.6-133. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
I-HD	N=6	N=12	N=12	N=24	N=30
Yes	3 (50.0)	7 (58.3)	6 (50.0)	13 (54.2)	16 (53.3)
No	3 (50.0)	5 (41.7)	6 (50.0)	11 (45.8)	14 (46.7)
95% Confidence Interval [A]	(11.81, 88.19)	(27.67, 84.83)	(21.09, 78.91)	(32.82, 74.45)	(34.33, 71.66)
I-HD-OL	N=0	N=5	N=7	N=12	N=12
Yes	0	2 (40.0)	3 (42.9)	5 (41.7)	5 (41.7)
No	0	3 (60.0)	4 (57.1)	7 (58.3)	7 (58.3)
95% Confidence Interval [A]	(NA, NA)	(5.27, 85.34)	(9.90, 81.59)	(15.17, 72.33)	(15.17, 72.33)
Sex - Male	N=5	N=10	N=11	N=21	N=26
Yes	1 (20.0)	4 (40.0)	5 (45.5)	9 (42.9)	10 (38.5)
No	4 (80.0)	6 (60.0)	6 (54.5)	12 (57.1)	16 (61.5)
95% Confidence Interval [A]	(0.51, 71.64)	(12.16, 73.76)	(16.75, 76.62)	(21.82, 65.98)	(20.23, 59.43)

表 2.7.3.6-133. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Sex - Female	N=3	N=11	N=14	N=25	N=28
Yes	2 (66.7)	5 (45.5)	6 (42.9)	11 (44.0)	13 (46.4)
No	1 (33.3)	6 (54.5)	8 (57.1)	14 (56.0)	15 (53.6)
95% Confidence Interval [A]	(9.43, 99.16)	(16.75, 76.62)	(17.66, 71.14)	(24.40, 65.07)	(27.51, 66.13)
Age < 13 Years	N=2	N=8	N=6	N=14	N=16
Yes	1 (50.0)	5 (62.5)	2 (33.3)	7 (50.0)	8 (50.0)
No	1 (50.0)	3 (37.5)	4 (66.7)	7 (50.0)	8 (50.0)
95% Confidence Interval [A]	(1.26, 98.74)	(24.49, 91.48)	(4.33, 77.72)	(23.04, 76.96)	(24.65, 75.35)
Age >= 13 Years	N=6	N=13	N=19	N=32	N=38
Yes	2 (33.3)	4 (30.8)	9 (47.4)	13 (40.6)	15 (39.5)
No	4 (66.7)	9 (69.2)	10 (52.6)	19 (59.4)	23 (60.5)
95% Confidence Interval [A]	(4.33, 77.72)	(9.09, 61.43)	(24.45, 71.14)	(23.70, 59.36)	(24.04, 56.61)

表 2.7.3.6-133. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Ethnicity - White	N=7	N=19	N=22	N=41	N=48
Yes	3 (42.9)	8 (42.1)	10 (45.5)	18 (43.9)	21 (43.8)
No	4 (57.1)	11 (57.9)	12 (54.5)	23 (56.1)	27 (56.3)
95% Confidence Interval [A]	(9.90, 81.59)	(20.25, 66.50)	(24.39, 67.79)	(28.47, 60.25)	(29.48, 58.82)
Ethnicity - Non-white	N=1	N=2	N=3	N=5	N=6
Yes	0	1 (50.0)	1 (33.3)	2 (40.0)	2 (33.3)
No	1 (100)	1 (50.0)	2 (66.7)	3 (60.0)	4 (66.7)
95% Confidence Interval [A]	(0.00, 97.50)	(1.26, 98.74)	(0.84, 90.57)	(5.27, 85.34)	(4.33, 77.72)
Geographic Region - North America	N=0	N=6	N=0	N=6	N=6
Yes	0	2 (33.3)	0	2 (33.3)	2 (33.3)
No	0	4 (66.7)	0	4 (66.7)	4 (66.7)
95% Confidence Interval [A]	(NA, NA)	(4.33, 77.72)	(NA, NA)	(4.33, 77.72)	(4.33, 77.72)

表 2.7.3.6-133. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Geographic Region - Western Europe	N=1	N=0	N=2	N=2	N=3
Yes	0	0	0	0	0
No	1 (100)	0	2 (100)	2 (100)	3 (100)
95% Confidence Interval [A]	(0.00, 97.50)	(NA, NA)	(0.00, 84.19)	(0.00, 84.19)	(0.00, 70.76)
Geographic Region - Eastern Europe	N=7	N=15	N=20	N=35	N=42
Yes	3 (42.9)	7 (46.7)	10 (50.0)	17 (48.6)	20 (47.6)
No	4 (57.1)	8 (53.3)	10 (50.0)	18 (51.4)	22 (52.4)
95% Confidence Interval [A]	(9.90, 81.59)	(21.27, 73.41)	(27.20, 72.80)	(31.38, 66.01)	(32.00, 63.58)
Geographic Region - Japan	N=0	N=0	N=3	N=3	N=3
Yes	0	0	1 (33.3)	1 (33.3)	1 (33.3)
No	0	0	2 (66.7)	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.84, 90.57)	(0.84, 90.57)	(0.84, 90.57)

表 2.7.3.6-133. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Baseline Mayo Score <= 9	N=7	N=18	N=21	N=39	N=46
Yes	3 (42.9)	8 (44.4)	8 (38.1)	16 (41.0)	19 (41.3)
No	4 (57.1)	10 (55.6)	13 (61.9)	23 (59.0)	27 (58.7)
95% Confidence Interval [A]	(9.90, 81.59)	(21.53, 69.24)	(18.11, 61.56)	(25.57, 57.90)	(27.00, 56.77)
Baseline Mayo Score > 9	N=1	N=3	N=4	N=7	N=8
Yes	0	1 (33.3)	3 (75.0)	4 (57.1)	4 (50.0)
No	1 (100)	2 (66.7)	1 (25.0)	3 (42.9)	4 (50.0)
95% Confidence Interval [A]	(0.00, 97.50)	(0.84, 90.57)	(19.41, 99.37)	(18.41, 90.10)	(15.70, 84.30)
Prior Anti-TNF Use	N=0	N=2	N=3	N=5	N=5
Yes	0	0	0	0	0
No	0	2 (100)	3 (100)	5 (100)	5 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(0.00, 70.76)	(0.00, 52.18)	(0.00, 52.18)

表 2.7.3.6-133. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Prior Anti-TNF Naive	N=8	N=19	N=22	N=41	N=49
Yes	3 (37.5)	9 (47.4)	11 (50.0)	20 (48.8)	23 (46.9)
No	5 (62.5)	10 (52.6)	11 (50.0)	21 (51.2)	26 (53.1)
95% Confidence Interval [A]	(8.52, 75.51)	(24.45, 71.14)	(28.22, 71.78)	(32.88, 64.87)	(32.53, 61.73)
Baseline Corticosteroid Use - Yes	N=5	N=8	N=12	N=20	N=25
Yes	2 (40.0)	4 (50.0)	6 (50.0)	10 (50.0)	12 (48.0)
No	3 (60.0)	4 (50.0)	6 (50.0)	10 (50.0)	13 (52.0)
95% Confidence Interval [A]	(5.27, 85.34)	(15.70, 84.30)	(21.09, 78.91)	(27.20, 72.80)	(27.80, 68.69)
Baseline Corticosteroid Use - No	N=3	N=13	N=13	N=26	N=29
Yes	1 (33.3)	5 (38.5)	5 (38.5)	10 (38.5)	11 (37.9)
No	2 (66.7)	8 (61.5)	8 (61.5)	16 (61.5)	18 (62.1)
95% Confidence Interval [A]	(0.84, 90.57)	(13.86, 68.42)	(13.86, 68.42)	(20.23, 59.43)	(20.69, 57.74)

表 2.7.3.6-133. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

Category Endpoint Met	mITT M-PL (N=12)	mITT-E M-SD (N=33)	mITT-E M-HD (N=35)	mITT-E Total (N=68)	mITT Total (N=80)
Baseline IMM Use - Yes	N=5	N=11	N=19	N=30	N=35
Yes	2 (40.0)	4 (36.4)	8 (42.1)	12 (40.0)	14 (40.0)
No	3 (60.0)	7 (63.6)	11 (57.9)	18 (60.0)	21 (60.0)
95% Confidence Interval [A]	(5.27, 85.34)	(10.93, 69.21)	(20.25, 66.50)	(22.66, 59.40)	(23.87, 57.89)
Baseline IMM Use - No	N=3	N=10	N=6	N=16	N=19
Yes	1 (33.3)	5 (50.0)	3 (50.0)	8 (50.0)	9 (47.4)
No	2 (66.7)	5 (50.0)	3 (50.0)	8 (50.0)	10 (52.6)
95% Confidence Interval [A]	(0.84, 90.57)	(18.71, 81.29)	(11.81, 88.19)	(24.65, 75.35)	(24.45, 71.14)
Weight < 40 kg	N=0	N=3	N=6	N=9	N=9
Yes	0	3 (100)	3 (50.0)	6 (66.7)	6 (66.7)
No	0	0	3 (50.0)	3 (33.3)	3 (33.3)
95% Confidence Interval [A]	(NA, NA)	(29.24, 100.00)	(11.81, 88.19)	(29.93, 92.51)	(29.93, 92.51)

表 2.7.3.6-133. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Weight >= 40 kg	N=8	N=18	N=19	N=37	N=45
Yes	3 (37.5)	6 (33.3)	8 (42.1)	14 (37.8)	17 (37.8)
No	5 (62.5)	12 (66.7)	11 (57.9)	23 (62.2)	28 (62.2)
95% Confidence Interval [A]	(8.52, 75.51)	(13.34, 59.01)	(20.25, 66.50)	(22.46, 55.24)	(23.77, 53.46)
Pancolitis - Yes	N=4	N=12	N=16	N=28	N=32
Yes	1 (25.0)	5 (41.7)	8 (50.0)	13 (46.4)	14 (43.8)
No	3 (75.0)	7 (58.3)	8 (50.0)	15 (53.6)	18 (56.3)
95% Confidence Interval [A]	(0.63, 80.59)	(15.17, 72.33)	(24.65, 75.35)	(27.51, 66.13)	(26.36, 62.34)
Pancolitis - No	N=4	N=9	N=9	N=18	N=22
Yes	2 (50.0)	4 (44.4)	3 (33.3)	7 (38.9)	9 (40.9)
No	2 (50.0)	5 (55.6)	6 (66.7)	11 (61.1)	13 (59.1)
95% Confidence Interval [A]	(6.76, 93.24)	(13.70, 78.80)	(7.49, 70.07)	(17.30, 64.25)	(20.71, 63.65)

表 2.7.3.6-133. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Disease Duration <= Baseline Median (18.9 Months)	N=3	N=10	N=10	N=20	N=23
Yes	0	3 (30.0)	5 (50.0)	8 (40.0)	8 (34.8)
No	3 (100)	7 (70.0)	5 (50.0)	12 (60.0)	15 (65.2)
95% Confidence Interval [A]	(0.00, 70.76)	(6.67, 65.25)	(18.71, 81.29)	(19.12, 63.95)	(16.38, 57.27)
Disease Duration > Baseline Median (18.9 Months)	N=5	N=11	N=15	N=26	N=31
Yes	3 (60.0)	6 (54.5)	6 (40.0)	12 (46.2)	15 (48.4)
No	2 (40.0)	5 (45.5)	9 (60.0)	14 (53.8)	16 (51.6)
95% Confidence Interval [A]	(14.66, 94.73)	(23.38, 83.25)	(16.34, 67.71)	(26.59, 66.63)	(30.15, 66.94)
Baseline hs-CRP <= Baseline Median (1.34 mg/L)	N=6	N=7	N=14	N=21	N=27
Yes	2 (33.3)	3 (42.9)	9 (64.3)	12 (57.1)	14 (51.9)
No	4 (66.7)	4 (57.1)	5 (35.7)	9 (42.9)	13 (48.1)
95% Confidence Interval [A]	(4.33, 77.72)	(9.90, 81.59)	(35.14, 87.24)	(34.02, 78.18)	(31.95, 71.33)

表 2.7.3.6-133. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Baseline hs-CRP > Baseline Median (1.34 mg/L)	N=1	N=12	N=10	N=22	N=23
Yes	0	4 (33.3)	2 (20.0)	6 (27.3)	6 (26.1)
No	1 (100)	8 (66.7)	8 (80.0)	16 (72.7)	17 (73.9)
95% Confidence Interval [A]	(0.00, 97.50)	(9.92, 65.11)	(2.52, 55.61)	(10.73, 50.22)	(10.23, 48.41)
Baseline Fecal Calprotectin <= Baseline Median (2302.5 ug/g)	N=1	N=3	N=1	N=4	N=5
Yes	0	1 (33.3)	1 (100)	2 (50.0)	2 (40.0)
No	1 (100)	2 (66.7)	0	2 (50.0)	3 (60.0)
95% Confidence Interval [A]	(0.00, 97.50)	(0.84, 90.57)	(2.50, 100.00)	(6.76, 93.24)	(5.27, 85.34)
Baseline Fecal Calprotectin > Baseline Median (2302.5 ug/g)	N=0	N=2	N=3	N=5	N=5
Yes	0	0	2 (66.7)	2 (40.0)	2 (40.0)
No	0	2 (100)	1 (33.3)	3 (60.0)	3 (60.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(9.43, 99.16)	(5.27, 85.34)	(5.27, 85.34)

表 2.7.3.6-133.　投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

Note: M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
[A] Clopper-Pearson confidence interval for proportion in remission.
[B1] Nominal p-values from a one-sample two-sided chi-square test.
[B2] Adjusted p-values from a sequentially rejective multiple test procedure (details in SAP), testing co-primary and ranked secondary endpoints first for M-SD/M-HD combined (p-value in 'Total' column) and then for individual ADA dose groups (p-values in 'M-HD' column and in 'M-SD' column, respectively) against the respective external placebo rate (here: 14.79%).
Non-responder imputation (NRI): missing data is imputed as not having met the endpoint. Subjects re-randomized due to disease flare are considered as not having met the endpoint at and after their 1st disease flare.
Clinical remission per Full Mayo Score (FMS) is defined as Mayo Score <= 2 and no individual subscore > 1.
Clinical remission per Partial Mayo Score (PMS) is defined as PMS <= 2 and no individual subscore > 1.

Cross reference: M11-290 CSR_Final Table 14.2__1.2.3_A

表 2.7.3.6-134. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Overall	N=0	N=0	N=3	N=3	N=3
Yes	0	0	1 (33.3)	1 (33.3)	1 (33.3)
No	0	0	2 (66.7)	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.84, 90.57)	(0.84, 90.57)	(0.84, 90.57)
P-Value [B1]		NA	0.366	0.366	
PMS Remission at Week 8 - Yes	N=0	N=0	N=3	N=3	N=3
Yes	0	0	1 (33.3)	1 (33.3)	1 (33.3)
No	0	0	2 (66.7)	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.84, 90.57)	(0.84, 90.57)	(0.84, 90.57)

表 2.7.3.6-134. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
PMS Remission at Week 8 - No	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
I-SD	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
I-HD/I-HD-OL	N=0	N=0	N=3	N=3	N=3
Yes	0	0	1 (33.3)	1 (33.3)	1 (33.3)
No	0	0	2 (66.7)	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.84, 90.57)	(0.84, 90.57)	(0.84, 90.57)

表 2.7.3.6-134. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
I-HD	N=0	N=0	N=2	N=2	N=2
Yes	0	0	1 (50.0)	1 (50.0)	1 (50.0)
No	0	0	1 (50.0)	1 (50.0)	1 (50.0)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(1.26, 98.74)	(1.26, 98.74)	(1.26, 98.74)
I-HD-OL	N=0	N=0	N=1	N=1	N=1
Yes	0	0	0	0	0
No	0	0	1 (100)	1 (100)	1 (100)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)	(0.00, 97.50)
Sex - Male	N=0	N=0	N=3	N=3	N=3
Yes	0	0	1 (33.3)	1 (33.3)	1 (33.3)
No	0	0	2 (66.7)	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.84, 90.57)	(0.84, 90.57)	(0.84, 90.57)

表 2.7.3.6-134. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Sex - Female	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Age < 13 Years	N=0	N=0	N=1	N=1	N=1
Yes	0	0	1 (100)	1 (100)	1 (100)
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(2.50, 100.00)	(2.50, 100.00)	(2.50, 100.00)
Age >= 13 Years	N=0	N=0	N=2	N=2	N=2
Yes	0	0	0	0	0
No	0	0	2 (100)	2 (100)	2 (100)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.00, 84.19)	(0.00, 84.19)	(0.00, 84.19)

表 2.7.3.6-134. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Ethnicity - White	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Ethnicity - Non-white	N=0	N=0	N=3	N=3	N=3
Yes	0	0	1 (33.3)	1 (33.3)	1 (33.3)
No	0	0	2 (66.7)	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.84, 90.57)	(0.84, 90.57)	(0.84, 90.57)
Geographic Region - Japan	N=0	N=0	N=3	N=3	N=3
Yes	0	0	1 (33.3)	1 (33.3)	1 (33.3)
No	0	0	2 (66.7)	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.84, 90.57)	(0.84, 90.57)	(0.84, 90.57)

表 2.7.3.6-134. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Baseline Mayo Score <= 9	N=0	N=0	N=3	N=3	N=3
Yes	0	0	1 (33.3)	1 (33.3)	1 (33.3)
No	0	0	2 (66.7)	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.84, 90.57)	(0.84, 90.57)	(0.84, 90.57)
Baseline Mayo Score > 9	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Prior Anti-TNF Use	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)

表 2.7.3.6-134. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Prior Anti-TNF Naive	N=0	N=0	N=3	N=3	N=3
Yes	0	0	1 (33.3)	1 (33.3)	1 (33.3)
No	0	0	2 (66.7)	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.84, 90.57)	(0.84, 90.57)	(0.84, 90.57)
Baseline Corticosteroid Use - Yes	N=0	N=0	N=1	N=1	N=1
Yes	0	0	1 (100)	1 (100)	1 (100)
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(2.50, 100.00)	(2.50, 100.00)	(2.50, 100.00)
Baseline Corticosteroid Use - No	N=0	N=0	N=2	N=2	N=2
Yes	0	0	0	0	0
No	0	0	2 (100)	2 (100)	2 (100)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.00, 84.19)	(0.00, 84.19)	(0.00, 84.19)

表 2.7.3.6-134. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Baseline IMM Use - Yes	N=0	N=0	N=3	N=3	N=3
Yes	0	0	1 (33.3)	1 (33.3)	1 (33.3)
No	0	0	2 (66.7)	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.84, 90.57)	(0.84, 90.57)	(0.84, 90.57)
Baseline IMM Use - No	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Weight < 40 kg	N=0	N=0	N=1	N=1	N=1
Yes	0	0	1 (100)	1 (100)	1 (100)
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(2.50, 100.00)	(2.50, 100.00)	(2.50, 100.00)

表 2.7.3.6-134. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Weight >= 40 kg	N=0	N=0	N=2	N=2	N=2
Yes	0	0	0	0	0
No	0	0	2 (100)	2 (100)	2 (100)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.00, 84.19)	(0.00, 84.19)	(0.00, 84.19)
Pancolitis - Yes	N=0	N=0	N=3	N=3	N=3
Yes	0	0	1 (33.3)	1 (33.3)	1 (33.3)
No	0	0	2 (66.7)	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.84, 90.57)	(0.84, 90.57)	(0.84, 90.57)
Pancolitis - No	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)

表 2.7.3.6-134. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Disease Duration <= Baseline Median (18.9 Months)	N=0	N=0	N=1	N=1	N=1
Yes	0	0	0	0	0
No	0	0	1 (100)	1 (100)	1 (100)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)	(0.00, 97.50)
Disease Duration > Baseline Median (18.9 Months)	N=0	N=0	N=2	N=2	N=2
Yes	0	0	1 (50.0)	1 (50.0)	1 (50.0)
No	0	0	1 (50.0)	1 (50.0)	1 (50.0)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(1.26, 98.74)	(1.26, 98.74)	(1.26, 98.74)
Baseline hs-CRP <= Baseline Median (1.34 mg/L)	N=0	N=0	N=2	N=2	N=2
Yes	0	0	1 (50.0)	1 (50.0)	1 (50.0)
No	0	0	1 (50.0)	1 (50.0)	1 (50.0)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(1.26, 98.74)	(1.26, 98.74)	(1.26, 98.74)

表 2.7.3.6-134. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Baseline hs-CRP > Baseline Median (1.34 mg/L)	N=0	N=0	N=1	N=1	N=1
Yes	0	0	0	0	0
No	0	0	1 (100)	1 (100)	1 (100)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)	(0.00, 97.50)
Baseline Fecal Calprotectin <= Baseline Median (2302.5 ug/g)	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Baseline Fecal Calprotectin > Baseline Median (2302.5 ug/g)	N=0	N=0	N=1	N=1	N=1
Yes	0	0	0	0	0
No	0	0	1 (100)	1 (100)	1 (100)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)	(0.00, 97.50)

表 2.7.3.6-134. 投与 8 週時の PMS 寛解例のうち，投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category	M-PL	M-SD	M-HD	Total	Total
Endpoint Met	(N=0)	(N=2)	(N=4)	(N=6)	(N=6)

Note: M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
[A] Clopper-Pearson confidence interval for proportion in remission.
[B1] Nominal p-values from a one-sample two-sided chi-square test.
Non-responder imputation (NRI): missing data is imputed as not having met the endpoint. Subjects re-randomized due to disease flare are considered as not having met the endpoint at and after their 1st disease flare.
Clinical remission per Full Mayo Score (FMS) is defined as Mayo Score <= 2 and no individual subscore > 1.
Clinical remission per Partial Mayo Score (PMS) is defined as PMS <= 2 and no individual subscore > 1.

Cross reference: M11-290 CSR_Final Table 14.2__1.2.3_J

表 2.7.3.6-135. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Overall	N=5	N=15	N=17	N=32	N=37
Yes	2 (40.0)	4 (26.7)	6 (35.3)	10 (31.3)	12 (32.4)
No	3 (60.0)	11 (73.3)	11 (64.7)	22 (68.8)	25 (67.6)
95% Confidence Interval [A]	(5.27, 85.34)	(7.79, 55.10)	(14.21, 61.67)	(16.12, 50.01)	(18.01, 49.79)
P-Value [B1]		0.815	0.280	0.343	
ADJ. P-Value [B2]		0.815	0.559	0.344	
P-Value [C]		0.599			
PMS Remission at Week 8 - Yes	N=5	N=8	N=12	N=20	N=25
Yes	2 (40.0)	4 (50.0)	6 (50.0)	10 (50.0)	12 (48.0)
No	3 (60.0)	4 (50.0)	6 (50.0)	10 (50.0)	13 (52.0)
95% Confidence Interval [A]	(5.27, 85.34)	(15.70, 84.30)	(21.09, 78.91)	(27.20, 72.80)	(27.80, 68.69)

表 2.7.3.6-135. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
PMS Remission at Week 8 - No	N=0	N=7	N=5	N=12	N=12
Yes	0	0	0	0	0
No	0	7 (100)	5 (100)	12 (100)	12 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 40.96)	(0.00, 52.18)	(0.00, 26.46)	(0.00, 26.46)
I-SD	N=0	N=5	N=3	N=8	N=8
Yes	0	0	0	0	0
No	0	5 (100)	3 (100)	8 (100)	8 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 52.18)	(0.00, 70.76)	(0.00, 36.94)	(0.00, 36.94)
I-HD/I-HD-OL	N=5	N=10	N=14	N=24	N=29
Yes	2 (40.0)	4 (40.0)	6 (42.9)	10 (41.7)	12 (41.4)
No	3 (60.0)	6 (60.0)	8 (57.1)	14 (58.3)	17 (58.6)
95% Confidence Interval [A]	(5.27, 85.34)	(12.16, 73.76)	(17.66, 71.14)	(22.11, 63.36)	(23.52, 61.06)

表 2.7.3.6-135. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
I-HD	N=5	N=6	N=9	N=15	N=20
Yes	2 (40.0)	3 (50.0)	4 (44.4)	7 (46.7)	9 (45.0)
No	3 (60.0)	3 (50.0)	5 (55.6)	8 (53.3)	11 (55.0)
95% Confidence Interval [A]	(5.27, 85.34)	(11.81, 88.19)	(13.70, 78.80)	(21.27, 73.41)	(23.06, 68.47)
I-HD-OL	N=0	N=4	N=5	N=9	N=9
Yes	0	1 (25.0)	2 (40.0)	3 (33.3)	3 (33.3)
No	0	3 (75.0)	3 (60.0)	6 (66.7)	6 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.63, 80.59)	(5.27, 85.34)	(7.49, 70.07)	(7.49, 70.07)
Sex - Male	N=4	N=7	N=8	N=15	N=19
Yes	1 (25.0)	1 (14.3)	4 (50.0)	5 (33.3)	6 (31.6)
No	3 (75.0)	6 (85.7)	4 (50.0)	10 (66.7)	13 (68.4)
95% Confidence Interval [A]	(0.63, 80.59)	(0.36, 57.87)	(15.70, 84.30)	(11.82, 61.62)	(12.58, 56.55)

表 2.7.3.6-135. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Sex - Female	N=1	N=8	N=9	N=17	N=18
Yes	1 (100)	3 (37.5)	2 (22.2)	5 (29.4)	6 (33.3)
No	0	5 (62.5)	7 (77.8)	12 (70.6)	12 (66.7)
95% Confidence Interval [A]	(2.50, 100.00)	(8.52, 75.51)	(2.81, 60.01)	(10.31, 55.96)	(13.34, 59.01)
Age < 13 Years	N=1	N=3	N=7	N=10	N=11
Yes	0	2 (66.7)	2 (28.6)	4 (40.0)	4 (36.4)
No	1 (100)	1 (33.3)	5 (71.4)	6 (60.0)	7 (63.6)
95% Confidence Interval [A]	(0.00, 97.50)	(9.43, 99.16)	(3.67, 70.96)	(12.16, 73.76)	(10.93, 69.21)
Age >= 13 Years	N=4	N=12	N=10	N=22	N=26
Yes	2 (50.0)	2 (16.7)	4 (40.0)	6 (27.3)	8 (30.8)
No	2 (50.0)	10 (83.3)	6 (60.0)	16 (72.7)	18 (69.2)
95% Confidence Interval [A]	(6.76, 93.24)	(2.09, 48.41)	(12.16, 73.76)	(10.73, 50.22)	(14.33, 51.79)

表 2.7.3.6-135. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Ethnicity - White	N=5	N=11	N=15	N=26	N=31
Yes	2 (40.0)	3 (27.3)	5 (33.3)	8 (30.8)	10 (32.3)
No	3 (60.0)	8 (72.7)	10 (66.7)	18 (69.2)	21 (67.7)
95% Confidence Interval [A]	(5.27, 85.34)	(6.02, 60.97)	(11.82, 61.62)	(14.33, 51.79)	(16.68, 51.37)
Ethnicity - Non-white	N=0	N=4	N=2	N=6	N=6
Yes	0	1 (25.0)	1 (50.0)	2 (33.3)	2 (33.3)
No	0	3 (75.0)	1 (50.0)	4 (66.7)	4 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.63, 80.59)	(1.26, 98.74)	(4.33, 77.72)	(4.33, 77.72)
Geographic Region - North America	N=0	N=5	N=2	N=7	N=7
Yes	0	1 (20.0)	0	1 (14.3)	1 (14.3)
No	0	4 (80.0)	2 (100)	6 (85.7)	6 (85.7)
95% Confidence Interval [A]	(NA, NA)	(0.51, 71.64)	(0.00, 84.19)	(0.36, 57.87)	(0.36, 57.87)

表 2.7.3.6-135. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Geographic Region - Western Europe	N=0	N=0	N=1	N=1	N=1
Yes	0	0	0	0	0
No	0	0	1 (100)	1 (100)	1 (100)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)	(0.00, 97.50)
Geographic Region - Eastern Europe	N=5	N=8	N=13	N=21	N=26
Yes	2 (40.0)	3 (37.5)	5 (38.5)	8 (38.1)	10 (38.5)
No	3 (60.0)	5 (62.5)	8 (61.5)	13 (61.9)	16 (61.5)
95% Confidence Interval [A]	(5.27, 85.34)	(8.52, 75.51)	(13.86, 68.42)	(18.11, 61.56)	(20.23, 59.43)
Geographic Region - Japan	N=0	N=2	N=1	N=3	N=3
Yes	0	0	1 (100)	1 (33.3)	1 (33.3)
No	0	2 (100)	0	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(2.50, 100.00)	(0.84, 90.57)	(0.84, 90.57)

表 2.7.3.6-135. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Baseline Mayo Score <= 9	N=4	N=13	N=16	N=29	N=33
Yes	2 (50.0)	3 (23.1)	5 (31.3)	8 (27.6)	10 (30.3)
No	2 (50.0)	10 (76.9)	11 (68.8)	21 (72.4)	23 (69.7)
95% Confidence Interval [A]	(6.76, 93.24)	(5.04, 53.81)	(11.02, 58.66)	(12.73, 47.24)	(15.59, 48.71)
Baseline Mayo Score > 9	N=1	N=2	N=1	N=3	N=4
Yes	0	1 (50.0)	1 (100)	2 (66.7)	2 (50.0)
No	1 (100)	1 (50.0)	0	1 (33.3)	2 (50.0)
95% Confidence Interval [A]	(0.00, 97.50)	(1.26, 98.74)	(2.50, 100.00)	(9.43, 99.16)	(6.76, 93.24)
Prior Anti-TNF Use	N=0	N=0	N=4	N=4	N=4
Yes	0	0	0	0	0
No	0	0	4 (100)	4 (100)	4 (100)
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(0.00, 60.24)	(0.00, 60.24)	(0.00, 60.24)

表 2.7.3.6-135. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Prior Anti-TNF Naive	N=5	N=15	N=13	N=28	N=33
Yes	2 (40.0)	4 (26.7)	6 (46.2)	10 (35.7)	12 (36.4)
No	3 (60.0)	11 (73.3)	7 (53.8)	18 (64.3)	21 (63.6)
95% Confidence Interval [A]	(5.27, 85.34)	(7.79, 55.10)	(19.22, 74.87)	(18.64, 55.93)	(20.40, 54.88)
Baseline Corticosteroid Use - Yes	N=5	N=15	N=17	N=32	N=37
Yes	2 (40.0)	4 (26.7)	6 (35.3)	10 (31.3)	12 (32.4)
No	3 (60.0)	11 (73.3)	11 (64.7)	22 (68.8)	25 (67.6)
95% Confidence Interval [A]	(5.27, 85.34)	(7.79, 55.10)	(14.21, 61.67)	(16.12, 50.01)	(18.01, 49.79)
Baseline Corticosteroid Use - No	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)

表 2.7.3.6-135. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Baseline IMM Use - Yes	N=2	N=6	N=8	N=14	N=16
Yes	1 (50.0)	1 (16.7)	3 (37.5)	4 (28.6)	5 (31.3)
No	1 (50.0)	5 (83.3)	5 (62.5)	10 (71.4)	11 (68.8)
95% Confidence Interval [A]	(1.26, 98.74)	(0.42, 64.12)	(8.52, 75.51)	(8.39, 58.10)	(11.02, 58.66)
Baseline IMM Use - No	N=3	N=9	N=9	N=18	N=21
Yes	1 (33.3)	3 (33.3)	3 (33.3)	6 (33.3)	7 (33.3)
No	2 (66.7)	6 (66.7)	6 (66.7)	12 (66.7)	14 (66.7)
95% Confidence Interval [A]	(0.84, 90.57)	(7.49, 70.07)	(7.49, 70.07)	(13.34, 59.01)	(14.59, 56.97)
Weight < 40 kg	N=0	N=2	N=6	N=8	N=8
Yes	0	1 (50.0)	2 (33.3)	3 (37.5)	3 (37.5)
No	0	1 (50.0)	4 (66.7)	5 (62.5)	5 (62.5)
95% Confidence Interval [A]	(NA, NA)	(1.26, 98.74)	(4.33, 77.72)	(8.52, 75.51)	(8.52, 75.51)

表 2.7.3.6-135. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Weight >= 40 kg	N=5	N=13	N=11	N=24	N=29
Yes	2 (40.0)	3 (23.1)	4 (36.4)	7 (29.2)	9 (31.0)
No	3 (60.0)	10 (76.9)	7 (63.6)	17 (70.8)	20 (69.0)
95% Confidence Interval [A]	(5.27, 85.34)	(5.04, 53.81)	(10.93, 69.21)	(12.62, 51.09)	(15.28, 50.83)
Pancolitis - Yes	N=1	N=12	N=7	N=19	N=20
Yes	0	3 (25.0)	4 (57.1)	7 (36.8)	7 (35.0)
No	1 (100)	9 (75.0)	3 (42.9)	12 (63.2)	13 (65.0)
95% Confidence Interval [A]	(0.00, 97.50)	(5.49, 57.19)	(18.41, 90.10)	(16.29, 61.64)	(15.39, 59.22)
Pancolitis - No	N=4	N=3	N=10	N=13	N=17
Yes	2 (50.0)	1 (33.3)	2 (20.0)	3 (23.1)	5 (29.4)
No	2 (50.0)	2 (66.7)	8 (80.0)	10 (76.9)	12 (70.6)
95% Confidence Interval [A]	(6.76, 93.24)	(0.84, 90.57)	(2.52, 55.61)	(5.04, 53.81)	(10.31, 55.96)

表 2.7.3.6-135. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Disease Duration <= Baseline Median (18.9 Months)	N=1	N=12	N=10	N=22	N=23
Yes	0	3 (25.0)	3 (30.0)	6 (27.3)	6 (26.1)
No	1 (100)	9 (75.0)	7 (70.0)	16 (72.7)	17 (73.9)
95% Confidence Interval [A]	(0.00, 97.50)	(5.49, 57.19)	(6.67, 65.25)	(10.73, 50.22)	(10.23, 48.41)
Disease Duration > Baseline Median (18.9 Months)	N=4	N=3	N=7	N=10	N=14
Yes	2 (50.0)	1 (33.3)	3 (42.9)	4 (40.0)	6 (42.9)
No	2 (50.0)	2 (66.7)	4 (57.1)	6 (60.0)	8 (57.1)
95% Confidence Interval [A]	(6.76, 93.24)	(0.84, 90.57)	(9.90, 81.59)	(12.16, 73.76)	(17.66, 71.14)
Baseline hs-CRP <= Baseline Median (1.34 mg/L)	N=4	N=8	N=11	N=19	N=23
Yes	2 (50.0)	1 (12.5)	5 (45.5)	6 (31.6)	8 (34.8)
No	2 (50.0)	7 (87.5)	6 (54.5)	13 (68.4)	15 (65.2)
95% Confidence Interval [A]	(6.76, 93.24)	(0.32, 52.65)	(16.75, 76.62)	(12.58, 56.55)	(16.38, 57.27)

表 2.7.3.6-135. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=12)	M-SD (N=33)	M-HD (N=35)	Total (N=68)	Total (N=80)
Baseline hs-CRP > Baseline Median (1.34 mg/L)	N=1	N=6	N=5	N=11	N=12
Yes	0	2 (33.3)	1 (20.0)	3 (27.3)	3 (25.0)
No	1 (100)	4 (66.7)	4 (80.0)	8 (72.7)	9 (75.0)
95% Confidence Interval [A]	(0.00, 97.50)	(4.33, 77.72)	(0.51, 71.64)	(6.02, 60.97)	(5.49, 57.19)
Baseline Fecal Calprotectin <= Baseline Median (2302.5 ug/g)	N=0	N=1	N=1	N=2	N=2
Yes	0	0	0	0	0
No	0	1 (100)	1 (100)	2 (100)	2 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)	(0.00, 84.19)	(0.00, 84.19)
Baseline Fecal Calprotectin > Baseline Median (2302.5 ug/g)	N=0	N=3	N=1	N=4	N=4
Yes	0	0	1 (100)	1 (25.0)	1 (25.0)
No	0	3 (100)	0	3 (75.0)	3 (75.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 70.76)	(2.50, 100.00)	(0.63, 80.59)	(0.63, 80.59)

表 2.7.3.6-135. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（統合 mITT 集団，M11-290 試験）（最終 CSR）（続き）

Note: M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
[A] Clopper-Pearson confidence interval for proportion in remission.
[B1] Nominal p-values from a one-sample two-sided chi-square test.
[B2] Adjusted p-values from a sequentially rejective multiple test procedure (details in SAP), testing co-primary and ranked secondary endpoints first for M-SD/M-HD combined (p-value in 'Total' column) and then for individual ADA dose groups (p-values in 'M-HD' column and in 'M-SD' column, respectively) against the respective external placebo rate (here: 24.08%).
[C] Nominal p-value for the exploratory comparison of M-SD vs. M-HD.
Non-responder imputation (NRI): missing data is imputed as not having met the endpoint. Subjects re-randomized due to disease flare are considered as not having met the endpoint at and after their 1st disease flare.
Corticosteroid-Free is defined as subjects receiving systemic corticosteroids (UC related or non-UC related) at baseline who have discontinued systemic corticosteroids prior to week 52.
Clinical remission per Full Mayo Score (FMS) is defined as Mayo Score <= 2 and no individual subscore > 1.
Clinical response per Partial Mayo Score (PMS) is defined as decrease in PMS >= 2 points and >= 30% from baseline.
Clinical remission per Partial Mayo Score (PMS) is defined as PMS <= 2 and no individual subscore > 1.

Cross reference: M11-290 CSR_Final Table 14.2__1.2.4_A

表 2.7.3.6-136. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Overall	N=0	N=2	N=1	N=3	N=3
Yes	0	0	1 (100)	1 (33.3)	1 (33.3)
No	0	2 (100)	0	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(2.50, 100.00)	(0.84, 90.57)	(0.84, 90.57)
P-Value [B1]		0.426	0.076	0.708	
P-Value [C]		0.083			
PMS Remission at Week 8 - Yes	N=0	N=0	N=1	N=1	N=1
Yes	0	0	1 (100)	1 (100)	1 (100)
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(2.50, 100.00)	(2.50, 100.00)	(2.50, 100.00)

表 2.7.3.6-136. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
PMS Remission at Week 8 - No	N=0	N=2	N=0	N=2	N=2
Yes	0	0	0	0	0
No	0	2 (100)	0	2 (100)	2 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(NA, NA)	(0.00, 84.19)	(0.00, 84.19)
I-SD	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
I-HD/I-HD-OL	N=0	N=2	N=1	N=3	N=3
Yes	0	0	1 (100)	1 (33.3)	1 (33.3)
No	0	2 (100)	0	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(2.50, 100.00)	(0.84, 90.57)	(0.84, 90.57)

表 2.7.3.6-136. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
I-HD	N=0	N=1	N=1	N=2	N=2
Yes	0	0	1 (100)	1 (50.0)	1 (50.0)
No	0	1 (100)	0	1 (50.0)	1 (50.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 97.50)	(2.50, 100.00)	(1.26, 98.74)	(1.26, 98.74)
I-HD-OL	N=0	N=1	N=0	N=1	N=1
Yes	0	0	0	0	0
No	0	1 (100)	0	1 (100)	1 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 97.50)	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)
Sex - Male	N=0	N=2	N=1	N=3	N=3
Yes	0	0	1 (100)	1 (33.3)	1 (33.3)
No	0	2 (100)	0	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(2.50, 100.00)	(0.84, 90.57)	(0.84, 90.57)

表 2.7.3.6-136. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Sex - Female	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Age < 13 Years	N=0	N=0	N=1	N=1	N=1
Yes	0	0	1 (100)	1 (100)	1 (100)
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(2.50, 100.00)	(2.50, 100.00)	(2.50, 100.00)
Age >= 13 Years	N=0	N=2	N=0	N=2	N=2
Yes	0	0	0	0	0
No	0	2 (100)	0	2 (100)	2 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(NA, NA)	(0.00, 84.19)	(0.00, 84.19)

表 2.7.3.6-136. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Ethnicity - White	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Ethnicity - Non-white	N=0	N=2	N=1	N=3	N=3
Yes	0	0	1 (100)	1 (33.3)	1 (33.3)
No	0	2 (100)	0	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(2.50, 100.00)	(0.84, 90.57)	(0.84, 90.57)
Geographic Region - Japan	N=0	N=2	N=1	N=3	N=3
Yes	0	0	1 (100)	1 (33.3)	1 (33.3)
No	0	2 (100)	0	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(2.50, 100.00)	(0.84, 90.57)	(0.84, 90.57)

表 2.7.3.6-136. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Baseline Mayo Score <= 9	N=0	N=2	N=1	N=3	N=3
Yes	0	0	1 (100)	1 (33.3)	1 (33.3)
No	0	2 (100)	0	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(2.50, 100.00)	(0.84, 90.57)	(0.84, 90.57)
Baseline Mayo Score > 9	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Prior Anti-TNF Use	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)

表 2.7.3.6-136. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Prior Anti-TNF Naive	N=0	N=2	N=1	N=3	N=3
Yes	0	0	1 (100)	1 (33.3)	1 (33.3)
No	0	2 (100)	0	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(2.50, 100.00)	(0.84, 90.57)	(0.84, 90.57)
Baseline Corticosteroid Use - Yes	N=0	N=2	N=1	N=3	N=3
Yes	0	0	1 (100)	1 (33.3)	1 (33.3)
No	0	2 (100)	0	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(2.50, 100.00)	(0.84, 90.57)	(0.84, 90.57)
Baseline Corticosteroid Use - No	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)

表 2.7.3.6-136. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Baseline IMM Use - Yes	N=0	N=2	N=1	N=3	N=3
Yes	0	0	1 (100)	1 (33.3)	1 (33.3)
No	0	2 (100)	0	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(2.50, 100.00)	(0.84, 90.57)	(0.84, 90.57)
Baseline IMM Use - No	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Weight < 40 kg	N=0	N=0	N=1	N=1	N=1
Yes	0	0	1 (100)	1 (100)	1 (100)
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(2.50, 100.00)	(2.50, 100.00)	(2.50, 100.00)

表 2.7.3.6-136. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Weight >= 40 kg	N=0	N=2	N=0	N=2	N=2
Yes	0	0	0	0	0
No	0	2 (100)	0	2 (100)	2 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(NA, NA)	(0.00, 84.19)	(0.00, 84.19)
Pancolitis - Yes	N=0	N=2	N=1	N=3	N=3
Yes	0	0	1 (100)	1 (33.3)	1 (33.3)
No	0	2 (100)	0	2 (66.7)	2 (66.7)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(2.50, 100.00)	(0.84, 90.57)	(0.84, 90.57)
Pancolitis - No	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)

表 2.7.3.6-136. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Disease Duration <= Baseline Median (18.9 Months)	N=0	N=1	N=0	N=1	N=1
Yes	0	0	0	0	0
No	0	1 (100)	0	1 (100)	1 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 97.50)	(NA, NA)	(0.00, 97.50)	(0.00, 97.50)
Disease Duration > Baseline Median (18.9 Months)	N=0	N=1	N=1	N=2	N=2
Yes	0	0	1 (100)	1 (50.0)	1 (50.0)
No	0	1 (100)	0	1 (50.0)	1 (50.0)
95% Confidence Interval [A]	(NA, NA)	(0.00, 97.50)	(2.50, 100.00)	(1.26, 98.74)	(1.26, 98.74)
Baseline hs-CRP <= Baseline Median (1.34 mg/L)	N=0	N=0	N=1	N=1	N=1
Yes	0	0	1 (100)	1 (100)	1 (100)
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(2.50, 100.00)	(2.50, 100.00)	(2.50, 100.00)

表 2.7.3.6-136. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

	mITT				
		mITT-E			
Category Endpoint Met	M-PL (N=0)	M-SD (N=2)	M-HD (N=4)	Total (N=6)	Total (N=6)
Baseline hs-CRP > Baseline Median (1.34 mg/L)	N=0	N=2	N=0	N=2	N=2
Yes	0	0	0	0	0
No	0	2 (100)	0	2 (100)	2 (100)
95% Confidence Interval [A]	(NA, NA)	(0.00, 84.19)	(NA, NA)	(0.00, 84.19)	(0.00, 84.19)
Baseline Fecal Calprotectin <= Baseline Median (2302.5 ug/g)	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)
Baseline Fecal Calprotectin > Baseline Median (2302.5 ug/g)	N=0	N=0	N=0	N=0	N=0
Yes	0	0	0	0	0
No	0	0	0	0	0
95% Confidence Interval [A]	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)	(NA, NA)

表 2.7.3.6-136. 投与 8 週時の PMS 改善例のうち，ベースラインで副腎皮質ステロイドを投与していた被験者で，投与 52 週時以前に副腎皮質ステロイドの投与を中止し，かつ投与 52 週時に FMS により寛解を達成した被験者の割合（NRI）（日本人 mITT 集団，M11-290 試験）（最終 CSR）（続き）

Note: M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
[A] Clopper-Pearson confidence interval for proportion in remission.
[B1] Nominal p-values from a one-sample two-sided chi-square test.
[C] Nominal p-value for the exploratory comparison of M-SD vs. M-HD.
Non-responder imputation (NRI): missing data is imputed as not having met the endpoint. Subjects re-randomized due to disease flare are considered as not having met the endpoint at and after their 1st disease flare.
Corticosteroid-Free is defined as subjects receiving systemic corticosteroids (UC related or non-UC related) at baseline who have discontinued systemic corticosteroids prior to week 52.
Clinical remission per Full Mayo Score (FMS) is defined as Mayo Score <= 2 and no individual subscore > 1.
Clinical response per Partial Mayo Score (PMS) is defined as decrease in PMS >= 2 points and >= 30% from baseline.
Clinical remission per Partial Mayo Score (PMS) is defined as PMS <= 2 and no individual subscore > 1.

Cross reference: M11-290 CSR_Final Table 14.2__1.2.4_J

表 2.7.3.6-137. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善，寛解を達成した被験者の割合（mNRI）（統合 RR 集団，M11-290 試験）（最終 CSR）

	With Re-Induction Dose				
Endpoint Endpoint Met	M-SD	M-HD	Total	M-PL	Total
FMS Response at Week 52 in Week 8 PMS Responders	N=4	N=3	N=7	N=4	N=11
Yes	1 (25.0)	1 (33.3)	2 (28.6)	1 (25.0)	3 (27.3)
No	3 (75.0)	2 (66.7)	5 (71.4)	3 (75.0)	8 (72.7)
95% Confidence Interval [A]	(0.63, 80.59)	(0.84, 90.57)	(3.67, 70.96)	(0.63, 80.59)	(6.02, 60.97)
FMS Remission at Week 52 in Week 8 PMS Responders	N=4	N=3	N=7	N=4	N=11
Yes	0	0	0	1 (25.0)	1 (9.1)
No	4 (100)	3 (100)	7 (100)	3 (75.0)	10 (90.9)
95% Confidence Interval [A]	(0.00, 60.24)	(0.00, 70.76)	(0.00, 40.96)	(0.63, 80.59)	(0.23, 41.28)

表 2.7.3.6-137. 投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善，寛解を達成した被験者の割合（mNRI）（統合 RR 集団，M11-290 試験）（最終 CSR）（続き）

	With Re-Induction Dose				
Endpoint Endpoint Met	M-SD	M-HD	Total	M-PL	Total
FMS Response at Week 52 in Week 8 PMS	N=4	N=7	N=11	N=3	N=14
Responders					
Yes	1 (25.0)	1 (14.3)	2 (18.2)	1 (33.3)	3 (21.4)
No	3 (75.0)	6 (85.7)	9 (81.8)	2 (66.7)	11 (78.6)
95% Confidence Interval [A]	(0.63, 80.59)	(0.36, 57.87)	(2.28, 51.78)	(0.84, 90.57)	(4.66, 50.80)
FMS Remission at Week 52 in Week 8 PMS	N=4	N=7	N=11	N=3	N=14
Responders					
Yes	0	0	0	0	0
No	4 (100)	7 (100)	11 (100)	3 (100)	14 (100)
95% Confidence Interval [A]	(0.00, 60.24)	(0.00, 40.96)	(0.00, 28.49)	(0.00, 70.76)	(0.00, 23.16)

表 2.7.3.6-137.　投与 8 週時の PMS 改善例のうち，投与 52 週時に FMS により改善，寛解を達成した被験者の割合（mNRI）（統合 RR 集団，M11-290 試験）（最終 CSR）（続き）

Note: M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
[A] Clopper-Pearson confidence interval for proportion in remission, response.
Modified NRI (mNRI): missing data is imputed as not having met the endpoint. Subjects re-randomized due to disease flare are considered as 'Non-Responders' at and after the switch to the open-label therapy (2nd disease flare).
FMS = full mayo score, PMS = partial mayo score.
Clinical response per full Mayo Score (FMS) is defined as decrease in Mayo Score >= 3 points and >= 30% from baseline.
Clinical remission per full Mayo Score (FMS) is defined as Mayo Score <= 2 and no individual subscore > 1.
Clinical response per Partial Mayo Score (PMS) is defined as decrease in PMS >= 2 points and >= 30% from baseline.

Cross reference: M11-290 CSR_Final Table 14.2__6_A

表 2.7.3.6-138. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（最終 CSR）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Body						
Week 8						
I-SD	29	10.4	10.3	-0.1	(-0.73, 0.53)	0.31
I-SD/-	9	9.7	9.1	-0.6	(-1.78, 0.67)	0.53
I-SD/M-PL	4	12.0	12.3	0.3	(-1.75, 2.25)	0.63
I-SD/M-SD	7	10.0	10.6	0.6	(-1.34, 2.49)	0.78
I-SD/M-HD	9	10.9	10.6	-0.3	(-1.55, 0.88)	0.53
I-HD	47	9.8	10.0	0.2	(-0.26, 0.72)	0.24
I-HD/-	7	8.0	8.6	0.6	(-0.72, 1.86)	0.53
I-HD/M-PL	8	9.1	10.3	1.1	(-0.99, 3.24)	0.90
I-HD/M-SD	15	10.6	10.8	0.2	(-0.59, 0.99)	0.37
I-HD/M-HD	17	10.1	9.8	-0.3	(-1.02, 0.43)	0.34
I-SD + I-HD Total	76	10.0	10.1	0.1	(-0.27, 0.49)	0.19
I-HD-OL	17	9.5	9.9	0.4	(-0.32, 1.14)	0.34
I-HD-OL/-	2	8.5	9.5	1.0		0.00
I-HD-OL/M-SD	8	9.1	9.5	0.4	(-0.80, 1.55)	0.50
I-HD-OL/M-HD	7	10.1	10.4	0.3	(-1.29, 1.86)	0.64
M-SD Total	30	10.1	10.4	0.3	(-0.24, 0.91)	0.28
M-HD Total	33	10.3	10.2	-0.2	(-0.71, 0.35)	0.26
M-SD + M-HD Total	63	10.2	10.3	0.1	(-0.32, 0.45)	0.19

表 2.7.3.6-138. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Body (Cont.)						
Week 26						
I-SD	19	10.8	11.1	0.3	(-0.47, 1.00)	0.35
I-SD/M-PL	4	12.0	11.8	-0.3	(-2.97, 2.47)	0.85
I-SD/M-SD	7	10.0	10.1	0.1	(-1.58, 1.87)	0.70
I-SD/M-HD	8	10.9	11.5	0.6	(-0.37, 1.62)	0.42
I-HD	40	10.1	10.3	0.2	(-0.38, 0.83)	0.30
I-HD/M-PL	8	9.1	9.5	0.4	(-2.03, 2.78)	1.02
I-HD/M-SD	15	10.6	11.1	0.5	(-0.40, 1.47)	0.43
I-HD/M-HD	17	10.1	10.0	-0.1	(-0.91, 0.67)	0.37
I-SD + I-HD Total	59	10.3	10.6	0.2	(-0.22, 0.70)	0.23
I-HD-OL	15	9.6	9.9	0.3	(-0.50, 1.16)	0.39
I-HD-OL/M-SD	8	9.1	9.5	0.4	(-0.80, 1.55)	0.50
I-HD-OL/M-HD	7	10.1	10.4	0.3	(-1.29, 1.86)	0.64
M-SD Total	30	10.1	10.5	0.4	(-0.20, 1.00)	0.29
M-HD Total	32	10.3	10.5	0.2	(-0.38, 0.69)	0.26
M-SD + M-HD Total	62	10.2	10.5	0.3	(-0.12, 0.66)	0.20

表 2.7.3.6-138. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Body (Cont.)						
Week 52						
I-SD	19	10.8	11.4	0.6	(-0.31, 1.46)	0.42
I-SD/M-PL	4	12.0	11.5	-0.5	(-3.81, 2.81)	1.04
I-SD/M-SD	7	10.0	10.9	0.9	(-1.03, 2.74)	0.77
I-SD/M-HD	8	10.9	11.8	0.9	(-0.42, 2.17)	0.55
I-HD	40	10.1	10.5	0.4	(-0.22, 1.02)	0.31
I-HD/M-PL	8	9.1	9.9	0.8	(-1.47, 2.97)	0.94
I-HD/M-SD	15	10.6	11.3	0.7	(-0.12, 1.58)	0.40
I-HD/M-HD	17	10.1	10.1	-0.1	(-1.05, 0.93)	0.47
I-SD + I-HD Total	59	10.3	10.8	0.5	(-0.04, 0.95)	0.25
I-HD-OL	15	9.6	10.1	0.5	(-0.56, 1.49)	0.48
I-HD-OL/M-SD	8	9.1	9.6	0.5	(-1.29, 2.29)	0.76
I-HD-OL/M-HD	7	10.1	10.6	0.4	(-1.07, 1.93)	0.61
M-SD Total	30	10.1	10.8	0.7	(0.04, 1.36)	0.32
M-HD Total	32	10.3	10.6	0.3	(-0.35, 0.92)	0.31
M-SD + M-HD Total	62	10.2	10.7	0.5	(0.04, 0.93)	0.22

表 2.7.3.6-138. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Bowel						
Week 8						
I-SD	29	21.05	25.38	4.33	(2.079, 6.574)	1.097
I-SD/-	9	21.11	22.78	1.67	(-1.408, 4.741)	1.333
I-SD/M-PL	4	25.00	28.00	3.00	(0.402, 5.598)	0.816
I-SD/M-SD	7	20.71	27.00	6.29	(-0.334, 12.906)	2.705
I-SD/M-HD	9	19.50	25.56	6.05	(0.554, 11.551)	2.384
I-HD	47	20.66	25.94	5.28	(3.721, 6.832)	0.773
I-HD/-	7	16.71	15.86	-0.86	(-3.386, 1.672)	1.033
I-HD/M-PL	8	18.88	26.50	7.63	(1.548, 13.702)	2.570
I-HD/M-SD	15	20.33	26.93	6.60	(4.377, 8.823)	1.036
I-HD/M-HD	17	23.41	28.94	5.53	(3.244, 7.815)	1.078
I-SD + I-HD Total	76	20.81	25.72	4.91	(3.653, 6.175)	0.633
I-HD-OL	17	19.00	25.35	6.35	(2.450, 10.256)	1.841
I-HD-OL/-	2	18.50	11.50	-7.00	(-57.825, 43.825)	4.000
I-HD-OL/M-SD	8	19.25	25.88	6.63	(1.834, 11.416)	2.026
I-HD-OL/M-HD	7	18.86	28.71	9.86	(4.297, 15.417)	2.272
M-SD Total	30	20.13	26.67	6.53	(4.617, 8.449)	0.937
M-HD Total	33	21.38	27.97	6.59	(4.570, 8.610)	0.992
M-SD + M-HD Total	63	20.79	27.35	6.56	(5.205, 7.921)	0.679

表 2.7.3.6-138. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Bowel (Cont.)						
Week 26						
I-SD	19	21.24	28.32	7.08	(3.757, 10.398)	1.580
I-SD/M-PL	4	25.00	29.50	4.50	(-0.274, 9.274)	1.500
I-SD/M-SD	7	20.71	26.86	6.14	(-1.167, 13.453)	2.988
I-SD/M-HD	8	19.82	29.00	9.18	(2.990, 15.378)	2.619
I-HD	40	21.35	27.90	6.55	(4.616, 8.484)	0.956
I-HD/M-PL	8	18.88	25.75	6.88	(-0.054, 13.804)	2.930
I-HD/M-SD	15	20.33	26.47	6.13	(2.785, 9.481)	1.561
I-HD/M-HD	17	23.41	30.18	6.76	(4.102, 9.427)	1.256
I-SD + I-HD Total	59	21.31	28.03	6.72	(5.085, 8.355)	0.817
I-HD-OL	15	19.07	26.73	7.67	(3.121, 12.212)	2.119
I-HD-OL/M-SD	8	19.25	25.50	6.25	(-1.076, 13.576)	3.098
I-HD-OL/M-HD	7	18.86	28.14	9.29	(2.009, 16.562)	2.974
M-SD Total	30	20.13	26.30	6.17	(3.550, 8.783)	1.279
M-HD Total	32	21.52	29.44	7.92	(5.647, 10.195)	1.115
M-SD + M-HD Total	62	20.85	27.92	7.07	(5.381, 8.763)	0.846

表 2.7.3.6-138. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Bowel (Cont.)						
Week 52						
I-SD	19	21.24	27.55	6.32	(2.580, 10.052)	1.778
I-SD/M-PL	4	25.00	29.50	4.50	(-0.274, 9.274)	1.500
I-SD/M-SD	7	20.71	25.43	4.71	(-1.552, 10.980)	2.561
I-SD/M-HD	8	19.82	28.44	8.63	(0.234, 17.016)	3.548
I-HD	40	21.35	27.85	6.50	(4.582, 8.418)	0.948
I-HD/M-PL	8	18.88	26.63	7.75	(0.860, 14.640)	2.914
I-HD/M-SD	15	20.33	27.47	7.13	(3.779, 10.488)	1.564
I-HD/M-HD	17	23.41	28.76	5.35	(2.874, 7.832)	1.169
I-SD + I-HD Total	59	21.31	27.75	6.44	(4.735, 8.146)	0.852
I-HD-OL	15	19.07	27.47	8.40	(5.052, 11.748)	1.561
I-HD-OL/M-SD	8	19.25	26.25	7.00	(2.714, 11.286)	1.813
I-HD-OL/M-HD	7	18.86	28.86	10.00	(3.526, 16.474)	2.646
M-SD Total	30	20.13	26.67	6.53	(4.337, 8.730)	1.074
M-HD Total	32	21.52	28.70	7.19	(4.679, 9.696)	1.230
M-SD + M-HD Total	62	20.85	27.72	6.87	(5.242, 8.500)	0.815

表 2.7.3.6-138. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Emotional						
Week 8						
I-SD	29	20.1	23.3	3.2	(1.01, 5.33)	1.05
I-SD/-	9	18.3	19.6	1.2	(-3.74, 6.19)	2.15
I-SD/M-PL	4	23.0	27.8	4.8	(-0.51, 10.01)	1.65
I-SD/M-SD	7	20.9	24.3	3.4	(-3.30, 10.16)	2.75
I-SD/M-HD	9	20.0	24.2	4.2	(0.75, 7.70)	1.51
I-HD	47	21.2	24.2	3.0	(1.73, 4.27)	0.63
I-HD/-	7	16.1	14.6	-1.6	(-3.49, 0.34)	0.78
I-HD/M-PL	8	20.1	25.1	5.0	(-0.29, 10.29)	2.24
I-HD/M-SD	15	21.3	25.4	4.1	(2.01, 6.12)	0.96
I-HD/M-HD	17	23.6	26.6	3.0	(1.32, 4.68)	0.79
I-SD + I-HD Total	76	20.8	23.8	3.1	(1.96, 4.17)	0.56
I-HD-OL	17	20.0	24.4	4.4	(2.27, 6.43)	0.98
I-HD-OL/-	2	17.0	17.5	0.5	(-18.56, 19.56)	1.50
I-HD-OL/M-SD	8	21.0	25.0	4.0	(-0.17, 8.17)	1.76
I-HD-OL/M-HD	7	19.7	25.6	5.9	(3.56, 8.15)	0.94
M-SD Total	30	21.1	25.0	3.9	(2.08, 5.72)	0.89
M-HD Total	33	21.8	25.7	3.9	(2.67, 5.21)	0.62
M-SD + M-HD Total	63	21.5	25.4	3.9	(2.86, 4.98)	0.53

表 2.7.3.6-138. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Emotional (Cont.)						
Week 26						
I-SD	19	21.3	27.9	6.6	(3.29, 9.87)	1.57
I-SD/M-PL	4	23.0	29.8	6.8	(-3.83, 17.33)	3.33
I-SD/M-SD	7	20.9	25.7	4.9	(-3.03, 12.75)	3.23
I-SD/M-HD	8	20.9	28.9	8.0	(3.17, 12.83)	2.04
I-HD	40	22.1	26.8	4.7	(3.11, 6.29)	0.79
I-HD/M-PL	8	20.1	25.5	5.4	(-0.17, 10.92)	2.34
I-HD/M-SD	15	21.3	25.5	4.1	(1.43, 6.84)	1.26
I-HD/M-HD	17	23.6	28.5	4.9	(2.60, 7.17)	1.08
I-SD + I-HD Total	59	21.8	27.1	5.3	(3.83, 6.78)	0.74
I-HD-OL	15	20.4	26.6	6.2	(3.49, 8.91)	1.26
I-HD-OL/M-SD	8	21.0	26.3	5.3	(1.21, 9.29)	1.71
I-HD-OL/M-HD	7	19.7	27.0	7.3	(2.58, 11.99)	1.92
M-SD Total	30	21.1	25.7	4.6	(2.47, 6.73)	1.04
M-HD Total	32	22.1	28.3	6.2	(4.39, 7.98)	0.88
M-SD + M-HD Total	62	21.6	27.0	5.4	(4.06, 6.78)	0.68

表 2.7.3.6-138. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Emotional (Cont.)						
Week 52						
I-SD	19	21.3	27.8	6.5	(2.98, 10.08)	1.69
I-SD/M-PL	4	23.0	29.8	6.8	(-4.97, 18.47)	3.68
I-SD/M-SD	7	20.9	25.4	4.6	(-1.86, 11.00)	2.63
I-SD/M-HD	8	20.9	29.0	8.1	(1.22, 15.03)	2.92
I-HD	40	22.1	26.0	3.9	(2.15, 5.70)	0.88
I-HD/M-PL	8	20.1	25.0	4.9	(-0.40, 10.15)	2.23
I-HD/M-SD	15	21.3	26.7	5.3	(2.25, 8.41)	1.44
I-HD/M-HD	17	23.6	25.8	2.2	(-0.33, 4.80)	1.21
I-SD + I-HD Total	59	21.8	26.6	4.8	(3.14, 6.39)	0.81
I-HD-OL	15	20.4	26.4	6.0	(2.93, 9.07)	1.43
I-HD-OL/M-SD	8	21.0	27.1	6.1	(3.18, 9.07)	1.25
I-HD-OL/M-HD	7	19.7	25.6	5.9	(-1.13, 12.85)	2.86
M-SD Total	30	21.1	26.5	5.4	(3.38, 7.35)	0.97
M-HD Total	32	22.1	26.6	4.5	(2.06, 6.94)	1.20
M-SD + M-HD Total	62	21.6	26.5	4.9	(3.38, 6.46)	0.77

表 2.7.3.6-138. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Social						
Week 8						
I-SD	29	40.01	43.17	3.16	(0.678, 5.644)	1.212
I-SD/-	9	38.54	38.44	-0.10	(-3.875, 3.679)	1.638
I-SD/M-PL	4	43.00	46.00	3.00	(-1.684, 7.684)	1.472
I-SD/M-SD	7	43.00	47.71	4.71	(-4.295, 13.724)	3.682
I-SD/M-HD	9	37.83	43.11	5.28	(0.976, 9.592)	1.868
I-HD	47	41.18	46.53	5.34	(3.653, 7.036)	0.840
I-HD/-	7	36.29	35.43	-0.86	(-4.832, 3.118)	1.625
I-HD/M-PL	8	36.88	45.25	8.38	(1.439, 15.311)	2.933
I-HD/M-SD	15	42.37	49.45	7.08	(4.864, 9.296)	1.033
I-HD/M-HD	17	44.18	49.12	4.94	(2.646, 7.237)	1.083
I-SD + I-HD Total	76	40.74	45.25	4.51	(3.114, 5.909)	0.702
I-HD-OL	17	41.88	47.35	5.47	(2.695, 8.246)	1.309
I-HD-OL/-	2	41.50	36.50	-5.00		0.000
I-HD-OL/M-SD	8	43.88	50.13	6.25	(2.626, 9.874)	1.532
I-HD-OL/M-HD	7	39.71	47.29	7.57	(4.200, 10.942)	1.378
M-SD Total	30	42.92	49.23	6.31	(4.168, 8.446)	1.046
M-HD Total	33	41.50	47.09	5.59	(3.952, 7.234)	0.806
M-SD + M-HD Total	63	42.17	48.11	5.93	(4.635, 7.230)	0.649

表 2.7.3.6-138. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Social (Cont.)						
Week 26						
I-SD	19	41.26	48.68	7.42	(3.020, 11.822)	2.095
I-SD/M-PL	4	43.00	48.75	5.75	(-5.455, 16.955)	3.521
I-SD/M-SD	7	43.00	48.14	5.14	(-6.622, 16.907)	4.808
I-SD/M-HD	8	38.88	49.13	10.25	(5.063, 15.437)	2.194
I-HD	40	42.04	48.29	6.26	(4.268, 8.242)	0.982
I-HD/M-PL	8	36.88	44.75	7.88	(0.789, 14.961)	2.997
I-HD/M-SD	15	42.37	48.18	5.81	(2.913, 8.715)	1.353
I-HD/M-HD	17	44.18	50.06	5.88	(2.756, 9.009)	1.475
I-SD + I-HD Total	59	41.79	48.42	6.63	(4.749, 8.512)	0.940
I-HD-OL	15	41.93	49.40	7.47	(4.956, 9.977)	1.171
I-HD-OL/M-SD	8	43.88	50.75	6.88	(4.806, 8.944)	0.875
I-HD-OL/M-HD	7	39.71	47.86	8.14	(2.308, 13.978)	2.385
M-SD Total	30	42.92	48.86	5.94	(3.337, 8.544)	1.273
M-HD Total	32	41.88	49.34	7.47	(5.218, 9.719)	1.103
M-SD + M-HD Total	62	42.38	49.11	6.73	(5.054, 8.404)	0.838

表 2.7.3.6-138. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Social (Cont.)						
Week 52						
I-SD	19	41.26	50.00	8.74	(3.867, 13.607)	2.318
I-SD/M-PL	4	43.00	50.75	7.75	(-1.653, 17.153)	2.955
I-SD/M-SD	7	43.00	48.14	5.14	(-5.285, 15.571)	4.262
I-SD/M-HD	8	38.88	51.25	12.38	(3.607, 21.143)	3.708
I-HD	40	42.04	48.02	5.98	(4.051, 7.909)	0.954
I-HD/M-PL	8	36.88	45.00	8.13	(1.153, 15.097)	2.949
I-HD/M-SD	15	42.37	48.72	6.35	(3.211, 9.483)	1.462
I-HD/M-HD	17	44.18	48.82	4.65	(2.032, 7.262)	1.234
I-SD + I-HD Total	59	41.79	48.66	6.87	(4.886, 8.850)	0.990
I-HD-OL	15	41.93	49.40	7.47	(3.891, 11.043)	1.667
I-HD-OL/M-SD	8	43.88	50.13	6.25	(3.294, 9.206)	1.250
I-HD-OL/M-HD	7	39.71	48.57	8.86	(0.664, 17.050)	3.348
M-SD Total	30	42.92	48.96	6.04	(3.534, 8.547)	1.226
M-HD Total	32	41.88	49.38	7.50	(4.607, 10.393)	1.418
M-SD + M-HD Total	62	42.38	49.17	6.79	(4.916, 8.672)	0.939

表 2.7.3.6-138. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Systemic						
Week 8						
I-SD	29	8.21	9.42	1.22	(-0.010, 2.442)	0.598
I-SD/-	9	7.22	6.89	-0.33	(-1.665, 0.998)	0.577
I-SD/M-PL	4	11.00	10.25	-0.75	(-3.468, 1.968)	0.854
I-SD/M-SD	7	7.86	10.89	3.04	(-0.402, 6.478)	1.406
I-SD/M-HD	9	8.22	10.44	2.22	(-0.570, 5.014)	1.211
I-HD	47	8.40	10.81	2.40	(1.586, 3.223)	0.407
I-HD/-	7	7.71	7.29	-0.43	(-3.196, 2.339)	1.131
I-HD/M-PL	8	8.38	11.25	2.88	(0.855, 4.895)	0.854
I-HD/M-SD	15	8.33	11.53	3.20	(1.941, 4.459)	0.587
I-HD/M-HD	17	8.76	11.41	2.65	(1.228, 4.066)	0.669
I-SD + I-HD Total	76	8.33	10.28	1.95	(1.266, 2.636)	0.344
I-HD-OL	17	8.47	10.59	2.12	(0.747, 3.489)	0.647
I-HD-OL/-	2	7.50	4.00	-3.50	(-9.853, 2.853)	0.500
I-HD-OL/M-SD	8	8.63	10.75	2.13	(0.681, 3.569)	0.611
I-HD-OL/M-HD	7	8.57	12.29	3.71	(2.438, 4.991)	0.522
M-SD Total	30	8.30	11.18	2.88	(1.939, 3.812)	0.458
M-HD Total	33	8.58	11.33	2.76	(1.770, 3.745)	0.485
M-SD + M-HD Total	63	8.44	11.26	2.81	(2.150, 3.478)	0.332

表 2.7.3.6-138. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Systemic (Cont.)						
Week 26						
I-SD	19	8.68	10.95	2.26	(0.855, 3.672)	0.670
I-SD/M-PL	4	11.00	11.00	0.00	(-3.898, 3.898)	1.225
I-SD/M-SD	7	7.86	10.14	2.29	(-1.079, 5.651)	1.375
I-SD/M-HD	8	8.25	11.63	3.38	(1.768, 4.982)	0.680
I-HD	40	8.53	11.23	2.70	(1.852, 3.548)	0.419
I-HD/M-PL	8	8.38	10.50	2.13	(0.056, 4.194)	0.875
I-HD/M-SD	15	8.33	11.60	3.27	(1.599, 4.934)	0.777
I-HD/M-HD	17	8.76	11.24	2.47	(1.210, 3.732)	0.595
I-SD + I-HD Total	59	8.58	11.14	2.56	(1.849, 3.269)	0.355
I-HD-OL	15	8.60	11.40	2.80	(1.273, 4.327)	0.712
I-HD-OL/M-SD	8	8.63	11.13	2.50	(-0.218, 5.218)	1.150
I-HD-OL/M-HD	7	8.57	11.71	3.14	(1.046, 5.240)	0.857
M-SD Total	30	8.30	11.13	2.83	(1.660, 4.006)	0.574
M-HD Total	32	8.59	11.44	2.84	(2.029, 3.658)	0.399
M-SD + M-HD Total	62	8.45	11.29	2.84	(2.153, 3.524)	0.343

表 2.7.3.6-138. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Systemic (Cont.)						
Week 52						
I-SD	19	8.68	11.21	2.53	(0.966, 4.087)	0.743
I-SD/M-PL	4	11.00	11.50	0.50	(-4.447, 5.447)	1.555
I-SD/M-SD	7	7.86	10.57	2.71	(-0.097, 5.525)	1.149
I-SD/M-HD	8	8.25	11.63	3.38	(0.516, 6.234)	1.209
I-HD	40	8.53	11.13	2.60	(1.732, 3.468)	0.429
I-HD/M-PL	8	8.38	10.75	2.38	(0.330, 4.420)	0.865
I-HD/M-SD	15	8.33	11.47	3.13	(1.500, 4.766)	0.761
I-HD/M-HD	17	8.76	11.00	2.24	(0.845, 3.626)	0.656
I-SD + I-HD Total	59	8.58	11.15	2.58	(1.829, 3.323)	0.373
I-HD-OL	15	8.60	11.13	2.53	(0.955, 4.112)	0.736
I-HD-OL/M-SD	8	8.63	11.13	2.50	(0.311, 4.689)	0.926
I-HD-OL/M-HD	7	8.57	11.14	2.57	(-0.489, 5.632)	1.251
M-SD Total	30	8.30	11.17	2.87	(1.821, 3.912)	0.511
M-HD Total	32	8.59	11.19	2.59	(1.526, 3.661)	0.523
M-SD + M-HD Total	62	8.45	11.18	2.73	(1.998, 3.453)	0.364

表 2.7.3.6-138. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Treatment						
Week 8						
I-SD	29	10.2	10.8	0.6	(-0.06, 1.31)	0.33
I-SD/-	9	8.9	9.0	0.1	(-1.54, 1.76)	0.72
I-SD/M-PL	4	12.5	11.8	-0.8	(-4.51, 3.01)	1.18
I-SD/M-SD	7	10.3	11.9	1.6	(0.67, 2.47)	0.37
I-SD/M-HD	9	10.4	11.4	1.0	(-0.02, 2.02)	0.44
I-HD	47	10.3	11.0	0.7	(-0.00, 1.36)	0.34
I-HD/-	7	8.3	7.4	-0.9	(-1.98, 0.27)	0.46
I-HD/M-PL	8	9.1	11.1	2.0	(-0.86, 4.86)	1.21
I-HD/M-SD	15	10.8	11.5	0.7	(-0.35, 1.68)	0.47
I-HD/M-HD	17	11.4	12.1	0.7	(-0.44, 1.85)	0.54
I-SD + I-HD Total	76	10.3	10.9	0.7	(0.17, 1.14)	0.24
I-HD-OL	17	10.8	11.6	0.8	(0.03, 1.50)	0.35
I-HD-OL/-	2	11.5	12.0	0.5	(-18.56, 19.56)	1.50
I-HD-OL/M-SD	8	11.3	11.6	0.4	(-0.96, 1.71)	0.56
I-HD-OL/M-HD	7	10.1	11.4	1.3	(0.26, 2.31)	0.42
M-SD Total	30	10.8	11.6	0.8	(0.19, 1.41)	0.30
M-HD Total	33	10.8	11.8	0.9	(0.27, 1.54)	0.31
M-SD + M-HD Total	63	10.8	11.7	0.9	(0.43, 1.29)	0.21

表 2.7.3.6-138. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Treatment (Cont.)						
Week 26						
I-SD	19	11.0	11.9	0.9	(0.03, 1.76)	0.41
I-SD/M-PL	4	12.5	13.3	0.8	(-0.77, 2.27)	0.48
I-SD/M-SD	7	10.3	11.0	0.7	(-1.26, 2.69)	0.81
I-SD/M-HD	8	10.9	12.0	1.1	(-0.51, 2.76)	0.69
I-HD	40	10.7	11.6	0.9	(0.06, 1.69)	0.40
I-HD/M-PL	8	9.1	11.3	2.1	(-1.02, 5.27)	1.33
I-HD/M-SD	15	10.8	11.6	0.8	(-0.37, 1.97)	0.55
I-HD/M-HD	17	11.4	11.7	0.4	(-0.77, 1.47)	0.53
I-SD + I-HD Total	59	10.8	11.7	0.9	(0.28, 1.49)	0.30
I-HD-OL	15	10.7	12.3	1.5	(0.30, 2.77)	0.58
I-HD-OL/M-SD	8	11.3	13.0	1.8	(-0.65, 4.15)	1.01
I-HD-OL/M-HD	7	10.1	11.4	1.3	(0.01, 2.56)	0.52
M-SD Total	30	10.8	11.8	1.0	(0.18, 1.89)	0.42
M-HD Total	32	11.0	11.7	0.8	(0.04, 1.46)	0.35
M-SD + M-HD Total	62	10.9	11.8	0.9	(0.35, 1.43)	0.27

表 2.7.3.6-138. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Treatment (Cont.)						
Week 52						
I-SD	19	11.0	12.0	1.0	(0.02, 1.98)	0.47
I-SD/M-PL	4	12.5	13.5	1.0	(-1.25, 3.25)	0.71
I-SD/M-SD	7	10.3	10.9	0.6	(-1.02, 2.16)	0.65
I-SD/M-HD	8	10.9	12.3	1.4	(-0.81, 3.56)	0.92
I-HD	40	10.7	11.4	0.7	(-0.03, 1.48)	0.37
I-HD/M-PL	8	9.1	10.9	1.8	(-0.77, 4.27)	1.06
I-HD/M-SD	15	10.8	11.7	0.9	(-0.16, 2.03)	0.51
I-HD/M-HD	17	11.4	11.4	0.1	(-1.11, 1.23)	0.55
I-SD + I-HD Total	59	10.8	11.6	0.8	(0.23, 1.40)	0.29
I-HD-OL	15	10.7	12.1	1.4	(0.20, 2.60)	0.56
I-HD-OL/M-SD	8	11.3	12.3	1.0	(-1.10, 3.10)	0.89
I-HD-OL/M-HD	7	10.1	12.0	1.9	(0.22, 3.50)	0.67
M-SD Total	30	10.8	11.7	0.9	(0.12, 1.62)	0.37
M-HD Total	32	11.0	11.8	0.8	(-0.06, 1.62)	0.41
M-SD + M-HD Total	62	10.9	11.7	0.8	(0.27, 1.37)	0.28

表 2.7.3.6-138. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III Total						
Week 8						
I-SD	29	110.03	122.42	12.39	(4.627, 20.160)	3.791
I-SD/-	9	103.76	105.78	2.01	(-9.864, 13.890)	5.151
I-SD/M-PL	4	126.50	136.00	9.50	(1.232, 17.768)	2.598
I-SD/M-SD	7	112.71	132.32	19.61	(-6.687, 45.905)	10.747
I-SD/M-HD	9	106.89	125.33	18.45	(3.237, 33.658)	6.596
I-HD	47	111.54	128.48	16.94	(11.827, 22.055)	2.541
I-HD/-	7	93.14	89.14	-4.00	(-11.920, 3.920)	3.237
I-HD/M-PL	8	102.50	129.50	27.00	(6.352, 47.648)	8.732
I-HD/M-SD	15	113.77	135.58	21.81	(14.943, 28.684)	3.203
I-HD/M-HD	17	121.41	137.94	16.53	(9.665, 23.394)	3.238
I-SD + I-HD Total	76	110.97	126.17	15.21	(10.951, 19.460)	2.136
I-HD-OL	17	109.65	129.12	19.47	(10.041, 28.901)	4.448
I-HD-OL/-	2	104.50	91.00	-13.50	(-32.559, 5.559)	1.500
I-HD-OL/M-SD	8	113.13	132.88	19.75	(6.685, 32.815)	5.525
I-HD-OL/M-HD	7	107.14	135.71	28.57	(17.158, 39.984)	4.664
M-SD Total	30	113.35	134.10	20.75	(14.263, 27.235)	3.171
M-HD Total	33	114.42	134.03	19.61	(14.130, 25.084)	2.689
M-SD + M-HD Total	63	113.91	134.06	20.15	(16.054, 24.247)	2.049

表 2.7.3.6-138. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III Total (Cont.)						
Week 26						
I-SD	19	114.29	138.79	24.50	(12.122, 36.874)	5.891
I-SD/M-PL	4	126.50	144.00	17.50	(-10.920, 45.920)	8.930
I-SD/M-SD	7	112.71	132.00	19.29	(-13.784, 52.356)	13.515
I-SD/M-HD	8	109.57	142.13	32.56	(17.295, 47.823)	6.455
I-HD	40	114.76	136.07	21.31	(15.131, 27.479)	3.052
I-HD/M-PL	8	102.50	127.25	24.75	(2.772, 46.728)	9.294
I-HD/M-SD	15	113.77	134.45	20.68	(10.345, 31.015)	4.819
I-HD/M-HD	17	121.41	141.65	20.24	(11.424, 29.047)	4.156
I-SD + I-HD Total	59	114.61	136.95	22.33	(16.760, 27.907)	2.784
I-HD-OL	15	110.33	136.33	26.00	(16.488, 35.512)	4.435
I-HD-OL/M-SD	8	113.13	136.13	23.00	(10.243, 35.757)	5.395
I-HD-OL/M-HD	7	107.14	136.57	29.43	(11.142, 47.715)	7.473
M-SD Total	30	113.35	134.33	20.97	(12.702, 29.246)	4.045
M-HD Total	32	115.33	140.66	25.33	(18.738, 31.917)	3.231
M-SD + M-HD Total	62	114.37	137.59	23.22	(18.092, 28.349)	2.565

表 2.7.3.6-138. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III Total (Cont.)						
Week 52						
I-SD	19	114.29	139.98	25.68	(11.614, 39.754)	6.697
I-SD/M-PL	4	126.50	146.50	20.00	(-11.100, 51.100)	9.772
I-SD/M-SD	7	112.71	131.29	18.57	(-8.780, 45.923)	11.178
I-SD/M-HD	8	109.57	144.32	34.75	(6.836, 62.664)	11.805
I-HD	40	114.76	134.89	20.13	(13.814, 26.446)	3.122
I-HD/M-PL	8	102.50	128.13	25.63	(4.045, 47.205)	9.126
I-HD/M-SD	15	113.77	137.38	23.61	(13.014, 34.214)	4.942
I-HD/M-HD	17	121.41	135.88	14.47	(5.898, 23.043)	4.044
I-SD + I-HD Total	59	114.61	136.53	21.92	(15.899, 27.938)	3.007
I-HD-OL	15	110.33	136.60	26.27	(16.125, 36.408)	4.728
I-HD-OL/M-SD	8	113.13	136.50	23.38	(15.533, 31.217)	3.316
I-HD-OL/M-HD	7	107.14	136.71	29.57	(5.885, 53.258)	9.680
M-SD Total	30	113.35	135.73	22.37	(15.060, 29.687)	3.576
M-HD Total	32	115.33	138.17	22.84	(13.958, 31.730)	4.357
M-SD + M-HD Total	62	114.37	136.99	22.62	(16.988, 28.244)	2.815

表 2.7.3.6-138.　治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Note: I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group,
M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
Note: baseline is defined as the last non-missing value prior to the first dose of study drug. Subjects with non-missing baseline and at least one post-baseline value are included in the analyses.
Last observation carried forward (LOCF): missing data is imputed by carrying forward the last non-missing post-baseline observation. For subjects re-randomized due to disease flare, the last non-missing value before the re-randomization after the first disease flare are carried forward.

Cross reference: M11-290 CSR_Final Table 14.2__1.3.7_A

表 2.7.3.6-139. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（最終 CSR）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Body						
Week 8						
I-SD	2	8.0	8.5	0.5	(-5.85, 6.85)	0.50
I-SD/-	2	8.0	8.5	0.5	(-5.85, 6.85)	0.50
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	8.5	8.8	0.3	(-0.55, 1.05)	0.25
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	9.0	9.0	0.0		
I-HD/M-HD	3	8.3	8.7	0.3	(-1.10, 1.77)	0.33
I-SD + I-HD Total	6	8.3	8.7	0.3	(-0.21, 0.88)	0.21
I-HD-OL	2	10.5	10.5	0.0		
I-HD-OL/-	0					
I-HD-OL/M-SD	1	10.0	10.0	0.0		
I-HD-OL/M-HD	1	11.0	11.0	0.0		
M-SD Total	2	9.5	9.5	0.0		
M-HD Total	4	9.0	9.3	0.3	(-0.55, 1.05)	0.25
M-SD + M-HD Total	6	9.2	9.3	0.2	(-0.26, 0.60)	0.17

表 2.7.3.6-139. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Body (Cont.)						
Week 26						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	8.5	8.8	0.3	(-0.55, 1.05)	0.25
I-HD/M-PL	0					
I-HD/M-SD	1	9.0	9.0	0.0		
I-HD/M-HD	3	8.3	8.7	0.3	(-1.10, 1.77)	0.33
I-SD + I-HD Total	4	8.5	8.8	0.3	(-0.55, 1.05)	0.25
I-HD-OL	2	10.5	11.0	0.5	(-5.85, 6.85)	0.50
I-HD-OL/M-SD	1	10.0	10.0	0.0		
I-HD-OL/M-HD	1	11.0	12.0	1.0		0.00
M-SD Total	2	9.5	9.5	0.0		
M-HD Total	4	9.0	9.5	0.5	(-0.42, 1.42)	0.29
M-SD + M-HD Total	6	9.2	9.5	0.3	(-0.21, 0.88)	0.21

表 2.7.3.6-139. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Body (Cont.)						
Week 52						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	8.5	8.8	0.3	(-0.55, 1.05)	0.25
I-HD/M-PL	0					
I-HD/M-SD	1	9.0	9.0	0.0		
I-HD/M-HD	3	8.3	8.7	0.3	(-1.10, 1.77)	0.33
I-SD + I-HD Total	4	8.5	8.8	0.3	(-0.55, 1.05)	0.25
I-HD-OL	2	10.5	11.0	0.5	(-5.85, 6.85)	0.50
I-HD-OL/M-SD	1	10.0	10.0	0.0		
I-HD-OL/M-HD	1	11.0	12.0	1.0		0.00
M-SD Total	2	9.5	9.5	0.0		
M-HD Total	4	9.0	9.5	0.5	(-0.42, 1.42)	0.29
M-SD + M-HD Total	6	9.2	9.5	0.3	(-0.21, 0.88)	0.21

表 2.7.3.6-139. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Bowel						
Week 8						
I-SD	2	21.0	24.5	3.5	(-40.97, 47.97)	3.50
I-SD/-	2	21.0	24.5	3.5	(-40.97, 47.97)	3.50
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	24.0	27.0	3.0	(-3.87, 9.87)	2.16
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	25.0	24.0	-1.0		0.00
I-HD/M-HD	3	23.7	28.0	4.3	(-6.01, 14.68)	2.40
I-SD + I-HD Total	6	23.0	26.2	3.2	(-1.05, 7.39)	1.64
I-HD-OL	2	21.5	26.5	5.0	(-7.71, 17.71)	1.00
I-HD-OL/-	0					
I-HD-OL/M-SD	1	20.0	26.0	6.0		0.00
I-HD-OL/M-HD	1	23.0	27.0	4.0		0.00
M-SD Total	2	22.5	25.0	2.5	(-41.97, 46.97)	3.50
M-HD Total	4	23.5	27.8	4.3	(-1.17, 9.67)	1.70
M-SD + M-HD Total	6	23.2	26.8	3.7	(-0.07, 7.40)	1.45

表 2.7.3.6-139. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Bowel (Cont.)						
Week 26						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	24.0	29.0	5.0	(-5.15, 15.15)	3.19
I-HD/M-PL	0					
I-HD/M-SD	1	25.0	24.0	-1.0		0.00
I-HD/M-HD	3	23.7	30.7	7.0	(-8.11, 22.11)	3.51
I-SD + I-HD Total	4	24.0	29.0	5.0	(-5.15, 15.15)	3.19
I-HD-OL	2	21.5	23.5	2.0	(-48.82, 52.82)	4.00
I-HD-OL/M-SD	1	20.0	26.0	6.0		0.00
I-HD-OL/M-HD	1	23.0	21.0	-2.0		0.00
M-SD Total	2	22.5	25.0	2.5	(-41.97, 46.97)	3.50
M-HD Total	4	23.5	28.3	4.8	(-5.91, 15.41)	3.35
M-SD + M-HD Total	6	23.2	27.2	4.0	(-2.05, 10.05)	2.35

表 2.7.3.6-139. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Bowel (Cont.)						
Week 52						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	24.0	27.0	3.0	(-1.68, 7.68)	1.47
I-HD/M-PL	0					
I-HD/M-SD	1	25.0	24.0	-1.0		0.00
I-HD/M-HD	3	23.7	28.0	4.3	(0.54, 8.13)	0.88
I-SD + I-HD Total	4	24.0	27.0	3.0	(-1.68, 7.68)	1.47
I-HD-OL	2	21.5	25.5	4.0	(-21.41, 29.41)	2.00
I-HD-OL/M-SD	1	20.0	26.0	6.0		0.00
I-HD-OL/M-HD	1	23.0	25.0	2.0		0.00
M-SD Total	2	22.5	25.0	2.5	(-41.97, 46.97)	3.50
M-HD Total	4	23.5	27.3	3.8	(1.03, 6.47)	0.85
M-SD + M-HD Total	6	23.2	26.5	3.3	(0.54, 6.12)	1.09

表 2.7.3.6-139. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Emotional						
Week 8						
I-SD	2	15.5	19.5	4.0	(-59.53, 67.53)	5.00
I-SD/-	2	15.5	19.5	4.0	(-59.53, 67.53)	5.00
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	23.3	25.5	2.3	(-4.55, 9.05)	2.14
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	25.0	24.0	-1.0		0.00
I-HD/M-HD	3	22.7	26.0	3.3	(-7.87, 14.53)	2.60
I-SD + I-HD Total	6	20.7	23.5	2.8	(-2.06, 7.73)	1.90
I-HD-OL	2	24.5	28.5	4.0		0.00
I-HD-OL/-	0					
I-HD-OL/M-SD	1	25.0	29.0	4.0		0.00
I-HD-OL/M-HD	1	24.0	28.0	4.0		0.00
M-SD Total	2	25.0	26.5	1.5	(-30.27, 33.27)	2.50
M-HD Total	4	23.0	26.5	3.5	(-2.38, 9.38)	1.85
M-SD + M-HD Total	6	23.7	26.5	2.8	(-0.77, 6.43)	1.40

表 2.7.3.6-139. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Emotional (Cont.)						
Week 26						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	23.3	27.8	4.5	(-3.46, 12.46)	2.50
I-HD/M-PL	0					
I-HD/M-SD	1	25.0	24.0	-1.0		0.00
I-HD/M-HD	3	22.7	29.0	6.3	(-4.01, 16.68)	2.40
I-SD + I-HD Total	4	23.3	27.8	4.5	(-3.46, 12.46)	2.50
I-HD-OL	2	24.5	31.0	6.5	(-25.27, 38.27)	2.50
I-HD-OL/M-SD	1	25.0	29.0	4.0		0.00
I-HD-OL/M-HD	1	24.0	33.0	9.0		0.00
M-SD Total	2	25.0	26.5	1.5	(-30.27, 33.27)	2.50
M-HD Total	4	23.0	30.0	7.0	(1.19, 12.81)	1.83
M-SD + M-HD Total	6	23.7	28.8	5.2	(0.64, 9.69)	1.76

表 2.7.3.6-139. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Emotional (Cont.)						
Week 52						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	23.3	27.3	4.0	(-2.62, 10.62)	2.08
I-HD/M-PL	0					
I-HD/M-SD	1	25.0	24.0	-1.0		0.00
I-HD/M-HD	3	22.7	28.3	5.7	(-1.92, 13.26)	1.76
I-SD + I-HD Total	4	23.3	27.3	4.0	(-2.62, 10.62)	2.08
I-HD-OL	2	24.5	30.5	6.0	(-19.41, 31.41)	2.00
I-HD-OL/M-SD	1	25.0	29.0	4.0		0.00
I-HD-OL/M-HD	1	24.0	32.0	8.0		0.00
M-SD Total	2	25.0	26.5	1.5	(-30.27, 33.27)	2.50
M-HD Total	4	23.0	29.3	6.3	(1.87, 10.63)	1.38
M-SD + M-HD Total	6	23.7	28.3	4.7	(0.87, 8.46)	1.48

表 2.7.3.6-139. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Social						
Week 8						
I-SD	2	37.5	42.0	4.5	(-1.85, 10.85)	0.50
I-SD/-	2	37.5	42.0	4.5	(-1.85, 10.85)	0.50
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	44.3	48.8	4.5	(-0.45, 9.45)	1.55
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	44.0	47.0	3.0		0.00
I-HD/M-HD	3	44.3	49.3	5.0	(-3.96, 13.96)	2.08
I-SD + I-HD Total	6	42.0	46.5	4.5	(1.95, 7.05)	0.99
I-HD-OL	2	47.5	53.5	6.0	(-32.12, 44.12)	3.00
I-HD-OL/-	0					
I-HD-OL/M-SD	1	43.0	52.0	9.0		0.00
I-HD-OL/M-HD	1	52.0	55.0	3.0		0.00
M-SD Total	2	43.5	49.5	6.0	(-32.12, 44.12)	3.00
M-HD Total	4	46.3	50.8	4.5	(-0.45, 9.45)	1.55
M-SD + M-HD Total	6	45.3	50.3	5.0	(1.68, 8.32)	1.29

表 2.7.3.6-139. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Social (Cont.)						
Week 26						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	44.3	50.8	6.5	(0.34, 12.66)	1.94
I-HD/M-PL	0					
I-HD/M-SD	1	44.0	47.0	3.0		0.00
I-HD/M-HD	3	44.3	52.0	7.7	(-1.74, 17.07)	2.19
I-SD + I-HD Total	4	44.3	50.8	6.5	(0.34, 12.66)	1.94
I-HD-OL	2	47.5	53.0	5.5	(-38.97, 49.97)	3.50
I-HD-OL/M-SD	1	43.0	52.0	9.0		0.00
I-HD-OL/M-HD	1	52.0	54.0	2.0		0.00
M-SD Total	2	43.5	49.5	6.0	(-32.12, 44.12)	3.00
M-HD Total	4	46.3	52.5	6.3	(-0.42, 12.92)	2.10
M-SD + M-HD Total	6	45.3	51.5	6.2	(2.22, 10.12)	1.54

表 2.7.3.6-139. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Social (Cont.)						
Week 52						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	44.3	48.3	4.0	(1.09, 6.91)	0.91
I-HD/M-PL	0					
I-HD/M-SD	1	44.0	47.0	3.0		0.00
I-HD/M-HD	3	44.3	48.7	4.3	(-0.84, 9.50)	1.20
I-SD + I-HD Total	4	44.3	48.3	4.0	(1.09, 6.91)	0.91
I-HD-OL	2	47.5	54.0	6.5	(-25.27, 38.27)	2.50
I-HD-OL/M-SD	1	43.0	52.0	9.0		0.00
I-HD-OL/M-HD	1	52.0	56.0	4.0		0.00
M-SD Total	2	43.5	49.5	6.0	(-32.12, 44.12)	3.00
M-HD Total	4	46.3	50.5	4.3	(1.53, 6.97)	0.85
M-SD + M-HD Total	6	45.3	50.2	4.8	(2.23, 7.44)	1.01

表 2.7.3.6-139. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Systemic						
Week 8						
I-SD	2	8.5	9.0	0.5	(-18.56, 19.56)	1.50
I-SD/-	2	8.5	9.0	0.5	(-18.56, 19.56)	1.50
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	8.3	11.0	2.8	(1.23, 4.27)	0.48
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	8.0	10.0	2.0		0.00
I-HD/M-HD	3	8.3	11.3	3.0	(0.52, 5.48)	0.58
I-SD + I-HD Total	6	8.3	10.3	2.0	(0.24, 3.76)	0.68
I-HD-OL	2	9.0	12.0	3.0		0.00
I-HD-OL/-	0					
I-HD-OL/M-SD	1	8.0	11.0	3.0		0.00
I-HD-OL/M-HD	1	10.0	13.0	3.0		0.00
M-SD Total	2	8.0	10.5	2.5	(-3.85, 8.85)	0.50
M-HD Total	4	8.8	11.8	3.0	(1.70, 4.30)	0.41
M-SD + M-HD Total	6	8.5	11.3	2.8	(2.04, 3.62)	0.31

表 2.7.3.6-139. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Systemic (Cont.)						
Week 26						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	8.3	10.8	2.5	(0.45, 4.55)	0.65
I-HD/M-PL	0					
I-HD/M-SD	1	8.0	10.0	2.0		0.00
I-HD/M-HD	3	8.3	11.0	2.7	(-1.13, 6.46)	0.88
I-SD + I-HD Total	4	8.3	10.8	2.5	(0.45, 4.55)	0.65
I-HD-OL	2	9.0	12.0	3.0		0.00
I-HD-OL/M-SD	1	8.0	11.0	3.0		0.00
I-HD-OL/M-HD	1	10.0	13.0	3.0		0.00
M-SD Total	2	8.0	10.5	2.5	(-3.85, 8.85)	0.50
M-HD Total	4	8.8	11.5	2.8	(0.75, 4.75)	0.63
M-SD + M-HD Total	6	8.5	11.2	2.7	(1.58, 3.75)	0.42

表 2.7.3.6-139. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Systemic (Cont.)						
Week 52						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	8.3	11.5	3.3	(1.73, 4.77)	0.48
I-HD/M-PL	0					
I-HD/M-SD	1	8.0	10.0	2.0		0.00
I-HD/M-HD	3	8.3	12.0	3.7	(2.23, 5.10)	0.33
I-SD + I-HD Total	4	8.3	11.5	3.3	(1.73, 4.77)	0.48
I-HD-OL	2	9.0	12.5	3.5	(-2.85, 9.85)	0.50
I-HD-OL/M-SD	1	8.0	11.0	3.0		0.00
I-HD-OL/M-HD	1	10.0	14.0	4.0		0.00
M-SD Total	2	8.0	10.5	2.5	(-3.85, 8.85)	0.50
M-HD Total	4	8.8	12.5	3.8	(2.95, 4.55)	0.25
M-SD + M-HD Total	6	8.5	11.8	3.3	(2.48, 4.19)	0.33

表 2.7.3.6-139. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Treatment						
Week 8						
I-SD	2	8.0	7.0	-1.0	(-26.41, 24.41)	2.00
I-SD/-	2	8.0	7.0	-1.0	(-26.41, 24.41)	2.00
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	11.5	11.8	0.3	(-2.47, 2.97)	0.85
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	11.0	12.0	1.0		0.00
I-HD/M-HD	3	11.7	11.7	0.0	(-4.97, 4.97)	1.15
I-SD + I-HD Total	6	10.3	10.2	-0.2	(-2.20, 1.87)	0.79
I-HD-OL	2	13.5	13.5	0.0		
I-HD-OL/-	0					
I-HD-OL/M-SD	1	15.0	15.0	0.0		
I-HD-OL/M-HD	1	12.0	12.0	0.0		
M-SD Total	2	13.0	13.5	0.5	(-5.85, 6.85)	0.50
M-HD Total	4	11.8	11.8	0.0	(-2.60, 2.60)	0.82
M-SD + M-HD Total	6	12.2	12.3	0.2	(-1.23, 1.56)	0.54

表 2.7.3.6-139. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Treatment (Cont.)						
Week 26						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	11.5	11.5	0.0	(-2.91, 2.91)	0.91
I-HD/M-PL	0					
I-HD/M-SD	1	11.0	12.0	1.0		0.00
I-HD/M-HD	3	11.7	11.3	-0.3	(-5.50, 4.84)	1.20
I-SD + I-HD Total	4	11.5	11.5	0.0	(-2.91, 2.91)	0.91
I-HD-OL	2	13.5	14.5	1.0	(-11.71, 13.71)	1.00
I-HD-OL/M-SD	1	15.0	15.0	0.0		
I-HD-OL/M-HD	1	12.0	14.0	2.0		0.00
M-SD Total	2	13.0	13.5	0.5	(-5.85, 6.85)	0.50
M-HD Total	4	11.8	12.0	0.3	(-3.03, 3.53)	1.03
M-SD + M-HD Total	6	12.2	12.5	0.3	(-1.38, 2.05)	0.67

表 2.7.3.6-139. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III - Treatment (Cont.)						
Week 52						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	11.5	10.8	-0.8	(-2.75, 1.25)	0.63
I-HD/M-PL	0					
I-HD/M-SD	1	11.0	12.0	1.0		0.00
I-HD/M-HD	3	11.7	10.3	-1.3	(-2.77, 0.10)	0.33
I-SD + I-HD Total	4	11.5	10.8	-0.8	(-2.75, 1.25)	0.63
I-HD-OL	2	13.5	15.0	1.5	(-17.56, 20.56)	1.50
I-HD-OL/M-SD	1	15.0	15.0	0.0		
I-HD-OL/M-HD	1	12.0	15.0	3.0		0.00
M-SD Total	2	13.0	13.5	0.5	(-5.85, 6.85)	0.50
M-HD Total	4	11.8	11.5	-0.3	(-3.78, 3.28)	1.11
M-SD + M-HD Total	6	12.2	12.2	0.0	(-1.88, 1.88)	0.73

表 2.7.3.6-139. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III Total						
Week 8						
I-SD	2	98.5	110.5	12.0	(-153.18, 177.18)	13.00
I-SD/-	2	98.5	110.5	12.0	(-153.18, 177.18)	13.00
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	119.8	132.8	13.0	(-4.33, 30.33)	5.45
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	122.0	126.0	4.0		0.00
I-HD/M-HD	3	119.0	135.0	16.0	(-11.66, 43.66)	6.43
I-SD + I-HD Total	6	112.7	125.3	12.7	(0.29, 25.04)	4.81
I-HD-OL	2	126.5	144.5	18.0	(-32.82, 68.82)	4.00
I-HD-OL/-	0					
I-HD-OL/M-SD	1	121.0	143.0	22.0		0.00
I-HD-OL/M-HD	1	132.0	146.0	14.0		0.00
M-SD Total	2	121.5	134.5	13.0	(-101.36, 127.36)	9.00
M-HD Total	4	122.3	137.8	15.5	(0.95, 30.05)	4.57
M-SD + M-HD Total	6	122.0	136.7	14.7	(5.03, 24.30)	3.75

表 2.7.3.6-139. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III Total (Cont.)						
Week 26						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	119.8	138.5	18.8	(-7.15, 44.65)	8.14
I-HD/M-PL	0					
I-HD/M-SD	1	122.0	126.0	4.0		0.00
I-HD/M-HD	3	119.0	142.7	23.7	(-15.79, 63.13)	9.17
I-SD + I-HD Total	4	119.8	138.5	18.8	(-7.15, 44.65)	8.14
I-HD-OL	2	126.5	145.0	18.5	(-25.97, 62.97)	3.50
I-HD-OL/M-SD	1	121.0	143.0	22.0		0.00
I-HD-OL/M-HD	1	132.0	147.0	15.0		0.00
M-SD Total	2	121.5	134.5	13.0	(-101.36, 127.36)	9.00
M-HD Total	4	122.3	143.8	21.5	(-0.26, 43.26)	6.84
M-SD + M-HD Total	6	122.0	140.7	18.7	(5.23, 32.10)	5.23

表 2.7.3.6-139. 治験期間中の IMPACT III スコアのベースラインからの変化（LOCF）（ベースライン時に 9 歳以上の日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
IMPACT III Total (Cont.)						
Week 52						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	119.8	133.5	13.8	(0.73, 26.77)	4.09
I-HD/M-PL	0					
I-HD/M-SD	1	122.0	126.0	4.0		0.00
I-HD/M-HD	3	119.0	136.0	17.0	(1.89, 32.11)	3.51
I-SD + I-HD Total	4	119.8	133.5	13.8	(0.73, 26.77)	4.09
I-HD-OL	2	126.5	148.5	22.0		0.00
I-HD-OL/M-SD	1	121.0	143.0	22.0		0.00
I-HD-OL/M-HD	1	132.0	154.0	22.0		0.00
M-SD Total	2	121.5	134.5	13.0	(-101.36, 127.36)	9.00
M-HD Total	4	122.3	140.5	18.3	(9.40, 27.10)	2.78
M-SD + M-HD Total	6	122.0	138.5	16.5	(8.49, 24.51)	3.12

Note: I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group, M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
Note: baseline is defined as the last non-missing value prior to the first dose of study drug. Subjects with non-missing baseline and at least one post-baseline value are included in the analyses.
Last observation carried forward (LOCF): missing data is imputed by carrying forward the last non-missing post-baseline observation. For subjects re-randomized due to disease flare, the last non-missing value before the re-randomization after the first disease flare are carried forward.

Cross reference: M11-290 CSR_Final Table 14.2__1.3.7_J

表 2.7.3.6-140.　治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%)						
Week 1						
I-SD	31	41.9	30.6	-11.3	(-17.41, -5.17)	3.00
I-SD/-	9	44.4	41.1	-3.3	(-11.02, 4.35)	3.33
I-SD/M-PL	4	60.0	37.5	-22.5	(-55.30, 10.30)	10.31
I-SD/M-SD	8	25.0	18.8	-6.3	(-21.03, 8.53)	6.25
I-SD/M-HD	10	46.0	28.0	-18.0	(-29.58, -6.42)	5.12
I-HD	49	46.7	35.7	-11.0	(-16.86, -5.18)	2.91
I-HD/-	8	58.8	48.8	-10.0	(-25.48, 5.48)	6.55
I-HD/M-PL	7	52.9	42.9	-10.0	(-20.68, 0.68)	4.36
I-HD/M-SD	16	48.8	38.8	-10.0	(-24.56, 4.56)	6.83
I-HD/M-HD	18	37.2	24.4	-12.8	(-21.61, -3.95)	4.19
I-SD + I-HD Total	80	44.9	33.8	-11.1	(-15.33, -6.92)	2.11
I-HD-OL	16	50.6	44.4	-6.3	(-19.28, 6.78)	6.12
I-HD-OL/-	2	50.0	55.0	5.0	(-58.53, 68.53)	5.00
I-HD-OL/M-SD	7	41.4	45.7	4.3	(-18.28, 26.85)	9.22
I-HD-OL/M-HD	7	60.0	40.0	-20.0	(-40.68, 0.68)	8.45
M-SD Total	31	41.0	35.2	-5.8	(-14.78, 3.17)	4.39
M-HD Total	35	44.3	28.6	-15.7	(-21.91, -9.52)	3.05
M-SD + M-HD Total	66	42.7	31.7	-11.1	(-16.40, -5.72)	2.67

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 2						
I-SD	32	41.6	26.9	-14.7	(-22.98, -6.40)	4.07
I-SD/-	10	43.0	38.0	-5.0	(-15.26, 5.26)	4.53
I-SD/M-PL	4	60.0	40.0	-20.0	(-49.05, 9.05)	9.13
I-SD/M-SD	8	25.0	20.0	-5.0	(-19.82, 9.82)	6.27
I-SD/M-HD	10	46.0	16.0	-30.0	(-50.23, -9.77)	8.94
I-HD	50	47.2	29.0	-18.2	(-24.02, -12.38)	2.90
I-HD/-	8	58.8	41.3	-17.5	(-29.11, -5.89)	4.91
I-HD/M-PL	7	52.9	28.6	-24.3	(-48.08, -0.49)	9.72
I-HD/M-SD	17	50.0	34.1	-15.9	(-28.35, -3.41)	5.88
I-HD/M-HD	18	37.2	18.9	-18.3	(-27.24, -9.43)	4.22
I-SD + I-HD Total	82	45.0	28.2	-16.8	(-21.54, -12.12)	2.37
I-HD-OL	17	51.8	32.9	-18.8	(-35.77, -1.88)	7.99
I-HD-OL/-	2	50.0	45.0	-5.0	(-195.59, 185.59)	15.00
I-HD-OL/M-SD	7	41.4	32.9	-8.6	(-45.34, 28.20)	15.03
I-HD-OL/M-HD	8	61.3	30.0	-31.3	(-53.79, -8.71)	9.53
M-SD Total	32	41.9	30.3	-11.6	(-21.13, -2.00)	4.69
M-HD Total	36	45.0	20.6	-24.4	(-32.35, -16.54)	3.89
M-SD + M-HD Total	68	43.5	25.1	-18.4	(-24.57, -12.20)	3.10

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 4						
I-SD	32	41.6	28.1	-13.4	(-20.63, -6.25)	3.52
I-SD/-	10	43.0	41.0	-2.0	(-10.12, 6.12)	3.59
I-SD/M-PL	4	60.0	32.5	-27.5	(-62.78, 7.78)	11.09
I-SD/M-SD	8	25.0	18.8	-6.3	(-18.02, 5.52)	4.98
I-SD/M-HD	10	46.0	21.0	-25.0	(-40.91, -9.09)	7.03
I-HD	50	47.2	25.2	-22.0	(-28.32, -15.68)	3.14
I-HD/-	8	58.8	25.0	-33.8	(-49.82, -17.68)	6.80
I-HD/M-PL	7	52.9	28.6	-24.3	(-44.16, -4.41)	8.12
I-HD/M-SD	17	50.0	30.6	-19.4	(-32.45, -6.37)	6.15
I-HD/M-HD	18	37.2	18.9	-18.3	(-28.46, -8.21)	4.80
I-SD + I-HD Total	82	45.0	26.3	-18.7	(-23.41, -13.90)	2.39
I-HD-OL	18	50.6	33.3	-17.2	(-37.75, 3.30)	9.73
I-HD-OL/-	2	50.0	40.0	-10.0	(-518.25, 498.25)	40.00
I-HD-OL/M-SD	8	40.0	42.5	2.5	(-24.96, 29.96)	11.61
I-HD-OL/M-HD	8	61.3	22.5	-38.8	(-72.32, -5.18)	14.20
M-SD Total	33	41.5	30.6	-10.9	(-20.22, -1.60)	4.57
M-HD Total	36	45.0	20.3	-24.7	(-33.78, -15.66)	4.46
M-SD + M-HD Total	69	43.3	25.2	-18.1	(-24.66, -11.57)	3.28

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 8						
I-SD	32	41.6	31.3	-10.3	(-20.53, -0.10)	5.01
I-SD/-	10	43.0	49.0	6.0	(-5.78, 17.78)	5.21
I-SD/M-PL	4	60.0	25.0	-35.0	(-55.54, -14.46)	6.45
I-SD/M-SD	8	25.0	22.5	-2.5	(-28.07, 23.07)	10.82
I-SD/M-HD	10	46.0	23.0	-23.0	(-44.61, -1.39)	9.55
I-HD	50	47.2	23.6	-23.6	(-30.58, -16.62)	3.47
I-HD/-	8	58.8	50.0	-8.8	(-36.09, 18.59)	11.56
I-HD/M-PL	7	52.9	24.3	-28.6	(-43.12, -14.02)	5.95
I-HD/M-SD	17	50.0	22.9	-27.1	(-40.51, -13.61)	6.35
I-HD/M-HD	18	37.2	12.2	-25.0	(-35.41, -14.59)	4.93
I-SD + I-HD Total	82	45.0	26.6	-18.4	(-24.29, -12.54)	2.95
I-HD-OL	18	50.6	37.2	-13.3	(-32.63, 5.96)	9.15
I-HD-OL/-	2	50.0	85.0	35.0	(-28.53, 98.53)	5.00
I-HD-OL/M-SD	8	40.0	30.0	-10.0	(-42.53, 22.53)	13.76
I-HD-OL/M-HD	8	61.3	32.5	-28.8	(-57.52, 0.02)	12.17
M-SD Total	33	41.5	24.5	-17.0	(-28.16, -5.77)	5.50
M-HD Total	36	45.0	19.7	-25.3	(-34.16, -16.40)	4.37
M-SD + M-HD Total	69	43.3	22.0	-21.3	(-28.27, -14.34)	3.49

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 12						
I-SD	21	39.0	21.4	-17.6	(-32.22, -3.02)	7.00
I-SD/M-PL	4	60.0	37.5	-22.5	(-55.30, 10.30)	10.31
I-SD/M-SD	8	25.0	20.0	-5.0	(-32.91, 22.91)	11.80
I-SD/M-HD	9	42.2	15.6	-26.7	(-53.02, -0.32)	11.43
I-HD	43	44.0	17.7	-26.3	(-35.06, -17.50)	4.35
I-HD/M-PL	8	46.3	16.3	-30.0	(-49.98, -10.02)	8.45
I-HD/M-SD	17	50.0	24.1	-25.9	(-45.13, -6.64)	9.08
I-HD/M-HD	18	37.2	12.2	-25.0	(-35.55, -14.45)	5.00
I-SD + I-HD Total	64	42.3	18.9	-23.4	(-30.87, -16.00)	3.72
I-HD-OL	16	50.6	32.5	-18.1	(-39.37, 3.12)	9.97
I-HD-OL/M-SD	8	40.0	42.5	2.5	(-26.37, 31.37)	12.21
I-HD-OL/M-HD	8	61.3	22.5	-38.8	(-68.20, -9.30)	12.46
M-SD Total	33	41.5	27.6	-13.9	(-27.06, -0.82)	6.44
M-HD Total	35	44.0	15.4	-28.6	(-38.22, -18.92)	4.75
M-SD + M-HD Total	68	42.8	21.3	-21.5	(-29.53, -13.41)	4.04

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 18						
I-SD	21	39.0	18.1	-21.0	(-34.52, -7.38)	6.51
I-SD/M-PL	4	60.0	22.5	-37.5	(-61.37, -13.63)	7.50
I-SD/M-SD	8	25.0	21.3	-3.8	(-28.20, 20.70)	10.34
I-SD/M-HD	9	42.2	13.3	-28.9	(-51.77, -6.01)	9.92
I-HD	43	44.0	17.7	-26.3	(-33.82, -18.74)	3.74
I-HD/M-PL	8	46.3	23.8	-22.5	(-45.61, 0.61)	9.77
I-HD/M-SD	17	50.0	22.9	-27.1	(-41.46, -12.66)	6.79
I-HD/M-HD	18	37.2	10.0	-27.2	(-37.43, -17.02)	4.84
I-SD + I-HD Total	64	42.3	17.8	-24.5	(-31.09, -17.98)	3.28
I-HD-OL	16	50.6	27.5	-23.1	(-43.97, -2.28)	9.78
I-HD-OL/M-SD	8	40.0	31.3	-8.8	(-42.32, 24.82)	14.20
I-HD-OL/M-HD	8	61.3	23.8	-37.5	(-66.37, -8.63)	12.21
M-SD Total	33	41.5	24.5	-17.0	(-28.44, -5.50)	5.63
M-HD Total	35	44.0	14.0	-30.0	(-38.97, -21.03)	4.42
M-SD + M-HD Total	68	42.8	19.1	-23.7	(-30.89, -16.46)	3.62

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 26						
I-SD	21	39.0	16.7	-22.4	(-36.70, -8.07)	6.86
I-SD/M-PL	4	60.0	25.0	-35.0	(-55.54, -14.46)	6.45
I-SD/M-SD	8	25.0	25.0	0.0	(-24.06, 24.06)	10.18
I-SD/M-HD	9	42.2	5.6	-36.7	(-59.40, -13.93)	9.86
I-HD	43	44.0	18.1	-25.8	(-33.54, -18.09)	3.83
I-HD/M-PL	8	46.3	20.0	-26.3	(-50.70, -1.80)	10.34
I-HD/M-SD	17	50.0	24.7	-25.3	(-39.51, -11.08)	6.70
I-HD/M-HD	18	37.2	11.1	-26.1	(-37.05, -15.17)	5.19
I-SD + I-HD Total	64	42.3	17.7	-24.7	(-31.47, -17.91)	3.39
I-HD-OL	16	50.6	26.9	-23.8	(-46.35, -1.15)	10.60
I-HD-OL/M-SD	8	40.0	32.5	-7.5	(-43.18, 28.18)	15.09
I-HD-OL/M-HD	8	61.3	21.3	-40.0	(-71.60, -8.40)	13.36
M-SD Total	33	41.5	26.7	-14.8	(-26.55, -3.15)	5.74
M-HD Total	35	44.0	12.0	-32.0	(-41.60, -22.40)	4.72
M-SD + M-HD Total	68	42.8	19.1	-23.7	(-31.30, -16.06)	3.82

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 34						
I-SD	21	39.0	15.7	-23.3	(-36.47, -10.19)	6.30
I-SD/M-PL	4	60.0	25.0	-35.0	(-55.54, -14.46)	6.45
I-SD/M-SD	8	25.0	23.8	-1.3	(-17.63, 15.13)	6.93
I-SD/M-HD	9	42.2	4.4	-37.8	(-60.77, -14.79)	9.97
I-HD	43	44.0	17.0	-27.0	(-34.88, -19.07)	3.92
I-HD/M-PL	8	46.3	20.0	-26.3	(-50.70, -1.80)	10.34
I-HD/M-SD	17	50.0	22.4	-27.6	(-42.91, -12.38)	7.20
I-HD/M-HD	18	37.2	10.6	-26.7	(-37.18, -16.15)	4.98
I-SD + I-HD Total	64	42.3	16.6	-25.8	(-32.42, -19.14)	3.32
I-HD-OL	16	50.6	25.0	-25.6	(-47.72, -3.53)	10.37
I-HD-OL/M-SD	8	40.0	30.0	-10.0	(-43.44, 23.44)	14.14
I-HD-OL/M-HD	8	61.3	20.0	-41.3	(-73.92, -8.58)	13.81
M-SD Total	33	41.5	24.5	-17.0	(-28.23, -5.70)	5.53
M-HD Total	35	44.0	11.1	-32.9	(-42.52, -23.19)	4.76
M-SD + M-HD Total	68	42.8	17.6	-25.1	(-32.60, -17.70)	3.73

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 42						
I-SD	21	39.0	14.3	-24.8	(-39.56, -9.97)	7.09
I-SD/M-PL	4	60.0	12.5	-47.5	(-87.28, -7.72)	12.50
I-SD/M-SD	8	25.0	23.8	-1.3	(-17.63, 15.13)	6.93
I-SD/M-HD	9	42.2	6.7	-35.6	(-61.37, -9.74)	11.19
I-HD	43	44.0	16.3	-27.7	(-35.30, -20.05)	3.78
I-HD/M-PL	8	46.3	20.0	-26.3	(-50.70, -1.80)	10.34
I-HD/M-SD	17	50.0	21.2	-28.8	(-43.24, -14.41)	6.80
I-HD/M-HD	18	37.2	10.0	-27.2	(-37.43, -17.02)	4.84
I-SD + I-HD Total	64	42.3	15.6	-26.7	(-33.54, -19.90)	3.41
I-HD-OL	16	50.6	20.6	-30.0	(-48.04, -11.96)	8.47
I-HD-OL/M-SD	8	40.0	22.5	-17.5	(-41.87, 6.87)	10.31
I-HD-OL/M-HD	8	61.3	18.8	-42.5	(-72.06, -12.94)	12.50
M-SD Total	33	41.5	22.1	-19.4	(-29.38, -9.41)	4.90
M-HD Total	35	44.0	11.1	-32.9	(-42.41, -23.30)	4.70
M-SD + M-HD Total	68	42.8	16.5	-26.3	(-33.24, -19.40)	3.47

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 52						
I-SD	21	39.0	12.9	-26.2	(-41.04, -11.34)	7.12
I-SD/M-PL	4	60.0	10.0	-50.0	(-88.98, -11.02)	12.25
I-SD/M-SD	8	25.0	22.5	-2.5	(-21.85, 16.85)	8.18
I-SD/M-HD	9	42.2	5.6	-36.7	(-60.97, -12.36)	10.54
I-HD	43	44.0	17.4	-26.5	(-34.71, -18.32)	4.06
I-HD/M-PL	8	46.3	20.0	-26.3	(-50.70, -1.80)	10.34
I-HD/M-SD	17	50.0	19.4	-30.6	(-46.89, -14.28)	7.69
I-HD/M-HD	18	37.2	14.4	-22.8	(-32.98, -12.57)	4.84
I-SD + I-HD Total	64	42.3	15.9	-26.4	(-33.52, -19.29)	3.56
I-HD-OL	16	50.6	21.3	-29.4	(-49.26, -9.49)	9.33
I-HD-OL/M-SD	8	40.0	25.0	-15.0	(-42.91, 12.91)	11.80
I-HD-OL/M-HD	8	61.3	17.5	-43.8	(-75.01, -12.49)	13.22
M-SD Total	33	41.5	21.5	-20.0	(-31.25, -8.75)	5.52
M-HD Total	35	44.0	12.9	-31.1	(-40.96, -21.33)	4.83
M-SD + M-HD Total	68	42.8	17.1	-25.7	(-33.10, -18.37)	3.69

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%)						
Week 1						
I-SD	21	44.3	35.7	-8.6	(-17.36, 0.22)	4.21
I-SD/-	6	55.0	41.7	-13.3	(-26.04, -0.62)	4.94
I-SD/M-PL	3	53.3	43.3	-10.0	(-75.72, 55.72)	15.28
I-SD/M-SD	4	42.5	32.5	-10.0	(-44.37, 24.37)	10.80
I-SD/M-HD	8	33.8	30.0	-3.8	(-22.68, 15.18)	8.00
I-HD	32	41.6	28.8	-12.8	(-22.90, -2.73)	4.94
I-HD/-	4	60.0	45.0	-15.0	(-89.07, 59.07)	23.27
I-HD/M-PL	6	50.0	46.7	-3.3	(-8.75, 2.09)	2.11
I-HD/M-SD	11	49.1	27.3	-21.8	(-45.63, 1.99)	10.69
I-HD/M-HD	11	22.7	14.5	-8.2	(-20.50, 4.14)	5.53
I-SD + I-HD Total	53	42.6	31.5	-11.1	(-17.96, -4.30)	3.40
I-HD-OL	6	38.3	36.7	-1.7	(-13.94, 10.60)	4.77
I-HD-OL/-	1	50.0	60.0	10.0		0.00
I-HD-OL/M-SD	1	0.0	10.0	10.0		0.00
I-HD-OL/M-HD	4	45.0	37.5	-7.5	(-22.73, 7.73)	4.79
M-SD Total	16	44.4	27.5	-16.9	(-33.81, 0.06)	7.94
M-HD Total	23	30.4	23.9	-6.5	(-14.41, 1.37)	3.80
M-SD + M-HD Total	39	36.2	25.4	-10.8	(-18.83, -2.71)	3.98

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 2						
I-SD	22	42.3	29.5	-12.7	(-21.61, -3.84)	4.27
I-SD/-	7	47.1	38.6	-8.6	(-26.62, 9.48)	7.38
I-SD/M-PL	3	53.3	40.0	-13.3	(-70.70, 44.04)	13.33
I-SD/M-SD	4	42.5	25.0	-17.5	(-57.28, 22.28)	12.50
I-SD/M-HD	8	33.8	20.0	-13.8	(-31.02, 3.52)	7.30
I-HD	33	42.4	23.0	-19.4	(-27.89, -10.89)	4.17
I-HD/-	4	60.0	30.0	-30.0	(-48.37, -11.63)	5.77
I-HD/M-PL	6	50.0	28.3	-21.7	(-49.37, 6.03)	10.78
I-HD/M-SD	12	50.8	27.5	-23.3	(-42.74, -3.92)	8.82
I-HD/M-HD	11	22.7	12.7	-10.0	(-20.83, 0.83)	4.86
I-SD + I-HD Total	55	42.4	25.6	-16.7	(-22.82, -10.64)	3.04
I-HD-OL	6	38.3	33.3	-5.0	(-24.63, 14.63)	7.64
I-HD-OL/-	1	50.0	60.0	10.0		0.00
I-HD-OL/M-SD	1	0.0	20.0	20.0		0.00
I-HD-OL/M-HD	4	45.0	30.0	-15.0	(-35.54, 5.54)	6.45
M-SD Total	17	45.9	26.5	-19.4	(-34.56, -4.26)	7.15
M-HD Total	23	30.4	18.3	-12.2	(-19.43, -4.92)	3.50
M-SD + M-HD Total	40	37.0	21.8	-15.3	(-22.60, -7.90)	3.63

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 4						
I-SD	22	42.3	27.7	-14.5	(-25.89, -3.20)	5.45
I-SD/-	7	47.1	38.6	-8.6	(-28.14, 11.00)	8.00
I-SD/M-PL	3	53.3	43.3	-10.0	(-99.57, 79.57)	20.82
I-SD/M-SD	4	42.5	20.0	-22.5	(-52.62, 7.62)	9.46
I-SD/M-HD	8	33.8	16.3	-17.5	(-43.46, 8.46)	10.98
I-HD	33	42.4	21.5	-20.9	(-30.59, -11.22)	4.75
I-HD/-	4	60.0	25.0	-35.0	(-72.88, 2.88)	11.90
I-HD/M-PL	6	50.0	30.0	-20.0	(-51.13, 11.13)	12.11
I-HD/M-SD	12	50.8	25.0	-25.8	(-46.90, -4.77)	9.57
I-HD/M-HD	11	22.7	11.8	-10.9	(-23.46, 1.64)	5.63
I-SD + I-HD Total	55	42.4	24.0	-18.4	(-25.55, -11.18)	3.58
I-HD-OL	7	37.1	27.1	-10.0	(-32.02, 12.02)	9.00
I-HD-OL/-	1	50.0	80.0	30.0		0.00
I-HD-OL/M-SD	2	15.0	10.0	-5.0	(-195.59, 185.59)	15.00
I-HD-OL/M-HD	4	45.0	22.5	-22.5	(-46.37, 1.37)	7.50
M-SD Total	18	45.0	22.2	-22.8	(-37.23, -8.32)	6.85
M-HD Total	23	30.4	15.2	-15.2	(-25.05, -5.38)	4.74
M-SD + M-HD Total	41	36.8	18.3	-18.5	(-26.63, -10.44)	4.01

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 8						
I-SD	22	42.3	25.5	-16.8	(-27.88, -5.75)	5.32
I-SD/-	7	47.1	44.3	-2.9	(-20.34, 14.62)	7.14
I-SD/M-PL	3	53.3	26.7	-26.7	(-89.18, 35.85)	14.53
I-SD/M-SD	4	42.5	15.0	-27.5	(-75.02, 20.02)	14.93
I-SD/M-HD	8	33.8	13.8	-20.0	(-41.89, 1.89)	9.26
I-HD	33	42.4	16.4	-26.1	(-35.40, -16.72)	4.58
I-HD/-	4	60.0	35.0	-25.0	(-77.77, 27.77)	16.58
I-HD/M-PL	6	50.0	26.7	-23.3	(-51.23, 4.56)	10.85
I-HD/M-SD	12	50.8	12.5	-38.3	(-56.67, -19.99)	8.33
I-HD/M-HD	11	22.7	8.2	-14.5	(-25.93, -3.16)	5.11
I-SD + I-HD Total	55	42.4	20.0	-22.4	(-29.38, -15.35)	3.50
I-HD-OL	7	37.1	30.0	-7.1	(-27.63, 13.34)	8.37
I-HD-OL/-	1	50.0	80.0	30.0		0.00
I-HD-OL/M-SD	2	15.0	5.0	-10.0	(-264.12, 244.12)	20.00
I-HD-OL/M-HD	4	45.0	30.0	-15.0	(-35.54, 5.54)	6.45
M-SD Total	18	45.0	12.2	-32.8	(-47.13, -18.43)	6.80
M-HD Total	23	30.4	13.9	-16.5	(-24.93, -8.11)	4.06
M-SD + M-HD Total	41	36.8	13.2	-23.7	(-31.57, -15.74)	3.92

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 12						
I-SD	15	40.0	17.3	-22.7	(-39.60, -5.73)	7.90
I-SD/M-PL	3	53.3	36.7	-16.7	(-88.38, 55.04)	16.67
I-SD/M-SD	4	42.5	10.0	-32.5	(-74.35, 9.35)	13.15
I-SD/M-HD	8	33.8	13.8	-20.0	(-49.64, 9.64)	12.54
I-HD	30	38.7	15.0	-23.7	(-35.37, -11.96)	5.72
I-HD/M-PL	7	42.9	21.4	-21.4	(-47.82, 4.96)	10.79
I-HD/M-SD	12	50.8	15.8	-35.0	(-59.00, -11.00)	10.91
I-HD/M-HD	11	22.7	10.0	-12.7	(-27.78, 2.32)	6.75
I-SD + I-HD Total	45	39.1	15.8	-23.3	(-32.57, -14.10)	4.58
I-HD-OL	7	41.4	30.0	-11.4	(-23.87, 1.01)	5.08
I-HD-OL/M-SD	3	36.7	33.3	-3.3	(-41.28, 34.61)	8.82
I-HD-OL/M-HD	4	45.0	27.5	-17.5	(-32.73, -2.27)	4.79
M-SD Total	19	46.8	17.4	-29.5	(-45.82, -13.13)	7.78
M-HD Total	23	30.4	14.3	-16.1	(-27.13, -5.04)	5.32
M-SD + M-HD Total	42	37.9	15.7	-22.1	(-31.49, -12.79)	4.63

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 18						
I-SD	15	40.0	16.0	-24.0	(-42.46, -5.54)	8.61
I-SD/M-PL	3	53.3	20.0	-33.3	(-85.04, 18.38)	12.02
I-SD/M-SD	4	42.5	20.0	-22.5	(-87.95, 42.95)	20.56
I-SD/M-HD	8	33.8	12.5	-21.3	(-51.70, 9.20)	12.88
I-HD	30	38.7	13.7	-25.0	(-35.82, -14.18)	5.29
I-HD/M-PL	7	42.9	25.7	-17.1	(-45.76, 11.47)	11.69
I-HD/M-SD	12	50.8	13.3	-37.5	(-56.68, -18.32)	8.71
I-HD/M-HD	11	22.7	6.4	-16.4	(-32.05, -0.67)	7.04
I-SD + I-HD Total	45	39.1	14.4	-24.7	(-33.72, -15.62)	4.49
I-HD-OL	7	41.4	20.0	-21.4	(-49.39, 6.54)	11.43
I-HD-OL/M-SD	3	36.7	6.7	-30.0	(-143.84, 83.84)	26.46
I-HD-OL/M-HD	4	45.0	30.0	-15.0	(-42.56, 12.56)	8.66
M-SD Total	19	46.8	13.7	-33.2	(-49.23, -17.09)	7.65
M-HD Total	23	30.4	12.6	-17.8	(-29.41, -6.24)	5.59
M-SD + M-HD Total	42	37.9	13.1	-24.8	(-34.28, -15.24)	4.71

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 26						
I-SD	15	40.0	14.0	-26.0	(-43.86, -8.14)	8.33
I-SD/M-PL	3	53.3	20.0	-33.3	(-71.28, 4.61)	8.82
I-SD/M-SD	4	42.5	25.0	-17.5	(-82.95, 47.95)	20.56
I-SD/M-HD	8	33.8	6.3	-27.5	(-56.72, 1.72)	12.36
I-HD	30	38.7	15.0	-23.7	(-36.17, -11.17)	6.11
I-HD/M-PL	7	42.9	20.0	-22.9	(-48.31, 2.59)	10.40
I-HD/M-SD	12	50.8	20.0	-30.8	(-58.79, -2.88)	12.70
I-HD/M-HD	11	22.7	6.4	-16.4	(-32.05, -0.67)	7.04
I-SD + I-HD Total	45	39.1	14.7	-24.4	(-34.28, -14.61)	4.88
I-HD-OL	7	41.4	15.7	-25.7	(-55.38, 3.95)	12.12
I-HD-OL/M-SD	3	36.7	6.7	-30.0	(-143.84, 83.84)	26.46
I-HD-OL/M-HD	4	45.0	22.5	-22.5	(-62.28, 17.28)	12.50
M-SD Total	19	46.8	18.9	-27.9	(-47.93, -7.86)	9.54
M-HD Total	23	30.4	9.1	-21.3	(-33.13, -9.48)	5.70
M-SD + M-HD Total	42	37.9	13.6	-24.3	(-34.95, -13.62)	5.28

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 34						
I-SD	15	40.0	15.3	-24.7	(-43.02, -6.32)	8.56
I-SD/M-PL	3	53.3	20.0	-33.3	(-71.28, 4.61)	8.82
I-SD/M-SD	4	42.5	27.5	-15.0	(-80.61, 50.61)	20.62
I-SD/M-HD	8	33.8	7.5	-26.3	(-56.54, 4.04)	12.81
I-HD	30	38.7	15.0	-23.7	(-36.28, -11.05)	6.17
I-HD/M-PL	7	42.9	20.0	-22.9	(-48.31, 2.59)	10.40
I-HD/M-SD	12	50.8	20.0	-30.8	(-59.18, -2.49)	12.88
I-HD/M-HD	11	22.7	6.4	-16.4	(-32.05, -0.67)	7.04
I-SD + I-HD Total	45	39.1	15.1	-24.0	(-33.97, -14.03)	4.95
I-HD-OL	7	41.4	18.6	-22.9	(-44.02, -1.69)	8.65
I-HD-OL/M-SD	3	36.7	13.3	-23.3	(-110.57, 63.91)	20.28
I-HD-OL/M-HD	4	45.0	22.5	-22.5	(-46.37, 1.37)	7.50
M-SD Total	19	46.8	20.5	-26.3	(-46.07, -6.56)	9.40
M-HD Total	23	30.4	9.6	-20.9	(-32.45, -9.29)	5.58
M-SD + M-HD Total	42	37.9	14.5	-23.3	(-33.81, -12.86)	5.19

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 42						
I-SD	15	40.0	12.7	-27.3	(-47.13, -7.54)	9.23
I-SD/M-PL	3	53.3	6.7	-46.7	(-109.18, 15.85)	14.53
I-SD/M-SD	4	42.5	25.0	-17.5	(-82.95, 47.95)	20.56
I-SD/M-HD	8	33.8	8.8	-25.0	(-56.60, 6.60)	13.36
I-HD	30	38.7	15.0	-23.7	(-36.24, -11.09)	6.15
I-HD/M-PL	7	42.9	20.0	-22.9	(-48.31, 2.59)	10.40
I-HD/M-SD	12	50.8	20.0	-30.8	(-59.05, -2.62)	12.82
I-HD/M-HD	11	22.7	6.4	-16.4	(-32.05, -0.67)	7.04
I-SD + I-HD Total	45	39.1	14.2	-24.9	(-35.11, -14.67)	5.07
I-HD-OL	7	41.4	14.3	-27.1	(-48.97, -5.31)	8.92
I-HD-OL/M-SD	3	36.7	13.3	-23.3	(-110.57, 63.91)	20.28
I-HD-OL/M-HD	4	45.0	15.0	-30.0	(-55.98, -4.02)	8.16
M-SD Total	19	46.8	20.0	-26.8	(-46.46, -7.23)	9.34
M-HD Total	23	30.4	8.7	-21.7	(-33.74, -9.74)	5.78
M-SD + M-HD Total	42	37.9	13.8	-24.0	(-34.60, -13.50)	5.23

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 52						
I-SD	15	40.0	10.7	-29.3	(-49.02, -9.65)	9.18
I-SD/M-PL	3	53.3	3.3	-50.0	(-99.68, -0.32)	11.55
I-SD/M-SD	4	42.5	25.0	-17.5	(-82.95, 47.95)	20.56
I-SD/M-HD	8	33.8	6.3	-27.5	(-59.02, 4.02)	13.33
I-HD	30	38.7	14.7	-24.0	(-36.96, -11.04)	6.34
I-HD/M-PL	7	42.9	20.0	-22.9	(-48.31, 2.59)	10.40
I-HD/M-SD	12	50.8	18.3	-32.5	(-61.95, -3.05)	13.38
I-HD/M-HD	11	22.7	7.3	-15.5	(-30.59, -0.32)	6.79
I-SD + I-HD Total	45	39.1	13.3	-25.8	(-36.19, -15.36)	5.17
I-HD-OL	7	41.4	14.3	-27.1	(-50.24, -4.04)	9.44
I-HD-OL/M-SD	3	36.7	10.0	-26.7	(-127.06, 73.73)	23.33
I-HD-OL/M-HD	4	45.0	17.5	-27.5	(-47.52, -7.48)	6.29
M-SD Total	19	46.8	18.4	-28.4	(-48.95, -7.89)	9.77
M-HD Total	23	30.4	8.7	-21.7	(-33.52, -9.96)	5.68
M-SD + M-HD Total	42	37.9	13.1	-24.8	(-35.58, -13.94)	5.36

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%)						
Week 1						
I-SD	20	48.892	37.969	-10.924	(-22.1023, 0.2551)	5.3409
I-SD/-	5	66.000	43.345	-22.655	(-44.5405, -0.7686)	7.8827
I-SD/M-PL	3	53.333	46.667	-6.667	(-82.5583, 69.2250)	17.6383
I-SD/M-SD	4	47.962	34.604	-13.357	(-56.2986, 29.5836)	13.4931
I-SD/M-HD	8	37.000	33.029	-3.971	(-24.9138, 16.9715)	8.8567
I-HD	31	45.916	32.777	-13.139	(-23.1646, -3.1139)	4.9089
I-HD/-	4	64.063	50.714	-13.348	(-84.7354, 58.0390)	22.4316
I-HD/M-PL	6	54.720	47.599	-7.121	(-16.2301, 1.9880)	3.5436
I-HD/M-SD	10	52.986	34.250	-18.736	(-44.6235, 7.1510)	11.4436
I-HD/M-HD	11	28.089	16.831	-11.258	(-24.0749, 1.5594)	5.7524
I-SD + I-HD Total	51	47.083	34.813	-12.270	(-19.5298, -5.0110)	3.6142
I-HD-OL	6	47.093	47.343	0.250	(-20.7508, 21.2511)	8.1697
I-HD-OL/-	1	57.143	62.353	5.210		0.0000
I-HD-OL/M-SD	1	0.000	10.000	10.000		0.0000
I-HD-OL/M-HD	4	56.354	52.927	-3.427	(-42.7123, 35.8578)	12.3443
M-SD Total	15	48.114	32.728	-15.386	(-33.3576, 2.5853)	8.3791
M-HD Total	23	36.104	28.743	-7.361	(-16.6645, 1.9416)	4.4858
M-SD + M-HD Total	38	40.845	30.316	-10.529	(-19.1599, -1.8983)	4.2596

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 2						
I-SD	22	46.973	32.660	-14.313	(-25.4994, -3.1265)	5.3791
I-SD/-	7	55.079	41.429	-13.651	(-36.3349, 9.0333)	9.2705
I-SD/M-PL	3	53.333	40.000	-13.333	(-70.7020, 44.0354)	13.3333
I-SD/M-SD	4	47.962	28.879	-19.082	(-71.7865, 33.6218)	16.5609
I-SD/M-HD	8	37.000	24.125	-12.875	(-35.8506, 10.1006)	9.7164
I-HD	33	47.692	25.845	-21.848	(-30.5273, -13.1678)	4.2612
I-HD/-	4	64.063	39.000	-25.063	(-55.5674, 5.4424)	9.5853
I-HD/M-PL	6	54.720	29.736	-24.984	(-52.5054, 2.5369)	10.7062
I-HD/M-SD	12	56.691	29.688	-27.003	(-45.8998, -8.1070)	8.5854
I-HD/M-HD	11	28.089	14.746	-13.343	(-26.2456, -0.4403)	5.7908
I-SD + I-HD Total	55	47.404	28.571	-18.834	(-25.5461, -12.1213)	3.3480
I-HD-OL	6	47.093	36.841	-10.252	(-31.6227, 11.1182)	8.3135
I-HD-OL/-	1	57.143	61.379	4.236		0.0000
I-HD-OL/M-SD	1	0.000	20.000	20.000		0.0000
I-HD-OL/M-HD	4	56.354	34.917	-21.438	(-40.8794, -1.9956)	6.1091
M-SD Total	17	51.302	28.927	-22.375	(-38.1786, -6.5709)	7.4550
M-HD Total	23	36.104	21.516	-14.588	(-23.6454, -5.5305)	4.3674
M-SD + M-HD Total	40	42.563	24.666	-17.897	(-26.0528, -9.7418)	4.0320

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 4						
I-SD	22	46.973	29.331	-17.642	(-30.4356, -4.8477)	6.1521
I-SD/-	7	55.079	42.592	-12.488	(-35.4517, 10.4766)	9.3850
I-SD/M-PL	3	53.333	43.333	-10.000	(-99.5669, 79.5669)	20.8167
I-SD/M-SD	4	47.962	20.000	-27.962	(-66.2793, 10.3560)	12.0403
I-SD/M-HD	8	37.000	17.143	-19.857	(-49.1955, 9.4812)	12.4072
I-HD	33	47.692	27.235	-20.457	(-30.9730, -9.9418)	5.1625
I-HD/-	4	64.063	39.000	-25.063	(-62.1252, 12.0002)	11.6460
I-HD/M-PL	6	54.720	33.179	-21.541	(-52.8604, 9.7777)	12.1837
I-HD/M-SD	12	56.691	33.431	-23.260	(-48.5004, 1.9803)	11.4678
I-HD/M-HD	11	28.089	12.955	-15.134	(-28.9114, -1.3568)	6.1833
I-SD + I-HD Total	55	47.404	28.073	-19.331	(-27.1985, -11.4637)	3.9241
I-HD-OL	6	47.093	32.417	-14.677	(-49.6736, 20.3204)	13.6144
I-HD-OL/-	1	57.143	82.500	25.357		0.0000
I-HD-OL/M-SD	1	0.000	10.000	10.000		0.0000
I-HD-OL/M-HD	4	56.354	25.500	-30.854	(-74.9331, 13.2248)	13.8507
M-SD Total	17	51.302	28.892	-22.410	(-40.7152, -4.1044)	8.6350
M-HD Total	23	36.104	16.593	-19.511	(-31.1196, -7.9021)	5.5976
M-SD + M-HD Total	40	42.563	21.820	-20.743	(-30.4890, -10.9968)	4.8184

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 8						
I-SD	22	46.973	27.866	-19.107	(-31.0191, -7.1943)	5.7282
I-SD/-	7	55.079	49.008	-6.072	(-26.1403, 13.9970)	8.2016
I-SD/M-PL	3	53.333	26.667	-26.667	(-89.1828, 35.8494)	14.5297
I-SD/M-SD	4	47.962	15.000	-32.962	(-87.7571, 21.8338)	17.2180
I-SD/M-HD	8	37.000	16.250	-20.750	(-43.8829, 2.3829)	9.7829
I-HD	33	47.692	17.792	-29.900	(-39.7914, -20.0094)	4.8558
I-HD/-	4	64.063	40.000	-24.063	(-78.0082, 29.8832)	16.9510
I-HD/M-PL	6	54.720	28.750	-25.970	(-54.9021, 2.9613)	11.2549
I-HD/M-SD	12	56.691	13.598	-43.093	(-62.1805, -24.0062)	8.6721
I-HD/M-HD	11	28.089	8.314	-19.775	(-33.6713, -5.8779)	6.2369
I-SD + I-HD Total	55	47.404	21.821	-25.583	(-33.0860, -18.0798)	3.7424
I-HD-OL	7	44.651	30.136	-14.515	(-36.6539, 7.6232)	9.0475
I-HD-OL/-	1	57.143	80.952	23.810		0.0000
I-HD-OL/M-SD	2	15.000	5.000	-10.000	(-264.1241, 244.1241)	20.0000
I-HD-OL/M-HD	4	56.354	30.000	-26.354	(-48.2460, -4.4623)	6.8789
M-SD Total	18	50.119	12.954	-37.165	(-52.5410, -21.7886)	7.2879
M-HD Total	23	36.104	14.846	-21.258	(-30.6314, -11.8849)	4.5197
M-SD + M-HD Total	41	42.257	14.015	-28.242	(-36.7615, -19.7216)	4.2155

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 12						
I-SD	15	43.190	20.000	-23.190	(-41.5453, -4.8343)	8.5582
I-SD/M-PL	3	53.333	36.667	-16.667	(-88.3775, 55.0442)	16.6667
I-SD/M-SD	4	47.962	17.500	-30.462	(-87.7734, 26.8501)	18.0087
I-SD/M-HD	8	37.000	15.000	-22.000	(-52.7531, 8.7531)	13.0055
I-HD	29	45.434	17.572	-27.862	(-40.1998, -15.5237)	6.0233
I-HD/M-PL	6	54.720	25.079	-29.641	(-60.0787, 0.7966)	11.8408
I-HD/M-SD	12	56.691	18.000	-38.691	(-63.4796, -13.9022)	11.2625
I-HD/M-HD	11	28.089	13.011	-15.078	(-30.5225, 0.3673)	6.9317
I-SD + I-HD Total	44	44.669	18.400	-26.269	(-36.1104, -16.4277)	4.8799
I-HD-OL	7	49.947	32.071	-17.875	(-32.5706, -3.1801)	6.0056
I-HD-OL/M-SD	3	41.404	30.000	-11.404	(-61.4519, 38.6449)	11.6320
I-HD-OL/M-HD	4	56.354	33.625	-22.729	(-42.9222, -2.5361)	6.3451
M-SD Total	19	52.439	19.789	-32.650	(-49.9754, -15.3244)	8.2466
M-HD Total	23	36.104	17.288	-18.816	(-30.3078, -7.3244)	5.5412
M-SD + M-HD Total	42	43.494	18.420	-25.074	(-34.9029, -15.2456)	4.8668

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 18						
I-SD	15	43.190	19.000	-24.190	(-45.5200, -2.8595)	9.9452
I-SD/M-PL	3	53.333	20.000	-33.333	(-85.0448, 18.3781)	12.0185
I-SD/M-SD	4	47.962	31.250	-16.712	(-99.5288, 66.1055)	26.0231
I-SD/M-HD	8	37.000	12.500	-24.500	(-58.0928, 9.0928)	14.2064
I-HD	29	45.434	17.682	-27.753	(-39.5956, -15.9095)	5.7816
I-HD/M-PL	6	54.720	31.052	-23.669	(-59.8295, 12.4919)	14.0671
I-HD/M-SD	12	56.691	19.583	-37.108	(-59.5113, -14.7038)	10.1790
I-HD/M-HD	11	28.089	8.314	-19.775	(-35.7841, -3.7651)	7.1851
I-SD + I-HD Total	44	44.669	18.131	-26.538	(-36.6998, -16.3761)	5.0389
I-HD-OL	7	49.947	30.429	-19.518	(-34.2557, -4.7807)	6.0229
I-HD-OL/M-SD	3	41.404	30.000	-11.404	(-61.4519, 38.6449)	11.6320
I-HD-OL/M-HD	4	56.354	30.750	-25.604	(-43.1809, -8.0274)	5.5230
M-SD Total	19	52.439	23.684	-28.755	(-46.6945, -10.8158)	8.5388
M-HD Total	23	36.104	13.672	-22.432	(-34.6280, -10.2361)	5.8807
M-SD + M-HD Total	42	43.494	18.201	-25.293	(-35.3668, -15.2182)	4.9884

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 26						
I-SD	15	43.190	15.067	-28.123	(-48.9806, -7.2656)	9.7247
I-SD/M-PL	3	53.333	20.000	-33.333	(-71.2792, 4.6125)	8.8192
I-SD/M-SD	4	47.962	29.000	-18.962	(-102.5639, 64.6406)	26.2698
I-SD/M-HD	8	37.000	6.250	-30.750	(-63.3433, 1.8433)	13.7837
I-HD	29	45.434	17.972	-27.462	(-40.4653, -14.4586)	6.3480
I-HD/M-PL	6	54.720	23.413	-31.308	(-59.8424, -2.7730)	11.1005
I-HD/M-SD	12	56.691	24.028	-32.663	(-61.2384, -4.0879)	12.9829
I-HD/M-HD	11	28.089	8.398	-19.690	(-35.7264, -3.6541)	7.1971
I-SD + I-HD Total	44	44.669	16.982	-27.687	(-38.3193, -17.0554)	5.2720
I-HD-OL	7	49.947	27.568	-22.379	(-43.7754, -0.9829)	8.7442
I-HD-OL/M-SD	3	41.404	30.000	-11.404	(-61.4519, 38.6449)	11.6320
I-HD-OL/M-HD	4	56.354	25.743	-30.611	(-69.2298, 8.0080)	12.1350
M-SD Total	19	52.439	26.018	-26.422	(-46.9680, -5.8756)	9.7796
M-HD Total	23	36.104	10.668	-25.436	(-38.0777, -12.7950)	6.0955
M-SD + M-HD Total	42	43.494	17.612	-25.882	(-36.9286, -14.8357)	5.4698

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 34						
I-SD	15	43.190	16.768	-26.422	(-47.6812, -5.1627)	9.9121
I-SD/M-PL	3	53.333	20.000	-33.333	(-71.2792, 4.6125)	8.8192
I-SD/M-SD	4	47.962	32.879	-15.082	(-97.7145, 67.5498)	25.9650
I-SD/M-HD	8	37.000	7.500	-29.500	(-63.1522, 4.1522)	14.2315
I-HD	29	45.434	17.940	-27.494	(-40.5751, -14.4128)	6.3860
I-HD/M-PL	6	54.720	23.413	-31.308	(-59.8424, -2.7730)	11.1005
I-HD/M-SD	12	56.691	24.028	-32.663	(-61.5107, -3.8156)	13.1066
I-HD/M-HD	11	28.089	8.314	-19.775	(-35.7841, -3.7651)	7.1851
I-SD + I-HD Total	44	44.669	17.540	-27.128	(-37.8783, -16.3787)	5.3304
I-HD-OL	7	49.947	20.238	-29.709	(-56.5250, -2.8923)	10.9593
I-HD-OL/M-SD	3	41.404	10.000	-31.404	(-136.0424, 73.2353)	24.3196
I-HD-OL/M-HD	4	56.354	27.917	-28.438	(-63.7885, 6.9135)	11.1081
M-SD Total	19	52.439	23.676	-28.763	(-50.0973, -7.4288)	10.1547
M-HD Total	23	36.104	11.440	-24.664	(-37.3750, -11.9529)	6.1291
M-SD + M-HD Total	42	43.494	16.976	-26.518	(-37.8745, -15.1620)	5.6232

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 42						
I-SD	15	43.190	14.101	-29.089	(-51.5404, -6.6369)	10.4681
I-SD/M-PL	3	53.333	6.667	-46.667	(-109.1828, 15.8494)	14.5297
I-SD/M-SD	4	47.962	30.379	-17.582	(-100.0783, 64.9136)	25.9222
I-SD/M-HD	8	37.000	8.750	-28.250	(-63.1797, 6.6797)	14.7718
I-HD	29	45.434	18.492	-26.942	(-39.8686, -14.0158)	6.3105
I-HD/M-PL	6	54.720	23.413	-31.308	(-59.8424, -2.7730)	11.1005
I-HD/M-SD	12	56.691	24.028	-32.663	(-61.3153, -4.0110)	13.0179
I-HD/M-HD	11	28.089	9.769	-18.320	(-33.2584, -3.3817)	6.7044
I-SD + I-HD Total	44	44.669	16.995	-27.674	(-38.5860, -16.7619)	5.4109
I-HD-OL	7	49.947	14.286	-35.661	(-60.4712, -10.8508)	10.1394
I-HD-OL/M-SD	3	41.404	10.000	-31.404	(-136.0424, 73.2353)	24.3196
I-HD-OL/M-HD	4	56.354	17.500	-38.854	(-62.7064, -15.0019)	7.4949
M-SD Total	19	52.439	23.150	-29.289	(-50.4454, -8.1333)	10.0699
M-HD Total	23	36.104	10.759	-25.345	(-38.1128, -12.5774)	6.1564
M-SD + M-HD Total	42	43.494	16.364	-27.129	(-38.4407, -15.8181)	5.6009

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 52						
I-SD	15	43.190	19.071	-24.119	(-44.9224, -3.3155)	9.6996
I-SD/M-PL	3	53.333	21.515	-31.818	(-74.9039, 11.2676)	10.0138
I-SD/M-SD	4	47.962	30.379	-17.582	(-100.0783, 64.9136)	25.9222
I-SD/M-HD	8	37.000	12.500	-24.500	(-57.2500, 8.2500)	13.8500
I-HD	29	45.434	17.998	-27.436	(-40.7526, -14.1204)	6.5007
I-HD/M-PL	6	54.720	23.413	-31.308	(-59.8424, -2.7730)	11.1005
I-HD/M-SD	12	56.691	22.361	-34.330	(-64.0952, -4.5644)	13.5237
I-HD/M-HD	11	28.089	10.284	-17.805	(-32.5172, -3.0926)	6.6030
I-SD + I-HD Total	44	44.669	18.363	-26.305	(-37.0974, -15.5135)	5.3513
I-HD-OL	7	49.947	16.429	-33.518	(-59.0279, -8.0085)	10.4253
I-HD-OL/M-SD	3	41.404	6.667	-34.737	(-152.1957, 82.7220)	27.2992
I-HD-OL/M-HD	4	56.354	23.750	-32.604	(-41.1013, -24.1070)	2.6700
M-SD Total	19	52.439	21.571	-30.868	(-52.8886, -8.8480)	10.4813
M-HD Total	23	36.104	13.397	-22.707	(-34.4800, -10.9348)	5.6766
M-SD + M-HD Total	42	43.494	17.095	-26.399	(-37.7679, -15.0305)	5.6293

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%)						
Week 1						
I-SD	20	12.266	4.842	-7.424	(-15.5656, 0.7181)	3.8900
I-SD/-	5	20.667	5.818	-14.848	(-42.5108, 12.8138)	9.9632
I-SD/M-PL	3	0.000	5.556	5.556	(-18.3481, 29.4592)	5.5556
I-SD/M-SD	4	12.997	2.708	-10.289	(-38.7282, 18.1505)	8.9363
I-SD/M-HD	8	11.250	5.032	-6.218	(-19.6088, 7.1729)	5.6630
I-HD	32	12.779	7.539	-5.240	(-10.3482, -0.1315)	2.5047
I-HD/-	4	31.696	28.571	-3.125	(-13.0701, 6.8201)	3.1250
I-HD/M-PL	6	8.191	1.699	-6.492	(-17.1682, 4.1841)	4.1532
I-HD/M-SD	11	12.860	7.133	-5.727	(-21.0584, 9.6039)	6.8807
I-HD/M-HD	11	8.322	3.483	-4.838	(-8.8080, -0.8688)	1.7816
I-SD + I-HD Total	52	12.582	6.502	-6.080	(-10.3560, -1.8036)	2.1300
I-HD-OL	6	18.909	17.750	-1.159	(-34.2100, 31.8918)	12.8574
I-HD-OL/-	1	14.286	5.882	-8.403		0.0000
I-HD-OL/M-SD	1	0.000	0.000	0.000		
I-HD-OL/M-HD	4	24.792	25.154	0.362	(-63.9219, 64.6462)	20.1996
M-SD Total	16	12.091	5.581	-6.510	(-17.4062, 4.3868)	5.1122
M-HD Total	23	12.205	7.791	-4.414	(-12.2153, 3.3878)	3.7618
M-SD + M-HD Total	39	12.158	6.884	-5.274	(-11.3778, 0.8305)	3.0153

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 2						
I-SD	22	11.656	5.313	-6.343	(-13.9083, 1.2231)	3.6380
I-SD/-	7	16.349	5.714	-10.635	(-27.5604, 6.2905)	6.9171
I-SD/M-PL	3	0.000	0.000	0.000		
I-SD/M-SD	4	12.997	6.724	-6.273	(-43.4897, 30.9437)	11.6944
I-SD/M-HD	8	11.250	6.250	-5.000	(-19.8211, 9.8211)	6.2678
I-HD	33	13.301	6.257	-7.044	(-11.3883, -2.7005)	2.1326
I-HD/-	4	31.696	30.000	-1.696	(-26.8361, 23.4432)	7.8995
I-HD/M-PL	6	8.191	2.269	-5.922	(-17.1293, 5.2848)	4.3597
I-HD/M-SD	12	14.289	3.244	-11.045	(-19.9549, -2.1344)	4.0483
I-HD/M-HD	11	8.322	3.084	-5.237	(-11.8544, 1.3800)	2.9698
I-SD + I-HD Total	55	12.643	5.879	-6.764	(-10.6086, -2.9187)	1.9178
I-HD-OL	6	18.909	6.686	-12.223	(-30.7964, 6.3506)	7.2254
I-HD-OL/-	1	14.286	3.448	-10.837		0.0000
I-HD-OL/M-SD	1	0.000	0.000	0.000		
I-HD-OL/M-HD	4	24.792	9.167	-15.625	(-49.6114, 18.3614)	10.6793
M-SD Total	17	13.144	3.872	-9.272	(-17.3651, -1.1794)	3.8176
M-HD Total	23	12.205	5.243	-6.961	(-13.4166, -0.5060)	3.1127
M-SD + M-HD Total	40	12.604	4.661	-7.943	(-12.7798, -3.1071)	2.3911

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 4						
I-SD	22	11.656	3.831	-7.825	(-16.9933, 1.3436)	4.4087
I-SD/-	7	16.349	11.020	-5.329	(-33.6101, 22.9525)	11.5580
I-SD/M-PL	3	0.000	0.000	0.000		
I-SD/M-SD	4	12.997	0.000	-12.997	(-40.4160, 14.4216)	8.6156
I-SD/M-HD	8	11.250	0.893	-10.357	(-24.8128, 4.0985)	6.1133
I-HD	33	13.301	10.266	-3.035	(-8.3150, 2.2457)	2.5923
I-HD/-	4	31.696	30.000	-1.696	(-26.8361, 23.4432)	7.8995
I-HD/M-PL	6	8.191	5.693	-2.498	(-15.5414, 10.5449)	5.0740
I-HD/M-SD	12	14.289	13.303	-0.986	(-14.1198, 12.1480)	5.9673
I-HD/M-HD	11	8.322	2.273	-6.049	(-11.7325, -0.3653)	2.5508
I-SD + I-HD Total	55	12.643	7.692	-4.951	(-9.6590, -0.2425)	2.3484
I-HD-OL	6	18.909	5.417	-13.492	(-41.3038, 14.3196)	10.8192
I-HD-OL/-	1	14.286	12.500	-1.786		0.0000
I-HD-OL/M-SD	1	0.000	0.000	0.000		
I-HD-OL/M-HD	4	24.792	5.000	-19.792	(-70.3937, 30.8103)	15.9004
M-SD Total	17	13.144	9.390	-3.754	(-13.7428, 6.2346)	4.7119
M-HD Total	23	12.205	2.267	-9.937	(-17.3123, -2.5627)	3.5561
M-SD + M-HD Total	40	12.604	5.294	-7.310	(-13.1060, -1.5131)	2.8657

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 8						
I-SD	22	11.656	5.217	-6.439	(-14.8965, 2.0184)	4.0668
I-SD/-	7	16.349	13.539	-2.810	(-30.1191, 24.4992)	11.1607
I-SD/M-PL	3	0.000	0.000	0.000		
I-SD/M-SD	4	12.997	0.000	-12.997	(-40.4160, 14.4216)	8.6156
I-SD/M-HD	8	11.250	2.500	-8.750	(-19.1704, 1.6704)	4.4068
I-HD	33	13.301	4.286	-9.015	(-14.0676, -3.9616)	2.4807
I-HD/-	4	31.696	25.000	-6.696	(-19.0549, 5.6621)	3.8833
I-HD/M-PL	6	8.191	4.167	-4.024	(-19.2553, 11.2071)	5.9252
I-HD/M-SD	12	14.289	1.220	-13.069	(-25.0134, -1.1251)	5.4267
I-HD/M-HD	11	8.322	0.165	-8.156	(-14.8764, -1.4363)	3.0160
I-SD + I-HD Total	55	12.643	4.659	-7.984	(-12.3724, -3.5963)	2.1887
I-HD-OL	7	16.207	0.680	-15.527	(-37.5550, 6.5006)	9.0023
I-HD-OL/-	1	14.286	4.762	-9.524		0.0000
I-HD-OL/M-SD	2	0.000	0.000	0.000		
I-HD-OL/M-HD	4	24.792	0.000	-24.792	(-71.1123, 21.5289)	14.5550
M-SD Total	18	12.414	0.813	-11.601	(-20.1982, -3.0039)	4.0748
M-HD Total	23	12.205	0.949	-11.256	(-18.1051, -4.4067)	3.3026
M-SD + M-HD Total	41	12.297	0.889	-11.407	(-16.5460, -6.2689)	2.5425

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 12						
I-SD	15	9.466	0.000	-9.466	(-17.7362, -1.1957)	3.8560
I-SD/M-PL	3	0.000	0.000	0.000		
I-SD/M-SD	4	12.997	0.000	-12.997	(-40.4160, 14.4216)	8.6156
I-SD/M-HD	8	11.250	0.000	-11.250	(-24.9781, 2.4781)	5.8056
I-HD	29	10.764	1.874	-8.889	(-14.4742, -3.3044)	2.7264
I-HD/M-PL	6	8.191	2.646	-5.545	(-16.3270, 5.2365)	4.1943
I-HD/M-SD	12	14.289	1.667	-12.622	(-24.7326, -0.5115)	5.5023
I-HD/M-HD	11	8.322	1.680	-6.641	(-14.0675, 0.7851)	3.3330
I-SD + I-HD Total	44	10.321	1.235	-9.086	(-13.5237, -4.6481)	2.2005
I-HD-OL	7	24.317	6.429	-17.888	(-43.7755, 7.9986)	10.5795
I-HD-OL/M-SD	3	23.684	0.000	-23.684	(-125.5891, 78.2207)	23.6842
I-HD-OL/M-HD	4	24.792	11.250	-13.542	(-44.8158, 17.7324)	9.8271
M-SD Total	19	15.500	1.053	-14.448	(-24.9567, -3.9387)	5.0021
M-HD Total	23	12.205	2.760	-9.444	(-15.5931, -3.2956)	2.9649
M-SD + M-HD Total	42	13.695	1.988	-11.708	(-17.3131, -6.1025)	2.7755

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 18						
I-SD	15	9.466	3.333	-6.133	(-16.8971, 4.6320)	5.0189
I-SD/M-PL	3	0.000	0.000	0.000		
I-SD/M-SD	4	12.997	12.500	-0.497	(-50.4200, 49.4257)	15.6870
I-SD/M-HD	8	11.250	0.000	-11.250	(-24.9781, 2.4781)	5.8056
I-HD	29	10.764	3.675	-7.089	(-13.2654, -0.9117)	3.0154
I-HD/M-PL	6	8.191	4.960	-3.230	(-17.5574, 11.0965)	5.5734
I-HD/M-SD	12	14.289	6.250	-8.039	(-22.0356, 5.9581)	6.3594
I-HD/M-HD	11	8.322	0.165	-8.156	(-14.8764, -1.4363)	3.0160
I-SD + I-HD Total	44	10.321	3.559	-6.763	(-11.9839, -1.5413)	2.5890
I-HD-OL	7	24.317	1.429	-22.888	(-49.9805, 4.2035)	11.0719
I-HD-OL/M-SD	3	23.684	0.000	-23.684	(-125.5891, 78.2207)	23.6842
I-HD-OL/M-HD	4	24.792	2.500	-22.292	(-61.0480, 16.4646)	12.1781
M-SD Total	19	15.500	6.579	-8.921	(-21.6755, 3.8327)	6.0707
M-HD Total	23	12.205	0.514	-11.691	(-18.3748, -5.0066)	3.2230
M-SD + M-HD Total	42	13.695	3.258	-10.438	(-16.9564, -3.9194)	3.2277

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 26						
I-SD	15	9.466	2.667	-6.799	(-17.6481, 4.0496)	5.0582
I-SD/M-PL	3	0.000	0.000	0.000		
I-SD/M-SD	4	12.997	10.000	-2.997	(-54.3990, 48.4047)	16.1517
I-SD/M-HD	8	11.250	0.000	-11.250	(-24.9781, 2.4781)	5.8056
I-HD	29	10.764	3.519	-7.245	(-13.5084, -0.9807)	3.0579
I-HD/M-PL	6	8.191	2.646	-5.545	(-16.3270, 5.2365)	4.1943
I-HD/M-SD	12	14.289	6.944	-7.344	(-22.2105, 7.5220)	6.7544
I-HD/M-HD	11	8.322	0.259	-8.063	(-14.8421, -1.2831)	3.0427
I-SD + I-HD Total	44	10.321	3.229	-7.093	(-12.3725, -1.8130)	2.6180
I-HD-OL	7	24.317	6.178	-18.139	(-41.5672, 5.2883)	9.5744
I-HD-OL/M-SD	3	23.684	0.000	-23.684	(-125.5891, 78.2207)	23.6842
I-HD-OL/M-HD	4	24.792	10.811	-13.981	(-30.4931, 2.5313)	5.1885
M-SD Total	19	15.500	6.491	-9.009	(-22.1314, 4.1132)	6.2460
M-HD Total	23	12.205	2.004	-10.201	(-15.5329, -4.8682)	2.5712
M-SD + M-HD Total	42	13.695	4.034	-9.662	(-15.9511, -3.3720)	3.1144

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 34						
I-SD	15	9.466	3.126	-6.339	(-17.1099, 4.4310)	5.0217
I-SD/M-PL	3	0.000	0.000	0.000		
I-SD/M-SD	4	12.997	11.724	-1.273	(-51.5249, 48.9789)	15.7903
I-SD/M-HD	8	11.250	0.000	-11.250	(-24.9781, 2.4781)	5.8056
I-HD	29	10.764	3.484	-7.280	(-13.5374, -1.0228)	3.0547
I-HD/M-PL	6	8.191	2.646	-5.545	(-16.3270, 5.2365)	4.1943
I-HD/M-SD	12	14.289	6.944	-7.344	(-22.2105, 7.5220)	6.7544
I-HD/M-HD	11	8.322	0.165	-8.156	(-14.8764, -1.4363)	3.0160
I-SD + I-HD Total	44	10.321	3.362	-6.959	(-12.2215, -1.6973)	2.6093
I-HD-OL	7	24.317	5.238	-19.079	(-47.1112, 8.9533)	11.4562
I-HD-OL/M-SD	3	23.684	0.000	-23.684	(-125.5891, 78.2207)	23.6842
I-HD-OL/M-HD	4	24.792	9.167	-15.625	(-57.0706, 25.8206)	13.0232
M-SD Total	19	15.500	6.854	-8.646	(-21.7457, 4.4534)	6.2351
M-HD Total	23	12.205	1.673	-10.531	(-17.1110, -3.9516)	3.1727
M-SD + M-HD Total	42	13.695	4.017	-9.678	(-16.2847, -3.0722)	3.2712

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 42						
I-SD	15	9.466	3.126	-6.339	(-17.1099, 4.4310)	5.0217
I-SD/M-PL	3	0.000	0.000	0.000		
I-SD/M-SD	4	12.997	11.724	-1.273	(-51.5249, 48.9789)	15.7903
I-SD/M-HD	8	11.250	0.000	-11.250	(-24.9781, 2.4781)	5.8056
I-HD	29	10.764	4.173	-6.590	(-12.7131, -0.4678)	2.9890
I-HD/M-PL	6	8.191	2.646	-5.545	(-16.3270, 5.2365)	4.1943
I-HD/M-SD	12	14.289	6.944	-7.344	(-22.2105, 7.5220)	6.7544
I-HD/M-HD	11	8.322	1.983	-6.338	(-11.9205, -0.7558)	2.5054
I-SD + I-HD Total	44	10.321	3.816	-6.505	(-11.6990, -1.3108)	2.5756
I-HD-OL	7	24.317	2.857	-21.460	(-46.9528, 4.0330)	10.4184
I-HD-OL/M-SD	3	23.684	0.000	-23.684	(-125.5891, 78.2207)	23.6842
I-HD-OL/M-HD	4	24.792	5.000	-19.792	(-51.1780, 11.5947)	9.8623
M-SD Total	19	15.500	6.854	-8.646	(-21.7457, 4.4534)	6.2351
M-HD Total	23	12.205	1.818	-10.386	(-16.4216, -4.3511)	2.9101
M-SD + M-HD Total	42	13.695	4.096	-9.599	(-16.0579, -3.1404)	3.1981

表 2.7.3.6-140. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 52						
I-SD	15	9.466	10.096	0.630	(-13.6947, 14.9551)	6.6789
I-SD/M-PL	3	0.000	18.182	18.182	(-60.0482, 96.4119)	18.1818
I-SD/M-SD	4	12.997	11.724	-1.273	(-51.5249, 48.9789)	15.7903
I-SD/M-HD	8	11.250	6.250	-5.000	(-22.8749, 12.8749)	7.5593
I-HD	29	10.764	4.058	-6.705	(-12.8281, -0.5827)	2.9890
I-HD/M-PL	6	8.191	2.646	-5.545	(-16.3270, 5.2365)	4.1943
I-HD/M-SD	12	14.289	6.944	-7.344	(-22.2105, 7.5220)	6.7544
I-HD/M-HD	11	8.322	1.680	-6.641	(-12.2283, -1.0540)	2.5075
I-SD + I-HD Total	44	10.321	6.117	-4.205	(-10.2771, 1.8678)	3.0111
I-HD-OL	7	24.317	5.238	-19.079	(-45.3614, 7.2035)	10.7411
I-HD-OL/M-SD	3	23.684	0.000	-23.684	(-125.5891, 78.2207)	23.6842
I-HD-OL/M-HD	4	24.792	9.167	-15.625	(-49.6114, 18.3614)	10.6793
M-SD Total	19	15.500	6.854	-8.646	(-21.7457, 4.4534)	6.2351
M-HD Total	23	12.205	4.572	-7.633	(-14.5209, -0.7446)	3.3214
M-SD + M-HD Total	42	13.695	5.604	-8.091	(-14.7798, -1.4026)	3.3119

Note: I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group, M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
Note: baseline is defined as the last non-missing value prior to the first dose of study drug. Subjects with non-missing baseline and at least one post-baseline value are included in the analyses.
Last observation carried forward (LOCF): missing data is imputed by carrying forward the last non-missing post-baseline observation. For subjects re-randomized due to disease flare, the last non-missing value before the re-randomization after the first disease flare are carried forward.
WPAI = work productivity and activity impairment.

Cross reference: M11-290 CSR_Final Table 14.2__1.3.8_A

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%)						
Week 1						
I-SD	1	40.0	30.0	-10.0		0.00
I-SD/-	1	40.0	30.0	-10.0		0.00
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	37.5	12.5	-25.0	(-62.88, 12.88)	11.90
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	50.0	-20.0		0.00
I-HD/M-HD	3	26.7	0.0	-26.7	(-98.38, 45.04)	16.67
I-SD + I-HD Total	5	38.0	16.0	-22.0	(-48.92, 4.92)	9.70
I-HD-OL	2	30.0	35.0	5.0	(-58.53, 68.53)	5.00
I-HD-OL/-	0					
I-HD-OL/M-SD	1	50.0	60.0	10.0		0.00
I-HD-OL/M-HD	1	10.0	10.0	0.0		
M-SD Total	2	60.0	55.0	-5.0	(-195.59, 185.59)	15.00
M-HD Total	4	22.5	2.5	-20.0	(-63.09, 23.09)	13.54
M-SD + M-HD Total	6	35.0	20.0	-15.0	(-40.49, 10.49)	9.92

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 2						
I-SD	2	35.0	40.0	5.0	(-58.53, 68.53)	5.00
I-SD/-	2	35.0	40.0	5.0	(-58.53, 68.53)	5.00
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	37.5	12.5	-25.0	(-62.88, 12.88)	11.90
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	50.0	-20.0		0.00
I-HD/M-HD	3	26.7	0.0	-26.7	(-98.38, 45.04)	16.67
I-SD + I-HD Total	6	36.7	21.7	-15.0	(-40.49, 10.49)	9.92
I-HD-OL	2	30.0	35.0	5.0	(-58.53, 68.53)	5.00
I-HD-OL/-	0					
I-HD-OL/M-SD	1	50.0	60.0	10.0		0.00
I-HD-OL/M-HD	1	10.0	10.0	0.0		
M-SD Total	2	60.0	55.0	-5.0	(-195.59, 185.59)	15.00
M-HD Total	4	22.5	2.5	-20.0	(-63.09, 23.09)	13.54
M-SD + M-HD Total	6	35.0	20.0	-15.0	(-40.49, 10.49)	9.92

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 4						
I-SD	2	35.0	35.0	0.0		
I-SD/-	2	35.0	35.0	0.0		
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	37.5	22.5	-15.0	(-64.47, 34.47)	15.55
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	80.0	10.0		0.00
I-HD/M-HD	3	26.7	3.3	-23.3	(-103.19, 56.52)	18.56
I-SD + I-HD Total	6	36.7	26.7	-10.0	(-36.55, 16.55)	10.33
I-HD-OL	2	30.0	40.0	10.0	(-117.06, 137.06)	10.00
I-HD-OL/-	0					
I-HD-OL/M-SD	1	50.0	70.0	20.0		0.00
I-HD-OL/M-HD	1	10.0	10.0	0.0		
M-SD Total	2	60.0	75.0	15.0	(-48.53, 78.53)	5.00
M-HD Total	4	22.5	5.0	-17.5	(-63.20, 28.20)	14.36
M-SD + M-HD Total	6	35.0	28.3	-6.7	(-36.10, 22.77)	11.45

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 8						
I-SD	2	35.0	25.0	-10.0	(-137.06, 117.06)	10.00
I-SD/-	2	35.0	25.0	-10.0	(-137.06, 117.06)	10.00
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	37.5	2.5	-35.0	(-90.88, 20.88)	17.56
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	0.0	-70.0		0.00
I-HD/M-HD	3	26.7	3.3	-23.3	(-103.19, 56.52)	18.56
I-SD + I-HD Total	6	36.7	10.0	-26.7	(-58.96, 5.62)	12.56
I-HD-OL	2	30.0	35.0	5.0	(-58.53, 68.53)	5.00
I-HD-OL/-	0					
I-HD-OL/M-SD	1	50.0	60.0	10.0		0.00
I-HD-OL/M-HD	1	10.0	10.0	0.0		
M-SD Total	2	60.0	30.0	-30.0	(-538.25, 478.25)	40.00
M-HD Total	4	22.5	5.0	-17.5	(-63.20, 28.20)	14.36
M-SD + M-HD Total	6	35.0	13.3	-21.7	(-57.67, 14.33)	14.00

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 12						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	37.5	2.5	-35.0	(-90.88, 20.88)	17.56
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	0.0	-70.0		0.00
I-HD/M-HD	3	26.7	3.3	-23.3	(-103.19, 56.52)	18.56
I-SD + I-HD Total	4	37.5	2.5	-35.0	(-90.88, 20.88)	17.56
I-HD-OL	2	30.0	30.0	0.0		
I-HD-OL/M-SD	1	50.0	50.0	0.0		
I-HD-OL/M-HD	1	10.0	10.0	0.0		
M-SD Total	2	60.0	25.0	-35.0	(-479.72, 409.72)	35.00
M-HD Total	4	22.5	5.0	-17.5	(-63.20, 28.20)	14.36
M-SD + M-HD Total	6	35.0	11.7	-23.3	(-57.61, 10.94)	13.33

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 18						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	37.5	2.5	-35.0	(-90.88, 20.88)	17.56
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	0.0	-70.0		0.00
I-HD/M-HD	3	26.7	3.3	-23.3	(-103.19, 56.52)	18.56
I-SD + I-HD Total	4	37.5	2.5	-35.0	(-90.88, 20.88)	17.56
I-HD-OL	2	30.0	30.0	0.0		
I-HD-OL/M-SD	1	50.0	50.0	0.0		
I-HD-OL/M-HD	1	10.0	10.0	0.0		
M-SD Total	2	60.0	25.0	-35.0	(-479.72, 409.72)	35.00
M-HD Total	4	22.5	5.0	-17.5	(-63.20, 28.20)	14.36
M-SD + M-HD Total	6	35.0	11.7	-23.3	(-57.61, 10.94)	13.33

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 26						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	37.5	5.0	-32.5	(-93.96, 28.96)	19.31
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	0.0	-70.0		0.00
I-HD/M-HD	3	26.7	6.7	-20.0	(-109.57, 69.57)	20.82
I-SD + I-HD Total	4	37.5	5.0	-32.5	(-93.96, 28.96)	19.31
I-HD-OL	2	30.0	30.0	0.0		
I-HD-OL/M-SD	1	50.0	50.0	0.0		
I-HD-OL/M-HD	1	10.0	10.0	0.0		
M-SD Total	2	60.0	25.0	-35.0	(-479.72, 409.72)	35.00
M-HD Total	4	22.5	7.5	-15.0	(-64.47, 34.47)	15.55
M-SD + M-HD Total	6	35.0	13.3	-21.7	(-57.67, 14.33)	14.00

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 34						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	37.5	2.5	-35.0	(-90.88, 20.88)	17.56
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	0.0	-70.0		0.00
I-HD/M-HD	3	26.7	3.3	-23.3	(-103.19, 56.52)	18.56
I-SD + I-HD Total	4	37.5	2.5	-35.0	(-90.88, 20.88)	17.56
I-HD-OL	2	30.0	30.0	0.0		
I-HD-OL/M-SD	1	50.0	50.0	0.0		
I-HD-OL/M-HD	1	10.0	10.0	0.0		
M-SD Total	2	60.0	25.0	-35.0	(-479.72, 409.72)	35.00
M-HD Total	4	22.5	5.0	-17.5	(-63.20, 28.20)	14.36
M-SD + M-HD Total	6	35.0	11.7	-23.3	(-57.61, 10.94)	13.33

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 42						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	37.5	2.5	-35.0	(-90.88, 20.88)	17.56
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	0.0	-70.0		0.00
I-HD/M-HD	3	26.7	3.3	-23.3	(-103.19, 56.52)	18.56
I-SD + I-HD Total	4	37.5	2.5	-35.0	(-90.88, 20.88)	17.56
I-HD-OL	2	30.0	30.0	0.0		
I-HD-OL/M-SD	1	50.0	50.0	0.0		
I-HD-OL/M-HD	1	10.0	10.0	0.0		
M-SD Total	2	60.0	25.0	-35.0	(-479.72, 409.72)	35.00
M-HD Total	4	22.5	5.0	-17.5	(-63.20, 28.20)	14.36
M-SD + M-HD Total	6	35.0	11.7	-23.3	(-57.61, 10.94)	13.33

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Activity Impairment (%) (Cont.)						
Week 52						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	37.5	2.5	-35.0	(-90.88, 20.88)	17.56
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	0.0	-70.0		0.00
I-HD/M-HD	3	26.7	3.3	-23.3	(-103.19, 56.52)	18.56
I-SD + I-HD Total	4	37.5	2.5	-35.0	(-90.88, 20.88)	17.56
I-HD-OL	2	30.0	30.0	0.0		
I-HD-OL/M-SD	1	50.0	50.0	0.0		
I-HD-OL/M-HD	1	10.0	10.0	0.0		
M-SD Total	2	60.0	25.0	-35.0	(-479.72, 409.72)	35.00
M-HD Total	4	22.5	5.0	-17.5	(-63.20, 28.20)	14.36
M-SD + M-HD Total	6	35.0	11.7	-23.3	(-57.61, 10.94)	13.33

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%)						
Week 1						
I-SD	1	40.0	10.0	-30.0		0.00
I-SD/-	1	40.0	10.0	-30.0		0.00
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	20.0	12.5	-7.5	(-22.73, 7.73)	4.79
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	50.0	-20.0		0.00
I-HD/M-HD	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
I-SD + I-HD Total	5	24.0	12.0	-12.0	(-28.19, 4.19)	5.83
I-HD-OL	0					
I-HD-OL/-	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	70.0	50.0	-20.0		0.00
M-HD Total	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
M-SD + M-HD Total	4	20.0	12.5	-7.5	(-22.73, 7.73)	4.79

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 2						
I-SD	2	20.0	30.0	10.0	(-244.12, 264.12)	20.00
I-SD/-	2	20.0	30.0	10.0	(-244.12, 264.12)	20.00
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	20.0	15.0	-5.0	(-14.19, 4.19)	2.89
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	60.0	-10.0		0.00
I-HD/M-HD	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
I-SD + I-HD Total	6	20.0	20.0	0.0	(-16.26, 16.26)	6.32
I-HD-OL	0					
I-HD-OL/-	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	70.0	60.0	-10.0		0.00
M-HD Total	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
M-SD + M-HD Total	4	20.0	15.0	-5.0	(-14.19, 4.19)	2.89

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 4						
I-SD	2	20.0	20.0	0.0	(-381.19, 381.19)	30.00
I-SD/-	2	20.0	20.0	0.0	(-381.19, 381.19)	30.00
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	20.0	22.5	2.5	(-17.52, 22.52)	6.29
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	90.0	20.0		0.00
I-HD/M-HD	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
I-SD + I-HD Total	6	20.0	21.7	1.7	(-20.76, 24.09)	8.72
I-HD-OL	0					
I-HD-OL/-	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	70.0	90.0	20.0		0.00
M-HD Total	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
M-SD + M-HD Total	4	20.0	22.5	2.5	(-17.52, 22.52)	6.29

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 8						
I-SD	2	20.0	20.0	0.0	(-381.19, 381.19)	30.00
I-SD/-	2	20.0	20.0	0.0	(-381.19, 381.19)	30.00
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	0.0	-70.0		0.00
I-HD/M-HD	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
I-SD + I-HD Total	6	20.0	6.7	-13.3	(-48.87, 22.20)	13.82
I-HD-OL	0					
I-HD-OL/-	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	70.0	0.0	-70.0		0.00
M-HD Total	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
M-SD + M-HD Total	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 12						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	0.0	-70.0		0.00
I-HD/M-HD	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
I-SD + I-HD Total	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	70.0	0.0	-70.0		0.00
M-HD Total	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
M-SD + M-HD Total	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 18						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	0.0	-70.0		0.00
I-HD/M-HD	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
I-SD + I-HD Total	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	70.0	0.0	-70.0		0.00
M-HD Total	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
M-SD + M-HD Total	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 26						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	0.0	-70.0		0.00
I-HD/M-HD	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
I-SD + I-HD Total	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	70.0	0.0	-70.0		0.00
M-HD Total	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
M-SD + M-HD Total	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 34						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	0.0	-70.0		0.00
I-HD/M-HD	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
I-SD + I-HD Total	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	70.0	0.0	-70.0		0.00
M-HD Total	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
M-SD + M-HD Total	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 42						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	0.0	-70.0		0.00
I-HD/M-HD	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
I-SD + I-HD Total	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	70.0	0.0	-70.0		0.00
M-HD Total	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
M-SD + M-HD Total	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Impairment While Working (%) (Cont.)						
Week 52						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83
I-HD/M-PL	0					
I-HD/M-SD	1	70.0	0.0	-70.0		0.00
I-HD/M-HD	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
I-SD + I-HD Total	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	70.0	0.0	-70.0		0.00
M-HD Total	3	3.3	0.0	-3.3	(-17.68, 11.01)	3.33
M-SD + M-HD Total	4	20.0	0.0	-20.0	(-73.57, 33.57)	16.83

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%)						
Week 1						
I-SD	1	40.0	10.0	-30.0		0.00
I-SD/-	1	40.0	10.0	-30.0		0.00
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	28.4	12.5	-15.9	(-46.16, 14.40)	9.52
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	88.0	50.0	-38.0		0.00
I-HD/M-HD	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
I-SD + I-HD Total	5	30.7	12.0	-18.7	(-40.62, 3.21)	7.89
I-HD-OL	0					
I-HD-OL/-	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	88.0	50.0	-38.0		0.00
M-HD Total	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
M-SD + M-HD Total	4	28.4	12.5	-15.9	(-46.16, 14.40)	9.52

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 2						
I-SD	2	20.0	30.0	10.0	(-244.12, 264.12)	20.00
I-SD/-	2	20.0	30.0	10.0	(-244.12, 264.12)	20.00
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	28.4	17.0	-11.4	(-32.59, 9.83)	6.67
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	88.0	68.0	-20.0		0.00
I-HD/M-HD	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
I-SD + I-HD Total	6	25.6	21.3	-4.3	(-24.94, 16.43)	8.05
I-HD-OL	0					
I-HD-OL/-	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	88.0	68.0	-20.0		0.00
M-HD Total	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
M-SD + M-HD Total	4	28.4	17.0	-11.4	(-32.59, 9.83)	6.67

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 4						
I-SD	2	20.0	20.0	0.0	(-381.19, 381.19)	30.00
I-SD/-	2	20.0	20.0	0.0	(-381.19, 381.19)	30.00
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	28.4	24.0	-4.4	(-27.59, 18.83)	7.29
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	88.0	96.0	8.0		0.00
I-HD/M-HD	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
I-SD + I-HD Total	6	25.6	22.7	-2.9	(-26.22, 20.38)	9.06
I-HD-OL	0					
I-HD-OL/-	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	88.0	96.0	8.0		0.00
M-HD Total	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
M-SD + M-HD Total	4	28.4	24.0	-4.4	(-27.59, 18.83)	7.29

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 8						
I-SD	2	20.0	20.0	0.0	(-381.19, 381.19)	30.00
I-SD/-	2	20.0	20.0	0.0	(-381.19, 381.19)	30.00
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	88.0	0.0	-88.0		0.00
I-HD/M-HD	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
I-SD + I-HD Total	6	25.6	6.7	-18.9	(-61.02, 23.18)	16.38
I-HD-OL	0					
I-HD-OL/-	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	88.0	0.0	-88.0		0.00
M-HD Total	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
M-SD + M-HD Total	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 12						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76
I-HD/M-PL	0					
I-HD/M-SD	1	88.0	0.0	-88.0		0.00
I-HD/M-HD	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
I-SD + I-HD Total	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	88.0	0.0	-88.0		0.00
M-HD Total	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
M-SD + M-HD Total	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 18						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76
I-HD/M-PL	0					
I-HD/M-SD	1	88.0	0.0	-88.0		0.00
I-HD/M-HD	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
I-SD + I-HD Total	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	88.0	0.0	-88.0		0.00
M-HD Total	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
M-SD + M-HD Total	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 26						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76
I-HD/M-PL	0					
I-HD/M-SD	1	88.0	0.0	-88.0		0.00
I-HD/M-HD	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
I-SD + I-HD Total	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	88.0	0.0	-88.0		0.00
M-HD Total	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
M-SD + M-HD Total	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 34						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76
I-HD/M-PL	0					
I-HD/M-SD	1	88.0	0.0	-88.0		0.00
I-HD/M-HD	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
I-SD + I-HD Total	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	88.0	0.0	-88.0		0.00
M-HD Total	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
M-SD + M-HD Total	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 42						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76
I-HD/M-PL	0					
I-HD/M-SD	1	88.0	0.0	-88.0		0.00
I-HD/M-HD	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
I-SD + I-HD Total	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	88.0	0.0	-88.0		0.00
M-HD Total	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
M-SD + M-HD Total	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Overall Work Impairment (%) (Cont.)						
Week 52						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76
I-HD/M-PL	0					
I-HD/M-SD	1	88.0	0.0	-88.0		0.00
I-HD/M-HD	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
I-SD + I-HD Total	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	88.0	0.0	-88.0		0.00
M-HD Total	3	8.5	0.0	-8.5	(-45.10, 28.09)	8.51
M-SD + M-HD Total	4	28.4	0.0	-28.4	(-94.46, 37.70)	20.76

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%)						
Week 1						
I-SD	1	0.0	0.0	0.0		
I-SD/-	1	0.0	0.0	0.0		
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	60.0	0.0	-60.0		0.00
I-HD/M-HD	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
I-SD + I-HD Total	5	15.4	0.0	-15.4	(-47.73, 16.84)	11.63
I-HD-OL	0					
I-HD-OL/-	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	60.0	0.0	-60.0		0.00
M-HD Total	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
M-SD + M-HD Total	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 2						
I-SD	2	0.0	0.0	0.0		
I-SD/-	2	0.0	0.0	0.0		
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	19.3	5.0	-14.3	(-44.48, 15.85)	9.48
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	60.0	20.0	-40.0		0.00
I-HD/M-HD	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
I-SD + I-HD Total	6	12.9	3.3	-9.5	(-26.79, 7.71)	6.71
I-HD-OL	0					
I-HD-OL/-	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	60.0	20.0	-40.0		0.00
M-HD Total	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
M-SD + M-HD Total	4	19.3	5.0	-14.3	(-44.48, 15.85)	9.48

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 4						
I-SD	2	0.0	0.0	0.0		
I-SD/-	2	0.0	0.0	0.0		
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	19.3	15.0	-4.3	(-18.03, 9.41)	4.31
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	60.0	60.0	0.0		
I-HD/M-HD	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
I-SD + I-HD Total	6	12.9	10.0	-2.9	(-10.26, 4.51)	2.87
I-HD-OL	0					
I-HD-OL/-	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	60.0	60.0	0.0		
M-HD Total	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
M-SD + M-HD Total	4	19.3	15.0	-4.3	(-18.03, 9.41)	4.31

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 8						
I-SD	2	0.0	0.0	0.0		
I-SD/-	2	0.0	0.0	0.0		
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16
I-HD/-	0					
I-HD/M-PL	0					
I-HD/M-SD	1	60.0	0.0	-60.0		0.00
I-HD/M-HD	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
I-SD + I-HD Total	6	12.9	0.0	-12.9	(-38.16, 12.41)	9.84
I-HD-OL	0					
I-HD-OL/-	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	60.0	0.0	-60.0		0.00
M-HD Total	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
M-SD + M-HD Total	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 12						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16
I-HD/M-PL	0					
I-HD/M-SD	1	60.0	0.0	-60.0		0.00
I-HD/M-HD	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
I-SD + I-HD Total	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	60.0	0.0	-60.0		0.00
M-HD Total	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
M-SD + M-HD Total	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 18						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16
I-HD/M-PL	0					
I-HD/M-SD	1	60.0	0.0	-60.0		0.00
I-HD/M-HD	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
I-SD + I-HD Total	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	60.0	0.0	-60.0		0.00
M-HD Total	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
M-SD + M-HD Total	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 26						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16
I-HD/M-PL	0					
I-HD/M-SD	1	60.0	0.0	-60.0		0.00
I-HD/M-HD	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
I-SD + I-HD Total	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	60.0	0.0	-60.0		0.00
M-HD Total	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
M-SD + M-HD Total	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 34						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16
I-HD/M-PL	0					
I-HD/M-SD	1	60.0	0.0	-60.0		0.00
I-HD/M-HD	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
I-SD + I-HD Total	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	60.0	0.0	-60.0		0.00
M-HD Total	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
M-SD + M-HD Total	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 42						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16
I-HD/M-PL	0					
I-HD/M-SD	1	60.0	0.0	-60.0		0.00
I-HD/M-HD	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
I-SD + I-HD Total	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	60.0	0.0	-60.0		0.00
M-HD Total	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
M-SD + M-HD Total	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16

表 2.7.3.6-141. 治験期間中の WPAI スコアのベースラインからの変化（LOCF）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Baseline Mean	Visit Mean	Within Group Change from Baseline: Change	95% CI	SE
WPAI - Work Time Missed (%) (Cont.)						
Week 52						
I-SD	0					
I-SD/M-PL	0					
I-SD/M-SD	0					
I-SD/M-HD	0					
I-HD	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16
I-HD/M-PL	0					
I-HD/M-SD	1	60.0	0.0	-60.0		0.00
I-HD/M-HD	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
I-SD + I-HD Total	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16
I-HD-OL	0					
I-HD-OL/M-SD	0					
I-HD-OL/M-HD	0					
M-SD Total	1	60.0	0.0	-60.0		0.00
M-HD Total	3	5.7	0.0	-5.7	(-30.48, 18.98)	5.75
M-SD + M-HD Total	4	19.3	0.0	-19.3	(-64.37, 25.75)	14.16

Note: I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group, M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
Note: baseline is defined as the last non-missing value prior to the first dose of study drug. Subjects with non-missing baseline and at least one post-baseline value are included in the analyses.
Last observation carried forward (LOCF): missing data is imputed by carrying forward the last non-missing post-baseline observation. For subjects re-randomized due to disease flare, the last non-missing value before the re-randomization after the first disease flare are carried forward.
WPAI = work productivity and activity impairment.

Cross reference: M11-290 CSR_Final Table 14.2__1.3.8_J

表 2.7.3.6-142.　治験期間中に入院した，又は結腸切除を行った被験者の割合（OC）（統合 ITT 集団，M11-290 試験）（最終 CSR）

Parameter / Timepoint / Treatment Group	N	Endpoint Met n (%)	Endpoint Met 95% CI $
Hospitalized (All Cause)			
During Induction	101	24 (23.8)	(15.86, 33.26)
I-SD	32	9 (28.1)	(13.75, 46.75)
I-HD	51	11 (21.6)	(11.29, 35.32)
I-HD-OL	18	4 (22.2)	(6.41, 47.64)
During Maintenance	80	15 (18.8)	(10.89, 29.03)
M-PL	12	1 (8.3)	(0.21, 38.48)
I-SD	4	0	(0.00, 60.24)
I-HD	8	1 (12.5)	(0.32, 52.65)
M-SD	33	8 (24.2)	(11.09, 42.26)
I-SD	8	2 (25.0)	(3.19, 65.09)
I-HD/I-HD-OL	25	6 (24.0)	(9.36, 45.13)
M-HD	35	6 (17.1)	(6.56, 33.65)
I-SD	9	2 (22.2)	(2.81, 60.01)
I-HD/I-HD-OL	26	4 (15.4)	(4.36, 34.87)

表 2.7.3.6-142.　治験期間中に入院した，又は結腸切除を行った被験者の割合（OC）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Endpoint Met n (%)	Endpoint Met 95% CI $
Hospitalized (UC-Related)			
During Induction	101	14 (13.9)	(7.79, 22.16)
I-SD	32	5 (15.6)	(5.28, 32.79)
I-HD	51	6 (11.8)	(4.44, 23.87)
I-HD-OL	18	3 (16.7)	(3.58, 41.42)
During Maintenance	80	7 (8.8)	(3.59, 17.20)
M-PL	12	0	(0.00, 26.46)
I-SD	4	0	(0.00, 60.24)
I-HD	8	0	(0.00, 36.94)
M-SD	33	6 (18.2)	(6.98, 35.46)
I-SD	8	1 (12.5)	(0.32, 52.65)
I-HD/I-HD-OL	25	5 (20.0)	(6.83, 40.70)
M-HD	35	1 (2.9)	(0.07, 14.92)
I-SD	9	1 (11.1)	(0.28, 48.25)
I-HD/I-HD-OL	26	0	(0.00, 13.23)

表 2.7.3.6-142.　治験期間中に入院した，又は結腸切除を行った被験者の割合（OC）（統合 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Endpoint Met n (%)	Endpoint Met 95% CI $
Underwent Colectomy			
During Induction	101	1 (1.0)	(0.03, 5.39)
I-SD	32	0	(0.00, 10.89)
I-HD	51	1 (2.0)	(0.05, 10.45)
I-HD-OL	18	0	(0.00, 18.53)
During Maintenance	80	0	(0.00, 4.51)
M-PL	12	0	(0.00, 26.46)
I-SD	4	0	(0.00, 60.24)
I-HD	8	0	(0.00, 36.94)
M-SD	33	0	(0.00, 10.58)
I-SD	8	0	(0.00, 36.94)
I-HD/I-HD-OL	25	0	(0.00, 13.72)
M-HD	35	0	(0.00, 10.00)
I-SD	9	0	(0.00, 33.63)
I-HD/I-HD-OL	26	0	(0.00, 13.23)

Note: I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group, M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
$ Clopper-Pearson confidence interval for proportion of patients with adjudicated event.
Observed cases (OC): missing values are not imputed for the observed case analysis. For subjects re-randomized due to disease flare, only non-missing data up to before the first disease flare is used.

Cross reference: M11-290 CSR_Final Table 14.2__1.3.28_A

表 2.7.3.6-143.　治験期間中に入院した，又は結腸切除を行った被験者の割合（OC）（日本人 ITT 集団，M11-290 試験）（最終 CSR）

Parameter / Timepoint / Treatment Group	N	Endpoint Met n (%)	Endpoint Met 95% CI $
Hospitalized (All Cause)			
During Induction	8	2 (25.0)	(3.19, 65.09)
I-SD	2	0	(0.00, 84.19)
I-HD	4	1 (25.0)	(0.63, 80.59)
I-HD-OL	2	1 (50.0)	(1.26, 98.74)
During Maintenance	6	2 (33.3)	(4.33, 77.72)
M-PL	0	0	
I-SD	0	0	
I-HD	0	0	
M-SD	2	2 (100)	(15.81, 100.00)
I-SD	0	0	
I-HD/I-HD-OL	2	2 (100)	(15.81, 100.00)
M-HD	4	0	(0.00, 60.24)
I-SD	0	0	
I-HD/I-HD-OL	4	0	(0.00, 60.24)

表 2.7.3.6-143.　治験期間中に入院した，又は結腸切除を行った被験者の割合（OC）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Endpoint Met n (%)	Endpoint Met 95% CI $
Hospitalized (UC-Related)			
During Induction	8	1 (12.5)	(0.32, 52.65)
I-SD	2	0	(0.00, 84.19)
I-HD	4	0	(0.00, 60.24)
I-HD-OL	2	1 (50.0)	(1.26, 98.74)
During Maintenance	6	1 (16.7)	(0.42, 64.12)
M-PL	0	0	
I-SD	0	0	
I-HD	0	0	
M-SD	2	1 (50.0)	(1.26, 98.74)
I-SD	0	0	
I-HD/I-HD-OL	2	1 (50.0)	(1.26, 98.74)
M-HD	4	0	(0.00, 60.24)
I-SD	0	0	
I-HD/I-HD-OL	4	0	(0.00, 60.24)

表 2.7.3.6-143.　治験期間中に入院した，又は結腸切除を行った被験者の割合（OC）（日本人 ITT 集団，M11-290 試験）（最終 CSR）（続き）

Parameter / Timepoint / Treatment Group	N	Endpoint Met n (%)	Endpoint Met 95% CI $
Underwent Colectomy			
During Induction	8	0	(0.00, 36.94)
I-SD	2	0	(0.00, 84.19)
I-HD	4	0	(0.00, 60.24)
I-HD-OL	2	0	(0.00, 84.19)
During Maintenance	6	0	(0.00, 45.93)
M-PL	0	0	
I-SD	0	0	
I-HD	0	0	
M-SD	2	0	(0.00, 84.19)
I-SD	0	0	
I-HD/I-HD-OL	2	0	(0.00, 84.19)
M-HD	4	0	(0.00, 60.24)
I-SD	0	0	
I-HD/I-HD-OL	4	0	(0.00, 60.24)

Note: I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group, M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
$ Clopper-Pearson confidence interval for proportion of patients with adjudicated event.
Observed cases (OC): missing values are not imputed for the observed case analysis. For subjects re-randomized due to disease flare, only non-missing data up to before the first disease flare is used.

Cross reference: M11-290 CSR_Final Table 14.2__1.3.28_J

図 2.7.3.6-1. 主要評価項目及び順位付き副次評価項目の多重検定手順の結果
（ITT-E 集団，M11-290 試験の主試験）（中間 CSR）



The nominal *P*-value for SDS1 was 0.0000081.

C = testing the endpoint for the combined high and standard adalimumab dose groups against external placebo.

HD = testing the endpoint for the high adalimumab dose against external placebo.

SD = testing the endpoint for the standard adalimumab dose against external placebo.

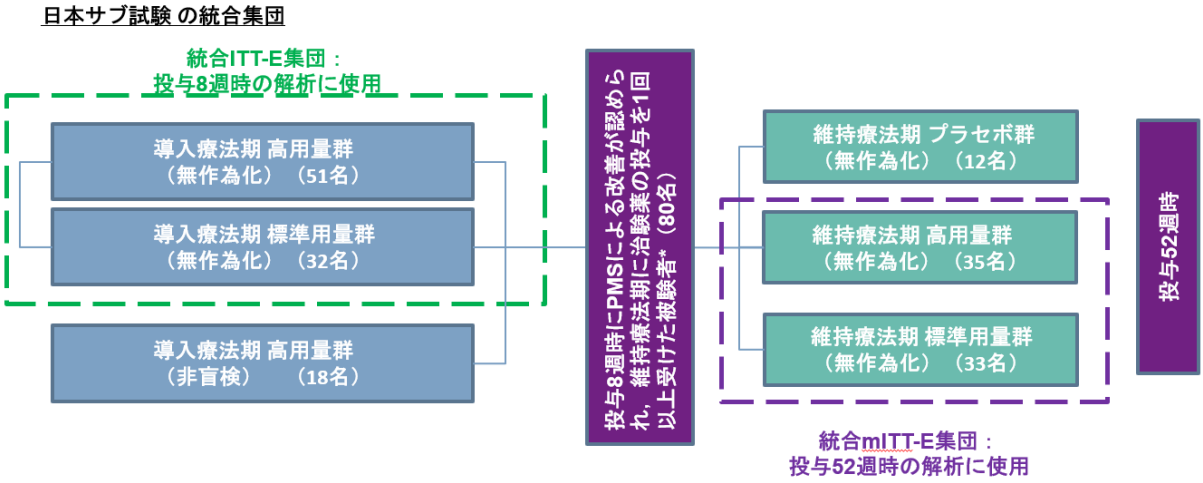
P1 = co-primary induction endpoint; P2 = co-primary maintenance endpoint; Si = ranked secondary endpoint i (i=1,..., 4).

Value inside the circle = nominal p-value; Value below the circle = alpha; Number above the circle = testing sequence.

Rejected null hypothesis = green; not rejected null hypothesis = red.

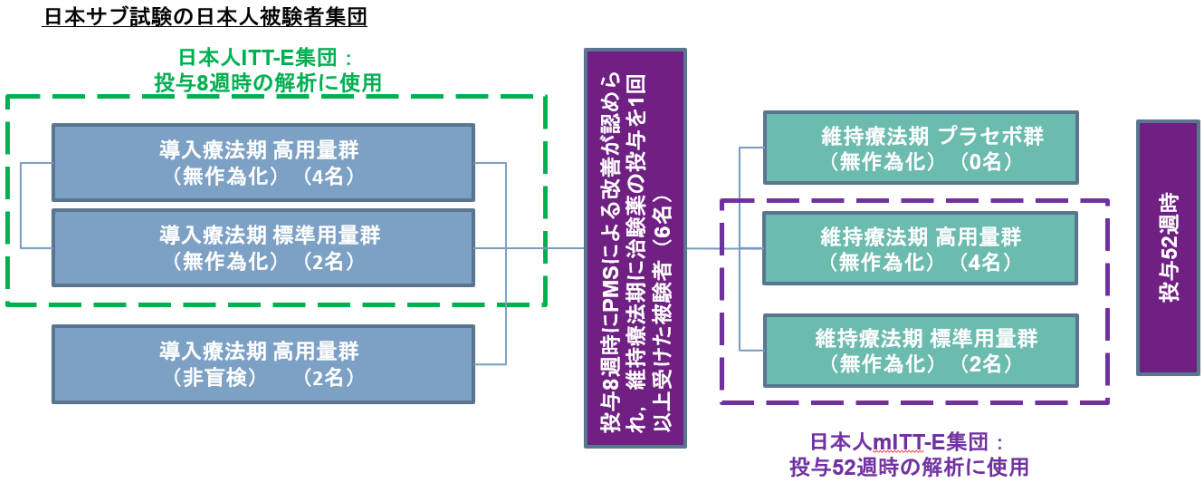
Cross reference: M11-290 Main-study CSR_Interim Figure 14.2__7

図 2.7.3.6-2. M11-290 日本サブ試験の統合集団の内訳（最終 CSR）



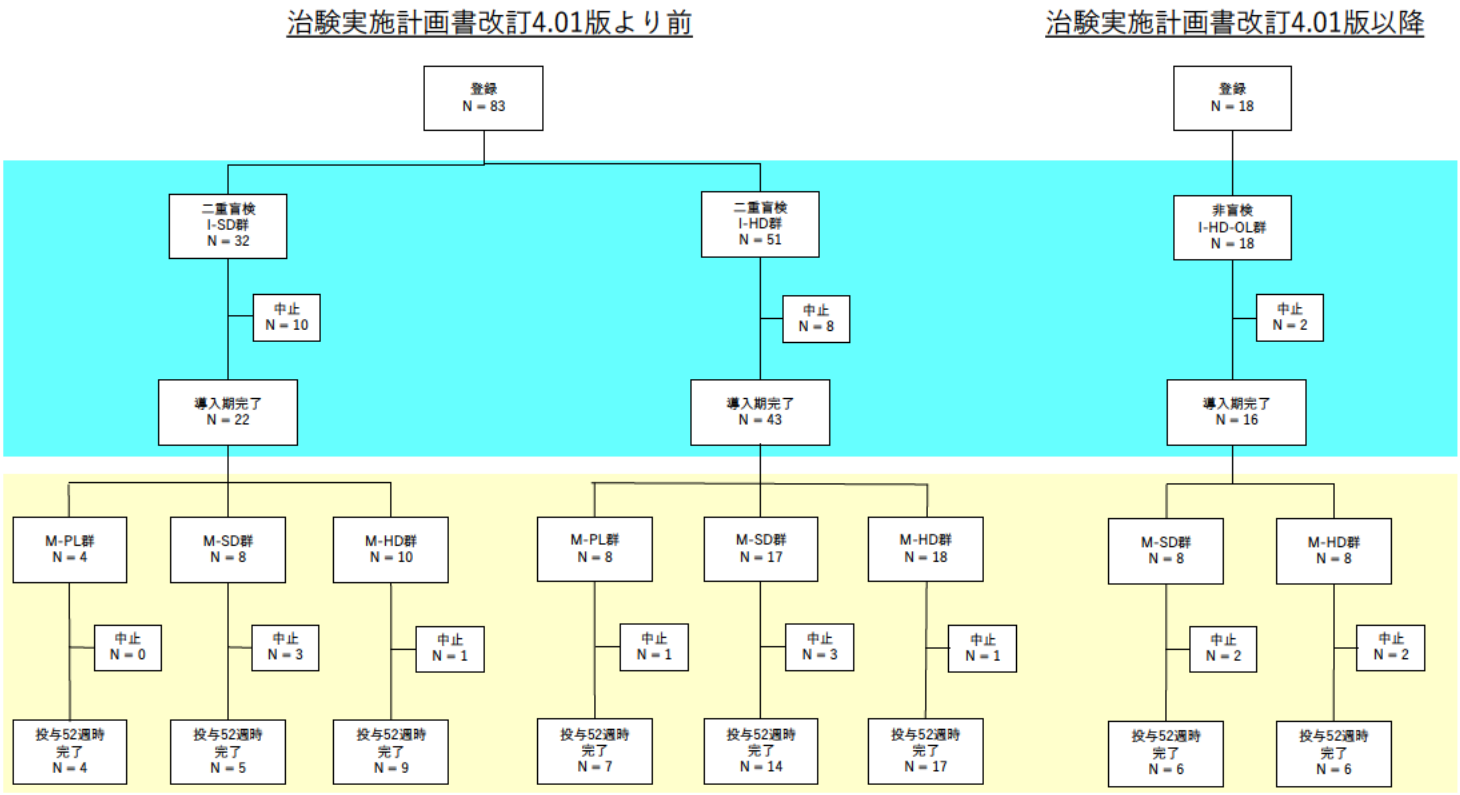
PMS = Partial Mayo score（部分的 Mayo スコア）
*：PMS の改善が認められず無作為化された 1 例を維持療法期の安全性解析に含めた。
Cross reference: M11-290 CSR_Final Table 14.1__1.1_A

図 2.7.3.6-3. M11-290 日本サブ試験の日本人被験者集団の内訳（最終 CSR）



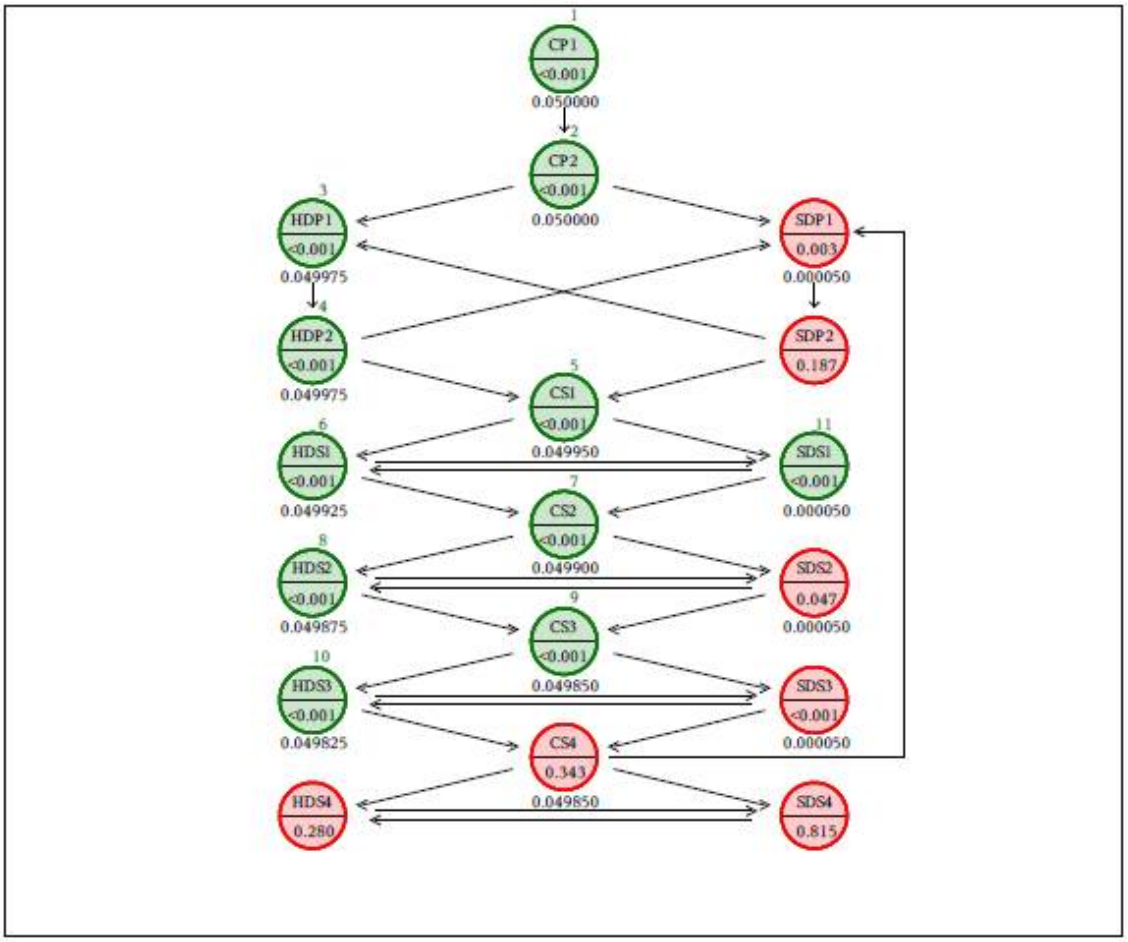
PMS = Partial Mayo score（部分的 Mayo スコア）
Cross reference: M11-290 CSR_Final Table 14.1__1.1_J

図 2.7.3.6-4.　被験者の内訳（統合集団，M11-290 試験の日本サブ試験）（最終 CSR）



Cross reference: M11-290 CSR_Final Table 14.1__1.1_A 及び Table 14.1__2.2_A

図 2.7.3.6-5. 主要評価項目及び順位付き副次評価項目の多重検定手順の結果
（統合 mITT-E 集団，M11-290 試験の日本サブ試験）（最終 CSR）



The nominal p-value for SDS1 was 0.000038.

C = testing the endpoint for the combined high and standard adalimumab dose groups against external placebo.

HD = testing the endpoint for the high adalimumab dose against external placebo.

SD = testing the endpoint for the standard adalimumab dose against external placebo.

P1 = co-primary induction endpoint; P2 = co-primary maintenance endpoint; Si = ranked secondary endpoint i (i=1,..., 4).

Value inside the circle = nominal p-value; Value below the circle = alpha; Number above the circle = testing sequence.

Rejected null hy pothesis = green; not rejected null hy pothesis = red.

Cross reference: M11-290 CSR_Final Figure 14.2__7_A

2.7.4 成人 臨床的安全性

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略語及び定義一覧

略語又は用語	省略していない表現又は説明（英語）	省略していない表現又は説明（日本語）
AE	Adverse event	有害事象
AESI	Adverse event of special interest	特に注目すべき有害事象
ALT (SGPT)	Alanine aminotransferase	アラニンアミノトランスフェラーゼ
AST (SGOT)	Aspartate aminotransferase	アスパラギン酸アミノトランスフェラーゼ
CSR	Clinical study report	治験総括報告書
CTCAE	Common Terminology Criteria for Adverse Events	有害事象共通用語規準
EOW	Every other week	隔週
EW	Every week	週 1 回
ICH	International Conference on Harmonization	医薬品規制調和国際会議
MedDRA	Medical Dictionary for Regulatory Activities	ICH 国際医薬品用語集
MedDRA/J	Medical Dictionary for Regulatory Activities/Japanese version	MedDRA の日本語版
NCI	National Cancer Institute	米国国立がん研究所
PT	Preferred term	（ICH 国際医薬用語集の）基本語
SAE	Serious adverse event	重篤な有害事象
SOC	System organ class	（ICH 国際医薬用語集の）器官別大分類
TDM	Therapeutic drug monitoring	薬物治療モニタリング
TNF	Tumor necrosis factor	腫瘍壊死因子
UC	Ulcerative colitis	潰瘍性大腸炎
ULN	Upper limit of normal	基準値の上限

2.7.4.1 成人 医薬品への曝露

2.7.4.1.1 成人 総括的安全性評価計画及び安全性試験の記述

2.7.4.1.1.1 成人 安全性の評価に用いた臨床試験

成人潰瘍性大腸炎（以下「UC」）患者に対するアダリムマブの高用量での導入療法及び維持療法の臨床開発プログラムでは，日本人を含む国際共同試験である第 III 相試験 1 試験（M14-033 試験）を評価試験とした。M14-033 試験は導入療法試験と維持療法試験で構成され，それぞれが日本以外の他国の治験実施医療機関で登録された被験者を対象とする主試験と，日本の治験実施医療機関で登録された被験者を対象とする日本サブ試験で構成される。本項には，主試験データに基づいた解析結果，日本サブ試験データ（日本人被験者集団データ，主試験及び日本サブ試験の被験者からなる統合集団データ）に基づいた解析結果を記載した。M14-033 試験では導入療法試験及び維持療法試験について，それぞれに治験総括報告書（以下「CSR」）を作成しており，合計 4 報の CSR（M14-033 導入療法試験 主試験 中間 CSR 及び日本サブ試験 中間 CSR，M14-033 維持療法試験 主試験 中間 CSR 及び日本サブ試験 中間 CSR）を安全性の評価資料とした（試験デザインは 2.7.3.1.2 成人参照）。

本申請では 70 日後の追跡調査までに得られた安全性データの解析結果（導入療法試験の 70 日後の追跡調査終了日：20[redacted] 年 [redacted] 月 [redacted] 日，維持療法試験の 70 日後の追跡調査終了日：2019 年 11 月 [redacted] 日）を提示した。M14-033 試験（導入療法試験，維持療法試験）では，内視鏡検査時に採取していた組織を用いた組織学的評価を目的にした生体組織診断（以下「生検」）を実施し，その組織学的検査データが得られたことから（組織学的評価項目のみのデータベースロック日：20[redacted] 年 [redacted] 月 [redacted] 日），その生検結果を反映した最終 CSR を作成した。この組織学的評価は，追加評価項目であり探索的に実施したもので，組織採取後即時に実施されるものではなく，本評価は，有効性及び安全性の主たる評価項目とは別に，治験終了後に実施した。なお，データエラーの判明により最終 CSR の修正版を作成し，その修正版を追加提出した（導入療法試験 主試験 最終 CSR［5.3.5.1-1 項］及び日本サブ試験 最終 CSR［5.3.5.1-2 項］，維持療法試験 主試験 最終 CSR［5.3.5.1-3 項］及び日本サブ試験 最終 CSR［5.3.5.1-4 項］）。

2.7.4.1.1.2 成人 安全性に関する評価方法

M14-033 試験では，試験期間を通して有害事象，臨床検査値及びバイタルサインから安全性を評価した。

2.7.4.1.1.2.1 成人 解析対象

M14-033 導入療法試験

導入療法試験で治験薬の投与を 1 回以上受けた日本以外のすべての被験者を，主試験安全性解析対象集団と定義した。また，導入療法試験で治験薬の投与を 1 回以上受けた日本及び日本以外のすべての被験者を，統合安全性解析対象集団と定義し，治験薬の投与を 1 回以上受けた

すべての日本の被験者を，日本人安全性解析対象集団と定義した。解析は実際に投与された治療に基づき行った。主試験安全性解析対象集団は 852 例，統合安全性解析対象集団は 952 例，日本人安全性解析対象集団は 100 例であった。

当初，本試験の被験者数は主試験 525 例，日本サブ試験 80 例とする計画であったが，治験実施計画書改訂 3 版で主試験 840 例，日本サブ試験 100 例に変更した。なお，本試験の開始時では，M14-033 試験の導入療法期及び維持療法期として計画されていたが，治験実施計画書改訂 3 版で導入療法試験及び維持療法試験へ記載変更した。以下，導入療法期又は維持療法期とせず，導入療法試験又は維持療法試験と記載した。

M14-033 維持療法試験

維持療法試験で治験薬の投与を 1 回以上受けた日本以外のすべての被験者を，主試験安全性解析対象集団と定義した。また，維持療法試験で治験薬の投与を 1 回以上受けた日本及び日本以外のすべての被験者を，統合安全性解析対象集団と定義し，治験薬の投与を 1 回以上受けたすべての日本の被験者を，日本人安全性解析対象集団と定義した。解析は実際に投与された治療に基づき行った。主試験安全性解析対象集団は 757 例，統合安全性解析対象集団は 846 例，日本人安全性解析対象集団は 89 例であった。

2.7.4.1.1.2.2 成人 有害事象

有害事象は，治験薬との因果関係の有無にかかわらず，治験薬を投与された被験者に生じたあらゆる好ましくない医療上のできごととした。導入療法試験の有害事象の収集期間は，治験薬の初回投与日から，投与 8 週時に再無作為化された被験者については維持療法試験の初回投与日まで，再無作為化されなかった被験者については治験薬の最終投与の 70 日後までとした。維持療法試験の有害事象の収集期間は，維持療法試験での治験薬の初回投与日から最終投与の 70 日後までとした。

すべての有害事象を，医薬品規制調和国際会議（以下「ICH」）国際医薬品用語集（以下「MedDRA」，バージョン 22.0）の器官別大分類（以下「SOC」）及び基本語（以下「PT」）に基づきコード化した。有害事象名の和訳には，MedDRA の日本語版（以下「MedDRA/J」，バージョン 22.0）を用いた。

有害事象の重症度，治験薬との因果関係，重篤な有害事象，及び特に注目すべき有害事象（以下「AESI」）の定義は以下のとおりである。

有害事象の重症度の定義

治験責任（分担）医師は，以下の定義に従って有害事象の重症度を評価した。

- 軽度　：一時的でたやすく忍容できるもの
- 中等度　：被験者に不安や苦痛を与え，日常生活に支障をきたすもの

- 高度　　：日常生活に重大な支障をきたし，機能障害，あるいは生命を脅かす可能性のあるもの

治験薬との因果関係の定義

治験責任（分担）医師は，以下の定義に従って有害事象の治験薬との因果関係を評価した。

- 関連あり（Reasonable possibility）：
  治験薬と有害事象の因果関係が示唆される証拠が存在する有害事象
- 関連なし（No reasonable possibility）：
  治験薬と有害事象の因果関係が示唆される証拠が存在しない有害事象

重篤な有害事象の定義

有害事象が以下の基準と合致する場合，重篤な有害事象とした。

- 死亡
- 生命を脅かすもの
- 入院又は入院期間の延長
- 先天性の異常
- 永続的又は顕著な障害 / 機能不全
- 重篤な転帰を防ぐために内科的，又は外科的処置を必要とする医学的に重要な事象

特に注目すべき有害事象

腫瘍壊死因子（以下「TNF」）阻害剤の生物学的療法で同定されたリスク及び潜在的なリスクを AESI のカテゴリー（付録 表 2.7.4.7-1）に含め，要約した。

2.7.4.1.1.2.3　　成人 臨床検査

血液学的検査，血液生化学検査及び尿検査について経時的な要約統計量を算出し，ベースラインから最低値，最高値及び最終測定値までの変化量の要約統計量を算出した。また，ベースラインが正常値若しくは異常高値であった検査値が最終測定時に異常低値に変動した被験者の割合，及びベースラインが異常低値若しくは正常値であった検査値が最終測定時に異常高値に変動した被験者の割合を算出した。

臨床検査値は，米国国立がん研究所（以下「NCI」）の有害事象共通用語規準（以下「CTCAE」）（第 3.0 版）を用いて評価し，CTC グレード 3 以上の異常値が認められた被験者の一覧を作成し，CTC グレード 3 以上の異常値の有無についてベースラインからのシフトテーブルを作成した。

肝機能検査値（アラニンアミノトランスフェラーゼ［以下「ALT」］ / 血清グルタミン酸ピルビン酸トランスアミナーゼ［以下「SGPT」］，アスパラギン酸アミノトランスフェラーゼ［以下「AST」］ / 血清グルタミン酸オキサロ酢酸トランスアミナーゼ［以下「SGOT」］，アルカリホスファターゼ及び総ビリルビン）に対しては，以下の基準を設定し，いずれかに合致した被験者に対して，臨床的に意味のある肝機能検査値（potentially clinically significant liver function laboratory values）の一覧を作成した。

- ALT：≥ 2.5 × 基準値の上限（以下「ULN」）
- AST：≥ 2.5 × ULN
- アルカリホスファターゼ：≥ 2.5 × ULN
- 総ビリルビン：≥ 1.5 × ULN

2.7.4.1.1.2.4 成人 バイタルサイン及び心電図

バイタルサイン（血圧［収縮期及び拡張期］，脈拍数，呼吸数，体重及び体温）について要約統計量を算出した。

2.7.4.1.2 成人 全般的な曝露状況

2.7.4.1.2.1 M14-033 導入療法試験

主試験安全性解析対象集団の治験薬の曝露期間を付録 表 2.7.4.7-2 に示した。

主試験安全性解析対象集団（852 例）の導入療法試験での治験薬の平均曝露期間は 56.2 日であり，内訳は標準用量群（投与 0 週時に 160 mg 及び 2 週時に 80 mg を投与，投与 4 週及び 6 週時に 40 mg を投与）（340 例）が 58.0 日，高用量群（投与 0 週，1 週，2 週及び 3 週時に 160 mg を投与，投与 4 週及び 6 週時に 40 mg を投与）（512 例）が 55.1 日であった。

統合安全性解析対象集団及び日本人安全性解析対象集団の治験薬の曝露期間を付録 表 2.7.4.7-3 に示した。

統合安全性解析対象集団（952 例）の導入療法試験での治験薬の平均曝露期間は 56.0 日であり，内訳は標準用量群（379 例）が 57.5 日，高用量群（573 例）が 55.0 日であった。

日本人安全性解析対象集団（100 例）の導入療法試験での治験薬の平均曝露期間は 54.1 日であり，内訳は標準用量群（39 例）が 53.0 日，高用量群（61 例）が 54.8 日であった。

2.7.4.1.2.2 M14-033 維持療法試験

主試験安全性解析対象集団の治験薬の曝露期間を付録 表 2.7.4.7-4 に示した。

主試験安全性解析対象集団（757 例）の維持療法試験での治験薬の平均曝露期間は 256.3 日であり，内訳は 40 mg 隔週投与群（302 例）が 249.5 日，40 mg 週 1 回投与群（304 例）が 263.1 日，薬物治療モニタリング（以下「TDM」）群（151 例）が 255.9 日であった。

統合安全性解析対象集団及び日本人安全性解析対象集団の治験薬の曝露期間を付録 表 2.7.4.7-5 に示した。

統合安全性解析対象集団（846 例）の維持療法試験での治験薬の平均曝露期間は 257.1 日であり，内訳は 40 mg 隔週投与群（345 例）が 251.5 日，40 mg 週 1 回投与群（350 例）が 263.1 日，TDM 群（151 例）が 255.9 日であった。

日本人安全性解析対象集団（89 例）の維持療法試験での治験薬の平均曝露期間は 264.1 日であり，内訳は 40 mg 隔週投与群（43 例）が 265.2 日，40 mg 週 1 回投与群（46 例）が 263.1 日であった。

2.7.4.1.3 成人 治験対象集団の人口統計学的特性及びその他の特性

M14-033 試験の人口統計学的特性及びその他の特性は，2.7.3.3.1.1 成人に示した。

2.7.4.2 成人 有害事象

2.7.4.2.1 成人 有害事象の解析

M14-033 導入療法試験

主試験安全性解析対象集団における有害事象の概要を表 2.7.4.2-1 に示した。

主試験安全性解析対象集団の 852 例中 455 例（53.4%）に有害事象が発現した。有害事象の発現割合は，標準用量群（340 例中 184 例，54.1%）と高用量群（512 例中 271 例，52.9%）で同程度であった。また，重篤な有害事象が 36 例（4.2%）に発現した。重篤な有害事象の発現割合は，標準用量群（17 例，5.0%）と高用量群（19 例，3.7%）で同程度であった。治験薬投与の中止に至った有害事象は 49 例（5.8%）に発現した。導入療法試験中に 2 例（0.2%）が死亡し，いずれも高用量群の被験者であった。死亡はいずれも治験薬と関連なしと判断された。

表 2.7.4.2-1. 有害事象の概要（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）

	アダリムマブ導入療法		
	標準用量 (N = 340) n (%)	高用量 (N = 512) n (%)	合計 (N = 852) n (%)
有害事象	184 (54.1)	271 (52.9)	455 (53.4)
治験薬との因果関係が関連ありと医師により判断された有害事象	75 (22.1)	138 (27.0)	213 (25.0)
高度の有害事象	16 (4.7)	23 (4.5)	39 (4.6)
重篤な有害事象	17 (5.0)	19 (3.7)	36 (4.2)
治験薬投与の中止に至った有害事象	19 (5.6)	30 (5.9)	49 (5.8)
死亡に至った有害事象	0	1 (0.2)	1 (0.1)
死亡	0	2 (0.4)	2 (0.2)

Note: Treatment-emergent adverse events during induction study are defined as events that begin or worsen either on or after the first dose of the study medication and up to the first dose of the study medication in maintenance study for those who are re-randomized at Week 8, or events that begin or worsen either on or after the first dose of the study drug and within 70 days after the last dose of the study medication in the induction study for subjects who are not re-randomized. Events with unknown severity are counted as severe.
Events with unknown relationship to study drug are counted as drug related.

Cross reference: M14-033 Induction Main-study Final CSR Table 14.3 1.1.1

統合安全性解析対象集団及び日本人安全性解析対象集団における有害事象の概要を表 2.7.4.2-2 に示した。

統合安全性解析対象集団の 952 例中 505 例（53.0%）に有害事象が発現した。有害事象の発現割合は，標準用量群（379 例中 200 例，52.8%）と高用量群（573 例中 305 例，53.2%）で同程度であった。また，重篤な有害事象が 41 例（4.3%）に発現した。重篤な有害事象の発現割合は，標準用量群（19 例，5.0%）と高用量群（22 例，3.8%）で同程度であった。治験薬投与の中止に至った有害事象は 53 例（5.6%）に発現した。導入療法試験中に 2 例（0.2%）が死亡し，いずれも高用量群の被験者であった。死亡はいずれも治験薬と関連なしと判断された。

日本人安全性解析対象集団の 100 例中 50 例（50.0%）に有害事象が発現した。有害事象の発現割合は，高用量群（61 例中 34 例，55.7%）の方が標準用量群（39 例中 16 例，41.0%）よりも高かった。また，重篤な有害事象が 5 例（5.0%）に発現した。重篤な有害事象の発現割合は，標準用量群（2 例，5.1%）と高用量群（3 例，4.9%）で同程度であった。治験薬投与の中止に至った有害事象は 4 例（4.0%）に発現した。日本人安全性解析対象集団で死亡は認められなかった。

表 2.7.4.2-2. 有害事象の概要（日本人安全性解析対象集団及び統合安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）

	日本人安全性解析対象集団			統合安全性解析対象集団		
	アダリムマブ導入療法			アダリムマブ導入療法		
	標準用量 (N = 39) n (%)	高用量 (N = 61) n (%)	合計 (N = 100) n (%)	標準用量 (N = 379) n (%)	高用量 (N = 573) n (%)	合計 (N = 952) n (%)
有害事象	16 (41.0)	34 (55.7)	50 (50.0)	200 (52.8)	305 (53.2)	505 (53.0)
治験薬との因果関係が関連ありと医師により判断された有害事象	8 (20.5)	11 (18.0)	19 (19.0)	83 (21.9)	149 (26.0)	232 (24.4)
高度の有害事象	1 (2.6)	1 (1.6)	2 (2.0)	17 (4.5)	24 (4.2)	41 (4.3)
重篤な有害事象	2 (5.1)	3 (4.9)	5 (5.0)	19 (5.0)	22 (3.8)	41 (4.3)
治験薬投与の中止に至った有害事象	3 (7.7)	1 (1.6)	4 (4.0)	22 (5.8)	31 (5.4)	53 (5.6)
死亡に至った有害事象	0	0	0	0	1 (0.2)	1 (0.1)
死亡	0	0	0	0	2 (0.3)	2 (0.2)

Note: Treatment-emergent adverse events during induction study are defined as events that begin or worsen either on or after the first dose of the study medication and up to the first dose of the study medication in maintenance study for those who are re-randomized at Week 8, or events that begin or worsen either on or after the first dose of the study drug and within 70 days after the last dose of the study medication in the induction study for subjects who are not re-randomized. Events with unknown severity are counted as severe.
Events with unknown relationship to study drug are counted as drug related.

Cross reference: M14-033 Induction Japan Sub-study Final CSR Table 14.3　1.1.1_J

M14-033 維持療法試験

主試験安全性解析対象集団における有害事象の概要を表 2.7.4.2-3 に示した。

主試験安全性解析対象集団の 757 例中 538 例（71.1%）に有害事象が発現した。有害事象の発現割合は，40 mg 隔週投与群（302 例中 220 例，72.8%），40 mg 週 1 回投与群（304 例中 222 例，73.0%）及び TDM 群（151 例中 96 例，63.6%）で同程度であった。また，重篤な有害事象が 97 例（12.8%）に発現した。重篤な有害事象の発現割合は，40 mg 隔週投与群（42 例，13.9%），40 mg 週 1 回投与群（40 例，13.2%）及び TDM 群（15 例，9.9%）で同程度であった。治験薬投与の中止に至った有害事象は 85 例（11.2%）に発現した。維持療法試験中に 4 例（0.5%）が死亡し，内訳は 40 mg 隔週投与群が 2 例（0.7%），40 mg 週 1 回投与群が 2 例（0.7%）であった。死亡はいずれも治験薬と関連なしと判断された。

表 2.7.4.2-3. 有害事象の概要（主試験安全性解析対象集団，M14-033 主試験の維持療法試験）

	アダリムマブ維持療法			
	40 mg EOW (N = 302) n (%)	40 mg EW (N = 304) n (%)	TDM (N = 151) n (%)	合計 (N = 757) n (%)
有害事象	220 (72.8)	222 (73.0)	96 (63.6)	538 (71.1)
治験薬との因果関係が関連ありと医師により判断された有害事象	82 (27.2)	104 (34.2)	49 (32.5)	235 (31.0)
高度の有害事象	28 (9.3)	38 (12.5)	10 (6.6)	76 (10.0)
重篤な有害事象	42 (13.9)	40 (13.2)	15 (9.9)	97 (12.8)
治験薬投与の中止に至った有害事象	38 (12.6)	30 (9.9)	17 (11.3)	85 (11.2)
死亡に至った有害事象	2 (0.7)	2 (0.7)	0	4 (0.5)
死亡	2 (0.7)	2 (0.7)	0	4 (0.5)

EOW = every other week; EW = every week; TDM = therapeutic drug monitoring

Note: Treatment-emergent adverse events during the maintenance study are defined as events that begin or worsen either on or after the first dose of the study drug in the maintenance study and within 70 days after the last dose of the study drug.

Cross reference: M14-033 Maintenance Main-study Final CSR Table 14.3 1.1.1

統合安全性解析対象集団及び日本人安全性解析対象集団における有害事象の概要を表 2.7.4.2-4 に示した。

統合安全性解析対象集団の 846 例中 616 例（72.8%）に有害事象が発現した。有害事象の発現割合は，40 mg 隔週投与群（345 例中 257 例，74.5%），40 mg 週 1 回投与群（350 例中 263 例，75.1%）及び TDM 群（151 例中 96 例，63.6%）で同程度であった。また，重篤な有害事象が 103 例（12.2%）に発現した。重篤な有害事象の発現割合は，40 mg 隔週投与群（44 例，12.8%），40 mg 週 1 回投与群（44 例，12.6%）及び TDM 群（15 例，9.9%）で同程度であった。治験薬投与の中止に至った有害事象は 92 例（10.9%）に発現した。維持療法試験中に 4 例（0.5%）が死亡し，内訳は 40 mg 隔週投与群が 2 例（0.6%），40 mg 週 1 回投与群が 2 例（0.6%）であった。死亡はいずれも治験薬と関連なしと判断された。

日本人安全性解析対象集団の 89 例中 78 例（87.6%）に有害事象が発現した。有害事象の発現割合は，40 mg 隔週投与群（43 例中 37 例，86.0%）と 40 mg 週 1 回投与群（46 例中 41 例，89.1%）で同程度であった。また，重篤な有害事象が 6 例（6.7%）に発現し，内訳は 40 mg 隔週投与群が 2 例（4.7%），40 mg 週 1 回投与群が 4 例（8.7%）であった。治験薬投与の中止に至った有害事象は 7 例（7.9%）に発現した。日本人安全性解析対象集団で死亡は認められなかった。

表 2.7.4.2-4. 有害事象の概要（日本人安全性解析対象集団及び統合安全性解析対象集団，M14-033 日本サブ試験の維持療法試験）

	日本人安全性解析対象集団			統合安全性解析対象集団			
	アダリムマブ維持療法			アダリムマブ維持療法			
	40 mg EOW (N = 43) n (%)	40 mg EW (N = 46) n (%)	合計 (N = 89) n (%)	40 mg EOW (N = 345) n (%)	40 mg EW (N = 350) n (%)	TDM (N = 151) n (%)	合計 (N = 846) n (%)
有害事象	37 (86.0)	41 (89.1)	78 (87.6)	257 (74.5)	263 (75.1)	96 (63.6)	616 (72.8)
治験薬との因果関係が関連ありと医師により判断された有害事象	7 (16.3)	13 (28.3)	20 (22.5)	89 (25.8)	117 (33.4)	49 (32.5)	255 (30.1)
高度の有害事象	1 (2.3)	3 (6.5)	4 (4.5)	29 (8.4)	41 (11.7)	10 (6.6)	80 (9.5)
重篤な有害事象	2 (4.7)	4 (8.7)	6 (6.7)	44 (12.8)	44 (12.6)	15 (9.9)	103 (12.2)
治験薬投与の中止に至った有害事象	2 (4.7)	5 (10.9)	7 (7.9)	40 (11.6)	35 (10.0)	17 (11.3)	92 (10.9)
死亡に至った有害事象	0	0	0	2 (0.6)	2 (0.6)	0	4 (0.5)
死亡	0	0	0	2 (0.6)	2 (0.6)	0	4 (0.5)

EOW = every other week; EW = every week; TDM = therapeutic drug monitoring

Notes: Treatment-emergent adverse events during the maintenance study are defined as events that begin or worsen either on or after the first dose of the study drug in the maintenance study and within 70 days after the last dose of the study drug. Event with unknown severity is being counted as severe. Event with unknown relationship to study drug is being counted as drug-related.

Cross reference: M14-033 Maintenance Japan Sub-study Final CSR Table 14.3　1.1.1 J

2.7.4.2.1.1 成人 比較的よく見られる有害事象

2.7.4.2.1.1.1 成人 発現割合の高い有害事象

M14-033 導入療法試験

主試験安全性解析対象集団で 5%以上の被験者に発現した有害事象の発現割合及び 100 人年あたりの発現率を表 2.7.4.2-5 に示した。

主試験安全性解析対象集団（852 例）で 5%以上の被験者に発現した有害事象は，頭痛（70 例，8.2%）及び潰瘍性大腸炎（59 例，6.9%）であった。100 人年あたりの発現率は，頭痛が 70.9 件/100 人年，潰瘍性大腸炎が 51.1 件/100 人年であった。

表 2.7.4.2-5. 5%以上の被験者に発現した有害事象の発現割合及び 100 人年あたりの発現率（MedDRA PT 別）
（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）

	アダリムマブ導入療法					
	標準用量 (N = 340; PYs = 54.0)		高用量 (N = 512; PYs = 77.2)		合計 (N = 852; PYs = 131.2)	
MedDRA 22.0 PT	n (%)	E (E/100 PYs)	n (%)	E (E/100 PYs)	n (%)	E (E/100 PYs)
頭痛	23 (6.8)	32 (59.3)	47 (9.2)	61 (79.0)	70 (8.2)	93 (70.9)
潰瘍性大腸炎	30 (8.8)	37 (68.5)	29 (5.7)	30 (38.9)	59 (6.9)	67 (51.1)

E = event; MedDRA = Medical Dictionary for Regulatory Activities; PT = preferred term; PY = patient year

Note: Treatment-emergent adverse events during induction study are defined as events that begin or worsen either on or after the first dose of the study medication and up to the first dose of the study medication in maintenance study for those who are re-randomized at Week 8, or events that begin or worsen either on or after the first dose of the study drug and within 70 days after the last dose of the study medication in the induction study for subjects who are not re-randomized.

Cross reference: M14-033 Induction Main-study Final CSR Table 14.3 1.2.1, Table 14.3 1.2.2

統合安全性解析対象集団で 5%以上の被験者に発現した有害事象を表 2.7.4.2-6 に，日本人安全性解析対象集団で 5%以上の被験者に発現した有害事象を表 2.7.4.2-7 に示した。

統合安全性解析対象集団（952 例）で 5%以上の被験者に発現した有害事象は，頭痛（71 例，7.5%）及び潰瘍性大腸炎（63 例，6.6%）であった。

日本人安全性解析対象集団（100 例）で 5%以上の被験者に発現した有害事象は，上咽頭炎（12 例，12.0%），注射部位反応（8 例，8.0%）及び発熱（5 例，5.0%）であった。

表 2.7.4.2-6. 5%以上の被験者に発現した有害事象の発現割合（MedDRA PT 別）
（統合安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）

	アダリムマブ導入療法		
MedDRA 22.0 PT	標準用量 (N = 379) n (%)	高用量 (N = 573) n (%)	合計 (N = 952) n (%)
頭痛	23 (6.1)	48 (8.4)	71 (7.5)
潰瘍性大腸炎	32 (8.4)	31 (5.4)	63 (6.6)

MedDRA = Medical Dictionary for Regulatory Activities; PT = preferred term

Note: Treatment-emergent adverse events during induction study are defined as events that begin or worsen either on or after the first dose of the study medication and up to the first dose of the study medication in maintenance study for those who are re-randomized at Week 8, or events that begin or worsen either on or after the first dose of the study drug and within 70 days after the last dose of the study medication in the induction study for subjects who are not re-randomized.

Cross reference: M14-033 Induction Japan Sub-study Final CSR Table 14.3 1.3 J

表 2.7.4.2-7. 5%以上の被験者に発現した有害事象の発現割合（MedDRA PT 別）
（日本人安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）

	アダリムマブ導入療法		
MedDRA 22.0 PT	標準用量 (N = 39) n (%)	高用量 (N = 61) n (%)	合計 (N = 100) n (%)
上咽頭炎	2 (5.1)	10 (16.4)	12 (12.0)
注射部位反応	2 (5.1)	6 (9.8)	8 (8.0)
発熱	2 (5.1)	3 (4.9)	5 (5.0)

MedDRA = Medical Dictionary for Regulatory Activities; PT = preferred term

Note: Treatment-emergent adverse events during induction study are defined as events that begin or worsen either on or after the first dose of the study medication and up to the first dose of the study medication in maintenance study for those who are re-randomized at Week 8, or events that begin or worsen either on or after the first dose of the study drug and within 70 days after the last dose of the study medication in the induction study for subjects who are not re-randomized.

Cross reference: M14-033 Induction Japan Sub-study Final CSR Table 14.3 1.3 J

M14-033 維持療法試験

主試験安全性解析対象集団で 5%以上の被験者に発現した有害事象の発現割合及び 100 人年あたりの発現率を表 2.7.4.2-8 に示した。

主試験安全性解析対象集団（757 例）で 5%以上の被験者に発現した有害事象は，潰瘍性大腸炎（163 例，21.5%），上咽頭炎（72 例，9.5%），関節痛（53 例，7.0%），上気道感染（47 例，6.2%）及び頭痛（44 例，5.8%）であった。これらの有害事象の発現割合は，投与群間でおおむね同程度であった。100 人年あたりの発現率は，潰瘍性大腸炎が 38.0 件/100 人年，上咽頭炎が 18.3 件/100 人年，関節痛が 11.9 件/100 人年，上気道感染が 9.8 件/100 人年，頭痛が 11.5 件/100 人年であった。

表 2.7.4.2-8. 5%以上の被験者に発現した有害事象の発現割合及び 100 人年あたりの発現率（MedDRA PT 別）
（主試験安全性解析対象集団，M14-033 主試験の維持療法試験）

	アダリムマブ維持療法							
	40 mg EOW (N = 302; PYs = 206.3)		40 mg EW (N = 304; PYs = 219)		TDM (N = 151; PYs = 105.8)		合計 (N = 757; PYs = 531.1)	
MedDRA 22.0 PT	n (%)	E (E/100 PYs)	n (%)	E (E/100 PYs)	n (%)	E (E/100 PYs)	n (%)	E (E/100 PYs)
潰瘍性大腸炎	74 (24.5)	88 (42.7)	60 (19.7)	77 (35.2)	29 (19.2)	37 (35.0)	163 (21.5)	202 (38.0)
上咽頭炎	31 (10.3)	38 (18.4)	30 (9.9)	39 (17.8)	11 (7.3)	20 (18.9)	72 (9.5)	97 (18.3)
関節痛	24 (7.9)	28 (13.6)	24 (7.9)	30 (13.7)	5 (3.3)	5 (4.7)	53 (7.0)	63 (11.9)
上気道感染	21 (7.0)	24 (11.6)	17 (5.6)	18 (8.2)	9 (6.0)	10 (9.5)	47 (6.2)	52 (9.8)
頭痛	16 (5.3)	18 (8.7)	20 (6.6)	34 (15.5)	8 (5.3)	9 (8.5)	44 (5.8)	61 (11.5)

E = event; EOW = every other week; EW = every week; MedDRA = Medical Dictionary for Regulatory Activities;
PT = preferred term; PY = patient years; TDM = Therapeutic Drug Monitoring
Note: Treatment-emergent adverse events during the maintenance study are defined as events that begin or worsen either on or after the first dose of the study drug in the maintenance study and within 70 days after the last dose of the study drug
Cross reference: M14-033 Maintenance Main-study Final CSR Table 14.3 1.3.1, Table 14.3 1.3.2

統合安全性解析対象集団で 5%以上の被験者に発現した有害事象の発現割合及び 100 人年あたりの発現率を表 2.7.4.2-9 に，日本人安全性解析対象集団で 5%以上の被験者に発現した有害事象の発現割合及び 100 人年あたりの発現率を表 2.7.4.2-10 に示した。

統合安全性解析対象集団（846 例）で 5%以上の被験者に発現した有害事象は，潰瘍性大腸炎（170 例，20.1%），上咽頭炎（104 例，12.3%），関節痛（54 例，6.4%），上気道感染（50 例，5.9%）及び頭痛（47 例，5.6%）であった。これらの有害事象の発現割合は，投与群間でおおむね同程度であった。また，100 人年あたりの発現率は，潰瘍性大腸炎が 35.1 件/100 人年，上咽頭炎が 23.2 件/100 人年，関節痛が 10.7 件/100 人年，上気道感染が 9.2 件/100 人年，頭痛が 10.7 件/100 人年であった。

日本人安全性解析対象集団（89 例）で 5%以上の被験者に発現した有害事象は，上咽頭炎（32 例，36.0%），貧血（8 例，9.0%），インフルエンザ及び潰瘍性大腸炎（各 7 例，7.9%），発熱（6 例，6.7%）並びに悪心及び膀胱炎（各 5 例，5.6%）であった。これらの有害事象の発現割合は，投与群間でおおむね同程度であった。また，100 人年あたりの発現率は，上咽頭炎が 63.7 件/100 人年，貧血が 12.4 件/100 人年，インフルエンザ及び潰瘍性大腸炎が 10.9 件/100 人年，発熱が 17.1 件/100 人年，悪心及び膀胱炎が 7.8 件/100 人年であった。

表 2.7.4.2-9. 5%以上の被験者に発現した有害事象の発現割合及び 100 人年あたりの発現率（MedDRA PT 別）
（統合安全性解析対象集団，M14-033 日本サブ試験の維持療法試験）

	統合安全性解析対象集団							
	アダリムマブ維持療法							
	40 mg EOW (N = 345; PYs = 237.5)		40 mg EW (N = 350; PYs = 252.1)		TDM (N = 151; PYs = 105.8)		合計 (N = 846; PYs = 595.5)	
MedDRA 22.0 PT	n (%)	E (E/100 PYs)	n (%)	E (E/100 PYs)	n (%)	E (E/100 PYs)	n (%)	E (E/100 PYs)
潰瘍性大腸炎	76 (22.0)	90 (37.9)	65 (18.6)	82 (32.5)	29 (19.2)	37 (35.0)	170 (20.1)	209 (35.1)
上咽頭炎	47 (13.6)	61 (25.7)	46 (13.1)	57 (22.6)	11 (7.3)	20 (18.9)	104 (12.3)	138 (23.2)
関節痛	24 (7.0)	28 (11.8)	25 (7.1)	31 (12.3)	5 (3.3)	5 (4.7)	54 (6.4)	64 (10.7)
上気道感染	22 (6.4)	25 (10.5)	19 (5.4)	20 (7.9)	9 (6.0)	10 (9.5)	50 (5.9)	55 (9.2)
頭痛	17 (4.9)	19 (8.0)	22 (6.3)	36 (14.3)	8 (5.3)	9 (8.5)	47 (5.6)	64 (10.7)

E = event; EOW = every other week; EW = every week; MedDRA = Medical Dictionary for Regulatory Activities;
PT = preferred term; PY = patient year; TDM = therapeutic drug monitoring
Note: The ≥ 5% of subjects presented in this table is for total values.
Cross reference: M14-033 Maintenance Japan Sub-study Final CSR Table 14.3　1.3.1_J, Table 14.3　1.3.2_J

表 2.7.4.2-10. 5%以上の被験者に発現した有害事象の発現割合及び 100 人年あたりの発現率（MedDRA PT 別）
（日本人安全性解析対象集団，M14-033 日本サブ試験の維持療法試験）

	日本人安全性解析対象集団					
	アダリムマブ維持療法					
	40 mg EOW (N = 43; PYs = 31.2)		40 mg EW (N = 46; PYs = 33.1)		合計 (N = 89; PYs = 64.4)	
MedDRA 22.0 PT	n (%)	E (E/100 PYs)	n (%)	E (E/100 PYs)	n (%)	E (E/100 PYs)
上咽頭炎	16 (37.2)	23 (73.7)	16 (34.8)	18 (54.4)	32 (36.0)	41 (63.7)
貧血	3 (7.0)	3 (9.6)	5 (10.9)	5 (15.1)	8 (9.0)	8 (12.4)
インフルエンザ	3 (7.0)	3 (9.6)	4 (8.7)	4 (12.1)	7 (7.9)	7 (10.9)
潰瘍性大腸炎	2 (4.7)	2 (6.4)	5 (10.9)	5 (15.1)	7 (7.9)	7 (10.9)
発熱	2 (4.7)	4 (12.8)	4 (8.7)	7 (21.1)	6 (6.7)	11 (17.1)
悪心	1 (2.3)	1 (3.2)	4 (8.7)	4 (12.1)	5 (5.6)	5 (7.8)
膀胱炎	2 (4.7)	2 (6.4)	3 (6.5)	3 (9.1)	5 (5.6)	5 (7.8)

E = event; EOW = every other week; EW = every week; MedDRA = Medical Dictionary for Regulatory Activities;
PT = preferred term; PY = patient year
Note: By decreasing frequency of the total in the Japan Population.
Cross reference: M14-033 Maintenance Japan Sub-study Final CSR Table 14.3　1.3.1_J, Table 14.3　1.3.2_J

2.7.4.2.1.1.2 成人 治験薬と関連ありの有害事象

M14-033 導入療法試験

主試験安全性解析対象集団で発現した治験薬と関連ありの有害事象を付録 表 2.7.4.7-6 に示した。

主試験安全性解析対象集団の 852 例中 213 例（25.0%）に治験薬と関連ありの有害事象が発現した。治験薬と関連ありの有害事象の発現割合は，標準用量群（340 例中 75 例，22.1%）と高用量群（512 例中 138 例，27.0%）で同程度であった。全体で 10 例以上に発現した治験薬と関連ありの有害事象は，頭痛（24 例，2.8%），注射部位反応（20 例，2.3%），注射部位紅斑（16 例，1.9%），注射部位そう痒感（15 例，1.8%），疲労（14 例，1.6%），悪心（13 例，1.5%），注射部位腫脹（11 例，1.3%）及び関節痛（10 例，1.2%）であった。各事象の発現割合は標準用量群と高用量群でおおむね同程度であったが，注射部位反応（注射部位反応，注射部位紅斑，注射部位そう痒感及び注射部位腫脹）の発現割合は高用量群の方が標準用量群よりも高かった。

統合安全性解析対象集団及び日本人安全性解析対象集団で発現した治験薬と関連ありの有害事象を付録 表 2.7.4.7-7 に示した。

統合安全性解析対象集団の 952 例中 232 例（24.4%）に治験薬と関連ありの有害事象が発現した。治験薬と関連ありの有害事象の発現割合は，標準用量群（379 例中 83 例，21.9%）と高用量群（573 例中 149 例，26.0%）で同程度であった。全体で 10 例以上に発現した治験薬と関連ありの有害事象は，頭痛（24 例，2.5%），注射部位反応（27 例，2.8%），注射部位紅斑（17 例，1.8%），注射部位そう痒感（15 例，1.6%），疲労（14 例，1.5%），悪心（13 例，1.4%）並びに注射部位腫脹及び関節痛（各 11 例，1.2%）であった。各事象の発現割合は標準用量群と高用量群でおおむね同程度であったが，注射部位反応（注射部位反応，注射部位紅斑，注射部位そう痒感及び注射部位腫脹）の発現割合は高用量群の方が標準用量群よりも高かった。

日本人安全性解析対象集団の 100 例中 19 例（19.0%）に治験薬と関連ありの有害事象が発現した。治験薬と関連ありの有害事象の発現割合は，標準用量群（39 例中 8 例，20.5%）と高用量群（61 例中 11 例，18.0%）で同程度であった。全体で 5 例以上に発現した治験薬と関連ありの有害事象は注射部位反応（7 例，7.0%）であり，その発現割合は高用量群（5 例，8.2%）の方が標準用量群（2 例，5.1%）よりも高かった。

M14-033 維持療法試験

主試験安全性解析対象集団で発現した治験薬と関連ありの有害事象を付録 表 2.7.4.7-8 に示した。

主試験安全性解析対象集団の 757 例中 235 例（31.0%）に治験薬と関連ありの有害事象が発現し，内訳は 40 mg 隔週投与群が 302 例中 82 例（27.2%），40 mg 週 1 回投与群が 304 例中 104 例（34.2%），TDM 群が 151 例中 49 例（32.5%）であった。各事象の発現割合は投与群間でおおむね同程度であった。全体で 10 例以上に発現した治験薬と関連ありの有害事象は，関節痛（21

例，2.8%），上咽頭炎及び発疹（各 20 例，2.6%），上気道感染（14 例，1.8%），潰瘍性大腸炎（12 例，1.6%），並びに頭痛及び脱毛症（各 11 例，1.5%）であった。

統合安全性解析対象集団及び日本人安全性解析対象集団で発現した治験薬と関連ありの有害事象を付録 表 2.7.4.7-9 に示した。

統合安全性解析対象集団の 846 例中 255 例（30.1%）に治験薬と関連ありの有害事象が発現し，内訳は 40 mg 隔週投与群が 345 例中 89 例（25.8%），40 mg 週 1 回投与群が 350 例中 117 例（33.4%），TDM 群が 151 例中 49 例（32.5%）であった。各事象の発現割合は投与群間でおおむね同程度であった。全体で 10 例以上に発現した治験薬と関連ありの有害事象は，発疹（22 例，2.6%），関節痛及び上咽頭炎（各 21 例，2.5%），上気道感染（14 例，1.7%），潰瘍性大腸炎（12 例，1.4%）並びに頭痛及び脱毛症（各 11 例，1.3%）であった。

日本人安全性解析対象集団の 89 例中 20 例（22.5%）に治験薬と関連ありの有害事象が発現し，内訳は 40 mg 隔週投与群が 43 例中 7 例（16.3%），40 mg 週 1 回投与群が 46 例中 13 例（28.3%）であった。各事象の発現割合は投与群間でおおむね同程度であった。全体で 5 例以上に発現した治験薬と関連ありの有害事象はなく，複数の被験者に発現した治験薬と関連ありの有害事象は膀胱炎，インフルエンザ，不眠症及び発疹（各 2 例，2.2%）であった。

2.7.4.2.1.1.3 成人 高度の有害事象

M14-033 導入療法試験

主試験安全性解析対象集団で発現した有害事象を重症度別に付録 表 2.7.4.7-10 に示した。

主試験安全性解析対象集団で発現した有害事象の大部分は，重症度が軽度又は中等度と判断された。高度の有害事象は 852 例中 39 例（4.6%）に発現し，内訳は標準用量群が 340 例中 16 例（4.7%），高用量群が 512 例中 23 例（4.5%）であった。複数の被験者に発現した高度の有害事象は，潰瘍性大腸炎（21 例，2.5%），貧血（5 例，0.6%），下痢（3 例，0.4%）及び腹痛（2 例，0.2%）であった。

統合安全性解析対象集団及び日本人安全性解析対象集団で発現した有害事象を重症度別に付録 表 2.7.4.7-11 に示した。

統合安全性解析対象集団で発現した有害事象の大部分は，重症度が軽度又は中等度と判断された。高度の有害事象は 952 例中 41 例（4.3%）に発現し，内訳は標準用量群が 379 例中 17 例（4.5%），高用量群が 573 例中 24 例（4.2%）であった。複数の被験者に発現した高度の有害事象は，潰瘍性大腸炎（22 例，2.3%），貧血（5 例，0.5%），下痢（3 例，0.3%）並びに腹痛及び肺炎（各 2 例，0.2%）であった。

日本人安全性解析対象集団で発現した有害事象の大部分は，重症度が軽度又は中等度と判断された。高度の有害事象は 100 例中 2 例（2.0%）に発現し，内訳は標準用量群が 39 例中 1 例（2.6%），高用量群が 61 例中 1 例（1.6%）であった。発現した高度の有害事象は肺炎（標準用量群）及び潰瘍性大腸炎（高用量群）であり，いずれも重篤であった。

M14-033 維持療法試験

主試験安全性解析対象集団で発現した有害事象を重症度別に付録 表 2.7.4.7-12 に示した。

主試験安全性解析対象集団で発現した有害事象の大部分は，重症度が軽度又は中等度と判断された。高度の有害事象は 757 例中 76 例（10.0%）に発現し，内訳は 40 mg 隔週投与群が 302 例中 28 例（9.3%），40 mg 週 1 回投与群が 304 例中 38 例（12.5%），TDM 群が 151 例中 10 例（6.6%）であった。複数の被験者に発現した高度の有害事象は，潰瘍性大腸炎（26 例，3.4%），肺炎，関節痛及び肺塞栓症（各 4 例，0.5%），貧血（3 例，0.4%）並びに腹痛，大腸炎，血小板増加症，クロストリジウム・ディフィシレ感染及び脱水（各 2 例，0.3%）であった。

統合安全性解析対象集団及び日本人安全性解析対象集団で発現した有害事象を重症度別に付録 表 2.7.4.7-13 に示した。

統合安全性解析対象集団で発現した有害事象の大部分は，重症度が軽度又は中等度と判断された。高度の有害事象は 846 例中 80 例（9.5%）に発現し，内訳は 40 mg 隔週投与群が 345 例中 29 例（8.4%），40 mg 週 1 回投与群が 350 例中 41 例（11.7%），TDM 群が 151 例中 10 例（6.6%）であった。複数の被験者に発現した高度の有害事象は，潰瘍性大腸炎（29 例，3.4%），肺炎，関節痛及び肺塞栓症（各 4 例，0.5%），貧血（3 例，0.4%）並びに腹痛，大腸炎，血小板増加症，クロストリジウム・ディフィシレ感染及び脱水（各 2 例，0.2%）であった。

日本人安全性解析対象集団で発現した有害事象の大部分は，重症度が軽度又は中等度と判断された。高度の有害事象は 89 例中 4 例（4.5%）に発現し，内訳は 40 mg 隔週投与群が 43 例中 1 例（2.3%），40 mg 週 1 回投与群が 46 例中 3 例（6.5%）であった。40 mg 隔週投与群の 1 例に発現した高度の有害事象は意識変容状態であり，40 mg 週 1 回投与群の 3 例に発現した高度の有害事象はいずれも潰瘍性大腸炎であった。

2.7.4.2.1.2 成人 死亡

M14-033 導入療法試験

主試験安全性解析対象集団で発現した死亡に至った有害事象の一覧を付録 表 2.7.4.7-14 に示した。

主試験では高用量群の 2 例が死亡した。死亡はいずれも治験薬と関連なしと判断された。

主試験では，高用量群の 1 例が 3 回目の治験薬投与後 3 日目の心停止のため死亡した。また，高用量群の別の 1 例が，治験薬の最終投与後 78 日目（有害事象の集計期間外）に術後腹膜炎のため死亡した。

日本サブ試験の日本人安全性解析対象集団では，死亡は認められなかった。

M14-033 維持療法試験

主試験安全性解析対象集団で発現した死亡に至った有害事象の一覧を付録 表 2.7.4.7-15 に示した。

主試験では 4 例が死亡し，内訳は 40 mg 隔週投与群の被験者が 2 例，40 mg 週 1 回投与群の被験者が 2 例であった。死亡はいずれも治験薬と関連なしと判断された。

40 mg 隔週投与群の 1 例は，維持療法試験の投与 36 日目に重篤な高度の肺塞栓症が発現したため治験薬投与が中止された。本事象の発現前に，肩骨折が発現していた。本被験者は事象の発現後 6 日目に死亡した。40 mg 隔週投与群の他の 1 例は，維持療法試験の投与 87 日目に重篤な高度の非小細胞肺癌が発現したため治験薬投与が中止され，併用薬が処方された。本被験者は事象の発現後 84 日目に死亡した。本被験者には 1 日 2.5 パック，44 年間の喫煙歴があった。40 mg 週 1 回投与群の 1 例は，治験薬の最終投与後 52 日目に重篤な高度の食道腺癌が発現し，併用薬が処方された。本被験者は事象の発現後 31 日目に死亡した。リスク因子として胃食道逆流性疾患の病歴があり，1 日 1 パック，28 年間の喫煙歴がある喫煙者であった。40 mg 週 1 回投与群の他の 1 例は，治験薬投与の中止後 17 日目に重篤な高度の肺炎が発現したため入院し，併用薬の投与が中止された。本被験者は事象の発現後 3 日目に死亡した。リスク因子として，1 日 1 パック，20 年間の喫煙歴がある元喫煙者であり，UC の悪化による直近の入院があった。

日本サブ試験の日本人安全性解析対象集団では，死亡は認められなかった。

2.7.4.2.1.3 成人 その他の重篤な有害事象

M14-033 導入療法試験

主試験安全性解析対象集団で発現した重篤な有害事象を付録 表 2.7.4.7-16 に，治験薬と関連ありの重篤な有害事象を付録 表 2.7.4.7-17 に示した。また，主試験安全性解析対象集団で発現した重篤な有害事象の一覧を付録 表 2.7.4.7-18 に示した。

主試験安全性解析対象集団の 852 例中 36 例（4.2%）に重篤な有害事象が発現した。重篤な有害事象の発現割合は，標準用量群（340 例中 17 例，5.0%）と高用量群（512 例中 19 例，3.7%）で同程度であった。複数の被験者に発現した重篤な有害事象は，潰瘍性大腸炎（21 例，2.5%）及び貧血（5 例，0.6%）であった。治験薬と関連ありの重篤な有害事象は 3 例（0.4%）に発現した。内訳は，標準用量群の 1 例に発現した帯状疱疹，標準用量群で約 2 週間の投与を受けた 1 例に発現した表皮内悪性黒色腫，及び高用量群の 1 例に発現したクロストリジウム・ディフィシレ感染であった。

統合安全性解析対象集団及び日本人安全性解析対象集団で発現した重篤な有害事象を付録 表 2.7.4.7-19 に，治験薬と関連ありの重篤な有害事象を付録 表 2.7.4.7-20 に示した。また，日本人安全性解析対象集団で発現した重篤な有害事象の一覧を付録 表 2.7.4.7-21 に示した。

統合安全性解析対象集団の 952 例中 41 例（4.3%）に重篤な有害事象が発現した。重篤な有害事象の発現割合は，標準用量群（379 例中 19 例，5.0%）と高用量群（573 例中 22 例，3.8%）で同程度であった。複数の被験者に発現した重篤な有害事象は，潰瘍性大腸炎（25 例，2.6%），貧血（5 例，0.5%）及び腹痛（2 例，0.2%）であった。治験薬と関連ありの重篤な有害事象は 4 例（0.4%）に発現した。内訳は，標準用量群の 1 例に発現した帯状疱疹，標準用量群の 1 例に

発現した肺炎，標準用量群で約 2 週間の投与を受けた 1 例に発現した表皮内悪性黒色腫，及び高用量群の 1 例に発現したクロストリジウム・ディフィシレ感染であった。

日本人安全性解析対象集団の 100 例中 5 例（5.0%）に重篤な有害事象が発現した。重篤な有害事象の発現割合は，標準用量群（39 例中 2 例，5.1%）と高用量群（61 例中 3 例，4.9%）で同程度であった。重篤な有害事象として，潰瘍性大腸炎が 4 例（各群 2 例）に発現した。このうち，標準用量群の 2 例は治験薬投与を中止した。他の重篤な有害事象はいずれも 1 例のみの発現であった（標準用量群で肺炎が 1 例，高用量群で腹痛，水痘が各 1 例）。重篤な肺炎は治験薬と関連ありと判断された。発現した重篤な有害事象はいずれも最終的に消失した。

M14-033 維持療法試験

主試験安全性解析対象集団で発現した重篤な有害事象を付録 表 2.7.4.7-22 に，治験薬と関連ありの重篤な有害事象を付録 表 2.7.4.7-23 に示した。また，主試験安全性解析対象集団で発現した重篤な有害事象の一覧を付録 表 2.7.4.7-24 に示した。

主試験安全性解析対象集団の 757 例中 97 例（12.8%）に重篤な有害事象が発現した。重篤な有害事象の発現割合は，40 mg 隔週投与群（302 例中 42 例，13.9%），40 mg 週 1 回投与群（304 例中 40 例，13.2%）及び TDM 群（151 例中 15 例，9.9%）で同程度であった。全体で 5 例以上に発現した重篤な有害事象は，潰瘍性大腸炎（37 例，4.9%）及び肺炎（6 例，0.8%）であった。治験薬と関連ありの重篤な有害事象は 21 例（2.8%）に発現し，重症度は大部分が中等度又は高度であった。複数の被験者に発現した治験薬と関連ありの重篤な有害事象は，潰瘍性大腸炎及び肺炎（各 2 例，0.3%）であった。

統合安全性解析対象集団及び日本人安全性解析対象集団で発現した重篤な有害事象を付録 表 2.7.4.7-25 に，治験薬と関連ありの重篤な有害事象を付録 表 2.7.4.7-26 に示した。また，日本人安全性解析対象集団で発現した重篤な有害事象の一覧を付録 表 2.7.4.7-27 に示した。

統合安全性解析対象集団の 846 例中 103 例（12.2%）に重篤な有害事象が発現した。重篤な有害事象の発現割合は，40 mg 隔週投与群（345 例中 44 例，12.8%），40 mg 週 1 回投与群（350 例中 44 例，12.6%）及び TDM 群（151 例中 15 例，9.9%）で同程度であった。全体で 5 例以上に発現した重篤な有害事象は，潰瘍性大腸炎（40 例，4.7%）及び肺炎（6 例，0.7%）であった。治験薬と関連ありの重篤な有害事象は 22 例（2.6%）に発現し，重症度は大部分が中等度又は高度であった。複数の被験者に発現した治験薬と関連ありの重篤な有害事象は，潰瘍性大腸炎及び肺炎（各 2 例，0.2%）であった。

日本人安全性解析対象集団の 89 例中 6 例（6.7%）に重篤な有害事象が発現し，内訳は 40 mg 隔週投与群が 43 例中 2 例（4.7%），40 mg 週 1 回投与群が 46 例中 4 例（8.7%）であった。複数の被験者に発現した重篤な有害事象は潰瘍性大腸炎（3 例，3.4%）であった。治験薬と関連ありの重篤な有害事象は 1 例（1.1%）に発現した。本被験者は 40 mg 隔週投与群の被験者であり，意識変容状態が発現した。

2.7.4.2.1.4 成人 その他の重要な有害事象

M14-033 導入療法試験

主試験安全性解析対象集団で発現した治験薬投与の中止に至った有害事象を付録 表 2.7.4.7-28 に，治験薬と関連ありの治験薬投与の中止に至った有害事象を付録 表 2.7.4.7-29 に示した。

主試験安全性解析対象集団の 852 例中 49 例（5.8%）に治験薬投与の中止に至った有害事象が発現した。治験薬投与の中止に至った有害事象の発現割合は，標準用量群（340 例中 19 例，5.6%）と高用量群（512 例中 30 例，5.9%）で同程度であった。複数の被験者に発現した治験薬投与の中止に至った有害事象は，潰瘍性大腸炎（29 例，3.4%）並びに貧血及び大腸炎（各 2 例，0.2%）であった。治験薬と関連ありの治験薬投与の中止に至った有害事象は 13 例（1.5%）に発現した。

統合安全性解析対象集団及び日本人安全性解析対象集団で発現した治験薬投与の中止に至った有害事象を付録 表 2.7.4.7-30 に，治験薬と関連ありの治験薬投与の中止に至った有害事象を付録 表 2.7.4.7-31 に示した。

統合安全性解析対象集団の 952 例中 53 例（5.6%）に治験薬投与の中止に至った有害事象が発現した。治験薬投与の中止に至った有害事象の発現割合は，標準用量群（379 例中 22 例，5.8%）と高用量群（573 例中 31 例，5.4%）で同程度であった。複数の被験者に発現した治験薬投与の中止に至った有害事象は，潰瘍性大腸炎（31 例，3.3%）並びに貧血及び大腸炎（各 2 例，0.2%）であった。治験薬と関連ありの治験薬投与の中止に至った有害事象は 15 例（1.6%）に発現した。

日本人安全性解析対象集団の 100 例中 4 例（4.0%）に治験薬投与の中止に至った有害事象が発現し，内訳は標準用量群が 39 例中 3 例（7.7%），高用量群が 61 例中 1 例（1.6%）であった。標準用量群の 2 例に発現した事象は重篤な潰瘍性大腸炎であり，いずれも治験薬と関連なしと判断された。標準用量群の別の 1 例に発現した事象は注射部位紅斑，高用量群の 1 例に発現した事象は湿疹であり，いずれも非重篤で治験薬と関連ありと判断された。

M14-033 維持療法試験

主試験安全性解析対象集団で発現した治験薬投与の中止に至った有害事象を付録 表 2.7.4.7-32 に，治験薬と関連ありの治験薬投与の中止に至った有害事象を付録 表 2.7.4.7-33 に示した。

主試験安全性解析対象集団の 757 例中 85 例（11.2%）に治験薬投与の中止に至った有害事象が発現した。治験薬投与の中止に至った有害事象の発現割合は，40 mg 隔週投与群（302 例中 38 例，12.6%），40 mg 週 1 回投与群（304 例中 30 例，9.9%）及び TDM 群（151 例中 17 例，11.3%）で同程度であった。全体で 5 例以上に発現した治験薬投与の中止に至った有害事象は，潰瘍性大腸炎（40 例，5.3%）及び大腸炎（5 例，0.7%）であった。治験薬投与の中止に至った有害事象のうち，38 例（5.0%）に発現した事象は重篤であった。治験薬と関連ありの治験薬投与の中止に至った有害事象は 33 例（4.4%）に発現した。

統合安全性解析対象集団及び日本人安全性解析対象集団で発現した治験薬投与の中止に至った有害事象を付録 表 2.7.4.7-34 に，治験薬と関連ありの治験薬投与の中止に至った有害事象を付録 表 2.7.4.7-35 に示した。

統合安全性解析対象集団の 846 例中 92 例（10.9%）に治験薬投与の中止に至った有害事象が発現した。治験薬投与の中止に至った有害事象の発現割合は，40 mg 隔週投与群（345 例中 40 例，11.6%），40 mg 週 1 回投与群（350 例中 35 例，10.0%）及び TDM 群（151 例中 17 例，11.3%）で同程度であった。全体で 5 例以上に発現した治験薬投与の中止に至った有害事象は，潰瘍性大腸炎（45 例，5.3%）及び大腸炎（5 例，0.6%）であった。治験薬投与の中止に至った有害事象のうち，40 例（4.7%）に発現した事象は重篤であった。治験薬と関連ありの治験薬投与の中止に至った有害事象は 35 例（4.1%）に発現した。

日本人安全性解析対象集団では，治験薬投与の中止に至った有害事象が 89 例中 7 例（7.9%）に発現し，内訳は 40 mg 隔週投与群が 43 例中 2 例（4.7%），40 mg 週 1 回投与群が 46 例中 5 例（10.9%）であった。全体で 5 例以上に発現した治験薬投与の中止に至った有害事象は潰瘍性大腸炎（5 例，5.6%）であった。治験薬と関連ありの治験薬投与の中止に至った有害事象は 2 例（2.2%）に発現した（40 mg 隔週投与群で肝胆道系疾患が 1 例，40 mg 週 1 回投与群でループス様症候群が 1 例）。

2.7.4.2.1.5 成人 器官別又は症候群別有害事象の解析

2.7.4.2.1.5.1 成人 概要

M14-033 導入療法試験

主試験安全性解析対象集団で発現した AESI の概要を表 2.7.4.2-11 に示した。

主試験安全性解析対象集団（852 例）では，AESI のカテゴリーのうち，すべての感染症が 127 例（14.9%），重篤な感染症が 5 例（0.6%），口腔カンジダ症及び結核を除く日和見感染症が 2 例（0.2%），活動性結核が 1 例（0.1%），寄生虫感染が 1 例（0.1%），悪性腫瘍が 3 例（0.4%）（うち，非黒色腫皮膚癌が 1 例［0.1%］，黒色腫が 1 例［0.1%］，その他の悪性腫瘍［非黒色腫皮膚癌，黒色腫，リンパ腫，肝脾 T 細胞リンパ腫，白血病を除く］が 1 例［0.1%］），血管浮腫 / アナフィラキシーを含むアレルギー反応が 13 例（1.5%），膵炎が 1 例（0.1%），乾癬の悪化又は新規発症が 3 例（0.4%），汎血球減少症を含む血液障害が 38 例（4.5%），肝不全及びその他の肝臓関連事象（胆嚢関連の事象を除く）が 2 例（0.2%），注射部位反応が 75 例（8.8%）に発現した。

主試験安全性解析対象集団では，上記以外の AESI は発現しなかった。

表 2.7.4.2-11. AESI の概要（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）

	アダリムマブ導入療法					
	標準用量 (N=340)		高用量 (N=512)		合計 (N=852)	
	n	(%)	n	(%)	n	(%)
Any infection	58	(17.1)	69	(13.5)	127	(14.9)
Any serious infection	2	(0.6)	3	(0.6)	5	(0.6)
Any opportunistic inf. excl. oral candidiasis and TB	1	(0.3)	1	(0.2)	2	(0.2)
Any active tuberculosis	0		1	(0.2)	1	(0.1)
Any parasitic infection	0		1	(0.2)	1	(0.1)
Any malignancy	3	(0.9)	0		3	(0.4)
Any non-melanoma skin cancer (NMSC)	1	(0.3)	0		1	(0.1)
Any melanoma	1	(0.3)	0		1	(0.1)
Any malignancy other than NMSC, melanoma, lymphoma, HSTCL, and leukemia	1	(0.3)	0		1	(0.1)
Any allergic reaction (including angioedema/anaphylaxis)	5	(1.5)	8	(1.6)	13	(1.5)
Any pancreatitis	0		1	(0.2)	1	(0.1)
Any worsening/new onset of psoriasis	2	(0.6)	1	(0.2)	3	(0.4)
Any hematologic disorders (including pancytopenia)	16	(4.7)	22	(4.3)	38	(4.5)
Any liver failure and other liver event (except gall bladder related)	0		2	(0.4)	2	(0.2)
Any injection site reaction	13	(3.8)	62	(12.1)	75	(8.8)

Note: Treatment-emergent adverse events during induction study are defined as events that begin or worsen either on or after the first dose of the study medication and up to the first dose of the study medication in maintenance study for those who are re-randomized at Week 8, or events that begin or worsen either on or after the first dose of the study drug and within 70 days after the last dose of the study medication in the induction study for subjects who are not re-randomized.

Cross reference: M14-033 Induction Main-study Final CSR Table 14.3 1.1.3

統合安全性解析対象集団及び日本人安全性解析対象集団で発現した AESI の概要を表 2.7.4.2-12 に示した。

統合安全性解析対象集団（952 例）では，AESI のカテゴリーのうち，すべての感染症が 145 例（15.2%），重篤な感染症が 7 例（0.7%），口腔カンジダ症及び結核を除く日和見感染症が 2 例（0.2%），活動性結核が 1 例（0.1%），寄生虫感染が 1 例（0.1%），悪性腫瘍が 3 例（0.3%）（うち，非黒色腫皮膚癌が 1 例［0.1%］，黒色腫が 1 例［0.1%］，その他の悪性腫瘍［非黒色腫皮膚癌，黒色腫，リンパ腫，肝脾 T 細胞リンパ腫，白血病を除く］が 1 例［0.1%］），血管浮腫 / アナフィラキシーを含むアレルギー反応が 15 例（1.6%），膵炎が 1 例（0.1%），乾癬の悪化又は新規発症が 3 例（0.3%），汎血球減少症を含む血液障害が 44 例（4.6%），肝不全及びその他の肝臓関連事象（胆嚢関連の事象を除く）が 2 例（0.2%），注射部位反応が 85 例（8.9%）に発現した。

日本人安全性解析対象集団（100 例）では，AESI のカテゴリーのうち，すべての感染症が 18 例（18.0%），重篤な感染症が 2 例（2.0%），血管浮腫 / アナフィラキシーを含むアレルギー反応が 2 例（2.0%），汎血球減少症を含む血液障害が 6 例（6.0%），注射部位反応が 10 例（10.0%）に発現した。

統合安全性解析対象集団及び日本人安全性解析対象集団では，上記以外の AESI は発現しなかった。

表 2.7.4.2-12. AESI の概要（日本人安全性解析対象集団及び統合安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）

	日本人安全性解析対象集団			統合安全性解析対象集団		
	アダリムマブ導入療法			アダリムマブ導入療法		
	標準用量 (N=39) n (%)	高用量 (N=61) n (%)	合計 (N=100) n (%)	標準用量 (N=379) n (%)	高用量 (N=573) n (%)	合計 (N=952) n (%)
Any infection	4 (10.3)	14 (23.0)	18 (18.0)	62 (16.4)	83 (14.5)	145 (15.2)
Any serious infection	1 (2.6)	1 (1.6)	2 (2.0)	3 (0.8)	4 (0.7)	7 (0.7)
Any opportunistic inf. excl. oral candidiasis and TB	0	0	0	1 (0.3)	1 (0.2)	2 (0.2)
Any active tuberculosis	0	0	0	0	1 (0.2)	1 (0.1)
Any parasitic infection	0	0	0	0	1 (0.2)	1 (0.1)
Any malignancy	0	0	0	3 (0.8)	0	3 (0.3)
Any non-melanoma skin cancer (NMSC)	0	0	0	1 (0.3)	0	1 (0.1)
Any melanoma	0	0	0	1 (0.3)	0	1 (0.1)
Any malignancy other than NMSC, melanoma, lymphoma, HSTCL, and leukemia	0	0	0	1 (0.3)	0	1 (0.1)
Any allergic reaction (including angioedema/anaphylaxis)	1 (2.6)	1 (1.6)	2 (2.0)	6 (1.6)	9 (1.6)	15 (1.6)
Any pancreatitis	0	0	0	0	1 (0.2)	1 (0.1)
Any worsening/new onset of psoriasis	0	0	0	2 (0.5)	1 (0.2)	3 (0.3)
Any hematologic disorders (including pancytopenia)	2 (5.1)	4 (6.6)	6 (6.0)	18 (4.7)	26 (4.5)	44 (4.6)
Any liver failure and other liver event (except gall bladder related)	0	0	0	0	2 (0.3)	2 (0.2)
Any injection site reaction	3 (7.7)	7 (11.5)	10 (10.0)	16 (4.2)	69 (12.0)	85 (8.9)

Note: Treatment-emergent adverse events during induction study are defined as events that begin or worsen either on or after the first dose of the study medication and up to the first dose of the study medication in maintenance study for those who are re-randomized at Week 8, or events that begin or worsen either on or after the first dose of the study drug and within 70 days after the last dose of the study medication in the induction study for subjects who are not re-randomized.

Cross reference: M14-033 Induction Japan Sub-study Final CSR Table 14.3__1.1.2_J

M14-033 維持療法試験

主試験安全性解析対象集団で発現した AESI の概要を表 2.7.4.2-13 に示した。

主試験安全性解析対象集団（757 例）では，AESI のカテゴリーのうち，すべての感染症が 266 例（35.1%），重篤な感染症が 22 例（2.9%），憩室炎が 1 例（0.1%），口腔カンジダ症が 3 例（0.4%），活動性結核が 3 例（0.4%），寄生虫感染が 3 例（0.4%），悪性腫瘍が 6 例（0.8%）（うち，非黒色腫皮膚癌が 2 例［0.3%］，黒色腫が 1 例［0.1%］，その他の悪性腫瘍［非黒色腫皮膚癌，黒色腫，リンパ腫，肝脾 T 細胞リンパ腫，白血病を除く］が 3 例［0.4%］），血管浮腫 / アナフィラキシーを含むアレルギー反応が 10 例（1.3%），血管炎が 2 例（0.3%）（うち，皮膚血管炎が 1 例［0.1%］，皮膚以外の血管炎が 1 例［0.1%］），心筋梗塞に関連する事象が 1 例（0.1%），脳血管発作に関連する事象が 1 例（0.1%），うっ血性心不全に関連する事象が 1 例（0.1%），肺塞栓症に関連する事象が 4 例（0.5%），膵炎が 1 例（0.1%），乾癬の悪化又は新規発症が 4 例（0.5%），脱髄疾患が 1 例（0.1%），汎血球減少症を含む血液障害が 39 例（5.2%），肝不全及びその他の肝臓関連事象（胆嚢関連の事象を除く）が 2 例（0.3%），注射部位反応が 27 例（3.6%）に発現した。

主試験安全性解析対象集団では，上記以外の AESI は発現しなかった。

表 2.7.4.2-13. AESI の概要（主試験安全性解析対象集団，M14-033 主試験の維持療法試験）

	アダリムマブ維持療法			
	40mg EOW (N=302) n (%)	40mg EW (N=304) n (%)	TDM (N=151) n (%)	合計 (N=757) n (%)
Any infection	110 (36.4)	105 (34.5)	51 (33.8)	266 (35.1)
Any serious infection	10 (3.3)	9 (3.0)	3 (2.0)	22 (2.9)
Any diverticulitis infection	0	1 (0.3)	0	1 (0.1)
Any oral candidiasis	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
Any active tuberculosis	0	2 (0.7)	1 (0.7)	3 (0.4)
Any parasitic infection	0	2 (0.7)	1 (0.7)	3 (0.4)
Any malignancy	2 (0.7)	4 (1.3)	0	6 (0.8)
Any non-melanoma skin cancer (NMSC)	1 (0.3)	1 (0.3)	0	2 (0.3)
Any melanoma	0	1 (0.3)	0	1 (0.1)
Any malignancy other than NMSC, melanoma, lymphoma, HSTCL, and leukemia	1 (0.3)	2 (0.7)	0	3 (0.4)
Any allergic reaction (including angioedema/anaphylaxis)	4 (1.3)	6 (2.0)	0	10 (1.3)
Any vasculitis	0	1 (0.3)	1 (0.7)	2 (0.3)
Any cutaneous vasculitis	0	0	1 (0.7)	1 (0.1)
Any non-cutaneous vasculitis	0	1 (0.3)	0	1 (0.1)
Any myocardial infarction related	1 (0.3)	0	0	1 (0.1)
Any cerebrovascular accident related	0	0	1 (0.7)	1 (0.1)
Any congestive heart failure related	1 (0.3)	0	0	1 (0.1)
Any pulmonary embolism related	1 (0.3)	3 (1.0)	0	4 (0.5)
Any pancreatitis	1 (0.3)	0	0	1 (0.1)
Any worsening/new onset of psoriasis	2 (0.7)	1 (0.3)	1 (0.7)	4 (0.5)
Any demyelinating disorder	0	0	1 (0.7)	1 (0.1)
Any hematologic disorders (including pancytopenia)	14 (4.6)	17 (5.6)	8 (5.3)	39 (5.2)
Any liver failure and other liver event (except gall bladder related)	1 (0.3)	1 (0.3)	0	2 (0.3)
Any injection site reaction	8 (2.6)	14 (4.6)	5 (3.3)	27 (3.6)

Note: Treatment-emergent adverse events during the maintenance study are defined as events that begin or worsen either on or after the first dose of the study drug in the maintenance study and within 70 days after the last dose of the study drug.

Cross reference: M14-033 Maintenance Main-study Final CSR Table 14.3 1.1.3

統合安全性解析対象集団及び日本人安全性解析対象集団で発現した AESI の概要を表 2.7.4.2-14 に示した。

統合安全性解析対象集団（846 例）では，AESI のカテゴリーのうち，すべての感染症が 313 例（37.0%），重篤な感染症が 23 例（2.7%），憩室炎が 1 例（0.1%），口腔カンジダ症が 4 例（0.5%），活動性結核が 3 例（0.4%），寄生虫感染が 3 例（0.4%），悪性腫瘍が 6 例（0.7%）（うち，非黒色腫皮膚癌が 2 例［0.2%］，黒色腫が 1 例［0.1%］，その他の悪性腫瘍［非黒色腫皮膚癌，黒色腫，リンパ腫，肝脾 T 細胞リンパ腫，白血病を除く］が 3 例［0.4%］），血管浮腫 / アナフィラキシーを含むアレルギー反応が 11 例（1.3%），ループス様反応及び全身性エリテマトーデスが 1 例（0.1%），血管炎が 2 例（0.2%）（うち，皮膚血管炎が 1 例［0.1%］，皮膚以外の血管炎が 1 例［0.1%］），心筋梗塞に関連する事象が 1 例（0.1%），脳血管発作に関連する事象が 1 例（0.1%），うっ血性心不全に関連する事象が 1 例（0.1%），肺塞栓症に関連する事象が 4 例（0.5%），膵炎が 1 例（0.1%），乾癬の悪化又は新規発症が 4 例（0.5%），脱髄疾患が 1 例（0.1%），汎血球減少症を含む血液障害が 48 例（5.7%），肝不全及びその他の肝臓関連事象（胆嚢関連の事象を除く）が 4 例（0.5%），注射部位反応が 29 例（3.4%）に発現した。

日本人安全性解析対象集団（89 例）では，AESI のカテゴリーのうち，すべての感染症が 47 例（52.8%），重篤な感染症が 1 例（1.1%），口腔カンジダ症が 1 例（1.1%），血管浮腫 / アナフィラキシーを含むアレルギー反応が 1 例（1.1%），ループス様反応及び全身性エリテマトーデスが 1 例（1.1%），汎血球減少症を含む血液障害が 9 例（10.1%），肝不全及びその他の肝臓関連事象（胆嚢関連の事象を除く）が 2 例（2.2%），注射部位反応が 2 例（2.2%）に発現した。

統合安全性解析対象集団及び日本人安全性解析対象集団では，上記以外の AESI は発現しなかった。

表 2.7.4.2-14.　AESI の概要（日本人安全性解析対象集団及び統合安全性解析対象集団，M14-033 日本サブ試験の維持療法試験）

	日本人安全性解析対象集団			統合安全性解析対象集団			
	アダリムマブ維持療法			アダリムマブ維持療法			
	40mg EOW (N=43) n (%)	40mg EW (N=46) n (%)	合計 (N=89) n (%)	40mg EOW (N=345) n (%)	40mg EW (N=350) n (%)	TDM (N=151) n (%)	合計 (N=846) n (%)
Any infection	22 (51.2)	25 (54.3)	47 (52.8)	132 (38.3)	130 (37.1)	51 (33.8)	313 (37.0)
Any serious infection	1 (2.3)	0	1 (1.1)	11 (3.2)	9 (2.6)	3 (2.0)	23 (2.7)
Any diverticulitis infection	0	0	0	0	1 (0.3)	0	1 (0.1)
Any oral candidiasis	1 (2.3)	0	1 (1.1)	2 (0.6)	1 (0.3)	1 (0.7)	4 (0.5)
Any active tuberculosis	0	0	0	0	2 (0.6)	1 (0.7)	3 (0.4)
Any parasitic infection	0	0	0	0	2 (0.6)	1 (0.7)	3 (0.4)
Any malignancy	0	0	0	2 (0.6)	4 (1.1)	0	6 (0.7)
Any non-melanoma skin cancer (NMSC)	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
Any melanoma	0	0	0	0	1 (0.3)	0	1 (0.1)
Any malignancy other than NMSC, melanoma, lymphoma, HSTCL, and leukemia	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)
Any allergic reaction (including angioedema/anaphylaxis)	0	1 (2.2)	1 (1.1)	4 (1.2)	7 (2.0)	0	11 (1.3)
Any lupus-like reactions and systemic lupus erythematosus	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)
Any vasculitis	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
Any cutaneous vasculitis	0	0	0	0	0	1 (0.7)	1 (0.1)
Any non-cutaneous vasculitis	0	0	0	0	1 (0.3)	0	1 (0.1)
Any myocardial infarction related	0	0	0	1 (0.3)	0	0	1 (0.1)
Any cerebrovascular accident related	0	0	0	0	0	1 (0.7)	1 (0.1)
Any congestive heart failure related	0	0	0	1 (0.3)	0	0	1 (0.1)
Any pulmonary embolism related	0	0	0	1 (0.3)	3 (0.9)	0	4 (0.5)
Any pancreatitis	0	0	0	1 (0.3)	0	0	1 (0.1)
Any worsening/new onset of psoriasis	0	0	0	2 (0.6)	1 (0.3)	1 (0.7)	4 (0.5)
Any demyelinating disorder	0	0	0	0	0	1 (0.7)	1 (0.1)
Any hematologic disorders (including pancytopenia)	3 (7.0)	6 (13.0)	9 (10.1)	17 (4.9)	23 (6.6)	8 (5.3)	48 (5.7)
Any liver failure and other liver event (except gall bladder related)	1 (2.3)	1 (2.2)	2 (2.2)	2 (0.6)	2 (0.6)	0	4 (0.5)
Any injection site reaction	0	2 (4.3)	2 (2.2)	8 (2.3)	16 (4.6)	5 (3.3)	29 (3.4)

表 2.7.4.2-14.　　AESI の概要（日本人安全性解析対象集団及び統合安全性解析対象集団，M14-033 日本サブ試験の維持療法試験）（続き）

Note: Treatment-emergent adverse events during the maintenance study are defined as events that begin or worsen either on or after the first dose of the study drug in the maintenance study and within 70 days after the last dose of the study drug.

Cross reference: M14-033 Maintenance Japan Sub-study Final CSR Table 14.3　1.1.3_J

2.7.4.2.1.5.2 成人 すべての感染症

M14-033 導入療法試験

主試験安全性解析対象集団で発現したすべての感染症を付録 表 2.7.4.7-36 に示す。

主試験安全性解析対象集団の 852 例中 127 例（14.9%）に感染症が発現した。感染症の発現割合は，標準用量群（340 例中 58 例，17.1%）と高用量群（512 例中 69 例，13.5%）で同程度であった。発現した感染症の大部分は非重篤であり，治験薬と関連なしと判断された。全体で 10 例以上に発現した感染症は，上咽頭炎（33 例，3.9%）及び尿路感染（11 例，1.3%）であった。

統合安全性解析対象集団及び日本人安全性解析対象集団で発現したすべての感染症を付録 表 2.7.4.7-37 に示す。

統合安全性解析対象集団の 952 例中 145 例（15.2%）に感染症が発現した。感染症の発現割合は，標準用量群（379 例中 62 例，16.4%）と高用量群（573 例中 83 例，14.5%）で同程度であった。発現した感染症の大部分は非重篤であり，治験薬と関連なしと判断された。全体で 10 例以上に発現した感染症は，上咽頭炎（45 例，4.7%）及び尿路感染（11 例，1.2%）であった。

日本人安全性解析対象集団の 100 例中 18 例（18.0%）に感染症が発現した。感染症の発現割合は，高用量群（61 例中 14 例，23.0%）の方が標準用量群（39 例中 4 例，10.3%）よりも高かった。発現した感染症の大部分は非重篤であり，治験薬と関連なしと判断された。複数の被験者に発現した感染症は上咽頭炎（12 例，12.0%）であった。

M14-033 維持療法試験

主試験安全性解析対象集団で発現したすべての感染症を付録 表 2.7.4.7-38 に示す。

主試験安全性解析対象集団の 757 例中 266 例（35.1%）に感染症が発現した。感染症の発現割合は，40 mg 隔週投与群（302 例中 110 例，36.4%），40 mg 週 1 回投与群（304 例中 105 例，34.5%）及び TDM 群（151 例中 51 例，33.8%）で同程度であった。発現した感染症の大部分は非重篤で，重症度は軽度又は中等度であり，治験薬と関連なしと判断された。全体で 10 例以上に発現した感染症は，上咽頭炎（72 例，9.5%），上気道感染（47 例，6.2%），インフルエンザ及び副鼻腔炎（各 29 例，3.8%），尿路感染（16 例，2.1%），咽頭炎（15 例，2.0%），胃腸炎（12 例，1.6%）並びに肺炎（11 例，1.5%）であった。

統合安全性解析対象集団及び日本人安全性解析対象集団で発現したすべての感染症を付録 表 2.7.4.7-39 に示す。

統合安全性解析対象集団の 846 例中 313 例（37.0%）に感染症が発現した。感染症の発現割合は，40 mg 隔週投与群（345 例中 132 例，38.3%），40 mg 週 1 回投与群（350 例中 130 例，37.1%）及び TDM 群（151 例中 51 例，33.8%）で同程度であった。発現した感染症の大部分は非重篤で，重症度は軽度又は中等度であり，治験薬と関連なしと判断された。全体で 10 例以上に発現した感染症は，上咽頭炎（104 例，12.3%），上気道感染（50 例，5.9%），インフルエンザ（36 例，4.3%），副鼻腔炎（32 例，3.8%），咽頭炎（17 例，2.0%），尿路感染（16 例，1.9%），胃腸炎（13 例，1.5%），肺炎（12 例，1.4%）及び気管支炎（10 例，1.2%）であった。

日本人安全性解析対象集団の 89 例中 47 例（52.8%）に感染症が発現した。感染症の発現割合は，40 mg 隔週投与群（43 例中 22 例，51.2%）と 40 mg 週 1 回投与群（46 例中 25 例，54.3%）で同程度であった。発現した感染症の大部分は非重篤であり，治験薬と関連なしと判断された。複数の被験者に発現した感染症は上咽頭炎（32 例，36.0%），インフルエンザ（7 例，7.9%），副鼻腔炎及び上気道感染（各 3 例，3.4%）並びに気管支炎，歯周炎及び咽頭炎（各 2 例，2.2%）であった。

2.7.4.2.1.5.3 成人 重篤な感染症

M14-033 導入療法試験

主試験安全性解析対象集団で発現した重篤な感染症を付録 表 2.7.4.7-40 に示す。

主試験安全性解析対象集団の 852 例中 5 例（0.6%）に重篤な感染症が発現した。標準用量群では丹毒及び帯状疱疹が各 1 例に発現し，高用量群ではクロストリジウム・ディフィシレ感染，サイトメガロウイルス性大腸炎及び感染が各 1 例に発現した。治験薬との因果関係は，クロストリジウム・ディフィシレ感染及び帯状疱疹が関連ありと判断され，他の事象は関連なしと判断された。

統合安全性解析対象集団及び日本人安全性解析対象集団で発現した重篤な感染症を付録 表 2.7.4.7-41 に示す。

統合安全性解析対象集団の 952 例中 7 例（0.7%）に重篤な感染症が発現した。標準用量群では丹毒，帯状疱疹及び肺炎が各 1 例に発現し，高用量群ではクロストリジウム・ディフィシレ感染，サイトメガロウイルス性大腸炎，感染及び水痘が各 1 例に発現した。治験薬との因果関係は，クロストリジウム・ディフィシレ感染，帯状疱疹及び肺炎が関連ありと判断され，他の事象は関連なしと判断された。

日本人安全性解析対象集団の 100 例中 2 例（2.0%）に重篤な感染症が発現した。標準用量群では肺炎が 1 例に発現し，高用量群では水痘が 1 例に発現した。治験薬との因果関係は，肺炎が関連ありと判断され，水痘は関連なしと判断された。いずれの事象も最終的に消失した。

M14-033 維持療法試験

主試験安全性解析対象集団で発現した重篤な感染症を付録 表 2.7.4.7-42 に示す。

主試験安全性解析対象集団の 757 例中 22 例（2.9%）に重篤な感染症が発現した。40 mg 隔週投与群ではクロストリジウム・ディフィシレ感染が 3 例に，肺炎が 2 例に，外耳蜂巣炎，消化管感染，外耳炎，会陰膿瘍，胸骨炎及びウイルス感染が各 1 例に発現した。40 mg 週 1 回投与群では肺炎が 4 例に，虫垂炎，骨盤内炎症性疾患，扁桃周囲膿瘍，結核及び胸腔内リンパ節結核が各 1 例に発現した。TDM 群では気管支炎，敗血症及び結核が各 1 例に発現した。治験薬との因果関係は，肺炎の 2 例並びに外耳蜂巣炎，外耳炎，クロストリジウム・ディフィシレ感染，結核，敗血症の各 1 例が関連ありと判断され，他の事象は関連なしと判断された。

統合安全性解析対象集団及び日本人安全性解析対象集団で発現した重篤な感染症を付録表 2.7.4.7-43 に示す。

統合安全性解析対象集団の 846 例中 23 例（2.7%）に重篤な感染症が発現した。40 mg 隔週投与群ではクロストリジウム・ディフィシレ感染が 3 例に，肺炎が 2 例に，外耳蜂巣炎，胃腸炎，消化管感染，外耳炎，会陰膿瘍，胸骨炎及びウイルス感染が各 1 例に発現した。40 mg 週 1 回投与群では肺炎が 4 例に，虫垂炎，骨盤内炎症性疾患，扁桃周囲膿瘍，結核及び胸腔内リンパ節結核が各 1 例に発現した。TDM 群では気管支炎，敗血症及び結核が各 1 例に発現した。治験薬との因果関係は，肺炎の 2 例並びに外耳蜂巣炎，外耳炎，クロストリジウム・ディフィシレ感染，結核，敗血症の各 1 例が関連ありと判断され，他の事象は関連なしと判断された。

日本人安全性解析対象集団の 89 例中 1 例（1.1%）に重篤な感染症が発現した。本被験者は 40 mg 隔週投与群の被験者であり，胃腸炎が発現した。治験薬との因果関係は関連なしと判断された。

2.7.4.2.1.5.4 成人 憩室炎

M14-033 導入療法試験

M14-033 導入療法試験では，憩室炎は発現しなかった。

M14-033 維持療法試験

主試験安全性解析対象集団で発現した憩室炎を付録 表 2.7.4.7-44 に示す。

主試験安全性解析対象集団の 757 例中 1 例（0.1%）に憩室炎が発現した。本被験者は 40 mg 週 1 回投与群の被験者であり，非重篤な軽度の憩室炎が発現した。治験薬との因果関係は関連なしと判断された。

日本サブ試験の日本人安全性解析対象集団では，憩室炎は発現しなかった。そのため，統合安全性解析対象集団の結果（846 例中 1 例［0.1%］）は主試験安全性解析対象集団と同様であった。

2.7.4.2.1.5.5 成人 口腔カンジダ症及び結核を除く日和見感染症

M14-033 導入療法試験

主試験安全性解析対象集団で発現した口腔カンジダ症及び結核を除く日和見感染症を付録表 2.7.4.7-45 に示す。

主試験安全性解析対象集団の 852 例中 2 例（0.2%）に口腔カンジダ症及び結核を除く日和見感染症が発現した。標準用量群で中等度の食道カンジダ症が 1 例に発現し，治験薬との因果関係は関連ありと判断された。また，高用量群で高度のサイトメガロウイルス性大腸炎が 1 例に発現し，治験薬との因果関係は関連なしと判断された。

日本サブ試験の日本人安全性解析対象集団では，口腔カンジダ症及び結核を除く日和見感染症は発現しなかった。そのため，統合安全性解析対象集団の結果（952 例中 2 例［0.2%］）は主試験安全性解析対象集団と同様であった。

M14-033 維持療法試験

M14-033 維持療法試験では，口腔カンジダ症及び結核を除く日和見感染症は発現しなかった。

2.7.4.2.1.5.6 成人 口腔カンジダ症

M14-033 導入療法試験

M14-033 導入療法試験では，口腔カンジダ症は発現しなかった。

M14-033 維持療法試験

主試験安全性解析対象集団で発現した口腔カンジダ症を付録 表 2.7.4.7-46 に示す。

主試験安全性解析対象集団の 757 例中 3 例（0.4%）に口腔カンジダ症が発現した。内訳は，40 mg 隔週投与群で口腔カンジダ症が 1 例，40 mg 週 1 回投与群で口腔真菌感染が 1 例及び TDM 群で口腔カンジダ症が 1 例であった。いずれも非重篤で，重症度は中等度であった。治験薬との因果関係は，40 mg 隔週投与群の口腔カンジダ症及び 40 mg 週 1 回投与群の口腔真菌感染が関連あり，TDM 群の口腔カンジダ症が関連なしと判断された。

統合安全性解析対象集団及び日本人安全性解析対象集団で発現した口腔カンジダ症を付録 表 2.7.4.7-47 に示す。

統合安全性解析対象集団の 846 例中 4 例（0.5%）に口腔カンジダ症が発現した。内訳は，40 mg 隔週投与群で口腔カンジダ症が 2 例，40 mg 週 1 回投与群で口腔真菌感染が 1 例，TDM 群で口腔カンジダ症が 1 例であった。いずれも非重篤で，重症度は 40 mg 隔週投与群の 1 例に発現した口腔カンジダ症が軽度であったことを除き，いずれも中等度であった。治験薬との因果関係は，TDM 群の口腔カンジダ症を除きいずれも関連ありと判断された。

日本人安全性解析対象集団の 89 例中 1 例（1.1%）に口腔カンジダ症が発現した。本被験者は 40 mg 隔週投与群の被験者であり，非重篤な軽度の口腔カンジダ症が発現した。治験薬との因果関係は関連ありと判断された。

2.7.4.2.1.5.7 成人 活動性結核

M14-033 導入療法試験

主試験安全性解析対象集団で発現した活動性結核を付録 表 2.7.4.7-48 に示す。

主試験安全性解析対象集団の 852 例中 1 例（0.1%）に活動性結核が発現した。本被験者は高用量群の被験者であり，高度の結核が発現し，治験薬との因果関係は関連ありと判断された。本事象のため治験薬投与が中止された。

日本サブ試験の日本人安全性解析対象集団では，活動性結核は発現しなかった。そのため，統合安全性解析対象集団の結果（952 例中 1 例［0.1%］）は主試験安全性解析対象集団と同様であった。

M14-033 維持療法試験

主試験安全性解析対象集団で発現した活動性結核を付録 表 2.7.4.7-49 に示す。

主試験安全性解析対象集団の 757 例中 3 例（0.4%）に活動性結核が発現した。40 mg 週 1 回投与群の 1 例に重篤な高度の結核が発現し，治験薬との因果関係は関連ありと判断された。治験薬投与は中止され，併用薬が処方された。40 mg 週 1 回投与群の別の 1 例に重篤な高度の胸腔内リンパ節結核が発現し，治験薬との因果関係は関連なしと判断された。本事象の発現前に，被験者は重篤な潰瘍性大腸炎のため治験薬投与を中止していた。また，TDM 群の 1 例に重篤な中等度の結核が発現し，治験薬との因果関係は関連なしと判断された。治験薬投与は中止され，併用薬が処方された。なお，40 mg 隔週投与群では活動性結核は発現しなかった。

日本サブ試験の日本人安全性解析対象集団では，活動性結核は発現しなかった。そのため，統合安全性解析対象集団の結果（846 例中 3 例［0.4%］）は主試験安全性解析対象集団と同様であった。

2.7.4.2.1.5.8 成人 寄生虫感染

M14-033 導入療法試験

主試験安全性解析対象集団で発現した寄生虫感染を付録 表 2.7.4.7-50 に示す。

主試験安全性解析対象集団の 852 例中 1 例（0.1%）に寄生虫感染が発現した。本被験者は高用量群の被験者であり，軽度のブラストシスティス感染が発現し，治験薬との因果関係は関連ありと判断された。

日本サブ試験の日本人安全性解析対象集団では，寄生虫感染は発現しなかった。そのため，統合安全性解析対象集団の結果（952 例中 1 例［0.1%］）は主試験安全性解析対象集団と同様であった。

M14-033 維持療法試験

主試験安全性解析対象集団で発現した寄生虫感染を付録 表 2.7.4.7-51 に示す。

主試験安全性解析対象集団の 757 例中 3 例（0.4%）に寄生虫感染が発現した。40 mg 週 1 回投与群の 2 例に非重篤な軽度の蟯虫症が発現し，治験薬との因果関係は関連なしと判断された。

また，TDM 群の 1 例に非重篤な軽度の寄生虫性胃腸炎が発現し，治験薬との因果関係は関連なしと判断された。なお，40 mg 隔週投与群では寄生虫感染は発現しなかった。

日本サブ試験の日本人安全性解析対象集団では，寄生虫感染は発現しなかった。そのため，統合安全性解析対象集団の結果（846 例中 3 例［0.4%］）は主試験安全性解析対象集団と同様であった。

2.7.4.2.1.5.9 成人 悪性腫瘍

M14-033 導入療法試験

主試験安全性解析対象集団で発現した悪性腫瘍を付録 表 2.7.4.7-52 に示す。

主試験安全性解析対象集団の 852 例中 3 例（0.4%）に悪性腫瘍が発現し，いずれも標準用量群の被験者であった。

AESI カテゴリーで非黒色腫皮膚癌に該当する非重篤な中等度の基底細胞癌が 1 例に発現した。治験薬との因果関係は関連なしと判断された。

AESI カテゴリーで黒色腫に該当する重篤な高度の表皮内悪性黒色腫が 1 例に発現した。治験薬との因果関係は関連ありと判断された。

AESI カテゴリーでその他の悪性腫瘍（非黒色腫皮膚癌，黒色腫，リンパ腫，肝脾 T 細胞リンパ腫，白血病を除く）に該当する重篤な高度の子宮頚部扁平上皮癌が 1 例に発現した。治験薬との因果関係は関連なしと判断された。

日本サブ試験の日本人安全性解析対象集団では，悪性腫瘍は発現しなかった。そのため，統合安全性解析対象集団の結果（952 例中 3 例［0.3%］）は主試験安全性解析対象集団と同様であった。

M14-033 維持療法試験

主試験安全性解析対象集団で発現した悪性腫瘍を付録 表 2.7.4.7-53 に示す。

主試験安全性解析対象集団の 757 例中 6 例（0.8%）に悪性腫瘍が発現し，内訳は 40 mg 隔週投与群が 302 例中 2 例（0.7%），40 mg 週 1 回投与群が 304 例中 4 例（1.3%）であった。TDM 群では悪性腫瘍は発現しなかった。

AESI カテゴリーで非黒色腫皮膚癌に該当する非重篤な基底細胞癌が 40 mg 隔週投与群及び 40 mg 週 1 回投与群の各 1 例に発現した。40 mg 隔週投与群の 1 例に発現した事象は重症度が軽度であり，治験薬と関連なしと判断された。40 mg 週 1 回投与群の 1 例に発現した事象は重症度が中等度であり，治験薬と関連ありと判断された。

AESI カテゴリーで黒色腫に該当する重篤な悪性黒色腫が 40 mg 週 1 回投与群の 1 例に発現した。重症度は軽度であり，治験薬と関連なしと判断された。

AESI カテゴリーでその他の悪性腫瘍（非黒色腫皮膚癌，黒色腫，リンパ腫，肝脾 T 細胞リンパ腫，白血病を除く）に該当する非小細胞肺癌が 40 mg 隔週投与群の 1 例に，膀胱癌及び食道

腺癌が 40 mg 週 1 回投与群の各 1 例に発現した。いずれも重篤であり，重症度は高度，治験薬との因果関係は関連なしと判断された。非小細胞肺癌と膀胱癌は治験薬投与の中止に至った。

日本サブ試験の日本人安全性解析対象集団では，悪性腫瘍は発現しなかった。そのため，統合安全性解析対象集団の結果（846 例中 6 例［0.7%］）は主試験安全性解析対象集団と同様であった。

2.7.4.2.1.5.10 成人 血管浮腫 / アナフィラキシーを含むアレルギー反応

M14-033 導入療法試験

主試験安全性解析対象集団で発現した血管浮腫 / アナフィラキシーを含むアレルギー反応を付録 表 2.7.4.7-54 に示す。

主試験安全性解析対象集団の 852 例中 13 例（1.5%）に血管浮腫 / アナフィラキシーを含むアレルギー反応が発現した。重症度はいずれも軽度又は中等度であり，大部分は治験薬と関連ありと判断された。高用量群の 2 例がそれぞれ血管浮腫及び過敏症のため治験薬投与を中止した。また，高用量群の 1 例が喘息のため治験薬投与を中断した。

統合安全性解析対象集団及び日本人安全性解析対象集団で発現した血管浮腫 / アナフィラキシーを含むアレルギー反応を付録 表 2.7.4.7-55 に示す。

統合安全性解析対象集団の 952 例中 15 例（1.6%）に血管浮腫 / アナフィラキシーを含むアレルギー反応が発現した。重症度はいずれも軽度又は中等度であり，大部分は治験薬と関連ありと判断された。高用量群の 2 例がそれぞれ血管浮腫及び過敏症のため治験薬投与を中止した。また，高用量群の 1 例が喘息のため治験薬投与を中断した。

日本人安全性解析対象集団の 100 例中 2 例（2.0%）に血管浮腫 / アナフィラキシーを含むアレルギー反応が発現した。標準用量群の 1 例に蕁麻疹が発現し，治験薬との因果関係は関連なしと判断された。また，高用量群の 1 例に過敏症が発現し，治験薬との因果関係は関連ありと判断された。いずれの事象も非重篤であり，最終的に消失した。

M14-033 維持療法試験

主試験安全性解析対象集団で発現した血管浮腫 / アナフィラキシーを含むアレルギー反応を付録 表 2.7.4.7-56 に示す。

主試験安全性解析対象集団の 757 例中 10 例（1.3%）に血管浮腫 / アナフィラキシーを含むアレルギー反応が発現し，内訳は 40 mg 隔週投与群が 302 例中 4 例（1.3%），40 mg 週 1 回投与群が 304 例中 6 例（2.0%）であった。TDM 群では血管浮腫 / アナフィラキシーを含むアレルギー反応は発現しなかった。発現した事象はいずれも非重篤であり，重症度は軽度又は中等度であった。治験薬との因果関係は，40 mg 隔週投与群の 1 例（発疹）及び 40 mg 週 1 回投与群の 4 例（蕁麻疹が 2 例並びに薬疹及び喘鳴が各 1 例）が関連ありと判断された。治験薬投与の中止に至ったアレルギー反応は発現しなかった。

統合安全性解析対象集団及び日本人安全性解析対象集団で発現した血管浮腫 / アナフィラキシーを含むアレルギー反応を付録 表 2.7.4.7-57 に示す。

統合安全性解析対象集団の 846 例中 11 例（1.3%）に血管浮腫 / アナフィラキシーを含むアレルギー反応が発現し，内訳は 40 mg 隔週投与群が 345 例中 4 例（1.2%），40 mg 週 1 回投与群が 350 例中 7 例（2.0%）であった。TDM 群では血管浮腫 / アナフィラキシーを含むアレルギー反応は発現しなかった。発現した事象はいずれも非重篤であり，重症度は軽度又は中等度であった。治験薬との因果関係は，40 mg 隔週投与群の 1 例（発疹）及び 40 mg 週 1 回投与群の 5 例（蕁麻疹が 3 例並びに薬疹及び喘鳴が各 1 例）が関連ありと判断された。治験薬投与の中止に至ったアレルギー反応は発現しなかった。

日本人安全性解析対象集団では，89 例中 1 例（1.1%）に血管浮腫 / アナフィラキシーを含むアレルギー反応が発現した。本被験者は 40 mg 週 1 回投与群の被験者であり，非重篤な軽度の蕁麻疹が発現した。治験薬との因果関係は関連ありと判断された。治験薬投与は中止されなかった。

2.7.4.2.1.5.11 成人 ループス様反応及び全身性エリテマトーデス

M14-033 導入療法試験

M14-033 導入療法試験では，ループス様反応及び全身性エリテマトーデスは発現しなかった。

M14-033 維持療法試験

主試験安全性解析対象集団では，ループス様反応及び全身性エリテマトーデスは発現しなかった。

統合安全性解析対象集団及び日本人安全性解析対象集団で発現したループス様反応及び全身性エリテマトーデスを付録 表 2.7.4.7-58 に示す。

統合安全性解析対象集団の 846 例中 1 例（0.1%）（日本人安全性解析対象集団の 89 例中 1 例［1.1%］）に AESI カテゴリーでループス様反応及び全身性エリテマトーデスに該当する有害事象が発現した。発現した事象は非重篤な中等度のループス様症候群であり，治験薬と関連ありと判断された。

2.7.4.2.1.5.12 成人 血管炎

M14-033 導入療法試験

M14-033 導入療法試験では，血管炎は発現しなかった。

M14-033 維持療法試験

主試験安全性解析対象集団で発現した血管炎を付録 表 2.7.4.7-59 に示す。

主試験安全性解析対象集団の 757 例中 2 例（0.3%）に血管炎が発現し，内訳は 40 mg 週 1 回投与群が 304 例中 1 例（0.3%），TDM 群が 151 例中 1 例（0.7%）であった。40 mg 隔週投与群では血管炎は発現しなかった。

AESI カテゴリーで皮膚血管炎に該当する非重篤な過敏性血管炎が TDM 群の 1 例に発現した。重症度は軽度であり，治験薬との因果関係は関連なしと判断された。

AESI カテゴリーで皮膚以外の血管炎に該当する非重篤な動脈炎が 40 mg 週 1 回投与群の 1 例に発現した。重症度は軽度であり，治験薬との因果関係は関連なしと判断された。

日本サブ試験の日本人安全性解析対象集団では，血管炎は発現しなかった。そのため，統合安全性解析対象集団の結果（846 例中 2 例［0.2%］）は主試験安全性解析対象集団と同様であった。

2.7.4.2.1.5.13 成人 心筋梗塞に関連する事象

M14-033 導入療法試験

M14-033 導入療法試験では，心筋梗塞に関連する事象は発現しなかった。

M14-033 維持療法試験

主試験安全性解析対象集団で発現した心筋梗塞に関連する事象を付録 表 2.7.4.7-60 に示す。

主試験安全性解析対象集団の 757 例中 1 例（0.1%）に心筋梗塞に関連する事象が発現した。本被験者は 40 mg 隔週投与群の被験者であり，重篤な急性心筋梗塞が発現した。重症度は高度であり，治験薬との因果関係は関連なしと判断された。本事象のため輸血が実施された。

日本サブ試験の日本人安全性解析対象集団では，心筋梗塞に関連する事象は発現しなかった。そのため，統合安全性解析対象集団の結果（846 例中 1 例［0.1%］）は主試験安全性解析対象集団と同様であった。

2.7.4.2.1.5.14 成人 脳血管発作に関連する事象

M14-033 導入療法試験

M14-033 導入療法試験では，脳血管発作に関連する事象は発現しなかった。

M14-033 維持療法試験

主試験安全性解析対象集団で発現した脳血管発作に関連する事象を付録 表 2.7.4.7-61 に示す。

主試験安全性解析対象集団の 757 例中 1 例（0.1%）に脳血管発作に関連する事象が発現した。本被験者は TDM 群の被験者であり，重篤な虚血性脳卒中が発現した。重症度は高度であり，治験薬との因果関係は関連なしと判断された。本事象のため併用薬の投与が開始された。

日本サブ試験の日本人安全性解析対象集団では，脳血管発作に関連する事象は発現しなかった。そのため，統合安全性解析対象集団の結果（846 例中 1 例［0.1%］）は主試験安全性解析対象集団と同様であった。

2.7.4.2.1.5.15 成人 うっ血性心不全に関連する事象

M14-033 導入療法試験

M14-033 導入療法試験では，うっ血性心不全に関連する事象は発現しなかった。

M14-033 維持療法試験

主試験安全性解析対象集団で発現したうっ血性心不全に関連する事象を付録 表 2.7.4.7-62 に示す。

主試験安全性解析対象集団の 757 例中 1 例（0.1%）にうっ血性心不全に関連する事象が発現した。本被験者は 40 mg 隔週投与群の被験者であり，重篤なうっ血性心不全が発現した。重症度は高度であり，治験薬との因果関係は関連なしと判断された。本事象のため併用薬の投与が開始され，心エコー検査が実施された。

日本サブ試験の日本人安全性解析対象集団では，うっ血性心不全に関連する事象は発現しなかった。そのため，統合安全性解析対象集団の結果（846 例中 1 例［0.1%］）は主試験安全性解析対象集団と同様であった。

2.7.4.2.1.5.16 成人 肺塞栓症に関連する事象

M14-033 導入療法試験

M14-033 導入療法試験では，肺塞栓症に関連する事象は発現しなかった。

M14-033 維持療法試験

主試験安全性解析対象集団で発現した肺塞栓症に関連する事象を付録 表 2.7.4.7-63 に示す。

主試験安全性解析対象集団の 757 例中 4 例（0.5%）に肺塞栓症に関連する事象が発現し，内訳は 40 mg 隔週投与群が 302 例中 1 例（0.3%），40 mg 週 1 回投与群が 304 例中 3 例（1.0%）であった。TDM 群では肺塞栓症に関連する事象は発現しなかった。40 mg 隔週投与群の 1 例に重篤な高度の肺塞栓症が発現し，治験薬との因果関係は関連なしと判断された。本被験者は治験薬投与を中止した。また，40 mg 週 1 回投与群の 3 例に発現した事象はいずれも高度の肺塞栓症であり，治験薬との因果関係は関連なしと判断された。3 例のうち 2 例は重篤であった。いずれも併用薬が投与され，1 例は治験薬投与を中止した。

日本サブ試験の日本人安全性解析対象集団では，肺塞栓症に関連する事象は発現しなかった。そのため，統合安全性解析対象集団の結果（846 例中 4 例［0.5%］）は主試験安全性解析対象集団と同様であった。

2.7.4.2.1.5.17 成人 膵炎

M14-033 導入療法試験

主試験安全性解析対象集団で発現した膵炎を付録 表 2.7.4.7-64 に示す。

主試験安全性解析対象集団の 852 例中 1 例（0.1%）に膵炎が発現した。本被験者は高用量群の被験者であり，治験薬の投与中止後，70 日の追跡調査中に重篤な急性膵炎が発現した。重症度は中等度であり，治験薬との因果関係は関連なしと判断された。

日本サブ試験の日本人安全性解析対象集団では，膵炎は発現しなかった。そのため，統合安全性解析対象集団の結果（952 例中 1 例［0.1%］）は主試験安全性解析対象集団と同様であった。

M14-033 維持療法試験

主試験安全性解析対象集団で発現した膵炎を付録 表 2.7.4.7-65 に示す。

主試験安全性解析対象集団の 757 例中 1 例（0.1%）に膵炎が発現した。本被験者は 40 mg 隔週投与群の被験者であり，投与 345 日目に重篤な高度の急性膵炎が発現し，治験薬との因果関係は関連ありと判断された。本事象に対して併用薬が処方された。治験薬投与を変更することなく，本事象は発現後 16 日目に消失した。

日本サブ試験の日本人安全性解析対象集団では，膵炎は発現しなかった。そのため，統合安全性解析対象集団の結果（846 例中 1 例［0.1%］）は主試験安全性解析対象集団と同様であった。

2.7.4.2.1.5.18 成人 乾癬の悪化又は新規発症

M14-033 導入療法試験

主試験安全性解析対象集団で発現した乾癬の悪化又は新規発症を付録 表 2.7.4.7-66 に示す。

主試験安全性解析対象集団の 852 例中 3 例（0.4%）に乾癬の悪化又は新規発症が発現した。内訳は，標準用量群で中等度の乾癬様皮膚炎及び中等度の乾癬が各 1 例，高用量群で軽度の乾癬が 1 例であった。治験薬との因果関係はいずれも関連ありと判断された。

日本サブ試験の日本人安全性解析対象集団では，乾癬の悪化又は新規発症は発現しなかった。そのため，統合安全性解析対象集団の結果（952 例中 3 例［0.3%］）は主試験安全性解析対象集団と同様であった。

M14-033 維持療法試験

主試験安全性解析対象集団で発現した乾癬の悪化又は新規発症を付録 表 2.7.4.7-67 に示す。

主試験安全性解析対象集団の 757 例中 4 例（0.5%）に乾癬の悪化又は新規発症が発現した。発現した事象はいずれも乾癬であり，40 mg 隔週投与群の 2 例，40 mg 週 1 回投与群の 1 例，TDM 群の 1 例に発現した。40 mg 隔週投与群の 1 例に発現した乾癬は重症度が中等度で，治験薬と関連なしと判断された。他の事象はいずれも重症度が軽度で，治験薬と関連ありと判断された。40 mg 隔週投与群の 2 例及び 40 mg 週 1 回投与群の 1 例には併用薬が投与された。

日本サブ試験の日本人安全性解析対象集団では，乾癬の悪化又は新規発症は発現しなかった。そのため，統合安全性解析対象集団の結果（846 例中 4 例［0.5%］）は主試験安全性解析対象集団と同様であった。

2.7.4.2.1.5.19 成人 脱髄疾患

M14-033 導入療法試験

M14-033 導入療法試験では，脱髄疾患は発現しなかった。

M14-033 維持療法試験

主試験安全性解析対象集団で発現した脱髄疾患を付録 表 2.7.4.7-68 に示す。

主試験安全性解析対象集団の 757 例中 1 例（0.1%）に脱髄疾患が発現した。本被験者は TDM 群の被験者であり，重篤な中等度の慢性炎症性脱髄性多発根ニューロパチーが発現し，治験薬との因果関係は関連ありと判断された。本事象のため治験薬投与が中止された。本事象は治療により最終的に消失した。

日本サブ試験の日本人安全性解析対象集団では，脱髄疾患は発現しなかった。そのため，統合安全性解析対象集団の結果（846 例中 1 例［0.1%］）は主試験安全性解析対象集団と同様であった。

2.7.4.2.1.5.20 成人 汎血球減少症を含む血液障害

M14-033 導入療法試験

主試験安全性解析対象集団で発現した汎血球減少症を含む血液障害を付録 表 2.7.4.7-69 に示す。

主試験安全性解析対象集団の 852 例中 38 例（4.5%）に，AESI カテゴリーで汎血球減少症を含む血液障害に該当する有害事象が発現した。血液障害の発現割合は，標準用量群（340 例中 16 例，4.7%）と高用量群（512 例中 22 例，4.3%）で同程度であった。多く発現した事象は貧血（29 例，3.4%）であり，次いで白血球減少症（4 例，0.5%），リンパ球減少症及び血小板減少症（各 2 例，0.2%）並びに好中球減少症（1 例，0.1%）であった。重症度は大部分が軽度又は中等度であった。貧血が発現した被験者のうち 5 例は重篤であり，うち 2 例は治験薬投与を中止した。また，非重篤な血小板減少症のため 1 例が治験薬投与を中止した。

統合安全性解析対象集団及び日本人安全性解析対象集団で発現した汎血球減少症を含む血液障害を付録 表 2.7.4.7-70 に示す。

統合安全性解析対象集団の 952 例中 44 例（4.6%）に，AESI カテゴリーで汎血球減少症を含む血液障害に該当する有害事象が発現した。血液障害の発現割合は，標準用量群（379 例中 18 例，4.7%）と高用量群（573 例中 26 例，4.5%）で同程度であった。多く発現した事象は貧血（33 例，3.5%）であり，次いで白血球減少症（5 例，0.5%），リンパ球減少症及び血小板減少症（各 2 例，0.2%）並びに大球性貧血及び好中球減少症（各 1 例，0.1%）であった。重症度は大部分が軽度又は中等度であった。貧血が発現した被験者のうち 5 例は重篤であり，うち 2 例は治験薬投与を中止した。また，非重篤な血小板減少症のため 1 例が治験薬投与を中止した。

日本人安全性解析対象集団の 100 例中 6 例（6.0%）に，AESI カテゴリーで汎血球減少症を含む血液障害に該当する有害事象が発現した。血液障害の発現割合は，標準用量群（39 例中 2 例，5.1%）と高用量群（61 例中 4 例，6.6%）で同程度であった。発現した事象は，貧血（4 例，4.0%）並びに大球性貧血及び白血球減少症（各 1 例，1.0%）であった。いずれの事象も非重篤であり，治験薬と関連なしと判断された。2 例の貧血は最終観察時点で継続していた。他の事象はいずれも最終的に消失した。

M14-033 維持療法試験

主試験安全性解析対象集団で発現した汎血球減少症を含む血液障害を付録 表 2.7.4.7-71 に示す。

主試験安全性解析対象集団の 757 例中 39 例（5.2%）に，AESI カテゴリーで汎血球減少症を含む血液障害に該当する有害事象が発現した。血液障害の発現割合は，40 mg 隔週投与群（302 例中 14 例，4.6%），40 mg 週 1 回投与群（304 例中 17 例，5.6%）及び TDM 群（151 例中 8 例，5.3%）で同程度であった。多く発現した事象は貧血（30 例，4.0%）であり，次いで白血球減少症（5 例，0.7%），好中球減少症（3 例，0.4%），血小板減少症（2 例，0.3%）及びリンパ球減少症（1 例，0.1%）であった。発現した事象の大部分は非重篤であり，重症度は軽度又は中等度，治験薬との因果関係は関連なしと判断された。貧血が発現した被験者のうち 4 例は重篤であった。また，非重篤な白血球減少症のため 2 例が治験薬投与を中止した。

統合安全性解析対象集団及び日本人安全性解析対象集団で発現した汎血球減少症を含む血液障害を付録 表 2.7.4.7-72 に示す。

統合安全性解析対象集団の 846 例中 48 例（5.7%）に，AESI カテゴリーで汎血球減少症を含む血液障害に該当する有害事象が発現した。血液障害の発現割合は，40 mg 隔週投与群（345 例中 17 例，4.9%），40 mg 週 1 回投与群（350 例中 23 例，6.6%）及び TDM 群（151 例中 8 例，5.3%）で同程度であった。多く発現した事象は貧血（38 例，4.5%）であり，次いで白血球減少症（6 例，0.7%），好中球減少症（3 例，0.4%），血小板減少症（2 例，0.2%）及びリンパ球減少症（1 例，0.1%）であった。発現した事象の大部分は非重篤であり，重症度は軽度又は中等度，治験薬との因果関係は関連なしと判断された。貧血が発現した被験者のうち 4 例は重篤であった。また，非重篤な白血球減少症のため 2 例が治験薬投与を中止した。

日本人安全性解析対象集団の 89 例中 9 例（10.1%）に，AESI カテゴリーで汎血球減少症を含む血液障害に該当する有害事象が発現した。血液障害の発現割合は，40 mg 週 1 回投与群（46 例中 6 例，13.0%）の方が 40 mg 隔週投与群（43 例中 3 例，7.0%）よりも高かった。発現した事象は，貧血（8 例，9.0%）及び白血球減少症（1 例，1.1%）であった。いずれの事象も非重篤であり，重症度は軽度又は中等度，治験薬との因果関係は関連なしと判断された。いずれの事象も治験薬投与の中止には至らなかった。

2.7.4.2.1.5.21 成人 肝不全及びその他の肝臓関連事象（胆嚢関連の事象を除く）

M14-033 導入療法試験

主試験安全性解析対象集団で発現した肝不全及びその他の肝臓関連事象を付録 表 2.7.4.7-73 に示す。

主試験安全性解析対象集団の 852 例中 2 例（0.2%）に肝不全及びその他の肝臓関連事象が発現した。いずれも高用量群の被験者であり，発現した事象は脂肪肝及び重篤な肝炎が各 1 例であった。いずれも重症度は軽度であり，治験薬と関連なしと判断された。

日本サブ試験の日本人安全性解析対象集団では，肝不全及びその他の肝臓関連事象は発現しなかった。そのため，統合安全性解析対象集団の結果（952 例中 2 例［0.2%］）は主試験安全性解析対象集団と同様であった。

M14-033 維持療法試験

主試験安全性解析対象集団で発現した肝不全及びその他の肝臓関連事象を付録 表 2.7.4.7-74 に示す。

主試験安全性解析対象集団の 757 例中 2 例（0.3%）に肝不全及びその他の肝臓関連事象が発現した。40 mg 隔週投与群の 1 例に非重篤な軽度の非アルコール性脂肪性肝炎が発現し，治験薬との因果関係は関連ありと判断された。本被験者では併用薬の投与が開始された。また，40 mg 週 1 回投与群の 1 例に非重篤な軽度の脂肪肝が発現し，治験薬との因果関係は関連なしと判断された。

統合安全性解析対象集団及び日本人安全性解析対象集団で発現した肝不全及びその他の肝臓関連事象を付録 表 2.7.4.7-75 に示す。

統合安全性解析対象集団の 846 例中 4 例（0.5%）に肝不全及びその他の肝臓関連事象が発現した。40 mg 隔週投与群の 1 例に非重篤な軽度の非アルコール性脂肪性肝炎が発現し，治験薬との因果関係は関連ありと判断された。本被験者では併用薬の投与が開始された。また，40 mg 隔週投与群の別の 1 例に非重篤な中等度の肝胆道系疾患が発現し，治験薬との因果関係は関連ありと判断された。本被験者は治験薬投与を中止した。40 mg 週 1 回投与群の 1 例に非重篤な軽度の脂肪肝が発現し，治験薬との因果関係は関連なしと判断された。40 mg 週 1 回投与群の別の 1 例に非重篤な軽度の肝機能異常が発現し，治験薬との因果関係は関連なしと判断された。

日本人安全性解析対象集団の 89 例中 2 例（2.2%）に肝不全及びその他の肝臓関連事象が発現した。40 mg 隔週投与群の 1 例に非重篤な中等度の肝胆道系疾患が発現し，治験薬との因果関係は関連ありと判断された。本被験者は治験薬投与を中止した。また，40 mg 週 1 回投与群の 1 例に非重篤な軽度の肝機能異常が発現し，治験薬との因果関係は関連なしと判断された。

2.7.4.2.1.5.22　　成人 注射部位反応

M14-033 導入療法試験

主試験安全性解析対象集団で発現した注射部位反応を付録 表 2.7.4.7-76 に示す。

主試験安全性解析対象集団の 852 例中 75 例（8.8%）に注射部位反応が発現した。注射部位反応の発現割合は，高用量群（512 例中 62 例，12.1%）の方が標準用量群（340 例中 13 例，3.8%）よりも高かった。全体で 10 例以上に発現した注射部位反応は，注射部位反応（20 例，2.3%），注射部位紅斑（16 例，1.9%），注射部位そう痒感（15 例，1.8%）及び注射部位腫脹（11 例，1.3%）であった。注射部位反応の大部分は重症度が軽度又は中等度で，治験薬と関連ありと判断された。高用量群の 4 例に発現した注射部位反応（注射部位そう痒感及び注射部位腫脹が 1 例，注射部位疼痛が 1 例，注射部位反応が 1 例，注射部位過敏反応が 1 例）は治験薬投与の中止に至った。これらの事象は，いずれも治験薬と関連ありと判断された。

統合安全性解析対象集団及び日本人安全性解析対象集団で発現した注射部位反応を付録 表 2.7.4.7-77 に示す。

統合安全性解析対象集団の 952 例中 85 例（8.9%）に注射部位反応が発現した。注射部位反応の発現割合は，高用量群（573 例中 69 例，12.0%）の方が標準用量群（379 例中 16 例，4.2%）よりも高かった。全体で 10 例以上に発現した注射部位反応は，注射部位反応（28 例，2.9%），注射部位紅斑（17 例，1.8%），注射部位そう痒感（15 例，1.6%）及び注射部位腫脹（11 例，1.2%）であった。注射部位反応の大部分は重症度が軽度又は中等度で，治験薬と関連ありと判断された。標準用量群の 1 例に発現した注射部位紅斑及び高用量群の 4 例に発現した注射部位反応（注射部位そう痒感及び注射部位腫脹が 1 例，注射部位疼痛が 1 例，注射部位反応が 1 例，注射部位過敏反応が 1 例）は治験薬投与の中止に至った。これらの事象は，いずれも治験薬と関連ありと判断された。

日本人安全性解析対象集団の 100 例中 10 例（10.0%）に注射部位反応が発現した。注射部位反応の発現割合は，標準用量群（39 例中 3 例，7.7%）と高用量群（61 例中 7 例，11.5%）で同程度であった。発現した事象は，注射部位反応（8 例，8.0%）並びに注射部位紅斑及び注射に伴う反応（各 1 例，1.0%）であった。いずれも非重篤であり，重症度は軽度又は中等度であった。治験薬との因果関係は，1 例に発現した注射部位反応を除き関連ありと判断された。注射部位紅斑が発現した標準用量群の 1 例は治験薬投与を中止した。6 例に発現した注射部位反応（注射部位反応 5 例及び注射に伴う反応 1 例）は，断続的な発現であった。

M14-033 維持療法試験

主試験安全性解析対象集団で発現した注射部位反応を付録 表 2.7.4.7-78 に示す。

主試験安全性解析対象集団の 757 例中 27 例（3.6%）に注射部位反応が発現し，内訳は 40 mg 隔週投与群が 302 例中 8 例（2.6%），40 mg 週 1 回投与群が 304 例中 14 例（4.6%），TDM 群が 151 例中 5 例（3.3%）であった。全体で 5 例以上に発現した注射部位反応は，注射部位反応（7 例，0.9%）及び注射部位紅斑（6 例，0.8%）であった。発現した事象はいずれも非重篤であり，重症度は軽度又は中等度であった。治験薬との因果関係は，注射部位疼痛の 1 例を除きいずれも関連ありと判断された。注射部位そう痒感及び注射部位腫脹が発現した 40 mg 週 1 回投与群の 1 例と，注射に伴う反応が発現した TDM 群の 1 例は，治験薬投与を中断した。治験薬投与の中止に至った注射部位反応は発現しなかった。

統合安全性解析対象集団及び日本人安全性解析対象集団で発現した注射部位反応を付録 表 2.7.4.7-79 に示す。

統合安全性解析対象集団の 846 例中 29 例（3.4%）に注射部位反応が発現し，内訳は 40 mg 隔週投与群が 345 例中 8 例（2.3%），40 mg 週 1 回投与群が 350 例中 16 例（4.6%），TDM 群が 151 例中 5 例（3.3%）であった。全体で 5 例以上に発現した注射部位反応は，注射部位反応（8 例，0.9%）及び注射部位紅斑（6 例，0.7%）であった。発現した事象はいずれも非重篤であり，重症度は軽度又は中等度であった。治験薬との因果関係は，注射部位疼痛の 1 例を除きいずれも関連ありと判断された。注射部位そう痒感及び注射部位腫脹が発現した 40 mg 週 1 回投与群の 1 例と，注射に伴う反応が発現した TDM 群の 1 例は，治験薬投与を中断した。治験薬投与の中止に至った注射部位反応は発現しなかった。

日本人安全性解析対象集団の 89 例中 2 例（2.2%）に注射部位反応が発現した。いずれも 40 mg 週 1 回投与群の被験者であり，注射に伴う反応及び注射部位反応が各 1 例に発現した。いずれも非重篤であり，重症度は軽度，治験薬と関連ありと判断された。治験薬投与の中止に至った注射部位反応は発現しなかった。

2.7.4.2.2 成人 個別有害事象の文章による説明

M14-033 試験の重篤な有害事象の文章による説明を作成し，2.7.6 項に記載した。

内視鏡検査時に実施した生検結果が得られ，腺癌の組織学的所見を認めた海外の被験者 1 例（導入療法試験：高用量群、維持療法試験：TDM 群に参加）について医師により重篤な有害事象（以下「SAE」）と判断された（当該所見は導入療法試験時の生検結果，2.7.6 項に重篤な有害事象の文章による説明に記載）。M14-033 試験は，すべての治験実施医療機関において治験を終了し，臨床試験データの電子化システム（以下「EDC」）を使用できなかったことから，アッヴィ安全性担当者により各治験責任医師 / 治験施設に生検結果を報告し，併せて医師の SAE 判断を確認した。EDC を介した臨床データベースへの SAE データ入力はできない状況であったため，アッヴィ市販後データベースに AE 情報として入力した（当該 SAE は臨床データベースに含まれず，最終 CSR の AE 集計 / AE 帳票に含まれていない）。

2.7.4.3 成人 臨床検査値の評価

2.7.4.3.1 成人 治験期間を通しての臨床検査値

2.7.4.3.1.1 成人 血液学的検査，血液生化学検査及び尿検査

M14-033 導入療法試験

血液学的検査，血液生化学検査及び尿検査値の推移を M14-033 Induction Main-study Final CSR Table 14.3__4.1.1（主試験安全性解析対象集団）及び M14-033 Induction Japan Sub-study Final CSR Table 14.3__4.1.1_J（統合安全性解析対象集団及び日本人安全性解析対象集団）に示した。

主試験安全性解析対象集団，統合安全性解析対象集団及び日本人安全性解析対象集団の被験者において，血液学的検査，血液生化学検査及び尿検査の平均値の変化は臨床的に重要ではないと判断された。

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血液学的検査，血液生化学検査及び尿検査値の推移を M14-033 Maintenance Main-study Final CSR Table 14.3__4.1.1（主試験安全性解析対象集団）及び M14-033 Maintenance Japan Sub-study Final CSR Table 14.3__4.1.1_J（統合安全性解析対象集団及び日本人安全性解析対象集団）に示した。

主試験安全性解析対象集団，統合安全性解析対象集団及び日本人安全性解析対象集団の被験者において，血液学的検査，血液生化学検査及び尿検査の平均値の変化は臨床的に重要ではないと判断された。

2.7.4.3.2 成人 個々の被験者の変化

2.7.4.3.2.1 成人 血液学的検査，血液生化学検査及び尿検査

M14-033 導入療法試験

血液学的検査，血液生化学検査値及び尿検査値に関して，ベースラインが正常値若しくは異常高値であった検査値が最終測定時に異常低値に変動した被験者の割合，及びベースラインが異常低値若しくは正常値であった検査値が最終測定時に異常高値に変動した被験者の割合を M14-033 Induction Main-study Final CSR Table 14.3__4.2.2（主試験安全性解析対象集団）及び M14-033 Induction Japan Sub-study Final CSR Table 14.3__4.2.2_J（統合安全性解析対象集団及び日本人安全性解析対象集団）に示した。

主試験安全性解析対象集団，統合安全性解析対象集団及び日本人安全性解析対象集団の被験者で，血液学的検査，血液生化学検査値及び尿検査値に関して，ベースラインが正常値若しくは異常高値であった検査値が最終測定時に異常低値に変動した被験者，及びベースラインが異常低値若しくは正常値であった検査値が最終測定時に異常高値に変動した被験者は全般的に少数であり，臨床的に重要ではないと判断された。

M14-033 維持療法試験

血液学的検査，血液生化学検査値及び尿検査値に関して，ベースラインが正常値若しくは異常高値であった検査値が最終測定時に異常低値に変動した被験者の割合，及びベースラインが異常低値若しくは正常値であった検査値が最終測定時に異常高値に変動した被験者の割合を M14-033 Maintenance Main-study Final CSR Table 14.3__4.2.2（主試験安全性解析対象集団）及び M14-033 Maintenance Japan Sub-study Final CSR Table 14.3__4.2.2_J（統合安全性解析対象集団及び日本人安全性解析対象集団）に示した。

主試験安全性解析対象集団，統合安全性解析対象集団及び日本人安全性解析対象集団の被験者で，血液学的検査，血液生化学検査値及び尿検査値に関して，ベースラインが正常値若しくは異常高値であった検査値が最終測定時に異常低値に変動した被験者，及びベースラインが異常低値若しくは正常値であった検査値が最終測定時に異常高値に変動した被験者は全般的に少数であり，臨床的に重要ではないと判断された。

2.7.4.3.3 成人 個々の臨床的に重要な異常

2.7.4.3.3.1 成人 血液学的検査，血液生化学検査及び尿検査

M14-033 導入療法試験

CTC グレード 3 以上の臨床検査異常を M14-033 Induction Main-study Final CSR Table 14.3__4.3.1（主試験安全性解析対象集団）及び M14-033 Induction Japan Sub-study Final CSR Table 14.3__4.3.1_J（統合安全性解析対象集団及び日本人安全性解析対象集団）に示した。また，臨床的に意味のある肝機能検査値の一覧を M14-033 Induction Main-study Final CSR Table 14.3__4.4.4（主試験安全性解析対象集団）及び M14-033 Induction Japan Sub-study Final CSR Table 14.3__4.4.4_J（日本人安全性解析対象集団）に示した。

臨床的に重要と考えられる（CTC グレード 3 以上）血液学的検査値，血液生化学検査値及び尿検査値異常が認められた被験者は少数であった。臨床検査関連の重篤な有害事象又は治験薬投与の中止に至った有害事象は認められなかった。また，Hy's law の基準（ALT 又は AST が ULN の 3 倍超，かつ総ビリルビンが ULN の 2 倍超及び症候性）に該当した被験者は認められなかった。

M14-033 維持療法試験

CTC グレード 3 以上の臨床検査異常を M14-033 Maintenance Main-study Final CSR Table 14.3__4.3.1（主試験安全性解析対象集団）及び M14-033 Maintenance Japan Sub-study Final CSR Table 14.3__4.3.1_J（統合安全性解析対象集団及び日本人安全性解析対象集団）に示した。また，臨床的に意味のある肝機能検査値の一覧を M14-033 Maintenance Main-study Final CSR Table 14.3__4.4.4（主試験安全性解析対象集団）及び M14-033 Maintenance Japan Sub-study Final CSR Table 14.3__4.4.4_J（統合安全性解析対象集団）に示した。

臨床的に重要と考えられる（CTC グレード 3 以上）血液学的検査値，血液生化学検査値及び尿検査値異常が認められた被験者は少数であった。

主試験安全性解析対象集団では，臨床検査関連の重篤な有害事象として，40 mg 隔週投与群の 1 例にアラニンアミノトランスフェラーゼ増加及びアスパラギン酸アミノトランスフェラーゼ増加が，40 mg 週 1 回投与群の 1 例に低ナトリウム血症が，40 mg 週 1 回投与群の 1 例に好中球数減少が発現した（付録 表 2.7.4.7-22 参照）。また，臨床検査関連の治験薬投与の中止に至った有害事象として，40 mg 隔週投与群に好中球数減少，肝機能検査値上昇，及び血中クレアチニン増加が各 1 例，TDM 群に白血球数減少及び HIV 検査陽性が各 1 例発現した（付録 表 2.7.4.7-32 参照）。

日本人安全性解析対象集団では，臨床検査関連の重篤な有害事象又は治験薬投与の中止に至った有害事象は認められなかった。

Hy's law の基準（ALT 又は AST が ULN の 3 倍超，かつ総ビリルビンが ULN の 2 倍超及び症候性）に該当した被験者は認められなかった。

2.7.4.4 成人 バイタルサイン，身体的所見及び安全性に関連する他の観察項目

M14-033 導入療法試験

バイタルサインの推移を M14-033 Induction Main-study Final CSR Table 14.3__5.1（主試験安全性解析対象集団）及び M14-033 Induction Japan Sub-study Final CSR Table 14.3__5.1_J（統合安全性解析対象集団及び日本人安全性解析対象集団）に示した。また，臨床的に重要と考えられるバイタルサイン値を M14-033 Induction Main-study Final CSR Table 14.3__5.2（主試験安全性解析対象集団）及び M14-033 Induction Japan Sub-study Final CSR Table 14.3__5.2_J（統合安全性解析対象集団及び日本人安全性解析対象集団）に示した。

バイタルサインの平均値に，ベースラインからの顕著な変化は認められなかった。また，臨床的に重要と考えられるバイタルサイン値が認められた被験者は少数であった。

M14-033 維持療法試験

バイタルサインの推移を M14-033 Maintenance Main-study Final CSR Table 14.3__5.1（主試験安全性解析対象集団）及び M14-033 Maintenance Japan Sub-study Final CSR Table 14.3__5.1_J（統合安全性解析対象集団及び日本人安全性解析対象集団）に示した。また，臨床的に重要と考えられるバイタルサイン値を M14-033 Maintenance Main-study Final CSR Table 14.3__5.2（主試験安全性解析対象集団）及び M14-033 Maintenance Japan Sub-study Final CSR Table 14.3__5.2_J（統合安全性解析対象集団及び日本人安全性解析対象集団）に示した。

バイタルサインの平均値に，ベースラインからの顕著な変化は認められなかった。

2.7.4.5 成人 特別な患者集団及び状況下における安全性

2.7.4.5.1 成人 内因性要因

M14-033 主試験及び日本サブ試験の有害事象データを併合し，日本人を含む統合集団における内因性要因別に解析した結果を，付録 表 2.7.4.7-80 から付録 表 2.7.4.7-87（有害事象の概要），付録 表 2.7.4.7-88 から付録 表 2.7.4.7-95（有害事象の 100 人年あたりの発現頻度の概要）に示した。

有害事象を性別（男性，女性），年齢区分（38 歳以下，38 歳を上回る），人種（白人，白人以外）及び体重区分（73 kg 以下，73 kg を上回る）別に解析した結果，以下の点を除き，顕著な差は認められなかった。

導入療法試験（日本人を含む統合集団）：

- 有害事象，因果関係が関連ありの有害事象，感染症及び注射部位反応の発現割合が，男性の被験者（それぞれ 50.1%，18.6%，13.0%及び 6.8%）よりも女性の被験者（それぞれ 57.0%，32.1%，18.3%及び 11.9%）で高かった（付録 表 2.7.4.7-80）。
- 因果関係が関連ありの有害事象の発現割合が，白人以外の被験者（17.9%）よりも白人の被験者（25.5%）で高かった（付録 表 2.7.4.7-82）。

維持療法試験（日本人を含む統合集団）：

- 因果関係が関連ありの有害事象の発現割合が，38 歳以下の被験者（27.1%）よりも 38 歳を上回る被験者（33.0%）で高かった。また，感染症の発現割合が，38 歳を上回る被験者（34.5%）よりも 38 歳以下の被験者（39.7%）で高かった（付録 表 2.7.4.7-85）。
- 因果関係が関連ありの有害事象及び重篤な有害事象の発現割合が，白人以外の被験者（25.4%及び 7.9%）よりも白人の被験者（31.0%及び 12.9%）で高かった。また，有害事象及び感染症の発現割合が，白人の被験者（70.7%及び 35.0%）よりも白人以外の被験者（84.9%及び 48.4%）で高かった（付録 表 2.7.4.7-86）。

2.7.4.5.2 成人 外因性要因

M14-033 主試験及び日本サブ試験の有害事象データを併合し，日本人を含む統合集団における外因性要因別に解析した結果を，付録 表 2.7.4.7-96 から付録 表 2.7.4.7-103（有害事象の概要），付録 表 2.7.4.7-104 から付録 表 2.7.4.7-111（有害事象の 100 人年あたりの発現頻度の概要）に示した。

有害事象を抗 TNF 製剤の投与経験の有無，ベースラインにおけるコルチコステロイドの全身投与の有無，ベースラインにおける免疫抑制剤の使用の有無，及び Mayo スコアに基づく疾患重症度別（9 以下，9 を上回る）に解析した結果，以下の点を除き，顕著な差は認められなかった。

導入療法試験（日本人を含む統合集団）：

- 有害事象の発現割合が，抗 TNF 製剤の投与経験なしの被験者（51.8%）よりも投与経験ありの被験者（60.7%）で高かった（付録 表 2.7.4.7-96）。

- 有害事象，因果関係が関連ありの有害事象及び注射部位反応の発現割合が，コルチコステロイドの全身投与ありの被験者（それぞれ 48.6%，19.8%及び 6.3%）よりも投与なしの被験者（それぞれ 59.2%，30.7%及び 12.6%）で高かった（付録 表 2.7.4.7-97）。
- 因果関係が関連ありの有害事象の発現割合が，免疫抑制剤の使用ありの被験者（19.8%）よりも使用なしの被験者（26.2%）で高かった（付録 表 2.7.4.7-98）。
- 感染症の発現割合が，Mayo スコアに基づく疾患重症度 9 以下の被験者（13.2%）よりも 9 を上回る被験者（18.4%）で高かった（付録 表 2.7.4.7-99）。

維持療法試験（日本人を含む統合集団）：

- 有害事象の発現割合が，抗 TNF 製剤の投与経験なしの被験者（71.6%）よりも投与経験ありの被験者（80.3%）で高かった（付録 表 2.7.4.7-100）。
- 有害事象及び感染症の発現割合が，コルチコステロイドの全身投与ありの被験者（それぞれ 70.8%及び 33.3%）よりも投与なしの被験者（それぞれ 75.7%及び 42.4%）で高かった（付録 表 2.7.4.7-101）。
- 有害事象及び感染症の発現割合が，免疫抑制剤の使用なしの被験者（それぞれ 70.5%及び 32.2%）よりも使用ありの被験者（それぞれ 78.5%及び 48.8%）で高かった（付録 表 2.7.4.7-102）。

2.7.4.5.3 成人 薬物相互作用

M14-033 試験では，特定の薬物相互作用についての評価は行わなかった。

2.7.4.5.4 成人 妊娠及び授乳時の使用

M14-033 導入療法試験では，試験期間中の妊娠の報告はなかった。

M14-033 維持療法試験では，試験期間中に海外の被験者 5 例で妊娠が報告された。妊娠の転帰は，先天性異常なしの出産が 4 例，妊娠前期での自然流産が 1 例であった。日本の被験者では，試験期間中の妊娠の報告はなかった。

2.7.4.5.5 成人 過量投与

M14-033 試験では，アダリムマブの過量投与の報告はなかった。アダリムマブの過量投与に関して新たな情報は得られていない。

2.7.4.5.6 成人 薬物乱用

M14-033 試験では，アダリムマブの乱用の報告はなかった。アダリムマブが乱用を引き起こす根拠はなく，アダリムマブの乱用は予想されない。

2.7.4.5.7 成人 離脱症状及び反跳現象

M14-033 試験では，アダリムマブによる離脱症状及び反跳現象に着目した評価は行わなかった。なお，明らかに離脱症状及び反跳現象と思われる事象の報告はなかった。アダリムマブの投与中止後に適切なフォローアップを実施しなかった場合に UC の症状がコントロール不良となる可能性があることを除き，アダリムマブの離脱症状は予想されない。

2.7.4.5.8 成人 自動車運転及び機械操作に対する影響又は精神機能の障害

M14-033 試験では，アダリムマブによる自動車の運転能又は機械操作能への影響に着目した評価は行わなかった。アダリムマブが自動車運転及び機械操作に対する影響又は精神機能の障害を引き起こす根拠はなく，発現は予想されない。

2.7.4.6 市販後データ

アダリムマブは，米国で 2002 年 12 月 31 日（国際誕生日）に関節リウマチの適応で承認され，欧州連合及び本邦では，それぞれ 2003 年及び 2008 年に関節リウマチの適応で承認された。

定期的安全性報告（対象期間：2017 年 1 月 1 日 – 2019 年 12 月 31 日［5.3.6-1 項］）によれば，臨床試験でアダリムマブの投与を受けた推定被験者数は 34,830 例であり，本報告期間での製造販売後の推定曝露量は 2,744,359 人年，国際誕生日から 2019 年 12 月 31 日までの製造販売後の推定累積曝露量は約 783 万人年である。

2017 年 1 月 – 2019 年 12 月を対象期間とした定期的安全性報告の結論では，既承認の効能・効果でのアダリムマブのベネフィット-リスクプロファイルは良好であり，company core labeling（企業中核データシートの添付文書情報）の改訂は推奨されなかった。

2020 年 1 月 – 6 月を対象期間とした定期的安全性最新報告（5.3.6-2 項）では，この情報更新の期間中にアダリムマブのベネフィット-リスク評価に重大な影響を及ぼす新たな安全性の情報はなかった。

M14-033 試験の安全性結果では，成人及び小児で承認されている効能・効果での，アダリムマブの市販後安全性情報で知られていない新たな安全性に関わるシグナルは認められなかった。

成人 参考文献

該当なし

2.7.4 小児 臨床的安全性

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略語及び定義一覧

略語又は用語	省略していない表現又は説明（英語）	省略していない表現又は説明（日本語）
AE	Adverse Event	有害事象
AESI	Adverse event of special interest	特に注目すべき有害事象
ALT (SGPT)	Alanine aminotransferase	アラニンアミノトランスフェラーゼ
AST (SGOT)	Aspartate aminotransferase	アスパラギン酸アミノトランスフェラーゼ
BMI	Body Mass Index	体格指数
CSR	Clinical study report	治験総括報告書
CTCAE	Common Terminology Criteria for Adverse Events	有害事象共通用語規準
FAS	Full analysis set	最大の解析対象集団
ICH	International Conference on Harmonization	日米欧州連合（EU）医薬品ハーモナイゼーション国際会議
MedDRA	Medical Dictionary for Regulatory Activities	ICH 国際医薬品用語集
MedDRA/J	Medical Dictionary for Regulatory Activities/Japanese version	MedDRA の日本語版
NCI	National Cancer Institute	米国国立がん研究所
PT	Preferred Term	（ICH 国際医薬用語集の）基本語
SAE	Serious adverse event	重篤な有害事象
SOC	System Organ Class	（ICH 国際医薬用語集の）器官別大分類
TNF	Tumor necrosis factor	腫瘍壊死因子
UC	Ulcerative Colitis	潰瘍性大腸炎
ULN	Upper limit of normal	基準値の上限

2.7.4.1 小児 医薬品への曝露

2.7.4.1.1 小児 総括的安全性評価計画及び安全性試験の記述

2.7.4.1.1.1 小児 安全性の評価に用いた臨床試験

小児潰瘍性大腸炎（以下「UC」）を対象としたアダリムマブの臨床開発プログラムでは，国際共同第 III 相試験（M11-290 主試験 中間治験総括報告書［以下「CSR」］，M11-290 日本サブ試験 中間 CSR，M11-290 主試験及び日本サブ試験 最終 CSR）及び国際共同長期投与試験（M10-870 主試験 中間 CSR，M10-870 日本サブ試験 中間 CSR）の計 2 試験（中間 CSR 4 報及び最終 CSR 1 報）を安全性の評価資料とした（試験デザインは 2.7.3.1.2 項参照）。なお，本申請での評価資料の 2 試験は，日本以外の他国の治験実施医療機関で登録された被験者を対象とする主試験と，日本の治験実施医療機関で登録された被験者を対象とする日本サブ試験で構成される。本項には主試験データに基づいた解析結果，主試験及び日本サブ試験の被験者からなる統合集団データに基づいた解析結果を記載した。

本項では，特に断らない限り，カットオフ日（20[redacted] 年 [redacted] 月 [redacted] 日：M11-290 主試験のすべての被験者が試験を完了又は中止した時点）までの安全性データの中間解析結果（検証的解析を実施しそれを反映した中間 CSR の結果）を提示した。ただし，M11-290 試験の統合安全性解析対象集団及び日本人安全性解析対象集団については，すべての被験者が試験を完了又は中止した時点までの最終解析結果（探索的解析を実施しそれを反映した最終 CSR の結果）も補足的に提示した。なお，データエラーの判明により CSR それぞれについて修正版を作成し，追加提出した（M11-290 主試験 中間及び最終 CSR［5.3.5.1-5 項及び 5.3.5.1-7 項］，M11-290 日本サブ試験 中間及び最終 CSR［5.3.5.1-6 項及び 5.3.5.1-7 項］，及び M10-870 主試験 中間 CSR［5.3.5.2-1 項］，M10-870 日本サブ試験 中間 CSR［5.3.5.2-2 項］）。

2.7.4.1.1.2 小児 安全性に関する評価方法

M11-290 試験及び M10-870 試験では，試験期間を通して有害事象，臨床検査値及びバイタルサインから安全性を評価した。

2.7.4.1.1.2.1 小児 解析対象

M11-290 試験

治験薬の投与を 1 回以上受けた日本以外のすべての被験者を，主試験安全性解析対象集団と定義した。また，治験薬の投与を 1 回以上受けた日本及び日本以外のすべての被験者を，統合安全性解析対象集団と定義し，治験薬の投与を 1 回以上受けたすべての日本の被験者を，日本人安全性解析対象集団と定義した。本試験に 101 例（うち日本人 8 例）が登録されたが，カットオフ時点で日本人 1 例は盲検下での投与を継続中であったため，安全性の中間解析の対象に含めていない。そのため，中間解析（検証的解析）での主試験安全性解析対象集団は 93 例，統合安全性解析対象集団は 100 例，日本人安全性解析対象集団は 7 例である。なお，日本人最後

の 8 例目被験者を含めた最終解析（探索的解析）での主試験安全性解析対象集団は 93 例，統合安全性解析対象集団は 101 例，日本人安全性解析対象集団は 8 例である。

主試験の治験実施計画書の改訂に合わせ（例；第 4 版），日本サブ試験の治験実施計画書も改訂を行っており（例；第 4.01 版），日本サブ試験の試験デザインは主試験と同じである。本試験では，治験実施計画書の改訂により試験デザインが変更されたため，導入療法期及び維持療法期それぞれの投与群は以下のとおりであった（日本サブ試験での試験内容を中心に記述した）。

- 治験実施計画書改訂 4.01 版より前：
  登録された被験者を 2 つのアダリムマブ導入用量群（高用量群又は標準用量群）のいずれかに 3：2 の比率で無作為に割り付け，二重盲検下で投与した。また，投与 8 週時に部分的 Mayo スコア（以下「PMS」）による改善が認められた被験者を，2 つのアダリムマブ維持用量群（高用量群若しくは標準用量群）又はプラセボ群に 2：2：1 の比率で無作為に割り付け，二重盲検下で投与した（図 2.7.3-1 参照）。
- 治験実施計画書改訂 4.01 版以降：
  導入療法期の標準用量群と維持療法期のプラセボ群に新たな被験者を割り付けないこととした。すなわち，治験実施計画書改訂 4.01 版以降は，登録されたすべての被験者に導入療法期で高用量を非盲検下で投与した。また，投与 8 週時に PMS による改善が認められた被験者を，2 つのアダリムマブ維持用量群（高用量群又は標準用量群）のいずれかに 1：1 の比率で無作為に割り付け，二重盲検下で投与した（図 2.7.3-2 参照）。

導入療法期

- I-SD 群：治験実施計画書の改訂 4.01 版より前に，導入療法期の標準用量群に割り付けられた被験者
- I-HD 群：治験実施計画書の改訂 4.01 版より前に，導入療法期の高用量群に割り付けられた被験者
- I-HD-OL 群：治験実施計画書の改訂 4.01 版以降に，非盲検下で導入療法期の高用量を投与された被験者

維持療法期

- M-PL 群：治験実施計画書の改訂 4.01 版より前に，プラセボ群に割り付けられた被験者
- M-SD 群：維持療法期の標準用量群に割り付けられた被験者
- M-HD 群：維持療法期の高用量群に割り付けられた被験者

M10-870 試験（長期投与試験）

M10-870 試験で治験薬の投与を 1 回以上受けた日本以外のすべての被験者を主試験 Full analysis set（以下「FAS」）集団，M10-870 試験で治験薬の投与を 1 回以上受けた日本及び日本以外のすべての被験者を統合 FAS 集団と定義し，安全性の解析に用いた。なお，日本の被験者

数は少ないため（統合 FAS 集団 59 例，うち日本人被験者は 4 例），統合集団を使用した。なお，M10-870 試験の主試験の治験実施計画書の改訂に合わせ，日本サブ試験の治験実施計画書も改訂を行っており，日本サブ試験の試験デザインは主試験と同じである。

2.7.4.1.1.2.2 小児 有害事象

有害事象は，治験薬の初回投与日から最終投与の 70 日後までに発現又は悪化した，あらゆる好ましくない医療上のできごととした。ただし，M11-290 試験において，M10-870 試験に登録された被験者については，M11-290 試験の治験薬の初回投与日から最終投与の 70 日後，又は M10-870 試験の治験薬の初回投与日前のいずれか早い方までとした。

すべての有害事象を，医薬品規制調和国際会議（以下「ICH」）国際医薬品用語集（以下「MedDRA」，バージョン 22.0）の器官別大分類（以下「SOC」）及び基本語（以下「PT」）に基づきコード化した。有害事象名の和訳には，MedDRA の日本語版（以下「MedDRA/J」，バージョン 22.0）を用いた。

有害事象の重症度，治験薬との因果関係，重篤な有害事象，及び特に注目すべき有害事象（以下「AESI」）の定義は以下のとおりである。

有害事象の重症度の定義

治験責任（分担）医師は，以下の定義に従って有害事象の重症度を評価した。

- 軽度　：一時的でたやすく忍容できるもの
- 中等度：被験者に不安や苦痛を与え，日常生活に支障をきたすもの
- 高度　：日常生活に重大な支障を来たし，機能障害，あるいは生命を脅かす可能性のあるもの

治験薬との因果関係の定義

治験責任（分担）医師は，以下の定義に従って有害事象の治験薬との因果関係を評価した。

- 関連あり（Reasonable Possibility）：
  治験薬と有害事象の因果関係が示唆される証拠が存在する有害事象
- 関連なし（No reasonable Possibility）：
  治験薬と有害事象の因果関係が示唆される証拠が存在しない有害事象

重篤な有害事象の定義

有害事象が以下の基準と合致する場合，重篤な有害事象とした。

- 死亡
- 生命を脅かすもの
- 入院又は入院期間の延長

- 先天性の異常
- 永続的又は顕著な障害 / 機能不全
- 重篤な転帰を防ぐために内科的，又は外科的処置を必要とする医学的に重要な事象

特に注目すべき有害事象

腫瘍壊死因子（以下「TNF」）阻害剤の生物学的療法で同定されたリスク及び潜在的なリスクを AESI のカテゴリー（付録 表 2.7.4.7-1）に含め，要約した。

2.7.4.1.1.2.3 小児 臨床検査

血液学的検査，血液生化学検査及び尿検査について要約統計量を算出した。また，ベースラインから最低値，最高値及び最終測定値までの変化量の要約統計量を算出した。

臨床検査値は，米国国立がん研究所（以下「NCI」）の有害事象共通用語規準（以下「CTCAE」）（第 5.0 版）を用いて評価し，CTC グレード 3 以上の異常値が認められた被験者の一覧を作成した。また，ベースラインから最悪の CTC グレードへのシフトテーブルを作成した。M11-290 試験では，CTC グレード 3 以上の異常値の有無について，ベースラインからのシフトテーブルを作成した。

肝機能検査値（アラニンアミノトランスフェラーゼ［以下「ALT」］ / 血清グルタミン酸ピルビン酸トランスアミナーゼ［以下「SGPT」］，アスパラギン酸アミノトランスフェラーゼ［以下「AST」］ / 血清グルタミン酸オキサロ酢酸トランスアミナーゼ［以下「SGOT」］，アルカリホスファターゼ及び総ビリルビン）に対しては，以下の基準を設定し，いずれかに合致した被験者に対して，臨床的に意味のある肝機能検査値（potentially clinically significant liver function laboratory values）の一覧を作成した。

- ALT：≥ 3.0 × 基準値の上限（以下「ULN」）
- AST：≥ 3.0 × ULN
- アルカリホスファターゼ：≥ 1.5 × ULN
- 総ビリルビン：≥ 2.0 × ULN

2.7.4.1.1.2.4 小児 バイタルサイン及び心電図

バイタルサイン（血圧［収縮期及び拡張期］，脈拍数，呼吸数，体重，身長，体格指数［BMI］及び体温）について要約統計量を算出した。

2.7.4.1.2 小児 全般的な曝露状況

2.7.4.1.2.1 M11-290 試験

主試験安全性解析対象集団の治験薬の曝露期間を付録 表 2.7.4.7-67（導入療法期），付録 表 2.7.4.7-68（維持療法期）及び付録 表 2.7.4.7-69（試験期間全体）に示した。

主試験安全性解析対象集団（93 例）の導入療法期での治験薬の平均曝露期間は 54.6 日であった。主試験安全性解析対象集団の被験者のうち，75 例が維持療法期で治験薬の投与を 1 回以上受け，その平均曝露期間は 231.0 日であった（維持療法期のアダリムマブ投与では 63 例で平均曝露期間は 239.9 日であった）。試験期間全体での治験薬の平均曝露期間は 256.3 日であった。

統合安全性解析対象集団の治験薬の曝露期間を付録 表 2.7.4.7-2（導入療法期），付録 表 2.7.4.7-3（維持療法期）及び付録 表 2.7.4.7-4（試験期間全体）に示した。また，日本人安全性解析対象集団の治験薬の曝露期間を付録 表 2.7.4.7-5（導入療法期），付録 表 2.7.4.7-6（維持療法期）及び付録 表 2.7.4.7-7（試験期間全体）に示した。

統合安全性解析対象集団（100 例）の導入療法期での治験薬の平均曝露期間は 54.3 日であった。統合安全性解析対象集団の被験者のうち，80 例が維持療法期で治験薬の投与を 1 回以上受け，その平均曝露期間は 227.2 日であった（維持療法期のアダリムマブ投与では 68 例で平均曝露期間は 234.7 日であった）。試験期間全体での治験薬の平均曝露期間は 256.3 日であった。

日本人安全性解析対象集団（7 例）の導入療法期での治験薬の平均曝露期間は 49.9 日であった。日本人安全性解析対象集団の被験者のうち，5 例が維持療法期で治験薬の投与を 1 回以上受け，その平均曝露期間は 170.0 日であった（維持療法期のアダリムマブ投与では 5 例で平均曝露期間は 170.0 日であった）。試験期間全体での治験薬の平均曝露期間は 256.4 日であった。

最終解析（探索的解析）の統合安全性解析対象集団の治験薬の曝露期間を付録 表 2.7.4.7-152（導入療法期），付録 表 2.7.4.7-153（維持療法期）及び付録 表 2.7.4.7-154（試験期間全体）に示した。また，最終解析の日本人安全性解析対象集団の治験薬の曝露期間を付録 表 2.7.4.7-155（導入療法期），付録 表 2.7.4.7-156（維持療法期）及び付録 表 2.7.4.7-157（試験期間全体）に示した。

最終解析では，統合安全性解析対象集団（101 例）の導入療法期での治験薬の平均曝露期間は 54.3 日であった。統合安全性解析対象集団の被験者のうち，81 例が維持療法期で治験薬の投与を 1 回以上受け，その平均曝露期間は 226.8 日であった（維持療法期のアダリムマブ投与では 69 例で平均曝露期間は 234.2 日であった）。試験期間全体での治験薬の平均曝露期間は 256.3 日であった。

最終解析では，日本人安全性解析対象集団（8 例）の導入療法期での治験薬の平均曝露期間は 50.6 日であった。日本人安全性解析対象集団の被験者のうち，6 例が維持療法期で治験薬の投与を 1 回以上受け，その平均曝露期間は 175.0 日であった（維持療法期のアダリムマブ投与では 6 例で平均曝露期間は 175.0 日であった）。試験期間全体での治験薬の平均曝露期間は 256.8 日であった。

2.7.4.1.2.2 M10-870 試験（長期投与試験）

主試験 FAS 集団の治験薬の曝露期間を付録 表 2.7.4.7-70（M10-870 試験）及び付録 表 2.7.4.7-71（M11-290 試験及び M10-870 試験の合計）に示した。

主試験 FAS 集団（55 例）の M10-870 試験での治験薬の平均曝露期間は 529.7 日であった。主試験 FAS 集団の M11-290 試験及び M10-870 試験の合計での治験薬の平均曝露期間は 864.7 日であった。

統合 FAS 集団の治験薬の曝露期間を付録 表 2.7.4.7-8（M10-870 試験）及び付録 表 2.7.4.7-9（M11-290 試験及び M10-870 試験の合計）に示した。

統合 FAS 集団（59 例）の M10-870 試験での治験薬の平均曝露期間は 522.0 日であった。統合 FAS 集団の M11-290 試験及び M10-870 試験の合計での治験薬の平均曝露期間は 859.1 日であった。

2.7.4.1.3 小児 治験対象集団の人口統計学的特性及びその他の特性

M11-290 試験及び M10-870 試験の人口統計学的特性及びその他の特性は，2.7.3.3.1.1 項及び 2.7.3.3.1.2 項にそれぞれ示した。

2.7.4.2 小児 有害事象

2.7.4.2.1 小児 有害事象の解析

M11-290 試験

主試験安全性解析対象集団における導入療法期中の有害事象の概要を表 2.7.4.2-1 に示した。

導入療法期中，主試験安全性解析対象集団の被験者 93 例中 52 例（55.9%）に有害事象が発現した。有害事象の発現割合は，I-SD 群（30 例中 17 例，56.7%）と I-HD 群（47 例中 23 例，48.9%）で同程度であった。重篤な有害事象，高度の有害事象，治験薬投与の中止に至った有害事象の発現割合は，I-SD 群の方が I-HD 群よりも若干高かった。ただし，これらの事象は発現数が少なかったため，解釈には注意が必要である。死亡に至った有害事象は発現しなかった。

表 2.7.4.2-1. 導入療法期中の有害事象の概要（主試験安全性解析対象集団，M11-290 試験）

	I-SD (N=30) n (%)	I-HD (N=47) n (%)	I-HD-OL (N=16) n (%)	Total (N=93) n (%)
有害事象	17 (56.7)	23 (48.9)	12 (75.0)	52 (55.9)
重篤な有害事象	5 (16.7)	4 (8.5)	1 (6.3)	10 (10.8)
高度の有害事象	4 (13.3)	1 (2.1)	0	5 (5.4)
治験薬投与の中止に至った有害事象	2 (6.7)	1 (2.1)	0	3 (3.2)
治験薬との因果関係が関連ありと医師により判断された有害事象	4 (13.3)	7 (14.9)	1 (6.3)	12 (12.9)
治験薬との因果関係が関連ありと医師により判断された重篤な有害事象	2 (6.7)	1 (2.1)	1 (6.3)	4 (4.3)
死亡に至った有害事象	0	0	0	0
死亡	0	0	0	0

I-HD = induction high dose; I-HD-OL = induction high dose open-label; I-SD = induction standard dose

Note: Treatment-emergent adverse events are defined as events with an onset date on or after the first dose date of the study drug in the induction period and up to 70 days after the last dose date of the study drug in the induction period and prior to the first dose date of the study drug in the maintenance period if applicable.
Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent adverse events with unknown relationship were counted as "reasonable possibility of being related."
Treatment-emergent adverse events with unknown severity were counted as "severe."

Cross reference: M11-290 Main-study CSR Interim Table 14.3 1.1.1.1

統合安全性解析対象集団及び日本人安全性解析対象集団における導入療法期中の有害事象の概要を表 2.7.4.2-2 及び表 2.7.4.2-3 に示した。

導入療法期中，統合安全性解析対象集団の被験者 100 例中 59 例（59.0%）に有害事象が発現した。有害事象の発現割合は，I-SD 群（32 例中 19 例，59.4%）と I-HD 群（51 例中 27 例，52.9%）で同程度であった。重篤な有害事象，高度の有害事象，治験薬投与の中止に至った有害事象の発現割合は，I-SD 群の方が I-HD 群よりも若干高かった。ただし，これらの事象は発現数が少なかったため，解釈には注意が必要である。死亡に至った有害事象は発現しなかった。

日本人安全性解析対象集団では，7 例すべてに有害事象が発現した。重篤な有害事象及び高度の有害事象は発現せず，治験薬投与の中止に至った有害事象が 1 例に発現した。

表 2.7.4.2-2. 導入療法期中の有害事象の概要（統合安全性解析対象集団，M11-290 試験）

	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
有害事象	19 (59.4)	27 (52.9)	13 (76.5)	59 (59.0)
重篤な有害事象	5 (15.6)	4 (7.8)	1 (5.9)	10 (10.0)
高度の有害事象	4 (12.5)	1 (2.0)	0	5 (5.0)
治験薬投与の中止に至った有害事象	3 (9.4)	1 (2.0)	0	4 (4.0)
治験薬との因果関係が関連ありと医師により判断された有害事象	5 (15.6)	8 (15.7)	2 (11.8)	15 (15.0)
治験薬との因果関係が関連ありと医師により判断された重篤な有害事象	2 (6.3)	1 (2.0)	1 (5.9)	4 (4.0)
死亡に至った有害事象	0	0	0	0
死亡	0	0	0	0

I-HD = induction high dose; I-HD-OL = induction high dose open-label; I-SD = induction standard dose

Note: TEAEs are defined as events with an onset date on or after the first dose date of the study drug in the Induction period and up to 70 days after the last dose date of study drug in the Induction period and prior to the first dose date of study drug in the Maintenance period if applicable.

Subjects are counted once in each row, regardless of the number of events they may have had.

TEAEs with unknown relationship were counted as “reasonable possibility of being related”.

TEAEs with unknown severity were counted as “severe”.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.3_1.1.1.1_A

表 2.7.4.2-3. 導入療法期中の有害事象の概要（日本人安全性解析対象集団，M11-290 試験）

	I-SD (N=2) n (%)	I-HD (N=4) n (%)	I-HD-OL (N=1) n (%)	Total (N=7) n (%)
有害事象	2 (100)	4 (100)	1 (100)	7 (100)
重篤な有害事象	0	0	0	0
高度の有害事象	0	0	0	0
治験薬投与の中止に至った有害事象	1 (50.0)	0	0	1 (14.3)
治験薬との因果関係が関連ありと医師により判断された有害事象	1 (50.0)	1 (25.0)	1 (100)	3 (42.9)
治験薬との因果関係が関連ありと医師により判断された重篤な有害事象	0	0	0	0
死亡に至った有害事象	0	0	0	0
死亡	0	0	0	0

I-HD = induction high dose; I-HD-OL = induction high dose open-label; I-SD = induction standard dose

Note: TEAEs are defined as events with an onset date on or after the first dose date of the study drug in the Induction period and up to 70 days after the last dose date of study drug in the Induction period and prior to the first dose date of study drug in the Maintenance period if applicable.
Subjects are counted once in each row, regardless of the number of events they may have had.
TEAEs with unknown relationship were counted as “reasonable possibility of being related”.
TEAEs with unknown severity were counted as “severe”.
Cross reference: M11-290 Japan Sub-study CSR Interim Table 14.3 1.1.1.1 J

最終解析（探索的解析）の統合安全性解析対象集団及び日本人安全性解析対象集団における導入療法期中の有害事象の概要を付録 表 2.7.4.7-158 及び付録 表 2.7.4.7-159 に示した。

最終解析では，導入療法期中，統合安全性解析対象集団の被験者 101 例中 60 例（59.4%）に有害事象が発現した。また，日本人安全性解析対象集団では，8 例すべてに有害事象が発現した。中間解析から日本人最後の 8 例目被験者を含めた最終解析までの間に，新たな重篤な有害事象，高度の有害事象，治験薬投与の中止に至った有害事象，治験薬との因果関係が関連ありと医師により判断された有害事象，死亡に至った有害事象は認められなかった。

主試験安全性解析対象集団における維持療法期中の有害事象の概要を表 2.7.4.2-4 に示した。

維持療法期中にアダリムマブの投与を受けた主試験安全性解析対象集団の被験者 63 例中 42 例（66.7%）に有害事象が発現した。有害事象の発現割合は，M-SD 群（31 例中 20 例，64.5%）と M-HD 群（32 例中 22 例，68.8%）で同程度であった。高度の有害事象及び治験薬投与の中止に至った有害事象の発現割合は，M-SD 群の方が M-HD 群よりも若干高かった。ただし，これらの事象は発現数が少なかったため，解釈には注意が必要である。死亡に至った有害事象は発現しなかった。

表 2.7.4.2-4. 維持療法期中の有害事象の概要（主試験安全性解析対象集団，M11-290 試験）

	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total Adalimumab (N=63) n (%)	M-PL (N=12) n (%)
有害事象	20 (64.5)	22 (68.8)	42 (66.7)	10 (83.3)
重篤な有害事象	4 (12.9)	5 (15.6)	9 (14.3)	1 (8.3)
高度の有害事象	3 (9.7)	1 (3.1)	4 (6.3)	0
治験薬投与の中止に至った有害事象	2 (6.5)	0	2 (3.2)	0
治験薬との因果関係が関連ありと医師により判断された有害事象	8 (25.8)	10 (31.3)	18 (28.6)	5 (41.7)
治験薬との因果関係が関連ありと医師により判断された重篤な有害事象	0	1 (3.1)	1 (1.6)	1 (8.3)
死亡に至った有害事象	0	0	0	0
死亡	0	0	0	0

M-HD = maintenance high dose; M-PL = maintenance placebo; M-SD = maintenance standard dose

Note: Treatment-emergent adverse events are defined as events with an onset date on or after the first dose date of the study drug in the maintenance period and prior to re-randomization due to first disease flare if applicable and up to 70 days after the last dose date of the study drug in the maintenance period. The events with an onset date on or after the first dose date in Study M10-870 are excluded.
Subjects are counted once in each row, regardless of the number of events they may have had.
Treatment-emergent adverse events with unknown relationship were counted as "reasonable possibility of being related."
Treatment-emergent adverse events with unknown severity were counted as "severe."

Cross reference: M11-290 Main-study CSR Interim Table 14.3 1.1.1.2

統合安全性解析対象集団及び日本人安全性解析対象集団における維持療法期中の有害事象の概要を表 2.7.4.2-5 及び表 2.7.4.2-6 に示した。

維持療法期中にアダリムマブの投与を受けた統合安全性解析対象集団の被験者 68 例中 46 例（67.6%）に有害事象が発現した。有害事象の発現割合は，M-SD 群（33 例中 21 例，63.6%）と M-HD 群（35 例中 25 例，71.4%）で同程度であった。高度の有害事象及び治験薬投与の中止に至った有害事象の発現割合は，M-SD 群の方が M-HD 群よりも若干高かった。ただし，これらの事象は発現数が少なかったため，解釈には注意が必要である。死亡に至った有害事象は発現しなかった。

日本人安全性解析対象集団では，維持療法期中にアダリムマブの投与を受けた 5 例中 4 例に有害事象が発現した。高度の有害事象及び治験薬投与の中止に至った有害事象は発現せず，重篤な有害事象が 1 例に発現した。

表 2.7.4.2-5. 維持療法期中の有害事象の概要（統合安全性解析対象集団，M11-290 試験）

	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total Adalimumab (N=68) n (%)	M-PL (N=12) n (%)
有害事象	21 (63.6)	25 (71.4)	46 (67.6)	10 (83.3)
重篤な有害事象	5 (15.2)	5 (14.3)	10 (14.7)	1 (8.3)
高度の有害事象	3 (9.1)	1 (2.9)	4 (5.9)	0
治験薬投与の中止に至った有害事象	2 (6.1)	0	2 (2.9)	0
治験薬との因果関係が関連ありと医師により判断された有害事象	8 (24.2)	11 (31.4)	19 (27.9)	5 (41.7)
治験薬との因果関係が関連ありと医師により判断された重篤な有害事象	0	1 (2.9)	1 (1.5)	1 (8.3)
死亡に至った有害事象	0	0	0	0
死亡	0	0	0	0

M-HD = maintenance high dose; M-PL = maintenance placebo; M-SD = maintenance standard dose

Note: TEAEs are defined as events with an onset date on or after the first dose date of study drug in the Maintenance period and prior to re-randomization due to first disease flare if applicable and up to 70 days after the last dose date of the study drug in the Maintenance period.

Subjects are counted once in each row, regardless of the number of events they may have had.

TEAEs with unknown relationship were counted as “reasonable possibility of being related”.

TEAEs with unknown severity were counted as “severe”.

Data after the first disease flare for the Integrated RR population can be found in M11-290 Japan Sub-study CSR Interim Table 14.3 1.1.1.4 A.

Cross reference: M11-290 Japan Sub-study CSR Interim Table 14.3 1.1.1.2 A

表 2.7.4.2-6. 維持療法期中の有害事象の概要（日本人安全性解析対象集団，M11-290 試験）

	M-SD (N=2) n (%)	M-HD (N=3) n (%)	Total Adalimumab (N=5) n (%)	M-PL (N=0) n (%)
有害事象	1 (50.0)	3 (100)	4 (80.0)	—
重篤な有害事象	1 (50.0)	0	1 (20.0)	—
高度の有害事象	0	0	0	—
治験薬投与の中止に至った有害事象	0	0	0	—
治験薬との因果関係が関連ありと医師により判断された有害事象	0	1 (33.3)	1 (20.0)	—
治験薬との因果関係が関連ありと医師により判断された重篤な有害事象	0	0	0	—
死亡に至った有害事象	0	0	0	—
死亡	0	0	0	—

M-HD = maintenance high dose; M-PL = maintenance placebo; M-SD = maintenance standard dose

Note: TEAEs are defined as events with an onset date on or after the first dose date of study drug in the Maintenance period and prior to re-randomization due to first disease flare if applicable and up to 70 days after the last dose date of the study drug in the Maintenance period.

Subjects are counted once in each row, regardless of the number of events they may have had.

TEAEs with unknown relationship were counted as “reasonable possibility of being related”.

TEAEs with unknown severity were counted as “severe”.

Data after the first disease flare for the Integrated RR population can be found in M11-290 Japan Sub-study CSR Interim Table 14.3 1.1.1.4 A.

Cross reference: M11-290 Japan Sub-study CSR Interim Table 14.3 1.1.1.2 J

最終解析（探索的解析）の統合安全性解析対象集団及び日本人安全性解析対象集団における維持療法期中の有害事象の概要を付録 表 2.7.4.7-160 及び付録 表 2.7.4.7-161 に示した。

最終解析では，維持療法期中にアダリムマブの投与を受けた統合安全性解析対象集団の被験者 69 例中 47 例（68.1%）に有害事象が発現した。また，日本人安全性解析対象集団では，維持療法期中にアダリムマブの投与を受けた 6 例中 5 例に有害事象が発現した。中間解析から日本人最後の 8 例目被験者を含めた最終解析までの間に，新たな重篤な有害事象，高度の有害事象，治験薬投与の中止に至った有害事象，治験薬との因果関係が関連ありと医師により判断された有害事象，死亡に至った有害事象は認められなかった。

M10-870 試験（長期投与試験）

主試験 FAS 集団で発現した有害事象の概要を表 2.7.4.2-7 に示した。

主試験 FAS 集団の被験者 55 例中 36 例（65.5%）に有害事象が発現した。重篤な有害事象が 8 例（14.5%）に発現し，治験薬投与の中止に至った有害事象が 2 例（3.6%）に発現した。死亡に至った有害事象は発現しなかった。

表 2.7.4.2-7. 有害事象の概要（主試験 FAS 集団，M10-870 試験）

	Adalimumab (N=55) n (%)
有害事象	36 (65.5)
重篤な有害事象	8 (14.5)
高度の有害事象	2 (3.6)
治験薬投与の中止に至った有害事象	2 (3.6)
治験薬との因果関係が関連ありと医師により判断された有害事象	11 (20.0)
治験薬との因果関係が関連ありと医師により判断された重篤な有害事象	2 (3.6)
死亡に至った有害事象	0

Cross reference: M10-870 Main-study CSR_Interim Table 14.3_1.1.1

統合 FAS 集団で発現した有害事象の概要を表 2.7.4.2-8 に示した。

統合 FAS 集団の被験者 59 例中 40 例（67.8%）に有害事象が発現した。重篤な有害事象が 9 例（15.3%）に発現し，治験薬投与の中止に至った有害事象が 2 例（3.4%）に発現した。死亡に至った有害事象は発現しなかった。

表 2.7.4.2-8. 有害事象の概要（統合 FAS 集団，M10-870 試験）

	Adalimumab (N=59) n (%)
有害事象	40 (67.8)
重篤な有害事象	9 (15.3)
高度の有害事象	3 (5.1)
治験薬投与の中止に至った有害事象	2 (3.4)
治験薬との因果関係が関連ありと医師により判断された有害事象	13 (22.0)
治験薬との因果関係が関連ありと医師により判断された重篤な有害事象	2 (3.4)
死亡に至った有害事象	0

Cross reference: M10-870 Japan Sub-study CSR_Interim Table 14.3_1.1.1_A

2.7.4.2.1.1 小児 比較的よく見られる有害事象

2.7.4.2.1.1.1 小児 発現割合の高い有害事象

M11-290 試験

主試験安全性解析対象集団で導入療法期中に 5%以上の被験者に発現した有害事象を表 2.7.4.2-9 に，すべての有害事象を付録 表 2.7.4.7-72 に示した。

主試験安全性解析対象集団（93 例）で導入療法期中に 5%以上の被験者に発現した有害事象は，頭痛（13 例，14.0%），貧血及び潰瘍性大腸炎（各 7 例，7.5%）並びに上咽頭炎（5 例，5.4%）であった。頭痛，貧血及び潰瘍性大腸炎の発現割合は，I-SD 群の方が I-HD 群よりも若干高かった。

表 2.7.4.2-9. 導入療法期中に 5%以上の被験者に発現した有害事象（MedDRA PT 別）（主試験安全性解析対象集団，M11-290 試験）

MedDRA 22.0 PT	I-SD (N=30) n (%)	I-HD (N=47) n (%)	I-HD-OL (N=16) n (%)	Total (N=93) n (%)
有害事象	17 (56.7)	23 (48.9)	12 (75.0)	52 (55.9)
頭痛	4 (13.3)	5 (10.6)	4 (25.0)	13 (14.0)
貧血	3 (10.0)	3 (6.4)	1 (6.3)	7 (7.5)
潰瘍性大腸炎	4 (13.3)	2 (4.3)	1 (6.3)	7 (7.5)
上咽頭炎	2 (6.7)	2 (4.3)	1 (6.3)	5 (5.4)

I-HD = induction high dose; I-HD-OL = induction high dose open-label; I-SD = induction standard dose; MedDRA = Medical Dictionary for Regulatory Activities; PT = preferred term

Note: Treatment-emergent adverse events are defined as events with an onset date on or after the first dose date of the study drug in the induction period and up to 70 days after the last dose date of the study drug in the induction period and prior to the first dose date of the study drug in the maintenance period if applicable.
Subjects are counted once in each row, regardless of the number of events they may have had.

Cross reference: M11-290 Main-study CSR Interim Table 14.3 1.2.2.1.1

統合安全性解析対象集団で導入療法期中に 5%以上の被験者に発現した有害事象を表 2.7.4.2-10 に，日本人安全性解析対象集団で導入療法期中に発現したすべての有害事象を表 2.7.4.2-11 に示した。また，統合安全性解析対象集団で導入療法期中に発現したすべての有害事象を付録 表 2.7.4.7-10 に示した。

統合安全性解析対象集団（100 例）で導入療法期中に 5%以上の被験者に発現した有害事象は，頭痛（14 例，14.0%），貧血及び潰瘍性大腸炎（各 7 例，7.0%）並びに上咽頭炎（5 例，5.0%）であった。頭痛，貧血及び潰瘍性大腸炎の発現割合は，I-SD 群の方が I-HD 群よりも若干高かった。

日本人安全性解析対象集団では，導入療法期中，上気道感染が 2 例に発現し，それ以外の事象はいずれも 1 例のみの発現であった。解析対象集団が少ないためすべての事象の発現割合が5%以上であった。

表 2.7.4.2-10. 導入療法期中に 5%以上の被験者に発現した有害事象（MedDRA PT 別）（統合安全性解析対象集団，M11-290 試験）

MedDRA 22.0 PT	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
有害事象	19 (59.4)	27 (52.9)	13 (76.5)	59 (59.0)
頭痛	5 (15.6)	5 (9.8)	4 (23.5)	14 (14.0)
貧血	3 (9.4)	3 (5.9)	1 (5.9)	7 (7.0)
潰瘍性大腸炎	4 (12.5)	2 (3.9)	1 (5.9)	7 (7.0)
上咽頭炎	2 (6.3)	2 (3.9)	1 (5.9)	5 (5.0)

I-HD = induction high dose; I-HD-OL = induction high dose open-label; I-SD = induction standard dose;
MedDRA = Medical Dictionary for Regulatory Activities; PT = preferred term

Note: TEAEs are defined as events with an onset date on or after the first dose date of the study drug in the Induction period and up to 70 days after the last dose date of study drug in the Induction period and prior to the first dose date of study drug in the Maintenance period if applicable. Subjects are counted once in each row, regardless of the number of events they may have had.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.3_1.2.2.1.1_A

表 2.7.4.2-11. 導入療法期中に発現したすべての有害事象（MedDRA PT 別）
（日本人安全性解析対象集団，M11-290 試験）

MedDRA 22.0 PT	I-SD (N=2) n (%)	I-HD (N=4) n (%)	I-HD-OL (N=1) n (%)	Total (N=7) n (%)
有害事象	2 (100)	4 (100)	1 (100)	7 (100)
上気道感染	0	2 (50.0)	0	2 (28.6)
眼瞼炎	0	1 (25.0)	0	1 (14.3)
異常感	1 (50.0)	0	0	1 (14.3)
注射部位紅斑	0	1 (25.0)	0	1 (14.3)
注射部位疼痛	1 (50.0)	0	0	1 (14.3)
外耳炎	0	1 (25.0)	0	1 (14.3)
単球数減少	0	0	1 (100)	1 (14.3)
好中球数減少	0	0	1 (100)	1 (14.3)
白血球数減少	0	0	1 (100)	1 (14.3)
頭痛	1 (50.0)	0	0	1 (14.3)

I-HD = induction high dose; I-HD-OL = induction high dose open-label; I-SD = induction standard dose;
MedDRA = Medical Dictionary for Regulatory Activities; PT = preferred term

Note: TEAEs are defined as events with an onset date on or after the first dose date of the study drug in the Induction period and up to 70 days after the last dose date of study drug in the Induction period and prior to the first dose date of study drug in the Maintenance period if applicable. Subjects are counted once in each row, regardless of the number of events they may have had.

Cross reference: M11-290 Japan Sub-study CSR Interim Table 14.3 1.2.1.1.1 J

最終解析（探索的解析）の統合安全性解析対象集団で導入療法期中に 5%以上の被験者に発現した有害事象を付録 表 2.7.4.7-162 に，日本人安全性解析対象集団で導入療法期中に発現したすべての有害事象を付録 表 2.7.4.7-163 に，統合安全性解析対象集団で導入療法期中に発現したすべての有害事象を付録 表 2.7.4.7-164 に示した。

中間解析から日本人最後の 8 例目被験者を含めた最終解析までの間に新たに発現した導入療法期中の有害事象は，日本人安全性解析対象集団の 1 例に認められた末梢腫脹のみであった。そのため，導入療法期中の発現割合の高い有害事象の発現状況は，中間解析と最終解析で同様であった。

主試験安全性解析対象集団で維持療法期中に 5%以上の被験者に発現した有害事象を表 2.7.4.2-12 に，すべての有害事象を付録 表 2.7.4.7-73 に示した。

維持療法期中にアダリムマブの投与を受けた主試験安全性解析対象集団の被験者（63 例）で 5%以上に発現した有害事象は，潰瘍性大腸炎（10 例，15.9%），頭痛（8 例，12.7%），上咽頭

炎（7 例，11.1%），上気道感染（5 例，7.9%）並びに貧血及び咽頭炎（各 4 例，6.3%）であった。潰瘍性大腸炎，頭痛及び貧血の発現割合は，M-SD 群の方が M-HD 群よりも若干高かった。

表 2.7.4.2-12. 維持療法期中に 5%以上の被験者に発現した有害事象（MedDRA PT 別）（主試験安全性解析対象集団，M11-290 試験）

MedDRA 22.0 PT	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total Adalimumab (N=63) n (%)	M-PL (N=12) n (%)
有害事象	20 (64.5)	22 (68.8)	42 (66.7)	10 (83.3)
潰瘍性大腸炎	6 (19.4)	4 (12.5)	10 (15.9)	2 (16.7)
頭痛	6 (19.4)	2 (6.3)	8 (12.7)	2 (16.7)
上咽頭炎	3 (9.7)	4 (12.5)	7 (11.1)	1 (8.3)
上気道感染	2 (6.5)	3 (9.4)	5 (7.9)	2 (16.7)
貧血	3 (9.7)	1 (3.1)	4 (6.3)	1 (8.3)
咽頭炎	2 (6.5)	2 (6.3)	4 (6.3)	1 (8.3)

M-HD = maintenance high dose; M-PL = maintenance placebo; M-SD = maintenance standard dose; MedDRA = Medical Dictionary for Regulatory Activities; PT = preferred term

Note: Treatment-emergent adverse events are defined as events with an onset date on or after the first dose date of the study drug in the maintenance period and prior to re-randomization due to first disease flare if applicable and up to 70 days after the last dose date of the study drug in the maintenance period. The events with an onset date on or after the first dose date in Study M10-870 are excluded.
Subjects are counted once in each row, regardless of the number of events they may have had.

Cross reference: M11-290 Main-study CSR Interim Table 14.3 1.2.2.1.2

統合安全性解析対象集団で維持療法期中に 5%以上の被験者に発現した有害事象を表 2.7.4.2-13 に，日本人安全性解析対象集団で維持療法期中に発現したすべての有害事象を表 2.7.4.2-14 に示した。また，統合安全性解析対象集団で維持療法期中に発現したすべての有害事象を付録 表 2.7.4.7-11 に示した。

維持療法期中にアダリムマブの投与を受けた統合安全性解析対象集団の被験者（68 例）で 5%以上に発現した有害事象は，潰瘍性大腸炎（10 例，14.7%），頭痛（8 例，11.8%），上咽頭炎（7 例，10.3%），上気道感染（6 例，8.8%）並びに貧血及び咽頭炎（各 4 例，5.9%）であった。潰瘍性大腸炎，頭痛及び貧血の発現割合は，M-SD 群の方が M-HD 群よりも若干高かった。

日本人安全性解析対象集団では，維持療法期中に発現した有害事象は，いずれも 1 例のみの発現であった。解析対象集団が少ないためすべての事象の発現割合が 5%以上であった。

表 2.7.4.2-13. 維持療法期中に 5%以上の被験者に発現した有害事象（MedDRA PT 別）（統合安全性解析対象集団，M11-290 試験）

MedDRA 22.0 PT	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total Adalimumab (N=68) n (%)	M-PL (N=12) n (%)
有害事象	21 (63.6)	25 (71.4)	46 (67.6)	10 (83.3)
潰瘍性大腸炎	6 (18.2)	4 (11.4)	10 (14.7)	2 (16.7)
頭痛	6 (18.2)	2 (5.7)	8 (11.8)	2 (16.7)
上咽頭炎	3 (9.1)	4 (11.4)	7 (10.3)	1 (8.3)
上気道感染	2 (6.1)	4 (11.4)	6 (8.8)	2 (16.7)
貧血	3 (9.1)	1 (2.9)	4 (5.9)	1 (8.3)
咽頭炎	2 (6.1)	2 (5.7)	4 (5.9)	1 (8.3)

M-HD = maintenance high dose; M-PL = maintenance placebo; M-SD = maintenance standard dose; MedDRA = Medical Dictionary for Regulatory Activities; PT = preferred term

Note: TEAEs are defined as events with an onset date on or after the first dose date of study drug in the Maintenance period and prior to re-randomization due to first disease flare if applicable and up to 70 days after the last dose date of the study drug in the Maintenance period. Subjects are counted once in each row, regardless of the number of events they may have had.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.3_1.2.2.1.2_A

表 2.7.4.2-14. 維持療法期中に発現したすべての有害事象（MedDRA PT 別）（日本人安全性解析対象集団，M11-290 試験）

MedDRA 22.0 PT	M-SD (N=2) n (%)	M-HD (N=3) n (%)	Total Adalimumab (N=5) n (%)	M-PL (N=0) n (%)
有害事象	1 (50.0)	3 (100)	4 (80.0)	—
感染性腸炎	1 (50.0)	0	1 (20.0)	—
膿痂疹	0	1 (33.3)	1 (20.0)	—
インフルエンザ	0	1 (33.3)	1 (20.0)	—
上気道感染	0	1 (33.3)	1 (20.0)	—
眼瞼挫傷	0	1 (33.3)	1 (20.0)	—
手骨折	0	1 (33.3)	1 (20.0)	—
靭帯捻挫	0	1 (33.3)	1 (20.0)	—
紫斑	0	1 (33.3)	1 (20.0)	—

M-HD = maintenance high dose; M-PL = maintenance placebo; M-SD = maintenance standard dose; MedDRA = Medical Dictionary for Regulatory Activities; PT = preferred term

Note: TEAEs are defined as events with an onset date on or after the first dose date of study drug in the Maintenance period and prior to re-randomization due to first disease flare if applicable and up to 70 days after the last dose date of the

study drug in the Maintenance period. Subjects are counted once in each row, regardless of the number of events they may have had.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.3_1.2.1.1.2_J

最終解析（探索的解析）の統合安全性解析対象集団で維持療法期中に 5%以上の被験者に発現した有害事象を付録 表 2.7.4.7-165 に，日本人安全性解析対象集団で維持療法期中に発現したすべての有害事象を付録 表 2.7.4.7-166 に，統合安全性解析対象集団で維持療法期中に発現したすべての有害事象を付録 表 2.7.4.7-167 に示した。

中間解析から日本人最後の 8 例目被験者を含めた最終解析までの間に新たに発現した維持療法期中の有害事象は，日本人安全性解析対象集団の 1 例に認められた結膜炎のみであった。そのため，維持療法期中の発現割合の高い有害事象の発現状況は，中間解析と最終解析で同様であった。

M10-870 試験（長期投与試験）

主試験 FAS 集団で 5%以上の被験者に発現した有害事象を表 2.7.4.2-15 に示した。また，主試験 FAS 集団で発現したすべての有害事象を付録 表 2.7.4.7-74 に示した。

主試験 FAS 集団（55 例）で発現割合が高かった有害事象は，潰瘍性大腸炎（11 例，20.0%）及び上気道感染（6 例，10.9%）であった。他の有害事象の発現割合はいずれも 10%未満であった。

表 2.7.4.2-15. 5%以上の被験者に発現した有害事象（MedDRA PT 別）（主試験 FAS 集団，M10-870 試験）

MedDRA 22.0 PT	Adalimumab (N = 55) n (%)
有害事象	36 (65.5)
潰瘍性大腸炎	11 (20.0)
上気道感染	6 (10.9)
頭痛	5 (9.1)
貧血	4 (7.3)
関節痛	4 (7.3)
結核菌群検査陽性	4 (7.3)
気管支炎	3 (5.5)
胃炎	3 (5.5)
上咽頭炎	3 (5.5)

Cross reference: M10-870 Main-study CSR_Interim Table 14.3_1.2.2.1

統合 FAS 集団で 5%以上の被験者に発現した有害事象を表 2.7.4.2-16 に示した。また，統合 FAS 集団で発現したすべての有害事象を付録 表 2.7.4.7-12 に示した。

統合 FAS 集団（59 例）で発現割合が高かった有害事象は，潰瘍性大腸炎（12 例，20.3%）及び上気道感染（7 例，11.9%）であった。他の有害事象の発現割合はいずれも 10%未満であった。

表 2.7.4.2-16. 5%以上の被験者に発現した有害事象（MedDRA PT 別）（統合 FAS 集団，M10-870 試験）

MedDRA 22.0 PT	Adalimumab (N = 59) n (%)
有害事象	40 (67.8)
潰瘍性大腸炎	12 (20.3)
上気道感染	7 (11.9)
頭痛	5 (8.5)
上咽頭炎	5 (8.5)
貧血	4 (6.8)
関節痛	4 (6.8)
結核菌群検査陽性	4 (6.8)
咽頭炎	4 (6.8)
気管支炎	3 (5.1)
胃炎	3 (5.1)

Cross reference: M10-870 Japan Sub-study CSR Interim Table 14.3 1.2.2.1 A

2.7.4.2.1.1.2 小児 治験薬と関連ありの有害事象

M11-290 試験

主試験安全性解析対象集団で導入療法期中に発現した有害事象を治験薬との因果関係別に付録 表 2.7.4.7-75 に示した。また，主試験安全性解析対象集団で維持療法期中に発現した有害事象を治験薬との因果関係別に付録 表 2.7.4.7-76 に示した。

導入療法期中，治験薬と関連ありの有害事象は主試験安全性解析対象集団の被験者 93 例中 12 例（12.9%）に発現した。治験薬と関連ありの有害事象の発現割合は低く，I-SD 群（30 例中 4 例，13.3%）と I-HD 群（47 例中 7 例，14.9%）で同程度であった。主試験安全性解析対象集団で複数の被験者に認められた治験薬と関連ありの有害事象は頭痛（3 例，3.2%）であり，他の事象はいずれも 1 例のみの発現であった。

維持療法期中，治験薬と関連ありの有害事象はアダリムマブの投与を受けた主試験安全性解析対象集団の被験者 63 例中 18 例（28.6%）に発現した。治験薬と関連ありの有害事象の発現割合は低く，M-SD 群（31 例中 8 例，25.8%）と M-HD 群（32 例中 10 例，31.3%）で同程度であ

った。維持療法期中にアダリムマブの投与を受けた主試験安全性解析対象集団の被験者で複数に認められた治験薬と関連ありの有害事象は，潰瘍性大腸炎（3 例，4.8%）並びに疲労，頭痛及び発疹（各 2 例，3.2%）であり，他の事象はいずれも 1 例のみの発現であった。

統合安全性解析対象集団及び日本人安全性解析対象集団で導入療法期中に発現した有害事象を治験薬との因果関係別に付録 表 2.7.4.7-13 及び付録 表 2.7.4.7-14 に示した。また，統合安全性解析対象集団及び日本人安全性解析対象集団で維持療法期中に発現した有害事象を治験薬との因果関係別に付録 表 2.7.4.7-15 及び付録 表 2.7.4.7-16 に示した。

導入療法期中，治験薬と関連ありの有害事象は統合安全性解析対象集団の被験者 100 例中 15 例（15.0%）に発現した。治験薬と関連ありの有害事象の発現割合は低く，I-SD 群（32 例中 5 例，15.6%）と I-HD 群（51 例中 8 例，15.7%）で同程度であった。統合安全性解析対象集団で複数の被験者に認められた治験薬と関連ありの有害事象は，頭痛（3 例，3.0%）及び注射部位疼痛（2 例，2.0%）であり，他の事象はいずれも 1 例のみの発現であった。

日本人安全性解析対象集団では，治験薬と関連ありの有害事象はいずれも 1 例のみの発現であった。

維持療法期中，治験薬と関連ありの有害事象はアダリムマブの投与を受けた統合安全性解析対象集団の被験者 68 例中 19 例（27.9%）に発現した。治験薬と関連ありの有害事象の発現割合は低く，M-SD 群（33 例中 8 例，24.2%）と M-HD 群（35 例中 11 例，31.4%）で同程度であった。維持療法期中にアダリムマブの投与を受けた統合安全性解析対象集団の被験者で複数に認められた治験薬と関連ありの有害事象は，潰瘍性大腸炎（3 例，4.4%）並びに疲労，頭痛及び発疹（各 2 例，2.9%）であり，他の事象はいずれも 1 例のみの発現であった。

日本人安全性解析対象集団では，治験薬と関連ありのインフルエンザ及び紫斑が同一の 1 例に発現した。

最終解析（探索的解析）の統合安全性解析対象集団及び日本人安全性解析対象集団で導入療法期中に発現した有害事象を治験薬との因果関係別に付録 表 2.7.4.7-168 及び付録 表 2.7.4.7-169 に示した。また，最終解析の統合安全性解析対象集団及び日本人安全性解析対象集団で維持療法期中に発現した有害事象を治験薬との因果関係別に付録 表 2.7.4.7-170 及び付録 表 2.7.4.7-171 に示した。

中間解析から日本人最後の 8 例目被験者を含めた最終解析までの間に，新たな治験薬と関連ありの有害事象は認められなかった。

M10-870 試験（長期投与試験）

主試験 FAS 集団で発現した有害事象を治験薬との因果関係別に付録 表 2.7.4.7-77 に示した。

主試験 FAS 集団では，治験薬と関連ありの有害事象は 55 例中 11 例（20.0%）に発現した。複数の被験者に発現した治験薬と関連ありの有害事象は，関節痛（2 例，3.6%）であり，他の事象はいずれも 1 例のみの発現であった。

統合 FAS 集団で発現した有害事象を治験薬との因果関係別に付録 表 2.7.4.7-17 に示した。

治験薬と関連ありの有害事象は統合 FAS 集団の被験者 59 例中 13 例（22.0%）に発現した。複数の被験者に発現した治験薬と関連ありの有害事象は，関節痛，帯状疱疹及び上気道感染（各 2 例，3.4%）であり，他の事象はいずれも 1 例のみの発現であった。

2.7.4.2.1.1.3 小児 高度の有害事象

M11-290 試験

主試験安全性解析対象集団で導入療法期中に発現した有害事象を重症度別に付録 表 2.7.4.7-78 に示した。また，主試験安全性解析対象集団で維持療法期中に発現した有害事象を重症度別に付録 表 2.7.4.7-79 に示した。

主試験安全性解析対象集団で導入療法期中に発現した有害事象の大部分は，重症度が軽度又は中等度と判断された。高度の有害事象は主試験安全性解析対象集団の被験者 93 例中 5 例（5.4%）に発現し，発現割合は I-SD 群（30 例中 4 例，13.3%）の方が I-HD 群（47 例中 1 例，2.1%）よりも高かった。

主試験安全性解析対象集団で維持療法期中に発現した有害事象の大部分は，重症度が軽度又は中等度と判断された。高度の有害事象は維持療法期中にアダリムマブの投与を受けた被験者 63 例中 4 例（6.3%）に発現し，発現割合は M-SD 群（31 例中 3 例，9.7%）の方が M-HD 群（32 例中 1 例，3.1%）よりも高かった。

統合安全性解析対象集団及び日本人安全性解析対象集団で導入療法期中に発現した有害事象を重症度別に付録 表 2.7.4.7-18 及び付録 表 2.7.4.7-19 に示した。また，統合安全性解析対象集団及び日本人安全性解析対象集団で維持療法期中に発現した有害事象を重症度別に付録 表 2.7.4.7-20 及び付録 表 2.7.4.7-21 に示した。

統合安全性解析対象集団で導入療法期中に発現した有害事象の大部分は，重症度が軽度又は中等度と判断された。高度の有害事象は統合安全性解析対象集団の被験者 100 例中 5 例（5.0%）に発現し，発現割合は I-SD 群（32 例中 4 例，12.5%）の方が I-HD 群（51 例中 1 例，2.0%）よりも高かった。なお，統合安全性解析対象集団の I-HD-OL 群及び日本人安全性解析対象集団で発現した有害事象はいずれも軽度又は中等度であった。

統合安全性解析対象集団で維持療法期中に発現した有害事象の大部分は，重症度が軽度又は中等度と判断された。高度の有害事象は維持療法期中にアダリムマブの投与を受けた被験者 68 例中 4 例（5.9%）に発現し，発現割合は M-SD 群（33 例中 3 例，9.1%）の方が M-HD 群（35 例中 1 例，2.9%）よりも高かった。なお，日本人安全性解析対象集団で発現した有害事象はいずれも軽度であった。

最終解析（探索的解析）の統合安全性解析対象集団及び日本人安全性解析対象集団で導入療法期中に発現した有害事象を重症度別に付録 表 2.7.4.7-172 及び付録 表 2.7.4.7-173 に示した。また，最終解析の統合安全性解析対象集団及び日本人安全性解析対象集団で維持療法期中に発現した有害事象を重症度別に付録 表 2.7.4.7-174 及び付録 表 2.7.4.7-175 に示した。

中間解析から日本人最後の 8 例目被験者を含めた最終解析までの間に，新たな高度の有害事象は認められなかった。

M10-870 試験（長期投与試験）

主試験 FAS 集団で発現した有害事象を重症度別に付録 表 2.7.4.7-80 に示した。

有害事象の大部分は，重症度が軽度又は中等度と判断された。高度の有害事象は主試験 FAS 集団の被験者 55 例中 2 例（3.6%）に 3 件発現した（潰瘍性大腸炎が 2 例に，貧血が 1 例に発現）。高度の潰瘍性大腸炎が発現した 1 例は治験薬投与を中止した。

統合 FAS 集団で発現した有害事象を重症度別に付録 表 2.7.4.7-22 に示した。

有害事象の大部分は，重症度が軽度又は中等度と判断された。高度の有害事象は統合 FAS 集団の被験者 59 例中 3 例（5.1%）に 4 件発現した（潰瘍性大腸炎が 3 例に，貧血が 1 例に発現）。高度の有害事象はいずれも治験薬と関連なしと判断された。高度の潰瘍性大腸炎が発現した 1 例は治験薬投与を中止した。

2.7.4.2.1.2 小児 死亡

M11-290 試験

投与 52 週時までに死亡に至った有害事象は発現しなかった。

M10-870 試験（長期投与試験）

試験期間中に死亡に至った有害事象は発現しなかった。

2.7.4.2.1.3 小児 その他の重篤な有害事象

M11-290 試験

主試験安全性解析対象集団で導入療法期中に発現した重篤な有害事象を付録 表 2.7.4.7-81 に，重篤な有害事象の 100 人年あたりの発現頻度を付録 表 2.7.4.7-82 に，治験薬と関連ありの重篤な有害事象を付録 表 2.7.4.7-83 に示した。また，主試験安全性解析対象集団で維持療法期中に発現した重篤な有害事象を付録 表 2.7.4.7-84 に，重篤な有害事象の 100 人年あたりの発現頻度を付録 表 2.7.4.7-85 に，治験薬と関連ありの重篤な有害事象を付録 表 2.7.4.7-86 に示した。

導入療法期中，主試験安全性解析対象集団の被験者 93 例中 10 例（10.8%）に重篤な有害事象が発現した。重篤な有害事象の発現割合は，I-SD 群（30 例中 5 例，16.7%）の方が I-HD 群（47 例中 4 例，8.5%）よりも若干高かった。また，重篤な有害事象の 100 人年あたりの発現頻度も I-SD 群（159.1 件/100 人年）の方が I-HD 群（56.3 件/100 人年）よりも高かった。導入療法期で複数の被験者に発現した重篤な有害事象は，潰瘍性大腸炎（5 例，5.4%）及び貧血（2 例，2.2%）

であった。治験薬と関連ありの重篤な有害事象として，心膜炎，潰瘍性大腸炎，膵炎，頭痛及び意識消失が追跡調査中に各 1 例（1.1%）に発現したが，いずれも最終的に消失した。

維持療法期中にアダリムマブの投与を受けた主試験安全性解析対象集団の被験者 63 例中 9 例（14.3%）に重篤な有害事象が発現した。重篤な有害事象の発現割合は，M-SD 群（31 例中 4 例，12.9%）と M-HD 群（32 例中 5 例，15.6%）で同程度であった。ただし，重篤な有害事象の 100 人年あたりの発現頻度は M-SD 群（44.6 件/100 人年）の方が M-HD 群（28.3 件/100 人年）よりも高かった。複数の被験者に発現した重篤な有害事象は，潰瘍性大腸炎（3 例，4.8%）及び胃腸炎（2 例，3.2%）であった。治験薬と関連ありの重篤な有害事象として，無菌性髄膜炎が 1 例（1.6%）に発現した。

統合安全性解析対象集団で導入療法期中に発現した重篤な有害事象を付録 表 2.7.4.7-23 に，重篤な有害事象の 100 人年あたりの発現頻度を付録 表 2.7.4.7-24 に，治験薬と関連ありの重篤な有害事象を付録 表 2.7.4.7-25 に示した。統合安全性解析対象集団で維持療法期中に発現した重篤な有害事象を付録 表 2.7.4.7-26 に，重篤な有害事象の 100 人年あたりの発現頻度を付録 表 2.7.4.7-27 に，治験薬と関連ありの重篤な有害事象を付録 表 2.7.4.7-28 に示した。また，M11-290 試験で発現した重篤な有害事象の一覧を付録 表 2.7.4.7-29 に示した。重篤な有害事象の叙述は 2.7.6 項に示した。

導入療法期中，統合安全性解析対象集団の被験者 100 例中 10 例（10.0%）に重篤な有害事象が発現した。重篤な有害事象の発現割合は，I-SD 群（32 例中 5 例，15.6%）の方が I-HD 群（51 例中 4 例，7.8%）よりも若干高かった。また，重篤な有害事象の 100 人年あたりの発現頻度も I-SD 群（152.2 件/100 人年）の方が I-HD 群（51.9 件/100 人年）よりも高かった。導入療法期で複数の被験者に発現した重篤な有害事象は，潰瘍性大腸炎（5 例，5.0%）及び貧血（2 例，2.0%）であった。治験薬と関連ありの重篤な有害事象として，心膜炎，潰瘍性大腸炎，膵炎，頭痛及び意識消失が追跡調査中に各 1 例（1.0%）に発現したが，いずれも最終的に消失した。

維持療法期中にアダリムマブの投与を受けた統合安全性解析対象集団の被験者 68 例中 10 例（14.7%）に重篤な有害事象が発現した。重篤な有害事象の発現割合は，M-SD 群（33 例中 5 例，15.2%）と M-HD 群（35 例中 5 例，14.3%）で同程度であった。ただし，重篤な有害事象の 100 人年あたりの発現頻度は M-SD 群（48.8 件/100 人年）の方が M-HD 群（25.9 件/100 人年）よりも高かった。複数の被験者に発現した重篤な有害事象は，潰瘍性大腸炎（3 例，4.4%）及び胃腸炎（2 例，2.9%）であった。治験薬と関連ありの重篤な有害事象として，無菌性髄膜炎が 1 例（1.5%）に発現した。

日本人安全性解析対象集団では，導入療法期中に重篤な有害事象は発現せず，維持療法期中に重篤な感染性腸炎が 1 例に発現した。

最終解析（探索的解析）の統合安全性解析対象集団で導入療法期中に発現した重篤な有害事象を付録 表 2.7.4.7-176 に，重篤な有害事象の 100 人年あたりの発現頻度を付録 表 2.7.4.7-177 に，治験薬と関連ありの重篤な有害事象を付録 表 2.7.4.7-178 に示した。また，最終解析の統合安全性解析対象集団で維持療法期中に発現した重篤な有害事象を付録 表 2.7.4.7-179 に，重篤な

有害事象の 100 人年あたりの発現頻度を付録 表 2.7.4.7-180 に，治験薬と関連ありの重篤な有害事象を付録 表 2.7.4.7-181 に示した。

中間解析から日本人最後の 8 例目被験者を含めた最終解析までの間に，新たな重篤な有害事象は認められなかった。

M10-870 試験（長期投与試験）

主試験 FAS 集団で発現した重篤な有害事象を付録 表 2.7.4.7-87 に，重篤な有害事象の 100 人年あたりの発現頻度を付録 表 2.7.4.7-88 に，治験薬と関連ありの重篤な有害事象を付録 表 2.7.4.7-89 に示した。

重篤な有害事象は主試験 FAS 集団の被験者 55 例中 8 例（14.5%）に発現した。また，重篤な有害事象の 100 人年あたりの発現頻度は 17.5 件/100 人年であった。発現した重篤な有害事象の多くは，基礎疾患に関連するものと考えられた。複数の被験者に発現した重篤な有害事象は，貧血及び潰瘍性大腸炎（各 2 例，3.6%）であった。貧血の重症度は，1 例が中等度であり，M11-290 試験の登録前に貧血の病歴を有していた別の 1 例では高度であった。いずれの貧血も治験薬と関連なしと判断され，治験薬投与を中断することなく消失した。潰瘍性大腸炎の重症度は，1 例が中等度，1 例が高度であった。いずれの潰瘍性大腸炎も治験薬と関連なしと判断され，高度の事象が発現した 1 例は治験薬投与を中止した。治験薬と関連ありの重篤な有害事象として，胆嚢炎及び卵巣嚢胞が各 1 例（1.8%）に発現した。

統合 FAS 集団で発現した重篤な有害事象を付録 表 2.7.4.7-30 に，重篤な有害事象の 100 人年あたりの発現頻度を付録 表 2.7.4.7-31 に，治験薬と関連ありの重篤な有害事象を付録 表 2.7.4.7-32 に示した。また，M10-870 試験で発現した重篤な有害事象の一覧を付録 表 2.7.4.7-33 に示した。重篤な有害事象の叙述は 2.7.6 項に示した。

重篤な有害事象は統合 FAS 集団の被験者 59 例中 9 例（15.3%）に発現した。また，重篤な有害事象の 100 人年あたりの発現頻度は 20.2 件/100 人年であった。発現した重篤な有害事象の多くは，基礎疾患に関連するものと考えられた。複数の被験者に発現した重篤な有害事象は，潰瘍性大腸炎（3 例，5.1%）及び貧血（2 例，3.4%）であった。貧血の重症度は，1 例が中等度であり，M11-290 試験の登録前に貧血の病歴を有していた別の 1 例では高度であった。いずれの貧血も治験薬と関連なしと判断され，治験薬投与を中断することなく消失した。潰瘍性大腸炎の重症度は，1 例が中等度及び高度（2 件発現），1 例が中等度，1 例が高度であった。いずれの潰瘍性大腸炎も治験薬と関連なしと判断され，高度の事象が 1 件発現した 1 例は治験薬投与を中止したが，それ以外は治験薬投与を中断することなく消失した。治験薬と関連ありの重篤な有害事象として，胆嚢炎及び卵巣嚢胞が各 1 例（1.7%）に発現した。

日本の被験者では，1 例に 3 件の重篤な有害事象（中等度の潰瘍性大腸炎，中等度の敗血症，及び高度の潰瘍性大腸炎）が発現した。いずれの事象も治験薬と関連なしと判断され，治験薬投与を中断することなく消失した。

2.7.4.2.1.4 小児 その他の重要な有害事象

M11-290 試験

M11-290 試験で発現した治験薬投与の中止に至った有害事象の一覧を付録 表 2.7.4.7-34 に示した。

治験薬投与の中止に至った有害事象の発現は少なく，導入療法期中は統合安全性解析対象集団の被験者 100 例中 4 例（4.0%）に発現し，うち 3 例は日本以外の被験者（潰瘍性大腸炎及び心膜炎が 1 例，潰瘍性大腸炎が 2 例），1 例は日本の被験者（注射部位疼痛）であった。また，維持療法期中はアダリムマブの投与を受けた統合安全性解析対象集団の被験者 68 例中 2 例（2.9%）に発現し，いずれも日本以外の被験者であった（小腸炎が 1 例，貧血及び潰瘍性大腸炎が 1 例）。治験薬と関連ありの治験薬投与の中止に至った有害事象は導入療法期中に統合安全性解析対象集団の被験者 2 例（2.0%）に発現し，その内訳は，心膜炎が 1 例（日本以外の被験者）及び注射部位疼痛が 1 例（日本の被験者）であった。治験薬投与の中止に至った有害事象の大部分は消失した。

なお，中間解析から日本人最後の 8 例目被験者を含めた最終解析までの間に，新たな治験薬投与の中止に至った有害事象は認められなかった。

M10-870 試験（長期投与試験）

M10-870 試験で発現した治験薬投与の中止に至った有害事象の一覧を付録 表 2.7.4.7-35 に示した。

治験薬投与の中止に至った有害事象として，潰瘍性大腸炎が統合 FAS 集団の被験者 59 例中 2 例（3.4%）に発現し，いずれも日本以外の被験者であった。1 例に発現した潰瘍性大腸炎は重篤であり，重症度は高度，治験薬と関連なしと判断された。別の 1 例に発現した潰瘍性大腸炎は非重篤であり，重症度は中等度，治験薬と関連なしと判断された。

日本の被験者では，治験薬投与の中止に至った有害事象は発現しなかった。

2.7.4.2.1.5 小児 器官別又は症候群別有害事象の解析

TNF 阻害剤の生物学的療法で同定されたリスク及び潜在的リスクを示す AESI の分類の一覧を付録 表 2.7.4.7-1 に記載した。

2.7.4.2.1.5.1 小児 概要

M11-290 試験

M11-290 試験の主試験安全性解析対象集団で発現した AESI の概要を表 2.7.4.2-17 に示した。また，主試験安全性解析対象集団で発現した有害事象（AESI を含む）の 100 人年あたりの発現頻度の概要を付録 表 2.7.4.7-90（導入療法期）及び付録 表 2.7.4.7-91（維持療法期）に示した。

主試験安全性解析対象集団（93 例）では，導入療法期中に，AESI のカテゴリーのうち，すべての感染症が 20 例（21.5%），血管浮腫 / アナフィラキシーを含むアレルギー反応が 1 例（1.1%），膵炎が 1 例（1.1%），汎血球減少症を含む血液障害が 7 例（7.5%），注射部位反応が 2 例（2.2%）に発現した。

維持療法期中にアダリムマブの投与を受けた主試験安全性解析対象集団の被験者（63 例）では，AESI のカテゴリーのうち，すべての感染症が 23 例（36.5%），重篤な感染症が 5 例（7.9%），潜在性結核が 1 例（1.6%），血管浮腫 / アナフィラキシーを含むアレルギー反応が 3 例（4.8%），汎血球減少症を含む血液障害が 4 例（6.3%），注射部位反応が 6 例（9.5%）に発現した。

M11-290 試験の主試験安全性解析対象集団では，上記以外の AESI は発現しなかった。なお，1 回目の疾患再燃の後に再導入を受けた被験者 1 例に，口腔カンジダ症及び結核を除く日和見感染症が発現した。

表 2.7.4.2-17. AESI の概要（試験期別，用量群別）（主試験安全性解析対象集団及び主試験再無作為化集団，M11-290 試験）

	n (%) of Subjects						
	Safety					RR	Safety
	Induction[a]			Maintenance Up to First Disease Flare[b]		After First Disease Flare with Re-Induction[c]	Any Adalimumab[d]
AESI Category	I-SD	I-HD	I-HD-OL	M-SD	M-HD		
Safety / RR population	N = 30	N = 47	N = 16	N = 31	N = 32	N = 6	N = 93
Infection	6 (20.0)	8 (17.0)	6 (37.5)	10 (32.3)	13 (40.6)	2 (33.3)	44 (47.3)
Serious infection	0	0	0	2 (6.5)	3 (9.4)	0	5 (5.4)
Opportunistic infection excluding oral candidiasis and TB	0	0	0	0	0	1 (16.7)[e]	1 (1.1)
Latent TB	0	0	0	0	1 (3.1)	0	1 (1.1)
Allergic reactions including angioedema/anaphylaxis	0	1 (2.1)	0	1 (3.2)	2 (6.3)	0	4 (4.3)
Pancreatitis	0	1 (2.1)	0	0	0	0	1 (1.1)
Worsening or new onset of psoriasis	0	0	0	0	0	0	0
Hematologic disorders including pancytopenia	3 (10.0)	3 (6.4)	1 (6.3)	3 (9.7)	1 (3.1)	0	12 (12.9)
Injection site reaction	0	2 (4.3)	0	4 (12.9)	2 (6.3)	0	8 (8.6)

AESI = adverse event of special interest; I-HD = induction high dose; I-HD-OL = induction high dose open-label; I-SD = induction standard dose; M-HD = maintenance high dose; M-SD = maintenance standard dose; RR = re-randomized; TB = tuberculosis

a. TEAEs are defined as events with an onset date on or after the date of the first dose of study drug in the Induction period and up to 70 days after the last dose date of the study drug in the induction period and prior to the first dose date of study drug in the Maintenance period (if applicable).

b. Subjects with at least 1 dose of study drug during Maintenance period; TEAEs are defined as events with an onset date on or after the first dose date of study drug in the Maintenance period and prior to re-randomization due to the first disease flare (if applicable) and up to 70 days after the last dose date of study drug in the Maintenance period.

c. RR population with re-induction dose (shown is the total of M-SD and M-HD): TEAEs are defined as events with an onset date on or after the first dose date of study drug after re-randomization due to first disease flare and up to 70 days after the last dose date of study drug.

d. Subjects in the Any Adalimumab population may also be counted under the individual dose groups per study period, so the Any Adalimumab group is not the sum of subjects in the individual period dose groups.

e. M-SD group.

Note: TEAEs are defined as events with an onset date on or after the first dose date of adalimumab and up to 70 days after the last date of adalimumab in this study. For subjects randomized to placebo at Week 8 without disease flare, AEs with an onset date on or after the first dose date of placebo are excluded. For subjects randomized to placebo at Week 8 and were re-randomized due to disease flare, AEs with an onset date within the first dose date of placebo and last dose date of placebo are excluded. Subjects are counted once in each row, regardless of the number of events they may have had.

Cross reference: M11-290 Main-study CSR Interim Table 14.3 1.1.1.1, Table 14.3 1.1.1.2, Table 14.3 1.1.1.4, and Table 14.3 1.1.1.5

M11-290 試験の統合安全性解析対象集団で発現した AESI の概要を表 2.7.4.2-18 に示した。また，統合安全性解析対象集団で発現した有害事象（AESI を含む）の 100 人年あたりの発現頻度の概要を付録 表 2.7.4.7-36（導入療法期）及び付録 表 2.7.4.7-37（維持療法期）に，日本人安全性解析対象集団で発現した有害事象（AESI を含む）の 100 人年あたりの発現頻度の概要を付録 表 2.7.4.7-38（導入療法期）及び付録 表 2.7.4.7-39（維持療法期）に示した。

統合安全性解析対象集団（100 例）では，導入療法期中に，AESI のカテゴリーのうち，すべての感染症が 23 例（23.0%，うち 3 例は日本の被験者），血管浮腫 / アナフィラキシーを含むアレルギー反応が 1 例（1.0%），膵炎が 1 例（1.0%），汎血球減少症を含む血液障害が 7 例（7.0%），注射部位反応が 4 例（4.0%，うち 2 例は日本の被験者）に発現した。血管浮腫 / アナフィラキシーを含むアレルギー反応，膵炎，汎血球減少症を含む血液障害は日本人には発現しなかった。

維持療法期中にアダリムマブの投与を受けた統合安全性解析対象集団の被験者（68 例）では，AESI のカテゴリーのうち，すべての感染症が 27 例（39.7%，うち 4 例は日本の被験者），重篤な感染症が 6 例（8.8%，うち 1 例は日本の被験者），潜在性結核が 1 例（1.5%），血管浮腫 / アナフィラキシーを含むアレルギー反応が 3 例（4.4%），汎血球減少症を含む血液障害が 4 例（5.9%），注射部位反応が 6 例（8.8%）に発現した。また，乾癬の悪化又は新規発症が M-PL 群の 1 例に発現した。潜在性結核，血管浮腫 / アナフィラキシーを含むアレルギー反応，汎血球減少症を含む血液障害，注射部位反応，乾癬の悪化又は新規発症は日本人には発現しなかった。

M11-290 試験の統合安全性解析対象集団では，上記以外の AESI は発現しなかった。なお，1 回目の疾患再燃の後に再導入を受けた被験者 1 例に，口腔カンジダ症及び結核を除く日和見感染症が発現した。

表 2.7.4.2-18. AESI の概要（試験期別，用量群別）（統合安全性解析対象集団，日本人安全性解析対象集団及び統合再無作為化集団，M11-290 試験）

	n (%) of Subjects						
	Safety					RR	Safety
	Induction[a]			Maintenance Up to First Disease Flare[b]		After First Disease Flare with Re-Induction[c]	Any Adalimumab[d]
AESI Category	I-SD	I-HD	I-HD-OL	M-SD	M-HD		
Integrated population	N = 32	N = 51	N = 17	N = 33	N = 35	N = 8	N = 100
Infection	6 (18.8)	11 (21.6)	6 (35.3)	11 (33.3)	16 (45.7)	4 (50.0)	49 (49.0)
Serious infection	0	0	0	3 (9.1)	3 (8.6)	0	6 (6.0)
Opportunistic infection excluding oral candidiasis and TB	0	0	0	0	0	1 (12.5)[e]	1 (1.0)
Latent TB	0	0	0	0	1 (2.9)	0	1 (1.0)
Allergic reactions including angioedema/anaphylaxis	0	1 (2.0)	0	1 (3.0)	2 (5.7)	0	4 (4.0)
Pancreatitis	0	1 (2.0)	0	0	0	0	1 (1.0)
Worsening or new onset of psoriasis	0	0	0	0	0	0	0
Hematologic disorders including pancytopenia	3 (9.4)	3 (5.9)	1 (5.9)	3 (9.1)	1 (2.9)	0	12 (12.0)
Injection site reaction	1 (3.1)	3 (5.9)	0	4 (12.1)	2 (5.7)	0	10 (10.0)

表 2.7.4.2-18. AESI の概要（試験期別，用量群別）（統合安全性解析対象集団，日本人安全性解析対象集団及び統合再無作為化集団，M11-290 試験）（続き）

	n (%) of Subjects						
	Safety					RR	Safety
	Induction[a]			Maintenance Up to First Disease Flare[b]		After First Disease Flare with Re-Induction[c]	Any Adalimumab[d]
AESI Category	I-SD	I-HD	I-HD-OL	M-SD	M-HD		
Japan population	N = 2	N = 4	N = 1	N = 2	N = 3	—	N = 7
Infection	0	3 (75.0)	0	1 (50.0)	3 (100)	—	5 (71.4)
Serious infection	0	0	0	1 (50.0)	0	—	1 (14.3)
Latent TB	0	0	0	0	0	—	0
Allergic reactions including angioedema/anaphylaxis	0	0	0	0	0	—	0
Pancreatitis	0	0	0	0	0	—	0
Worsening or new onset of psoriasis	0	0	0	0	0	—	0
Hematologic disorders including pancytopenia	0	0	0	0	0	—	0
Injection site reaction	1 (50.0)	1 (25.0)	0	0	0	—	2 (28.6)

AESI = adverse event of special interest; I-HD = induction high dose; I-HD-OL = induction high dose open-label; I-SD = induction standard dose; M-HD = maintenance high dose; M-SD = maintenance standard dose; RR = re-randomized; TB = tuberculosis

a. Integrated Safety population; TEAEs are defined as events with an onset date on or after the date of the first dose of study drug in the Induction period and up to 70 days after the last dose date of the study drug in the induction period and prior to the first dose date of study drug in the Maintenance period (if applicable).

b. Integrated Safety population – subjects with at least 1 dose of study drug during Maintenance period; TEAEs are defined as events with an onset date on or after the first dose date of study drug in the Maintenance period and prior to re-randomization due to the first disease flare (if applicable) and up to 70 days after the last dose date of study drug in the Maintenance period.

c. Integrated RR population with re-induction dose (shown is the total of M-SD and M-HD): TEAEs are defined as events with an onset date on or after the first dose date of study drug after re-randomization due to first disease flare and up to 70 days after the last dose date of study drug.

d. Subjects in the Any Adalimumab population may also be counted under the individual dose groups per study period, so the Any Adalimumab group is not the sum of subjects in the individual period dose groups.

e. M-SD group.

Note: TEAEs are defined as events with an onset date on or after the first dose date of adalimumab and up to 70 days after the last date of adalimumab in this study. For subjects randomized to placebo at Week 8 without disease flare, AEs with an onset date on or after the first dose date of placebo are excluded. For subjects randomized to placebo at Week 8 and were re-randomized due to disease flare, AEs with an onset date within the first dose date of placebo and last dose date of placebo are excluded. Subjects are counted once in each row, regardless of the number of events they may have had.

Cross reference: M11-290 Japan Sub-study CSR Interim Table 14.3 1.1.1.1 A, Table 14.3 1.1.1.1 J, Table 14.3 1.1.1.2 A, Table 14.3 1.1.1.2 J, Table 14.3 1.1.1.4 A, Table 14.3 1.1.1.5 A, Table 14.3 1.1.1.5 J

M11-290 試験の最終解析（探索的解析）の統合安全性解析対象集団で発現した AESI の概要を付録 表 2.7.4.7-182 に，統合安全性解析対象集団で発現した有害事象（AESI を含む）の 100 人年あたりの発現頻度の概要を付録 表 2.7.4.7-183（導入療法期）及び付録 表 2.7.4.7-184（維持療法期）に，日本人安全性解析対象集団で発現した有害事象（AESI を含む）の 100 人年あたりの発現頻度の概要を付録 表 2.7.4.7-185（導入療法期）及び付録 表 2.7.4.7-186（維持療法期）に示した。

中間解析から日本人最後の 8 例目被験者を含めた最終解析までの間に，新たな AESI は認められなかった。

M10-870 試験（長期投与試験）

M10-870 試験の主試験 FAS 集団で発現した AESI の概要を表 2.7.4.2-19 に示した。また，M10-870 試験の主試験 FAS 集団で発現した有害事象（AESI を含む）の 100 人年あたりの発現頻度の概要を付録 表 2.7.4.7-92 に示した。

主試験 FAS 集団（55 例）では，AESI のカテゴリーのうち，すべての感染症が 20 例（36.4%），重篤な感染症が 1 例（1.8%），潜在性結核が 4 例（7.3%），血管浮腫 / アナフィラキシーを含むアレルギー反応が 2 例（3.6%），乾癬の悪化又は新規発症が 2 例（3.6%），汎血球減少症を含む血液障害が 4 例（7.3%）に発現した。M10-870 試験の主試験 FAS 集団では，上記以外の AESI は発現しなかった。

表 2.7.4.2-19.　AESI の概要（主試験 FAS 集団，M10-870 試験）

Subjects With Treatment-Emergent	Adalimumab (N = 55) n (%)
Infections	20 (36.4)
Serious infections	1 (1.8)
Latent tuberculosis	4 (7.3)
Allergic reactions including angioedema/anaphylaxis	2 (3.6)
Worsening or new onset of psoriasis	2 (3.6)
Hematologic disorders including pancytopenia	4 (7.3)

Cross reference: M10-870 Main-study CSR Interim Table 14.3 1.1.1

M10-870 試験の統合 FAS 集団で発現した AESI の概要を表 2.7.4.2-20 に示した。また，M10-870 試験の統合 FAS 集団で発現した有害事象（AESI を含む）の 100 人年あたりの発現頻度の概要を付録 表 2.7.4.7-40 に示した。

統合 FAS 集団（59 例）では，AESI のカテゴリーのうち，すべての感染症が 24 例（40.7%），重篤な感染症が 2 例（3.4%），潜在性結核が 4 例（6.8%），血管浮腫 / アナフィラキシーを含むアレルギー反応が 3 例（5.1%），乾癬の悪化又は新規発症が 2 例（3.4%），汎血球減少症を含む血液障害が 4 例（6.8%）に発現した。M10-870 試験の統合 FAS 集団では，上記以外の AESI は発現しなかった。

表 2.7.4.2-20.　　AESI の概要（統合 FAS 集団，M10-870 試験）

Subjects With Treatment-Emergent	Adalimumab (N = 59) n (%)
Infections	24 (40.7)
Serious infections	2 (3.4)
Latent tuberculosis	4 (6.8)
Allergic reactions including angioedema/anaphylaxis	3 (5.1)
Worsening or new onset of psoriasis	2 (3.4)
Hematologic disorders including pancytopenia	4 (6.8)

Cross reference: M10-870 Japan Sub-study CSR_Interim Table 14.3　1.1.1_A

2.7.4.2.1.5.2　　小児 すべての感染症

M11-290 試験

主試験安全性解析対象集団で導入療法期中に発現したすべての感染症を付録 表 2.7.4.7-93 に示した。また，主試験安全性解析対象集団で維持療法期中に発現したすべての感染症を付録 表 2.7.4.7-94 に示した。

導入療法期中に，主試験安全性解析対象集団の被験者 93 例中 20 例（21.5%）に感染症が発現した。発現した感染症はいずれも非重篤であった。3%以上の被験者に発現した感染症は，上咽頭炎（5 例，5.4%），咽頭炎（4 例，4.3%）及び口腔ヘルペス（3 例，3.2%）であった。感染症の発現割合は I-SD 群（30 例中 6 例，20.0%）と I-HD 群（47 例中 8 例，17.0%）で同程度であった。

導入療法期中，主試験安全性解析対象集団での感染症の 100 人年あたりの発現頻度は，I-SD 群（159.1 件/100 人年）と I-HD 群（140.8 件/100 人年）で同程度であった。I-HD-OL 群での感染症の発現割合（37.5%）及び 100 人年あたりの発現頻度（304.3 件/100 人年）は，I-HD 群よりも高かった（付録 表 2.7.4.7-90）。

維持療法期中にアダリムマブの投与を受けた主試験安全性解析対象集団の被験者 63 例中 23 例（36.5%）に感染症が発現した。5%超の被験者に発現した感染症は，上咽頭炎（7 例，

11.1%），上気道感染（5 例，7.9%）及び咽頭炎（4 例，6.3%）であった。感染症の発現割合は M-SD 群（31 例中 10 例，32.3%）と M-HD 群（32 例中 13 例，40.6%）で同程度であった。

維持療法期中にアダリムマブの投与を受けた主試験安全性解析対象集団の被験者で，感染症の 100 人年あたりの発現頻度は，M-SD 群（84.2 件/100 人年）と M-HD 群（89.6 件/100 人年）で同程度であった（付録 表 2.7.4.7-91）。

感染症の大部分は重症度が軽度で，自然治癒性又は容易に管理可能であり，速やかに消失した。試験期間全体で 3 件の感染症が治験薬と関連ありと判断され，うち 2 件（重篤な無菌性髄膜炎及び非重篤なサイトメガロウイルス性腸炎）は重症度が高度であった。いずれも投与中断を要したが，無菌性髄膜炎は発現後 7 日目に，サイトメガロウイルス性腸炎は発現後 25 日目に消失し，治験薬投与を再開した。

統合安全性解析対象集団及び日本人安全性解析対象集団で導入療法期中に発現したすべての感染症を付録 表 2.7.4.7-41 及び付録 表 2.7.4.7-42 に示した。統合安全性解析対象集団及び日本人安全性解析対象集団で維持療法期中に発現したすべての感染症を付録 表 2.7.4.7-43 及び付録 表 2.7.4.7-44 に示した。また，M11-290 試験で発現したすべての感染症の一覧を付録 表 2.7.4.7-45 に示した。

導入療法期中に，統合安全性解析対象集団の被験者 100 例中 23 例（23.0%）に感染症が発現し，うち 3 例は日本の被験者であった。発現した感染症はいずれも非重篤であった。3%以上の被験者に発現した感染症は，上咽頭炎（5 例，5.0%），咽頭炎（4 例，4.0%）並びに口腔ヘルペス及び上気道感染（各 3 例，3.0%）であった。感染症の発現割合は I-SD 群（32 例中 6 例，18.8%）と I-HD 群（51 例中 11 例，21.6%）で同程度であった。日本人安全性解析対象集団で発現した感染症は，上気道感染が 2 例，外耳炎が 1 例であった。

導入療法期中，統合安全性解析対象集団での感染症の 100 人年あたりの発現頻度は，I-SD 群（152.2 件/100 人年）と I-HD 群（168.8 件/100 人年）で同程度であった。I-HD-OL 群での感染症の発現割合（35.3%）及び 100 人年あたりの発現頻度（280.0 件/100 人年）は，I-HD 群よりも高かった（付録 表 2.7.4.7-36）。

維持療法期中にアダリムマブの投与を受けた統合安全性解析対象集団の被験者 68 例中 27 例（39.7%）に感染症が発現し，うち 4 例は日本の被験者であった。5%超の被験者に発現した感染症は，上咽頭炎（7 例，10.3%），上気道感染（6 例，8.8%）及び咽頭炎（4 例，5.9%）であった。感染症の発現割合は M-SD 群（33 例中 11 例，33.3%）と M-HD 群（35 例中 16 例，45.7%）で同程度であった。日本人安全性解析対象集団で発現した感染症は，感染性腸炎，膿痂疹，インフルエンザ及び上気道感染が各 1 例であった。

維持療法期中にアダリムマブの投与を受けた統合安全性解析対象集団の被験者で，感染症の 100 人年あたりの発現頻度は，M-SD 群（87.8 件/100 人年）と M-HD 群（94.8 件/100 人年）で同程度であった（付録 表 2.7.4.7-37）。

試験期間全体で，アダリムマブの投与を受けた被験者 100 例中 49 例（49.0%）に感染症が発現した（表 2.7.4.2-18）。感染症の大部分は重症度が軽度で，自然治癒性又は容易に管理可能であり，速やかに消失した。4 件の感染症が治験薬と関連ありと判断され，うち 2 件（重篤な無菌性髄膜炎及び非重篤なサイトメガロウイルス性腸炎）は重症度が高度であった。いずれも投与中断を要したが，無菌性髄膜炎は発現後 7 日目に，サイトメガロウイルス性腸炎は発現後 25 日目に消失し，治験薬投与を再開した。

最終解析（探索的解析）の統合安全性解析対象集団及び日本人安全性解析対象集団で導入療法期中に発現したすべての感染症を付録 表 2.7.4.7-187 及び付録 表 2.7.4.7-188 に示した。また，最終解析の統合安全性解析対象集団及び日本人安全性解析対象集団で維持療法期中に発現したすべての感染症を付録 表 2.7.4.7-189 及び付録 表 2.7.4.7-190 に示した。

中間解析から日本人最後の 8 例目被験者を含めた最終解析までの間に，新たな感染症は認められなかった。

M10-870 試験（長期投与試験）

主試験 FAS 集団で発現したすべての感染症を付録 表 2.7.4.7-95 に示した。

感染症は主試験 FAS 集団の被験者 55 例中 20 例（36.4%）に発現した。複数の被験者に発現した感染症は，上気道感染（6 例，10.9%），気管支炎及び上咽頭炎（各 3 例，5.5%）並びにウイルス性胃腸炎，咽頭炎，尿路感染，ウイルス感染及びウイルス性上気道感染（各 2 例，3.6%）であり，他の感染症はいずれも 1 例のみの発現であった。感染症の大部分は非重篤，重症度は軽度又は中等度であり，治験薬と関連なしと判断された。治験薬の投与中断を要した 1 例（上気道感染）を除き，いずれの感染症も治験薬投与を変更することなく管理可能であり，治験薬投与の中止に至った感染症は発現しなかった。

統合 FAS 集団で発現したすべての感染症を付録 表 2.7.4.7-46 に示した。また，M10-870 試験で発現したすべての感染症の一覧を付録 表 2.7.4.7-47 に示した。

感染症は統合 FAS 集団の被験者 59 例中 24 例（40.7%）に発現した。複数の被験者に発現した感染症は，上気道感染（7 例，11.9%），上咽頭炎（5 例，8.5%），咽頭炎（4 例，6.8%），気管支炎（3 例，5.1%）並びにウイルス性胃腸炎，帯状疱疹，尿路感染，ウイルス感染及びウイルス性上気道感染（各 2 例，3.4%）であり，他の感染症はいずれも 1 例のみの発現であった。感染症の大部分は非重篤，重症度は軽度又は中等度であり，治験薬と関連なしと判断された。治験薬の投与中断を要した 1 例（上気道感染）を除き，いずれの感染症も治験薬投与を変更することなく管理可能であり，治験薬投与の中止に至った感染症は発現しなかった。上気道感染及び膿痂疹の各 1 例（1.7%）は，カットオフ時点で事象が持続していた。

日本の被験者では，感染症は 4 例すべてに発現した。発現した感染症は，上咽頭炎及び咽頭炎が各 2 例，帯状疱疹，膿痂疹，敗血症，レンサ球菌感染及び上気道感染が各 1 例であった。

2.7.4.2.1.5.3 小児 重篤な感染症

M11-290 試験

統合安全性解析対象集団で維持療法期中に発現した重篤な感染症を付録 表 2.7.4.7-48 に示した。また，M11-290 試験で発現した重篤な感染症の一覧を付録 表 2.7.4.7-49 に示した。なお，導入療法期中に重篤な感染症は発現しなかった。

維持療法期中にアダリムマブの投与を受けた統合安全性解析対象集団の被験者 68 例中 6 例（8.8%）に重篤な感染症が発現し，うち 5 例は日本以外の被験者（胃腸炎が 2 例，尿路感染，咽頭炎，無菌性髄膜炎が各 1 例），1 例は日本の被験者（感染性腸炎）であった。複数の被験者に発現した重篤な感染症は胃腸炎（2 例，2.9%）のみであった。1 件の重篤な感染症（無菌性髄膜炎）が治験薬と関連ありと判断された。重篤な感染症の発現割合は，M-SD 群（33 例中 3 例，9.1%）と M-HD 群（35 例中 3 例，8.6%）で同程度であった。また，重篤な感染症の 100 人年あたりの発現頻度も M-SD 群（14.6 件/100 人年）と M-HD 群（12.9 件/100 人年）で同程度であった（付録 表 2.7.4.7-37）。

最終解析（探索的解析）の統合安全性解析対象集団で維持療法期中に発現した重篤な感染症を付録 表 2.7.4.7-191 に示した。なお，導入療法期中に重篤な感染症は発現しなかった。

中間解析から日本人最後の 8 例目被験者を含めた最終解析までの間に，新たな重篤な感染症は認められなかった。

M10-870 試験（長期投与試験）

M10-870 試験で発現した重篤な感染症の一覧を付録 表 2.7.4.7-50 に示した。

重篤な感染症が統合 FAS 集団の被験者 59 例中 2 例（3.4%）に発現し，内訳は日本以外の被験者 1 例に発現した気管支炎及び日本の被験者 1 例に発現した敗血症であった。気管支炎の重症度は中等度であり，治験薬と関連なしと判断された。治験薬投与は変更せず，併用薬の投与を開始し，発現後 11 日目に消失した。また，敗血症の重症度は中等度であり，治験薬と関連なしと判断された。治験薬投与は変更せず，併用薬の投与を開始し発現後 17 日目に消失した。

2.7.4.2.1.5.4 小児 口腔カンジダ症及び結核を除く日和見感染症

M11-290 試験

M11-290 試験で発現した口腔カンジダ症及び結核を除く日和見感染症の一覧を付録 表 2.7.4.7-51 に示した。

統合安全性解析対象集団で，導入療法期中及び維持療法期中に口腔カンジダ症及び結核を除く日和見感染症は発現しなかった。

1 回目の疾患再燃後にアダリムマブに再無作為化された日本以外の被験者 1 例で，アダリムマブの再導入から 92 日後に日和見感染症（サイトメガロウイルス性腸炎）が発現した。当該被験

者は，導入療法期中及び維持療法期中にアダリムマブの投与を受けていた（I-HD-OL 群及び M-SD 群）。本事象の重症度は高度であり，治験薬と関連ありと判断された。治験薬投与の中断に至ったが，発現後 25 日目に消失し，その後投与を再開した。

なお，中間解析から日本人最後の 8 例目被験者を含めた最終解析までの間に，新たな口腔カンジダ症及び結核を除く日和見感染症は認められなかった。

M10-870 試験（長期投与試験）

M10-870 試験では，口腔カンジダ症及び結核を除く日和見感染症は発現しなかった。

2.7.4.2.1.5.5 小児 潜在性結核

M11-290 試験

M11-290 試験で発現した潜在性結核の一覧を付録 表 2.7.4.7-52 に示した。

統合安全性解析対象集団で，導入療法期中に潜在性結核は発現しなかった。維持療法期中にアダリムマブの投与を受けた日本以外の被験者 1 例で結核検査陽性が認められた。本事象（結核菌群検査陽性）の重症度は軽度であり，治験薬と関連なしと判断された。当該被験者のスクリーニング及び追跡調査中の胸部 X 線所見は正常であり，後に結核の化学的予防を開始した。

なお，中間解析から日本人最後の 8 例目被験者を含めた最終解析までの間に，新たな潜在性結核は認められなかった。

M10-870 試験（長期投与試験）

M10-870 試験で発現した潜在性結核の一覧を付録 表 2.7.4.7-53 に示した。

非重篤な潜在性結核が統合 FAS 集団の被験者 59 例中 4 例（6.8%）に発現した。いずれも日本以外の被験者で，重症度は軽度であり，1 例を除き，治験薬と関連なしと判断された。M11-290 試験登録前のクォンティフェロン検査は 3 例が陰性であり，1 例が判定不能であった。M11-290 試験登録前に陰性であった 2 例及び判定不能であった 1 例は，M10-870 試験登録時の結核検査が陽性であった。いずれも治験薬投与を変更せず，イソニアジドによる化学的予防を完了した。M11-290 試験登録前に陰性であった別の 1 例は，M10-870 試験中に陽性となった。本被験者は化学的予防を開始する前に追跡不能となった。

2.7.4.2.1.5.6 小児 血管浮腫 / アナフィラキシーを含むアレルギー反応

M11-290 試験

M11-290 試験で発現した血管浮腫 / アナフィラキシーを含むアレルギー反応の一覧を付録 表 2.7.4.7-54 に示した。

導入療法期中に，統合安全性解析対象集団の被験者 100 例中 1 例（1.0%）に注射部位蕁麻疹が発現した。また，維持療法期中にアダリムマブの投与を受けた被験者 68 例中 3 例（4.4%）にアレルギー反応（注射部位蕁麻疹，薬物過敏症，喘息・発疹）が発現した。3 例はいずれもアレルギー反応の病歴を有していた。いずれの事象も日本以外の被験者で発現し，重症度は軽度，非重篤であった。2 件の注射部位蕁麻疹は治験薬と関連ありと判断された。治験薬投与の中断又は中止を要したアレルギー反応は発現しなかった。日本人安全性解析対象集団では，血管浮腫 / アナフィラキシーを含むアレルギー反応は発現しなかった。

なお，中間解析から日本人最後の 8 例目被験者を含めた最終解析までの間に，新たな血管浮腫 / アナフィラキシーを含むアレルギー反応は認められなかった。

M10-870 試験（長期投与試験）

M10-870 試験で発現した血管浮腫 / アナフィラキシーを含むアレルギー反応の一覧を付録 表 2.7.4.7-55 に示した。

血管浮腫 / アナフィラキシーを含むアレルギー反応は統合 FAS 集団の被験者 59 例中 3 例（5.1%）に発現した。日本以外の被験者 1 例に重篤な喘息が発現し，重症度は軽度，治験薬と関連なしと判断された。治験薬投与は変更されなかった。別の日本以外の被験者 1 例には非重篤な発疹が発現し，重症度は軽度，治験薬と関連なしと判断された。また，日本の被験者 1 例に非重篤な蕁麻疹が 2 件発現し，いずれも重症度は軽度，治験薬と関連なしと判断された。血管浮腫 / アナフィラキシーを含むアレルギー反応はいずれも治験薬投与中に消失した。

2.7.4.2.1.5.7 小児 膵炎

M11-290 試験

M11-290 試験で発現した膵炎の一覧を付録 表 2.7.4.7-56 に示した。

導入療法期中，統合安全性解析対象集団の被験者 100 例中 1 例（1.0%）に重篤な膵炎が発現した。本被験者は日本以外の I-HD 群の被験者であり，UC に続発する急性膵炎の病歴を有していた。投与 8 週時に寛解を達成せず，治験薬投与を中止した後の追跡調査中に重篤な膵炎が発現した。本事象の重症度は中等度であり，治験薬と関連ありと判断され，発現後 15 日目に消失した。

なお，中間解析から日本人最後の 8 例目被験者を含めた最終解析までの間に，新たな膵炎は認められなかった。

M10-870 試験（長期投与試験）

M10-870 試験では，膵炎は発現しなかった。

2.7.4.2.1.5.8 小児 乾癬の悪化又は新規発症

M11-290 試験

M11-290 試験で発現した乾癬の悪化又は新規発症の一覧を付録 表 2.7.4.7-57 に示した。

導入療法期中，統合安全性解析対象集団に乾癬の悪化又は新規発症は発現しなかった。

維持療法期においては，導入療法期中に I-HD 群でアダリムマブの投与を受けた，日本以外の M-PL 群の被験者 1 例で，乾癬の悪化又は新規発症が発現した。本事象は重篤であり，重症度は軽度，治験薬と関連ありと判断された。治験薬投与は変更されず，発現後 20 日目に消失した。

なお，中間解析から日本人最後の 8 例目被験者を含めた最終解析までの間に，新たな乾癬の悪化又は新規発症は認められなかった。

M10-870 試験（長期投与試験）

M10-870 試験で発現した乾癬の悪化又は新規発症の一覧を付録 表 2.7.4.7-58 に示した。

非重篤な乾癬の悪化又は新規発症が統合 FAS 集団の被験者 59 例中 2 例（3.4%）に発現した。いずれも日本以外の被験者であり，1 例には乾癬が発現し，セリアック病の病歴を有する別の 1 例には乾癬様皮膚炎が発現した。いずれの事象も重症度は軽度であり，治験薬と関連ありと判断された。治験薬投与は変更されず，いずれの事象もカットオフ時点で持続していた。

2.7.4.2.1.5.9 小児 汎血球減少症を含む血液障害

M11-290 試験

統合安全性解析対象集団で発現した汎血球減少症を含む血液障害を付録 表 2.7.4.7-59（導入療法期）及び付録 表 2.7.4.7-60（維持療法期）に示した。また，M11-290 試験で発現した汎血球減少症を含む血液障害の一覧を付録 表 2.7.4.7-61 に示した。なお，汎血球減少症を含む血液障害はいずれも日本以外の被験者で発現し，日本人安全性解析対象集団では発現しなかった。

導入療法期中，統合安全性解析対象集団の被験者 100 例中 7 例（7.0%）に，AESI カテゴリーで汎血球減少症を含む血液障害に該当する有害事象が発現した。発現した事象はいずれも貧血であり，発現割合は I-SD 群（32 例中 3 例，9.4%）と I-HD 群（51 例中 3 例，5.9%）で同程度であった。貧血が発現した被験者の大部分は，貧血の病歴を有していた。

維持療法期中にアダリムマブの投与を受けた統合安全性解析対象集団の被験者 68 例中 4 例（5.9%）に，AESI カテゴリーで汎血球減少症を含む血液障害に該当する有害事象が発現した。発現した事象はいずれも貧血であり，アダリムマブの投与中に発現した。汎血球減少症を含む血液障害の発現割合は，M-SD 群（33 例中 3 例，9.1%）の方が M-HD 群（35 例中 1 例，2.9%）よりも高かった。また，導入療法期中に I-SD 群でアダリムマブの投与を受けた M-PL 群の 1 例に好中球減少症が発現し，併用薬であるアザチオプリンの減量後に消失した。

試験期間全体で，重篤な貧血が 4 件発現し，うち 3 件は重症度が高度であった（2 件は同一の 1 例に発現）。重篤な貧血はいずれも治験薬と関連なしと判断された。重症度が高度の貧血 1 件は治験薬投与の中止に至った。試験期間中に重篤な貧血が発現した 3 例中 2 例は，関連する病歴を有していた。これらの他に，重症度が軽度又は中等度の貧血 3 件が治験薬と関連ありと判断された。

最終解析（探索的解析）の統合安全性解析対象集団で発現した汎血球減少症を含む血液障害を付録 表 2.7.4.7-192（導入療法期）及び付録 表 2.7.4.7-193（維持療法期）に示した。なお，汎血球減少症を含む血液障害はいずれも日本以外の被験者で発現し，日本人安全性解析対象集団では発現しなかった。

中間解析から日本人最後の 8 例目被験者を含めた最終解析までの間に，新たな汎血球減少症を含む血液障害は認められなかった。

M10-870 試験（長期投与試験）

M10-870 試験で発現した汎血球減少症を含む血液障害の一覧を付録 表 2.7.4.7-62 に示した。

AESI カテゴリーで汎血球減少症を含む血液障害に該当する有害事象として，統合 FAS 集団の被験者 59 例中 4 例（6.8%）に貧血が発現した。いずれも日本以外の被験者であり，うち 3 例は貧血の病歴を有していた。重篤な貧血は 2 例（3.4%）に発現し，重症度はそれぞれ中等度及び高度であり，いずれも治験薬と関連なしと判断された。貧血はいずれも，治験薬投与の中止には至らなかった。

2.7.4.2.1.5.10 小児 注射部位反応

M11-290 試験

導入療法期中に発現した注射部位反応を付録 表 2.7.4.7-63（統合安全性解析対象集団）及び付録 表 2.7.4.7-64（日本人安全性解析対象集団）に示した。統合安全性解析対象集団で維持療法期中に発現した注射部位反応を付録 表 2.7.4.7-65 に示した。また，M11-290 試験で発現した注射部位反応の一覧を付録 表 2.7.4.7-66 に示した。

導入療法期中，統合安全性解析対象集団の被験者 100 例中 4 例（4.0%）に非重篤な注射部位反応が発現し，内訳は，日本以外の被験者で注射部位疼痛及び注射部位蕁麻疹が各 1 例，日本の被験者で注射部位疼痛及び注射部位紅斑が各 1 例であった。I-HD-OL 群では注射部位反応は発現しなかった。日本の被験者で発現した注射部位疼痛は治験薬投与の中止に至った。

維持療法期中にアダリムマブの投与を受けた統合安全性解析対象集団の被験者 68 例中 6 例（8.8%）に注射部位反応が発現した。注射部位反応の発現割合は，M-SD 群（33 例中 4 例，12.1%）の方が M-HD 群（35 例中 2 例，5.7%）よりも高かった。維持療法期中の注射部位反応はいずれも日本以外の被験者に発現し，日本人安全性解析対象集団では発現しなかった。

試験期間全体で，アダリムマブの投与を受けた被験者 100 例中 10 例（10.0%）に注射部位反応が発現した（表 2.7.4.2-18）。注射部位反応はいずれも重症度が軽度又は中等度であり，非重篤であった。また，1 件を除くすべての注射部位反応が治験薬と関連ありと判断された。

最終解析（探索的解析）の導入療法期中に発現した注射部位反応を付録 表 2.7.4.7-194（統合安全性解析対象集団）及び付録 表 2.7.4.7-195（日本人安全性解析対象集団）に示した。また，最終解析の統合安全性解析対象集団で維持療法期中に発現した注射部位反応を付録 表 2.7.4.7-196 に示した。

中間解析から日本人最後の 8 例目被験者を含めた最終解析までの間に，新たな注射部位反応は認められなかった。

M10-870 試験（長期投与試験）

M10-870 試験では，注射部位反応は発現しなかった。

2.7.4.2.2 小児 個別有害事象の文章による説明

M11-290 試験及び M10-870 試験の重篤な有害事象の文章による説明を作成し，2.7.6 項に記載した。

2.7.4.3 小児 臨床検査値の評価

2.7.4.3.1 小児 試験期間を通しての臨床検査値

2.7.4.3.1.1 小児 血液学的検査，血液生化学検査及び尿検査

M11-290 試験

導入療法期における血液学的検査，血液生化学検査及び尿検査値の推移を M11-290 Main-study CSR_Interim Table 14.3__4.1.1.1（主試験安全性解析対象集団），M11-290 Japan Sub-study CSR_Interim Table 14.3__4.1.1.1_A（統合安全性解析対象集団）及び Table 14.3__4.1.1.1_J（日本人安全性解析対象集団）に，維持療法期における血液学的検査，血液生化学検査及び尿検査値の推移を M11-290 Main-study CSR_Interim Table 14.3__4.1.1.2（主試験安全性解析対象集団），M11-290 Japan Sub-study CSR_Interim Table 14.3__4.1.1.2_A（統合安全性解析対象集団）及び Table 14.3__4.1.1.2_J（日本人安全性解析対象集団）に示した。

導入療法期中及び維持療法期中のいずれについても，アダリムマブの投与を受けた主試験安全性解析対象集団，統合安全性解析対象集団及び日本人安全性解析対象集団の被験者において，血液学的検査，血液生化学検査及び尿検査の平均値の変化は臨床的に重要ではないと判断された。

最終解析（探索的解析）の導入療法期における血液学的検査，血液生化学検査及び尿検査値の推移を M11-290 CSR_Final Table 14.3__4.1.1.1_A（統合安全性解析対象集団）及び Table 14.3__4.1.1.1_J（日本人安全性解析対象集団）に，維持療法期における血液学的検査，血液生化学検査及び尿検査値の推移を M11-290 CSR_Final Table 14.3__4.1.1.2_A（統合安全性解析対象集団）及び Table 14.3__4.1.1.2_J（日本人安全性解析対象集団）に示した。

日本人最後の 8 例目被験者を含めた最終解析では中間解析と同様に，導入療法期中及び維持療法期中のいずれについても，アダリムマブの投与を受けた統合安全性解析対象集団及び日本人安全性解析対象集団の被験者において，血液学的検査，血液生化学検査及び尿検査の平均値の変化は臨床的に重要ではないと判断された。

M10-870 試験（長期投与試験）

血液学的検査，血液生化学検査及び尿検査値の推移を M10-870 Main-study CSR_Interim Table 14.3__4.1.1（主試験 FAS 集団）及び M10-870 Japan Sub-study CSR_Interim Table 14.3__4.1.1_A（統合 FAS 集団）に示した。

主試験 FAS 集団及び統合 FAS 集団の被験者において，試験期間中の血液学的検査，血液生化学検査及び尿検査の平均値の変化は臨床的に重要ではないと判断された。

2.7.4.3.2 小児 個々の被験者の変化

2.7.4.3.2.1 小児 血液学的検査，血液生化学検査及び尿検査

M11-290 試験

血液学的検査及び血液生化学検査値に関して，ベースラインが正常値若しくは異常高値であった検査値が最終測定時に異常低値に変動した被験者の割合，及びベースラインが異常低値若しくは正常値であった検査値が最終測定時に異常高値に変動した被験者の割合を，導入療法期について M11-290 Main-study CSR_Interim Table 14.3__4.2.2.1（主試験安全性解析対象集団），M11-290 Japan Sub-study CSR_Interim Table 14.3__4.2.2.1_A（統合安全性解析対象集団）及び Table 14.3__4.2.2.1_J（日本人安全性解析対象集団）に，維持療法期について M11-290 Main-study CSR_Interim Table 14.3__4.2.2.2（主試験安全性解析対象集団），M11-290 Japan Sub-study CSR_Interim Table 14.3__4.2.2.2_A（統合安全性解析対象集団）及び Table 14.3__4.2.2.2_J（日本人安全性解析対象集団）に示した。また，血液学的検査及び血液生化学検査値に関して，ベースラインから最悪の CTC グレードへのシフトテーブルを，導入療法期について M11-290 Main-study CSR_Interim Table 14.3__4.2.3.1（主試験安全性解析対象集団），M11-290 Japan Sub-study CSR_Interim Table 14.3__4.2.3.1_A（統合安全性解析対象集団）及び Table 14.3__4.2.3.1_J（日本人安全性解析対象集団）に，維持療法期について M11-290 Main-study CSR_Interim Table 14.3__4.2.3.2（主試験安全性解析対象集団），M11-290 Japan Sub-study

CSR_Interim Table 14.3__4.2.3.2_A（統合安全性解析対象集団）及び Table 14.3__4.2.3.2_J（日本人安全性解析対象集団）に示した。

アダリムマブの投与を受けた主試験安全性解析対象集団，統合安全性解析対象集団及び日本人安全性解析対象集団の被験者で，血液学的検査及び血液生化学検査値に関して，ベースラインが正常値若しくは異常高値であった検査値が最終測定時に異常低値に変動した被験者，及びベースラインが異常低値若しくは正常値であった検査値が最終測定時に異常高値に変動した被験者は全般的に少数であり，臨床的に重要ではないと判断された。

また，主試験安全性解析対象集団，統合安全性解析対象集団及び日本人安全性解析対象集団の被験者で，血液学的検査及び血液生化学検査値の CTC グレードがベースラインから悪化した被験者は少数であった。

最終解析（探索的解析）の血液学的検査及び血液生化学検査値に関して，ベースラインが正常値若しくは異常高値であった検査値が最終測定時に異常低値に変動した被験者の割合，及びベースラインが異常低値若しくは正常値であった検査値が最終測定時に異常高値に変動した被験者の割合を，導入療法期について M11-290 CSR_Final Table 14.3__4.2.2.1_A（統合安全性解析対象集団）及び Table 14.3__4.2.2.1_J（日本人安全性解析対象集団）に，維持療法期について M11-290 CSR_Final Table 14.3__4.2.2.2_A（統合安全性解析対象集団）及び Table 14.3__4.2.2.2_J（日本人安全性解析対象集団）に示した。また，最終解析の血液学的検査及び血液生化学検査値に関して，ベースラインから最悪の CTC グレードへのシフトテーブルを，導入療法期について M11-290 CSR_Final Table 14.3__4.2.3.1_A（統合安全性解析対象集団）及び Table 14.3__4.2.3.1_J（日本人安全性解析対象集団）に，維持療法期について M11-290 CSR_Final Table 14.3__4.2.3.2_A（統合安全性解析対象集団）及び Table 14.3__4.2.3.2_J（日本人安全性解析対象集団）に示した。

日本人最後の 8 例目被験者を含めた最終解析では中間解析と同様に，アダリムマブの投与を受けた統合安全性解析対象集団及び日本人安全性解析対象集団の被験者で，血液学的検査及び血液生化学検査値に関して，ベースラインが正常値若しくは異常高値であった検査値が最終測定時に異常低値に変動した被験者，及びベースラインが異常低値若しくは正常値であった検査値が最終測定時に異常高値に変動した被験者は全般的に少数であり，臨床的に重要ではないと判断された。

また，統合安全性解析対象集団及び日本人安全性解析対象集団の被験者で，血液学的検査及び血液生化学検査値の CTC グレードがベースラインから悪化した被験者は少数であった。

M10-870 試験（長期投与試験）

血液学的検査，血液生化学検査及び尿検査値に関して，ベースラインが正常値若しくは異常高値であった検査値が最終測定時に異常低値に変動した被験者，及びベースラインが異常低値若しくは正常値であった検査値が最終測定時に異常高値に変動した被験者の割合を M10-870

Main-study CSR_Interim Table 14.3__4.2.2（主試験 FAS 集団）及び M10-870 Japan Sub-study CSR_Interim Table 14.3__4.2.2_A（統合 FAS 集団）に示した。また，血液学的検査及び血液生化学検査値に関して，ベースラインから最悪の CTC グレードへのシフトテーブルを M10-870 Main-study CSR_Interim Table 14.3__4.2.3（主試験 FAS 集団）及び M10-870 Japan Sub-study CSR_Interim Table 14.3__4.2.3_A（統合 FAS 集団）に示した。

主試験 FAS 集団及び統合 FAS 集団の被験者で，血液学的検査，血液生化学検査及び尿検査値に関して，ベースラインが正常値若しくは異常高値であった検査値が最終測定時に異常低値に変動した被験者，及びベースラインが異常低値若しくは正常値であった検査値が最終測定時に異常高値に変動した被験者は全般的に少数であり，臨床的に重要ではないと判断された。

また，主試験 FAS 集団及び統合 FAS 集団の被験者で，血液学的検査及び血液生化学検査値の CTC グレードがベースラインから悪化した被験者は全般的に少数であった。

2.7.4.3.3 小児 個々の臨床的に重要な異常

2.7.4.3.3.1 小児 血液学的検査，血液生化学検査及び尿検査

M11-290 試験

アダリムマブへの曝露期間全体で認められた CTC グレード 3 以上の血液学的検査異常を M11-290 Main-study CSR_Interim Table 14.3__4.3.1.1.3（主試験安全性解析対象集団），M11-290 Japan Sub-study CSR_Interim Table 14.3__4.3.1.1.3_A（統合安全性解析対象集団）及び Table 14.3__4.3.1.1.3_J（日本人安全性解析対象集団）に示した。また，アダリムマブへの曝露期間全体で認められた臨床的に意味のある肝機能検査値の一覧を M11-290 Japan Sub-study CSR_Interim Table 14.3__4.3.2.2.3_A に示した。なお，アダリムマブへの曝露期間全体で CTC グレード 3 以上の血液生化学検査異常は認められなかった。

アダリムマブへの曝露期間全体を通して，ベースラインの CTC グレードが 3 未満であり，ベースライン後に臨床的に重要と考えられる（CTC グレード 3 以上）血液学的検査値が認められた被験者は少数であり，ヘモグロビン減少が 96 例中 9 例（9.4%），好中球数減少が 99 例中 5 例（5.1%），リンパ球数減少が 98 例中 1 例（1.0%）で認められた。このうち，好中球数減少の 1 例は日本の被験者であり，それ以外は日本以外の被験者であった。

アダリムマブへの曝露期間全体を通して，Hy's law の基準（ALT 又は AST が ULN の 3 倍超，かつ総ビリルビンが ULN の 2 倍超及び症候性）に該当した被験者は認められず，試験期間中に重要な薬剤誘発性の肝障害は発現しなかった。

最終解析（探索的解析）のアダリムマブへの曝露期間全体で認められた CTC グレード 3 以上の血液学的検査異常を M11-290 CSR_Final Table 14.3__4.3.1.1.3_A（統合安全性解析対象集団）及び Table 14.3__4.3.1.1.3_J（日本人安全性解析対象集団）に示した。また，最終解析のアダリムマブへの曝露期間全体で認められた臨床的に意味のある肝機能検査値の一覧を M11-290 CSR_Final

Table 14.3__4.3.2.2.3_A に示した。なお，アダリムマブへの曝露期間全体で CTC グレード 3 以上の血液生化学検査異常は認められなかった。

中間解析から日本人最後の 8 例目被験者を含めた最終解析までの間に，新たな CTC グレード 3 以上の血液学的検査異常は認められなかった。また，Hy's law の基準に該当した被験者は認められず，重要な薬剤誘発性の肝障害は発現しなかった。

M10-870 試験（長期投与試験）

CTC グレード 3 以上の血液学的検査異常を M10-870 Main-study CSR_Interim Table 14.3__4.3.1.1（主試験 FAS 集団）及び M10-870 Japan Sub-study CSR_Interim Table 14.3__4.3.1.1_A（統合 FAS 集団）に，CTC グレード 3 以上の血液生化学検査異常を M10-870 Main-study CSR_Interim Table 14.3__4.3.1.2（主試験 FAS 集団）及び M10-870 Japan Sub-study CSR_Interim Table 14.3__4.3.1.2_A（統合 FAS 集団）に示した。また，臨床的に意味のある肝機能検査値の一覧を M10-870 Japan Sub-study CSR_Interim Table 14.3__4.3.2.2_A に示した。

臨床的に重要と考えられる（CTC グレード 3 以上）血液学的検査及び血液生化学検査値が認められた被験者は少数（5 例以下）であった。重篤な有害事象として報告された臨床検査異常が日本以外の被験者 2 例に認められた（いずれも貧血，2.7.4.2.1.3 項参照）。治験薬投与の中止に至った臨床検査異常は認められなかった。

臨床的に意味のある肝機能検査値は日本以外の被験者 6 例に認められた。Hy's law の基準に該当した被験者は認められなかった。

2.7.4.4 小児 バイタルサイン，身体的所見及び安全性に関連する他の観察項目

M11-290 試験

アダリムマブへの曝露期間全体でのバイタルサインの推移を M11-290 Main-study CSR_Interim Table 14.3__5.1.1.3（主試験安全性解析対象集団），M11-290 Japan Sub-study CSR_Interim Table 14.3__5.1.1.3_A（統合安全性解析対象集団）及び Table 14.3__5.1.1.3_J（日本人安全性解析対象集団）に示した。また，アダリムマブへの曝露期間全体で認められた臨床的に重要と考えられるバイタルサイン値を M11-290 Main-study CSR_Interim Table 14.3__5.2.3（主試験安全性解析対象集団），M11-290 Japan Sub-study CSR_Interim Table 14.3__5.2.3_A（統合安全性解析対象集団）及び Table 14.3__5.2.3_J（日本人安全性解析対象集団）に示した。

ベースラインから投与 52 週時までのアダリムマブへの曝露期間全体を通して，バイタルサインの平均値に，臨床的に重要な変化は認められなかった。また，アダリムマブへの曝露期間全体を通して，臨床的に重要と考えられるバイタルサイン値が認められた被験者は少数であった。

最終解析（探索的解析）のアダリムマブへの曝露期間全体でのバイタルサインの推移を M11-290 CSR_Final Table 14.3__5.1.1.3_A（統合安全性解析対象集団）及び Table 14.3__5.1.1.3_J

（日本人安全性解析対象集団）に示した。また，アダリムマブへの曝露期間全体で認められた臨床的に重要と考えられるバイタルサイン値を M11-290 CSR_Final Table 14.3__5.2.3_A（統合安全性解析対象集団）及び Table 14.3__5.2.3_J（日本人安全性解析対象集団）に示した。

日本人最後の 8 例目被験者を含めた最終解析では中間解析と同様に，ベースラインから投与 52 週時までのアダリムマブへの曝露期間全体を通して，バイタルサインの平均値に，臨床的に重要な変化は認められなかった。また，アダリムマブへの曝露期間全体を通して，臨床的に重要と考えられるバイタルサイン値が認められた被験者は少数であった。

M10-870 試験（長期投与試験）

バイタルサインの推移を M10-870 Main-study CSR_Interim Table 14.3__5.1.1（主試験 FAS 集団）及び M10-870 Japan Sub-study CSR_Interim Table 14.3__5.1.1_A（統合 FAS 集団）に示した。また，臨床的に重要と考えられるバイタルサイン値を M10-870 Main-study CSR_Interim Table 14.3__5.2（主試験 FAS 集団）及び M10-870 Japan Sub-study CSR_Interim Table 14.3__5.2_A（統合 FAS 集団）に示した。

バイタルサインの平均値に，ベースラインからの顕著な変化は認められなかった。また，臨床的に重要と考えられるバイタルサイン値が認められた被験者は少数であった。

2.7.4.5 小児 特別な患者集団及び状況下における安全性

2.7.4.5.1 小児 内因性要因

M11-290 主試験及び M10-870 主試験の有害事象データを併合し，内因性要因別に解析した結果を，付録 表 2.7.4.7-96 から表 2.7.4.7-99（有害事象の概要），付録 表 2.7.4.7-100 から表 2.7.4.7-103（有害事象の 100 人年あたりの発現頻度の概要），付録 表 2.7.4.7-104 から表 2.7.4.7-107（SOC 及び PT 別の有害事象）に示した。

有害事象を性別（男児，女児），年齢区分（13 歳未満，13 歳以上），人種（白人，白人以外）及び体重区分（40 kg 未満，40 kg 以上）別に解析した結果，感染症の発現割合が女児（45.1%）よりも男児（64.3%）で高かった（付録 表 2.7.4.7-96）ことを除き，顕著な差は認められなかった。

M11-290 主試験及び日本サブ試験の有害事象データを併合し，日本人を含む統合集団における内因性要因別に解析した結果を，付録 表 2.7.4.7-108 から表 2.7.4.7-115（有害事象の概要），付録 表 2.7.4.7-116 から表 2.7.4.7-123（有害事象の 100 人年あたりの発現頻度の概要）に示した。

有害事象を性別（男児，女児），年齢区分（13 歳未満，13 歳以上），人種（白人，白人以外）及び体重区分（40 kg 未満，40 kg 以上）別に解析した結果，日本サブ試験での統合集団では，導入療法期において因果関係が関連ありの有害事象及び感染症の発現割合が女児（それぞれ 7.8%及び 17.6%）よりも男児（それぞれ 22.0%及び 28.0%）で高かった（付録 表 2.7.4.7-108 及

び付録 表 2.7.4.7-116）。なお，日本人被験者全 7 例はすべて男児であった。そのほか，年齢区分，人種及び体重区分においてもいくつかの差がみられたものの，母数となる部分集団の例数が大きく違っており顕著な差とは考えられなかった。維持療法期において，顕著な差は認められなかった。

2.7.4.5.2 小児 外因性要因

M11-290 主試験及び M10-870 主試験の有害事象データを併合し，外因性要因別に解析した結果を，付録 表 2.7.4.7-124 から付録 表 2.7.4.7-127（有害事象の概要），付録 表 2.7.4.7-128 から付録 表 2.7.4.7-131（有害事象の 100 人年あたりの発現頻度の概要），付録 表 2.7.4.7-132 から付録 表 2.7.4.7-135（SOC 及び PT 別の有害事象）に示した。

有害事象を抗 TNF 製剤の投与経験の有無，ベースラインにおけるコルチコステロイドの全身投与の有無，ベースラインにおける免疫抑制剤の使用の有無，及び Mayo スコアに基づく疾患重症度別に解析した結果，以下の点を除き，顕著な差は認められなかった。

- 重篤な有害事象，重篤な感染症及び血液障害の発現割合が，抗 TNF 製剤の投与経験なしの被験者（それぞれ 24.4%，3.8%及び 14.1%）よりも投与経験ありの被験者（それぞれ 46.7%，20.0%及び 26.7%）で高かった（付録 表 2.7.4.7-124）。
- 治験薬投与の中止に至った有害事象，重篤な感染症及び潜在性結核の発現割合が，ベースラインにおけるコルチコステロイドの全身投与なしの被験者（それぞれ 4.1%，2.0%及び 2.0%）よりも全身投与ありの被験者（それぞれ 11.4%，11.4%及び 9.1%）で高かった（付録 表 2.7.4.7-125）。
- 血液障害の発現割合が，ベースラインにおける免疫抑制剤の使用なしの被験者（7.9%）よりも使用ありの被験者（21.8%）で高かった（付録 表 2.7.4.7-126）。

M11-290 主試験及び日本サブ試験の有害事象データを併合し，日本人を含む統合集団における外因性要因別に解析した結果を，付録 表 2.7.4.7-136 から付録 表 2.7.4.7-143（有害事象の概要），付録 表 2.7.4.7-144 から付録 表 2.7.4.7-151（有害事象の 100 人年あたりの発現頻度の概要）に示した。

有害事象を抗 TNF 製剤の投与経験の有無，ベースラインにおけるコルチコステロイドの全身投与の有無，ベースラインにおける免疫抑制剤の使用の有無，及び Mayo スコアに基づく疾患重症度別に解析した結果，以下の点を除き，顕著な差は認められなかった。

導入療法期（日本人を含む統合集団）：

- 有害事象，高度の有害事象，治験薬投与の中止に至った有害事象及び注射部位反応の発現割合が，コルチコステロイドの全身投与なしの被験者（それぞれ 51.9%，1.9%，1.9%及び 1.9%）よりも，投与ありの被験者（それぞれ 67.3%，8.2%，6.1%及び 6.1%）で高かった（付録 表 2.7.4.7-137 及び付録 表 2.7.4.7-145）。
- 有害事象，因果関係が関連ありの有害事象，因果関係が関連ありの重篤な有害事象及び感染症の発現割合が，免疫抑制剤の使用ありの被験者（それぞれ 50.8%，7.9%，

1.6%及び 17.5%）よりも使用なしの被験者（それぞれ 73.7%，26.3%，7.9%及び 31.6%）で高かった（付録 表 2.7.4.7-138 及び付録 表 2.7.4.7-146）。

- 有害事象，重篤な有害事象及び注射部位反応の発現割合が，Mayo スコアに基づく疾患重症度 9 を上回る被験者（41.2%，5.9%及び 0%）よりも 9 以下の被験者（63.1%，10.7%及び 4.8%）で高かった（付録 表 2.7.4.7-139 及び付録 表 2.7.4.7-147）。

維持療法期（日本人を含む統合集団）：

- 重篤な有害事象，感染症及び重篤な感染症の発現割合が，抗 TNF 製剤の投与経験なしの被験者（それぞれ 13.1%，36.1%及び 6.6%）よりも，投与経験ありの被験者（それぞれ 25.0%，62.5%及び 25.0%）で高かった（付録 表 2.7.4.7-140 及び付録 表 2.7.4.7-148）。
- 有害事象，重篤な有害事象，感染症及び重篤な感染症の発現割合が，コルチコステロイドの全身投与なしの被験者（それぞれ 62.2%，5.4%，32.4%及び 2.7%）よりも，投与ありの被験者（それぞれ 75.0%，25.0%，46.9%及び 15.6%）で高かった（付録 表 2.7.4.7-141 及び付録 表 2.7.4.7-149）。
- 有害事象，因果関係が関連ありの有害事象及び注射部位反応の発現割合が，免疫抑制剤の使用ありの被験者（それぞれ 65.9%，20.5%及び 4.5%）よりも使用なしの被験者（それぞれ 72.0%，40.0%及び 16.0%）で高かった（付録 表 2.7.4.7-142 及び付録 表 2.7.4.7-150）。
- 有害事象，重篤な有害事象，因果関係が関連ありの有害事象，感染症，重篤な感染症及び注射部位反応の発現割合が，Mayo スコアに基づく疾患重症度 9 を上回る被験者（それぞれ 54.5%，0%，18.2%，27.3%，0%及び 0%）よりも 9 以下の被験者（それぞれ 70.7%，17.2%，29.3%，41.4%，10.3%及び 10.3%）で高かった。また，血液障害の発現割合が，Mayo スコアに基づく疾患重症度 9 以下の被験者（3.4%）よりも 9 を上回る被験者（18.2%）で高かった（付録 表 2.7.4.7-143 及び付録 表 2.7.4.7-151）。

2.7.4.5.3 小児 薬物相互作用

M11-290 試験及び M10-870 試験では，抗 TNF 製剤の投与経験の有無，ベースラインにおけるコルチコステロイドの全身投与の有無，及びベースラインにおける免疫抑制剤の使用の有無別の解析（2.7.4.5.2 項）を除き，薬物相互作用についての評価は行わなかった。

2.7.4.5.4 小児 妊娠及び授乳時の使用

M11-290 試験及び M10-870 試験では，試験期間中の妊娠の報告はなかった。アダリムマブの添付文書では妊婦及び授乳婦へのアダリムマブの投与は推奨しておらず，現時点でこの情報に変更はない。

2.7.4.5.5 小児 過量投与

M11-290 試験及び M10-870 試験では，アダリムマブの過量投与の報告はなかった。アダリムマブの過量投与に関して新たな情報は得られていない。

2.7.4.5.6 小児 薬物乱用

M11-290 試験及び M10-870 試験では，アダリムマブの乱用の報告はなかった。アダリムマブが乱用を引き起こす根拠はなく，アダリムマブの乱用は予想されない。

2.7.4.5.7 小児 離脱症状及び反跳現象

M11-290 試験及び M10-870 試験では，アダリムマブによる離脱症状及び反跳現象に着目した評価は行わなかった。なお，明らかに離脱症状及び反跳現象と思われる事象の報告はなかった。アダリムマブの投与中止後に適切なフォローアップを実施しなかった場合に UC の症状がコントロール不良となる可能性があることを除き，アダリムマブの離脱症状は予想されない。

2.7.4.5.8 小児 自動車運転及び機械操作に対する影響又は精神機能の障害

M11-290 試験及び M10-870 試験では，アダリムマブによる自動車の運転能又は機械操作能への影響に着目した評価は行わなかった。アダリムマブが自動車運転及び機械操作に対する影響又は精神機能の障害を引き起こす根拠はなく，発現は予想されない。

2.7.4.6 市販後データ

アダリムマブは，米国で 2002 年 12 月 31 日（国際誕生日）に関節リウマチの適応で承認され，欧州連合及び本邦では，それぞれ 2003 年及び 2008 年に関節リウマチの適応で承認された。

定期的安全性報告（対象期間：2017 年 1 月 1 日 – 2019 年 12 月 31 日［5.3.6-1 項］）によれば，臨床試験でアダリムマブの投与を受けた推定被験者数は 34,830 例であり，本報告期間での製造販売後の推定曝露量は 2,744,359 人年，国際誕生日から 2019 年 12 月 31 日までの製造販売後の推定累積曝露量は約 783 万人年である。

2017 年 1 月 – 2019 年 12 月を対象期間とした定期的安全性報告の結論では，既承認の効能・効果でのアダリムマブのベネフィット-リスクプロファイルは良好であり，company core labeling（企業中核データシートの添付文書情報）の改訂は推奨されなかった。

2020 年 1 月 – 6 月を対象期間とした定期的安全性最新報告（5.3.6-2 項）では，この情報更新の期間中にアダリムマブのベネフィット-リスク評価に重大な影響を及ぼす新たな安全性の情報はなかった。

UC 小児患者における臨床試験の安全性結果では，成人で承認されている効能・効果でのアダリムマブの市販後安全性情報で知られていない新たな安全性に関わるシグナルは認められなかった。

小児 参考文献

該当なし

2.7.4.7 成人 付録

表 2.7.4.7-1. 特に注目すべき有害事象（AESI）のカテゴリー

- すべての感染症
- 重篤な感染症
- レジオネラ感染
- 憩室炎
- 口腔カンジダ症及び結核を除く日和見感染症
- 口腔カンジダ症
- 結核（活動性結核 / 潜在性結核）
- 活動性結核
- 潜在性結核
- 寄生虫感染
- B 型肝炎再燃
- 進行性多巣性白質脳症
- 悪性腫瘍
- リンパ腫
- 肝脾 T 細胞リンパ腫
- 非黒色腫皮膚癌
- 黒色腫
- 白血病
- その他の悪性腫瘍（非黒色腫皮膚癌，黒色腫，リンパ腫，肝脾 T 細胞リンパ腫，白血病を除く）
- 血管浮腫 / アナフィラキシーを含むアレルギー反応
- ループス様反応及び全身性エリテマトーデス
- 血管炎
- 皮膚血管炎
- 皮膚以外の血管炎
- サルコイドーシス
- 自己免疫性肝炎
- 心筋梗塞に関連する事象
- 脳血管発作に関連する事象
- うっ血性心不全に関連する事象
- 肺塞栓症に関連する事象
- 間質性肺疾患
- 腸管穿孔

- 膵炎
- スティーブンス・ジョンソン症候群
- 多形紅斑に関連する事象
- 乾癬の悪化又は新規発症
- 脱髄疾患
- 筋萎縮性側索硬化症
- 可逆性後白質脳症症候群
- 汎血球減少症を含む血液障害
- 肝不全及びその他の肝臓関連事象（胆嚢関連の事象を除く）
- ヒュミラ投与に関連した投薬過誤
- 注射部位反応

表 2.7.4.7-2. 治験薬の曝露期間（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）

EXPOSURE TO STUDY MEDICATION TREATMENT	N	MEAN	SD	MIN	MEDIAN	MAX
DURATION (DAYS)						
TREATMENT GROUP AT BASELINE						
ADALIMUMAB STANDARD INDUCTION DOSE	340	58.0	58.70	14	56.0	1130
ADALIMUMAB HIGHER INDUCTION DOSE	512	55.1	6.06	14	56.0	72
TOTAL	852	56.2	37.38	14	56.0	1130

NOTE: TOTAL EXPOSURE FOR SUBJECTS WHO DISCONTINUED FROM THE INDUCTION STUDY = DATE OF LAST DOSE OF INDUCTION STUDY DRUG - DATE OF FIRST DOSE OF INDUCTION STUDY DRUG + 14 DAYS.
TOTAL EXPOSURE FOR SUBJECTS WHO COMPLETED THE INDUCTION STUDY = DATE OF FIRST DOSE OF MAINTENANCE STUDY DRUG - DATE OF FIRST DOSE OF INDUCTION STUDY DRUG.

Cross reference: M14-033 Induction Main-study Final CSR Table 14.1__6.1

表 2.7.4.7-3. 治験薬の曝露期間
（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）

	JAPAN SAFETY SET			INTEGRATED SAFETY SET			SAFETY SET		
	ADALIMUMAB			ADALIMUMAB			ADALIMUMAB		
STATISTICS	STANDARD DOSE	HIGHER DOSE	TOTAL	STANDARD DOSE	HIGHER DOSE	TOTAL	STANDARD DOSE	HIGHER DOSE	TOTAL
DURATION (DAYS)									
N	39	61	100	379	573	952	340	512	852
MEAN	53.0	54.8	54.1	57.5	55.0	56.0	58.0	55.1	56.2
SD	9.49	6.22	7.67	55.69	6.07	35.45	58.70	6.06	37.38
MEDIAN	56.0	56.0	56.0	56.0	56.0	56.0	56.0	56.0	56.0
MIN	14	21	14	14	14	14	14	14	14
MAX	59	59	59	1130	72	1130	1130	72	1130

NOTE: TOTAL EXPOSURE FOR SUBJECTS WHO DISCONTINUED FROM THE INDUCTION STUDY = DATE OF LAST DOSE OF INDUCTION STUDY DRUG - DATE OF FIRST DOSE OF INDUCTION STUDY DRUG + 14 DAYS.
TOTAL EXPOSURE FOR SUBJECTS WHO COMPLETED THE INDUCTION STUDY = DATE OF FIRST DOSE OF MAINTENANCE STUDY DRUG - DATE OF FIRST DOSE OF INDUCTION STUDY DRUG.

Cross reference: M14-033 Induction Japan Sub-study Final CSR Table 14.1__6.1_J

表 2.7.4.7-4.　　治験薬の曝露期間（主試験安全性解析対象集団，M14-033 主試験の維持療法試験）

Exposure to study medication Treatment	N	Mean	SD	Min	Median	Max
Duration (Days)						
Treatment group						
Adalimumab 40mg EOW	302	249.5	113.35	14	314.0	1073
Adalimumab 40mg EW	304	263.1	122.99	14	315.0	1117
Adalimumab TDM Regimen	151	255.9	99.30	14	314.0	351
Total	757	256.3	114.77	14	314.0	1117

Note: Total exposure for subjects = Date of last dose of maintenance study drug - Date of first dose of maintenance study drug + 14 days.

Cross reference: M14-033 Maintenance Main-study Final CSR Table 14.1__6.1

表 2.7.4.7-5. 治験薬の曝露期間（日本人安全性解析対象集団及び統合安全性解析対象集団，M14-033 日本サブ試験の維持療法試験）

Population Exposure to study medication Treatment	N	Mean	SD	Min	Median	Max
Japan						
Duration (Days)						
Treatment group						
Adalimumab 40mg EOW	43	265.2	89.98	14	315.0	319
Adalimumab 40mg EW	46	263.1	97.09	21	315.0	320
Total	89	264.1	93.20	14	315.0	320
Integrated						
Duration (Days)						
Treatment group						
Adalimumab 40mg EOW	345	251.5	110.71	14	314.0	1073
Adalimumab 40mg EW	350	263.1	119.78	14	315.0	1117
Adalimumab TDM Regimen	151	255.9	99.30	14	314.0	351
Total	846	257.1	112.67	14	314.0	1117

Note: Total exposure for subjects = Date of last dose of maintenance study drug - Date of first dose of maintenance study drug + 14 days.

Cross reference: M14-033 Maintenance Japan Sub-study Final CSR Table 14.1__6.1_J

表 2.7.4.7-6. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
ANY ADVERSE EVENT	75 (22.1)	138 (27.0)	213 (25.0)
血液およびリンパ系障害			
貧血	0	1 (0.2)	1 (0.1)
白血球減少症	0	1 (0.2)	1 (0.1)
リンパ節症	1 (0.3)	0	1 (0.1)
好中球減少症	1 (0.3)	0	1 (0.1)
血小板減少症	0	2 (0.4)	2 (0.2)
SUBJECTS WITH ONE OR MORE EVENTS	2 (0.6)	4 (0.8)	6 (0.7)
心臓障害			
動悸	1 (0.3)	1 (0.2)	2 (0.2)
SUBJECTS WITH ONE OR MORE EVENTS	1 (0.3)	1 (0.2)	2 (0.2)
先天性、家族性および遺伝性障害			
エーラース・ダンロス症候群	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (0.2)	1 (0.1)

表 2.7.4.7-6. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

	ADALIMUMAB		
SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM	STANDARD INDUCTION DOSE (N=340) n (%)	HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
眼障害			
眼瞼痙攣	0	1 (0.2)	1 (0.1)
ドライアイ	1 (0.3)	1 (0.2)	2 (0.2)
眼瞼湿疹	1 (0.3)	0	1 (0.1)
眼痛	1 (0.3)	0	1 (0.1)
眼瞼浮腫	1 (0.3)	0	1 (0.1)
羞明	0	2 (0.4)	2 (0.2)
SUBJECTS WITH ONE OR MORE EVENTS	4 (1.2)	4 (0.8)	8 (0.9)
胃腸障害			
腹痛	0	2 (0.4)	2 (0.2)
上腹部痛	1 (0.3)	1 (0.2)	2 (0.2)
根尖肉芽腫	0	1 (0.2)	1 (0.1)
潰瘍性大腸炎	0	1 (0.2)	1 (0.1)
下痢	0	1 (0.2)	1 (0.1)
鼓腸	1 (0.3)	3 (0.6)	4 (0.5)
歯肉出血	0	1 (0.2)	1 (0.1)
歯肉痛	0	1 (0.2)	1 (0.1)
血栓性痔核	1 (0.3)	0	1 (0.1)
悪心	6 (1.8)	7 (1.4)	13 (1.5)
嚥下痛	0	1 (0.2)	1 (0.1)

表 2.7.4.7-6. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
胃腸障害 (Cont.)			
直腸しぶり	0	1 (0.2)	1 (0.1)
嘔吐	2 (0.6)	3 (0.6)	5 (0.6)
SUBJECTS WITH ONE OR MORE EVENTS	10 (2.9)	16 (3.1)	26 (3.1)
一般・全身障害および投与部位の状態			
投与部位疼痛	1 (0.3)	0	1 (0.1)
適用部位そう痒感	0	1 (0.2)	1 (0.1)
適用部位反応	0	1 (0.2)	1 (0.1)
無力症	3 (0.9)	3 (0.6)	6 (0.7)
胸痛	2 (0.6)	0	2 (0.2)
悪寒	1 (0.3)	1 (0.2)	2 (0.2)
疲労	5 (1.5)	9 (1.8)	14 (1.6)
冷感	1 (0.3)	1 (0.2)	2 (0.2)
インフルエンザ様疾患	1 (0.3)	0	1 (0.1)
注射部位内出血	1 (0.3)	3 (0.6)	4 (0.5)
注射部位紅斑	2 (0.6)	14 (2.7)	16 (1.9)
注射部位過敏反応	0	3 (0.6)	3 (0.4)
注射部位硬結	0	1 (0.2)	1 (0.1)
注射部位炎症	0	2 (0.4)	2 (0.2)
注射部位腫瘤	0	1 (0.2)	1 (0.1)

表 2.7.4.7-6. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
一般・全身障害および投与部位の状態 (Cont.)			
注射部位浮腫	0	1 (0.2)	1 (0.1)
注射部位疼痛	3 (0.9)	6 (1.2)	9 (1.1)
注射部位そう痒感	2 (0.6)	13 (2.5)	15 (1.8)
注射部位発疹	1 (0.3)	4 (0.8)	5 (0.6)
注射部位反応	1 (0.3)	19 (3.7)	20 (2.3)
注射部位腫脹	2 (0.6)	9 (1.8)	11 (1.3)
注射部位蕁麻疹	1 (0.3)	1 (0.2)	2 (0.2)
末梢性浮腫	0	1 (0.2)	1 (0.1)
疼痛	1 (0.3)	0	1 (0.1)
発熱	3 (0.9)	0	3 (0.4)
腫脹	1 (0.3)	0	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	21 (6.2)	71 (13.9)	92 (10.8)
肝胆道系障害			
高トランスアミナーゼ血症	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (0.2)	1 (0.1)

表 2.7.4.7-6. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
免疫系障害			
薬物過敏症	0	1 (0.2)	1 (0.1)
過敏症	1 (0.3)	2 (0.4)	3 (0.4)
SUBJECTS WITH ONE OR MORE EVENTS	1 (0.3)	3 (0.6)	4 (0.5)
感染症および寄生虫症			
四肢膿瘍	0	1 (0.2)	1 (0.1)
ブラストシスティス感染	0	1 (0.2)	1 (0.1)
ウイルス性気管支炎	1 (0.3)	0	1 (0.1)
カンジダ感染	0	1 (0.2)	1 (0.1)
クロストリジウム・ディフィシレ感染	0	1 (0.2)	1 (0.1)
結膜炎	1 (0.3)	0	1 (0.1)
膀胱炎	0	1 (0.2)	1 (0.1)
毛包炎	0	1 (0.2)	1 (0.1)
真菌感染	0	1 (0.2)	1 (0.1)
胃腸炎	0	1 (0.2)	1 (0.1)
ヘルペスウイルス感染	0	1 (0.2)	1 (0.1)
帯状疱疹	1 (0.3)	0	1 (0.1)
麦粒腫	0	1 (0.2)	1 (0.1)
感染性嚢腫	0	1 (0.2)	1 (0.1)
インフルエンザ	1 (0.3)	0	1 (0.1)

表 2.7.4.7-6. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

	ADALIMUMAB		
SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM	STANDARD INDUCTION DOSE (N=340) n (%)	HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
感染症および寄生虫症 (Cont.)			
喉頭炎	1 (0.3)	0	1 (0.1)
上咽頭炎	3 (0.9)	3 (0.6)	6 (0.7)
食道カンジダ症	1 (0.3)	0	1 (0.1)
口腔ヘルペス	1 (0.3)	1 (0.2)	2 (0.2)
咽頭炎	2 (0.6)	0	2 (0.2)
肺炎	1 (0.3)	1 (0.2)	2 (0.2)
膿疱性皮疹	2 (0.6)	1 (0.2)	3 (0.4)
副鼻腔炎	1 (0.3)	1 (0.2)	2 (0.2)
白癬感染	0	1 (0.2)	1 (0.1)
歯感染	0	1 (0.2)	1 (0.1)
結核	0	1 (0.2)	1 (0.1)
上気道感染	1 (0.3)	1 (0.2)	2 (0.2)
尿路感染	1 (0.3)	2 (0.4)	3 (0.4)
ウイルス性上気道感染	1 (0.3)	0	1 (0.1)
外陰部腟カンジダ症	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	17 (5.0)	23 (4.5)	40 (4.7)

表 2.7.4.7-6. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

	ADALIMUMAB		
	STANDARD INDUCTION DOSE	HIGHER INDUCTION DOSE	TOTAL
SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM	(N=340) n (%)	(N=512) n (%)	(N=852) n (%)
傷害、中毒および処置合併症			
挫傷	0	1 (0.2)	1 (0.1)
注射に伴う反応	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	0	2 (0.4)	2 (0.2)
臨床検査			
アラニンアミノトランスフェラーゼ増加	0	2 (0.4)	2 (0.2)
アスパラギン酸アミノトランスフェラーゼ増加	0	1 (0.2)	1 (0.1)
血中ビリルビン増加	1 (0.3)	2 (0.4)	3 (0.4)
血中コレステロール増加	1 (0.3)	0	1 (0.1)
血中リン減少	1 (0.3)	0	1 (0.1)
血圧上昇	1 (0.3)	0	1 (0.1)
血中トリグリセリド増加	0	1 (0.2)	1 (0.1)
呼吸音異常	1 (0.3)	0	1 (0.1)
C－反応性蛋白増加	1 (0.3)	0	1 (0.1)
クロストリジウム検査陽性	0	1 (0.2)	1 (0.1)
白血球数減少	1 (0.3)	1 (0.2)	2 (0.2)
SUBJECTS WITH ONE OR MORE EVENTS	6 (1.8)	7 (1.4)	13 (1.5)

表 2.7.4.7-6. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
代謝および栄養障害			
高コレステロール血症	1 (0.3)	1 (0.2)	2 (0.2)
高血糖	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	1 (0.3)	2 (0.4)	3 (0.4)
筋骨格系および結合組織障害			
関節痛	5 (1.5)	5 (1.0)	10 (1.2)
背部痛	0	2 (0.4)	2 (0.2)
側腹部痛	1 (0.3)	0	1 (0.1)
関節雑音	0	1 (0.2)	1 (0.1)
関節可動域低下	1 (0.3)	0	1 (0.1)
関節腫脹	1 (0.3)	0	1 (0.1)
筋痙縮	1 (0.3)	1 (0.2)	2 (0.2)
筋骨格痛	0	1 (0.2)	1 (0.1)
筋肉痛	1 (0.3)	0	1 (0.1)
顎痛	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	8 (2.4)	11 (2.1)	19 (2.2)

表 2.7.4.7-6. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）			
肛門性器疣贅	0	1 (0.2)	1 (0.1)
表皮内悪性黒色腫	1 (0.3)	0	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	1 (0.3)	1 (0.2)	2 (0.2)
神経系障害			
浮動性めまい	1 (0.3)	3 (0.6)	4 (0.5)
蟻走感	1 (0.3)	0	1 (0.1)
頭痛	12 (3.5)	12 (2.3)	24 (2.8)
片頭痛	0	3 (0.6)	3 (0.4)
神経痛	0	1 (0.2)	1 (0.1)
痙攣発作	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	13 (3.8)	20 (3.9)	33 (3.9)
精神障害			
不安	1 (0.3)	0	1 (0.1)
不眠症	1 (0.3)	0	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	2 (0.6)	0	2 (0.2)

表 2.7.4.7-6. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
腎および尿路障害			
着色尿	0	1 (0.2)	1 (0.1)
排尿困難	0	1 (0.2)	1 (0.1)
血尿	0	1 (0.2)	1 (0.1)
高シュウ酸尿症	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	0	2 (0.4)	2 (0.2)
生殖系および乳房障害			
バルトリン嚢腫	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (0.2)	1 (0.1)
呼吸器、胸郭および縦隔障害			
咳嗽	4 (1.2)	5 (1.0)	9 (1.1)
呼吸困難	1 (0.3)	0	1 (0.1)
鼻出血	0	1 (0.2)	1 (0.1)
鼻閉	1 (0.3)	0	1 (0.1)
口腔咽頭痛	0	4 (0.8)	4 (0.5)
咽頭障害	0	1 (0.2)	1 (0.1)
鼻漏	0	1 (0.2)	1 (0.1)

表 2.7.4.7-6. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)			
副鼻腔うっ血	1 (0.3)	0	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	7 (2.1)	10 (2.0)	17 (2.0)
皮膚および皮下組織障害			
脱毛症	3 (0.9)	4 (0.8)	7 (0.8)
血管浮腫	0	1 (0.2)	1 (0.1)
冷汗	0	1 (0.2)	1 (0.1)
皮膚炎	1 (0.3)	2 (0.4)	3 (0.4)
アトピー性皮膚炎	0	1 (0.2)	1 (0.1)
乾癬様皮膚炎	1 (0.3)	0	1 (0.1)
皮膚乾燥	1 (0.3)	0	1 (0.1)
湿疹	1 (0.3)	1 (0.2)	2 (0.2)
紅斑	0	4 (0.8)	4 (0.5)
多汗症	1 (0.3)	0	1 (0.1)
寝汗	0	1 (0.2)	1 (0.1)
そう痒症	3 (0.9)	1 (0.2)	4 (0.5)
全身性そう痒症	0	1 (0.2)	1 (0.1)
乾癬	1 (0.3)	1 (0.2)	2 (0.2)
発疹	4 (1.2)	3 (0.6)	7 (0.8)
紅斑性皮疹	2 (0.6)	1 (0.2)	3 (0.4)

表 2.7.4.7-6. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
皮膚および皮下組織障害 (Cont.)			
丘疹性皮疹	0	1 (0.2)	1 (0.1)
蕁麻疹	1 (0.3)	0	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	18 (5.3)	23 (4.5)	41 (4.8)
血管障害			
血腫	1 (0.3)	1 (0.2)	2 (0.2)
低血圧	1 (0.3)	0	1 (0.1)
末梢静脈疾患	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	2 (0.6)	2 (0.4)	4 (0.5)

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
TREATMENT-EMERGENT ADVERSE EVENTS DURING INDUCTION STUDY ARE DEFINED AS EVENTS THAT BEGIN OR WORSEN EITHER ON OR AFTER THE FIRST DOSE OF THE STUDY MEDICATION AND UP TO THE FIRST DOSE OF THE STUDY MEDICATION IN MAINTENANCE STUDY FOR THOSE WHO ARE RE-RANDOMIZED AT WEEK 8, OR EVENTS THAT BEGIN OR WORSEN EITHER ON OR AFTER THE FIRST DOSE OF THE STUDY DRUG AND WITHIN 70 DAYS AFTER THE LAST DOSE OF THE STUDY MEDICATION IN THE INDUCTION STUDY FOR SUBJECTS WHO ARE NOT RE-RANDOMIZED.
EVENT WITH UNKNOWN RELATIONSHIP TO STUDY DRUG IS BEING COUNTED AS DRUG-RELATED.

Cross reference: M14-033 Induction Main-study Final CSR Table 14.3__1.6

表 2.7.4.7-7. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（日本人安全性解析対象集団，
統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）

	JAPAN SAFETY SET ADALIMUMAB			INTEGRATED SAFETY SET ADALIMUMAB			SAFETY SET ADALIMUMAB		
SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM	STANDARD DOSE (N=39) n (%)	HIGHER DOSE (N=61) n (%)	TOTAL (N=100) n (%)	STANDARD DOSE (N=379) n (%)	HIGHER DOSE (N=573) n (%)	TOTAL (N=952) n (%)	STANDARD DOSE (N=340) n (%)	HIGHER DOSE (N=512) n (%)	TOTAL (N=852) n (%)
ANY ADVERSE EVENT	8 (20.5)	11 (18.0)	19 (19.0)	83 (21.9)	149 (26.0)	232 (24.4)	75 (22.1)	138 (27.0)	213 (25.0)
血液およびリンパ系障害									
貧血	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
白血球減少症	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
リンパ節症	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
好中球減少症	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
血小板減少症	0	0	0	0	2 (0.3)	2 (0.2)	0	2 (0.4)	2 (0.2)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	2 (0.5)	4 (0.7)	6 (0.6)	2 (0.6)	4 (0.8)	6 (0.7)
心臓障害									
動悸	0	0	0	1 (0.3)	1 (0.2)	2 (0.2)	1 (0.3)	1 (0.2)	2 (0.2)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	1 (0.3)	1 (0.2)	2 (0.2)	1 (0.3)	1 (0.2)	2 (0.2)

表 2.7.4.7-7. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

	JAPAN SAFETY SET ADALIMUMAB			INTEGRATED SAFETY SET ADALIMUMAB			SAFETY SET ADALIMUMAB		
SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM	STANDARD DOSE (N=39) n (%)	HIGHER DOSE (N=61) n (%)	TOTAL (N=100) n (%)	STANDARD DOSE (N=379) n (%)	HIGHER DOSE (N=573) n (%)	TOTAL (N=952) n (%)	STANDARD DOSE (N=340) n (%)	HIGHER DOSE (N=512) n (%)	TOTAL (N=852) n (%)
先天性、家族性および遺伝性障害									
エーラース・ダンロス症候群	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
眼障害									
眼瞼痙攣	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
ドライアイ	0	0	0	1 (0.3)	1 (0.2)	2 (0.2)	1 (0.3)	1 (0.2)	2 (0.2)
眼瞼湿疹	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
眼痛	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
眼瞼浮腫	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
羞明	0	0	0	0	2 (0.3)	2 (0.2)	0	2 (0.4)	2 (0.2)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	4 (1.1)	4 (0.7)	8 (0.8)	4 (1.2)	4 (0.8)	8 (0.9)
胃腸障害									
腹部膨満	1 (2.6)	0	1 (1.0)	1 (0.3)	0	1 (0.1)	0	0	0
腹痛	0	0	0	0	2 (0.3)	2 (0.2)	0	2 (0.4)	2 (0.2)

表 2.7.4.7-7. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

	JAPAN SAFETY SET ADALIMUMAB			INTEGRATED SAFETY SET ADALIMUMAB			SAFETY SET ADALIMUMAB		
SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM	STANDARD DOSE (N=39) n (%)	HIGHER DOSE (N=61) n (%)	TOTAL (N=100) n (%)	STANDARD DOSE (N=379) n (%)	HIGHER DOSE (N=573) n (%)	TOTAL (N=952) n (%)	STANDARD DOSE (N=340) n (%)	HIGHER DOSE (N=512) n (%)	TOTAL (N=852) n (%)
胃腸障害 (Cont.)									
上腹部痛	0	0	0	1 (0.3)	1 (0.2)	2 (0.2)	1 (0.3)	1 (0.2)	2 (0.2)
根尖肉芽腫	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
潰瘍性大腸炎	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
下痢	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
鼓腸	0	0	0	1 (0.3)	3 (0.5)	4 (0.4)	1 (0.3)	3 (0.6)	4 (0.5)
歯肉出血	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
歯肉痛	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
血栓性痔核	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
悪心	0	0	0	6 (1.6)	7 (1.2)	13 (1.4)	6 (1.8)	7 (1.4)	13 (1.5)
嚥下痛	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
直腸しぶり	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
嘔吐	0	1 (1.6)	1 (1.0)	2 (0.5)	4 (0.7)	6 (0.6)	2 (0.6)	3 (0.6)	5 (0.6)
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.6)	1 (1.6)	2 (2.0)	11 (2.9)	17 (3.0)	28 (2.9)	10 (2.9)	16 (3.1)	26 (3.1)

表 2.7.4.7-7. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

	JAPAN SAFETY SET ADALIMUMAB			INTEGRATED SAFETY SET ADALIMUMAB			SAFETY SET ADALIMUMAB		
SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM	STANDARD DOSE (N=39) n (%)	HIGHER DOSE (N=61) n (%)	TOTAL (N=100) n (%)	STANDARD DOSE (N=379) n (%)	HIGHER DOSE (N=573) n (%)	TOTAL (N=952) n (%)	STANDARD DOSE (N=340) n (%)	HIGHER DOSE (N=512) n (%)	TOTAL (N=852) n (%)
一般・全身障害および投与部位の状態									
投与部位疼痛	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
適用部位そう痒感	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
適用部位反応	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
無力症	0	0	0	3 (0.8)	3 (0.5)	6 (0.6)	3 (0.9)	3 (0.6)	6 (0.7)
胸痛	0	0	0	2 (0.5)	0	2 (0.2)	2 (0.6)	0	2 (0.2)
悪寒	0	0	0	1 (0.3)	1 (0.2)	2 (0.2)	1 (0.3)	1 (0.2)	2 (0.2)
疲労	0	0	0	5 (1.3)	9 (1.6)	14 (1.5)	5 (1.5)	9 (1.8)	14 (1.6)
冷感	0	0	0	1 (0.3)	1 (0.2)	2 (0.2)	1 (0.3)	1 (0.2)	2 (0.2)
インフルエンザ様疾患	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
注射部位内出血	0	0	0	1 (0.3)	3 (0.5)	4 (0.4)	1 (0.3)	3 (0.6)	4 (0.5)
注射部位紅斑	1 (2.6)	0	1 (1.0)	3 (0.8)	14 (2.4)	17 (1.8)	2 (0.6)	14 (2.7)	16 (1.9)
注射部位過敏反応	0	0	0	0	3 (0.5)	3 (0.3)	0	3 (0.6)	3 (0.4)
注射部位硬結	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
注射部位炎症	0	0	0	0	2 (0.3)	2 (0.2)	0	2 (0.4)	2 (0.2)
注射部位腫瘤	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
注射部位浮腫	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
注射部位疼痛	0	0	0	3 (0.8)	6 (1.0)	9 (0.9)	3 (0.9)	6 (1.2)	9 (1.1)
注射部位そう痒感	0	0	0	2 (0.5)	13 (2.3)	15 (1.6)	2 (0.6)	13 (2.5)	15 (1.8)

表 2.7.4.7-7. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

	JAPAN SAFETY SET ADALIMUMAB			INTEGRATED SAFETY SET ADALIMUMAB			SAFETY SET ADALIMUMAB		
SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM	STANDARD DOSE (N=39) n (%)	HIGHER DOSE (N=61) n (%)	TOTAL (N=100) n (%)	STANDARD DOSE (N=379) n (%)	HIGHER DOSE (N=573) n (%)	TOTAL (N=952) n (%)	STANDARD DOSE (N=340) n (%)	HIGHER DOSE (N=512) n (%)	TOTAL (N=852) n (%)
一般・全身障害および投与部位の状態 (Cont.)									
注射部位発疹	0	0	0	1 (0.3)	4 (0.7)	5 (0.5)	1 (0.3)	4 (0.8)	5 (0.6)
注射部位反応	2 (5.1)	5 (8.2)	7 (7.0)	3 (0.8)	24 (4.2)	27 (2.8)	1 (0.3)	19 (3.7)	20 (2.3)
注射部位腫脹	0	0	0	2 (0.5)	9 (1.6)	11 (1.2)	2 (0.6)	9 (1.8)	11 (1.3)
注射部位蕁麻疹	0	0	0	1 (0.3)	1 (0.2)	2 (0.2)	1 (0.3)	1 (0.2)	2 (0.2)
末梢性浮腫	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
疼痛	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
発熱	0	1 (1.6)	1 (1.0)	3 (0.8)	1 (0.2)	4 (0.4)	3 (0.9)	0	3 (0.4)
腫脹	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	3 (7.7)	6 (9.8)	9 (9.0)	24 (6.3)	77 (13.4)	101 (10.6)	21 (6.2)	71 (13.9)	92 (10.8)
肝胆道系障害									
高トランスアミナーゼ血症	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)

表 2.7.4.7-7. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

	JAPAN SAFETY SET ADALIMUMAB			INTEGRATED SAFETY SET ADALIMUMAB			SAFETY SET ADALIMUMAB		
SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM	STANDARD DOSE (N=39) n (%)	HIGHER DOSE (N=61) n (%)	TOTAL (N=100) n (%)	STANDARD DOSE (N=379) n (%)	HIGHER DOSE (N=573) n (%)	TOTAL (N=952) n (%)	STANDARD DOSE (N=340) n (%)	HIGHER DOSE (N=512) n (%)	TOTAL (N=852) n (%)
免疫系障害									
薬物過敏症	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
過敏症	0	1 (1.6)	1 (1.0)	1 (0.3)	3 (0.5)	4 (0.4)	1 (0.3)	2 (0.4)	3 (0.4)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (1.6)	1 (1.0)	1 (0.3)	4 (0.7)	5 (0.5)	1 (0.3)	3 (0.6)	4 (0.5)
感染症および寄生虫症									
四肢膿瘍	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
ブラストシスティス感染	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
ウイルス性気管支炎	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
カンジダ感染	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
クロストリジウム・ディフィシレ感染	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
結膜炎	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
膀胱炎	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
サイトメガロウイルス感染	1 (2.6)	0	1 (1.0)	1 (0.3)	0	1 (0.1)	0	0	0
毛包炎	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
真菌感染	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
胃腸炎	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)

表 2.7.4.7-7. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

	JAPAN SAFETY SET / ADALIMUMAB			INTEGRATED SAFETY SET / ADALIMUMAB			SAFETY SET / ADALIMUMAB		
SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM	STANDARD DOSE (N=39) n (%)	HIGHER DOSE (N=61) n (%)	TOTAL (N=100) n (%)	STANDARD DOSE (N=379) n (%)	HIGHER DOSE (N=573) n (%)	TOTAL (N=952) n (%)	STANDARD DOSE (N=340) n (%)	HIGHER DOSE (N=512) n (%)	TOTAL (N=852) n (%)
感染症および寄生虫症 (Cont.)									
消化管感染	0	1 (1.6)	1 (1.0)	0	1 (0.2)	1 (0.1)	0	0	0
単純ヘルペス	0	1 (1.6)	1 (1.0)	0	1 (0.2)	1 (0.1)	0	0	0
ヘルペスウイルス感染	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
帯状疱疹	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
麦粒腫	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
感染性嚢腫	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
インフルエンザ	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
喉頭炎	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
上咽頭炎	0	1 (1.6)	1 (1.0)	3 (0.8)	4 (0.7)	7 (0.7)	3 (0.9)	3 (0.6)	6 (0.7)
食道カンジダ症	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
口腔ヘルペス	0	0	0	1 (0.3)	1 (0.2)	2 (0.2)	1 (0.3)	1 (0.2)	2 (0.2)
咽頭炎	0	0	0	2 (0.5)	0	2 (0.2)	2 (0.6)	0	2 (0.2)
肺炎	1 (2.6)	0	1 (1.0)	2 (0.5)	1 (0.2)	3 (0.3)	1 (0.3)	1 (0.2)	2 (0.2)
膿疱性皮疹	0	0	0	2 (0.5)	1 (0.2)	3 (0.3)	2 (0.6)	1 (0.2)	3 (0.4)
副鼻腔炎	0	0	0	1 (0.3)	1 (0.2)	2 (0.2)	1 (0.3)	1 (0.2)	2 (0.2)
白癬感染	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
歯感染	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
結核	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)

表 2.7.4.7-7. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

	JAPAN SAFETY SET ADALIMUMAB			INTEGRATED SAFETY SET ADALIMUMAB			SAFETY SET ADALIMUMAB		
SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM	STANDARD DOSE (N=39) n (%)	HIGHER DOSE (N=61) n (%)	TOTAL (N=100) n (%)	STANDARD DOSE (N=379) n (%)	HIGHER DOSE (N=573) n (%)	TOTAL (N=952) n (%)	STANDARD DOSE (N=340) n (%)	HIGHER DOSE (N=512) n (%)	TOTAL (N=852) n (%)
感染症および寄生虫症 (Cont.)									
上気道感染	0	0	0	1 (0.3)	1 (0.2)	2 (0.2)	1 (0.3)	1 (0.2)	2 (0.2)
尿路感染	0	0	0	1 (0.3)	2 (0.3)	3 (0.3)	1 (0.3)	2 (0.4)	3 (0.4)
ウイルス性上気道感染	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
外陰部腟カンジダ症	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	2 (5.1)	3 (4.9)	5 (5.0)	19 (5.0)	26 (4.5)	45 (4.7)	17 (5.0)	23 (4.5)	40 (4.7)
傷害、中毒および処置合併症									
挫傷	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
注射に伴う反応	0	1 (1.6)	1 (1.0)	0	2 (0.3)	2 (0.2)	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (1.6)	1 (1.0)	0	3 (0.5)	3 (0.3)	0	2 (0.4)	2 (0.2)
臨床検査									
アラニンアミノトランスフェラーゼ増加	0	0	0	0	2 (0.3)	2 (0.2)	0	2 (0.4)	2 (0.2)
アスパラギン酸アミノトランスフェラーゼ増加	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)

表 2.7.4.7-7. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

	JAPAN SAFETY SET / ADALIMUMAB			INTEGRATED SAFETY SET / ADALIMUMAB			SAFETY SET / ADALIMUMAB		
SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM	STANDARD DOSE (N=39) n (%)	HIGHER DOSE (N=61) n (%)	TOTAL (N=100) n (%)	STANDARD DOSE (N=379) n (%)	HIGHER DOSE (N=573) n (%)	TOTAL (N=952) n (%)	STANDARD DOSE (N=340) n (%)	HIGHER DOSE (N=512) n (%)	TOTAL (N=852) n (%)
臨床検査 (Cont.)									
血中ビリルビン増加	0	0	0	1 (0.3)	2 (0.3)	3 (0.3)	1 (0.3)	2 (0.4)	3 (0.4)
血中コレステロール増加	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
血中リン減少	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
血圧上昇	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
血中トリグリセリド増加	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
呼吸音異常	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
C－反応性蛋白増加	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
クロストリジウム検査陽性	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
白血球数減少	0	0	0	1 (0.3)	1 (0.2)	2 (0.2)	1 (0.3)	1 (0.2)	2 (0.2)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	6 (1.6)	7 (1.2)	13 (1.4)	6 (1.8)	7 (1.4)	13 (1.5)
代謝および栄養障害									
高コレステロール血症	0	0	0	1 (0.3)	1 (0.2)	2 (0.2)	1 (0.3)	1 (0.2)	2 (0.2)
高血糖	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	1 (0.3)	2 (0.3)	3 (0.3)	1 (0.3)	2 (0.4)	3 (0.4)

表 2.7.4.7-7. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

	JAPAN SAFETY SET ADALIMUMAB			INTEGRATED SAFETY SET ADALIMUMAB			SAFETY SET ADALIMUMAB		
SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM	STANDARD DOSE (N=39) n (%)	HIGHER DOSE (N=61) n (%)	TOTAL (N=100) n (%)	STANDARD DOSE (N=379) n (%)	HIGHER DOSE (N=573) n (%)	TOTAL (N=952) n (%)	STANDARD DOSE (N=340) n (%)	HIGHER DOSE (N=512) n (%)	TOTAL (N=852) n (%)
筋骨格系および結合組織障害									
関節痛	0	1 (1.6)	1 (1.0)	5 (1.3)	6 (1.0)	11 (1.2)	5 (1.5)	5 (1.0)	10 (1.2)
背部痛	0	0	0	0	2 (0.3)	2 (0.2)	0	2 (0.4)	2 (0.2)
側腹部痛	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
関節雑音	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
関節可動域低下	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
関節腫脹	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
筋痙縮	0	0	0	1 (0.3)	1 (0.2)	2 (0.2)	1 (0.3)	1 (0.2)	2 (0.2)
筋骨格痛	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
筋肉痛	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
頚部痛	1 (2.6)	0	1 (1.0)	1 (0.3)	0	1 (0.1)	0	0	0
四肢痛	0	1 (1.6)	1 (1.0)	0	1 (0.2)	1 (0.1)	0	0	0
顎痛	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.6)	1 (1.6)	2 (2.0)	9 (2.4)	12 (2.1)	21 (2.2)	8 (2.4)	11 (2.1)	19 (2.2)

表 2.7.4.7-7. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

	JAPAN SAFETY SET ADALIMUMAB			INTEGRATED SAFETY SET ADALIMUMAB			SAFETY SET ADALIMUMAB		
SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM	STANDARD DOSE (N=39) n (%)	HIGHER DOSE (N=61) n (%)	TOTAL (N=100) n (%)	STANDARD DOSE (N=379) n (%)	HIGHER DOSE (N=573) n (%)	TOTAL (N=952) n (%)	STANDARD DOSE (N=340) n (%)	HIGHER DOSE (N=512) n (%)	TOTAL (N=852) n (%)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）									
肛門性器疣贅	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
表皮内悪性黒色腫	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	1 (0.3)	1 (0.2)	2 (0.2)	1 (0.3)	1 (0.2)	2 (0.2)
神経系障害									
浮動性めまい	0	1 (1.6)	1 (1.0)	1 (0.3)	4 (0.7)	5 (0.5)	1 (0.3)	3 (0.6)	4 (0.5)
蟻走感	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
頭痛	0	0	0	12 (3.2)	12 (2.1)	24 (2.5)	12 (3.5)	12 (2.3)	24 (2.8)
片頭痛	0	0	0	0	3 (0.5)	3 (0.3)	0	3 (0.6)	3 (0.4)
神経痛	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
痙攣発作	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (1.6)	1 (1.0)	13 (3.4)	21 (3.7)	34 (3.6)	13 (3.8)	20 (3.9)	33 (3.9)

表 2.7.4.7-7. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

	JAPAN SAFETY SET ADALIMUMAB			INTEGRATED SAFETY SET ADALIMUMAB			SAFETY SET ADALIMUMAB		
SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM	STANDARD DOSE (N=39) n (%)	HIGHER DOSE (N=61) n (%)	TOTAL (N=100) n (%)	STANDARD DOSE (N=379) n (%)	HIGHER DOSE (N=573) n (%)	TOTAL (N=952) n (%)	STANDARD DOSE (N=340) n (%)	HIGHER DOSE (N=512) n (%)	TOTAL (N=852) n (%)
精神障害									
不安	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
不眠症	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	2 (0.5)	0	2 (0.2)	2 (0.6)	0	2 (0.2)
腎および尿路障害									
着色尿	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
排尿困難	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
血尿	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
高シュウ酸尿症	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	0	2 (0.3)	2 (0.2)	0	2 (0.4)	2 (0.2)
生殖系および乳房障害									
バルトリン嚢腫	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)

表 2.7.4.7-7. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

	JAPAN SAFETY SET ADALIMUMAB			INTEGRATED SAFETY SET ADALIMUMAB			SAFETY SET ADALIMUMAB		
SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM	STANDARD DOSE (N=39) n (%)	HIGHER DOSE (N=61) n (%)	TOTAL (N=100) n (%)	STANDARD DOSE (N=379) n (%)	HIGHER DOSE (N=573) n (%)	TOTAL (N=952) n (%)	STANDARD DOSE (N=340) n (%)	HIGHER DOSE (N=512) n (%)	TOTAL (N=852) n (%)
呼吸器、胸郭および縦隔障害									
咳嗽	0	0	0	4 (1.1)	5 (0.9)	9 (0.9)	4 (1.2)	5 (1.0)	9 (1.1)
呼吸困難	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
鼻出血	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
鼻閉	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
口腔咽頭痛	1 (2.6)	1 (1.6)	2 (2.0)	1 (0.3)	5 (0.9)	6 (0.6)	0	4 (0.8)	4 (0.5)
咽頭障害	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
鼻漏	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
副鼻腔うっ血	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.6)	1 (1.6)	2 (2.0)	8 (2.1)	11 (1.9)	19 (2.0)	7 (2.1)	10 (2.0)	17 (2.0)
皮膚および皮下組織障害									
脱毛症	1 (2.6)	0	1 (1.0)	4 (1.1)	4 (0.7)	8 (0.8)	3 (0.9)	4 (0.8)	7 (0.8)
血管浮腫	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
冷汗	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
皮膚炎	0	0	0	1 (0.3)	2 (0.3)	3 (0.3)	1 (0.3)	2 (0.4)	3 (0.4)
アトピー性皮膚炎	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)

表 2.7.4.7-7. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

	JAPAN SAFETY SET ADALIMUMAB			INTEGRATED SAFETY SET ADALIMUMAB			SAFETY SET ADALIMUMAB		
SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM	STANDARD DOSE (N=39) n (%)	HIGHER DOSE (N=61) n (%)	TOTAL (N=100) n (%)	STANDARD DOSE (N=379) n (%)	HIGHER DOSE (N=573) n (%)	TOTAL (N=952) n (%)	STANDARD DOSE (N=340) n (%)	HIGHER DOSE (N=512) n (%)	TOTAL (N=852) n (%)
皮膚および皮下組織障害 (Cont.)									
乾癬様皮膚炎	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
皮膚乾燥	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
湿疹	0	1 (1.6)	1 (1.0)	1 (0.3)	2 (0.3)	3 (0.3)	1 (0.3)	1 (0.2)	2 (0.2)
紅斑	0	0	0	0	4 (0.7)	4 (0.4)	0	4 (0.8)	4 (0.5)
多汗症	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
寝汗	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
そう痒症	0	0	0	3 (0.8)	1 (0.2)	4 (0.4)	3 (0.9)	1 (0.2)	4 (0.5)
全身性そう痒症	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
乾癬	0	0	0	1 (0.3)	1 (0.2)	2 (0.2)	1 (0.3)	1 (0.2)	2 (0.2)
発疹	2 (5.1)	0	2 (2.0)	6 (1.6)	3 (0.5)	9 (0.9)	4 (1.2)	3 (0.6)	7 (0.8)
紅斑性皮疹	0	0	0	2 (0.5)	1 (0.2)	3 (0.3)	2 (0.6)	1 (0.2)	3 (0.4)
丘疹性皮疹	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
蕁麻疹	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	3 (7.7)	1 (1.6)	4 (4.0)	21 (5.5)	24 (4.2)	45 (4.7)	18 (5.3)	23 (4.5)	41 (4.8)

表 2.7.4.7-7. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

	JAPAN SAFETY SET / ADALIMUMAB			INTEGRATED SAFETY SET / ADALIMUMAB			SAFETY SET / ADALIMUMAB		
SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM	STANDARD DOSE (N=39) n (%)	HIGHER DOSE (N=61) n (%)	TOTAL (N=100) n (%)	STANDARD DOSE (N=379) n (%)	HIGHER DOSE (N=573) n (%)	TOTAL (N=952) n (%)	STANDARD DOSE (N=340) n (%)	HIGHER DOSE (N=512) n (%)	TOTAL (N=852) n (%)
血管障害									
血腫	0	0	0	1 (0.3)	1 (0.2)	2 (0.2)	1 (0.3)	1 (0.2)	2 (0.2)
低血圧	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
末梢静脈疾患	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	2 (0.5)	2 (0.3)	4 (0.4)	2 (0.6)	2 (0.4)	4 (0.5)

NOTE: THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
TREATMENT-EMERGENT ADVERSE EVENTS DURING INDUCTION STUDY ARE DEFINED AS EVENTS THAT BEGIN OR WORSEN EITHER ON OR AFTER THE FIRST DOSE OF THE STUDY MEDICATION AND UP TO THE FIRST DOSE OF THE STUDY MEDICATION IN MAINTENANCE STUDY FOR THOSE WHO ARE RE-RANDOMIZED AT WEEK 8, OR EVENTS THAT BEGIN OR WORSEN EITHER ON OR AFTER THE FIRST DOSE OF THE STUDY DRUG AND WITHIN 70 DAYS AFTER THE LAST DOSE OF THE STUDY MEDICATION IN THE INDUCTION STUDY FOR SUBJECTS WHO ARE NOT RE-RANDOMIZED.
EVENT WITH UNKNOWN RELATIONSHIP TO STUDY DRUG IS BEING COUNTED AS DRUG-RELATED.

Cross reference: M14-033 Induction Japan Sub-study Final CSR Table 14.3__1.5_J

表 2.7.4.7-8. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（主試験安全性解析対象集団，M14-033 主試験の維持療法試験）

MedDRA 22.0 System Organ Class Preferred Term	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
Any Adverse Event	82 (27.2)	104 (34.2)	49 (32.5)	235 (31.0)
血液およびリンパ系障害	3 (1.0)	6 (2.0)	4 (2.6)	13 (1.7)
貧血	0	1 (0.3)	0	1 (0.1)
白血球減少症	1 (0.3)	2 (0.7)	0	3 (0.4)
リンパ節症	0	2 (0.7)	1 (0.7)	3 (0.4)
リンパ球減少症	0	0	1 (0.7)	1 (0.1)
好中球減少症	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
血小板減少症	1 (0.3)	0	1 (0.7)	2 (0.3)
血小板増加症	1 (0.3)	0	0	1 (0.1)
耳および迷路障害	4 (1.3)	0	0	4 (0.5)
耳鳴	2 (0.7)	0	0	2 (0.3)
回転性めまい	2 (0.7)	0	0	2 (0.3)
眼障害	3 (1.0)	3 (1.0)	0	6 (0.8)
ドライアイ	0	1 (0.3)	0	1 (0.1)
眼の炎症	0	1 (0.3)	0	1 (0.1)
眼痛	1 (0.3)	0	0	1 (0.1)
眼瞼縁痂皮	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-8. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（主試験安全性解析対象集団，M14-033 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
眼障害 (Cont.)				
眼瞼下垂	0	1 (0.3)	0	1 (0.1)
視神経萎縮	1 (0.3)	0	0	1 (0.1)
視力障害	1 (0.3)	0	0	1 (0.1)
胃腸障害	9 (3.0)	13 (4.3)	7 (4.6)	29 (3.8)
腹部膨満	2 (0.7)	0	0	2 (0.3)
腹痛	0	1 (0.3)	0	1 (0.1)
上腹部痛	1 (0.3)	0	0	1 (0.1)
裂肛	0	1 (0.3)	0	1 (0.1)
肛門そう痒症	0	0	1 (0.7)	1 (0.1)
アフタ性潰瘍	0	0	1 (0.7)	1 (0.1)
潰瘍性大腸炎	3 (1.0)	6 (2.0)	3 (2.0)	12 (1.6)
クローン病	0	1 (0.3)	0	1 (0.1)
下痢	2 (0.7)	0	0	2 (0.3)
口内乾燥	0	1 (0.3)	0	1 (0.1)
鼓腸	0	0	1 (0.7)	1 (0.1)
歯肉出血	0	1 (0.3)	0	1 (0.1)
血便排泄	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-8. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（主試験安全性解析対象集団，M14-033 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
胃腸障害 (Cont.)				
痔核	0	1 (0.3)	0	1 (0.1)
粘液便	1 (0.3)	0	0	1 (0.1)
悪心	2 (0.7)	1 (0.3)	1 (0.7)	4 (0.5)
急性膵炎	1 (0.3)	0	0	1 (0.1)
肛門周囲痛	1 (0.3)	0	0	1 (0.1)
直腸出血	1 (0.3)	0	0	1 (0.1)
歯痛	0	2 (0.7)	0	2 (0.3)
一般・全身障害および投与部位の状態	14 (4.6)	26 (8.6)	6 (4.0)	46 (6.1)
無力症	3 (1.0)	4 (1.3)	0	7 (0.9)
嚢胞	1 (0.3)	0	0	1 (0.1)
薬物相互作用	0	1 (0.3)	0	1 (0.1)
異形成	0	0	1 (0.7)	1 (0.1)
疲労	2 (0.7)	2 (0.7)	0	4 (0.5)
高熱	0	0	1 (0.7)	1 (0.1)
インフルエンザ様疾患	0	2 (0.7)	0	2 (0.3)
注入部位紅斑	0	1 (0.3)	0	1 (0.1)
注入部位そう痒感	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-8. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（主試験安全性解析対象集団，M14-033 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
一般・全身障害および投与部位の状態 (Cont.)				
注射部位紅斑	3 (1.0)	2 (0.7)	1 (0.7)	6 (0.8)
注射部位過敏反応	0	1 (0.3)	0	1 (0.1)
注射部位硬結	1 (0.3)	0	0	1 (0.1)
注射部位炎症	0	2 (0.7)	0	2 (0.3)
注射部位結節	1 (0.3)	0	0	1 (0.1)
注射部位疼痛	2 (0.7)	1 (0.3)	0	3 (0.4)
注射部位そう痒感	0	2 (0.7)	1 (0.7)	3 (0.4)
注射部位発疹	1 (0.3)	2 (0.7)	0	3 (0.4)
注射部位反応	2 (0.7)	2 (0.7)	3 (2.0)	7 (0.9)
注射部位腫脹	1 (0.3)	2 (0.7)	0	3 (0.4)
限局性浮腫	1 (0.3)	0	0	1 (0.1)
末梢腫脹	0	1 (0.3)	0	1 (0.1)
発熱	0	4 (1.3)	0	4 (0.5)
腫脹	0	1 (0.3)	0	1 (0.1)
肝胆道系障害	2 (0.7)	1 (0.3)	4 (2.6)	7 (0.9)
高トランスアミナーゼ血症	1 (0.3)	1 (0.3)	4 (2.6)	6 (0.8)
非アルコール性脂肪性肝炎	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-8. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（主試験安全性解析対象集団，M14-033 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
感染症および寄生虫症	31 (10.3)	36 (11.8)	20 (13.2)	87 (11.5)
四肢膿瘍	0	2 (0.7)	0	2 (0.3)
急性副鼻腔炎	0	1 (0.3)	0	1 (0.1)
細菌性膣症	0	1 (0.3)	0	1 (0.1)
カンジダ感染	0	1 (0.3)	0	1 (0.1)
蜂巣炎	0	0	1 (0.7)	1 (0.1)
クロストリジウム・ディフィシレ感染	1 (0.3)	2 (0.7)	0	3 (0.4)
結膜炎	0	0	2 (1.3)	2 (0.3)
膀胱炎	1 (0.3)	0	2 (1.3)	3 (0.4)
サイトメガロウイルス感染	1 (0.3)	0	0	1 (0.1)
耳感染	2 (0.7)	0	0	2 (0.3)
エプスタイン・バーウイルス感染	1 (0.3)	0	0	1 (0.1)
外耳蜂巣炎	1 (0.3)	0	0	1 (0.1)
毛包炎	0	1 (0.3)	0	1 (0.1)
真菌感染	1 (0.3)	0	0	1 (0.1)
皮膚真菌感染	1 (0.3)	0	1 (0.7)	2 (0.3)
胃腸炎	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-8. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（主試験安全性解析対象集団，M14-033 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
感染症および寄生虫症 (Cont.)				
性器カンジダ症	0	1 (0.3)	0	1 (0.1)
歯肉膿瘍	0	1 (0.3)	0	1 (0.1)
ヘルペス眼感染	0	1 (0.3)	0	1 (0.1)
帯状疱疹	3 (1.0)	2 (0.7)	1 (0.7)	6 (0.8)
麦粒腫	0	1 (0.3)	0	1 (0.1)
インフルエンザ	1 (0.3)	5 (1.6)	1 (0.7)	7 (0.9)
下気道感染	0	0	1 (0.7)	1 (0.1)
鼓膜炎	0	0	1 (0.7)	1 (0.1)
上咽頭炎	6 (2.0)	9 (3.0)	5 (3.3)	20 (2.6)
口腔カンジダ症	1 (0.3)	0	0	1 (0.1)
口腔真菌感染	0	1 (0.3)	0	1 (0.1)
口腔ヘルペス	0	2 (0.7)	0	2 (0.3)
外耳炎	1 (0.3)	1 (0.3)	0	2 (0.3)
急性中耳炎	1 (0.3)	0	0	1 (0.1)
咽頭炎	0	1 (0.3)	1 (0.7)	2 (0.3)
レンサ球菌性咽頭炎	1 (0.3)	0	0	1 (0.1)
肺炎	1 (0.3)	3 (1.0)	1 (0.7)	5 (0.7)

表 2.7.4.7-8. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（主試験安全性解析対象集団，M14-033 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
感染症および寄生虫症 (Cont.)				
腎盂腎炎	0	0	1 (0.7)	1 (0.1)
急性腎盂腎炎	0	1 (0.3)	0	1 (0.1)
膿疱性皮疹	2 (0.7)	0	0	2 (0.3)
鼻炎	1 (0.3)	0	0	1 (0.1)
敗血症	0	0	1 (0.7)	1 (0.1)
副鼻腔炎	1 (0.3)	2 (0.7)	2 (1.3)	5 (0.7)
皮膚感染	0	1 (0.3)	0	1 (0.1)
扁桃炎	0	3 (1.0)	1 (0.7)	4 (0.5)
歯膿瘍	1 (0.3)	0	0	1 (0.1)
歯感染	0	1 (0.3)	0	1 (0.1)
結核	0	1 (0.3)	0	1 (0.1)
上気道感染	7 (2.3)	4 (1.3)	3 (2.0)	14 (1.8)
尿路感染	1 (0.3)	1 (0.3)	2 (1.3)	4 (0.5)
腟感染	1 (0.3)	0	0	1 (0.1)
ウイルス感染	0	1 (0.3)	0	1 (0.1)
ウイルス性咽頭炎	0	2 (0.7)	0	2 (0.3)
外陰部腟カンジダ症	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-8. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（主試験安全性解析対象集団，M14-033 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
感染症および寄生虫症 (Cont.)				
外陰膣真菌感染	0	1 (0.3)	0	1 (0.1)
外陰膣炎	0	0	1 (0.7)	1 (0.1)
傷害、中毒および処置合併症	0	0	1 (0.7)	1 (0.1)
注射に伴う反応	0	0	1 (0.7)	1 (0.1)
臨床検査	5 (1.7)	8 (2.6)	3 (2.0)	16 (2.1)
アラニンアミノトランスフェラーゼ増加	0	3 (1.0)	0	3 (0.4)
アスパラギン酸アミノトランスフェラーゼ増加	0	4 (1.3)	0	4 (0.5)
抱合ビリルビン増加	0	1 (0.3)	0	1 (0.1)
血中ビリルビン増加	0	1 (0.3)	0	1 (0.1)
血中コレステロール増加	0	0	1 (0.7)	1 (0.1)
血中クレアチニン増加	1 (0.3)	0	0	1 (0.1)
血中トリグリセリド増加	0	0	1 (0.7)	1 (0.1)
肝機能検査値上昇	2 (0.7)	0	0	2 (0.3)
好中球数減少	1 (0.3)	1 (0.3)	0	2 (0.3)
白血球数減少	1 (0.3)	3 (1.0)	2 (1.3)	6 (0.8)
代謝および栄養障害	5 (1.7)	1 (0.3)	0	6 (0.8)
食欲減退	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-8. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（主試験安全性解析対象集団，M14-033 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
代謝および栄養障害 (Cont.)				
コントロール不良の糖尿病	1 (0.3)	0	0	1 (0.1)
高コレステロール血症	1 (0.3)	0	0	1 (0.1)
高トリグリセリド血症	1 (0.3)	0	0	1 (0.1)
低カリウム血症	0	1 (0.3)	0	1 (0.1)
低リン酸血症	1 (0.3)	0	0	1 (0.1)
筋骨格系および結合組織障害	11 (3.6)	16 (5.3)	3 (2.0)	30 (4.0)
関節痛	9 (3.0)	10 (3.3)	2 (1.3)	21 (2.8)
関節炎	0	1 (0.3)	0	1 (0.1)
デュプイトラン拘縮	0	1 (0.3)	0	1 (0.1)
関節硬直	1 (0.3)	0	0	1 (0.1)
関節腫脹	0	1 (0.3)	0	1 (0.1)
筋痙縮	0	1 (0.3)	0	1 (0.1)
筋骨格系胸痛	0	1 (0.3)	0	1 (0.1)
筋肉痛	0	1 (0.3)	1 (0.7)	2 (0.3)
筋炎	1 (0.3)	0	0	1 (0.1)
骨減少症	0	1 (0.3)	0	1 (0.1)
四肢痛	2 (0.7)	3 (1.0)	0	5 (0.7)
腱痛	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-8. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（主試験安全性解析対象集団，M14-033 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0	5 (1.6)	0	5 (0.7)
アクロコルドン	0	2 (0.7)	0	2 (0.3)
肛門性器疣贅	0	1 (0.3)	0	1 (0.1)
基底細胞癌	0	1 (0.3)	0	1 (0.1)
線維腫症	0	1 (0.3)	0	1 (0.1)
神経系障害	3 (1.0)	12 (3.9)	6 (4.0)	21 (2.8)
健忘	0	0	1 (0.7)	1 (0.1)
慢性炎症性脱髄性多発根ニューロパチー	0	0	1 (0.7)	1 (0.1)
注意力障害	0	1 (0.3)	0	1 (0.1)
浮動性めまい	2 (0.7)	2 (0.7)	1 (0.7)	5 (0.7)
体位性めまい	0	1 (0.3)	0	1 (0.1)
頭部不快感	0	1 (0.3)	0	1 (0.1)
頭痛	0	8 (2.6)	3 (2.0)	11 (1.5)
感覚鈍麻	0	2 (0.7)	0	2 (0.3)
単ニューロパチー	0	1 (0.3)	0	1 (0.1)
錯感覚	1 (0.3)	1 (0.3)	0	2 (0.3)

表 2.7.4.7-8. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（主試験安全性解析対象集団，M14-033 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
精神障害	0	2 (0.7)	0	2 (0.3)
激越	0	1 (0.3)	0	1 (0.1)
うつ病	0	1 (0.3)	0	1 (0.1)
腎および尿路障害	2 (0.7)	0	1 (0.7)	3 (0.4)
腎結石症	1 (0.3)	0	0	1 (0.1)
ネフローゼ症候群	1 (0.3)	0	0	1 (0.1)
尿閉	0	0	1 (0.7)	1 (0.1)
生殖系および乳房障害	1 (0.3)	0	0	1 (0.1)
バルトリン嚢腫	1 (0.3)	0	0	1 (0.1)
呼吸器、胸郭および縦隔障害	5 (1.7)	11 (3.6)	5 (3.3)	21 (2.8)
咳嗽	3 (1.0)	4 (1.3)	0	7 (0.9)
呼吸困難	1 (0.3)	1 (0.3)	0	2 (0.3)
肺気腫	0	1 (0.3)	0	1 (0.1)
鼻出血	0	1 (0.3)	0	1 (0.1)
鼻閉	0	0	1 (0.7)	1 (0.1)
口腔咽頭痛	0	3 (1.0)	3 (2.0)	6 (0.8)
湿性咳嗽	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-8. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（主試験安全性解析対象集団，M14-033 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)				
鼻痛	1 (0.3)	0	0	1 (0.1)
鼻漏	0	1 (0.3)	1 (0.7)	2 (0.3)
喘鳴	0	1 (0.3)	0	1 (0.1)
皮膚および皮下組織障害	20 (6.6)	31 (10.2)	13 (8.6)	64 (8.5)
ざ瘡	2 (0.7)	2 (0.7)	2 (1.3)	6 (0.8)
脱毛症	2 (0.7)	6 (2.0)	3 (2.0)	11 (1.5)
皮膚炎	0	1 (0.3)	0	1 (0.1)
アトピー性皮膚炎	0	1 (0.3)	0	1 (0.1)
接触皮膚炎	0	1 (0.3)	0	1 (0.1)
薬疹	0	1 (0.3)	0	1 (0.1)
皮膚乾燥	1 (0.3)	2 (0.7)	0	3 (0.4)
湿疹	1 (0.3)	3 (1.0)	1 (0.7)	5 (0.7)
紅斑	2 (0.7)	2 (0.7)	2 (1.3)	6 (0.8)
結節性紅斑	1 (0.3)	0	0	1 (0.1)
剥脱性発疹	1 (0.3)	0	0	1 (0.1)
扁平苔癬	0	0	1 (0.7)	1 (0.1)
リニアIgA病	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-8. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）（主試験安全性解析対象集団，M14-033 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
皮膚および皮下組織障害 (Cont.)				
寝汗	0	1 (0.3)	0	1 (0.1)
類天疱瘡	0	0	1 (0.7)	1 (0.1)
そう痒症	2 (0.7)	5 (1.6)	0	7 (0.9)
乾癬	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
発疹	6 (2.0)	10 (3.3)	4 (2.6)	20 (2.6)
紅斑性皮疹	0	1 (0.3)	0	1 (0.1)
丘疹性皮疹	0	1 (0.3)	0	1 (0.1)
皮膚病変	2 (0.7)	1 (0.3)	1 (0.7)	4 (0.5)
角層下膿疱性皮膚症	0	1 (0.3)	0	1 (0.1)
蕁麻疹	0	2 (0.7)	0	2 (0.3)
血管障害	1 (0.3)	3 (1.0)	0	4 (0.5)
血腫	0	1 (0.3)	0	1 (0.1)
高血圧	1 (0.3)	2 (0.7)	0	3 (0.4)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
Treatment-emergent adverse events during the maintenance study are defined as events that begin or worsen either on or after the first dose of the study drug in the maintenance study and within 70 days after the last dose of the study drug.
Event with unknown relationship to study drug is being counted as drug-related.

Cross reference: M14-033 Maintenance Main-study Final CSR Table 14.3__1.6

表 2.7.4.7-9. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）
（日本人安全性解析対象集団及び統合安全性解析対象集団，M14-033 日本サブ試験の維持療法試験）

MedDRA 22.0 System Organ Class Preferred Term	Japan Safety Set Adalimumab 40mg EOW (N=43) n (%)	Japan Safety Set Adalimumab 40mg EW (N=46) n (%)	Japan Safety Set Total (N=89) n (%)	Integrated Safety Set Adalimumab 40mg EOW (N=345) n (%)	Integrated Safety Set Adalimumab 40mg EW (N=350) n (%)	Integrated Safety Set TDM Regimen (N=151) n (%)	Integrated Safety Set Total (N=846) n (%)
Any Adverse Event	7 (16.3)	13 (28.3)	20 (22.5)	89 (25.8)	117 (33.4)	49 (32.5)	255 (30.1)
血液およびリンパ系障害	0	0	0	3 (0.9)	6 (1.7)	4 (2.6)	13 (1.5)
貧血	0	0	0	0	1 (0.3)	0	1 (0.1)
白血球減少症	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)
リンパ節症	0	0	0	0	2 (0.6)	1 (0.7)	3 (0.4)
リンパ球減少症	0	0	0	0	0	1 (0.7)	1 (0.1)
好中球減少症	0	0	0	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
血小板減少症	0	0	0	1 (0.3)	0	1 (0.7)	2 (0.2)
血小板増加症	0	0	0	1 (0.3)	0	0	1 (0.1)
耳および迷路障害	0	0	0	4 (1.2)	0	0	4 (0.5)
耳鳴	0	0	0	2 (0.6)	0	0	2 (0.2)
回転性めまい	0	0	0	2 (0.6)	0	0	2 (0.2)
眼障害	0	0	0	3 (0.9)	3 (0.9)	0	6 (0.7)
ドライアイ	0	0	0	0	1 (0.3)	0	1 (0.1)
眼の炎症	0	0	0	0	1 (0.3)	0	1 (0.1)
眼痛	0	0	0	1 (0.3)	0	0	1 (0.1)
眼瞼縁痂皮	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-9. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）
（日本人安全性解析対象集団及び統合安全性解析対象集団，M14-033 日本サブ試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	Japan Safety Set Adalimumab 40mg EOW (N=43) n (%)	Japan Safety Set Adalimumab 40mg EW (N=46) n (%)	Japan Safety Set Adalimumab Total (N=89) n (%)	Integrated Safety Set Adalimumab 40mg EOW (N=345) n (%)	Integrated Safety Set Adalimumab 40mg EW (N=350) n (%)	Integrated Safety Set Adalimumab TDM Regimen (N=151) n (%)	Integrated Safety Set Adalimumab Total (N=846) n (%)
眼障害 (Cont.)							
眼瞼下垂	0	0	0	0	1 (0.3)	0	1 (0.1)
視神経萎縮	0	0	0	1 (0.3)	0	0	1 (0.1)
視力障害	0	0	0	1 (0.3)	0	0	1 (0.1)
胃腸障害	1 (2.3)	1 (2.2)	2 (2.2)	10 (2.9)	14 (4.0)	7 (4.6)	31 (3.7)
腹部膨満	0	0	0	2 (0.6)	0	0	2 (0.2)
腹痛	0	0	0	0	1 (0.3)	0	1 (0.1)
上腹部痛	0	0	0	1 (0.3)	0	0	1 (0.1)
裂肛	0	0	0	0	1 (0.3)	0	1 (0.1)
肛門そう痒症	0	0	0	0	0	1 (0.7)	1 (0.1)
アフタ性潰瘍	0	0	0	0	0	1 (0.7)	1 (0.1)
潰瘍性大腸炎	0	0	0	3 (0.9)	6 (1.7)	3 (2.0)	12 (1.4)
クローン病	0	0	0	0	1 (0.3)	0	1 (0.1)
下痢	0	0	0	2 (0.6)	0	0	2 (0.2)
口内乾燥	0	0	0	0	1 (0.3)	0	1 (0.1)
鼓腸	0	0	0	0	0	1 (0.7)	1 (0.1)
歯肉出血	0	0	0	0	1 (0.3)	0	1 (0.1)
舌炎	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-9. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）
（日本人安全性解析対象集団及び統合安全性解析対象集団，M14-033 日本サブ試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	Japan Safety Set Adalimumab 40mg EOW (N=43) n (%)	Japan Safety Set Adalimumab 40mg EW (N=46) n (%)	Japan Safety Set Adalimumab Total (N=89) n (%)	Integrated Safety Set Adalimumab 40mg EOW (N=345) n (%)	Integrated Safety Set Adalimumab 40mg EW (N=350) n (%)	Integrated Safety Set Adalimumab TDM Regimen (N=151) n (%)	Integrated Safety Set Adalimumab Total (N=846) n (%)
胃腸障害 (Cont.)							
血便排泄	0	0	0	1 (0.3)	0	0	1 (0.1)
痔核	0	0	0	0	1 (0.3)	0	1 (0.1)
粘液便	0	0	0	1 (0.3)	0	0	1 (0.1)
悪心	1 (2.3)	0	1 (1.1)	3 (0.9)	1 (0.3)	1 (0.7)	5 (0.6)
急性膵炎	0	0	0	1 (0.3)	0	0	1 (0.1)
肛門周囲痛	0	0	0	1 (0.3)	0	0	1 (0.1)
直腸出血	0	0	0	1 (0.3)	0	0	1 (0.1)
歯痛	0	0	0	0	2 (0.6)	0	2 (0.2)
一般・全身障害および投与部位の状態	1 (2.3)	1 (2.2)	2 (2.2)	15 (4.3)	27 (7.7)	6 (4.0)	48 (5.7)
無力症	0	0	0	3 (0.9)	4 (1.1)	0	7 (0.8)
嚢胞	0	0	0	1 (0.3)	0	0	1 (0.1)
薬物相互作用	0	0	0	0	1 (0.3)	0	1 (0.1)
異形成	0	0	0	0	0	1 (0.7)	1 (0.1)
疲労	0	0	0	2 (0.6)	2 (0.6)	0	4 (0.5)
高熱	0	0	0	0	0	1 (0.7)	1 (0.1)
インフルエンザ様疾患	0	0	0	0	2 (0.6)	0	2 (0.2)
注入部位紅斑	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-9. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）
（日本人安全性解析対象集団及び統合安全性解析対象集団，M14-033 日本サブ試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	Japan Safety Set Adalimumab 40mg EOW (N=43) n (%)	Japan Safety Set Adalimumab 40mg EW (N=46) n (%)	Japan Safety Set Adalimumab Total (N=89) n (%)	Integrated Safety Set Adalimumab 40mg EOW (N=345) n (%)	Integrated Safety Set Adalimumab 40mg EW (N=350) n (%)	Integrated Safety Set Adalimumab TDM Regimen (N=151) n (%)	Integrated Safety Set Adalimumab Total (N=846) n (%)
一般・全身障害および投与部位の状態 (Cont.)							
注入部位そう痒感	0	0	0	0	1 (0.3)	0	1 (0.1)
注射部位紅斑	0	0	0	3 (0.9)	2 (0.6)	1 (0.7)	6 (0.7)
注射部位過敏反応	0	0	0	0	1 (0.3)	0	1 (0.1)
注射部位硬結	0	0	0	1 (0.3)	0	0	1 (0.1)
注射部位炎症	0	0	0	0	2 (0.6)	0	2 (0.2)
注射部位結節	0	0	0	1 (0.3)	0	0	1 (0.1)
注射部位疼痛	0	0	0	2 (0.6)	1 (0.3)	0	3 (0.4)
注射部位そう痒感	0	0	0	0	2 (0.6)	1 (0.7)	3 (0.4)
注射部位発疹	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)
注射部位反応	0	1 (2.2)	1 (1.1)	2 (0.6)	3 (0.9)	3 (2.0)	8 (0.9)
注射部位腫脹	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)
限局性浮腫	0	0	0	1 (0.3)	0	0	1 (0.1)
浮腫	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
末梢腫脹	0	0	0	0	1 (0.3)	0	1 (0.1)
発熱	0	0	0	0	4 (1.1)	0	4 (0.5)
腫脹	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-9. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）
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肝胆道系障害	1 (2.3)	0	1 (1.1)	3 (0.9)	1 (0.3)	4 (2.6)	8 (0.9)
肝胆道系疾患	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
高トランスアミナーゼ血症	0	0	0	1 (0.3)	1 (0.3)	4 (2.6)	6 (0.7)
非アルコール性脂肪性肝炎	0	0	0	1 (0.3)	0	0	1 (0.1)
感染症および寄生虫症	3 (7.0)	4 (8.7)	7 (7.9)	34 (9.9)	40 (11.4)	20 (13.2)	94 (11.1)
四肢膿瘍	0	0	0	0	2 (0.6)	0	2 (0.2)
急性副鼻腔炎	0	0	0	0	1 (0.3)	0	1 (0.1)
細菌性膣症	0	0	0	0	1 (0.3)	0	1 (0.1)
カンジダ感染	0	0	0	0	1 (0.3)	0	1 (0.1)
蜂巣炎	0	0	0	0	0	1 (0.7)	1 (0.1)
クロストリジウム・ディフィシレ感染	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)
結膜炎	0	0	0	0	0	2 (1.3)	2 (0.2)
膀胱炎	0	2 (4.3)	2 (2.2)	1 (0.3)	2 (0.6)	2 (1.3)	5 (0.6)
サイトメガロウイルス感染	0	0	0	1 (0.3)	0	0	1 (0.1)
耳感染	0	0	0	2 (0.6)	0	0	2 (0.2)
エプスタイン・バーウイルス感染	0	0	0	1 (0.3)	0	0	1 (0.1)
外耳蜂巣炎	0	0	0	1 (0.3)	0	0	1 (0.1)
毛包炎	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-9. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）
（日本人安全性解析対象集団及び統合安全性解析対象集団，M14-033 日本サブ試験の維持療法試験）（続き）

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感染症および寄生虫症 (Cont.)							
真菌感染	0	0	0	1 (0.3)	0	0	1 (0.1)
皮膚真菌感染	0	0	0	1 (0.3)	0	1 (0.7)	2 (0.2)
胃腸炎	0	0	0	0	1 (0.3)	0	1 (0.1)
性器カンジダ症	0	0	0	0	1 (0.3)	0	1 (0.1)
歯肉膿瘍	0	0	0	0	1 (0.3)	0	1 (0.1)
ヘルペス眼感染	0	0	0	0	1 (0.3)	0	1 (0.1)
帯状疱疹	0	0	0	3 (0.9)	2 (0.6)	1 (0.7)	6 (0.7)
麦粒腫	0	0	0	0	1 (0.3)	0	1 (0.1)
インフルエンザ	1 (2.3)	1 (2.2)	2 (2.2)	2 (0.6)	6 (1.7)	1 (0.7)	9 (1.1)
下気道感染	0	0	0	0	0	1 (0.7)	1 (0.1)
鼓膜炎	0	0	0	0	0	1 (0.7)	1 (0.1)
上咽頭炎	0	1 (2.2)	1 (1.1)	6 (1.7)	10 (2.9)	5 (3.3)	21 (2.5)
口腔カンジダ症	1 (2.3)	0	1 (1.1)	2 (0.6)	0	0	2 (0.2)
口腔真菌感染	0	0	0	0	1 (0.3)	0	1 (0.1)
口腔ヘルペス	0	0	0	0	2 (0.6)	0	2 (0.2)
外耳炎	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
急性中耳炎	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-9. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）
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感染症および寄生虫症 (Cont.)							
咽頭炎	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
レンサ球菌性咽頭炎	0	0	0	1 (0.3)	0	0	1 (0.1)
肺炎	1 (2.3)	0	1 (1.1)	2 (0.6)	3 (0.9)	1 (0.7)	6 (0.7)
腎盂腎炎	0	0	0	0	0	1 (0.7)	1 (0.1)
急性腎盂腎炎	0	0	0	0	1 (0.3)	0	1 (0.1)
膿疱性皮疹	0	0	0	2 (0.6)	0	0	2 (0.2)
鼻炎	0	0	0	1 (0.3)	0	0	1 (0.1)
敗血症	0	0	0	0	0	1 (0.7)	1 (0.1)
副鼻腔炎	0	0	0	1 (0.3)	2 (0.6)	2 (1.3)	5 (0.6)
皮膚感染	0	0	0	0	1 (0.3)	0	1 (0.1)
扁桃炎	0	0	0	0	3 (0.9)	1 (0.7)	4 (0.5)
歯膿瘍	0	0	0	1 (0.3)	0	0	1 (0.1)
歯感染	0	0	0	0	1 (0.3)	0	1 (0.1)
結核	0	0	0	0	1 (0.3)	0	1 (0.1)
上気道感染	0	0	0	7 (2.0)	4 (1.1)	3 (2.0)	14 (1.7)
尿路感染	0	0	0	1 (0.3)	1 (0.3)	2 (1.3)	4 (0.5)
膣感染	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-9. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）
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感染症および寄生虫症 (Cont.)							
ウイルス感染	0	0	0	0	1 (0.3)	0	1 (0.1)
ウイルス性咽頭炎	0	0	0	0	2 (0.6)	0	2 (0.2)
外陰部腟カンジダ症	0	0	0	0	1 (0.3)	0	1 (0.1)
外陰腟真菌感染	0	0	0	0	1 (0.3)	0	1 (0.1)
外陰腟炎	0	0	0	0	0	1 (0.7)	1 (0.1)
傷害、中毒および処置合併症	0	1 (2.2)	1 (1.1)	0	1 (0.3)	1 (0.7)	2 (0.2)
注射に伴う反応	0	1 (2.2)	1 (1.1)	0	1 (0.3)	1 (0.7)	2 (0.2)
臨床検査	0	0	0	5 (1.4)	8 (2.3)	3 (2.0)	16 (1.9)
アラニンアミノトランスフェラーゼ増加	0	0	0	0	3 (0.9)	0	3 (0.4)
アスパラギン酸アミノトランスフェラーゼ増加	0	0	0	0	4 (1.1)	0	4 (0.5)
抱合ビリルビン増加	0	0	0	0	1 (0.3)	0	1 (0.1)
血中ビリルビン増加	0	0	0	0	1 (0.3)	0	1 (0.1)
血中コレステロール増加	0	0	0	0	0	1 (0.7)	1 (0.1)
血中クレアチニン増加	0	0	0	1 (0.3)	0	0	1 (0.1)
血中トリグリセリド増加	0	0	0	0	0	1 (0.7)	1 (0.1)
肝機能検査値上昇	0	0	0	2 (0.6)	0	0	2 (0.2)
好中球数減少	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
白血球数減少	0	0	0	1 (0.3)	3 (0.9)	2 (1.3)	6 (0.7)

表 2.7.4.7-9. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）
（日本人安全性解析対象集団及び統合安全性解析対象集団，M14-033 日本サブ試験の維持療法試験）（続き）

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代謝および栄養障害	0	0	0	5 (1.4)	1 (0.3)	0	6 (0.7)
食欲減退	0	0	0	1 (0.3)	0	0	1 (0.1)
コントロール不良の糖尿病	0	0	0	1 (0.3)	0	0	1 (0.1)
高コレステロール血症	0	0	0	1 (0.3)	0	0	1 (0.1)
高トリグリセリド血症	0	0	0	1 (0.3)	0	0	1 (0.1)
低カリウム血症	0	0	0	0	1 (0.3)	0	1 (0.1)
低リン酸血症	0	0	0	1 (0.3)	0	0	1 (0.1)
筋骨格系および結合組織障害	1 (2.3)	1 (2.2)	2 (2.2)	12 (3.5)	17 (4.9)	3 (2.0)	32 (3.8)
関節痛	0	0	0	9 (2.6)	10 (2.9)	2 (1.3)	21 (2.5)
関節炎	0	0	0	0	1 (0.3)	0	1 (0.1)
デュプイトラン拘縮	0	0	0	0	1 (0.3)	0	1 (0.1)
関節硬直	0	0	0	1 (0.3)	0	0	1 (0.1)
関節腫脹	0	0	0	0	1 (0.3)	0	1 (0.1)
ループス様症候群	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)
筋痙縮	0	0	0	0	1 (0.3)	0	1 (0.1)
筋骨格系胸痛	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-9. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）
（日本人安全性解析対象集団及び統合安全性解析対象集団，M14-033 日本サブ試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	Japan Safety Set Adalimumab 40mg EOW (N=43) n (%)	Japan Safety Set Adalimumab 40mg EW (N=46) n (%)	Japan Safety Set Adalimumab Total (N=89) n (%)	Integrated Safety Set Adalimumab 40mg EOW (N=345) n (%)	Integrated Safety Set Adalimumab 40mg EW (N=350) n (%)	Integrated Safety Set Adalimumab TDM Regimen (N=151) n (%)	Integrated Safety Set Adalimumab Total (N=846) n (%)
筋骨格系および結合組織障害 (Cont.)							
筋肉痛	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
筋炎	0	0	0	1 (0.3)	0	0	1 (0.1)
骨減少症	0	0	0	0	1 (0.3)	0	1 (0.1)
骨粗鬆症	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
四肢痛	0	0	0	2 (0.6)	3 (0.9)	0	5 (0.6)
腱痛	0	0	0	0	1 (0.3)	0	1 (0.1)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0	0	0	0	5 (1.4)	0	5 (0.6)
アクロコルドン	0	0	0	0	2 (0.6)	0	2 (0.2)
肛門性器疣贅	0	0	0	0	1 (0.3)	0	1 (0.1)
基底細胞癌	0	0	0	0	1 (0.3)	0	1 (0.1)
線維腫症	0	0	0	0	1 (0.3)	0	1 (0.1)
神経系障害	1 (2.3)	1 (2.2)	2 (2.2)	4 (1.2)	13 (3.7)	6 (4.0)	23 (2.7)
意識変容状態	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
健忘	0	1 (2.2)	1 (1.1)	0	1 (0.3)	1 (0.7)	2 (0.2)
慢性炎症性脱髄性多発根ニューロパチー	0	0	0	0	0	1 (0.7)	1 (0.1)
注意力障害	0	0	0	0	1 (0.3)	0	1 (0.1)
浮動性めまい	0	0	0	2 (0.6)	2 (0.6)	1 (0.7)	5 (0.6)

表 2.7.4.7-9. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）
（日本人安全性解析対象集団及び統合安全性解析対象集団，M14-033 日本サブ試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	Japan Safety Set Adalimumab 40mg EOW (N=43) n (%)	Japan Safety Set Adalimumab 40mg EW (N=46) n (%)	Japan Safety Set Adalimumab Total (N=89) n (%)	Integrated Safety Set Adalimumab 40mg EOW (N=345) n (%)	Integrated Safety Set Adalimumab 40mg EW (N=350) n (%)	Integrated Safety Set Adalimumab TDM Regimen (N=151) n (%)	Integrated Safety Set Adalimumab Total (N=846) n (%)
神経系障害 (Cont.)							
体位性めまい	0	0	0	0	1 (0.3)	0	1 (0.1)
頭部不快感	0	0	0	0	1 (0.3)	0	1 (0.1)
頭痛	0	0	0	0	8 (2.3)	3 (2.0)	11 (1.3)
感覚鈍麻	0	0	0	0	2 (0.6)	0	2 (0.2)
単ニューロパチー	0	0	0	0	1 (0.3)	0	1 (0.1)
錯感覚	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
精神障害	1 (2.3)	1 (2.2)	2 (2.2)	1 (0.3)	3 (0.9)	0	4 (0.5)
激越	0	0	0	0	1 (0.3)	0	1 (0.1)
うつ病	0	0	0	0	1 (0.3)	0	1 (0.1)
不眠症	1 (2.3)	1 (2.2)	2 (2.2)	1 (0.3)	1 (0.3)	0	2 (0.2)
腎および尿路障害	0	0	0	2 (0.6)	0	1 (0.7)	3 (0.4)
腎結石症	0	0	0	1 (0.3)	0	0	1 (0.1)
ネフローゼ症候群	0	0	0	1 (0.3)	0	0	1 (0.1)
尿閉	0	0	0	0	0	1 (0.7)	1 (0.1)
生殖系および乳房障害	0	0	0	1 (0.3)	0	0	1 (0.1)
バルトリン嚢腫	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-9. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）
（日本人安全性解析対象集団及び統合安全性解析対象集団，M14-033 日本サブ試験の維持療法試験）（続き）

	Japan Safety Set			Integrated Safety Set			
	Adalimumab			Adalimumab			
MedDRA 22.0 System Organ Class Preferred Term	40mg EOW (N=43) n (%)	40mg EW (N=46) n (%)	Total (N=89) n (%)	40mg EOW (N=345) n (%)	40mg EW (N=350) n (%)	TDM Regimen (N=151) n (%)	Total (N=846) n (%)
呼吸器、胸郭および縦隔障害	0	0	0	5 (1.4)	11 (3.1)	5 (3.3)	21 (2.5)
咳嗽	0	0	0	3 (0.9)	4 (1.1)	0	7 (0.8)
呼吸困難	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
肺気腫	0	0	0	0	1 (0.3)	0	1 (0.1)
鼻出血	0	0	0	0	1 (0.3)	0	1 (0.1)
鼻閉	0	0	0	0	0	1 (0.7)	1 (0.1)
口腔咽頭痛	0	0	0	0	3 (0.9)	3 (2.0)	6 (0.7)
湿性咳嗽	0	0	0	0	1 (0.3)	0	1 (0.1)
鼻痛	0	0	0	1 (0.3)	0	0	1 (0.1)
鼻漏	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
喘鳴	0	0	0	0	1 (0.3)	0	1 (0.1)
皮膚および皮下組織障害	2 (4.7)	3 (6.5)	5 (5.6)	22 (6.4)	34 (9.7)	13 (8.6)	69 (8.2)
ざ瘡	0	0	0	2 (0.6)	2 (0.6)	2 (1.3)	6 (0.7)
脱毛症	0	0	0	2 (0.6)	6 (1.7)	3 (2.0)	11 (1.3)
皮膚炎	0	0	0	0	1 (0.3)	0	1 (0.1)
アトピー性皮膚炎	0	0	0	0	1 (0.3)	0	1 (0.1)
接触皮膚炎	0	0	0	0	1 (0.3)	0	1 (0.1)
薬疹	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-9. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）
（日本人安全性解析対象集団及び統合安全性解析対象集団，M14-033 日本サブ試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	Japan Safety Set Adalimumab 40mg EOW (N=43) n (%)	Japan Safety Set Adalimumab 40mg EW (N=46) n (%)	Japan Safety Set Adalimumab Total (N=89) n (%)	Integrated Safety Set Adalimumab 40mg EOW (N=345) n (%)	Integrated Safety Set Adalimumab 40mg EW (N=350) n (%)	Integrated Safety Set Adalimumab TDM Regimen (N=151) n (%)	Integrated Safety Set Adalimumab Total (N=846) n (%)
皮膚および皮下組織障害 (Cont.)							
皮膚乾燥	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)
湿疹	0	1 (2.2)	1 (1.1)	1 (0.3)	4 (1.1)	1 (0.7)	6 (0.7)
紅斑	0	0	0	2 (0.6)	2 (0.6)	2 (1.3)	6 (0.7)
結節性紅斑	0	0	0	1 (0.3)	0	0	1 (0.1)
剥脱性発疹	0	0	0	1 (0.3)	0	0	1 (0.1)
過角化	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
扁平苔癬	0	0	0	0	0	1 (0.7)	1 (0.1)
リニアIgA病	0	0	0	1 (0.3)	0	0	1 (0.1)
寝汗	0	0	0	0	1 (0.3)	0	1 (0.1)
類天疱瘡	0	0	0	0	0	1 (0.7)	1 (0.1)
そう痒症	0	0	0	2 (0.6)	5 (1.4)	0	7 (0.8)
乾癬	0	0	0	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
発疹	1 (2.3)	1 (2.2)	2 (2.2)	7 (2.0)	11 (3.1)	4 (2.6)	22 (2.6)
紅斑性皮疹	0	0	0	0	1 (0.3)	0	1 (0.1)
丘疹性皮疹	0	0	0	0	1 (0.3)	0	1 (0.1)
皮膚病変	0	0	0	2 (0.6)	1 (0.3)	1 (0.7)	4 (0.5)
角層下膿疱性皮膚症	0	0	0	0	1 (0.3)	0	1 (0.1)
蕁麻疹	0	1 (2.2)	1 (1.1)	0	3 (0.9)	0	3 (0.4)

表 2.7.4.7-9. 治験薬と関連ありの有害事象（MedDRA SOC 及び PT 別）
（日本人安全性解析対象集団及び統合安全性解析対象集団，M14-033 日本サブ試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	Japan Safety Set Adalimumab 40mg EOW (N=43) n (%)	Japan Safety Set Adalimumab 40mg EW (N=46) n (%)	Japan Safety Set Adalimumab Total (N=89) n (%)	Integrated Safety Set Adalimumab 40mg EOW (N=345) n (%)	Integrated Safety Set Adalimumab 40mg EW (N=350) n (%)	Integrated Safety Set Adalimumab TDM Regimen (N=151) n (%)	Integrated Safety Set Adalimumab Total (N=846) n (%)
血管障害	0	0	0	1 (0.3)	3 (0.9)	0	4 (0.5)
血腫	0	0	0	0	1 (0.3)	0	1 (0.1)
高血圧	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)

Note: The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total. A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
Treatment-emergent adverse events during the maintenance study are defined as events that begin or worsen either on or after the first dose of the study drug in the maintenance study and within 70 days after the last dose of the study drug.
Event with unknown relationship to study drug is being counted as drug-related.

Cross reference: M14-033 Maintenance Japan Sub-study Final CSR Table 14.3__1.6_J

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
ANY ADVERSE EVENT	184 (54.1)	271 (52.9)	455 (53.4)
MILD	91	136	227
MODERATE	77	112	189
SEVERE	16	23	39
血液およびリンパ系障害			
貧血	13 (3.8)	16 (3.1)	29 (3.4)
MILD	4	6	10
MODERATE	6	8	14
SEVERE	3	2	5
鉄欠乏性貧血	1 (0.3)	0	1 (0.1)
MILD	1	0	1
白血球減少症	1 (0.3)	3 (0.6)	4 (0.5)
MILD	1	1	2
MODERATE	0	2	2
リンパ節症	2 (0.6)	2 (0.4)	4 (0.5)
MILD	1	2	3
MODERATE	1	0	1

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
リンパ球減少症	1 (0.3)	1 (0.2)	2 (0.2)
MILD	1	1	2
好中球減少症	1 (0.3)	0	1 (0.1)
MODERATE	1	0	1
血小板減少症	0	2 (0.4)	2 (0.2)
MILD	0	1	1
MODERATE	0	1	1
SUBJECTS WITH ONE OR MORE EVENTS	19 (5.6)	24 (4.7)	43 (5.0)
MILD	8	11	19
MODERATE	8	11	19
SEVERE	3	2	5
心臓障害			
心停止	0	1 (0.2)	1 (0.1)
SEVERE	0	1	1

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
動悸	1 (0.3)	1 (0.2)	2 (0.2)
MILD	1	0	1
MODERATE	0	1	1
SUBJECTS WITH ONE OR MORE EVENTS	1 (0.3)	2 (0.4)	3 (0.4)
MILD	1	0	1
MODERATE	0	1	1
SEVERE	0	1	1
先天性、家族性および遺伝性障害			
エーラース・ダンロス症候群	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
包皮小帯	0	1 (0.2)	1 (0.1)
MILD	0	1	1
SUBJECTS WITH ONE OR MORE EVENTS	0	2 (0.4)	2 (0.2)
MILD	0	1	1
MODERATE	0	1	1

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
耳および迷路障害			
聴力低下	0	1 (0.2)	1 (0.1)
MILD	0	1	1
耳鳴	1 (0.3)	0	1 (0.1)
MILD	1	0	1
回転性めまい	1 (0.3)	0	1 (0.1)
MODERATE	1	0	1
SUBJECTS WITH ONE OR MORE EVENTS	2 (0.6)	1 (0.2)	3 (0.4)
MILD	1	1	2
MODERATE	1	0	1
内分泌障害			
ステロイド離脱症候群	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
眼障害			
眼瞼痙攣	0	1 (0.2)	1 (0.1)
MILD	0	1	1
後天性涙道狭窄	0	1 (0.2)	1 (0.1)
MILD	0	1	1
ドライアイ	2 (0.6)	1 (0.2)	3 (0.4)
MILD	0	1	1
MODERATE	2	0	2
眼瞼湿疹	1 (0.3)	0	1 (0.1)
MILD	1	0	1
上強膜炎	0	1 (0.2)	1 (0.1)
MILD	0	1	1
眼の障害	1 (0.3)	1 (0.2)	2 (0.2)
MILD	1	1	2

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

	ADALIMUMAB		
SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	STANDARD INDUCTION DOSE (N=340) n (%)	HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
眼痛	1 (0.3)	0	1 (0.1)
MODERATE	1	0	1
眼部腫脹	0	1 (0.2)	1 (0.1)
MILD	0	1	1
眼瞼浮腫	1 (0.3)	0	1 (0.1)
MILD	1	0	1
羞明	0	2 (0.4)	2 (0.2)
MILD	0	1	1
MODERATE	0	1	1
視力低下	1 (0.3)	0	1 (0.1)
MILD	1	0	1
SUBJECTS WITH ONE OR MORE EVENTS	7 (2.1)	8 (1.6)	15 (1.8)
MILD	4	7	11
MODERATE	3	1	4

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
胃腸障害			
腹部不快感	1 (0.3)	1 (0.2)	2 (0.2)
MILD	1	1	2
腹部膨満	3 (0.9)	1 (0.2)	4 (0.5)
MILD	3	0	3
MODERATE	0	1	1
腹痛	6 (1.8)	11 (2.1)	17 (2.0)
MILD	1	4	5
MODERATE	4	6	10
SEVERE	1	1	2
上腹部痛	3 (0.9)	4 (0.8)	7 (0.8)
MILD	2	2	4
MODERATE	1	2	3
腹部圧痛	0	2 (0.4)	2 (0.2)
MILD	0	1	1
SEVERE	0	1	1
裂肛	1 (0.3)	1 (0.2)	2 (0.2)
MILD	1	0	1
MODERATE	0	1	1

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
アフタ性潰瘍	3 (0.9)	1 (0.2)	4 (0.5)
MILD	3	1	4
根尖肉芽腫	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
大腸炎	3 (0.9)	2 (0.4)	5 (0.6)
MODERATE	3	2	5
潰瘍性大腸炎	30 (8.8)	29 (5.7)	59 (6.9)
MILD	6	1	7
MODERATE	15	16	31
SEVERE	9	12	21
便秘	1 (0.3)	2 (0.4)	3 (0.4)
MILD	1	2	3
便意切迫	1 (0.3)	0	1 (0.1)
MODERATE	1	0	1
下痢	5 (1.5)	12 (2.3)	17 (2.0)
MILD	3	7	10
MODERATE	1	3	4
SEVERE	1	2	3

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
消化不良	8 (2.4)	2 (0.4)	10 (1.2)
MILD	7	2	9
MODERATE	1	0	1
心窩部不快感	0	1 (0.2)	1 (0.1)
MILD	0	1	1
鼓腸	1 (0.3)	8 (1.6)	9 (1.1)
MILD	0	6	6
MODERATE	1	2	3
食中毒	1 (0.3)	1 (0.2)	2 (0.2)
MILD	1	1	2
胃食道逆流性疾患	1 (0.3)	3 (0.6)	4 (0.5)
MILD	0	3	3
MODERATE	1	0	1
歯肉出血	0	1 (0.2)	1 (0.1)
MILD	0	1	1
歯肉痛	0	1 (0.2)	1 (0.1)
MILD	0	1	1

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
血便排泄	1 (0.3)	0	1 (0.1)
MILD	1	0	1
痔核	2 (0.6)	5 (1.0)	7 (0.8)
MILD	2	4	6
MODERATE	0	1	1
血栓性痔核	1 (0.3)	3 (0.6)	4 (0.5)
MILD	0	1	1
MODERATE	1	1	2
SEVERE	0	1	1
歯の知覚過敏	1 (0.3)	0	1 (0.1)
MILD	1	0	1
大腸狭窄	0	1 (0.2)	1 (0.1)
SEVERE	0	1	1
悪心	9 (2.6)	17 (3.3)	26 (3.1)
MILD	7	11	18
MODERATE	2	6	8
嚥下痛	0	1 (0.2)	1 (0.1)
MILD	0	1	1

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
急性膵炎	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
肛門周囲痛	3 (0.9)	1 (0.2)	4 (0.5)
MODERATE	3	1	4
直腸出血	1 (0.3)	0	1 (0.1)
MILD	1	0	1
直腸しぶり	0	1 (0.2)	1 (0.1)
MILD	0	1	1
脂肪便	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
歯の障害	1 (0.3)	1 (0.2)	2 (0.2)
MILD	1	1	2
歯痛	1 (0.3)	2 (0.4)	3 (0.4)
MILD	0	2	2
MODERATE	1	0	1
臍ヘルニア	1 (0.3)	0	1 (0.1)
MODERATE	1	0	1

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
嘔吐	4 (1.2)	9 (1.8)	13 (1.5)
MILD	3	6	9
MODERATE	1	3	4
SUBJECTS WITH ONE OR MORE EVENTS	75 (22.1)	92 (18.0)	167 (19.6)
MILD	32	38	70
MODERATE	33	38	71
SEVERE	10	16	26
一般・全身障害および投与部位の状態			
投与部位疼痛	1 (0.3)	0	1 (0.1)
MILD	1	0	1
適用部位そう痒感	0	1 (0.2)	1 (0.1)
MILD	0	1	1
適用部位反応	0	1 (0.2)	1 (0.1)
MILD	0	1	1
無力症	6 (1.8)	8 (1.6)	14 (1.6)
MILD	5	6	11
MODERATE	1	2	3

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	ADALIMUMAB TOTAL (N=852) n (%)
腋窩痛	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
胸部不快感	1 (0.3)	0	1 (0.1)
MILD	1	0	1
胸痛	3 (0.9)	1 (0.2)	4 (0.5)
MILD	2	1	3
MODERATE	1	0	1
悪寒	2 (0.6)	1 (0.2)	3 (0.4)
MILD	2	1	3
不快感	0	1 (0.2)	1 (0.1)
MILD	0	1	1
疲労	9 (2.6)	13 (2.5)	22 (2.6)
MILD	6	10	16
MODERATE	3	3	6
異常感	2 (0.6)	0	2 (0.2)
MILD	2	0	2

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
冷感	1 (0.3)	1 (0.2)	2 (0.2)
MILD	1	1	2
体温変動感	0	1 (0.2)	1 (0.1)
MILD	0	1	1
炎症	1 (0.3)	0	1 (0.1)
MILD	1	0	1
インフルエンザ様疾患	2 (0.6)	0	2 (0.2)
MILD	1	0	1
MODERATE	1	0	1
注射部位内出血	3 (0.9)	4 (0.8)	7 (0.8)
MILD	2	4	6
MODERATE	1	0	1
注射部位紅斑	2 (0.6)	14 (2.7)	16 (1.9)
MILD	1	9	10
MODERATE	1	5	6
注射部位血腫	0	1 (0.2)	1 (0.1)
MILD	0	1	1

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
注射部位過敏反応	0	3 (0.6)	3 (0.4)
MILD	0	3	3
注射部位硬結	0	1 (0.2)	1 (0.1)
MILD	0	1	1
注射部位炎症	0	2 (0.4)	2 (0.2)
MILD	0	2	2
注射部位腫瘤	0	1 (0.2)	1 (0.1)
MILD	0	1	1
注射部位浮腫	0	1 (0.2)	1 (0.1)
MILD	0	1	1
注射部位疼痛	3 (0.9)	6 (1.2)	9 (1.1)
MILD	3	3	6
MODERATE	0	3	3
注射部位そう痒感	2 (0.6)	13 (2.5)	15 (1.8)
MILD	1	9	10
MODERATE	1	3	4
SEVERE	0	1	1

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
注射部位発疹	1 (0.3)	4 (0.8)	5 (0.6)
MILD	1	4	5
注射部位反応	1 (0.3)	19 (3.7)	20 (2.3)
MILD	1	16	17
MODERATE	0	2	2
SEVERE	0	1	1
注射部位腫脹	2 (0.6)	9 (1.8)	11 (1.3)
MILD	1	3	4
MODERATE	1	5	6
SEVERE	0	1	1
注射部位蕁麻疹	1 (0.3)	1 (0.2)	2 (0.2)
MILD	1	0	1
MODERATE	0	1	1
倦怠感	1 (0.3)	1 (0.2)	2 (0.2)
MILD	1	1	2
非心臓性胸痛	1 (0.3)	0	1 (0.1)
MODERATE	1	0	1

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
末梢性浮腫	0	2 (0.4)	2 (0.2)
MILD	0	2	2
疼痛	1 (0.3)	0	1 (0.1)
MODERATE	1	0	1
末梢腫脹	1 (0.3)	1 (0.2)	2 (0.2)
MILD	1	1	2
発熱	5 (1.5)	7 (1.4)	12 (1.4)
MILD	2	5	7
MODERATE	3	2	5
腫脹	1 (0.3)	0	1 (0.1)
MILD	1	0	1
SUBJECTS WITH ONE OR MORE EVENTS	39 (11.5)	89 (17.4)	128 (15.0)
MILD	28	66	94
MODERATE	11	21	32
SEVERE	0	2	2

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
肝胆道系障害			
肝病変	1 (0.3)	0	1 (0.1)
MILD	1	0	1
脂肪肝	0	1 (0.2)	1 (0.1)
MILD	0	1	1
肝炎	0	1 (0.2)	1 (0.1)
MILD	0	1	1
高トランスアミナーゼ血症	0	1 (0.2)	1 (0.1)
MILD	0	1	1
SUBJECTS WITH ONE OR MORE EVENTS	1 (0.3)	3 (0.6)	4 (0.5)
MILD	1	3	4
免疫系障害			
薬物過敏症	1 (0.3)	1 (0.2)	2 (0.2)
MILD	0	1	1
MODERATE	1	0	1

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
過敏症	1 (0.3)	2 (0.4)	3 (0.4)
MILD	1	2	3
季節性アレルギー	0	3 (0.6)	3 (0.4)
MILD	0	2	2
MODERATE	0	1	1
SUBJECTS WITH ONE OR MORE EVENTS	2 (0.6)	6 (1.2)	8 (0.9)
MILD	1	5	6
MODERATE	1	1	2
感染症および寄生虫症			
膿瘍	1 (0.3)	0	1 (0.1)
MILD	1	0	1
四肢膿瘍	1 (0.3)	1 (0.2)	2 (0.2)
MODERATE	1	1	2
肛門膿瘍	0	1 (0.2)	1 (0.1)
MILD	0	1	1

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
ブラストシスティス感染	0	1 (0.2)	1 (0.1)
MILD	0	1	1
気管支炎	1 (0.3)	1 (0.2)	2 (0.2)
MILD	1	0	1
MODERATE	0	1	1
ウイルス性気管支炎	1 (0.3)	0	1 (0.1)
MILD	1	0	1
カンジダ感染	0	1 (0.2)	1 (0.1)
MILD	0	1	1
蜂巣炎	1 (0.3)	0	1 (0.1)
MODERATE	1	0	1
クロストリジウム・ディフィシレ感染	0	2 (0.4)	2 (0.2)
MODERATE	0	2	2
結膜炎	1 (0.3)	1 (0.2)	2 (0.2)
MILD	1	1	2
膀胱炎	0	1 (0.2)	1 (0.1)
MILD	0	1	1

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
サイトメガロウイルス性大腸炎	0	1 (0.2)	1 (0.1)
SEVERE	0	1	1
耳感染	1 (0.3)	2 (0.4)	3 (0.4)
MODERATE	1	2	3
丹毒	1 (0.3)	0	1 (0.1)
MILD	1	0	1
毛包炎	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
真菌感染	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
胃腸炎	0	1 (0.2)	1 (0.1)
MILD	0	1	1
ウイルス性胃腸炎	1 (0.3)	2 (0.4)	3 (0.4)
MILD	1	1	2
MODERATE	0	1	1
ヘルペスウイルス感染	0	1 (0.2)	1 (0.1)
MILD	0	1	1

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
帯状疱疹	2 (0.6)	0	2 (0.2)
MILD	1	0	1
MODERATE	1	0	1
麦粒腫	0	1 (0.2)	1 (0.1)
MILD	0	1	1
膿痂疹	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
感染性嚢腫	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
感染	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
インフルエンザ	6 (1.8)	1 (0.2)	7 (0.8)
MILD	3	0	3
MODERATE	3	1	4
喉頭炎	1 (0.3)	0	1 (0.1)
MILD	1	0	1

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
限局性感染	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
上咽頭炎	14 (4.1)	19 (3.7)	33 (3.9)
MILD	11	13	24
MODERATE	2	6	8
SEVERE	1	0	1
食道カンジダ症	1 (0.3)	0	1 (0.1)
MODERATE	1	0	1
爪真菌症	0	1 (0.2)	1 (0.1)
MILD	0	1	1
口腔ヘルペス	2 (0.6)	2 (0.4)	4 (0.5)
MILD	1	2	3
MODERATE	1	0	1
中耳炎	1 (0.3)	0	1 (0.1)
MODERATE	1	0	1
咽頭炎	5 (1.5)	3 (0.6)	8 (0.9)
MILD	4	2	6
MODERATE	1	1	2

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
細菌性咽頭炎	1 (0.3)	0	1 (0.1)
MILD	1	0	1
レンサ球菌性咽頭炎	0	1 (0.2)	1 (0.1)
MILD	0	1	1
肺炎	2 (0.6)	1 (0.2)	3 (0.4)
MODERATE	2	0	2
SEVERE	0	1	1
腎盂腎炎	1 (0.3)	0	1 (0.1)
MODERATE	1	0	1
膿疱性皮疹	2 (0.6)	1 (0.2)	3 (0.4)
MILD	2	1	3
気道感染	0	1 (0.2)	1 (0.1)
MILD	0	1	1
鼻炎	3 (0.9)	2 (0.4)	5 (0.6)
MILD	3	2	5

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
副鼻腔炎	4 (1.2)	5 (1.0)	9 (1.1)
MILD	3	3	6
MODERATE	1	2	3
皮膚感染	0	1 (0.2)	1 (0.1)
MILD	0	1	1
白癬感染	0	2 (0.4)	2 (0.2)
MILD	0	2	2
歯感染	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
結核	0	1 (0.2)	1 (0.1)
SEVERE	0	1	1
上気道感染	3 (0.9)	6 (1.2)	9 (1.1)
MILD	1	5	6
MODERATE	2	1	3
尿路感染	5 (1.5)	6 (1.2)	11 (1.3)
MILD	5	3	8
MODERATE	0	3	3

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
腟感染	1 (0.3)	0	1 (0.1)
MILD	1	0	1
ウイルス感染	0	3 (0.6)	3 (0.4)
MILD	0	1	1
MODERATE	0	2	2
ウイルス性上気道感染	1 (0.3)	0	1 (0.1)
MILD	1	0	1
外陰部腟カンジダ症	1 (0.3)	2 (0.4)	3 (0.4)
MILD	1	1	2
MODERATE	0	1	1
外陰腟真菌感染	0	1 (0.2)	1 (0.1)
MILD	0	1	1
SUBJECTS WITH ONE OR MORE EVENTS	59 (17.4)	70 (13.7)	129 (15.1)
MILD	39	40	79
MODERATE	19	28	47
SEVERE	1	2	3

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
傷害、中毒および処置合併症			
動物による引っかき傷	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
節足動物咬傷	1 (0.3)	0	1 (0.1)
MODERATE	1	0	1
挫傷	2 (0.6)	4 (0.8)	6 (0.7)
MILD	1	4	5
MODERATE	1	0	1
角膜擦過傷	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
転倒	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
注入に伴う反応	1 (0.3)	0	1 (0.1)
MODERATE	1	0	1
注射に伴う反応	0	1 (0.2)	1 (0.1)
MILD	0	1	1

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
関節損傷	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
靭帯捻挫	0	1 (0.2)	1 (0.1)
MILD	0	1	1
四肢損傷	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
肉離れ	0	1 (0.2)	1 (0.1)
MILD	0	1	1
処置による疼痛	1 (0.3)	0	1 (0.1)
MILD	1	0	1
交通事故	1 (0.3)	1 (0.2)	2 (0.2)
MILD	1	0	1
MODERATE	0	1	1
皮膚擦過傷	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
脊柱損傷	0	1 (0.2)	1 (0.1)
MILD	0	1	1

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
スポーツ損傷	1 (0.3)	0	1 (0.1)
MILD	1	0	1
舌損傷	0	1 (0.2)	1 (0.1)
MILD	0	1	1
尺骨神経損傷	0	1 (0.2)	1 (0.1)
MILD	0	1	1
上肢骨折	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
SUBJECTS WITH ONE OR MORE EVENTS	6 (1.8)	16 (3.1)	22 (2.6)
MILD	3	10	13
MODERATE	3	6	9
臨床検査			
アラニンアミノトランスフェラーゼ増加	1 (0.3)	2 (0.4)	3 (0.4)
MILD	0	2	2
MODERATE	1	0	1

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
アスパラギン酸アミノトランスフェラーゼ増加	2 (0.6)	1 (0.2)	3 (0.4)
MILD	1	0	1
MODERATE	1	1	2
細菌検査陽性	0	1 (0.2)	1 (0.1)
MILD	0	1	1
血中ビリルビン増加	1 (0.3)	2 (0.4)	3 (0.4)
MILD	1	2	3
血中コレステロール増加	1 (0.3)	1 (0.2)	2 (0.2)
MILD	1	1	2
血中クレアチニン増加	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
血中ブドウ糖増加	0	1 (0.2)	1 (0.1)
MILD	0	1	1
血中リン減少	1 (0.3)	0	1 (0.1)
SEVERE	1	0	1
血圧上昇	1 (0.3)	0	1 (0.1)
MILD	1	0	1

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
血中トリグリセリド増加	1 (0.3)	2 (0.4)	3 (0.4)
MILD	1	1	2
MODERATE	0	1	1
血中尿素増加	1 (0.3)	1 (0.2)	2 (0.2)
MILD	1	1	2
血中尿素窒素／クレアチニン比増加	0	1 (0.2)	1 (0.1)
MILD	0	1	1
呼吸音異常	1 (0.3)	0	1 (0.1)
MODERATE	1	0	1
C－反応性蛋白増加	2 (0.6)	0	2 (0.2)
MILD	2	0	2
クロストリジウム検査陽性	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
ヘマトクリット減少	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
ヘモグロビン減少	1 (0.3)	0	1 (0.1)
MILD	1	0	1

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
好中球数増加	0	1 (0.2)	1 (0.1)
MILD	0	1	1
血小板数増加	0	2 (0.4)	2 (0.2)
MILD	0	2	2
尿中赤血球陽性	1 (0.3)	1 (0.2)	2 (0.2)
MILD	1	1	2
皮膚ツルゴール低下	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
体重減少	1 (0.3)	1 (0.2)	2 (0.2)
MILD	1	0	1
MODERATE	0	1	1
白血球数減少	1 (0.3)	1 (0.2)	2 (0.2)
MILD	0	1	1
MODERATE	1	0	1
白血球数増加	0	1 (0.2)	1 (0.1)
MILD	0	1	1

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
尿中白血球陽性	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
SUBJECTS WITH ONE OR MORE EVENTS	14 (4.1)	19 (3.7)	33 (3.9)
MILD	10	11	21
MODERATE	3	8	11
SEVERE	1	0	1
代謝および栄養障害			
食欲減退	1 (0.3)	1 (0.2)	2 (0.2)
MILD	1	0	1
MODERATE	0	1	1
脱水	1 (0.3)	2 (0.4)	3 (0.4)
MODERATE	1	1	2
SEVERE	0	1	1
高コレステロール血症	1 (0.3)	1 (0.2)	2 (0.2)
MILD	1	1	2

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
高血糖	1 (0.3)	2 (0.4)	3 (0.4)
MILD	1	1	2
MODERATE	0	1	1
高トリグリセリド血症	1 (0.3)	0	1 (0.1)
MILD	1	0	1
低アルブミン血症	1 (0.3)	0	1 (0.1)
MODERATE	1	0	1
低カリウム血症	3 (0.9)	0	3 (0.4)
MILD	2	0	2
MODERATE	1	0	1
血液量減少症	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
空腹時血中ブドウ糖不良	1 (0.3)	0	1 (0.1)
MILD	1	0	1
食欲亢進	0	1 (0.2)	1 (0.1)
MILD	0	1	1

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
代謝性アシドーシス	1 (0.3)	0	1 (0.1)
MODERATE	1	0	1
ビタミンD欠乏	2 (0.6)	0	2 (0.2)
MILD	2	0	2
SUBJECTS WITH ONE OR MORE EVENTS	10 (2.9)	7 (1.4)	17 (2.0)
MILD	7	3	10
MODERATE	3	3	6
SEVERE	0	1	1
筋骨格系および結合組織障害			
関節痛	9 (2.6)	17 (3.3)	26 (3.1)
MILD	8	12	20
MODERATE	1	5	6
軸性脊椎関節炎	1 (0.3)	0	1 (0.1)
MODERATE	1	0	1
背部痛	3 (0.9)	12 (2.3)	15 (1.8)
MILD	0	8	8
MODERATE	3	4	7

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
滑液包炎	2 (0.6)	0	2 (0.2)
MILD	1	0	1
MODERATE	1	0	1
側腹部痛	1 (0.3)	0	1 (0.1)
MILD	1	0	1
尺径部痛	0	1 (0.2)	1 (0.1)
MILD	0	1	1
関節雑音	0	1 (0.2)	1 (0.1)
MILD	0	1	1
関節可動域低下	1 (0.3)	0	1 (0.1)
MODERATE	1	0	1
関節腫脹	2 (0.6)	0	2 (0.2)
MILD	1	0	1
MODERATE	1	0	1
筋痙縮	1 (0.3)	3 (0.6)	4 (0.5)
MILD	1	2	3
MODERATE	0	1	1

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
筋緊張	0	1 (0.2)	1 (0.1)
MILD	0	1	1
筋骨格痛	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
筋骨格硬直	2 (0.6)	1 (0.2)	3 (0.4)
MILD	2	1	3
筋肉痛	1 (0.3)	2 (0.4)	3 (0.4)
MILD	0	1	1
MODERATE	1	1	2
頚部痛	0	1 (0.2)	1 (0.1)
MILD	0	1	1
変形性関節症	1 (0.3)	0	1 (0.1)
MODERATE	1	0	1
四肢痛	1 (0.3)	1 (0.2)	2 (0.2)
MODERATE	1	0	1
SEVERE	0	1	1

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
顎痛	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
肩回旋筋腱板症候群	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
仙腸骨炎	1 (0.3)	0	1 (0.1)
MODERATE	1	0	1
SUBJECTS WITH ONE OR MORE EVENTS	23 (6.8)	41 (8.0)	64 (7.5)
MILD	14	26	40
MODERATE	9	14	23
SEVERE	0	1	1
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）			
肛門性器疣贅	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
基底細胞癌	1 (0.3)	0	1 (0.1)
MODERATE	1	0	1

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
表皮内悪性黒色腫	1 (0.3)	0	1 (0.1)
SEVERE	1	0	1
子宮頚部扁平上皮癌	1 (0.3)	0	1 (0.1)
SEVERE	1	0	1
SUBJECTS WITH ONE OR MORE EVENTS	3 (0.9)	1 (0.2)	4 (0.5)
MODERATE	1	1	2
SEVERE	2	0	2
神経系障害			
浮動性めまい	4 (1.2)	12 (2.3)	16 (1.9)
MILD	3	7	10
MODERATE	1	4	5
SEVERE	0	1	1
蟻走感	1 (0.3)	0	1 (0.1)
MILD	1	0	1

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
頭痛	23 (6.8)	47 (9.2)	70 (8.2)
MILD	15	30	45
MODERATE	8	16	24
SEVERE	0	1	1
感覚鈍麻	1 (0.3)	3 (0.6)	4 (0.5)
MILD	1	2	3
MODERATE	0	1	1
嗜眠	2 (0.6)	1 (0.2)	3 (0.4)
MILD	2	0	2
SEVERE	0	1	1
片頭痛	2 (0.6)	4 (0.8)	6 (0.7)
MILD	2	2	4
MODERATE	0	2	2
神経痛	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
錯感覚	1 (0.3)	4 (0.8)	5 (0.6)
MILD	1	3	4
MODERATE	0	1	1

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
失神寸前の状態	2 (0.6)	2 (0.4)	4 (0.5)
MILD	2	0	2
MODERATE	0	2	2
神経根障害	0	1 (0.2)	1 (0.1)
MILD	0	1	1
痙攣発作	0	1 (0.2)	1 (0.1)
MILD	0	1	1
失神	1 (0.3)	1 (0.2)	2 (0.2)
MODERATE	1	1	2
振戦	1 (0.3)	1 (0.2)	2 (0.2)
MILD	1	1	2
SUBJECTS WITH ONE OR MORE EVENTS	34 (10.0)	67 (13.1)	101 (11.9)
MILD	25	40	65
MODERATE	9	24	33
SEVERE	0	3	3

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
精神障害			
不安	1 (0.3)	1 (0.2)	2 (0.2)
MILD	1	0	1
MODERATE	0	1	1
抑うつ気分	0	1 (0.2)	1 (0.1)
MILD	0	1	1
不眠症	2 (0.6)	2 (0.4)	4 (0.5)
MILD	0	1	1
MODERATE	1	1	2
SEVERE	1	0	1
パニック発作	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
SUBJECTS WITH ONE OR MORE EVENTS	3 (0.9)	5 (1.0)	8 (0.9)
MILD	1	2	3
MODERATE	1	3	4
SEVERE	1	0	1

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
腎および尿路障害			
急性腎障害	1 (0.3)	0	1 (0.1)
MILD	1	0	1
着色尿	0	1 (0.2)	1 (0.1)
MILD	0	1	1
排尿困難	1 (0.3)	1 (0.2)	2 (0.2)
MILD	1	1	2
血尿	1 (0.3)	2 (0.4)	3 (0.4)
MILD	1	2	3
高シュウ酸尿症	0	1 (0.2)	1 (0.1)
MILD	0	1	1
腎結石症	1 (0.3)	1 (0.2)	2 (0.2)
MILD	0	1	1
MODERATE	1	0	1
夜間頻尿	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
多尿	1 (0.3)	0	1 (0.1)
MILD	1	0	1
腎仙痛	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
腎不全	1 (0.3)	1 (0.2)	2 (0.2)
MODERATE	1	1	2
SUBJECTS WITH ONE OR MORE EVENTS	5 (1.5)	7 (1.4)	12 (1.4)
MILD	4	4	8
MODERATE	1	3	4
生殖系および乳房障害			
バルトリン嚢腫	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
不正子宮出血	1 (0.3)	0	1 (0.1)
MODERATE	1	0	1
卵巣嚢胞	1 (0.3)	0	1 (0.1)
MILD	1	0	1

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
骨盤痛	1 (0.3)	0	1 (0.1)
MODERATE	1	0	1
SUBJECTS WITH ONE OR MORE EVENTS	2 (0.6)	1 (0.2)	3 (0.4)
MILD	1	0	1
MODERATE	1	1	2
呼吸器、胸郭および縦隔障害			
喘息	0	2 (0.4)	2 (0.2)
MODERATE	0	2	2
咳嗽	6 (1.8)	9 (1.8)	15 (1.8)
MILD	6	4	10
MODERATE	0	5	5
発声障害	0	1 (0.2)	1 (0.1)
MILD	0	1	1
呼吸困難	1 (0.3)	2 (0.4)	3 (0.4)
MILD	1	2	3

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
鼻出血	0	3 (0.6)	3 (0.4)
MILD	0	3	3
鼻閉	1 (0.3)	0	1 (0.1)
MILD	1	0	1
口腔咽頭痛	5 (1.5)	15 (2.9)	20 (2.3)
MILD	5	12	17
MODERATE	0	3	3
咽頭障害	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
湿性咳嗽	0	1 (0.2)	1 (0.1)
MILD	0	1	1
鼻漏	0	2 (0.4)	2 (0.2)
MILD	0	2	2
副鼻腔うっ血	1 (0.3)	0	1 (0.1)
MILD	1	0	1

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
SUBJECTS WITH ONE OR MORE EVENTS	13 (3.8)	28 (5.5)	41 (4.8)
MILD	13	20	33
MODERATE	0	8	8
皮膚および皮下組織障害			
ざ瘡	3 (0.9)	1 (0.2)	4 (0.5)
MILD	2	1	3
MODERATE	1	0	1
脱毛症	7 (2.1)	4 (0.8)	11 (1.3)
MILD	7	3	10
MODERATE	0	1	1
血管浮腫	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
冷汗	0	1 (0.2)	1 (0.1)
MILD	0	1	1
頭部粃糠疹	1 (0.3)	1 (0.2)	2 (0.2)
MILD	1	1	2

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
皮膚炎	1 (0.3)	3 (0.6)	4 (0.5)
MILD	1	2	3
MODERATE	0	1	1
アトピー性皮膚炎	0	1 (0.2)	1 (0.1)
MILD	0	1	1
接触皮膚炎	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
乾癬様皮膚炎	1 (0.3)	0	1 (0.1)
MODERATE	1	0	1
皮膚乾燥	1 (0.3)	1 (0.2)	2 (0.2)
MILD	1	1	2
湿疹	2 (0.6)	1 (0.2)	3 (0.4)
MILD	1	1	2
MODERATE	1	0	1
紅斑	1 (0.3)	5 (1.0)	6 (0.7)
MILD	1	4	5
MODERATE	0	1	1

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
結節性紅斑	0	1 (0.2)	1 (0.1)
MILD	0	1	1
男性型多毛症	1 (0.3)	0	1 (0.1)
MILD	1	0	1
多汗症	1 (0.3)	0	1 (0.1)
MILD	1	0	1
多毛症	1 (0.3)	0	1 (0.1)
MILD	1	0	1
寝汗	1 (0.3)	1 (0.2)	2 (0.2)
MILD	1	1	2
そう痒症	3 (0.9)	3 (0.6)	6 (0.7)
MILD	2	3	5
MODERATE	1	0	1
全身性そう痒症	0	1 (0.2)	1 (0.1)
MILD	0	1	1

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
乾癬	1 (0.3)	1 (0.2)	2 (0.2)
MILD	0	1	1
MODERATE	1	0	1
発疹	8 (2.4)	10 (2.0)	18 (2.1)
MILD	8	9	17
MODERATE	0	1	1
紅斑性皮疹	2 (0.6)	1 (0.2)	3 (0.4)
MILD	2	1	3
斑状丘疹状皮疹	0	1 (0.2)	1 (0.1)
MILD	0	1	1
丘疹性皮疹	0	1 (0.2)	1 (0.1)
MILD	0	1	1
顔面腫脹	0	1 (0.2)	1 (0.1)
MILD	0	1	1
蕁麻疹	1 (0.3)	1 (0.2)	2 (0.2)
MODERATE	1	1	2

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
SUBJECTS WITH ONE OR MORE EVENTS	31 (9.1)	38 (7.4)	69 (8.1)
MILD	26	31	57
MODERATE	5	7	12
外科および内科処置			
創部ドレナージ	0	1 (0.2)	1 (0.1)
SEVERE	0	1	1
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (0.2)	1 (0.1)
SEVERE	0	1	1
血管障害			
血腫	1 (0.3)	3 (0.6)	4 (0.5)
MILD	1	3	4

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
出血	0	1 (0.2)	1 (0.1)
MILD	0	1	1
高血圧	2 (0.6)	1 (0.2)	3 (0.4)
MILD	1	1	2
MODERATE	1	0	1
低血圧	1 (0.3)	1 (0.2)	2 (0.2)
MILD	1	1	2
蒼白	1 (0.3)	0	1 (0.1)
MILD	1	0	1
末梢静脈疾患	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
表在性静脈炎	2 (0.6)	0	2 (0.2)
MILD	2	0	2
血栓性静脈炎	0	1 (0.2)	1 (0.1)
MODERATE	0	1	1
静脈血栓症	1 (0.3)	0	1 (0.1)
MODERATE	1	0	1

表 2.7.4.7-10. 有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	ADALIMUMAB STANDARD INDUCTION DOSE (N=340) n (%)	ADALIMUMAB HIGHER INDUCTION DOSE (N=512) n (%)	TOTAL (N=852) n (%)
SUBJECTS WITH ONE OR MORE EVENTS	8 (2.4)	7 (1.4)	15 (1.8)
MILD	6	5	11
MODERATE	2	2	4

NOTE: TABLE DEPICTS THE MOST SEVERE ADVERSE EVENT FOR EACH PREFERRED TERM AS ASSESSED FOR EACH SUBJECT.
THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL. TREATMENT-EMERGENT ADVERSE EVENTS DURING INDUCTION STUDY ARE DEFINED AS EVENTS THAT BEGIN OR WORSEN EITHER ON OR AFTER THE FIRST DOSE OF THE STUDY MEDICATION AND UP TO THE FIRST DOSE OF THE STUDY MEDICATION IN MAINTENANCE STUDY FOR THOSE WHO ARE RE-RANDOMIZED AT WEEK 8, OR EVENTS THAT BEGIN OR WORSEN EITHER ON OR AFTER THE FIRST DOSE OF THE STUDY DRUG AND WITHIN 70 DAYS AFTER THE LAST DOSE OF THE STUDY MEDICATION IN THE INDUCTION STUDY FOR SUBJECTS WHO ARE NOT RE-RANDOMIZED.

Cross reference: M14-033 Induction Main-study Final CSR Table 14.3__1.5

表 2.7.4.7-11. 有害事象（MedDRA SOC 及び PT 別，重症度別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	JAPAN SAFETY SET – ADALIMUMAB STANDARD DOSE (N=39) n (%)	JAPAN SAFETY SET – ADALIMUMAB HIGHER DOSE (N=61) n (%)	JAPAN SAFETY SET – ADALIMUMAB TOTAL (N=100) n (%)	INTEGRATED SAFETY SET – ADALIMUMAB STANDARD DOSE (N=379) n (%)	INTEGRATED SAFETY SET – ADALIMUMAB HIGHER DOSE (N=573) n (%)	INTEGRATED SAFETY SET – ADALIMUMAB TOTAL (N=952) n (%)	SAFETY SET – ADALIMUMAB STANDARD DOSE (N=340) n (%)	SAFETY SET – ADALIMUMAB HIGHER DOSE (N=512) n (%)	SAFETY SET – ADALIMUMAB TOTAL (N=852) n (%)
ANY ADVERSE EVENT	16 (41.0)	34 (55.7)	50 (50.0)	200 (52.8)	305 (53.2)	505 (53.0)	184 (54.1)	271 (52.9)	455 (53.4)
MILD	13	22	35	104	158	262	91	136	227
MODERATE	2	11	13	79	123	202	77	112	189
SEVERE	1	1	2	17	24	41	16	23	39
血液およびリンパ系障害									
貧血	2 (5.1)	2 (3.3)	4 (4.0)	15 (4.0)	18 (3.1)	33 (3.5)	13 (3.8)	16 (3.1)	29 (3.4)
MILD	1	2	3	5	8	13	4	6	10
MODERATE	1	0	1	7	8	15	6	8	14
SEVERE	0	0	0	3	2	5	3	2	5
大球性貧血	0	1 (1.6)	1 (1.0)	0	1 (0.2)	1 (0.1)	0	0	0
MODERATE	0	1	1	0	1	1	0	0	0
鉄欠乏性貧血	0	1 (1.6)	1 (1.0)	1 (0.3)	1 (0.2)	2 (0.2)	1 (0.3)	0	1 (0.1)
MILD	0	0	0	1	0	1	1	0	1
MODERATE	0	1	1	0	1	1	0	0	0

表 2.7.4.7-11. 有害事象（MedDRA SOC 及び PT 別，重症度別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	JAPAN SAFETY SET - ADALIMUMAB STANDARD DOSE (N=39) n (%)	JAPAN SAFETY SET - ADALIMUMAB HIGHER DOSE (N=61) n (%)	JAPAN SAFETY SET - ADALIMUMAB TOTAL (N=100) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB STANDARD DOSE (N=379) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB HIGHER DOSE (N=573) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB TOTAL (N=952) n (%)	SAFETY SET - ADALIMUMAB STANDARD DOSE (N=340) n (%)	SAFETY SET - ADALIMUMAB HIGHER DOSE (N=512) n (%)	SAFETY SET - ADALIMUMAB TOTAL (N=852) n (%)
白血球減少症	0	1 (1.6)	1 (1.0)	1 (0.3)	4 (0.7)	5 (0.5)	1 (0.3)	3 (0.6)	4 (0.5)
MILD	0	0	0	1	1	2	1	1	2
MODERATE	0	1	1	0	3	3	0	2	2
リンパ節症	0	0	0	2 (0.5)	2 (0.3)	4 (0.4)	2 (0.6)	2 (0.4)	4 (0.5)
MILD	0	0	0	1	2	3	1	2	3
MODERATE	0	0	0	1	0	1	1	0	1
リンパ球減少症	0	0	0	1 (0.3)	1 (0.2)	2 (0.2)	1 (0.3)	1 (0.2)	2 (0.2)
MILD	0	0	0	1	1	2	1	1	2
好中球減少症	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
MODERATE	0	0	0	1	0	1	1	0	1
血小板減少症	0	0	0	0	2 (0.3)	2 (0.2)	0	2 (0.4)	2 (0.2)
MILD	0	0	0	0	1	1	0	1	1
MODERATE	0	0	0	0	1	1	0	1	1

表 2.7.4.7-11. 有害事象（MedDRA SOC 及び PT 別，重症度別）（日本人安全性解析対象集団，
統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	JAPAN SAFETY SET – ADALIMUMAB STANDARD DOSE (N=39) n (%)	JAPAN SAFETY SET – ADALIMUMAB HIGHER DOSE (N=61) n (%)	JAPAN SAFETY SET – ADALIMUMAB TOTAL (N=100) n (%)	INTEGRATED SAFETY SET – ADALIMUMAB STANDARD DOSE (N=379) n (%)	INTEGRATED SAFETY SET – ADALIMUMAB HIGHER DOSE (N=573) n (%)	INTEGRATED SAFETY SET – ADALIMUMAB TOTAL (N=952) n (%)	SAFETY SET – ADALIMUMAB STANDARD DOSE (N=340) n (%)	SAFETY SET – ADALIMUMAB HIGHER DOSE (N=512) n (%)	SAFETY SET – ADALIMUMAB TOTAL (N=852) n (%)
SUBJECTS WITH ONE OR MORE EVENTS	2 (5.1)	4 (6.6)	6 (6.0)	21 (5.5)	28 (4.9)	49 (5.1)	19 (5.6)	24 (4.7)	43 (5.0)
MILD	1	2	3	9	13	22	8	11	19
MODERATE	1	2	3	9	13	22	8	11	19
SEVERE	0	0	0	3	2	5	3	2	5
心臓障害									
心停止	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
SEVERE	0	0	0	0	1	1	0	1	1
動悸	0	0	0	1 (0.3)	1 (0.2)	2 (0.2)	1 (0.3)	1 (0.2)	2 (0.2)
MILD	0	0	0	1	0	1	1	0	1
MODERATE	0	0	0	0	1	1	0	1	1
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	1 (0.3)	2 (0.3)	3 (0.3)	1 (0.3)	2 (0.4)	3 (0.4)
MILD	0	0	0	1	0	1	1	0	1
MODERATE	0	0	0	0	1	1	0	1	1
SEVERE	0	0	0	0	1	1	0	1	1

表 2.7.4.7-11. 有害事象（MedDRA SOC 及び PT 別，重症度別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	JAPAN SAFETY SET - ADALIMUMAB STANDARD DOSE (N=39) n (%)	JAPAN SAFETY SET - ADALIMUMAB HIGHER DOSE (N=61) n (%)	JAPAN SAFETY SET - ADALIMUMAB TOTAL (N=100) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB STANDARD DOSE (N=379) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB HIGHER DOSE (N=573) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB TOTAL (N=952) n (%)	SAFETY SET - ADALIMUMAB STANDARD DOSE (N=340) n (%)	SAFETY SET - ADALIMUMAB HIGHER DOSE (N=512) n (%)	SAFETY SET - ADALIMUMAB TOTAL (N=852) n (%)
先天性、家族性および遺伝性障害									
エーラース・ダンロス症候群	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MODERATE	0	0	0	0	1	1	0	1	1
包皮小帯	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MILD	0	0	0	0	1	1	0	1	1
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	0	2 (0.3)	2 (0.2)	0	2 (0.4)	2 (0.2)
MILD	0	0	0	0	1	1	0	1	1
MODERATE	0	0	0	0	1	1	0	1	1
耳および迷路障害									
聴力低下	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MILD	0	0	0	0	1	1	0	1	1
耳鳴	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
MILD	0	0	0	1	0	1	1	0	1

表 2.7.4.7-11. 有害事象（MedDRA SOC 及び PT 別，重症度別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	JAPAN SAFETY SET - ADALIMUMAB STANDARD DOSE (N=39) n (%)	JAPAN SAFETY SET - ADALIMUMAB HIGHER DOSE (N=61) n (%)	JAPAN SAFETY SET - ADALIMUMAB TOTAL (N=100) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB STANDARD DOSE (N=379) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB HIGHER DOSE (N=573) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB TOTAL (N=952) n (%)	SAFETY SET - ADALIMUMAB STANDARD DOSE (N=340) n (%)	SAFETY SET - ADALIMUMAB HIGHER DOSE (N=512) n (%)	SAFETY SET - ADALIMUMAB TOTAL (N=852) n (%)
回転性めまい	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
MODERATE	0	0	0	1	0	1	1	0	1
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	2 (0.5)	1 (0.2)	3 (0.3)	2 (0.6)	1 (0.2)	3 (0.4)
MILD	0	0	0	1	1	2	1	1	2
MODERATE	0	0	0	1	0	1	1	0	1
内分泌障害									
ステロイド離脱症候群	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MODERATE	0	0	0	0	1	1	0	1	1
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MODERATE	0	0	0	0	1	1	0	1	1
眼障害									
アレルギー性眼瞼炎	1 (2.6)	0	1 (1.0)	1 (0.3)	0	1 (0.1)	0	0	0
MILD	1	0	1	1	0	1	0	0	0

表 2.7.4.7-11. 有害事象（MedDRA SOC 及び PT 別，重症度別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	JAPAN SAFETY SET - ADALIMUMAB STANDARD DOSE (N=39) n (%)	JAPAN SAFETY SET - ADALIMUMAB HIGHER DOSE (N=61) n (%)	JAPAN SAFETY SET - ADALIMUMAB TOTAL (N=100) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB STANDARD DOSE (N=379) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB HIGHER DOSE (N=573) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB TOTAL (N=952) n (%)	SAFETY SET - ADALIMUMAB STANDARD DOSE (N=340) n (%)	SAFETY SET - ADALIMUMAB HIGHER DOSE (N=512) n (%)	SAFETY SET - ADALIMUMAB TOTAL (N=852) n (%)
眼瞼痙攣	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MILD	0	0	0	0	1	1	0	1	1
アレルギー性結膜炎	0	1 (1.6)	1 (1.0)	0	1 (0.2)	1 (0.1)	0	0	0
MILD	0	1	1	0	1	1	0	0	0
後天性涙道狭窄	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MILD	0	0	0	0	1	1	0	1	1
ドライアイ	0	0	0	2 (0.5)	1 (0.2)	3 (0.3)	2 (0.6)	1 (0.2)	3 (0.4)
MILD	0	0	0	0	1	1	0	1	1
MODERATE	0	0	0	2	0	2	2	0	2
眼瞼湿疹	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
MILD	0	0	0	1	0	1	1	0	1
上強膜炎	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MILD	0	0	0	0	1	1	0	1	1
眼の障害	0	0	0	1 (0.3)	1 (0.2)	2 (0.2)	1 (0.3)	1 (0.2)	2 (0.2)
MILD	0	0	0	1	1	2	1	1	2

表 2.7.4.7-11. 有害事象（MedDRA SOC 及び PT 別，重症度別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	JAPAN SAFETY SET - ADALIMUMAB STANDARD DOSE (N=39) n (%)	JAPAN SAFETY SET - ADALIMUMAB HIGHER DOSE (N=61) n (%)	JAPAN SAFETY SET - ADALIMUMAB TOTAL (N=100) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB STANDARD DOSE (N=379) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB HIGHER DOSE (N=573) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB TOTAL (N=952) n (%)	SAFETY SET - ADALIMUMAB STANDARD DOSE (N=340) n (%)	SAFETY SET - ADALIMUMAB HIGHER DOSE (N=512) n (%)	SAFETY SET - ADALIMUMAB TOTAL (N=852) n (%)
眼痛	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
MODERATE	0	0	0	1	0	1	1	0	1
眼部腫脹	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MILD	0	0	0	0	1	1	0	1	1
眼瞼浮腫	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
MILD	0	0	0	1	0	1	1	0	1
緑内障	0	1 (1.6)	1 (1.0)	0	1 (0.2)	1 (0.1)	0	0	0
MODERATE	0	1	1	0	1	1	0	0	0
羞明	0	0	0	0	2 (0.3)	2 (0.2)	0	2 (0.4)	2 (0.2)
MILD	0	0	0	0	1	1	0	1	1
MODERATE	0	0	0	0	1	1	0	1	1
視力低下	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
MILD	0	0	0	1	0	1	1	0	1

表 2.7.4.7-11. 有害事象（MedDRA SOC 及び PT 別，重症度別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

	JAPAN SAFETY SET — ADALIMUMAB			INTEGRATED SAFETY SET — ADALIMUMAB			SAFETY SET — ADALIMUMAB		
SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	STANDARD DOSE (N=39) n (%)	HIGHER DOSE (N=61) n (%)	TOTAL (N=100) n (%)	STANDARD DOSE (N=379) n (%)	HIGHER DOSE (N=573) n (%)	TOTAL (N=952) n (%)	STANDARD DOSE (N=340) n (%)	HIGHER DOSE (N=512) n (%)	TOTAL (N=852) n (%)
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.6)	2 (3.3)	3 (3.0)	8 (2.1)	10 (1.7)	18 (1.9)	7 (2.1)	8 (1.6)	15 (1.8)
MILD	1	1	2	5	8	13	4	7	11
MODERATE	0	1	1	3	2	5	3	1	4
胃腸障害									
腹部不快感	0	0	0	1 (0.3)	1 (0.2)	2 (0.2)	1 (0.3)	1 (0.2)	2 (0.2)
MILD	0	0	0	1	1	2	1	1	2
腹部膨満	1 (2.6)	0	1 (1.0)	4 (1.1)	1 (0.2)	5 (0.5)	3 (0.9)	1 (0.2)	4 (0.5)
MILD	1	0	1	4	0	4	3	0	3
MODERATE	0	0	0	0	1	1	0	1	1
腹痛	0	2 (3.3)	2 (2.0)	6 (1.6)	13 (2.3)	19 (2.0)	6 (1.8)	11 (2.1)	17 (2.0)
MILD	0	1	1	1	5	6	1	4	5
MODERATE	0	1	1	4	7	11	4	6	10
SEVERE	0	0	0	1	1	2	1	1	2
上腹部痛	0	0	0	3 (0.8)	4 (0.7)	7 (0.7)	3 (0.9)	4 (0.8)	7 (0.8)
MILD	0	0	0	2	2	4	2	2	4
MODERATE	0	0	0	1	2	3	1	2	3

表 2.7.4.7-11. 有害事象（MedDRA SOC 及び PT 別，重症度別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	JAPAN SAFETY SET - ADALIMUMAB STANDARD DOSE (N=39) n (%)	JAPAN SAFETY SET - ADALIMUMAB HIGHER DOSE (N=61) n (%)	JAPAN SAFETY SET - ADALIMUMAB TOTAL (N=100) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB STANDARD DOSE (N=379) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB HIGHER DOSE (N=573) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB TOTAL (N=952) n (%)	SAFETY SET - ADALIMUMAB STANDARD DOSE (N=340) n (%)	SAFETY SET - ADALIMUMAB HIGHER DOSE (N=512) n (%)	SAFETY SET - ADALIMUMAB TOTAL (N=852) n (%)
腹部圧痛	0	0	0	0	2 (0.3)	2 (0.2)	0	2 (0.4)	2 (0.2)
MILD	0	0	0	0	1	1	0	1	1
SEVERE	0	0	0	0	1	1	0	1	1
裂肛	0	0	0	1 (0.3)	1 (0.2)	2 (0.2)	1 (0.3)	1 (0.2)	2 (0.2)
MILD	0	0	0	1	0	1	1	0	1
MODERATE	0	0	0	0	1	1	0	1	1
アフタ性潰瘍	0	1 (1.6)	1 (1.0)	3 (0.8)	2 (0.3)	5 (0.5)	3 (0.9)	1 (0.2)	4 (0.5)
MILD	0	0	0	3	1	4	3	1	4
MODERATE	0	1	1	0	1	1	0	0	0
根尖肉芽腫	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MODERATE	0	0	0	0	1	1	0	1	1
大腸炎	0	0	0	3 (0.8)	2 (0.3)	5 (0.5)	3 (0.9)	2 (0.4)	5 (0.6)
MODERATE	0	0	0	3	2	5	3	2	5

表 2.7.4.7-11. 有害事象（MedDRA SOC 及び PT 別，重症度別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	JAPAN SAFETY SET - ADALIMUMAB STANDARD DOSE (N=39) n (%)	JAPAN SAFETY SET - ADALIMUMAB HIGHER DOSE (N=61) n (%)	JAPAN SAFETY SET - ADALIMUMAB TOTAL (N=100) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB STANDARD DOSE (N=379) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB HIGHER DOSE (N=573) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB TOTAL (N=952) n (%)	SAFETY SET - ADALIMUMAB STANDARD DOSE (N=340) n (%)	SAFETY SET - ADALIMUMAB HIGHER DOSE (N=512) n (%)	SAFETY SET - ADALIMUMAB TOTAL (N=852) n (%)
潰瘍性大腸炎	2 (5.1)	2 (3.3)	4 (4.0)	32 (8.4)	31 (5.4)	63 (6.6)	30 (8.8)	29 (5.7)	59 (6.9)
MILD	0	0	0	6	1	7	6	1	7
MODERATE	2	1	3	17	17	34	15	16	31
SEVERE	0	1	1	9	13	22	9	12	21
便秘	0	0	0	1 (0.3)	2 (0.3)	3 (0.3)	1 (0.3)	2 (0.4)	3 (0.4)
MILD	0	0	0	1	2	3	1	2	3
便意切迫	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
MODERATE	0	0	0	1	0	1	1	0	1
齲歯	1 (2.6)	1 (1.6)	2 (2.0)	1 (0.3)	1 (0.2)	2 (0.2)	0	0	0
MILD	1	1	2	1	1	2	0	0	0
下痢	0	0	0	5 (1.3)	12 (2.1)	17 (1.8)	5 (1.5)	12 (2.3)	17 (2.0)
MILD	0	0	0	3	7	10	3	7	10
MODERATE	0	0	0	1	3	4	1	3	4
SEVERE	0	0	0	1	2	3	1	2	3

表 2.7.4.7-11. 有害事象（MedDRA SOC 及び PT 別，重症度別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	JAPAN SAFETY SET - ADALIMUMAB STANDARD DOSE (N=39) n (%)	JAPAN SAFETY SET - ADALIMUMAB HIGHER DOSE (N=61) n (%)	JAPAN SAFETY SET - ADALIMUMAB TOTAL (N=100) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB STANDARD DOSE (N=379) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB HIGHER DOSE (N=573) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB TOTAL (N=952) n (%)	SAFETY SET - ADALIMUMAB STANDARD DOSE (N=340) n (%)	SAFETY SET - ADALIMUMAB HIGHER DOSE (N=512) n (%)	SAFETY SET - ADALIMUMAB TOTAL (N=852) n (%)
消化不良	0	1 (1.6)	1 (1.0)	8 (2.1)	3 (0.5)	11 (1.2)	8 (2.4)	2 (0.4)	10 (1.2)
MILD	0	1	1	7	3	10	7	2	9
MODERATE	0	0	0	1	0	1	1	0	1
心窩部不快感	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MILD	0	0	0	0	1	1	0	1	1
鼓腸	0	0	0	1 (0.3)	8 (1.4)	9 (0.9)	1 (0.3)	8 (1.6)	9 (1.1)
MILD	0	0	0	0	6	6	0	6	6
MODERATE	0	0	0	1	2	3	1	2	3
食中毒	0	0	0	1 (0.3)	1 (0.2)	2 (0.2)	1 (0.3)	1 (0.2)	2 (0.2)
MILD	0	0	0	1	1	2	1	1	2
胃食道逆流性疾患	0	1 (1.6)	1 (1.0)	1 (0.3)	4 (0.7)	5 (0.5)	1 (0.3)	3 (0.6)	4 (0.5)
MILD	0	1	1	0	4	4	0	3	3
MODERATE	0	0	0	1	0	1	1	0	1
歯肉出血	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MILD	0	0	0	0	1	1	0	1	1

表 2.7.4.7-11. 有害事象（MedDRA SOC 及び PT 別，重症度別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	JAPAN SAFETY SET - ADALIMUMAB STANDARD DOSE (N=39) n (%)	JAPAN SAFETY SET - ADALIMUMAB HIGHER DOSE (N=61) n (%)	JAPAN SAFETY SET - ADALIMUMAB TOTAL (N=100) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB STANDARD DOSE (N=379) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB HIGHER DOSE (N=573) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB TOTAL (N=952) n (%)	SAFETY SET - ADALIMUMAB STANDARD DOSE (N=340) n (%)	SAFETY SET - ADALIMUMAB HIGHER DOSE (N=512) n (%)	SAFETY SET - ADALIMUMAB TOTAL (N=852) n (%)
歯肉痛	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MILD	0	0	0	0	1	1	0	1	1
血便排泄	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
MILD	0	0	0	1	0	1	1	0	1
痔核	0	0	0	2 (0.5)	5 (0.9)	7 (0.7)	2 (0.6)	5 (1.0)	7 (0.8)
MILD	0	0	0	2	4	6	2	4	6
MODERATE	0	0	0	0	1	1	0	1	1
血栓性痔核	0	0	0	1 (0.3)	3 (0.5)	4 (0.4)	1 (0.3)	3 (0.6)	4 (0.5)
MILD	0	0	0	0	1	1	0	1	1
MODERATE	0	0	0	1	1	2	1	1	2
SEVERE	0	0	0	0	1	1	0	1	1
歯の知覚過敏	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
MILD	0	0	0	1	0	1	1	0	1
大腸狭窄	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
SEVERE	0	0	0	0	1	1	0	1	1

表 2.7.4.7-11. 有害事象（MedDRA SOC 及び PT 別，重症度別）（日本人安全性解析対象集団，
統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	JAPAN SAFETY SET - ADALIMUMAB STANDARD DOSE (N=39) n (%)	JAPAN SAFETY SET - ADALIMUMAB HIGHER DOSE (N=61) n (%)	JAPAN SAFETY SET - ADALIMUMAB TOTAL (N=100) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB STANDARD DOSE (N=379) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB HIGHER DOSE (N=573) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB TOTAL (N=952) n (%)	SAFETY SET - ADALIMUMAB STANDARD DOSE (N=340) n (%)	SAFETY SET - ADALIMUMAB HIGHER DOSE (N=512) n (%)	SAFETY SET - ADALIMUMAB TOTAL (N=852) n (%)
悪心	1 (2.6)	1 (1.6)	2 (2.0)	10 (2.6)	18 (3.1)	28 (2.9)	9 (2.6)	17 (3.3)	26 (3.1)
MILD	1	0	1	8	11	19	7	11	18
MODERATE	0	1	1	2	7	9	2	6	8
嚥下痛	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MILD	0	0	0	0	1	1	0	1	1
急性膵炎	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MODERATE	0	0	0	0	1	1	0	1	1
肛門周囲痛	0	0	0	3 (0.8)	1 (0.2)	4 (0.4)	3 (0.9)	1 (0.2)	4 (0.5)
MODERATE	0	0	0	3	1	4	3	1	4
直腸出血	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
MILD	0	0	0	1	0	1	1	0	1
直腸しぶり	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MILD	0	0	0	0	1	1	0	1	1
脂肪便	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MODERATE	0	0	0	0	1	1	0	1	1

表 2.7.4.7-11. 有害事象（MedDRA SOC 及び PT 別，重症度別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	JAPAN SAFETY SET – ADALIMUMAB STANDARD DOSE (N=39) n (%)	JAPAN SAFETY SET – ADALIMUMAB HIGHER DOSE (N=61) n (%)	JAPAN SAFETY SET – ADALIMUMAB TOTAL (N=100) n (%)	INTEGRATED SAFETY SET – ADALIMUMAB STANDARD DOSE (N=379) n (%)	INTEGRATED SAFETY SET – ADALIMUMAB HIGHER DOSE (N=573) n (%)	INTEGRATED SAFETY SET – ADALIMUMAB TOTAL (N=952) n (%)	SAFETY SET – ADALIMUMAB STANDARD DOSE (N=340) n (%)	SAFETY SET – ADALIMUMAB HIGHER DOSE (N=512) n (%)	SAFETY SET – ADALIMUMAB TOTAL (N=852) n (%)
歯の障害	0	0	0	1 (0.3)	1 (0.2)	2 (0.2)	1 (0.3)	1 (0.2)	2 (0.2)
MILD	0	0	0	1	1	2	1	1	2
歯痛	0	0	0	1 (0.3)	2 (0.3)	3 (0.3)	1 (0.3)	2 (0.4)	3 (0.4)
MILD	0	0	0	0	2	2	0	2	2
MODERATE	0	0	0	1	0	1	1	0	1
臍ヘルニア	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
MODERATE	0	0	0	1	0	1	1	0	1
嘔吐	1 (2.6)	2 (3.3)	3 (3.0)	5 (1.3)	11 (1.9)	16 (1.7)	4 (1.2)	9 (1.8)	13 (1.5)
MILD	1	2	3	4	8	12	3	6	9
MODERATE	0	0	0	1	3	4	1	3	4
SUBJECTS WITH ONE OR MORE EVENTS	3 (7.7)	10 (16.4)	13 (13.0)	78 (20.6)	102 (17.8)	180 (18.9)	75 (22.1)	92 (18.0)	167 (19.6)
MILD	1	6	7	33	44	77	32	38	70
MODERATE	2	3	5	35	41	76	33	38	71
SEVERE	0	1	1	10	17	27	10	16	26

表 2.7.4.7-11. 有害事象（MedDRA SOC 及び PT 別，重症度別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	JAPAN SAFETY SET - ADALIMUMAB STANDARD DOSE (N=39) n (%)	JAPAN SAFETY SET - ADALIMUMAB HIGHER DOSE (N=61) n (%)	JAPAN SAFETY SET - ADALIMUMAB TOTAL (N=100) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB STANDARD DOSE (N=379) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB HIGHER DOSE (N=573) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB TOTAL (N=952) n (%)	SAFETY SET - ADALIMUMAB STANDARD DOSE (N=340) n (%)	SAFETY SET - ADALIMUMAB HIGHER DOSE (N=512) n (%)	SAFETY SET - ADALIMUMAB TOTAL (N=852) n (%)
一般・全身障害および投与部位の状態									
投与部位疼痛	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
MILD	0	0	0	1	0	1	1	0	1
適用部位そう痒感	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MILD	0	0	0	0	1	1	0	1	1
適用部位反応	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MILD	0	0	0	0	1	1	0	1	1
無力症	0	0	0	6 (1.6)	8 (1.4)	14 (1.5)	6 (1.8)	8 (1.6)	14 (1.6)
MILD	0	0	0	5	6	11	5	6	11
MODERATE	0	0	0	1	2	3	1	2	3
腋窩痛	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MODERATE	0	0	0	0	1	1	0	1	1
胸部不快感	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
MILD	0	0	0	1	0	1	1	0	1

表 2.7.4.7-11. 有害事象（MedDRA SOC 及び PT 別，重症度別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

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胸痛	1 (2.6)	0	1 (1.0)	4 (1.1)	1 (0.2)	5 (0.5)	3 (0.9)	1 (0.2)	4 (0.5)
MILD	0	0	0	2	1	3	2	1	3
MODERATE	1	0	1	2	0	2	1	0	1
悪寒	0	1 (1.6)	1 (1.0)	2 (0.5)	2 (0.3)	4 (0.4)	2 (0.6)	1 (0.2)	3 (0.4)
MILD	0	1	1	2	2	4	2	1	3
不快感	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MILD	0	0	0	0	1	1	0	1	1
疲労	0	0	0	9 (2.4)	13 (2.3)	22 (2.3)	9 (2.6)	13 (2.5)	22 (2.6)
MILD	0	0	0	6	10	16	6	10	16
MODERATE	0	0	0	3	3	6	3	3	6
異常感	0	0	0	2 (0.5)	0	2 (0.2)	2 (0.6)	0	2 (0.2)
MILD	0	0	0	2	0	2	2	0	2
冷感	0	0	0	1 (0.3)	1 (0.2)	2 (0.2)	1 (0.3)	1 (0.2)	2 (0.2)
MILD	0	0	0	1	1	2	1	1	2

表 2.7.4.7-11. 有害事象（MedDRA SOC 及び PT 別，重症度別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	JAPAN SAFETY SET - ADALIMUMAB STANDARD DOSE (N=39) n (%)	JAPAN SAFETY SET - ADALIMUMAB HIGHER DOSE (N=61) n (%)	JAPAN SAFETY SET - ADALIMUMAB TOTAL (N=100) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB STANDARD DOSE (N=379) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB HIGHER DOSE (N=573) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB TOTAL (N=952) n (%)	SAFETY SET - ADALIMUMAB STANDARD DOSE (N=340) n (%)	SAFETY SET - ADALIMUMAB HIGHER DOSE (N=512) n (%)	SAFETY SET - ADALIMUMAB TOTAL (N=852) n (%)
体温変動感	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MILD	0	0	0	0	1	1	0	1	1
炎症	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
MILD	0	0	0	1	0	1	1	0	1
インフルエンザ様疾患	0	0	0	2 (0.5)	0	2 (0.2)	2 (0.6)	0	2 (0.2)
MILD	0	0	0	1	0	1	1	0	1
MODERATE	0	0	0	1	0	1	1	0	1
注射部位内出血	0	0	0	3 (0.8)	4 (0.7)	7 (0.7)	3 (0.9)	4 (0.8)	7 (0.8)
MILD	0	0	0	2	4	6	2	4	6
MODERATE	0	0	0	1	0	1	1	0	1
注射部位紅斑	1 (2.6)	0	1 (1.0)	3 (0.8)	14 (2.4)	17 (1.8)	2 (0.6)	14 (2.7)	16 (1.9)
MILD	1	0	1	2	9	11	1	9	10
MODERATE	0	0	0	1	5	6	1	5	6
注射部位血腫	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MILD	0	0	0	0	1	1	0	1	1

表 2.7.4.7-11. 有害事象（MedDRA SOC 及び PT 別，重症度別）（日本人安全性解析対象集団，
統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	JAPAN SAFETY SET / ADALIMUMAB STANDARD DOSE (N=39) n (%)	JAPAN SAFETY SET / ADALIMUMAB HIGHER DOSE (N=61) n (%)	JAPAN SAFETY SET / ADALIMUMAB TOTAL (N=100) n (%)	INTEGRATED SAFETY SET / ADALIMUMAB STANDARD DOSE (N=379) n (%)	INTEGRATED SAFETY SET / ADALIMUMAB HIGHER DOSE (N=573) n (%)	INTEGRATED SAFETY SET / ADALIMUMAB TOTAL (N=952) n (%)	SAFETY SET / ADALIMUMAB STANDARD DOSE (N=340) n (%)	SAFETY SET / ADALIMUMAB HIGHER DOSE (N=512) n (%)	SAFETY SET / ADALIMUMAB TOTAL (N=852) n (%)
注射部位過敏反応	0	0	0	0	3 (0.5)	3 (0.3)	0	3 (0.6)	3 (0.4)
MILD	0	0	0	0	3	3	0	3	3
注射部位硬結	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MILD	0	0	0	0	1	1	0	1	1
注射部位炎症	0	0	0	0	2 (0.3)	2 (0.2)	0	2 (0.4)	2 (0.2)
MILD	0	0	0	0	2	2	0	2	2
注射部位腫瘤	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MILD	0	0	0	0	1	1	0	1	1
注射部位浮腫	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MILD	0	0	0	0	1	1	0	1	1
注射部位疼痛	0	0	0	3 (0.8)	6 (1.0)	9 (0.9)	3 (0.9)	6 (1.2)	9 (1.1)
MILD	0	0	0	3	3	6	3	3	6
MODERATE	0	0	0	0	3	3	0	3	3

表 2.7.4.7-11. 有害事象（MedDRA SOC 及び PT 別，重症度別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	JAPAN SAFETY SET – ADALIMUMAB STANDARD DOSE (N=39) n (%)	JAPAN SAFETY SET – ADALIMUMAB HIGHER DOSE (N=61) n (%)	JAPAN SAFETY SET – ADALIMUMAB TOTAL (N=100) n (%)	INTEGRATED SAFETY SET – ADALIMUMAB STANDARD DOSE (N=379) n (%)	INTEGRATED SAFETY SET – ADALIMUMAB HIGHER DOSE (N=573) n (%)	INTEGRATED SAFETY SET – ADALIMUMAB TOTAL (N=952) n (%)	SAFETY SET – ADALIMUMAB STANDARD DOSE (N=340) n (%)	SAFETY SET – ADALIMUMAB HIGHER DOSE (N=512) n (%)	SAFETY SET – ADALIMUMAB TOTAL (N=852) n (%)
注射部位そう痒感	0	0	0	2 (0.5)	13 (2.3)	15 (1.6)	2 (0.6)	13 (2.5)	15 (1.8)
MILD	0	0	0	1	9	10	1	9	10
MODERATE	0	0	0	1	3	4	1	3	4
SEVERE	0	0	0	0	1	1	0	1	1
注射部位発疹	0	0	0	1 (0.3)	4 (0.7)	5 (0.5)	1 (0.3)	4 (0.8)	5 (0.6)
MILD	0	0	0	1	4	5	1	4	5
注射部位反応	2 (5.1)	6 (9.8)	8 (8.0)	3 (0.8)	25 (4.4)	28 (2.9)	1 (0.3)	19 (3.7)	20 (2.3)
MILD	2	6	8	3	22	25	1	16	17
MODERATE	0	0	0	0	2	2	0	2	2
SEVERE	0	0	0	0	1	1	0	1	1
注射部位腫脹	0	0	0	2 (0.5)	9 (1.6)	11 (1.2)	2 (0.6)	9 (1.8)	11 (1.3)
MILD	0	0	0	1	3	4	1	3	4
MODERATE	0	0	0	1	5	6	1	5	6
SEVERE	0	0	0	0	1	1	0	1	1
注射部位蕁麻疹	0	0	0	1 (0.3)	1 (0.2)	2 (0.2)	1 (0.3)	1 (0.2)	2 (0.2)
MILD	0	0	0	1	0	1	1	0	1
MODERATE	0	0	0	0	1	1	0	1	1

表 2.7.4.7-11. 有害事象（MedDRA SOC 及び PT 別，重症度別）（日本人安全性解析対象集団，
統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	JAPAN SAFETY SET / ADALIMUMAB STANDARD DOSE (N=39) n (%)	JAPAN SAFETY SET / ADALIMUMAB HIGHER DOSE (N=61) n (%)	JAPAN SAFETY SET / ADALIMUMAB TOTAL (N=100) n (%)	INTEGRATED SAFETY SET / ADALIMUMAB STANDARD DOSE (N=379) n (%)	INTEGRATED SAFETY SET / ADALIMUMAB HIGHER DOSE (N=573) n (%)	INTEGRATED SAFETY SET / ADALIMUMAB TOTAL (N=952) n (%)	SAFETY SET / ADALIMUMAB STANDARD DOSE (N=340) n (%)	SAFETY SET / ADALIMUMAB HIGHER DOSE (N=512) n (%)	SAFETY SET / ADALIMUMAB TOTAL (N=852) n (%)
倦怠感	0	0	0	1 (0.3)	1 (0.2)	2 (0.2)	1 (0.3)	1 (0.2)	2 (0.2)
MILD	0	0	0	1	1	2	1	1	2
非心臓性胸痛	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
MODERATE	0	0	0	1	0	1	1	0	1
浮腫	1 (2.6)	0	1 (1.0)	1 (0.3)	0	1 (0.1)	0	0	0
MILD	1	0	1	1	0	1	0	0	0
末梢性浮腫	0	0	0	0	2 (0.3)	2 (0.2)	0	2 (0.4)	2 (0.2)
MILD	0	0	0	0	2	2	0	2	2
疼痛	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
MODERATE	0	0	0	1	0	1	1	0	1
末梢腫脹	0	0	0	1 (0.3)	1 (0.2)	2 (0.2)	1 (0.3)	1 (0.2)	2 (0.2)
MILD	0	0	0	1	1	2	1	1	2
発熱	2 (5.1)	3 (4.9)	5 (5.0)	7 (1.8)	10 (1.7)	17 (1.8)	5 (1.5)	7 (1.4)	12 (1.4)
MILD	1	3	4	3	8	11	2	5	7
MODERATE	1	0	1	4	2	6	3	2	5

表 2.7.4.7-11. 有害事象（MedDRA SOC 及び PT 別，重症度別）（日本人安全性解析対象集団，
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SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	JAPAN SAFETY SET - ADALIMUMAB STANDARD DOSE (N=39) n (%)	JAPAN SAFETY SET - ADALIMUMAB HIGHER DOSE (N=61) n (%)	JAPAN SAFETY SET - ADALIMUMAB TOTAL (N=100) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB STANDARD DOSE (N=379) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB HIGHER DOSE (N=573) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB TOTAL (N=952) n (%)	SAFETY SET - ADALIMUMAB STANDARD DOSE (N=340) n (%)	SAFETY SET - ADALIMUMAB HIGHER DOSE (N=512) n (%)	SAFETY SET - ADALIMUMAB TOTAL (N=852) n (%)
腫脹	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
MILD	0	0	0	1	0	1	1	0	1
SUBJECTS WITH ONE OR MORE EVENTS	5 (12.8)	10 (16.4)	15 (15.0)	44 (11.6)	99 (17.3)	143 (15.0)	39 (11.5)	89 (17.4)	128 (15.0)
MILD	3	10	13	31	76	107	28	66	94
MODERATE	2	0	2	13	21	34	11	21	32
SEVERE	0	0	0	0	2	2	0	2	2
肝胆道系障害									
肝病変	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
MILD	0	0	0	1	0	1	1	0	1
脂肪肝	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MILD	0	0	0	0	1	1	0	1	1
肝炎	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MILD	0	0	0	0	1	1	0	1	1

表 2.7.4.7-11. 有害事象（MedDRA SOC 及び PT 別，重症度別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	JAPAN SAFETY SET - ADALIMUMAB STANDARD DOSE (N=39) n (%)	JAPAN SAFETY SET - ADALIMUMAB HIGHER DOSE (N=61) n (%)	JAPAN SAFETY SET - ADALIMUMAB TOTAL (N=100) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB STANDARD DOSE (N=379) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB HIGHER DOSE (N=573) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB TOTAL (N=952) n (%)	SAFETY SET - ADALIMUMAB STANDARD DOSE (N=340) n (%)	SAFETY SET - ADALIMUMAB HIGHER DOSE (N=512) n (%)	SAFETY SET - ADALIMUMAB TOTAL (N=852) n (%)
高トランスアミナーゼ血症	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MILD	0	0	0	0	1	1	0	1	1
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	1 (0.3)	3 (0.5)	4 (0.4)	1 (0.3)	3 (0.6)	4 (0.5)
MILD	0	0	0	1	3	4	1	3	4
免疫系障害									
薬物過敏症	0	0	0	1 (0.3)	1 (0.2)	2 (0.2)	1 (0.3)	1 (0.2)	2 (0.2)
MILD	0	0	0	0	1	1	0	1	1
MODERATE	0	0	0	1	0	1	1	0	1
過敏症	0	1 (1.6)	1 (1.0)	1 (0.3)	3 (0.5)	4 (0.4)	1 (0.3)	2 (0.4)	3 (0.4)
MILD	0	1	1	1	3	4	1	2	3
季節性アレルギー	0	0	0	0	3 (0.5)	3 (0.3)	0	3 (0.6)	3 (0.4)
MILD	0	0	0	0	2	2	0	2	2
MODERATE	0	0	0	0	1	1	0	1	1

表 2.7.4.7-11. 有害事象（MedDRA SOC 及び PT 別，重症度別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

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SUBJECTS WITH ONE OR MORE EVENTS	0	1 (1.6)	1 (1.0)	2 (0.5)	7 (1.2)	9 (0.9)	2 (0.6)	6 (1.2)	8 (0.9)
MILD	0	1	1	1	6	7	1	5	6
MODERATE	0	0	0	1	1	2	1	1	2
感染症および寄生虫症									
膿瘍	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
MILD	0	0	0	1	0	1	1	0	1
四肢膿瘍	0	0	0	1 (0.3)	1 (0.2)	2 (0.2)	1 (0.3)	1 (0.2)	2 (0.2)
MODERATE	0	0	0	1	1	2	1	1	2
肛門膿瘍	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MILD	0	0	0	0	1	1	0	1	1
ブラストシスティス感染	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MILD	0	0	0	0	1	1	0	1	1

表 2.7.4.7-11. 有害事象（MedDRA SOC 及び PT 別，重症度別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

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気管支炎	0	0	0	1 (0.3)	1 (0.2)	2 (0.2)	1 (0.3)	1 (0.2)	2 (0.2)
MILD	0	0	0	1	0	1	1	0	1
MODERATE	0	0	0	0	1	1	0	1	1
ウイルス性気管支炎	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
MILD	0	0	0	1	0	1	1	0	1
カンジダ感染	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MILD	0	0	0	0	1	1	0	1	1
蜂巣炎	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
MODERATE	0	0	0	1	0	1	1	0	1
クロストリジウム・ディフィシレ感染	0	0	0	0	2 (0.3)	2 (0.2)	0	2 (0.4)	2 (0.2)
MODERATE	0	0	0	0	2	2	0	2	2
結膜炎	0	0	0	1 (0.3)	1 (0.2)	2 (0.2)	1 (0.3)	1 (0.2)	2 (0.2)
MILD	0	0	0	1	1	2	1	1	2
膀胱炎	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MILD	0	0	0	0	1	1	0	1	1

表 2.7.4.7-11. 有害事象（MedDRA SOC 及び PT 別，重症度別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	JAPAN SAFETY SET - ADALIMUMAB STANDARD DOSE (N=39) n (%)	JAPAN SAFETY SET - ADALIMUMAB HIGHER DOSE (N=61) n (%)	JAPAN SAFETY SET - ADALIMUMAB TOTAL (N=100) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB STANDARD DOSE (N=379) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB HIGHER DOSE (N=573) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB TOTAL (N=952) n (%)	SAFETY SET - ADALIMUMAB STANDARD DOSE (N=340) n (%)	SAFETY SET - ADALIMUMAB HIGHER DOSE (N=512) n (%)	SAFETY SET - ADALIMUMAB TOTAL (N=852) n (%)
サイトメガロウイルス性大腸炎	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
SEVERE	0	0	0	0	1	1	0	1	1
サイトメガロウイルス感染	1 (2.6)	0	1 (1.0)	1 (0.3)	0	1 (0.1)	0	0	0
MODERATE	1	0	1	1	0	1	0	0	0
耳感染	0	0	0	1 (0.3)	2 (0.3)	3 (0.3)	1 (0.3)	2 (0.4)	3 (0.4)
MODERATE	0	0	0	1	2	3	1	2	3
丹毒	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
MILD	0	0	0	1	0	1	1	0	1
毛包炎	0	1 (1.6)	1 (1.0)	0	2 (0.3)	2 (0.2)	0	1 (0.2)	1 (0.1)
MILD	0	1	1	0	1	1	0	0	0
MODERATE	0	0	0	0	1	1	0	1	1
真菌感染	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MODERATE	0	0	0	0	1	1	0	1	1
胃腸炎	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MILD	0	0	0	0	1	1	0	1	1

表 2.7.4.7-11. 有害事象（MedDRA SOC 及び PT 別，重症度別）（日本人安全性解析対象集団，
統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	JAPAN SAFETY SET - ADALIMUMAB STANDARD DOSE (N=39) n (%)	JAPAN SAFETY SET - ADALIMUMAB HIGHER DOSE (N=61) n (%)	JAPAN SAFETY SET - ADALIMUMAB TOTAL (N=100) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB STANDARD DOSE (N=379) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB HIGHER DOSE (N=573) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB TOTAL (N=952) n (%)	SAFETY SET - ADALIMUMAB STANDARD DOSE (N=340) n (%)	SAFETY SET - ADALIMUMAB HIGHER DOSE (N=512) n (%)	SAFETY SET - ADALIMUMAB TOTAL (N=852) n (%)
ウイルス性胃腸炎	0	0	0	1 (0.3)	2 (0.3)	3 (0.3)	1 (0.3)	2 (0.4)	3 (0.4)
MILD	0	0	0	1	1	2	1	1	2
MODERATE	0	0	0	0	1	1	0	1	1
消化管感染	0	1 (1.6)	1 (1.0)	0	1 (0.2)	1 (0.1)	0	0	0
MODERATE	0	1	1	0	1	1	0	0	0
単純ヘルペス	0	1 (1.6)	1 (1.0)	0	1 (0.2)	1 (0.1)	0	0	0
MILD	0	1	1	0	1	1	0	0	0
ヘルペスウイルス感染	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MILD	0	0	0	0	1	1	0	1	1
帯状疱疹	0	0	0	2 (0.5)	0	2 (0.2)	2 (0.6)	0	2 (0.2)
MILD	0	0	0	1	0	1	1	0	1
MODERATE	0	0	0	1	0	1	1	0	1
麦粒腫	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MILD	0	0	0	0	1	1	0	1	1

表 2.7.4.7-11. 有害事象（MedDRA SOC 及び PT 別，重症度別）（日本人安全性解析対象集団，
統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	JAPAN SAFETY SET - ADALIMUMAB STANDARD DOSE (N=39) n (%)	JAPAN SAFETY SET - ADALIMUMAB HIGHER DOSE (N=61) n (%)	JAPAN SAFETY SET - ADALIMUMAB TOTAL (N=100) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB STANDARD DOSE (N=379) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB HIGHER DOSE (N=573) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB TOTAL (N=952) n (%)	SAFETY SET - ADALIMUMAB STANDARD DOSE (N=340) n (%)	SAFETY SET - ADALIMUMAB HIGHER DOSE (N=512) n (%)	SAFETY SET - ADALIMUMAB TOTAL (N=852) n (%)
膿痂疹	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MODERATE	0	0	0	0	1	1	0	1	1
感染性嚢腫	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MODERATE	0	0	0	0	1	1	0	1	1
感染	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MODERATE	0	0	0	0	1	1	0	1	1
インフルエンザ	0	1 (1.6)	1 (1.0)	6 (1.6)	2 (0.3)	8 (0.8)	6 (1.8)	1 (0.2)	7 (0.8)
MILD	0	1	1	3	1	4	3	0	3
MODERATE	0	0	0	3	1	4	3	1	4
喉頭炎	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
MILD	0	0	0	1	0	1	1	0	1
限局性感染	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MODERATE	0	0	0	0	1	1	0	1	1

表 2.7.4.7-11. 有害事象（MedDRA SOC 及び PT 別，重症度別）（日本人安全性解析対象集団，
統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	JAPAN SAFETY SET - ADALIMUMAB STANDARD DOSE (N=39) n (%)	JAPAN SAFETY SET - ADALIMUMAB HIGHER DOSE (N=61) n (%)	JAPAN SAFETY SET - ADALIMUMAB TOTAL (N=100) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB STANDARD DOSE (N=379) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB HIGHER DOSE (N=573) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB TOTAL (N=952) n (%)	SAFETY SET - ADALIMUMAB STANDARD DOSE (N=340) n (%)	SAFETY SET - ADALIMUMAB HIGHER DOSE (N=512) n (%)	SAFETY SET - ADALIMUMAB TOTAL (N=852) n (%)
上咽頭炎	2 (5.1)	10 (16.4)	12 (12.0)	16 (4.2)	29 (5.1)	45 (4.7)	14 (4.1)	19 (3.7)	33 (3.9)
MILD	2	9	11	13	22	35	11	13	24
MODERATE	0	1	1	2	7	9	2	6	8
SEVERE	0	0	0	1	0	1	1	0	1
食道カンジダ症	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
MODERATE	0	0	0	1	0	1	1	0	1
爪真菌症	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MILD	0	0	0	0	1	1	0	1	1
口腔ヘルペス	0	0	0	2 (0.5)	2 (0.3)	4 (0.4)	2 (0.6)	2 (0.4)	4 (0.5)
MILD	0	0	0	1	2	3	1	2	3
MODERATE	0	0	0	1	0	1	1	0	1
中耳炎	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
MODERATE	0	0	0	1	0	1	1	0	1
咽頭炎	0	0	0	5 (1.3)	3 (0.5)	8 (0.8)	5 (1.5)	3 (0.6)	8 (0.9)
MILD	0	0	0	4	2	6	4	2	6
MODERATE	0	0	0	1	1	2	1	1	2

表 2.7.4.7-11. 有害事象（MedDRA SOC 及び PT 別，重症度別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	JAPAN SAFETY SET - ADALIMUMAB STANDARD DOSE (N=39) n (%)	JAPAN SAFETY SET - ADALIMUMAB HIGHER DOSE (N=61) n (%)	JAPAN SAFETY SET - ADALIMUMAB TOTAL (N=100) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB STANDARD DOSE (N=379) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB HIGHER DOSE (N=573) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB TOTAL (N=952) n (%)	SAFETY SET - ADALIMUMAB STANDARD DOSE (N=340) n (%)	SAFETY SET - ADALIMUMAB HIGHER DOSE (N=512) n (%)	SAFETY SET - ADALIMUMAB TOTAL (N=852) n (%)
細菌性咽頭炎	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
MILD	0	0	0	1	0	1	1	0	1
レンサ球菌性咽頭炎	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MILD	0	0	0	0	1	1	0	1	1
肺炎	1 (2.6)	0	1 (1.0)	3 (0.8)	1 (0.2)	4 (0.4)	2 (0.6)	1 (0.2)	3 (0.4)
MODERATE	0	0	0	2	0	2	2	0	2
SEVERE	1	0	1	1	1	2	0	1	1
腎盂腎炎	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
MODERATE	0	0	0	1	0	1	1	0	1
膿疱性皮疹	0	0	0	2 (0.5)	1 (0.2)	3 (0.3)	2 (0.6)	1 (0.2)	3 (0.4)
MILD	0	0	0	2	1	3	2	1	3
気道感染	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MILD	0	0	0	0	1	1	0	1	1
鼻炎	0	0	0	3 (0.8)	2 (0.3)	5 (0.5)	3 (0.9)	2 (0.4)	5 (0.6)
MILD	0	0	0	3	2	5	3	2	5

表 2.7.4.7-11. 有害事象（MedDRA SOC 及び PT 別，重症度別）（日本人安全性解析対象集団，統合安全性解析対象集団及び主試験安全性解析対象集団，M14-033 日本サブ試験の導入療法試験）（続き）

SYSTEM ORGAN CLASS MEDDRA 22.0 PREFERRED TERM SEVERITY	JAPAN SAFETY SET - ADALIMUMAB STANDARD DOSE (N=39) n (%)	JAPAN SAFETY SET - ADALIMUMAB HIGHER DOSE (N=61) n (%)	JAPAN SAFETY SET - ADALIMUMAB TOTAL (N=100) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB STANDARD DOSE (N=379) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB HIGHER DOSE (N=573) n (%)	INTEGRATED SAFETY SET - ADALIMUMAB TOTAL (N=952) n (%)	SAFETY SET - ADALIMUMAB STANDARD DOSE (N=340) n (%)	SAFETY SET - ADALIMUMAB HIGHER DOSE (N=512) n (%)	SAFETY SET - ADALIMUMAB TOTAL (N=852) n (%)
副鼻腔炎	0	0	0	4 (1.1)	5 (0.9)	9 (0.9)	4 (1.2)	5 (1.0)	9 (1.1)
MILD	0	0	0	3	3	6	3	3	6
MODERATE	0	0	0	1	2	3	1	2	3
皮膚感染	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MILD	0	0	0	0	1	1	0	1	1
白癬感染	0	0	0	0	2 (0.3)	2 (0.2)	0	2 (0.4)	2 (0.2)
MILD	0	0	0	0	2	2	0	2	2
歯感染	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
MODERATE	0	0	0	0	1	1	0	1	1
結核	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
SEVERE	0	0	0	0	1	1	0	1	1
上気道感染	0	0	0	3 (0.8)	6 (1.0)	9 (0.9)	3 (0.9)	6 (1.2)	9 (1.1)
MILD	0	0	0	1	5	6	1	5	6
MODERATE	0	0	0	2	1	3	2	1	3