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 (%)
尿路感染	0	0	0	5 (1.3)	6 (1.0)	11 (1.2)	5 (1.5)	6 (1.2)	11 (1.3)
MILD	0	0	0	5	3	8	5	3	8
MODERATE	0	0	0	0	3	3	0	3	3
腟感染	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
水痘	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
ウイルス感染	0	0	0	0	3 (0.5)	3 (0.3)	0	3 (0.6)	3 (0.4)
MILD	0	0	0	0	1	1	0	1	1
MODERATE	0	0	0	0	2	2	0	2	2
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)
MILD	0	0	0	1	0	1	1	0	1
外陰部腟カンジダ症	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

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 (%)
外陰腟真菌感染	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
SUBJECTS WITH ONE OR MORE EVENTS	4 (10.3)	14 (23.0)	18 (18.0)	63 (16.6)	84 (14.7)	147 (15.4)	59 (17.4)	70 (13.7)	129 (15.1)
MILD	2	11	13	41	51	92	39	40	79
MODERATE	1	3	4	20	31	51	19	28	47
SEVERE	1	0	1	2	2	4	1	2	3
傷害、中毒および処置合併症									
動物による引っかき傷	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
節足動物咬傷	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
挫傷	1 (2.6)	1 (1.6)	2 (2.0)	3 (0.8)	5 (0.9)	8 (0.8)	2 (0.6)	4 (0.8)	6 (0.7)
MILD	1	1	2	2	5	7	1	4	5
MODERATE	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 (%)
角膜擦過傷	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
転倒	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
注入に伴う反応	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
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)
MILD	0	0	0	0	1	1	0	1	1
MODERATE	0	1	1	0	1	1	0	0	0
関節損傷	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
靱帯捻挫	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
四肢損傷	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 (%)
肉離れ	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
処置による疼痛	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
交通事故	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
皮膚擦過傷	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
脊柱損傷	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
脊椎圧迫骨折	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
スポーツ損傷	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 (%)
舌損傷	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
尺骨神経損傷	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
上肢骨折	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	1 (2.6)	3 (4.9)	4 (4.0)	7 (1.8)	19 (3.3)	26 (2.7)	6 (1.8)	16 (3.1)	22 (2.6)
MILD	1	1	2	4	11	15	3	10	13
MODERATE	0	2	2	3	8	11	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	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

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 (%)
アスパラギン酸アミノトランスフェラーゼ増加	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)
MILD	1	0	1	2	0	2	1	0	1
MODERATE	0	0	0	1	1	2	1	1	2
細菌検査陽性	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)
MILD	0	0	0	1	2	3	1	2	3
血中コレステロール増加	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
血中クレアチニン増加	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
血中ブドウ糖増加	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
血中リン減少	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
SEVERE	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 (%)
血圧上昇	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
血中トリグリセリド増加	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
血中尿素増加	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
血中尿素窒素／クレアチニン比増加	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
呼吸音異常	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
C－反応性蛋白増加	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
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)
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 (%)
ヘマトクリット減少	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
ヘモグロビン減少	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
好中球数増加	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
膵酵素増加	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
血小板数増加	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
尿中赤血球陽性	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
皮膚ツルゴール低下	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 (%)
体重減少	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
白血球数減少	1 (2.6)	1 (1.6)	2 (2.0)	2 (0.5)	2 (0.3)	4 (0.4)	1 (0.3)	1 (0.2)	2 (0.2)
MILD	1	1	2	1	2	3	0	1	1
MODERATE	0	0	0	1	0	1	1	0	1
白血球数増加	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
尿中白血球陽性	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	2 (5.1)	2 (3.3)	4 (4.0)	16 (4.2)	21 (3.7)	37 (3.9)	14 (4.1)	19 (3.7)	33 (3.9)
MILD	2	2	4	12	13	25	10	11	21
MODERATE	0	0	0	3	8	11	3	8	11
SEVERE	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 (%)
代謝および栄養障害									
食欲減退	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
脱水	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	1	2	1	1	2
SEVERE	0	0	0	0	1	1	0	1	1
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)
MILD	0	0	0	1	1	2	1	1	2
高血糖	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
高トリグリセリド血症	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
低アルブミン血症	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

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 (%)
低カリウム血症	0	0	0	3 (0.8)	0	3 (0.3)	3 (0.9)	0	3 (0.4)
MILD	0	0	0	2	0	2	2	0	2
MODERATE	0	0	0	1	0	1	1	0	1
血液量減少症	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
空腹時血中ブドウ糖不良	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
食欲亢進	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	2	2	0	1	1
代謝性アシドーシス	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
ビタミンD欠乏	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

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	0	1 (1.6)	1 (1.0)	10 (2.6)	8 (1.4)	18 (1.9)	10 (2.9)	7 (1.4)	17 (2.0)
MILD	0	1	1	7	4	11	7	3	10
MODERATE	0	0	0	3	3	6	3	3	6
SEVERE	0	0	0	0	1	1	0	1	1
筋骨格系および結合組織障害									
関節痛	2 (5.1)	1 (1.6)	3 (3.0)	11 (2.9)	18 (3.1)	29 (3.0)	9 (2.6)	17 (3.3)	26 (3.1)
MILD	2	1	3	10	13	23	8	12	20
MODERATE	0	0	0	1	5	6	1	5	6
関節炎	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
軸性脊椎関節炎	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
背部痛	1 (2.6)	2 (3.3)	3 (3.0)	4 (1.1)	14 (2.4)	18 (1.9)	3 (0.9)	12 (2.3)	15 (1.8)
MILD	1	2	3	1	10	11	0	8	8
MODERATE	0	0	0	3	4	7	3	4	7

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 (%)
滑液包炎	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
側腹部痛	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
帯径部痛	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
関節雑音	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
関節可動域低下	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
関節腫脹	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

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			INTEGRATED SAFETY SET			SAFETY SET		
	ADALIMUMAB			ADALIMUMAB			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 (%)
筋痙縮	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	2	3	1	2	3
MODERATE	0	0	0	0	1	1	0	1	1
筋緊張	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
筋骨格痛	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
筋骨格硬直	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
筋肉痛	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	1	1	0	1	1
MODERATE	0	0	0	1	1	2	1	1	2
頚部痛	1 (2.6)	0	1 (1.0)	1 (0.3)	1 (0.2)	2 (0.2)	0	1 (0.2)	1 (0.1)
MILD	1	0	1	1	1	2	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 (%)
変形性関節症	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
四肢痛	1 (2.6)	1 (1.6)	2 (2.0)	2 (0.5)	2 (0.3)	4 (0.4)	1 (0.3)	1 (0.2)	2 (0.2)
MILD	1	1	2	1	1	2	0	0	0
MODERATE	0	0	0	1	0	1	1	0	1
SEVERE	0	0	0	0	1	1	0	1	1
顎痛	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
肩回旋筋腱板症候群	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
仙腸骨炎	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
SUBJECTS WITH ONE OR MORE EVENTS	3 (7.7)	4 (6.6)	7 (7.0)	26 (6.9)	45 (7.9)	71 (7.5)	23 (6.8)	41 (8.0)	64 (7.5)
MILD	3	3	6	17	29	46	14	26	40
MODERATE	0	1	1	9	15	24	9	14	23
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 (%)
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)
MODERATE	0	0	0	0	1	1	0	1	1
基底細胞癌	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
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)
SEVERE	0	0	0	1	0	1	1	0	1
メラノサイト性母斑	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
子宮頚部扁平上皮癌	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
SEVERE	0	0	0	1	0	1	1	0	1
SUBJECTS WITH ONE OR MORE EVENTS	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)
MODERATE	0	1	1	1	2	3	1	1	2
SEVERE	0	0	0	2	0	2	2	0	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 (%)
神経系障害									
浮動性めまい	0	2 (3.3)	2 (2.0)	4 (1.1)	14 (2.4)	18 (1.9)	4 (1.2)	12 (2.3)	16 (1.9)
MILD	0	2	2	3	9	12	3	7	10
MODERATE	0	0	0	1	4	5	1	4	5
SEVERE	0	0	0	0	1	1	0	1	1
蟻走感	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
頭痛	0	1 (1.6)	1 (1.0)	23 (6.1)	48 (8.4)	71 (7.5)	23 (6.8)	47 (9.2)	70 (8.2)
MILD	0	1	1	15	31	46	15	30	45
MODERATE	0	0	0	8	16	24	8	16	24
SEVERE	0	0	0	0	1	1	0	1	1
感覚鈍麻	1 (2.6)	0	1 (1.0)	2 (0.5)	3 (0.5)	5 (0.5)	1 (0.3)	3 (0.6)	4 (0.5)
MILD	1	0	1	2	2	4	1	2	3
MODERATE	0	0	0	0	1	1	0	1	1
嗜眠	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	0	2	2	0	2
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，
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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 (%)
片頭痛	0	0	0	2 (0.5)	4 (0.7)	6 (0.6)	2 (0.6)	4 (0.8)	6 (0.7)
MILD	0	0	0	2	2	4	2	2	4
MODERATE	0	0	0	0	2	2	0	2	2
神経痛	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
錯感覚	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	3	4	1	3	4
MODERATE	0	0	0	0	1	1	0	1	1
失神寸前の状態	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	2	0	2	2	0	2
MODERATE	0	0	0	0	2	2	0	2	2
神経根障害	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
痙攣発作	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 (%)
傾眠	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
失神	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
振戦	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
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.6)	3 (4.9)	4 (4.0)	35 (9.2)	70 (12.2)	105 (11.0)	34 (10.0)	67 (13.1)	101 (11.9)
MILD	1	3	4	26	43	69	25	40	65
MODERATE	0	0	0	9	24	33	9	24	33
SEVERE	0	0	0	0	3	3	0	3	3
精神障害									
不安	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 (%)
抑うつ気分	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
不眠症	0	1 (1.6)	1 (1.0)	2 (0.5)	3 (0.5)	5 (0.5)	2 (0.6)	2 (0.4)	4 (0.5)
MILD	0	1	1	0	2	2	0	1	1
MODERATE	0	0	0	1	1	2	1	1	2
SEVERE	0	0	0	1	0	1	1	0	1
パニック発作	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	1 (1.6)	1 (1.0)	3 (0.8)	6 (1.0)	9 (0.9)	3 (0.9)	5 (1.0)	8 (0.9)
MILD	0	1	1	1	3	4	1	2	3
MODERATE	0	0	0	1	3	4	1	3	4
SEVERE	0	0	0	1	0	1	1	0	1
腎および尿路障害									
急性腎障害	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 (%)
着色尿	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
排尿困難	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
血尿	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
高シュウ酸尿症	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
腎結石症	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
夜間頻尿	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
多尿	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 (%)
腎仙痛	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
腎不全	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
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	5 (1.3)	7 (1.2)	12 (1.3)	5 (1.5)	7 (1.4)	12 (1.4)
MILD	0	0	0	4	4	8	4	4	8
MODERATE	0	0	0	1	3	4	1	3	4
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)
MODERATE	0	0	0	0	1	1	0	1	1
不正子宮出血	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
卵巣嚢胞	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			INTEGRATED SAFETY SET			SAFETY SET		
	ADALIMUMAB			ADALIMUMAB			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 (%)
骨盤痛	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
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	0	1	1	0	1
MODERATE	0	0	0	1	1	2	1	1	2
呼吸器、胸郭および縦隔障害									
喘息	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
咳嗽	0	0	0	6 (1.6)	9 (1.6)	15 (1.6)	6 (1.8)	9 (1.8)	15 (1.8)
MILD	0	0	0	6	4	10	6	4	10
MODERATE	0	0	0	0	5	5	0	5	5
発声障害	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 (%)
呼吸困難	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
鼻出血	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
鼻閉	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
口腔咽頭痛	1 (2.6)	2 (3.3)	3 (3.0)	6 (1.6)	17 (3.0)	23 (2.4)	5 (1.5)	15 (2.9)	20 (2.3)
MILD	1	2	3	6	14	20	5	12	17
MODERATE	0	0	0	0	3	3	0	3	3
咽頭障害	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
湿性咳嗽	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
鼻漏	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

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 (%)
副鼻腔うっ血	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
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.6)	2 (3.3)	3 (3.0)	14 (3.7)	30 (5.2)	44 (4.6)	13 (3.8)	28 (5.5)	41 (4.8)
MILD	1	2	3	14	22	36	13	20	33
MODERATE	0	0	0	0	8	8	0	8	8
皮膚および皮下組織障害									
ざ瘡	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	1	1	2	2	4	2	1	3
MODERATE	0	0	0	1	0	1	1	0	1
脱毛症	1 (2.6)	1 (1.6)	2 (2.0)	8 (2.1)	5 (0.9)	13 (1.4)	7 (2.1)	4 (0.8)	11 (1.3)
MILD	1	1	2	8	4	12	7	3	10
MODERATE	0	0	0	0	1	1	0	1	1
血管浮腫	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

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 (%)
冷汗	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
頭部粃糠疹	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	1	2	1	1	2
皮膚炎	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	2	3	1	2	3
MODERATE	0	0	0	0	1	1	0	1	1
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)
MILD	0	0	0	0	1	1	0	1	1
接触皮膚炎	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
乾癬様皮膚炎	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
皮膚乾燥	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 (%)
湿疹	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	0	0	1	1	2	1	1	2
MODERATE	0	1	1	1	1	2	1	0	1
紅斑	1 (2.6)	0	1 (1.0)	2 (0.5)	5 (0.9)	7 (0.7)	1 (0.3)	5 (1.0)	6 (0.7)
MILD	1	0	1	2	4	6	1	4	5
MODERATE	0	0	0	0	1	1	0	1	1
結節性紅斑	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
男性型多毛症	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
多汗症	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
多毛症	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

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 (%)
寝汗	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
そう痒症	0	0	0	3 (0.8)	3 (0.5)	6 (0.6)	3 (0.9)	3 (0.6)	6 (0.7)
MILD	0	0	0	2	3	5	2	3	5
MODERATE	0	0	0	1	0	1	1	0	1
全身性そう痒症	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
乾癬	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
発疹	3 (7.7)	0	3 (3.0)	11 (2.9)	10 (1.7)	21 (2.2)	8 (2.4)	10 (2.0)	18 (2.1)
MILD	3	0	3	11	9	20	8	9	17
MODERATE	0	0	0	0	1	1	0	1	1
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)
MILD	0	0	0	2	1	3	2	1	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 (%)
斑状丘疹状皮疹	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
丘疹性皮疹	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
顔面腫脹	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
蕁麻疹	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)
MILD	1	0	1	1	0	1	0	0	0
MODERATE	0	0	0	1	1	2	1	1	2
SUBJECTS WITH ONE OR MORE EVENTS	5 (12.8)	3 (4.9)	8 (8.0)	36 (9.5)	41 (7.2)	77 (8.1)	31 (9.1)	38 (7.4)	69 (8.1)
MILD	5	2	7	31	33	64	26	31	57
MODERATE	0	1	1	5	8	13	5	7	12

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 (%)
外科および内科処置									
創部ドレナージ	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
SUBJECTS WITH ONE OR MORE EVENTS	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
血管障害									
血腫	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
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 (%)
高血圧	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
低血圧	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
蒼白	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
末梢静脈疾患	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
表在性静脈炎	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
血栓性静脈炎	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
静脈血栓症	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

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			INTEGRATED SAFETY SET			SAFETY SET		
	ADALIMUMAB			ADALIMUMAB			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	0	0	0	8 (2.1)	7 (1.2)	15 (1.6)	8 (2.4)	7 (1.4)	15 (1.8)
MILD	0	0	0	6	5	11	6	5	11
MODERATE	0	0	0	2	2	4	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 Japan Sub-study Final CSR Table 14.3__1.4_J

表 2.7.4.7-12. 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 主試験の維持療法試験）

MedDRA 22.0 System Organ Class Preferred Term Severity	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	220 (72.8)	222 (73.0)	96 (63.6)	538 (71.1)
Mild	64 (21.2)	63 (20.7)	35 (23.2)	162 (21.4)
Moderate	128 (42.4)	121 (39.8)	51 (33.8)	300 (39.6)
Severe	28 (9.3)	38 (12.5)	10 (6.6)	76 (10.0)
血液およびリンパ系障害	17 (5.6)	26 (8.6)	9 (6.0)	52 (6.9)
Mild	4 (1.3)	12 (3.9)	6 (4.0)	22 (2.9)
Moderate	11 (3.6)	10 (3.3)	3 (2.0)	24 (3.2)
Severe	2 (0.7)	4 (1.3)	0	6 (0.8)
貧血	12 (4.0)	13 (4.3)	5 (3.3)	30 (4.0)
Mild	4 (1.3)	4 (1.3)	3 (2.0)	11 (1.5)
Moderate	7 (2.3)	7 (2.3)	2 (1.3)	16 (2.1)
Severe	1 (0.3)	2 (0.7)	0	3 (0.4)
内出血発生の増加傾向	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
鉄欠乏性貧血	2 (0.7)	2 (0.7)	0	4 (0.5)
Moderate	2 (0.7)	1 (0.3)	0	3 (0.4)
Severe	0	1 (0.3)	0	1 (0.1)
白血球増加症	1 (0.3)	2 (0.7)	0	3 (0.4)
Mild	0	1 (0.3)	0	1 (0.1)
Moderate	1 (0.3)	1 (0.3)	0	2 (0.3)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
血液およびリンパ系障害 (Cont.)				
白血球減少症	1 (0.3)	4 (1.3)	0	5 (0.7)
Mild	0	3 (1.0)	0	3 (0.4)
Moderate	1 (0.3)	1 (0.3)	0	2 (0.3)
リンパ節症	0	2 (0.7)	1 (0.7)	3 (0.4)
Mild	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	1 (0.7)	1 (0.1)
Severe	0	1 (0.3)	0	1 (0.1)
リンパ球減少症	0	0	1 (0.7)	1 (0.1)
Mild	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)
Mild	0	1 (0.3)	1 (0.7)	2 (0.3)
Moderate	1 (0.3)	0	0	1 (0.1)
血小板減少症	1 (0.3)	0	1 (0.7)	2 (0.3)
Mild	0	0	1 (0.7)	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
血小板増加症	1 (0.3)	3 (1.0)	0	4 (0.5)
Mild	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
Severe	1 (0.3)	1 (0.3)	0	2 (0.3)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
心臓障害	6 (2.0)	4 (1.3)	1 (0.7)	11 (1.5)
Mild	3 (1.0)	2 (0.7)	0	5 (0.7)
Moderate	1 (0.3)	2 (0.7)	1 (0.7)	4 (0.5)
Severe	2 (0.7)	0	0	2 (0.3)
急性心筋梗塞	1 (0.3)	0	0	1 (0.1)
Severe	1 (0.3)	0	0	1 (0.1)
心房細動	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
Moderate	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
うっ血性心不全	1 (0.3)	0	0	1 (0.1)
Severe	1 (0.3)	0	0	1 (0.1)
冠動脈疾患	1 (0.3)	0	0	1 (0.1)
Severe	1 (0.3)	0	0	1 (0.1)
心筋虚血	1 (0.3)	0	0	1 (0.1)
Severe	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
心臓障害 (Cont.)				
動悸	2 (0.7)	2 (0.7)	0	4 (0.5)
Mild	2 (0.7)	1 (0.3)	0	3 (0.4)
Moderate	0	1 (0.3)	0	1 (0.1)
洞性徐脈	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
頻脈	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
耳および迷路障害	5 (1.7)	3 (1.0)	1 (0.7)	9 (1.2)
Mild	5 (1.7)	2 (0.7)	1 (0.7)	8 (1.1)
Moderate	0	1 (0.3)	0	1 (0.1)
外耳道狭窄	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
耳痛	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
耳および迷路障害 (Cont.)				
耳鳴	2 (0.7)	2 (0.7)	1 (0.7)	5 (0.7)
Mild	2 (0.7)	2 (0.7)	1 (0.7)	5 (0.7)
回転性めまい	2 (0.7)	0	0	2 (0.3)
Mild	2 (0.7)	0	0	2 (0.3)
内分泌障害	3 (1.0)	3 (1.0)	0	6 (0.8)
Mild	2 (0.7)	3 (1.0)	0	5 (0.7)
Moderate	1 (0.3)	0	0	1 (0.1)
クッシング様症状	2 (0.7)	0	0	2 (0.3)
Mild	2 (0.7)	0	0	2 (0.3)
甲状腺腫	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
甲状腺機能低下症	1 (0.3)	2 (0.7)	0	3 (0.4)
Mild	0	2 (0.7)	0	2 (0.3)
Moderate	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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	9 (3.0)	16 (5.3)	2 (1.3)	27 (3.6)
Mild	6 (2.0)	13 (4.3)	2 (1.3)	21 (2.8)
Moderate	3 (1.0)	2 (0.7)	0	5 (0.7)
Severe	0	1 (0.3)	0	1 (0.1)
閉塞隅角緑内障	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
乱視	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
眼瞼炎	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
眼瞼痙攣	0	2 (0.7)	0	2 (0.3)
Mild	0	2 (0.7)	0	2 (0.3)
白内障	1 (0.3)	1 (0.3)	0	2 (0.3)
Moderate	1 (0.3)	1 (0.3)	0	2 (0.3)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
複視	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
ドライアイ	1 (0.3)	1 (0.3)	0	2 (0.3)
Mild	1 (0.3)	1 (0.3)	0	2 (0.3)
眼瞼紅斑	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
眼の炎症	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
眼刺激	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
眼痛	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
眼瞼縁痂皮	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
眼瞼下垂	0	2 (0.7)	0	2 (0.3)
Mild	0	1 (0.3)	0	1 (0.1)
Severe	0	1 (0.3)	0	1 (0.1)
眼瞼そう痒症	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
緑内障	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
眼充血	0	1 (0.3)	1 (0.7)	2 (0.3)
Mild	0	1 (0.3)	1 (0.7)	2 (0.3)
眼酒さ	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
視神経萎縮	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
老視	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
網膜剥離	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
眼瞼腫脹	0	3 (1.0)	0	3 (0.4)
Mild	0	3 (1.0)	0	3 (0.4)
霧視	0	1 (0.3)	1 (0.7)	2 (0.3)
Mild	0	1 (0.3)	1 (0.7)	2 (0.3)
視力低下	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
視力障害	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
胃腸障害	128 (42.4)	103 (33.9)	45 (29.8)	276 (36.5)
Mild	39 (12.9)	38 (12.5)	15 (9.9)	92 (12.2)
Moderate	74 (24.5)	49 (16.1)	25 (16.6)	148 (19.6)
Severe	15 (5.0)	16 (5.3)	5 (3.3)	36 (4.8)
腹部不快感	1 (0.3)	2 (0.7)	0	3 (0.4)
Mild	1 (0.3)	1 (0.3)	0	2 (0.3)
Moderate	0	1 (0.3)	0	1 (0.1)
腹部膨満	5 (1.7)	1 (0.3)	1 (0.7)	7 (0.9)
Mild	4 (1.3)	1 (0.3)	1 (0.7)	6 (0.8)
Moderate	1 (0.3)	0	0	1 (0.1)
腹部ヘルニア	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
腹痛	7 (2.3)	6 (2.0)	1 (0.7)	14 (1.8)
Mild	4 (1.3)	4 (1.3)	1 (0.7)	9 (1.2)
Moderate	1 (0.3)	2 (0.7)	0	3 (0.4)
Severe	2 (0.7)	0	0	2 (0.3)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
下腹部痛	2 (0.7)	2 (0.7)	0	4 (0.5)
Mild	2 (0.7)	2 (0.7)	0	4 (0.5)
上腹部痛	3 (1.0)	6 (2.0)	1 (0.7)	10 (1.3)
Mild	1 (0.3)	6 (2.0)	0	7 (0.9)
Moderate	1 (0.3)	0	1 (0.7)	2 (0.3)
Severe	1 (0.3)	0	0	1 (0.1)
腹部圧痛	2 (0.7)	0	1 (0.7)	3 (0.4)
Mild	2 (0.7)	0	1 (0.7)	3 (0.4)
後天性食道ウエッブ	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
裂肛	0	4 (1.3)	0	4 (0.5)
Mild	0	2 (0.7)	0	2 (0.3)
Moderate	0	2 (0.7)	0	2 (0.3)
肛門出血	1 (0.3)	1 (0.3)	0	2 (0.3)
Mild	1 (0.3)	1 (0.3)	0	2 (0.3)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
肛門失禁	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
肛門そう痒症	0	0	1 (0.7)	1 (0.1)
Mild	0	0	1 (0.7)	1 (0.1)
肛門性器異形成	0	2 (0.7)	0	2 (0.3)
Mild	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
アフタ性潰瘍	0	0	1 (0.7)	1 (0.1)
Mild	0	0	1 (0.7)	1 (0.1)
呼気臭	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
口唇のひび割れ	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
口唇炎	0	0	1 (0.7)	1 (0.1)
Mild	0	0	1 (0.7)	1 (0.1)
大腸炎	6 (2.0)	1 (0.3)	1 (0.7)	8 (1.1)
Moderate	4 (1.3)	1 (0.3)	1 (0.7)	6 (0.8)
Severe	2 (0.7)	0	0	2 (0.3)
潰瘍性大腸炎	74 (24.5)	60 (19.7)	29 (19.2)	163 (21.5)
Mild	14 (4.6)	10 (3.3)	5 (3.3)	29 (3.8)
Moderate	52 (17.2)	36 (11.8)	20 (13.2)	108 (14.3)
Severe	8 (2.6)	14 (4.6)	4 (2.6)	26 (3.4)
結腸異形成	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
便秘	3 (1.0)	5 (1.6)	1 (0.7)	9 (1.2)
Mild	1 (0.3)	3 (1.0)	1 (0.7)	5 (0.7)
Moderate	2 (0.7)	2 (0.7)	0	4 (0.5)
クローン病	0	1 (0.3)	0	1 (0.1)
Severe	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
便意切迫	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
齲歯	2 (0.7)	1 (0.3)	0	3 (0.4)
Mild	1 (0.3)	1 (0.3)	0	2 (0.3)
Moderate	1 (0.3)	0	0	1 (0.1)
歯嚢胞	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
下痢	10 (3.3)	7 (2.3)	1 (0.7)	18 (2.4)
Mild	4 (1.3)	6 (2.0)	1 (0.7)	11 (1.5)
Moderate	6 (2.0)	1 (0.3)	0	7 (0.9)
憩室	0	2 (0.7)	0	2 (0.3)
Mild	0	2 (0.7)	0	2 (0.3)
口内乾燥	0	1 (0.3)	1 (0.7)	2 (0.3)
Mild	0	1 (0.3)	1 (0.7)	2 (0.3)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
穿孔性十二指腸潰瘍	0	1 (0.3)	0	1 (0.1)
Severe	0	1 (0.3)	0	1 (0.1)
十二指腸炎	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
十二指腸胃逆流	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	1 (0.7)	1 (0.1)
排便困難	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
消化不良	3 (1.0)	4 (1.3)	3 (2.0)	10 (1.3)
Mild	2 (0.7)	3 (1.0)	3 (2.0)	8 (1.1)
Moderate	1 (0.3)	1 (0.3)	0	2 (0.3)
嚥下障害	0	3 (1.0)	0	3 (0.4)
Mild	0	2 (0.7)	0	2 (0.3)
Moderate	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
小腸炎	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
鼓腸	3 (1.0)	1 (0.3)	4 (2.6)	8 (1.1)
Mild	2 (0.7)	1 (0.3)	2 (1.3)	5 (0.7)
Moderate	1 (0.3)	0	2 (1.3)	3 (0.4)
排便回数増加	1 (0.3)	2 (0.7)	0	3 (0.4)
Mild	1 (0.3)	2 (0.7)	0	3 (0.4)
胃炎	1 (0.3)	0	1 (0.7)	2 (0.3)
Moderate	1 (0.3)	0	1 (0.7)	2 (0.3)
びらん性胃炎	0	2 (0.7)	1 (0.7)	3 (0.4)
Mild	0	0	1 (0.7)	1 (0.1)
Moderate	0	2 (0.7)	0	2 (0.3)
胃腸障害	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
胃腸の炎症	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
胃食道逆流性疾患	0	7 (2.3)	1 (0.7)	8 (1.1)
Mild	0	5 (1.6)	0	5 (0.7)
Moderate	0	2 (0.7)	1 (0.7)	3 (0.4)
歯肉出血	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
歯肉障害	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
舌炎	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
血便排泄	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
痔出血	1 (0.3)	1 (0.3)	0	2 (0.3)
Mild	1 (0.3)	1 (0.3)	0	2 (0.3)
痔核	7 (2.3)	6 (2.0)	1 (0.7)	14 (1.8)
Mild	5 (1.7)	5 (1.6)	0	10 (1.3)
Moderate	2 (0.7)	1 (0.3)	1 (0.7)	4 (0.5)
裂孔ヘルニア	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
大腸ポリープ	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
Mild	0	1 (0.3)	1 (0.7)	2 (0.3)
Moderate	1 (0.3)	0	0	1 (0.1)
マロリー・ワイス症候群	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	1 (0.7)	1 (0.1)
口腔内潰瘍形成	1 (0.3)	1 (0.3)	0	2 (0.3)
Mild	1 (0.3)	1 (0.3)	0	2 (0.3)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
粘液便	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
悪心	13 (4.3)	6 (2.0)	3 (2.0)	22 (2.9)
Mild	9 (3.0)	4 (1.3)	3 (2.0)	16 (2.1)
Moderate	3 (1.0)	2 (0.7)	0	5 (0.7)
Severe	1 (0.3)	0	0	1 (0.1)
口腔障害	0	0	1 (0.7)	1 (0.1)
Mild	0	0	1 (0.7)	1 (0.1)
膵不全	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
急性膵炎	1 (0.3)	0	0	1 (0.1)
Severe	1 (0.3)	0	0	1 (0.1)
肛門周囲痛	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
Mild	0	1 (0.3)	1 (0.7)	2 (0.3)
Moderate	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
直腸炎	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
偽性ポリポーシス	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
直腸出血	2 (0.7)	4 (1.3)	0	6 (0.8)
Mild	1 (0.3)	3 (1.0)	0	4 (0.5)
Moderate	1 (0.3)	1 (0.3)	0	2 (0.3)
直腸ポリープ	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
唾液腺障害	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
小腸閉塞	0	0	1 (0.7)	1 (0.1)
Severe	0	0	1 (0.7)	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
口内炎	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
歯の障害	0	2 (0.7)	1 (0.7)	3 (0.4)
Mild	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	1 (0.7)	2 (0.3)
埋伏歯	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
歯痛	4 (1.3)	6 (2.0)	1 (0.7)	11 (1.5)
Mild	1 (0.3)	3 (1.0)	0	4 (0.5)
Moderate	2 (0.7)	3 (1.0)	1 (0.7)	6 (0.8)
Severe	1 (0.3)	0	0	1 (0.1)
上部消化管出血	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	1 (0.7)	1 (0.1)
嘔吐	7 (2.3)	8 (2.6)	2 (1.3)	17 (2.2)
Mild	5 (1.7)	7 (2.3)	2 (1.3)	14 (1.8)
Moderate	1 (0.3)	1 (0.3)	0	2 (0.3)
Severe	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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	40 (13.2)	51 (16.8)	12 (7.9)	103 (13.6)
Mild	27 (8.9)	38 (12.5)	10 (6.6)	75 (9.9)
Moderate	12 (4.0)	13 (4.3)	2 (1.3)	27 (3.6)
Severe	1 (0.3)	0	0	1 (0.1)
医薬品副作用	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
無力症	4 (1.3)	7 (2.3)	2 (1.3)	13 (1.7)
Mild	3 (1.0)	6 (2.0)	2 (1.3)	11 (1.5)
Moderate	1 (0.3)	1 (0.3)	0	2 (0.3)
胸部不快感	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
胸痛	6 (2.0)	2 (0.7)	0	8 (1.1)
Mild	6 (2.0)	2 (0.7)	0	8 (1.1)
悪寒	2 (0.7)	1 (0.3)	0	3 (0.4)
Mild	2 (0.7)	1 (0.3)	0	3 (0.4)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
嚢胞	1 (0.3)	1 (0.3)	0	2 (0.3)
Mild	1 (0.3)	1 (0.3)	0	2 (0.3)
不快感	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
薬物相互作用	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
異形成	1 (0.3)	0	2 (1.3)	3 (0.4)
Mild	1 (0.3)	0	1 (0.7)	2 (0.3)
Moderate	0	0	1 (0.7)	1 (0.1)
早期満腹	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
疲労	4 (1.3)	6 (2.0)	0	10 (1.3)
Mild	2 (0.7)	2 (0.7)	0	4 (0.5)
Moderate	1 (0.3)	4 (1.3)	0	5 (0.7)
Severe	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
歩行障害	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
異常高熱	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
高熱	0	0	1 (0.7)	1 (0.1)
Mild	0	0	1 (0.7)	1 (0.1)
インフルエンザ様疾患	2 (0.7)	4 (1.3)	0	6 (0.8)
Mild	1 (0.3)	2 (0.7)	0	3 (0.4)
Moderate	1 (0.3)	2 (0.7)	0	3 (0.4)
注入部位紅斑	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
注入部位血腫	0	0	1 (0.7)	1 (0.1)
Mild	0	0	1 (0.7)	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
注入部位そう痒感	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
注射部位紅斑	3 (1.0)	2 (0.7)	1 (0.7)	6 (0.8)
Mild	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)
Mild	0	1 (0.3)	0	1 (0.1)
注射部位硬結	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
注射部位炎症	0	2 (0.7)	0	2 (0.3)
Mild	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
注射部位結節	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
注射部位疼痛	2 (0.7)	2 (0.7)	0	4 (0.5)
Mild	2 (0.7)	2 (0.7)	0	4 (0.5)
注射部位そう痒感	0	2 (0.7)	1 (0.7)	3 (0.4)
Mild	0	1 (0.3)	1 (0.7)	2 (0.3)
Moderate	0	1 (0.3)	0	1 (0.1)
注射部位発疹	1 (0.3)	2 (0.7)	0	3 (0.4)
Mild	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)
Mild	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)
Mild	1 (0.3)	1 (0.3)	0	2 (0.3)
Moderate	0	1 (0.3)	0	1 (0.1)
限局性浮腫	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
小結節	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
非心臓性胸痛	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
末梢性浮腫	4 (1.3)	2 (0.7)	0	6 (0.8)
Mild	2 (0.7)	2 (0.7)	0	4 (0.5)
Moderate	2 (0.7)	0	0	2 (0.3)
疼痛	2 (0.7)	4 (1.3)	0	6 (0.8)
Mild	1 (0.3)	3 (1.0)	0	4 (0.5)
Moderate	1 (0.3)	1 (0.3)	0	2 (0.3)
末梢腫脹	2 (0.7)	1 (0.3)	0	3 (0.4)
Mild	0	1 (0.3)	0	1 (0.1)
Moderate	2 (0.7)	0	0	2 (0.3)
ポリープ	0	0	1 (0.7)	1 (0.1)
Mild	0	0	1 (0.7)	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
偽ポリープ	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
発熱	8 (2.6)	12 (3.9)	1 (0.7)	21 (2.8)
Mild	5 (1.7)	11 (3.6)	0	16 (2.1)
Moderate	3 (1.0)	1 (0.3)	1 (0.7)	5 (0.7)
腫脹	1 (0.3)	3 (1.0)	0	4 (0.5)
Mild	1 (0.3)	2 (0.7)	0	3 (0.4)
Moderate	0	1 (0.3)	0	1 (0.1)
圧痛	1 (0.3)	2 (0.7)	0	3 (0.4)
Mild	1 (0.3)	2 (0.7)	0	3 (0.4)
組織変色	0	0	1 (0.7)	1 (0.1)
Mild	0	0	1 (0.7)	1 (0.1)
血管穿刺部位血腫	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
肝胆道系障害	3 (1.0)	4 (1.3)	7 (4.6)	14 (1.8)
Mild	3 (1.0)	1 (0.3)	3 (2.0)	7 (0.9)
Moderate	0	3 (1.0)	4 (2.6)	7 (0.9)
胆管結石	0	1 (0.3)	1 (0.7)	2 (0.3)
Moderate	0	1 (0.3)	1 (0.7)	2 (0.3)
胆石症	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
胆嚢ポリープ	1 (0.3)	0	1 (0.7)	2 (0.3)
Mild	1 (0.3)	0	1 (0.7)	2 (0.3)
脂肪肝	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
高ビリルビン血症	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
肝胆道系障害 (Cont.)				
高トランスアミナーゼ血症	1 (0.3)	1 (0.3)	4 (2.6)	6 (0.8)
Mild	1 (0.3)	0	2 (1.3)	3 (0.4)
Moderate	0	1 (0.3)	2 (1.3)	3 (0.4)
非アルコール性脂肪性肝炎	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
門脈脾静脈腸間膜静脈血栓症	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	1 (0.7)	1 (0.1)
免疫系障害	2 (0.7)	4 (1.3)	1 (0.7)	7 (0.9)
Mild	2 (0.7)	3 (1.0)	1 (0.7)	6 (0.8)
Moderate	0	1 (0.3)	0	1 (0.1)
節足動物刺傷アレルギー	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
薬物過敏症	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
免疫系障害 (Cont.)				
過敏症	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
複合アレルギー	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
季節性アレルギー	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
Mild	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
感染症および寄生虫症	114 (37.7)	106 (34.9)	52 (34.4)	272 (35.9)
Mild	53 (17.5)	45 (14.8)	25 (16.6)	123 (16.2)
Moderate	56 (18.5)	52 (17.1)	24 (15.9)	132 (17.4)
Severe	5 (1.7)	9 (3.0)	3 (2.0)	17 (2.2)
四肢膿瘍	0	2 (0.7)	0	2 (0.3)
Moderate	0	2 (0.7)	0	2 (0.3)
急性副鼻腔炎	0	2 (0.7)	0	2 (0.3)
Moderate	0	2 (0.7)	0	2 (0.3)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
肛門膿瘍	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
虫垂炎	0	1 (0.3)	0	1 (0.1)
Severe	0	1 (0.3)	0	1 (0.1)
無症候性細菌尿	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
細菌感染	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
細菌性膣症	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
気管支炎	4 (1.3)	1 (0.3)	3 (2.0)	8 (1.1)
Mild	2 (0.7)	0	1 (0.7)	3 (0.4)
Moderate	2 (0.7)	1 (0.3)	2 (1.3)	5 (0.7)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
カンジダ感染	1 (0.3)	2 (0.7)	1 (0.7)	4 (0.5)
Mild	1 (0.3)	2 (0.7)	1 (0.7)	4 (0.5)
蜂巣炎	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
Mild	0	0	1 (0.7)	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
Severe	1 (0.3)	0	0	1 (0.1)
クロストリジウム・ディフィシレ感染	4 (1.3)	2 (0.7)	0	6 (0.8)
Moderate	3 (1.0)	1 (0.3)	0	4 (0.5)
Severe	1 (0.3)	1 (0.3)	0	2 (0.3)
結膜炎	5 (1.7)	2 (0.7)	3 (2.0)	10 (1.3)
Mild	2 (0.7)	2 (0.7)	2 (1.3)	6 (0.8)
Moderate	3 (1.0)	0	1 (0.7)	4 (0.5)
膀胱炎	1 (0.3)	0	2 (1.3)	3 (0.4)
Mild	0	0	1 (0.7)	1 (0.1)
Moderate	1 (0.3)	0	1 (0.7)	2 (0.3)
サイトメガロウイルス感染	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
憩室炎	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
耳感染	3 (1.0)	2 (0.7)	3 (2.0)	8 (1.1)
Mild	1 (0.3)	0	3 (2.0)	4 (0.5)
Moderate	2 (0.7)	2 (0.7)	0	4 (0.5)
蟯虫症	0	2 (0.7)	0	2 (0.3)
Mild	0	2 (0.7)	0	2 (0.3)
エプスタイン・バーウイルス感染	2 (0.7)	0	0	2 (0.3)
Mild	2 (0.7)	0	0	2 (0.3)
外耳蜂巣炎	1 (0.3)	0	0	1 (0.1)
Severe	1 (0.3)	0	0	1 (0.1)
眼瞼感染	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
毛包炎	0	4 (1.3)	1 (0.7)	5 (0.7)
Mild	0	2 (0.7)	0	2 (0.3)
Moderate	0	2 (0.7)	1 (0.7)	3 (0.4)
真菌感染	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
皮膚真菌感染	1 (0.3)	0	1 (0.7)	2 (0.3)
Mild	1 (0.3)	0	1 (0.7)	2 (0.3)
せつ	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
胃腸炎	5 (1.7)	5 (1.6)	2 (1.3)	12 (1.6)
Mild	3 (1.0)	4 (1.3)	2 (1.3)	9 (1.2)
Moderate	2 (0.7)	1 (0.3)	0	3 (0.4)
ウイルス性胃腸炎	1 (0.3)	2 (0.7)	0	3 (0.4)
Mild	1 (0.3)	2 (0.7)	0	3 (0.4)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
消化管感染	1 (0.3)	0	0	1 (0.1)
Severe	1 (0.3)	0	0	1 (0.1)
性器カンジダ症	1 (0.3)	1 (0.3)	0	2 (0.3)
Moderate	1 (0.3)	1 (0.3)	0	2 (0.3)
歯肉膿瘍	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
ヘリコバクター感染	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
ヘルペス眼感染	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
単純ヘルペス	2 (0.7)	0	0	2 (0.3)
Mild	2 (0.7)	0	0	2 (0.3)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
帯状疱疹	3 (1.0)	3 (1.0)	1 (0.7)	7 (0.9)
Mild	1 (0.3)	2 (0.7)	0	3 (0.4)
Moderate	2 (0.7)	1 (0.3)	1 (0.7)	4 (0.5)
麦粒腫	1 (0.3)	2 (0.7)	0	3 (0.4)
Mild	1 (0.3)	1 (0.3)	0	2 (0.3)
Moderate	0	1 (0.3)	0	1 (0.1)
膿痂疹	1 (0.3)	1 (0.3)	0	2 (0.3)
Mild	1 (0.3)	1 (0.3)	0	2 (0.3)
インフルエンザ	13 (4.3)	11 (3.6)	5 (3.3)	29 (3.8)
Mild	4 (1.3)	7 (2.3)	1 (0.7)	12 (1.6)
Moderate	9 (3.0)	4 (1.3)	4 (2.6)	17 (2.2)
喉頭炎	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
限局性感染	1 (0.3)	1 (0.3)	0	2 (0.3)
Mild	0	1 (0.3)	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
下気道感染	0	1 (0.3)	1 (0.7)	2 (0.3)
Mild	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	1 (0.7)	1 (0.1)
ライム病	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
伝染性軟属腫	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
鼓膜炎	0	0	1 (0.7)	1 (0.1)
Mild	0	0	1 (0.7)	1 (0.1)
鼻ヘルペス	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
上咽頭炎	31 (10.3)	30 (9.9)	11 (7.3)	72 (9.5)
Mild	23 (7.6)	24 (7.9)	8 (5.3)	55 (7.3)
Moderate	8 (2.6)	6 (2.0)	3 (2.0)	17 (2.2)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
口腔カンジダ症	1 (0.3)	0	1 (0.7)	2 (0.3)
Moderate	1 (0.3)	0	1 (0.7)	2 (0.3)
口腔真菌感染	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
口腔ヘルペス	2 (0.7)	3 (1.0)	1 (0.7)	6 (0.8)
Mild	1 (0.3)	3 (1.0)	1 (0.7)	5 (0.7)
Moderate	1 (0.3)	0	0	1 (0.1)
外耳炎	1 (0.3)	2 (0.7)	0	3 (0.4)
Mild	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
Severe	1 (0.3)	0	0	1 (0.1)
中耳炎	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	1 (0.7)	1 (0.1)
急性中耳炎	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
寄生虫性胃腸炎	0	0	1 (0.7)	1 (0.1)
Mild	0	0	1 (0.7)	1 (0.1)
爪囲炎	1 (0.3)	1 (0.3)	0	2 (0.3)
Moderate	1 (0.3)	1 (0.3)	0	2 (0.3)
骨盤膿瘍	0	1 (0.3)	0	1 (0.1)
Severe	0	1 (0.3)	0	1 (0.1)
骨盤内感染	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
骨盤内炎症性疾患	0	1 (0.3)	0	1 (0.1)
Severe	0	1 (0.3)	0	1 (0.1)
会陰膿瘍	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
歯周炎	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
扁桃周囲膿瘍	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
咽頭炎	3 (1.0)	6 (2.0)	6 (4.0)	15 (2.0)
Mild	0	2 (0.7)	5 (3.3)	7 (0.9)
Moderate	3 (1.0)	4 (1.3)	1 (0.7)	8 (1.1)
レンサ球菌性咽頭炎	4 (1.3)	0	1 (0.7)	5 (0.7)
Mild	1 (0.3)	0	1 (0.7)	2 (0.3)
Moderate	3 (1.0)	0	0	3 (0.4)
咽頭扁桃炎	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
肺炎	3 (1.0)	7 (2.3)	1 (0.7)	11 (1.5)
Moderate	2 (0.7)	5 (1.6)	0	7 (0.9)
Severe	1 (0.3)	2 (0.7)	1 (0.7)	4 (0.5)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
マイコプラズマ性肺炎	0	0	1 (0.7)	1 (0.1)
Severe	0	0	1 (0.7)	1 (0.1)
処置後感染	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
腎盂腎炎	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	1 (0.7)	1 (0.1)
急性腎盂腎炎	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
膿疱性皮疹	2 (0.7)	0	0	2 (0.3)
Mild	2 (0.7)	0	0	2 (0.3)
気道感染	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	1 (0.7)	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
ウイルス性気道感染	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
鼻炎	3 (1.0)	3 (1.0)	0	6 (0.8)
Mild	3 (1.0)	3 (1.0)	0	6 (0.8)
敗血症	0	0	1 (0.7)	1 (0.1)
Severe	0	0	1 (0.7)	1 (0.1)
副鼻腔炎	13 (4.3)	9 (3.0)	7 (4.6)	29 (3.8)
Mild	5 (1.7)	3 (1.0)	3 (2.0)	11 (1.5)
Moderate	8 (2.6)	6 (2.0)	4 (2.6)	18 (2.4)
皮膚カンジダ	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
皮膚感染	0	2 (0.7)	0	2 (0.3)
Moderate	0	2 (0.7)	0	2 (0.3)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
ブドウ球菌感染	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
胸骨炎	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
レンサ球菌感染	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
頭部白癬	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
癜風	1 (0.3)	0	1 (0.7)	2 (0.3)
Mild	1 (0.3)	0	1 (0.7)	2 (0.3)
扁桃炎	2 (0.7)	3 (1.0)	2 (1.3)	7 (0.9)
Moderate	2 (0.7)	2 (0.7)	2 (1.3)	6 (0.8)
Severe	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
歯膿瘍	2 (0.7)	0	2 (1.3)	4 (0.5)
Mild	0	0	1 (0.7)	1 (0.1)
Moderate	2 (0.7)	0	1 (0.7)	3 (0.4)
歯感染	2 (0.7)	4 (1.3)	0	6 (0.8)
Mild	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	4 (1.3)	0	5 (0.7)
結核	0	1 (0.3)	1 (0.7)	2 (0.3)
Moderate	0	0	1 (0.7)	1 (0.1)
Severe	0	1 (0.3)	0	1 (0.1)
胸腔内リンパ節結核	0	1 (0.3)	0	1 (0.1)
Severe	0	1 (0.3)	0	1 (0.1)
上気道感染	21 (7.0)	17 (5.6)	9 (6.0)	47 (6.2)
Mild	17 (5.6)	9 (3.0)	7 (4.6)	33 (4.4)
Moderate	4 (1.3)	8 (2.6)	2 (1.3)	14 (1.8)
尿路感染	8 (2.6)	4 (1.3)	4 (2.6)	16 (2.1)
Mild	6 (2.0)	3 (1.0)	2 (1.3)	11 (1.5)
Moderate	2 (0.7)	1 (0.3)	2 (1.3)	5 (0.7)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
膣感染	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
ウイルス感染	1 (0.3)	2 (0.7)	1 (0.7)	4 (0.5)
Mild	0	2 (0.7)	0	2 (0.3)
Moderate	1 (0.3)	0	1 (0.7)	2 (0.3)
ウイルス性咽頭炎	0	2 (0.7)	0	2 (0.3)
Mild	0	2 (0.7)	0	2 (0.3)
外陰部膣カンジダ症	0	3 (1.0)	0	3 (0.4)
Mild	0	3 (1.0)	0	3 (0.4)
外陰膣真菌感染	1 (0.3)	2 (0.7)	1 (0.7)	4 (0.5)
Mild	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
Moderate	0	1 (0.3)	0	1 (0.1)
外陰膣炎	0	0	1 (0.7)	1 (0.1)
Mild	0	0	1 (0.7)	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
エルシニア感染	1 (0.3)	1 (0.3)	0	2 (0.3)
Mild	1 (0.3)	1 (0.3)	0	2 (0.3)
傷害、中毒および処置合併症	17 (5.6)	16 (5.3)	8 (5.3)	41 (5.4)
Mild	9 (3.0)	6 (2.0)	5 (3.3)	20 (2.6)
Moderate	6 (2.0)	7 (2.3)	3 (2.0)	16 (2.1)
Severe	2 (0.7)	3 (1.0)	0	5 (0.7)
動物咬傷	2 (0.7)	0	0	2 (0.3)
Moderate	1 (0.3)	0	0	1 (0.1)
Severe	1 (0.3)	0	0	1 (0.1)
節足動物咬傷	0	0	1 (0.7)	1 (0.1)
Mild	0	0	1 (0.7)	1 (0.1)
節足動物刺傷	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
第2度熱傷	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	1 (0.7)	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
傷害、中毒および処置合併症 (Cont.)				
術後錯乱	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
挫傷	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
転倒	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
尾骨骨折	0	0	1 (0.7)	1 (0.1)
Mild	0	0	1 (0.7)	1 (0.1)
仙骨骨折	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
上腕骨骨折	1 (0.3)	1 (0.3)	0	2 (0.3)
Moderate	1 (0.3)	1 (0.3)	0	2 (0.3)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
傷害、中毒および処置合併症 (Cont.)				
注射に伴う反応	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	1 (0.7)	1 (0.1)
関節脱臼	1 (0.3)	1 (0.3)	0	2 (0.3)
Mild	1 (0.3)	0	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
関節損傷	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
靭帯捻挫	2 (0.7)	0	0	2 (0.3)
Mild	2 (0.7)	0	0	2 (0.3)
四肢損傷	0	0	1 (0.7)	1 (0.1)
Mild	0	0	1 (0.7)	1 (0.1)
半月板損傷	1 (0.3)	1 (0.3)	0	2 (0.3)
Mild	1 (0.3)	1 (0.3)	0	2 (0.3)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
傷害、中毒および処置合併症 (Cont.)				
肉離れ	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
膝蓋骨骨折	0	1 (0.3)	0	1 (0.1)
Severe	0	1 (0.3)	0	1 (0.1)
処置後出血	0	1 (0.3)	1 (0.7)	2 (0.3)
Moderate	0	0	1 (0.7)	1 (0.1)
Severe	0	1 (0.3)	0	1 (0.1)
術後高血圧	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
処置による疼痛	2 (0.7)	1 (0.3)	0	3 (0.4)
Moderate	2 (0.7)	0	0	2 (0.3)
Severe	0	1 (0.3)	0	1 (0.1)
橈骨骨折	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
傷害、中毒および処置合併症 (Cont.)				
肋骨骨折	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
交通事故	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
瘢痕	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
皮膚裂傷	2 (0.7)	0	1 (0.7)	3 (0.4)
Mild	2 (0.7)	0	1 (0.7)	3 (0.4)
ストーマ合併症	0	0	1 (0.7)	1 (0.1)
Mild	0	0	1 (0.7)	1 (0.1)
熱傷	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
傷害、中毒および処置合併症 (Cont.)				
脛骨骨折	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
上肢骨折	1 (0.3)	0	0	1 (0.1)
Severe	1 (0.3)	0	0	1 (0.1)
創傷	0	1 (0.3)	1 (0.7)	2 (0.3)
Mild	0	0	1 (0.7)	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
臨床検査	21 (7.0)	23 (7.6)	12 (7.9)	56 (7.4)
Mild	9 (3.0)	13 (4.3)	7 (4.6)	29 (3.8)
Moderate	12 (4.0)	10 (3.3)	4 (2.6)	26 (3.4)
Severe	0	0	1 (0.7)	1 (0.1)
アラニンアミノトランスフェラーゼ増加	2 (0.7)	4 (1.3)	0	6 (0.8)
Mild	1 (0.3)	2 (0.7)	0	3 (0.4)
Moderate	1 (0.3)	2 (0.7)	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	4 (1.3)	6 (2.0)	1 (0.7)	11 (1.5)
Mild	1 (0.3)	6 (2.0)	0	7 (0.9)
Moderate	3 (1.0)	0	1 (0.7)	4 (0.5)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
臨床検査 (Cont.)				
抱合ビリルビン増加	1 (0.3)	1 (0.3)	0	2 (0.3)
Mild	1 (0.3)	1 (0.3)	0	2 (0.3)
血中ビリルビン増加	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
Mild	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
血中コレステロール増加	0	0	3 (2.0)	3 (0.4)
Mild	0	0	2 (1.3)	2 (0.3)
Moderate	0	0	1 (0.7)	1 (0.1)
血中クレアチニン増加	1 (0.3)	1 (0.3)	0	2 (0.3)
Mild	0	1 (0.3)	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
血中ブドウ糖増加	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
血中鉄減少	1 (0.3)	1 (0.3)	0	2 (0.3)
Mild	1 (0.3)	0	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
臨床検査 (Cont.)				
血圧上昇	0	1 (0.3)	1 (0.7)	2 (0.3)
Mild	0	1 (0.3)	1 (0.7)	2 (0.3)
血中甲状腺刺激ホルモン正常	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
血中トリグリセリド増加	0	1 (0.3)	2 (1.3)	3 (0.4)
Mild	0	0	1 (0.7)	1 (0.1)
Moderate	0	1 (0.3)	1 (0.7)	2 (0.3)
体温上昇	0	0	1 (0.7)	1 (0.1)
Mild	0	0	1 (0.7)	1 (0.1)
C－反応性蛋白増加	4 (1.3)	2 (0.7)	0	6 (0.8)
Mild	2 (0.7)	2 (0.7)	0	4 (0.5)
Moderate	2 (0.7)	0	0	2 (0.3)
心雑音	0	0	1 (0.7)	1 (0.1)
Mild	0	0	1 (0.7)	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
臨床検査 (Cont.)				
クロストリジウム検査陽性	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
尿中結晶陽性	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	1 (0.7)	1 (0.1)
ヘマトクリット減少	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
ヘモグロビン減少	2 (0.7)	1 (0.3)	0	3 (0.4)
Mild	0	1 (0.3)	0	1 (0.1)
Moderate	2 (0.7)	0	0	2 (0.3)
心拍数不整	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
肝酵素上昇	0	1 (0.3)	1 (0.7)	2 (0.3)
Mild	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	1 (0.7)	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
臨床検査 (Cont.)				
HIV検査陽性	0	0	1 (0.7)	1 (0.1)
Mild	0	0	1 (0.7)	1 (0.1)
リパーゼ増加	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
肝機能検査値上昇	3 (1.0)	2 (0.7)	0	5 (0.7)
Mild	2 (0.7)	1 (0.3)	0	3 (0.4)
Moderate	1 (0.3)	1 (0.3)	0	2 (0.3)
リンパ球数増加	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
好中球数減少	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
Mild	0	0	1 (0.7)	1 (0.1)
Moderate	1 (0.3)	1 (0.3)	0	2 (0.3)
血小板数増加	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
臨床検査 (Cont.)				
赤血球数減少	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
サイロキシン増加	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
トランスアミナーゼ上昇	0	0	1 (0.7)	1 (0.1)
Mild	0	0	1 (0.7)	1 (0.1)
トリヨードチロニン正常	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
尿検査異常	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
体重減少	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
臨床検査 (Cont.)				
白血球数減少	1 (0.3)	3 (1.0)	3 (2.0)	7 (0.9)
Mild	0	0	1 (0.7)	1 (0.1)
Moderate	1 (0.3)	3 (1.0)	1 (0.7)	5 (0.7)
Severe	0	0	1 (0.7)	1 (0.1)
白血球数増加	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
尿中白血球陽性	0	0	1 (0.7)	1 (0.1)
Mild	0	0	1 (0.7)	1 (0.1)
代謝および栄養障害	14 (4.6)	15 (4.9)	4 (2.6)	33 (4.4)
Mild	9 (3.0)	11 (3.6)	3 (2.0)	23 (3.0)
Moderate	3 (1.0)	3 (1.0)	1 (0.7)	7 (0.9)
Severe	2 (0.7)	1 (0.3)	0	3 (0.4)
食欲減退	2 (0.7)	2 (0.7)	0	4 (0.5)
Mild	2 (0.7)	1 (0.3)	0	3 (0.4)
Moderate	0	1 (0.3)	0	1 (0.1)
脱水	1 (0.3)	2 (0.7)	0	3 (0.4)
Mild	0	1 (0.3)	0	1 (0.1)
Severe	1 (0.3)	1 (0.3)	0	2 (0.3)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
糖尿病	1 (0.3)	2 (0.7)	0	3 (0.4)
Mild	0	1 (0.3)	0	1 (0.1)
Moderate	1 (0.3)	1 (0.3)	0	2 (0.3)
コントロール不良の糖尿病	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
痛風	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
高カルシウム血症	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
高コレステロール血症	6 (2.0)	2 (0.7)	1 (0.7)	9 (1.2)
Mild	6 (2.0)	1 (0.3)	1 (0.7)	8 (1.1)
Moderate	0	1 (0.3)	0	1 (0.1)
高脂血症	1 (0.3)	1 (0.3)	0	2 (0.3)
Mild	1 (0.3)	1 (0.3)	0	2 (0.3)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
高トリグリセリド血症	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
Mild	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
低アルブミン血症	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
低カリウム血症	1 (0.3)	4 (1.3)	1 (0.7)	6 (0.8)
Mild	0	3 (1.0)	0	3 (0.4)
Moderate	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
低ナトリウム血症	0	1 (0.3)	0	1 (0.1)
Severe	0	1 (0.3)	0	1 (0.1)
低リン酸血症	1 (0.3)	0	1 (0.7)	2 (0.3)
Mild	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	1 (0.7)	1 (0.1)
ビタミン欠乏症	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
血液量減少症	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	1 (0.7)	1 (0.1)
空腹時血中ブドウ糖不良	0	0	1 (0.7)	1 (0.1)
Mild	0	0	1 (0.7)	1 (0.1)
鉄欠乏	1 (0.3)	2 (0.7)	1 (0.7)	4 (0.5)
Mild	0	2 (0.7)	1 (0.7)	3 (0.4)
Moderate	1 (0.3)	0	0	1 (0.1)
栄養障害	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
代謝性アルカローシス	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	1 (0.7)	1 (0.1)
ビタミンB12欠乏	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
ビタミンD欠乏	1 (0.3)	0	1 (0.7)	2 (0.3)
Mild	0	0	1 (0.7)	1 (0.1)
Severe	1 (0.3)	0	0	1 (0.1)
筋骨格系および結合組織障害	45 (14.9)	52 (17.1)	14 (9.3)	111 (14.7)
Mild	22 (7.3)	27 (8.9)	7 (4.6)	56 (7.4)
Moderate	22 (7.3)	21 (6.9)	7 (4.6)	50 (6.6)
Severe	1 (0.3)	4 (1.3)	0	5 (0.7)
関節痛	24 (7.9)	24 (7.9)	5 (3.3)	53 (7.0)
Mild	11 (3.6)	15 (4.9)	4 (2.6)	30 (4.0)
Moderate	12 (4.0)	6 (2.0)	1 (0.7)	19 (2.5)
Severe	1 (0.3)	3 (1.0)	0	4 (0.5)
関節炎	2 (0.7)	1 (0.3)	2 (1.3)	5 (0.7)
Mild	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	1 (0.3)	2 (1.3)	4 (0.5)
関節障害	0	0	1 (0.7)	1 (0.1)
Mild	0	0	1 (0.7)	1 (0.1)
腋窩腫瘤	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
筋骨格系および結合組織障害 (Cont.)				
背部痛	6 (2.0)	9 (3.0)	3 (2.0)	18 (2.4)
Mild	2 (0.7)	4 (1.3)	1 (0.7)	7 (0.9)
Moderate	4 (1.3)	5 (1.6)	2 (1.3)	11 (1.5)
尾骨痛	2 (0.7)	0	0	2 (0.3)
Mild	2 (0.7)	0	0	2 (0.3)
デュプイトラン拘縮	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
瘻孔	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
側腹部痛	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	1 (0.7)	1 (0.1)
単径部痛	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
筋骨格系および結合組織障害 (Cont.)				
椎間板変性症	0	2 (0.7)	0	2 (0.3)
Mild	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
椎間板突出	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
関節硬直	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
関節腫脹	0	1 (0.3)	0	1 (0.1)
Severe	0	1 (0.3)	0	1 (0.1)
運動性低下	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
筋痙縮	4 (1.3)	2 (0.7)	1 (0.7)	7 (0.9)
Mild	2 (0.7)	1 (0.3)	1 (0.7)	4 (0.5)
Moderate	2 (0.7)	1 (0.3)	0	3 (0.4)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
筋骨格系および結合組織障害 (Cont.)				
筋力低下	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
筋骨格系胸痛	0	2 (0.7)	0	2 (0.3)
Mild	0	2 (0.7)	0	2 (0.3)
筋骨格痛	0	3 (1.0)	1 (0.7)	4 (0.5)
Mild	0	1 (0.3)	1 (0.7)	2 (0.3)
Moderate	0	2 (0.7)	0	2 (0.3)
筋肉痛	6 (2.0)	4 (1.3)	1 (0.7)	11 (1.5)
Mild	6 (2.0)	3 (1.0)	0	9 (1.2)
Moderate	0	1 (0.3)	1 (0.7)	2 (0.3)
筋炎	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
頚部痛	0	2 (0.7)	0	2 (0.3)
Mild	0	2 (0.7)	0	2 (0.3)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
筋骨格系および結合組織障害 (Cont.)				
変形性関節症	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
骨減少症	0	3 (1.0)	0	3 (0.4)
Mild	0	1 (0.3)	0	1 (0.1)
Moderate	0	2 (0.7)	0	2 (0.3)
四肢痛	2 (0.7)	9 (3.0)	1 (0.7)	12 (1.6)
Mild	1 (0.3)	5 (1.6)	1 (0.7)	7 (0.9)
Moderate	1 (0.3)	3 (1.0)	0	4 (0.5)
Severe	0	1 (0.3)	0	1 (0.1)
顎痛	0	0	1 (0.7)	1 (0.1)
Mild	0	0	1 (0.7)	1 (0.1)
肩回旋筋腱板症候群	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
仙腸骨炎	0	2 (0.7)	0	2 (0.3)
Moderate	0	2 (0.7)	0	2 (0.3)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
筋骨格系および結合組織障害 (Cont.)				
脊椎痛	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
滑液嚢腫	1 (0.3)	0	1 (0.7)	2 (0.3)
Mild	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	1 (0.7)	1 (0.1)
滑膜炎	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
顎関節症候群	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
腱痛	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
筋骨格系および結合組織障害 (Cont.)				
腱炎	1 (0.3)	1 (0.3)	0	2 (0.3)
Mild	0	1 (0.3)	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
斜頚	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	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）	5 (1.7)	11 (3.6)	3 (2.0)	19 (2.5)
Mild	4 (1.3)	3 (1.0)	2 (1.3)	9 (1.2)
Moderate	0	6 (2.0)	1 (0.7)	7 (0.9)
Severe	1 (0.3)	2 (0.7)	0	3 (0.4)
アクロコルドン	0	2 (0.7)	0	2 (0.3)
Mild	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
肛門性器疣贅	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
基底細胞癌	1 (0.3)	1 (0.3)	0	2 (0.3)
Mild	1 (0.3)	0	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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） (Cont.)				
膀胱癌	0	1 (0.3)	0	1 (0.1)
Severe	0	1 (0.3)	0	1 (0.1)
線維腫症	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
胃腸管腺腫	0	1 (0.3)	1 (0.7)	2 (0.3)
Mild	0	0	1 (0.7)	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
脂肪腫	0	1 (0.3)	1 (0.7)	2 (0.3)
Mild	0	1 (0.3)	1 (0.7)	2 (0.3)
悪性黒色腫	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
メラノサイト性母斑	3 (1.0)	0	1 (0.7)	4 (0.5)
Mild	3 (1.0)	0	0	3 (0.4)
Moderate	0	0	1 (0.7)	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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） (Cont.)				
新生物	0	1 (0.3)	0	1 (0.1)
Severe	0	1 (0.3)	0	1 (0.1)
非小細胞肺癌	1 (0.3)	0	0	1 (0.1)
Severe	1 (0.3)	0	0	1 (0.1)
食道腺癌	0	1 (0.3)	0	1 (0.1)
Severe	0	1 (0.3)	0	1 (0.1)
子宮平滑筋腫	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
神経系障害	27 (8.9)	40 (13.2)	13 (8.6)	80 (10.6)
Mild	17 (5.6)	19 (6.3)	7 (4.6)	43 (5.7)
Moderate	10 (3.3)	19 (6.3)	5 (3.3)	34 (4.5)
Severe	0	2 (0.7)	1 (0.7)	3 (0.4)
健忘	0	0	1 (0.7)	1 (0.1)
Mild	0	0	1 (0.7)	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
神経系障害 (Cont.)				
脳血管障害	0	0	1 (0.7)	1 (0.1)
Moderate	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)
Moderate	0	0	1 (0.7)	1 (0.1)
注意力障害	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
浮動性めまい	5 (1.7)	5 (1.6)	2 (1.3)	12 (1.6)
Mild	5 (1.7)	3 (1.0)	2 (1.3)	10 (1.3)
Moderate	0	2 (0.7)	0	2 (0.3)
体位性めまい	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
頭部不快感	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
神経系障害 (Cont.)				
頭痛	16 (5.3)	20 (6.6)	8 (5.3)	44 (5.8)
Mild	8 (2.6)	9 (3.0)	4 (2.6)	21 (2.8)
Moderate	8 (2.6)	11 (3.6)	4 (2.6)	23 (3.0)
知覚過敏	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
感覚鈍麻	0	4 (1.3)	0	4 (0.5)
Moderate	0	3 (1.0)	0	3 (0.4)
Severe	0	1 (0.3)	0	1 (0.1)
虚血性脳卒中	0	0	1 (0.7)	1 (0.1)
Severe	0	0	1 (0.7)	1 (0.1)
腰仙部神経根障害	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
片頭痛	2 (0.7)	5 (1.6)	0	7 (0.9)
Mild	2 (0.7)	1 (0.3)	0	3 (0.4)
Moderate	0	3 (1.0)	0	3 (0.4)
Severe	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
神経系障害 (Cont.)				
単ニューロパチー	0	1 (0.3)	0	1 (0.1)
Severe	0	1 (0.3)	0	1 (0.1)
末梢性ニューロパチー	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
錯感覚	4 (1.3)	2 (0.7)	2 (1.3)	8 (1.1)
Mild	3 (1.0)	2 (0.7)	2 (1.3)	7 (0.9)
Moderate	1 (0.3)	0	0	1 (0.1)
坐骨神経痛	3 (1.0)	2 (0.7)	0	5 (0.7)
Mild	2 (0.7)	0	0	2 (0.3)
Moderate	1 (0.3)	2 (0.7)	0	3 (0.4)
視野欠損	0	2 (0.7)	0	2 (0.3)
Mild	0	2 (0.7)	0	2 (0.3)
精神障害	9 (3.0)	10 (3.3)	6 (4.0)	25 (3.3)
Mild	7 (2.3)	6 (2.0)	1 (0.7)	14 (1.8)
Moderate	1 (0.3)	3 (1.0)	5 (3.3)	9 (1.2)
Severe	1 (0.3)	1 (0.3)	0	2 (0.3)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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 (Cont.)				
抑うつ気分を伴う適応障害	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
激越	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
不安	5 (1.7)	1 (0.3)	2 (1.3)	8 (1.1)
Mild	3 (1.0)	1 (0.3)	1 (0.7)	5 (0.7)
Moderate	2 (0.7)	0	1 (0.7)	3 (0.4)
むちゃ飲み	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	1 (0.7)	1 (0.1)
双極性障害	0	1 (0.3)	0	1 (0.1)
Severe	0	1 (0.3)	0	1 (0.1)
抑うつ気分	1 (0.3)	0	2 (1.3)	3 (0.4)
Mild	1 (0.3)	0	1 (0.7)	2 (0.3)
Moderate	0	0	1 (0.7)	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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 (Cont.)				
うつ病	2 (0.7)	2 (0.7)	1 (0.7)	5 (0.7)
Mild	1 (0.3)	2 (0.7)	0	3 (0.4)
Moderate	0	0	1 (0.7)	1 (0.1)
Severe	1 (0.3)	0	0	1 (0.1)
感情的苦悩	0	0	1 (0.7)	1 (0.1)
Mild	0	0	1 (0.7)	1 (0.1)
疾病恐怖	0	0	1 (0.7)	1 (0.1)
Mild	0	0	1 (0.7)	1 (0.1)
不眠症	2 (0.7)	1 (0.3)	1 (0.7)	4 (0.5)
Mild	2 (0.7)	0	0	2 (0.3)
Moderate	0	1 (0.3)	1 (0.7)	2 (0.3)
精神疲労	0	0	1 (0.7)	1 (0.1)
Mild	0	0	1 (0.7)	1 (0.1)
落ち着きのなさ	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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 (Cont.)				
睡眠障害	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
ストレス	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
自殺念慮	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
腎および尿路障害	9 (3.0)	7 (2.3)	3 (2.0)	19 (2.5)
Mild	4 (1.3)	7 (2.3)	2 (1.3)	13 (1.7)
Moderate	4 (1.3)	0	1 (0.7)	5 (0.7)
Severe	1 (0.3)	0	0	1 (0.1)
尿路結石	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
排尿困難	1 (0.3)	1 (0.3)	0	2 (0.3)
Mild	0	1 (0.3)	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
腎および尿路障害 (Cont.)				
血尿	1 (0.3)	2 (0.7)	0	3 (0.4)
Mild	0	2 (0.7)	0	2 (0.3)
Severe	1 (0.3)	0	0	1 (0.1)
腎結石症	3 (1.0)	1 (0.3)	2 (1.3)	6 (0.8)
Mild	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
Moderate	2 (0.7)	0	1 (0.7)	3 (0.4)
ネフローゼ症候群	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
夜間頻尿	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
頻尿	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
腎前性腎不全	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
腎および尿路障害 (Cont.)				
腎仙痛	2 (0.7)	0	0	2 (0.3)
Mild	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
腎嚢胞	0	0	1 (0.7)	1 (0.1)
Mild	0	0	1 (0.7)	1 (0.1)
尿失禁	1 (0.3)	1 (0.3)	0	2 (0.3)
Mild	1 (0.3)	1 (0.3)	0	2 (0.3)
尿閉	0	1 (0.3)	1 (0.7)	2 (0.3)
Mild	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	1 (0.7)	1 (0.1)
生殖系および乳房障害	7 (2.3)	5 (1.6)	1 (0.7)	13 (1.7)
Mild	3 (1.0)	3 (1.0)	0	6 (0.8)
Moderate	4 (1.3)	2 (0.7)	1 (0.7)	7 (0.9)
無月経	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
生殖系および乳房障害 (Cont.)				
バルトリン嚢腫	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
乳房腫瘤	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
月経困難症	3 (1.0)	0	1 (0.7)	4 (0.5)
Mild	1 (0.3)	0	0	1 (0.1)
Moderate	2 (0.7)	0	1 (0.7)	3 (0.4)
卵管障害	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
卵巣嚢胞	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
多嚢胞性卵巣	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
生殖系および乳房障害 (Cont.)				
前立腺炎	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
前立腺腫大	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
精索静脈瘤	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
呼吸器、胸郭および縦隔障害	30 (9.9)	40 (13.2)	9 (6.0)	79 (10.4)
Mild	24 (7.9)	27 (8.9)	6 (4.0)	57 (7.5)
Moderate	5 (1.7)	9 (3.0)	3 (2.0)	17 (2.2)
Severe	1 (0.3)	4 (1.3)	0	5 (0.7)
喘息	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
咳嗽	8 (2.6)	11 (3.6)	2 (1.3)	21 (2.8)
Mild	6 (2.0)	9 (3.0)	1 (0.7)	16 (2.1)
Moderate	2 (0.7)	2 (0.7)	1 (0.7)	5 (0.7)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
発声障害	0	1 (0.3)	0	1 (0.1)
Severe	0	1 (0.3)	0	1 (0.1)
呼吸困難	4 (1.3)	2 (0.7)	0	6 (0.8)
Mild	4 (1.3)	1 (0.3)	0	5 (0.7)
Moderate	0	1 (0.3)	0	1 (0.1)
肺気腫	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
鼻出血	1 (0.3)	2 (0.7)	0	3 (0.4)
Mild	1 (0.3)	2 (0.7)	0	3 (0.4)
喀血	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
鼻閉	4 (1.3)	4 (1.3)	1 (0.7)	9 (1.2)
Mild	2 (0.7)	4 (1.3)	1 (0.7)	7 (0.9)
Moderate	2 (0.7)	0	0	2 (0.3)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
鼻汁変色	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
鼻の炎症	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
鼻粘膜潰瘍	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
鼻茸	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
鼻中隔弯曲	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
鼻潰瘍	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
口腔咽頭痛	5 (1.7)	11 (3.6)	5 (3.3)	21 (2.8)
Mild	5 (1.7)	9 (3.0)	3 (2.0)	17 (2.2)
Moderate	0	2 (0.7)	2 (1.3)	4 (0.5)
咽頭の炎症	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
胸膜炎	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
湿性咳嗽	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
肺塞栓症	1 (0.3)	3 (1.0)	0	4 (0.5)
Severe	1 (0.3)	3 (1.0)	0	4 (0.5)
ラ音	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
気道うっ血	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
鼻痛	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
アレルギー性鼻炎	1 (0.3)	3 (1.0)	0	4 (0.5)
Mild	1 (0.3)	1 (0.3)	0	2 (0.3)
Moderate	0	2 (0.7)	0	2 (0.3)
鼻漏	1 (0.3)	2 (0.7)	1 (0.7)	4 (0.5)
Mild	1 (0.3)	2 (0.7)	1 (0.7)	4 (0.5)
副鼻腔うっ血	3 (1.0)	3 (1.0)	0	6 (0.8)
Mild	3 (1.0)	2 (0.7)	0	5 (0.7)
Moderate	0	1 (0.3)	0	1 (0.1)
副鼻腔ポリープ	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
睡眠時無呼吸症候群	2 (0.7)	0	0	2 (0.3)
Moderate	2 (0.7)	0	0	2 (0.3)
上気道咳症候群	4 (1.3)	1 (0.3)	0	5 (0.7)
Mild	4 (1.3)	1 (0.3)	0	5 (0.7)
喘鳴	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
皮膚および皮下組織障害	44 (14.6)	59 (19.4)	19 (12.6)	122 (16.1)
Mild	29 (9.6)	42 (13.8)	15 (9.9)	86 (11.4)
Moderate	14 (4.6)	15 (4.9)	3 (2.0)	32 (4.2)
Severe	1 (0.3)	2 (0.7)	1 (0.7)	4 (0.5)
ざ瘡	7 (2.3)	4 (1.3)	3 (2.0)	14 (1.8)
Mild	7 (2.3)	4 (1.3)	2 (1.3)	13 (1.7)
Moderate	0	0	1 (0.7)	1 (0.1)
脱毛症	4 (1.3)	7 (2.3)	3 (2.0)	14 (1.8)
Mild	3 (1.0)	7 (2.3)	3 (2.0)	13 (1.7)
Moderate	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
血管浮腫	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
水疱	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
頭部粃糠疹	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
皮膚嚢腫	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
皮膚炎	1 (0.3)	3 (1.0)	0	4 (0.5)
Mild	1 (0.3)	2 (0.7)	0	3 (0.4)
Moderate	0	1 (0.3)	0	1 (0.1)
アレルギー性皮膚炎	1 (0.3)	0	1 (0.7)	2 (0.3)
Mild	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	1 (0.7)	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
アトピー性皮膚炎	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
接触皮膚炎	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
Mild	1 (0.3)	0	0	1 (0.1)
Moderate	0	1 (0.3)	1 (0.7)	2 (0.3)
薬疹	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
皮膚乾燥	2 (0.7)	3 (1.0)	0	5 (0.7)
Mild	2 (0.7)	3 (1.0)	0	5 (0.7)
斑状出血	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
湿疹	1 (0.3)	3 (1.0)	2 (1.3)	6 (0.8)
Mild	1 (0.3)	3 (1.0)	1 (0.7)	5 (0.7)
Moderate	0	0	1 (0.7)	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
紅斑	3 (1.0)	7 (2.3)	2 (1.3)	12 (1.6)
Mild	2 (0.7)	6 (2.0)	2 (1.3)	10 (1.3)
Moderate	1 (0.3)	1 (0.3)	0	2 (0.3)
結節性紅斑	2 (0.7)	1 (0.3)	1 (0.7)	4 (0.5)
Mild	1 (0.3)	1 (0.3)	0	2 (0.3)
Moderate	1 (0.3)	0	1 (0.7)	2 (0.3)
過剰皮膚	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
剥脱性発疹	1 (0.3)	1 (0.3)	0	2 (0.3)
Mild	1 (0.3)	0	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
過敏性血管炎	0	0	1 (0.7)	1 (0.1)
Mild	0	0	1 (0.7)	1 (0.1)
間擦疹	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
扁平苔癬	0	0	1 (0.7)	1 (0.1)
Mild	0	0	1 (0.7)	1 (0.1)
リニアIgA病	1 (0.3)	0	0	1 (0.1)
Severe	1 (0.3)	0	0	1 (0.1)
爪の障害	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
寝汗	2 (0.7)	2 (0.7)	0	4 (0.5)
Mild	1 (0.3)	1 (0.3)	0	2 (0.3)
Moderate	1 (0.3)	1 (0.3)	0	2 (0.3)
類天疱瘡	0	0	1 (0.7)	1 (0.1)
Severe	0	0	1 (0.7)	1 (0.1)
色素沈着障害	0	0	1 (0.7)	1 (0.1)
Mild	0	0	1 (0.7)	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
そう痒症	6 (2.0)	8 (2.6)	1 (0.7)	15 (2.0)
Mild	6 (2.0)	7 (2.3)	0	13 (1.7)
Moderate	0	1 (0.3)	1 (0.7)	2 (0.3)
乾癬	2 (0.7)	1 (0.3)	1 (0.7)	4 (0.5)
Mild	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
Moderate	1 (0.3)	0	0	1 (0.1)
発疹	10 (3.3)	19 (6.3)	4 (2.6)	33 (4.4)
Mild	4 (1.3)	12 (3.9)	4 (2.6)	20 (2.6)
Moderate	6 (2.0)	6 (2.0)	0	12 (1.6)
Severe	0	1 (0.3)	0	1 (0.1)
紅斑性皮疹	1 (0.3)	1 (0.3)	0	2 (0.3)
Mild	1 (0.3)	1 (0.3)	0	2 (0.3)
斑状皮疹	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
丘疹性皮疹	2 (0.7)	2 (0.7)	1 (0.7)	5 (0.7)
Mild	2 (0.7)	2 (0.7)	1 (0.7)	5 (0.7)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
酒さ	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
脂漏性皮膚炎	0	0	1 (0.7)	1 (0.1)
Mild	0	0	1 (0.7)	1 (0.1)
皮膚灼熱感	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
皮膚病変	2 (0.7)	2 (0.7)	1 (0.7)	5 (0.7)
Mild	1 (0.3)	2 (0.7)	1 (0.7)	4 (0.5)
Moderate	1 (0.3)	0	0	1 (0.1)
皮膚線条	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
角層下膿疱性皮膚症	0	1 (0.3)	0	1 (0.1)
Severe	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	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.)				
顔面腫脹	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
蕁麻疹	1 (0.3)	2 (0.7)	0	3 (0.4)
Mild	0	1 (0.3)	0	1 (0.1)
Moderate	1 (0.3)	1 (0.3)	0	2 (0.3)
社会環境	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
閉経	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
血管障害	9 (3.0)	12 (3.9)	3 (2.0)	24 (3.2)
Mild	5 (1.7)	6 (2.0)	2 (1.3)	13 (1.7)
Moderate	3 (1.0)	6 (2.0)	1 (0.7)	10 (1.3)
Severe	1 (0.3)	0	0	1 (0.1)
大動脈瘤	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
大動脈硬化症	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
動脈炎	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
本態性高血圧症	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	1 (0.7)	1 (0.1)
潮紅	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
血管障害 (Cont.)				
血腫	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (0.3)	0	1 (0.1)
高血圧	6 (2.0)	6 (2.0)	1 (0.7)	13 (1.7)
Mild	5 (1.7)	3 (1.0)	1 (0.7)	9 (1.2)
Moderate	0	3 (1.0)	0	3 (0.4)
Severe	1 (0.3)	0	0	1 (0.1)
高血圧性血管障害	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
高血圧クリーゼ	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)
起立性低血圧	0	0	1 (0.7)	1 (0.1)
Mild	0	0	1 (0.7)	1 (0.1)
蒼白	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-12. 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 主試験の維持療法試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab 40mg EOW (N=302) n (%)	Adalimumab 40mg EW (N=304) n (%)	Adalimumab TDM Regimen (N=151) n (%)	Total (N=757) n (%)
血管障害 (Cont.)				
静脈炎	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (0.3)	0	1 (0.1)
血栓性静脈炎	1 (0.3)	0	0	1 (0.1)
Mild	1 (0.3)	0	0	1 (0.1)
血栓症	1 (0.3)	0	0	1 (0.1)
Moderate	1 (0.3)	0	0	1 (0.1)

Note: Table depicts the most severe adverse event for each preferred term as assessed by the investigator 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 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__1.5

表 2.7.4.7-13. 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 Severity	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	37 (86.0)	41 (89.1)	78 (87.6)	257 (74.5)	263 (75.1)	96 (63.6)	616 (72.8)
Mild	22 (51.2)	20 (43.5)	42 (47.2)	86 (24.9)	83 (23.7)	35 (23.2)	204 (24.1)
Moderate	14 (32.6)	18 (39.1)	32 (36.0)	142 (41.2)	139 (39.7)	51 (33.8)	332 (39.2)
Severe	1 (2.3)	3 (6.5)	4 (4.5)	29 (8.4)	41 (11.7)	10 (6.6)	80 (9.5)
血液およびリンパ系障害	4 (9.3)	6 (13.0)	10 (11.2)	21 (6.1)	32 (9.1)	9 (6.0)	62 (7.3)
Mild	3 (7.0)	2 (4.3)	5 (5.6)	7 (2.0)	14 (4.0)	6 (4.0)	27 (3.2)
Moderate	1 (2.3)	4 (8.7)	5 (5.6)	12 (3.5)	14 (4.0)	3 (2.0)	29 (3.4)
Severe	0	0	0	2 (0.6)	4 (1.1)	0	6 (0.7)
貧血	3 (7.0)	5 (10.9)	8 (9.0)	15 (4.3)	18 (5.1)	5 (3.3)	38 (4.5)
Mild	2 (4.7)	2 (4.3)	4 (4.5)	6 (1.7)	6 (1.7)	3 (2.0)	15 (1.8)
Moderate	1 (2.3)	3 (6.5)	4 (4.5)	8 (2.3)	10 (2.9)	2 (1.3)	20 (2.4)
Severe	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)
内出血発生の増加傾向	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
鉄欠乏性貧血	1 (2.3)	0	1 (1.1)	3 (0.9)	2 (0.6)	0	5 (0.6)
Mild	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	2 (0.6)	1 (0.3)	0	3 (0.4)
Severe	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
血液およびリンパ系障害 (Cont.)							
白血球増加症	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
白血球減少症	0	1 (2.2)	1 (1.1)	1 (0.3)	5 (1.4)	0	6 (0.7)
Mild	0	0	0	0	3 (0.9)	0	3 (0.4)
Moderate	0	1 (2.2)	1 (1.1)	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)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	0	1 (0.7)	1 (0.1)
Severe	0	0	0	0	1 (0.3)	0	1 (0.1)
リンパ球減少症	0	0	0	0	0	1 (0.7)	1 (0.1)
Mild	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)
Mild	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
血液およびリンパ系障害 (Cont.)							
血小板減少症	0	0	0	1 (0.3)	0	1 (0.7)	2 (0.2)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
血小板増加症	0	0	0	1 (0.3)	3 (0.9)	0	4 (0.5)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
Severe	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
心臓障害	0	0	0	6 (1.7)	4 (1.1)	1 (0.7)	11 (1.3)
Mild	0	0	0	3 (0.9)	2 (0.6)	0	5 (0.6)
Moderate	0	0	0	1 (0.3)	2 (0.6)	1 (0.7)	4 (0.5)
Severe	0	0	0	2 (0.6)	0	0	2 (0.2)
急性心筋梗塞	0	0	0	1 (0.3)	0	0	1 (0.1)
Severe	0	0	0	1 (0.3)	0	0	1 (0.1)
心房細動	0	0	0	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
Moderate	0	0	0	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)

表 2.7.4.7-13. 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 Severity	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 (%)
心臓障害 (Cont.)							
うっ血性心不全	0	0	0	1 (0.3)	0	0	1 (0.1)
Severe	0	0	0	1 (0.3)	0	0	1 (0.1)
冠動脈疾患	0	0	0	1 (0.3)	0	0	1 (0.1)
Severe	0	0	0	1 (0.3)	0	0	1 (0.1)
心筋虚血	0	0	0	1 (0.3)	0	0	1 (0.1)
Severe	0	0	0	1 (0.3)	0	0	1 (0.1)
動悸	0	0	0	2 (0.6)	2 (0.6)	0	4 (0.5)
Mild	0	0	0	2 (0.6)	1 (0.3)	0	3 (0.4)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
洞性徐脈	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
心臓障害 (Cont.)							
頻脈	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
耳および迷路障害	2 (4.7)	0	2 (2.2)	7 (2.0)	3 (0.9)	1 (0.7)	11 (1.3)
Mild	2 (4.7)	0	2 (2.2)	7 (2.0)	2 (0.6)	1 (0.7)	10 (1.2)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
感音性難聴	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
Mild	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
外耳道狭窄	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
耳痛	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
耳および迷路障害 (Cont.)							
耳鳴	0	0	0	2 (0.6)	2 (0.6)	1 (0.7)	5 (0.6)
Mild	0	0	0	2 (0.6)	2 (0.6)	1 (0.7)	5 (0.6)
回転性めまい	1 (2.3)	0	1 (1.1)	3 (0.9)	0	0	3 (0.4)
Mild	1 (2.3)	0	1 (1.1)	3 (0.9)	0	0	3 (0.4)
内分泌障害	0	0	0	3 (0.9)	3 (0.9)	0	6 (0.7)
Mild	0	0	0	2 (0.6)	3 (0.9)	0	5 (0.6)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
クッシング様症状	0	0	0	2 (0.6)	0	0	2 (0.2)
Mild	0	0	0	2 (0.6)	0	0	2 (0.2)
甲状腺腫	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
内分泌障害 (Cont.)							
甲状腺機能低下症	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)
Mild	0	0	0	0	2 (0.6)	0	2 (0.2)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
眼障害	2 (4.7)	1 (2.2)	3 (3.4)	11 (3.2)	17 (4.9)	2 (1.3)	30 (3.5)
Mild	2 (4.7)	0	2 (2.2)	8 (2.3)	13 (3.7)	2 (1.3)	23 (2.7)
Moderate	0	1 (2.2)	1 (1.1)	3 (0.9)	3 (0.9)	0	6 (0.7)
Severe	0	0	0	0	1 (0.3)	0	1 (0.1)
閉塞隅角緑内障	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
乱視	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
眼瞼炎	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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.)							
眼瞼痙攣	0	0	0	0	2 (0.6)	0	2 (0.2)
Mild	0	0	0	0	2 (0.6)	0	2 (0.2)
白内障	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
Moderate	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
アレルギー性結膜炎	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
Mild	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
複視	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
ドライアイ	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
Mild	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)

表 2.7.4.7-13. 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 Severity	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 (%)
眼障害 (Cont.)							
上強膜炎	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
Mild	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
眼瞼紅斑	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
眼の炎症	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
眼刺激	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
眼痛	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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.)							
眼瞼縁痂皮	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
眼瞼下垂	0	0	0	0	2 (0.6)	0	2 (0.2)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
Severe	0	0	0	0	1 (0.3)	0	1 (0.1)
眼瞼そう痒症	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
緑内障	0	1 (2.2)	1 (1.1)	1 (0.3)	1 (0.3)	0	2 (0.2)
Moderate	0	1 (2.2)	1 (1.1)	1 (0.3)	1 (0.3)	0	2 (0.2)
眼充血	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
Mild	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)

表 2.7.4.7-13. 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 Severity	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 (%)
眼障害 (Cont.)							
眼酒さ	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	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)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
老視	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
網膜剥離	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
眼瞼腫脹	0	0	0	0	3 (0.9)	0	3 (0.4)
Mild	0	0	0	0	3 (0.9)	0	3 (0.4)

表 2.7.4.7-13. 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 Severity	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 (%)
眼障害 (Cont.)							
霧視	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
Mild	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
視力低下	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	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)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
胃腸障害	10 (23.3)	13 (28.3)	23 (25.8)	138 (40.0)	116 (33.1)	45 (29.8)	299 (35.3)
Mild	4 (9.3)	5 (10.9)	9 (10.1)	43 (12.5)	43 (12.3)	15 (9.9)	101 (11.9)
Moderate	6 (14.0)	5 (10.9)	11 (12.4)	80 (23.2)	54 (15.4)	25 (16.6)	159 (18.8)
Severe	0	3 (6.5)	3 (3.4)	15 (4.3)	19 (5.4)	5 (3.3)	39 (4.6)
腹部不快感	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)
Mild	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
胃腸障害 (Cont.)							
腹部膨満	0	1 (2.2)	1 (1.1)	5 (1.4)	2 (0.6)	1 (0.7)	8 (0.9)
Mild	0	1 (2.2)	1 (1.1)	4 (1.2)	2 (0.6)	1 (0.7)	7 (0.8)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
腹部ヘルニア	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
腹痛	1 (2.3)	0	1 (1.1)	8 (2.3)	6 (1.7)	1 (0.7)	15 (1.8)
Mild	1 (2.3)	0	1 (1.1)	5 (1.4)	4 (1.1)	1 (0.7)	10 (1.2)
Moderate	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)
Severe	0	0	0	2 (0.6)	0	0	2 (0.2)
下腹部痛	0	0	0	2 (0.6)	2 (0.6)	0	4 (0.5)
Mild	0	0	0	2 (0.6)	2 (0.6)	0	4 (0.5)
上腹部痛	0	1 (2.2)	1 (1.1)	3 (0.9)	7 (2.0)	1 (0.7)	11 (1.3)
Mild	0	1 (2.2)	1 (1.1)	1 (0.3)	7 (2.0)	0	8 (0.9)
Moderate	0	0	0	1 (0.3)	0	1 (0.7)	2 (0.2)
Severe	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
胃腸障害 (Cont.)							
腹部圧痛	0	0	0	2 (0.6)	0	1 (0.7)	3 (0.4)
Mild	0	0	0	2 (0.6)	0	1 (0.7)	3 (0.4)
後天性食道ウエッブ	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
裂肛	0	1 (2.2)	1 (1.1)	0	5 (1.4)	0	5 (0.6)
Mild	0	1 (2.2)	1 (1.1)	0	3 (0.9)	0	3 (0.4)
Moderate	0	0	0	0	2 (0.6)	0	2 (0.2)
肛門出血	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
Mild	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
肛門失禁	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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.)							
肛門そう痒症	0	0	0	0	0	1 (0.7)	1 (0.1)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
肛門性器異形成	0	0	0	0	2 (0.6)	0	2 (0.2)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
アフタ性潰瘍	1 (2.3)	0	1 (1.1)	1 (0.3)	0	1 (0.7)	2 (0.2)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
Moderate	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
呼気臭	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
口唇のひび割れ	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
胃腸障害 (Cont.)							
口唇炎	0	0	0	0	0	1 (0.7)	1 (0.1)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
大腸炎	0	0	0	6 (1.7)	1 (0.3)	1 (0.7)	8 (0.9)
Moderate	0	0	0	4 (1.2)	1 (0.3)	1 (0.7)	6 (0.7)
Severe	0	0	0	2 (0.6)	0	0	2 (0.2)
潰瘍性大腸炎	2 (4.7)	5 (10.9)	7 (7.9)	76 (22.0)	65 (18.6)	29 (19.2)	170 (20.1)
Mild	0	0	0	14 (4.1)	10 (2.9)	5 (3.3)	29 (3.4)
Moderate	2 (4.7)	2 (4.3)	4 (4.5)	54 (15.7)	38 (10.9)	20 (13.2)	112 (13.2)
Severe	0	3 (6.5)	3 (3.4)	8 (2.3)	17 (4.9)	4 (2.6)	29 (3.4)
結腸異形成	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
便秘	0	0	0	3 (0.9)	5 (1.4)	1 (0.7)	9 (1.1)
Mild	0	0	0	1 (0.3)	3 (0.9)	1 (0.7)	5 (0.6)
Moderate	0	0	0	2 (0.6)	2 (0.6)	0	4 (0.5)

表 2.7.4.7-13. 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 Severity	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 (%)
胃腸障害 (Cont.)							
クローン病	0	0	0	0	1 (0.3)	0	1 (0.1)
Severe	0	0	0	0	1 (0.3)	0	1 (0.1)
便意切迫	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
齲歯	1 (2.3)	1 (2.2)	2 (2.2)	3 (0.9)	2 (0.6)	0	5 (0.6)
Mild	1 (2.3)	0	1 (1.1)	2 (0.6)	1 (0.3)	0	3 (0.4)
Moderate	0	1 (2.2)	1 (1.1)	1 (0.3)	1 (0.3)	0	2 (0.2)
歯嚢胞	1 (2.3)	0	1 (1.1)	2 (0.6)	0	0	2 (0.2)
Moderate	1 (2.3)	0	1 (1.1)	2 (0.6)	0	0	2 (0.2)
下痢	1 (2.3)	0	1 (1.1)	11 (3.2)	7 (2.0)	1 (0.7)	19 (2.2)
Mild	1 (2.3)	0	1 (1.1)	5 (1.4)	6 (1.7)	1 (0.7)	12 (1.4)
Moderate	0	0	0	6 (1.7)	1 (0.3)	0	7 (0.8)

表 2.7.4.7-13. 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 Severity	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 (%)
胃腸障害 (Cont.)							
憩室	0	0	0	0	2 (0.6)	0	2 (0.2)
Mild	0	0	0	0	2 (0.6)	0	2 (0.2)
口内乾燥	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
Mild	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
穿孔性十二指腸潰瘍	0	0	0	0	1 (0.3)	0	1 (0.1)
Severe	0	0	0	0	1 (0.3)	0	1 (0.1)
十二指腸炎	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
十二指腸胃逆流	0	0	0	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	0	0	0	1 (0.7)	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
胃腸障害 (Cont.)							
排便困難	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
消化不良	1 (2.3)	0	1 (1.1)	4 (1.2)	4 (1.1)	3 (2.0)	11 (1.3)
Mild	1 (2.3)	0	1 (1.1)	3 (0.9)	3 (0.9)	3 (2.0)	9 (1.1)
Moderate	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
嚥下障害	0	1 (2.2)	1 (1.1)	0	4 (1.1)	0	4 (0.5)
Mild	0	1 (2.2)	1 (1.1)	0	3 (0.9)	0	3 (0.4)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
小腸炎	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
鼓腸	0	0	0	3 (0.9)	1 (0.3)	4 (2.6)	8 (0.9)
Mild	0	0	0	2 (0.6)	1 (0.3)	2 (1.3)	5 (0.6)
Moderate	0	0	0	1 (0.3)	0	2 (1.3)	3 (0.4)

表 2.7.4.7-13. 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 Severity	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 (%)
胃腸障害 (Cont.)							
排便回数増加	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)
Mild	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)
胃炎	0	1 (2.2)	1 (1.1)	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
Mild	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	1 (0.7)	2 (0.2)
びらん性胃炎	0	0	0	0	2 (0.6)	1 (0.7)	3 (0.4)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	0	0	2 (0.6)	0	2 (0.2)
胃腸障害	1 (2.3)	0	1 (1.1)	2 (0.6)	0	0	2 (0.2)
Mild	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
胃腸の炎症	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
胃腸障害 (Cont.)							
胃食道逆流性疾患	0	0	0	0	7 (2.0)	1 (0.7)	8 (0.9)
Mild	0	0	0	0	5 (1.4)	0	5 (0.6)
Moderate	0	0	0	0	2 (0.6)	1 (0.7)	3 (0.4)
歯肉出血	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
歯肉障害	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
舌炎	0	1 (2.2)	1 (1.1)	1 (0.3)	1 (0.3)	0	2 (0.2)
Moderate	0	1 (2.2)	1 (1.1)	1 (0.3)	1 (0.3)	0	2 (0.2)
血便排泄	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
胃腸障害 (Cont.)							
痔出血	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
Mild	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
痔核	1 (2.3)	2 (4.3)	3 (3.4)	8 (2.3)	8 (2.3)	1 (0.7)	17 (2.0)
Mild	0	2 (4.3)	2 (2.2)	5 (1.4)	7 (2.0)	0	12 (1.4)
Moderate	1 (2.3)	0	1 (1.1)	3 (0.9)	1 (0.3)	1 (0.7)	5 (0.6)
裂孔ヘルニア	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
過敏性腸症候群	0	2 (4.3)	2 (2.2)	0	2 (0.6)	0	2 (0.2)
Mild	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)
大腸ポリープ	0	0	0	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
Mild	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
胃腸障害 (Cont.)							
マロリー・ワイス症候群	0	0	0	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	0	0	0	1 (0.7)	1 (0.1)
口腔内潰瘍形成	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
Mild	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
粘液便	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
悪心	1 (2.3)	4 (8.7)	5 (5.6)	14 (4.1)	10 (2.9)	3 (2.0)	27 (3.2)
Mild	0	4 (8.7)	4 (4.5)	9 (2.6)	8 (2.3)	3 (2.0)	20 (2.4)
Moderate	1 (2.3)	0	1 (1.1)	4 (1.2)	2 (0.6)	0	6 (0.7)
Severe	0	0	0	1 (0.3)	0	0	1 (0.1)
口腔障害	0	0	0	0	0	1 (0.7)	1 (0.1)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 Adalimumab TDM Regimen (N=151) n (%)	Integrated Safety Set Total (N=846) n (%)
胃腸障害 (Cont.)							
膵不全	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
急性膵炎	0	0	0	1 (0.3)	0	0	1 (0.1)
Severe	0	0	0	1 (0.3)	0	0	1 (0.1)
肛門周囲痛	0	0	0	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
Mild	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
直腸炎	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
偽性ポリポーシス	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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.)							
直腸出血	0	0	0	2 (0.6)	4 (1.1)	0	6 (0.7)
Mild	0	0	0	1 (0.3)	3 (0.9)	0	4 (0.5)
Moderate	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
直腸ポリープ	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
唾液腺障害	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
小腸閉塞	0	0	0	0	0	1 (0.7)	1 (0.1)
Severe	0	0	0	0	0	1 (0.7)	1 (0.1)
口内炎	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
胃腸障害 (Cont.)							
歯の障害	0	0	0	0	2 (0.6)	1 (0.7)	3 (0.4)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
埋伏歯	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
歯痛	0	0	0	4 (1.2)	6 (1.7)	1 (0.7)	11 (1.3)
Mild	0	0	0	1 (0.3)	3 (0.9)	0	4 (0.5)
Moderate	0	0	0	2 (0.6)	3 (0.9)	1 (0.7)	6 (0.7)
Severe	0	0	0	1 (0.3)	0	0	1 (0.1)
上部消化管出血	0	0	0	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	0	0	0	1 (0.7)	1 (0.1)
嘔吐	0	1 (2.2)	1 (1.1)	7 (2.0)	9 (2.6)	2 (1.3)	18 (2.1)
Mild	0	1 (2.2)	1 (1.1)	5 (1.4)	8 (2.3)	2 (1.3)	15 (1.8)
Moderate	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
Severe	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
一般・全身障害および投与部位の状態	4 (9.3)	6 (13.0)	10 (11.2)	44 (12.8)	57 (16.3)	12 (7.9)	113 (13.4)
Mild	3 (7.0)	5 (10.9)	8 (9.0)	30 (8.7)	43 (12.3)	10 (6.6)	83 (9.8)
Moderate	1 (2.3)	1 (2.2)	2 (2.2)	13 (3.8)	14 (4.0)	2 (1.3)	29 (3.4)
Severe	0	0	0	1 (0.3)	0	0	1 (0.1)
医薬品副作用	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
無力症	0	0	0	4 (1.2)	7 (2.0)	2 (1.3)	13 (1.5)
Mild	0	0	0	3 (0.9)	6 (1.7)	2 (1.3)	11 (1.3)
Moderate	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
胸部不快感	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
胸痛	0	0	0	6 (1.7)	2 (0.6)	0	8 (0.9)
Mild	0	0	0	6 (1.7)	2 (0.6)	0	8 (0.9)

表 2.7.4.7-13. 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 Severity	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 (%)
一般・全身障害および投与部位の状態 (Cont.)							
悪寒	0	0	0	2 (0.6)	1 (0.3)	0	3 (0.4)
Mild	0	0	0	2 (0.6)	1 (0.3)	0	3 (0.4)
嚢胞	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
Mild	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
不快感	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	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)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
異形成	0	0	0	1 (0.3)	0	2 (1.3)	3 (0.4)
Mild	0	0	0	1 (0.3)	0	1 (0.7)	2 (0.2)
Moderate	0	0	0	0	0	1 (0.7)	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
一般・全身障害および投与部位の状態 (Cont.)							
早期満腹	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
疲労	0	0	0	4 (1.2)	6 (1.7)	0	10 (1.2)
Mild	0	0	0	2 (0.6)	2 (0.6)	0	4 (0.5)
Moderate	0	0	0	1 (0.3)	4 (1.1)	0	5 (0.6)
Severe	0	0	0	1 (0.3)	0	0	1 (0.1)
歩行障害	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
異常高熱	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
高熱	0	0	0	0	0	1 (0.7)	1 (0.1)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
一般・全身障害および投与部位の状態 (Cont.)							
インフルエンザ様疾患	0	0	0	2 (0.6)	4 (1.1)	0	6 (0.7)
Mild	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)
Moderate	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)
注入部位紅斑	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
注入部位血腫	0	0	0	0	0	1 (0.7)	1 (0.1)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
注入部位そう痒感	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	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)
Mild	0	0	0	3 (0.9)	2 (0.6)	1 (0.7)	6 (0.7)

表 2.7.4.7-13. 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 Severity	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 (%)
一般・全身障害および投与部位の状態 (Cont.)							
注射部位過敏反応	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	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)
Mild	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)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
注射部位結節	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
注射部位疼痛	0	0	0	2 (0.6)	2 (0.6)	0	4 (0.5)
Mild	0	0	0	2 (0.6)	2 (0.6)	0	4 (0.5)

表 2.7.4.7-13. 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 Severity	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 (%)
一般・全身障害および投与部位の状態 (Cont.)							
注射部位そう痒感	0	0	0	0	2 (0.6)	1 (0.7)	3 (0.4)
Mild	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
注射部位発疹	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)
Mild	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)
Mild	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)
Mild	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
限局性浮腫	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
一般・全身障害および投与部位の状態 (Cont.)							
倦怠感	1 (2.3)	1 (2.2)	2 (2.2)	1 (0.3)	1 (0.3)	0	2 (0.2)
Mild	1 (2.3)	1 (2.2)	2 (2.2)	1 (0.3)	1 (0.3)	0	2 (0.2)
小結節	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
非心臓性胸痛	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	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)
Mild	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
末梢性浮腫	0	0	0	4 (1.2)	2 (0.6)	0	6 (0.7)
Mild	0	0	0	2 (0.6)	2 (0.6)	0	4 (0.5)
Moderate	0	0	0	2 (0.6)	0	0	2 (0.2)

表 2.7.4.7-13. 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 Severity	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 (%)
一般・全身障害および投与部位の状態 (Cont.)							
疼痛	0	0	0	2 (0.6)	4 (1.1)	0	6 (0.7)
Mild	0	0	0	1 (0.3)	3 (0.9)	0	4 (0.5)
Moderate	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
末梢腫脹	0	0	0	2 (0.6)	1 (0.3)	0	3 (0.4)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	2 (0.6)	0	0	2 (0.2)
ポリープ	0	0	0	0	0	1 (0.7)	1 (0.1)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
偽ポリープ	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
発熱	2 (4.7)	4 (8.7)	6 (6.7)	10 (2.9)	16 (4.6)	1 (0.7)	27 (3.2)
Mild	1 (2.3)	3 (6.5)	4 (4.5)	6 (1.7)	14 (4.0)	0	20 (2.4)
Moderate	1 (2.3)	1 (2.2)	2 (2.2)	4 (1.2)	2 (0.6)	1 (0.7)	7 (0.8)

表 2.7.4.7-13. 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 Severity	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 (%)
一般・全身障害および投与部位の状態 (Cont.)							
腫脹	0	0	0	1 (0.3)	3 (0.9)	0	4 (0.5)
Mild	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
圧痛	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)
Mild	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)
組織変色	0	0	0	0	0	1 (0.7)	1 (0.1)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
血管穿刺部位血腫	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
肝胆道系障害	1 (2.3)	2 (4.3)	3 (3.4)	4 (1.2)	6 (1.7)	7 (4.6)	17 (2.0)
Mild	0	2 (4.3)	2 (2.2)	3 (0.9)	3 (0.9)	3 (2.0)	9 (1.1)
Moderate	1 (2.3)	0	1 (1.1)	1 (0.3)	3 (0.9)	4 (2.6)	8 (0.9)

表 2.7.4.7-13. 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 Severity	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 (%)
肝胆道系障害 (Cont.)							
胆管結石	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
Moderate	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
胆石症	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
胆嚢ポリープ	0	0	0	1 (0.3)	0	1 (0.7)	2 (0.2)
Mild	0	0	0	1 (0.3)	0	1 (0.7)	2 (0.2)
肝機能異常	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)
脂肪肝	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
肝胆道系障害 (Cont.)							
肝胆道系疾患	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
Moderate	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
高ビリルビン血症	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	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)
Mild	0	0	0	1 (0.3)	0	2 (1.3)	3 (0.4)
Moderate	0	0	0	0	1 (0.3)	2 (1.3)	3 (0.4)
肝損傷	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)
非アルコール性脂肪性肝炎	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
肝胆道系障害 (Cont.)							
門脈脾静脈腸間膜静脈血栓症	0	0	0	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	0	0	0	1 (0.7)	1 (0.1)
免疫系障害	0	2 (4.3)	2 (2.2)	2 (0.6)	6 (1.7)	1 (0.7)	9 (1.1)
Mild	0	2 (4.3)	2 (2.2)	2 (0.6)	5 (1.4)	1 (0.7)	8 (0.9)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
節足動物刺傷アレルギー	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
薬物過敏症	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
過敏症	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
免疫系障害 (Cont.)							
複合アレルギー	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
季節性アレルギー	0	2 (4.3)	2 (2.2)	1 (0.3)	3 (0.9)	1 (0.7)	5 (0.6)
Mild	0	2 (4.3)	2 (2.2)	1 (0.3)	3 (0.9)	1 (0.7)	5 (0.6)
感染症および寄生虫症	24 (55.8)	28 (60.9)	52 (58.4)	138 (40.0)	134 (38.3)	52 (34.4)	324 (38.3)
Mild	19 (44.2)	23 (50.0)	42 (47.2)	72 (20.9)	68 (19.4)	25 (16.6)	165 (19.5)
Moderate	5 (11.6)	5 (10.9)	10 (11.2)	61 (17.7)	57 (16.3)	24 (15.9)	142 (16.8)
Severe	0	0	0	5 (1.4)	9 (2.6)	3 (2.0)	17 (2.0)
四肢膿瘍	0	0	0	0	2 (0.6)	0	2 (0.2)
Moderate	0	0	0	0	2 (0.6)	0	2 (0.2)
急性副鼻腔炎	0	0	0	0	2 (0.6)	0	2 (0.2)
Moderate	0	0	0	0	2 (0.6)	0	2 (0.2)

表 2.7.4.7-13. 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 Severity	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 (%)
感染症および寄生虫症 (Cont.)							
肛門膿瘍	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
虫垂炎	0	0	0	0	1 (0.3)	0	1 (0.1)
Severe	0	0	0	0	1 (0.3)	0	1 (0.1)
無症候性細菌尿	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
細菌感染	0	1 (2.2)	1 (1.1)	1 (0.3)	1 (0.3)	0	2 (0.2)
Mild	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
細菌性膣症	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
感染症および寄生虫症 (Cont.)							
細菌性外陰膣炎	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
Mild	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
気管支炎	1 (2.3)	1 (2.2)	2 (2.2)	5 (1.4)	2 (0.6)	3 (2.0)	10 (1.2)
Mild	1 (2.3)	1 (2.2)	2 (2.2)	3 (0.9)	1 (0.3)	1 (0.7)	5 (0.6)
Moderate	0	0	0	2 (0.6)	1 (0.3)	2 (1.3)	5 (0.6)
カンジダ感染	0	0	0	1 (0.3)	2 (0.6)	1 (0.7)	4 (0.5)
Mild	0	0	0	1 (0.3)	2 (0.6)	1 (0.7)	4 (0.5)
蜂巣炎	0	0	0	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
Severe	0	0	0	1 (0.3)	0	0	1 (0.1)
クロストリジウム・ディフィシレ感染	0	0	0	4 (1.2)	2 (0.6)	0	6 (0.7)
Moderate	0	0	0	3 (0.9)	1 (0.3)	0	4 (0.5)
Severe	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)

表 2.7.4.7-13. 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 Severity	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 (%)
感染症および寄生虫症 (Cont.)							
結膜炎	0	0	0	5 (1.4)	2 (0.6)	3 (2.0)	10 (1.2)
Mild	0	0	0	2 (0.6)	2 (0.6)	2 (1.3)	6 (0.7)
Moderate	0	0	0	3 (0.9)	0	1 (0.7)	4 (0.5)
膀胱炎	2 (4.7)	3 (6.5)	5 (5.6)	3 (0.9)	3 (0.9)	2 (1.3)	8 (0.9)
Mild	2 (4.7)	3 (6.5)	5 (5.6)	2 (0.6)	3 (0.9)	1 (0.7)	6 (0.7)
Moderate	0	0	0	1 (0.3)	0	1 (0.7)	2 (0.2)
サイトメガロウイルス感染	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
憩室炎	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
耳感染	0	0	0	3 (0.9)	2 (0.6)	3 (2.0)	8 (0.9)
Mild	0	0	0	1 (0.3)	0	3 (2.0)	4 (0.5)
Moderate	0	0	0	2 (0.6)	2 (0.6)	0	4 (0.5)

表 2.7.4.7-13. 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 Severity	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 (%)
感染症および寄生虫症 (Cont.)							
蟯虫症	0	0	0	0	2 (0.6)	0	2 (0.2)
Mild	0	0	0	0	2 (0.6)	0	2 (0.2)
エプスタイン・バーウイルス感染	0	0	0	2 (0.6)	0	0	2 (0.2)
Mild	0	0	0	2 (0.6)	0	0	2 (0.2)
外耳蜂巣炎	0	0	0	1 (0.3)	0	0	1 (0.1)
Severe	0	0	0	1 (0.3)	0	0	1 (0.1)
眼瞼感染	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
毛包炎	0	0	0	0	4 (1.1)	1 (0.7)	5 (0.6)
Mild	0	0	0	0	2 (0.6)	0	2 (0.2)
Moderate	0	0	0	0	2 (0.6)	1 (0.7)	3 (0.4)

表 2.7.4.7-13. 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 Severity	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 (%)
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)
Mild	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)
Mild	0	0	0	1 (0.3)	0	1 (0.7)	2 (0.2)
せつ	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
胃腸炎	1 (2.3)	0	1 (1.1)	6 (1.7)	5 (1.4)	2 (1.3)	13 (1.5)
Mild	0	0	0	3 (0.9)	4 (1.1)	2 (1.3)	9 (1.1)
Moderate	1 (2.3)	0	1 (1.1)	3 (0.9)	1 (0.3)	0	4 (0.5)
細菌性胃腸炎	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
感染症および寄生虫症 (Cont.)							
ウイルス性胃腸炎	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)
Mild	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)
消化管感染	0	0	0	1 (0.3)	0	0	1 (0.1)
Severe	0	0	0	1 (0.3)	0	0	1 (0.1)
性器カンジダ症	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
Moderate	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
歯肉膿瘍	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
ヘリコバクター感染	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
感染症および寄生虫症 (Cont.)							
ヘルペス眼感染	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
単純ヘルペス	0	0	0	2 (0.6)	0	0	2 (0.2)
Mild	0	0	0	2 (0.6)	0	0	2 (0.2)
帯状疱疹	0	0	0	3 (0.9)	3 (0.9)	1 (0.7)	7 (0.8)
Mild	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)
Moderate	0	0	0	2 (0.6)	1 (0.3)	1 (0.7)	4 (0.5)
麦粒腫	0	1 (2.2)	1 (1.1)	1 (0.3)	3 (0.9)	0	4 (0.5)
Mild	0	1 (2.2)	1 (1.1)	1 (0.3)	2 (0.6)	0	3 (0.4)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
膿痂疹	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
Mild	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)

表 2.7.4.7-13. 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 Severity	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 (%)
感染症および寄生虫症 (Cont.)							
インフルエンザ	3 (7.0)	4 (8.7)	7 (7.9)	16 (4.6)	15 (4.3)	5 (3.3)	36 (4.3)
Mild	2 (4.7)	3 (6.5)	5 (5.6)	6 (1.7)	10 (2.9)	1 (0.7)	17 (2.0)
Moderate	1 (2.3)	1 (2.2)	2 (2.2)	10 (2.9)	5 (1.4)	4 (2.6)	19 (2.2)
喉頭炎	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
限局性感染	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
下気道感染	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	0	1 (0.7)	1 (0.1)
ライム病	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
感染症および寄生虫症 (Cont.)							
伝染性軟属腫	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
鼓膜炎	0	0	0	0	0	1 (0.7)	1 (0.1)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
鼻ヘルペス	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
上咽頭炎	16 (37.2)	16 (34.8)	32 (36.0)	47 (13.6)	46 (13.1)	11 (7.3)	104 (12.3)
Mild	15 (34.9)	12 (26.1)	27 (30.3)	38 (11.0)	36 (10.3)	8 (5.3)	82 (9.7)
Moderate	1 (2.3)	4 (8.7)	5 (5.6)	9 (2.6)	10 (2.9)	3 (2.0)	22 (2.6)
口腔カンジダ症	1 (2.3)	0	1 (1.1)	2 (0.6)	0	1 (0.7)	3 (0.4)
Mild	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	1 (0.7)	2 (0.2)

表 2.7.4.7-13. 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 Severity	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 (%)
感染症および寄生虫症 (Cont.)							
口腔真菌感染	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
口腔ヘルペス	0	0	0	2 (0.6)	3 (0.9)	1 (0.7)	6 (0.7)
Mild	0	0	0	1 (0.3)	3 (0.9)	1 (0.7)	5 (0.6)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
外耳炎	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
Severe	0	0	0	1 (0.3)	0	0	1 (0.1)
中耳炎	0	0	0	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	0	0	0	1 (0.7)	1 (0.1)
急性中耳炎	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
感染症および寄生虫症 (Cont.)							
寄生虫性胃腸炎	0	0	0	0	0	1 (0.7)	1 (0.1)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
爪囲炎	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
Moderate	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
骨盤膿瘍	0	0	0	0	1 (0.3)	0	1 (0.1)
Severe	0	0	0	0	1 (0.3)	0	1 (0.1)
骨盤内感染	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
骨盤内炎症性疾患	0	0	0	0	1 (0.3)	0	1 (0.1)
Severe	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
感染症および寄生虫症 (Cont.)							
歯冠周囲炎	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)
会陰膿瘍	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
歯周炎	2 (4.7)	0	2 (2.2)	3 (0.9)	0	0	3 (0.4)
Moderate	2 (4.7)	0	2 (2.2)	3 (0.9)	0	0	3 (0.4)
扁桃周囲膿瘍	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
咽頭炎	1 (2.3)	1 (2.2)	2 (2.2)	4 (1.2)	7 (2.0)	6 (4.0)	17 (2.0)
Mild	1 (2.3)	0	1 (1.1)	1 (0.3)	2 (0.6)	5 (3.3)	8 (0.9)
Moderate	0	1 (2.2)	1 (1.1)	3 (0.9)	5 (1.4)	1 (0.7)	9 (1.1)

表 2.7.4.7-13. 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 Severity	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 (%)
感染症および寄生虫症 (Cont.)							
レンサ球菌性咽頭炎	0	0	0	4 (1.2)	0	1 (0.7)	5 (0.6)
Mild	0	0	0	1 (0.3)	0	1 (0.7)	2 (0.2)
Moderate	0	0	0	3 (0.9)	0	0	3 (0.4)
咽頭扁桃炎	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
肺炎	1 (2.3)	0	1 (1.1)	4 (1.2)	7 (2.0)	1 (0.7)	12 (1.4)
Mild	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	2 (0.6)	5 (1.4)	0	7 (0.8)
Severe	0	0	0	1 (0.3)	2 (0.6)	1 (0.7)	4 (0.5)
マイコプラズマ性肺炎	0	0	0	0	0	1 (0.7)	1 (0.1)
Severe	0	0	0	0	0	1 (0.7)	1 (0.1)
処置後感染	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
感染症および寄生虫症 (Cont.)							
化膿	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)
腎盂腎炎	0	0	0	0	0	1 (0.7)	1 (0.1)
Moderate	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)
Moderate	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)
Mild	0	0	0	2 (0.6)	0	0	2 (0.2)
気道感染	0	0	0	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	0	0	0	1 (0.7)	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
感染症および寄生虫症 (Cont.)							
ウイルス性気道感染	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
鼻炎	0	1 (2.2)	1 (1.1)	3 (0.9)	4 (1.1)	0	7 (0.8)
Mild	0	1 (2.2)	1 (1.1)	3 (0.9)	4 (1.1)	0	7 (0.8)
敗血症	0	0	0	0	0	1 (0.7)	1 (0.1)
Severe	0	0	0	0	0	1 (0.7)	1 (0.1)
副鼻腔炎	1 (2.3)	2 (4.3)	3 (3.4)	14 (4.1)	11 (3.1)	7 (4.6)	32 (3.8)
Mild	1 (2.3)	2 (4.3)	3 (3.4)	6 (1.7)	5 (1.4)	3 (2.0)	14 (1.7)
Moderate	0	0	0	8 (2.3)	6 (1.7)	4 (2.6)	18 (2.1)
皮膚カンジダ	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
感染症および寄生虫症 (Cont.)							
皮膚感染	0	0	0	0	2 (0.6)	0	2 (0.2)
Moderate	0	0	0	0	2 (0.6)	0	2 (0.2)
ブドウ球菌感染	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
胸骨炎	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
レンサ球菌感染	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
頭部白癬	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
感染症および寄生虫症 (Cont.)							
癜風	0	0	0	1 (0.3)	0	1 (0.7)	2 (0.2)
Mild	0	0	0	1 (0.3)	0	1 (0.7)	2 (0.2)
扁桃炎	1 (2.3)	0	1 (1.1)	3 (0.9)	3 (0.9)	2 (1.3)	8 (0.9)
Mild	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	2 (0.6)	2 (0.6)	2 (1.3)	6 (0.7)
Severe	0	0	0	0	1 (0.3)	0	1 (0.1)
歯膿瘍	0	0	0	2 (0.6)	0	2 (1.3)	4 (0.5)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	0	2 (0.6)	0	1 (0.7)	3 (0.4)
歯感染	0	0	0	2 (0.6)	4 (1.1)	0	6 (0.7)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	4 (1.1)	0	5 (0.6)
結核	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
Moderate	0	0	0	0	0	1 (0.7)	1 (0.1)
Severe	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
感染症および寄生虫症 (Cont.)							
胸腔内リンパ節結核	0	0	0	0	1 (0.3)	0	1 (0.1)
Severe	0	0	0	0	1 (0.3)	0	1 (0.1)
上気道感染	1 (2.3)	2 (4.3)	3 (3.4)	22 (6.4)	19 (5.4)	9 (6.0)	50 (5.9)
Mild	1 (2.3)	2 (4.3)	3 (3.4)	18 (5.2)	11 (3.1)	7 (4.6)	36 (4.3)
Moderate	0	0	0	4 (1.2)	8 (2.3)	2 (1.3)	14 (1.7)
尿路感染	0	0	0	8 (2.3)	4 (1.1)	4 (2.6)	16 (1.9)
Mild	0	0	0	6 (1.7)	3 (0.9)	2 (1.3)	11 (1.3)
Moderate	0	0	0	2 (0.6)	1 (0.3)	2 (1.3)	5 (0.6)
腟感染	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
ウイルス感染	0	0	0	1 (0.3)	2 (0.6)	1 (0.7)	4 (0.5)
Mild	0	0	0	0	2 (0.6)	0	2 (0.2)
Moderate	0	0	0	1 (0.3)	0	1 (0.7)	2 (0.2)

表 2.7.4.7-13. 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 Severity	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 (%)
感染症および寄生虫症 (Cont.)							
ウイルス性咽頭炎	0	0	0	0	2 (0.6)	0	2 (0.2)
Mild	0	0	0	0	2 (0.6)	0	2 (0.2)
外陰部腟カンジダ症	0	0	0	0	3 (0.9)	0	3 (0.4)
Mild	0	0	0	0	3 (0.9)	0	3 (0.4)
外陰腟真菌感染	0	0	0	1 (0.3)	2 (0.6)	1 (0.7)	4 (0.5)
Mild	0	0	0	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
Moderate	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)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
エルシニア感染	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
Mild	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)

表 2.7.4.7-13. 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 Severity	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 (%)
傷害、中毒および処置合併症	2 (4.7)	2 (4.3)	4 (4.5)	19 (5.5)	18 (5.1)	8 (5.3)	45 (5.3)
Mild	1 (2.3)	2 (4.3)	3 (3.4)	10 (2.9)	8 (2.3)	5 (3.3)	23 (2.7)
Moderate	1 (2.3)	0	1 (1.1)	7 (2.0)	7 (2.0)	3 (2.0)	17 (2.0)
Severe	0	0	0	2 (0.6)	3 (0.9)	0	5 (0.6)
動物咬傷	0	0	0	2 (0.6)	0	0	2 (0.2)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
Severe	0	0	0	1 (0.3)	0	0	1 (0.1)
足関節部骨折	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
Moderate	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
節足動物咬傷	0	0	0	0	0	1 (0.7)	1 (0.1)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
節足動物刺傷	0	1 (2.2)	1 (1.1)	1 (0.3)	1 (0.3)	0	2 (0.2)
Mild	0	1 (2.2)	1 (1.1)	1 (0.3)	1 (0.3)	0	2 (0.2)

表 2.7.4.7-13. 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 Severity	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 (%)
傷害、中毒および処置合併症 (Cont.)							
第2度熱傷	0	0	0	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	0	0	0	1 (0.7)	1 (0.1)
術後錯乱	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
挫傷	1 (2.3)	0	1 (1.1)	1 (0.3)	1 (0.3)	0	2 (0.2)
Mild	1 (2.3)	0	1 (1.1)	1 (0.3)	1 (0.3)	0	2 (0.2)
転倒	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
尾骨骨折	0	0	0	0	0	1 (0.7)	1 (0.1)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
傷害、中毒および処置合併症 (Cont.)							
骨折	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
上腕骨骨折	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
Moderate	0	0	0	1 (0.3)	1 (0.3)	0	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)
Mild	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	0	1 (0.7)	1 (0.1)
関節脱臼	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
関節損傷	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
傷害、中毒および処置合併症 (Cont.)							
靭帯捻挫	0	0	0	2 (0.6)	0	0	2 (0.2)
Mild	0	0	0	2 (0.6)	0	0	2 (0.2)
四肢損傷	0	0	0	0	0	1 (0.7)	1 (0.1)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
半月板損傷	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
Mild	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
肉離れ	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
膝蓋骨骨折	0	0	0	0	1 (0.3)	0	1 (0.1)
Severe	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
傷害、中毒および処置合併症 (Cont.)							
処置後出血	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
Moderate	0	0	0	0	0	1 (0.7)	1 (0.1)
Severe	0	0	0	0	1 (0.3)	0	1 (0.1)
術後高血圧	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
処置による疼痛	0	0	0	2 (0.6)	1 (0.3)	0	3 (0.4)
Moderate	0	0	0	2 (0.6)	0	0	2 (0.2)
Severe	0	0	0	0	1 (0.3)	0	1 (0.1)
橈骨骨折	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
肋骨骨折	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
傷害、中毒および処置合併症 (Cont.)							
交通事故	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
瘢痕	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
皮膚裂傷	0	0	0	2 (0.6)	0	1 (0.7)	3 (0.4)
Mild	0	0	0	2 (0.6)	0	1 (0.7)	3 (0.4)
ストーマ合併症	0	0	0	0	0	1 (0.7)	1 (0.1)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
熱傷	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
傷害、中毒および処置合併症 (Cont.)							
脛骨骨折	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
上肢骨折	0	0	0	1 (0.3)	0	0	1 (0.1)
Severe	0	0	0	1 (0.3)	0	0	1 (0.1)
創傷	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
臨床検査	4 (9.3)	5 (10.9)	9 (10.1)	25 (7.2)	28 (8.0)	12 (7.9)	65 (7.7)
Mild	3 (7.0)	2 (4.3)	5 (5.6)	12 (3.5)	15 (4.3)	7 (4.6)	34 (4.0)
Moderate	1 (2.3)	3 (6.5)	4 (4.5)	13 (3.8)	13 (3.7)	4 (2.6)	30 (3.5)
Severe	0	0	0	0	0	1 (0.7)	1 (0.1)
アラニンアミノトランスフェラーゼ増加	0	1 (2.2)	1 (1.1)	2 (0.6)	5 (1.4)	0	7 (0.8)
Mild	0	1 (2.2)	1 (1.1)	1 (0.3)	3 (0.9)	0	4 (0.5)
Moderate	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)

表 2.7.4.7-13. 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 Severity	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 (%)
臨床検査 (Cont.)							
アスパラギン酸アミノトランスフェラーゼ増加	0	1 (2.2)	1 (1.1)	4 (1.2)	7 (2.0)	1 (0.7)	12 (1.4)
Mild	0	1 (2.2)	1 (1.1)	1 (0.3)	7 (2.0)	0	8 (0.9)
Moderate	0	0	0	3 (0.9)	0	1 (0.7)	4 (0.5)
抱合ビリルビン増加	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
Mild	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
血中ビリルビン増加	0	1 (2.2)	1 (1.1)	1 (0.3)	2 (0.6)	1 (0.7)	4 (0.5)
Mild	0	1 (2.2)	1 (1.1)	1 (0.3)	2 (0.6)	1 (0.7)	4 (0.5)
血中コレステロール増加	0	0	0	0	0	3 (2.0)	3 (0.4)
Mild	0	0	0	0	0	2 (1.3)	2 (0.2)
Moderate	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)	1 (0.3)	0	2 (0.2)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
臨床検査 (Cont.)							
血中ブドウ糖増加	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
血中鉄減少	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
血圧上昇	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
Mild	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
血中甲状腺刺激ホルモン正常	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	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	1 (0.3)	2 (1.3)	3 (0.4)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)

表 2.7.4.7-13. 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 Severity	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 (%)
臨床検査 (Cont.)							
体温上昇	0	0	0	0	0	1 (0.7)	1 (0.1)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
C－反応性蛋白増加	0	0	0	4 (1.2)	2 (0.6)	0	6 (0.7)
Mild	0	0	0	2 (0.6)	2 (0.6)	0	4 (0.5)
Moderate	0	0	0	2 (0.6)	0	0	2 (0.2)
心雑音	0	0	0	0	0	1 (0.7)	1 (0.1)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
クロストリジウム検査陽性	0	1 (2.2)	1 (1.1)	1 (0.3)	1 (0.3)	0	2 (0.2)
Mild	0	1 (2.2)	1 (1.1)	1 (0.3)	1 (0.3)	0	2 (0.2)
尿中結晶陽性	0	0	0	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	0	0	0	1 (0.7)	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
臨床検査 (Cont.)							
握力低下	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
Mild	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
ヘマトクリット減少	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
ヘモグロビン減少	0	0	0	2 (0.6)	1 (0.3)	0	3 (0.4)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	2 (0.6)	0	0	2 (0.2)
心拍数不整	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
肝酵素上昇	1 (2.3)	0	1 (1.1)	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
Mild	1 (2.3)	0	1 (1.1)	1 (0.3)	1 (0.3)	0	2 (0.2)
Moderate	0	0	0	0	0	1 (0.7)	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
臨床検査 (Cont.)							
HIV検査陽性	0	0	0	0	0	1 (0.7)	1 (0.1)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
リパーゼ増加	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
肝機能検査値上昇	0	0	0	3 (0.9)	2 (0.6)	0	5 (0.6)
Mild	0	0	0	2 (0.6)	1 (0.3)	0	3 (0.4)
Moderate	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
リンパ球数増加	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
好中球数減少	0	0	0	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)

表 2.7.4.7-13. 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 Severity	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 (%)
臨床検査 (Cont.)							
血小板数増加	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
赤血球数減少	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
サイロキシン増加	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
トランスアミナーゼ上昇	0	0	0	0	0	1 (0.7)	1 (0.1)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
トリヨードチロニン正常	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
臨床検査 (Cont.)							
尿検査異常	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
尿中ウロビリノーゲン増加	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
Mild	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
体重減少	1 (2.3)	1 (2.2)	2 (2.2)	1 (0.3)	2 (0.6)	0	3 (0.4)
Moderate	1 (2.3)	1 (2.2)	2 (2.2)	1 (0.3)	2 (0.6)	0	3 (0.4)
体重増加	2 (4.7)	0	2 (2.2)	2 (0.6)	0	0	2 (0.2)
Mild	2 (4.7)	0	2 (2.2)	2 (0.6)	0	0	2 (0.2)
白血球数減少	1 (2.3)	2 (4.3)	3 (3.4)	2 (0.6)	5 (1.4)	3 (2.0)	10 (1.2)
Mild	1 (2.3)	0	1 (1.1)	1 (0.3)	0	1 (0.7)	2 (0.2)
Moderate	0	2 (4.3)	2 (2.2)	1 (0.3)	5 (1.4)	1 (0.7)	7 (0.8)
Severe	0	0	0	0	0	1 (0.7)	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
臨床検査 (Cont.)							
白血球数増加	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
尿中白血球陽性	0	0	0	0	0	1 (0.7)	1 (0.1)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
代謝および栄養障害	2 (4.7)	0	2 (2.2)	16 (4.6)	15 (4.3)	4 (2.6)	35 (4.1)
Mild	2 (4.7)	0	2 (2.2)	11 (3.2)	11 (3.1)	3 (2.0)	25 (3.0)
Moderate	0	0	0	3 (0.9)	3 (0.9)	1 (0.7)	7 (0.8)
Severe	0	0	0	2 (0.6)	1 (0.3)	0	3 (0.4)
食欲減退	1 (2.3)	0	1 (1.1)	3 (0.9)	2 (0.6)	0	5 (0.6)
Mild	1 (2.3)	0	1 (1.1)	3 (0.9)	1 (0.3)	0	4 (0.5)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
脱水	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
Severe	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)

表 2.7.4.7-13. 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 Severity	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 (%)
代謝および栄養障害 (Cont.)							
糖尿病	1 (2.3)	0	1 (1.1)	2 (0.6)	2 (0.6)	0	4 (0.5)
Mild	1 (2.3)	0	1 (1.1)	1 (0.3)	1 (0.3)	0	2 (0.2)
Moderate	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
コントロール不良の糖尿病	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
痛風	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
高カルシウム血症	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
高コレステロール血症	0	0	0	6 (1.7)	2 (0.6)	1 (0.7)	9 (1.1)
Mild	0	0	0	6 (1.7)	1 (0.3)	1 (0.7)	8 (0.9)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
代謝および栄養障害 (Cont.)							
高脂血症	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
Mild	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
高トリグリセリド血症	0	0	0	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
Mild	0	0	0	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
低アルブミン血症	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
低カリウム血症	0	0	0	1 (0.3)	4 (1.1)	1 (0.7)	6 (0.7)
Mild	0	0	0	0	3 (0.9)	0	3 (0.4)
Moderate	0	0	0	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
低ナトリウム血症	0	0	0	0	1 (0.3)	0	1 (0.1)
Severe	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
代謝および栄養障害 (Cont.)							
低リン酸血症	0	0	0	1 (0.3)	0	1 (0.7)	2 (0.2)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	0	0	1 (0.7)	1 (0.1)
ビタミン欠乏症	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
血液量減少症	0	0	0	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	0	0	0	1 (0.7)	1 (0.1)
空腹時血中ブドウ糖不良	0	0	0	0	0	1 (0.7)	1 (0.1)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
鉄欠乏	0	0	0	1 (0.3)	2 (0.6)	1 (0.7)	4 (0.5)
Mild	0	0	0	0	2 (0.6)	1 (0.7)	3 (0.4)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
代謝および栄養障害 (Cont.)							
栄養障害	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
代謝性アルカローシス	0	0	0	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	0	0	0	1 (0.7)	1 (0.1)
ビタミンB12欠乏	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
ビタミンD欠乏	0	0	0	1 (0.3)	0	1 (0.7)	2 (0.2)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
Severe	0	0	0	1 (0.3)	0	0	1 (0.1)
筋骨格系および結合組織障害	4 (9.3)	4 (8.7)	8 (9.0)	49 (14.2)	56 (16.0)	14 (9.3)	119 (14.1)
Mild	1 (2.3)	3 (6.5)	4 (4.5)	23 (6.7)	30 (8.6)	7 (4.6)	60 (7.1)
Moderate	3 (7.0)	1 (2.2)	4 (4.5)	25 (7.2)	22 (6.3)	7 (4.6)	54 (6.4)
Severe	0	0	0	1 (0.3)	4 (1.1)	0	5 (0.6)

表 2.7.4.7-13. 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 Severity	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 (%)
筋骨格系および結合組織障害 (Cont.)							
関節痛	0	1 (2.2)	1 (1.1)	24 (7.0)	25 (7.1)	5 (3.3)	54 (6.4)
Mild	0	1 (2.2)	1 (1.1)	11 (3.2)	16 (4.6)	4 (2.6)	31 (3.7)
Moderate	0	0	0	12 (3.5)	6 (1.7)	1 (0.7)	19 (2.2)
Severe	0	0	0	1 (0.3)	3 (0.9)	0	4 (0.5)
関節炎	0	0	0	2 (0.6)	1 (0.3)	2 (1.3)	5 (0.6)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	1 (0.3)	2 (1.3)	4 (0.5)
関節障害	0	0	0	0	0	1 (0.7)	1 (0.1)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
腋窩腫瘤	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
背部痛	3 (7.0)	1 (2.2)	4 (4.5)	9 (2.6)	10 (2.9)	3 (2.0)	22 (2.6)
Mild	1 (2.3)	1 (2.2)	2 (2.2)	3 (0.9)	5 (1.4)	1 (0.7)	9 (1.1)
Moderate	2 (4.7)	0	2 (2.2)	6 (1.7)	5 (1.4)	2 (1.3)	13 (1.5)

表 2.7.4.7-13. 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 Severity	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 (%)
筋骨格系および結合組織障害 (Cont.)							
尾骨痛	0	0	0	2 (0.6)	0	0	2 (0.2)
Mild	0	0	0	2 (0.6)	0	0	2 (0.2)
デュプイトラン拘縮	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
瘻孔	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
側腹部痛	0	0	0	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	0	0	0	1 (0.7)	1 (0.1)
単径部痛	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
筋骨格系および結合組織障害 (Cont.)							
椎間板変性症	0	0	0	0	2 (0.6)	0	2 (0.2)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
椎間板突出	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	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)
Mild	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)
Severe	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)
Moderate	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
筋骨格系および結合組織障害 (Cont.)							
運動性低下	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
筋痙縮	0	0	0	4 (1.2)	2 (0.6)	1 (0.7)	7 (0.8)
Mild	0	0	0	2 (0.6)	1 (0.3)	1 (0.7)	4 (0.5)
Moderate	0	0	0	2 (0.6)	1 (0.3)	0	3 (0.4)
筋力低下	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
筋骨格系胸痛	0	0	0	0	2 (0.6)	0	2 (0.2)
Mild	0	0	0	0	2 (0.6)	0	2 (0.2)
筋骨格痛	0	0	0	0	3 (0.9)	1 (0.7)	4 (0.5)
Mild	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
Moderate	0	0	0	0	2 (0.6)	0	2 (0.2)

表 2.7.4.7-13. 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 Severity	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 (%)
筋骨格系および結合組織障害 (Cont.)							
筋肉痛	0	0	0	6 (1.7)	4 (1.1)	1 (0.7)	11 (1.3)
Mild	0	0	0	6 (1.7)	3 (0.9)	0	9 (1.1)
Moderate	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)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
頚部痛	0	0	0	0	2 (0.6)	0	2 (0.2)
Mild	0	0	0	0	2 (0.6)	0	2 (0.2)
変形性関節症	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
骨減少症	0	0	0	0	3 (0.9)	0	3 (0.4)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	2 (0.6)	0	2 (0.2)

表 2.7.4.7-13. 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 Severity	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.)							
骨粗鬆症	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
Moderate	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
四肢痛	0	0	0	2 (0.6)	9 (2.6)	1 (0.7)	12 (1.4)
Mild	0	0	0	1 (0.3)	5 (1.4)	1 (0.7)	7 (0.8)
Moderate	0	0	0	1 (0.3)	3 (0.9)	0	4 (0.5)
Severe	0	0	0	0	1 (0.3)	0	1 (0.1)
顎痛	0	0	0	0	0	1 (0.7)	1 (0.1)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
関節周囲炎	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)
肩回旋筋腱板症候群	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
筋骨格系および結合組織障害 (Cont.)							
仙腸骨炎	0	0	0	0	2 (0.6)	0	2 (0.2)
Moderate	0	0	0	0	2 (0.6)	0	2 (0.2)
変形性脊椎症	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)
脊椎痛	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
滑液嚢腫	0	0	0	1 (0.3)	0	1 (0.7)	2 (0.2)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	0	0	1 (0.7)	1 (0.1)
滑膜炎	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
筋骨格系および結合組織障害 (Cont.)							
顎関節症候群	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
腱痛	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
腱炎	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
斜頚	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	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	1 (2.2)	1 (1.1)	5 (1.4)	12 (3.4)	3 (2.0)	20 (2.4)
Mild	0	1 (2.2)	1 (1.1)	4 (1.2)	4 (1.1)	2 (1.3)	10 (1.2)
Moderate	0	0	0	0	6 (1.7)	1 (0.7)	7 (0.8)
Severe	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)

表 2.7.4.7-13. 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 Severity	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 (%)
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）(Cont.)							
アクロコルドン	0	0	0	0	2 (0.6)	0	2 (0.2)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
肛門性器疣贅	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
基底細胞癌	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
膀胱癌	0	0	0	0	1 (0.3)	0	1 (0.1)
Severe	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)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
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）(Cont.)							
胃腸管腺腫	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
脂肪腫	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
Mild	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
悪性黒色腫	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
メラノサイト性母斑	0	0	0	3 (0.9)	0	1 (0.7)	4 (0.5)
Mild	0	0	0	3 (0.9)	0	0	3 (0.4)
Moderate	0	0	0	0	0	1 (0.7)	1 (0.1)
新生物	0	0	0	0	1 (0.3)	0	1 (0.1)
Severe	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
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）(Cont.)							
非小細胞肺癌	0	0	0	1 (0.3)	0	0	1 (0.1)
Severe	0	0	0	1 (0.3)	0	0	1 (0.1)
食道腺癌	0	0	0	0	1 (0.3)	0	1 (0.1)
Severe	0	0	0	0	1 (0.3)	0	1 (0.1)
脂漏性角化症	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)
Mild	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)
子宮平滑筋腫	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
神経系障害	4 (9.3)	2 (4.3)	6 (6.7)	31 (9.0)	42 (12.0)	13 (8.6)	86 (10.2)
Mild	2 (4.7)	2 (4.3)	4 (4.5)	19 (5.5)	21 (6.0)	7 (4.6)	47 (5.6)
Moderate	1 (2.3)	0	1 (1.1)	11 (3.2)	19 (5.4)	5 (3.3)	35 (4.1)
Severe	1 (2.3)	0	1 (1.1)	1 (0.3)	2 (0.6)	1 (0.7)	4 (0.5)

表 2.7.4.7-13. 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 Severity	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.)							
意識変容状態	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
Severe	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)
Mild	0	1 (2.2)	1 (1.1)	0	1 (0.3)	1 (0.7)	2 (0.2)
脳血管障害	0	0	0	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	0	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	0	0	0	1 (0.7)	1 (0.1)
Moderate	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)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
神経系障害 (Cont.)							
浮動性めまい	1 (2.3)	0	1 (1.1)	6 (1.7)	5 (1.4)	2 (1.3)	13 (1.5)
Mild	1 (2.3)	0	1 (1.1)	6 (1.7)	3 (0.9)	2 (1.3)	11 (1.3)
Moderate	0	0	0	0	2 (0.6)	0	2 (0.2)
体位性めまい	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	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)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
頭痛	1 (2.3)	2 (4.3)	3 (3.4)	17 (4.9)	22 (6.3)	8 (5.3)	47 (5.6)
Mild	0	2 (4.3)	2 (2.2)	8 (2.3)	11 (3.1)	4 (2.6)	23 (2.7)
Moderate	1 (2.3)	0	1 (1.1)	9 (2.6)	11 (3.1)	4 (2.6)	24 (2.8)
知覚過敏	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
神経系障害 (Cont.)							
感覚鈍麻	1 (2.3)	0	1 (1.1)	1 (0.3)	4 (1.1)	0	5 (0.6)
Mild	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	0	3 (0.9)	0	3 (0.4)
Severe	0	0	0	0	1 (0.3)	0	1 (0.1)
虚血性脳卒中	0	0	0	0	0	1 (0.7)	1 (0.1)
Severe	0	0	0	0	0	1 (0.7)	1 (0.1)
腰仙部神経根障害	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
片頭痛	0	0	0	2 (0.6)	5 (1.4)	0	7 (0.8)
Mild	0	0	0	2 (0.6)	1 (0.3)	0	3 (0.4)
Moderate	0	0	0	0	3 (0.9)	0	3 (0.4)
Severe	0	0	0	0	1 (0.3)	0	1 (0.1)
単ニューロパチー	0	0	0	0	1 (0.3)	0	1 (0.1)
Severe	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
神経系障害 (Cont.)							
末梢性ニューロパチー	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
錯感覚	0	0	0	4 (1.2)	2 (0.6)	2 (1.3)	8 (0.9)
Mild	0	0	0	3 (0.9)	2 (0.6)	2 (1.3)	7 (0.8)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
坐骨神経痛	0	0	0	3 (0.9)	2 (0.6)	0	5 (0.6)
Mild	0	0	0	2 (0.6)	0	0	2 (0.2)
Moderate	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)
視野欠損	0	0	0	0	2 (0.6)	0	2 (0.2)
Mild	0	0	0	0	2 (0.6)	0	2 (0.2)
精神障害	1 (2.3)	3 (6.5)	4 (4.5)	10 (2.9)	13 (3.7)	6 (4.0)	29 (3.4)
Mild	0	3 (6.5)	3 (3.4)	7 (2.0)	9 (2.6)	1 (0.7)	17 (2.0)
Moderate	1 (2.3)	0	1 (1.1)	2 (0.6)	3 (0.9)	5 (3.3)	10 (1.2)
Severe	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)

表 2.7.4.7-13. 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 Severity	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 (%)
精神障害 (Cont.)							
抑うつ気分を伴う適応障害	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
激越	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
不安	0	0	0	5 (1.4)	1 (0.3)	2 (1.3)	8 (0.9)
Mild	0	0	0	3 (0.9)	1 (0.3)	1 (0.7)	5 (0.6)
Moderate	0	0	0	2 (0.6)	0	1 (0.7)	3 (0.4)
むちゃ飲み	0	0	0	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	0	0	0	1 (0.7)	1 (0.1)
双極性障害	0	0	0	0	1 (0.3)	0	1 (0.1)
Severe	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
精神障害 (Cont.)							
抑うつ気分	0	0	0	1 (0.3)	0	2 (1.3)	3 (0.4)
Mild	0	0	0	1 (0.3)	0	1 (0.7)	2 (0.2)
Moderate	0	0	0	0	0	1 (0.7)	1 (0.1)
うつ病	0	0	0	2 (0.6)	2 (0.6)	1 (0.7)	5 (0.6)
Mild	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)
Moderate	0	0	0	0	0	1 (0.7)	1 (0.1)
Severe	0	0	0	1 (0.3)	0	0	1 (0.1)
感情的苦悩	0	0	0	0	0	1 (0.7)	1 (0.1)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
疾病恐怖	0	0	0	0	0	1 (0.7)	1 (0.1)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
不眠症	1 (2.3)	3 (6.5)	4 (4.5)	3 (0.9)	4 (1.1)	1 (0.7)	8 (0.9)
Mild	0	3 (6.5)	3 (3.4)	2 (0.6)	3 (0.9)	0	5 (0.6)
Moderate	1 (2.3)	0	1 (1.1)	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)

表 2.7.4.7-13. 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 Severity	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 (%)
精神障害 (Cont.)							
精神疲労	0	0	0	0	0	1 (0.7)	1 (0.1)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
落ち着きのなさ	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
睡眠障害	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
ストレス	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
自殺念慮	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
腎および尿路障害	0	2 (4.3)	2 (2.2)	9 (2.6)	9 (2.6)	3 (2.0)	21 (2.5)
Mild	0	2 (4.3)	2 (2.2)	4 (1.2)	9 (2.6)	2 (1.3)	15 (1.8)
Moderate	0	0	0	4 (1.2)	0	1 (0.7)	5 (0.6)
Severe	0	0	0	1 (0.3)	0	0	1 (0.1)
尿路結石	0	1 (2.2)	1 (1.1)	1 (0.3)	1 (0.3)	0	2 (0.2)
Mild	0	1 (2.2)	1 (1.1)	1 (0.3)	1 (0.3)	0	2 (0.2)
排尿困難	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
血尿	0	1 (2.2)	1 (1.1)	1 (0.3)	3 (0.9)	0	4 (0.5)
Mild	0	1 (2.2)	1 (1.1)	0	3 (0.9)	0	3 (0.4)
Severe	0	0	0	1 (0.3)	0	0	1 (0.1)
腎結石症	0	0	0	3 (0.9)	1 (0.3)	2 (1.3)	6 (0.7)
Mild	0	0	0	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
Moderate	0	0	0	2 (0.6)	0	1 (0.7)	3 (0.4)

表 2.7.4.7-13. 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 Severity	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 (%)
腎および尿路障害 (Cont.)							
ネフローゼ症候群	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
夜間頻尿	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
頻尿	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
腎前性腎不全	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
腎仙痛	0	0	0	2 (0.6)	0	0	2 (0.2)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
腎および尿路障害 (Cont.)							
腎嚢胞	0	0	0	0	0	1 (0.7)	1 (0.1)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
尿失禁	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
Mild	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
尿閉	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	0	1 (0.7)	1 (0.1)
生殖系および乳房障害	1 (2.3)	0	1 (1.1)	8 (2.3)	5 (1.4)	1 (0.7)	14 (1.7)
Mild	1 (2.3)	0	1 (1.1)	4 (1.2)	3 (0.9)	0	7 (0.8)
Moderate	0	0	0	4 (1.2)	2 (0.6)	1 (0.7)	7 (0.8)
無月経	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
生殖系および乳房障害 (Cont.)							
バルトリン嚢腫	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
乳房腫瘤	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
月経困難症	0	0	0	3 (0.9)	0	1 (0.7)	4 (0.5)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	2 (0.6)	0	1 (0.7)	3 (0.4)
卵管障害	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
卵巣嚢胞	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
生殖系および乳房障害 (Cont.)							
多嚢胞性卵巣	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
前立腺炎	1 (2.3)	0	1 (1.1)	1 (0.3)	1 (0.3)	0	2 (0.2)
Mild	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
前立腺腫大	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
精索静脈瘤	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
呼吸器、胸郭および縦隔障害	4 (9.3)	4 (8.7)	8 (9.0)	34 (9.9)	44 (12.6)	9 (6.0)	87 (10.3)
Mild	4 (9.3)	4 (8.7)	8 (9.0)	28 (8.1)	31 (8.9)	6 (4.0)	65 (7.7)
Moderate	0	0	0	5 (1.4)	9 (2.6)	3 (2.0)	17 (2.0)
Severe	0	0	0	1 (0.3)	4 (1.1)	0	5 (0.6)

表 2.7.4.7-13. 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 Severity	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 (Cont.)							
喘息	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
咳嗽	0	1 (2.2)	1 (1.1)	8 (2.3)	12 (3.4)	2 (1.3)	22 (2.6)
Mild	0	1 (2.2)	1 (1.1)	6 (1.7)	10 (2.9)	1 (0.7)	17 (2.0)
Moderate	0	0	0	2 (0.6)	2 (0.6)	1 (0.7)	5 (0.6)
発声障害	0	0	0	0	1 (0.3)	0	1 (0.1)
Severe	0	0	0	0	1 (0.3)	0	1 (0.1)
呼吸困難	0	0	0	4 (1.2)	2 (0.6)	0	6 (0.7)
Mild	0	0	0	4 (1.2)	1 (0.3)	0	5 (0.6)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
肺気腫	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (Cont.)							
鼻出血	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)
Mild	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)
喀血	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
鼻閉	1 (2.3)	0	1 (1.1)	5 (1.4)	4 (1.1)	1 (0.7)	10 (1.2)
Mild	1 (2.3)	0	1 (1.1)	3 (0.9)	4 (1.1)	1 (0.7)	8 (0.9)
Moderate	0	0	0	2 (0.6)	0	0	2 (0.2)
鼻汁変色	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
鼻の炎症	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (Cont.)							
鼻粘膜潰瘍	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
鼻茸	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
鼻中隔弯曲	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
鼻潰瘍	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
口腔咽頭痛	0	1 (2.2)	1 (1.1)	5 (1.4)	12 (3.4)	5 (3.3)	22 (2.6)
Mild	0	1 (2.2)	1 (1.1)	5 (1.4)	10 (2.9)	3 (2.0)	18 (2.1)
Moderate	0	0	0	0	2 (0.6)	2 (1.3)	4 (0.5)

表 2.7.4.7-13. 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 Severity	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 (Cont.)							
咽頭の炎症	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
胸膜炎	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
湿性咳嗽	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
肺塞栓症	0	0	0	1 (0.3)	3 (0.9)	0	4 (0.5)
Severe	0	0	0	1 (0.3)	3 (0.9)	0	4 (0.5)
肺痛	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
Mild	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
呼吸器、胸郭および縦隔障害 (Cont.)							
ラ音	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
気道うっ血	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
鼻痛	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
アレルギー性鼻炎	0	1 (2.2)	1 (1.1)	1 (0.3)	4 (1.1)	0	5 (0.6)
Mild	0	1 (2.2)	1 (1.1)	1 (0.3)	2 (0.6)	0	3 (0.4)
Moderate	0	0	0	0	2 (0.6)	0	2 (0.2)
鼻漏	0	0	0	1 (0.3)	2 (0.6)	1 (0.7)	4 (0.5)
Mild	0	0	0	1 (0.3)	2 (0.6)	1 (0.7)	4 (0.5)

表 2.7.4.7-13. 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 Severity	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 (%)
呼吸器、胸郭および縦隔障害 (Cont.)							
副鼻腔うっ血	0	0	0	3 (0.9)	3 (0.9)	0	6 (0.7)
Mild	0	0	0	3 (0.9)	2 (0.6)	0	5 (0.6)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
副鼻腔ポリープ	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
睡眠時無呼吸症候群	0	0	0	2 (0.6)	0	0	2 (0.2)
Moderate	0	0	0	2 (0.6)	0	0	2 (0.2)
上気道の炎症	2 (4.7)	1 (2.2)	3 (3.4)	2 (0.6)	1 (0.3)	0	3 (0.4)
Mild	2 (4.7)	1 (2.2)	3 (3.4)	2 (0.6)	1 (0.3)	0	3 (0.4)
上気道咳症候群	0	0	0	4 (1.2)	1 (0.3)	0	5 (0.6)
Mild	0	0	0	4 (1.2)	1 (0.3)	0	5 (0.6)

表 2.7.4.7-13. 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 Severity	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 (%)
呼吸器、胸郭および縦隔障害 (Cont.)							
喘鳴	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
皮膚および皮下組織障害	6 (14.0)	10 (21.7)	16 (18.0)	50 (14.5)	69 (19.7)	19 (12.6)	138 (16.3)
Mild	6 (14.0)	6 (13.0)	12 (13.5)	35 (10.1)	48 (13.7)	15 (9.9)	98 (11.6)
Moderate	0	4 (8.7)	4 (4.5)	14 (4.1)	19 (5.4)	3 (2.0)	36 (4.3)
Severe	0	0	0	1 (0.3)	2 (0.6)	1 (0.7)	4 (0.5)
ざ瘡	0	3 (6.5)	3 (3.4)	7 (2.0)	7 (2.0)	3 (2.0)	17 (2.0)
Mild	0	2 (4.3)	2 (2.2)	7 (2.0)	6 (1.7)	2 (1.3)	15 (1.8)
Moderate	0	1 (2.2)	1 (1.1)	0	1 (0.3)	1 (0.7)	2 (0.2)
脱毛症	0	2 (4.3)	2 (2.2)	4 (1.2)	9 (2.6)	3 (2.0)	16 (1.9)
Mild	0	0	0	3 (0.9)	7 (2.0)	3 (2.0)	13 (1.5)
Moderate	0	2 (4.3)	2 (2.2)	1 (0.3)	2 (0.6)	0	3 (0.4)
血管浮腫	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
皮膚および皮下組織障害 (Cont.)							
水疱	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
頭部粃糠疹	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
皮膚嚢腫	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
皮膚炎	0	0	0	1 (0.3)	3 (0.9)	0	4 (0.5)
Mild	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
アレルギー性皮膚炎	0	0	0	1 (0.3)	0	1 (0.7)	2 (0.2)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	0	0	1 (0.7)	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
皮膚および皮下組織障害 (Cont.)							
アトピー性皮膚炎	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
接触皮膚炎	0	0	0	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
薬疹	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
皮膚乾燥	0	0	0	2 (0.6)	3 (0.9)	0	5 (0.6)
Mild	0	0	0	2 (0.6)	3 (0.9)	0	5 (0.6)
斑状出血	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
皮膚および皮下組織障害 (Cont.)							
湿疹	1 (2.3)	1 (2.2)	2 (2.2)	2 (0.6)	4 (1.1)	2 (1.3)	8 (0.9)
Mild	1 (2.3)	1 (2.2)	2 (2.2)	2 (0.6)	4 (1.1)	1 (0.7)	7 (0.8)
Moderate	0	0	0	0	0	1 (0.7)	1 (0.1)
紅斑	1 (2.3)	0	1 (1.1)	4 (1.2)	7 (2.0)	2 (1.3)	13 (1.5)
Mild	1 (2.3)	0	1 (1.1)	3 (0.9)	6 (1.7)	2 (1.3)	11 (1.3)
Moderate	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
結節性紅斑	0	0	0	2 (0.6)	1 (0.3)	1 (0.7)	4 (0.5)
Mild	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
Moderate	0	0	0	1 (0.3)	0	1 (0.7)	2 (0.2)
過剰皮膚	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
剥脱性発疹	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
皮膚および皮下組織障害 (Cont.)							
過角化	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
Mild	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
過敏性血管炎	0	0	0	0	0	1 (0.7)	1 (0.1)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
間擦疹	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
扁平苔癬	0	0	0	0	0	1 (0.7)	1 (0.1)
Mild	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)
Severe	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
皮膚および皮下組織障害 (Cont.)							
汗疹	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)
Moderate	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)
爪の障害	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
寝汗	0	0	0	2 (0.6)	2 (0.6)	0	4 (0.5)
Mild	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
Moderate	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
掌蹠角皮症	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
Mild	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
類天疱瘡	0	0	0	0	0	1 (0.7)	1 (0.1)
Severe	0	0	0	0	0	1 (0.7)	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
皮膚および皮下組織障害 (Cont.)							
色素沈着障害	0	0	0	0	0	1 (0.7)	1 (0.1)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
そう痒症	1 (2.3)	1 (2.2)	2 (2.2)	7 (2.0)	9 (2.6)	1 (0.7)	17 (2.0)
Mild	1 (2.3)	1 (2.2)	2 (2.2)	7 (2.0)	8 (2.3)	0	15 (1.8)
Moderate	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
乾癬	0	0	0	2 (0.6)	1 (0.3)	1 (0.7)	4 (0.5)
Mild	0	0	0	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
発疹	1 (2.3)	1 (2.2)	2 (2.2)	11 (3.2)	20 (5.7)	4 (2.6)	35 (4.1)
Mild	1 (2.3)	1 (2.2)	2 (2.2)	5 (1.4)	13 (3.7)	4 (2.6)	22 (2.6)
Moderate	0	0	0	6 (1.7)	6 (1.7)	0	12 (1.4)
Severe	0	0	0	0	1 (0.3)	0	1 (0.1)
紅斑性皮疹	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
Mild	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)

表 2.7.4.7-13. 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 Severity	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 (%)
皮膚および皮下組織障害 (Cont.)							
斑状皮疹	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
丘疹性皮疹	0	0	0	2 (0.6)	2 (0.6)	1 (0.7)	5 (0.6)
Mild	0	0	0	2 (0.6)	2 (0.6)	1 (0.7)	5 (0.6)
酒さ	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
脂漏性皮膚炎	0	0	0	0	0	1 (0.7)	1 (0.1)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
皮膚灼熱感	0	0	0	1 (0.3)	0	0	1 (0.1)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
皮膚および皮下組織障害 (Cont.)							
皮膚病変	0	0	0	2 (0.6)	2 (0.6)	1 (0.7)	5 (0.6)
Mild	0	0	0	1 (0.3)	2 (0.6)	1 (0.7)	4 (0.5)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
皮膚線条	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
角層下膿疱性皮膚症	0	0	0	0	1 (0.3)	0	1 (0.1)
Severe	0	0	0	0	1 (0.3)	0	1 (0.1)
顔面腫脹	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
蕁麻疹	0	1 (2.2)	1 (1.1)	1 (0.3)	3 (0.9)	0	4 (0.5)
Mild	0	1 (2.2)	1 (1.1)	0	2 (0.6)	0	2 (0.2)
Moderate	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)

表 2.7.4.7-13. 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 Severity	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 (%)
社会環境	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
閉経	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
血管障害	1 (2.3)	2 (4.3)	3 (3.4)	10 (2.9)	14 (4.0)	3 (2.0)	27 (3.2)
Mild	1 (2.3)	1 (2.2)	2 (2.2)	6 (1.7)	7 (2.0)	2 (1.3)	15 (1.8)
Moderate	0	1 (2.2)	1 (1.1)	3 (0.9)	7 (2.0)	1 (0.7)	11 (1.3)
Severe	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
血管障害 (Cont.)							
大動脈瘤	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
大動脈硬化症	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
動脈炎	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
本態性高血圧症	0	0	0	0	0	1 (0.7)	1 (0.1)
Moderate	0	0	0	0	0	1 (0.7)	1 (0.1)
潮紅	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
血管障害 (Cont.)							
血腫	0	0	0	0	1 (0.3)	0	1 (0.1)
Mild	0	0	0	0	1 (0.3)	0	1 (0.1)
高血圧	0	1 (2.2)	1 (1.1)	6 (1.7)	7 (2.0)	1 (0.7)	14 (1.7)
Mild	0	1 (2.2)	1 (1.1)	5 (1.4)	4 (1.1)	1 (0.7)	10 (1.2)
Moderate	0	0	0	0	3 (0.9)	0	3 (0.4)
Severe	0	0	0	1 (0.3)	0	0	1 (0.1)
高血圧性血管障害	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
高血圧クリーゼ	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
低血圧	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
Mild	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-13. 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 Severity	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 (%)
血管障害 (Cont.)							
起立性低血圧	0	0	0	0	0	1 (0.7)	1 (0.1)
Mild	0	0	0	0	0	1 (0.7)	1 (0.1)
蒼白	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)
静脈炎	0	0	0	0	1 (0.3)	0	1 (0.1)
Moderate	0	0	0	0	1 (0.3)	0	1 (0.1)
血栓性静脈炎	0	1 (2.2)	1 (1.1)	1 (0.3)	1 (0.3)	0	2 (0.2)
Mild	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)
血栓症	0	0	0	1 (0.3)	0	0	1 (0.1)
Moderate	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-13.　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: Table depicts the most severe adverse event for each preferred term as assessed by the investigator 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 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__1.5_J

表 2.7.4.7-14.　死亡に至った有害事象の一覧（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE								
[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:99.0 KG								
	POST	18 TO	3	20	R: CARDIAC ARREST S: CARDIAC DISORDERS P: 心停止 L: CARDIAC ARREST	E: 20 L: 1 DAY I: NO	S: SEVERE R: NO REASONABLE POSSIBILITY A: DISCONT. STUDY DRUG O: OTHER: NO ACTION TAKEN. PATIENT WAS FOUND DEAD IN BED	M: NO S: YES, LIFE THREATENING, DEATH OF SUBJECT O: NO KNOWN AT THIS TIME A: NO REASONABLE POSSIBILITY

Subject prematurely discontinued.

Cross reference: M14-033 Induction Main-study Final CSR Table 14.3__2.5.3.1

表 2.7.4.7-15.　死亡に至った有害事象の一覧（主試験安全性解析対象集団，M14-033 主試験の維持療法試験）

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK									
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:76.0 KG								
	DB2	57 TO 95	36	92		R: EMBOLIA PULMONUM S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 肺塞栓症 L: PULMONARY EMBOLISM	E: 97 L: 6 DAYS I: NO	S: Severe R: No reasonable possibility A: DISCONT. STUDY DRUG O: OTHER: HOSPITALIZATION	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY, IMPORTANT MEDICAL OR SURGICAL INTERVENTION, LIFE THREATENING, DEATH OF SUBJECT O: POSSIBLE ALTERNATIVE ETIOLOGY FOR THE FATAL EVENT :RIGHT SHOULDER FRACTURE BUT NO AVAILABLE DOCUMENTATION/INFORMATION OF THE ETIOLOGY A: No reasonable possibility

表 2.7.4.7-15.　死亡に至った有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:122.0 KG							
	OFF	359 TO 52	410		R: ESOPHAGEAL INVASIVE ADENOSQUAMOUS CARCINOMA S: NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) P: 食道腺癌 L: OESOPHAGEAL ADENOCARCINOMA	E: 440 L: 31 DAYS I: NO	S: Severe R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY, IMPORTANT MEDICAL OR SURGICAL INTERVENTION, LIFE THREATENING, DEATH OF SUBJECT O: TO FOLLOW A: No reasonable possibility

表 2.7.4.7-15. 死亡に至った有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:96.7 KG							
	OFF	142 TO	3	144	R: DISSEMINATED NON-SMALL CELL CARCINOMA PROBABLE PRIMARY LOCALISATION LUNG S: NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) P: 非小細胞肺癌 L: NON-SMALL CELL LUNG CANCER	E: 227 L: 84 DAYS I: NO	S: Severe R: No reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION, LIFE THREATENING, DEATH OF SUBJECT O: SMOKING A: No reasonable possibility

表 2.7.4.7-15. 死亡に至った有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:68.0 KG							
	OFF	184 TO	17	200	R: PNEUMONIA WORSENING S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA AGGRAVATED	E: 202 L: 3 DAYS I: NO	S: Severe R: No reasonable possibility A: OTHER: PATIENT PREVIOUSLY WITHDRAWN FROM THE STUDY O: CONCOMITANT MEDICATION DISCONTINUED O: OTHER: HOSPITALISATION	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, LIFE THREATENING, DEATH OF SUBJECT O: INFORMATION WILL BE UPDATED WHEN AVAILABLE A: No reasonable possibility

+ RX day relative to first dose of study drug during induction study.
DB2 = Double blind maintenance study.
# Subject prematurely discontinued.

Cross reference: M14-033 Maintenance Main-study Final CSR Table 14.3__2.5.3.1

表 2.7.4.7-16. 重篤な有害事象（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）

	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 (%)
ANY ADVERSE EVENT	17 (5.0)	19 (3.7)	36 (4.2)
血液およびリンパ系障害			
貧血	3 (0.9)	2 (0.4)	5 (0.6)
SUBJECTS WITH ONE OR MORE EVENTS	3 (0.9)	2 (0.4)	5 (0.6)
心臓障害			
心停止	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (0.2)	1 (0.1)
胃腸障害			
腹痛	1 (0.3)	0	1 (0.1)
大腸炎	0	1 (0.2)	1 (0.1)
潰瘍性大腸炎	10 (2.9)	11 (2.1)	21 (2.5)
下痢	1 (0.3)	0	1 (0.1)
痔核	0	1 (0.2)	1 (0.1)
大腸狭窄	0	1 (0.2)	1 (0.1)
急性膵炎	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	11 (3.2)	14 (2.7)	25 (2.9)

表 2.7.4.7-16. 重篤な有害事象（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			
発熱	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (0.2)	1 (0.1)
肝胆道系障害			
肝炎	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (0.2)	1 (0.1)
感染症および寄生虫症			
クロストリジウム・ディフィシレ感染	0	1 (0.2)	1 (0.1)
サイトメガロウイルス性大腸炎	0	1 (0.2)	1 (0.1)
丹毒	1 (0.3)	0	1 (0.1)
帯状疱疹	1 (0.3)	0	1 (0.1)
感染	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	2 (0.6)	3 (0.6)	5 (0.6)
代謝および栄養障害			
血液量減少症	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (0.2)	1 (0.1)

表 2.7.4.7-16. 重篤な有害事象（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 (%)
筋骨格系および結合組織障害			
四肢痛	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (0.2)	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）			
表皮内悪性黒色腫	1 (0.3)	0	1 (0.1)
子宮頚部扁平上皮癌	1 (0.3)	0	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	2 (0.6)	0	2 (0.2)
腎および尿路障害			
腎不全	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (0.2)	1 (0.1)
外科および内科処置			
創部ドレナージ	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (0.2)	1 (0.1)

表 2.7.4.7-16.　　重篤な有害事象（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）

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.

Cross reference: M14-033 Induction Main-study Final CSR Table 14.3__2.1.1

表 2.7.4.7-17. 治験薬と関連ありの重篤な有害事象（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）

	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 (%)
ANY ADVERSE EVENT	2 (0.6)	1 (0.2)	3 (0.4)
感染症および寄生虫症			
クロストリジウム・ディフィシレ感染	0	1 (0.2)	1 (0.1)
帯状疱疹	1 (0.3)	0	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	1 (0.3)	1 (0.2)	2 (0.2)
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）			
表皮内悪性黒色腫	1 (0.3)	0	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	1 (0.3)	0	1 (0.1)

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__2.1.2

表 2.7.4.7-18. 重篤な有害事象の一覧（主試験安全性解析対象集団，M14-033 主試験の導入療法試験）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE								
[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:85.0 KG								
	DB1	1 TO 29	29	29	R: EXACERBATION OF ULCERATIVE COLITIS S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	O: YES I: NO	S: MODERATE R: NO REASONABLE POSSIBILITY A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ULCERATIVE COLITIS A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE								
[redacted]	AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:55.0 KG							
	DB1	1 TO 43	15	15	R: MELANOMA IN SITU (BRESLOW 0.4 MM) S: NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) P: 表皮内悪性黒色腫 L: MELANOMA IN SITU	E: 29 L: 15 DAYS I: NO	S: SEVERE R: REASONABLE POSSIBILITY A: DISCONT. STUDY DRUG O: NONE	S: YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE								
[redacted]	AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:59.2 KG							
	POST	29 TO	11	39	R: SQUAMUS CARCINOMA OF CERVIX, FIGO STAGE 1A1&CIN3 S: NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) P: 子宮頚部扁平上皮癌 L: SQUAMOUS CELL CARCINOMA OF THE CERVIX	O: YES I: NO	S: SEVERE R: NO REASONABLE POSSIBILITY A: DISCONT. STUDY DRUG O: NONE	S: YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: ABNORMAL SMEAR A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE								
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:63.9 KG							
	DB1	1 TO 27	27	27	R: WORSENING OF ULCERATIVE COLITIS S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 50 L: 24 DAYS I: NO	S: SEVERE R: NO REASONABLE POSSIBILITY A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ULCERATIVE COLITIS A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE								
[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:57.0 KG								
	DB1	1 TO 59	15	15	R: ULCERATIVE COLITIS AGGRAVATED S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 25 L: 11 DAYS I: NO	S: SEVERE R: NO REASONABLE POSSIBILITY A: INTERRUPTION OF STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ULCERATIVE COLITIS WITH SEVERE COURSE WITHIN LAST 2-3 YRS, GRADUALLY WORSENING DISEASE AFTER CORTICOSTEROIDS HAD BEEN STOPPED. A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE								
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:87.5 KG							
	POST	32 TO	8	39	R: FLARE OF ULCERATIVE COLITIS S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 40 L: 2 DAYS I: NO	S: SEVERE R: NO REASONABLE POSSIBILITY A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FLARE OF ULCERATIVE COLITIS A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE								
[redacted] AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:56.4 KG								
	DB1	1 TO 51	1	1	R: HEPATITIS OF UNKNOWN ETIOLOGY S: HEPATOBILIARY DISORDERS P: 肝炎 L: HEPATITIS	E: 28 L: 28 DAYS I: NO	S: MILD R: NO REASONABLE POSSIBILITY A: NONE O: CONCOMITANT MEDICATION DISCONTINUED O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: SEROLOGY OF VIRAL HEPATITIS	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: USE OF MELANOTAN, A COMPOUND THAT INDUCES SKIN PIGMENTATION A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE								
[redacted]	AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:67.8 KG							
	POST	23 TO	3	25	R: UC WORSENING S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 39 L: 15 DAYS I: NO	S: SEVERE R: NO REASONABLE POSSIBILITY A: DISCONT. STUDY DRUG O: NONE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ULCERATIVE COLITIS SEVERE A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE								
[redacted]	AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:74.0 KG							
	DB1	1	1	1	R: ACUTE SEVERE COLITIS S: GASTROINTESTINAL DISORDERS P: 大腸炎 L: COLITIS	E: 9 L: 9 DAYS I: NO	S: MODERATE R: NO REASONABLE POSSIBILITY A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ULCERATIVE COLITIS A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE								
[redacted] AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:81.0 KG								
	DB1	1 TO 49	35	35	R: UC FLARE S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 56 L: 22 DAYS I: NO	S: SEVERE R: NO REASONABLE POSSIBILITY A: DISCONT. STUDY DRUG O: OTHER: TOTAL COLECTOMY [redacted] 20[redacted]	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY O: LACK OF RESPONSE TO INVESTIGATIONAL THERAPY A:NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE								
[redacted]	AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:81.0 KG							
	DB1	1 TO 49	49	49	R: SEVERE ANEMIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 貧血 L: ANEMIA	E: 52 L: 4 DAYS I: NO	S: SEVERE R: NO REASONABLE POSSIBILITY A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY, IMPORTANT MEDICAL OR SURGICAL INTERVENTION, LIFE THREATENING O: SEVERE ULCERATIVE COLITIS, UNCONTROLLED BY THE SUDY MEDICATION A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE								
[redacted] AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:64.5 KG								
	DB1	1 TO 58	35	35	R: EXACERBATION OF UC S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 42 L: 8 DAYS I: YES	S: MODERATE R: NO REASONABLE POSSIBILITY A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THE PATIENT WAS ADMITTED TO THE HOSPITAL DUE INFLAMMATION OF ULCERATIVE COLITIS. THE PATIENT STOPPED SMOKING. A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE								
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:70.1 KG							
	POST	44 TO	14	57	R: COLONIC STENOSIS S: GASTROINTESTINAL DISORDERS P: 大腸狭窄 L: COLONIC STENOSIS	E: 102 L: 46 DAYS I: NO	S: SEVERE R: NO REASONABLE POSSIBILITY A: DISCONT. STUDY DRUG O: OTHER: SURGICAL INTERVENTION RECOMMENDED (AND PERFORMED LATER)	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY, IMPORTANT MEDICAL OR SURGICAL INTERVENTION, LIFE THREATENING O: COMPLICATION OF THE MAIN DISEASE, DESCENDING COLON STRICTURE A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE								
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:84.1 KG							
	POST	46 TO	19	64	R: WORSENING OF ULCERATIVE COLITIS S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 71 L: 8 DAYS I: NO	S: SEVERE R: NO REASONABLE POSSIBILITY A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PT. DID NOT RESPOND TO STUDY MEDICATION A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE								
[redacted] AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:54.2 KG								
	POST	23 TO	9	31	R: UC EXACERBATION S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	O: YES I: NO	S: SEVERE R: NO REASONABLE POSSIBILITY A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: EXACERBATION OF THE DISEASE A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE								
[redacted]	AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:54.2 KG							
	POST	23 TO	50	72	R: ACUTE PANCREATITIS S: GASTROINTESTINAL DISORDERS P: 急性膵炎 L: ACUTE PANCREATITIS	E: 76 L: 5 DAYS I: YES	S: MODERATE R: NO REASONABLE POSSIBILITY A: OTHER: NA O: CONCOMITANT MEDICATION DISCONTINUED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ACUTE PANCREATITIS SECONDARY TO RAFASSAL TREATMENT A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE								
[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:86.0 KG								
	DB1	1 TO 56	43	43	R: SEVERE LEG PAIN DRAINING WOUND S: MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS P: 四肢痛 L: LEG PAIN	E: 49 L: 7 DAYS I: NO	S: SEVERE R: NO REASONABLE POSSIBILITY A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: ACTIVE DIABETES A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE								
[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:86.0 KG								
	DB1	1 TO 56	43	43	R: SEVERE LEG PAIN DRAINING WOUND S: SURGICAL AND MEDICAL PROCEDURES P: 創部ドレナージ L: WOUND DRAINAGE	E: 49 L: 7 DAYS I: NO	S: SEVERE R: NO REASONABLE POSSIBILITY A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: ACTIVE DIABETES A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE								
[redacted] AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:62.5 KG								
	DB1	1 TO 59	36	36	R: ANEMIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 貧血 L: ANEMIA	E: 37 L: 2 DAYS I: NO	S: MODERATE R: NO REASONABLE POSSIBILITY A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: BLOOD INFUSION	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CLOSTRIDIUM DIFFICILE INFECTION A: REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE								
[redacted] AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:62.5 KG								
	DB1	1 TO 59	36	36	R: CLOSTRIDIUM DIFFICILE INFECTION S: INFECTIONS AND INFESTATIONS P: クロストリジウム・ディフィシレ感染 L: CLOSTRIDIUM DIFFICILE INFECTION	E: 41 L: 6 DAYS I: NO	S: MODERATE R: REASONABLE POSSIBILITY A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE								
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:61.8 KG							
	POST	17 TO	1	17	R: CUTANEOUS ZONA S: INFECTIONS AND INFESTATIONS P: 帯状疱疹 L: ZONA	O: YES I: NO	S: MODERATE R: REASONABLE POSSIBILITY A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE								
[redacted]	AGE:5[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:79.7 KG				
	POST	21 TO	14	34	R: FLARE UP OF ULCERATIVE COLITIS S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 40 L: 7 DAYS I: NO	S: SEVERE R: NO REASONABLE POSSIBILITY A: OTHER: NOT APPLICABLE BECAUSE THE PATIENT ALREADY EARLY WITHDRAWN FROM THE STUDY DUE TO STUDY TREATMENT INEFFICIENCY O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: HOSPITALIZATION	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: EVOLUTION OF THE ULCERATIVE COLITIS AND STUDY TREATMENT FAILURE A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE								
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:79.7 KG							
	POST	21 TO	27	47	R: FLARE OF ULCERATIVE COLITIS S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 54 L: 8 DAYS I: NO	S: SEVERE R: NO REASONABLE POSSIBILITY A: OTHER: NOT APPLICABLE BECAUSE THE PATIENT ALREADY EARLY WITHDRAWN FROM THE STUDY DUE TO STUDY TREATMENT INEFFICIENCY O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: HOSPITALIZATION	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FLARE OF ULCERATIVE COLITIS A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE								
[redacted]	AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:66.6 KG							
	DB1	1 TO 63	56	56	R: SECONDARY ANEMIA INCREASING, ULCERATIVE COLITIS FLARE S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 貧血 L: ANEMIA AGGRAVATED	E: 63 L: 8 DAYS I: YES	S: SEVERE R: NO REASONABLE POSSIBILITY A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SYMPTOMATIC SECONDARY ANEMIA A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE								
[redacted]	AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:66.6 KG							
	DB1	1 TO 63	56	56	R: SECONDARY ANEMIA INCREASING, ULCERATIVE COLITIS FLARE S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 63 L: 8 DAYS I: YES	S: SEVERE R: NO REASONABLE POSSIBILITY A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SYMPTOMATIC SECONDARY ANEMIA A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE								
[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:96.0 KG								
	DB1	1 TO 59	47	47	R: WORSENING OF ULCERATIVE COLITIS S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	O: YES I: NO	S: SEVERE R: NO REASONABLE POSSIBILITY A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: WORSENING OF ULCERATIVE COLITIS; NOT RESPONDING TO HUMIRA A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE								
[redacted]	AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:99.0 KG							
	POST	18 TO	3	20	R: CARDIAC ARREST S: CARDIAC DISORDERS P: 心停止 L: CARDIAC ARREST	E: 20 L: 1 DAY I: NO	S: SEVERE R: NO REASONABLE POSSIBILITY A: DISCONT. STUDY DRUG O: OTHER: NO ACTION TAKEN. PATIENT WAS FOUND DEAD IN BED	M: NO S: YES, LIFE THREATENING, DEATH OF SUBJECT O: NO KNOWN AT THIS TIME A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE								
[redacted] AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:91.3 KG								
	DB1	1 TO 56	17	17	R: WORSENING OF ULCERATIVE COLITIS S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	O: YES I: YES	S: MODERATE R: NO REASONABLE POSSIBILITY A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ULCERATIVE COLITIS A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE								
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:84.0 KG							
	DB1	1 TO 43	40	40	R: WORSENING OF ULCERATIVE COLITIS DUE TO CMV-COLITIS S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	O: YES I: NO	S: SEVERE R: NO REASONABLE POSSIBILITY A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ULCERATIVE COLITIS A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE								
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:84.0 KG							
	DB1	1 TO 43	40	40	R: WORSENING OF ULCERATIVE COLITIS DUE TO CMV-COLITIS S: INFECTIONS AND INFESTATIONS P: サイトメガロウイルス性大腸炎 L: CMV COLITIS	O: YES I: NO	S: SEVERE R: NO REASONABLE POSSIBILITY A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ULCERATIVE COLITIS A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE								
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:75.0 KG							
	POST	44 TO 8	51		R: ERYTHEMATOUS ERYSIPELAS LOWER THIRD OF THE RIGHT TIBIA AND ANKLE JOINT. S: INFECTIONS AND INFESTATIONS P: 丹毒 L: ERYSIPELAS	E: 107 L: 57 DAYS I: NO	S: MILD R: NO REASONABLE POSSIBILITY A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PATIENT HOSPITALISED A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE								
[redacted] AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:115.2 KG								
	DB1	1 TO 56	3	3	R: ANAEMIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 貧血 L: ANAEMIA	E: 10 L: 8 DAYS I: YES	S: MILD R: NO REASONABLE POSSIBILITY A: NONE O: OTHER: HAEMOTRANSFUSION	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PLANNED HAEMOTRANSFUSION FOR SECONDARY ANAEMIA A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE								
[redacted]	AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:85.0 KG							
	DB1	1 TO 56	29	29	R: EXACERBATION OF ULCERATIVE COLITIS S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 37 L: 9 DAYS I: NO	S: SEVERE R: NO REASONABLE POSSIBILITY A: INTERRUPTION OF STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: WORSENING OF ULCERATIVE COLITIS A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE								
[redacted]	AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:85.0 KG							
	DB1	1 TO 56	42	42	R: EXACERBATION OF ULCERATIVE COLITIS S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 43 L: 2 DAYS I: NO	S: SEVERE R: NO REASONABLE POSSIBILITY A: INTERRUPTION OF STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: WORSENING OF ULCERATIVE COLITIS A: NO REASONABLE POSSIBILITY
[redacted]	AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:60.0 KG							
	DB1	1 TO 42	6	6	R: ANEMIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 貧血 L: ANEMIA	E: 33 L: 28 DAYS I: NO	S: SEVERE R: NO REASONABLE POSSIBILITY A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NORMAL DISEASE FLARE OF UC A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE								
[redacted]	AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:75.0 KG							
	DB1	1 TO 45	13	13	R: WORSENING OF UC S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 22 L: 10 DAYS I: YES	S: SEVERE R: NO REASONABLE POSSIBILITY A: INTERRUPTION OF STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: HOSPITALISATION	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: ACUTE FLARE A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE								
[redacted]	AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:75.0 KG							
	DB1	1 TO 45	43	43	R: WORSENING OF UC S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 67 L: 25 DAYS I: YES	S: MODERATE R: NO REASONABLE POSSIBILITY A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: WORSENING OF UC A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE								
[redacted]	AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:110.0 KG							
	POST	45 TO	9	53	R: WORSENING OF COLITIS ULCEROSA DISEASE S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 71 L: 19 DAYS I: YES	S: SEVERE R: NO REASONABLE POSSIBILITY A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: THE ULCERATIVE COLITIS DISEASE IS DEGRADED. A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE								
[redacted]	AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:62.0 KG							
	POST	8 TO	5	12	R: WORSENING OF ULCERATIVE COLITIS S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 19 L: 8 DAYS I: NO	S: MODERATE R: NO REASONABLE POSSIBILITY A: INTERRUPTION OF STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PRIMARY DISEASE A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE								
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:73.0 KG							
	DB1	1 TO 58	55	55	R: ULCERATIVE COLITIS S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: ULCERATIVE COLITIS	E: 56 L: 2 DAYS I: NO	S: SEVERE R: NO REASONABLE POSSIBILITY A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE UNDER STUDY A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE								
[redacted]	AGE:5[redacted] SEX:MALE RACE:BLACK WEIGHT:77.0 KG							
	POST	16 TO	9	24	R: ULCERATIVE COLITIS EXACERBATION S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 36 L: 13 DAYS I: NO	S: SEVERE R: NO REASONABLE POSSIBILITY A: OTHER: DRUG WAS ALREADY WITHDRAWN O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE UNDER STUDY A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE								
[redacted]	AGE:5[redacted] SEX:MALE RACE:BLACK WEIGHT:77.0 KG							
	POST	16 TO	9	24	R: RENAL INSUFFICIENCY WITH VOLUME DEPLETION S: METABOLISM AND NUTRITION DISORDERS P: 血液量減少症 L: VOLUME DEPLETION	E: 36 L: 13 DAYS I: NO	S: MODERATE R: NO REASONABLE POSSIBILITY A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ULCERATIVE COLITIS EXACERBATION A: NO REASONABLE POSSIBILITY
				24	R: RENAL INSUFFICIENCY WITH VOLUME DEPLETION S: RENAL AND URINARY DISORDERS P: 腎不全 L: RENAL INSUFFICIENCY	E: 36 L: 13 DAYS I: NO	S: MODERATE R: NO REASONABLE POSSIBILITY A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ULCERATIVE COLITIS EXACERBATION A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE								
[redacted]	AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:94.0 KG							
	DB1	1 TO 29	3	3	R: ABDOMINAL PAIN WITH DIARRHOE S: GASTROINTESTINAL DISORDERS P: 腹痛 L: ABDOMINAL PAIN	E: 6 L: 4 DAYS I: NO	S: SEVERE R: NO REASONABLE POSSIBILITY A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PATIENT HOSPITALIZED ON [redacted] 20[redacted] FOR ABDOMINAL PAIN WITH DIARRHOE A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE								
[redacted]	AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:94.0 KG							
	DB1	1 TO 29	3	3	R: ABDOMINAL PAIN WITH DIARRHOE S: GASTROINTESTINAL DISORDERS P: 下痢 L: DIARRHOEA	E: 6 L: 4 DAYS I: NO	S: SEVERE R: NO REASONABLE POSSIBILITY A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PATIENT HOSPITALIZED ON [redacted] 20[redacted] FOR ABDOMINAL PAIN WITH DIARRHOE A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE								
[redacted]	AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:55.8 KG							
	DB1	1 TO 22	12	12	R: WORSENING OF UC S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 24 L: 13 DAYS I: NO	S: SEVERE R: NO REASONABLE POSSIBILITY A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE UNDER STUDY A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE								
[redacted]	AGE:2[redacted]	SEX:MALE	RACE:WHITE	WEIGHT:55.8 KG				
	POST	23 TO	3	25	R: WORSENING OF ULCERATIVE COLITIS S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 83 L: 59 DAYS I: NO	S: SEVERE R: NO REASONABLE POSSIBILITY A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ULCERATIVE COLITIS A: NO REASONABLE POSSIBILITY
			62	84	R: WORSENING OF ULCERATIVE COLITIS S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 99 L: 16 DAYS I: NO	S: SEVERE R: NO REASONABLE POSSIBILITY A: NONE O: CONCOMITANT MEDICATION DISCONTINUED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE UNDER STUDY A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE								
[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:102.2 KG								
	DB1	1 TO 55	44	44	R: FEVERISH INFECTION S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 発熱 L: FEVER	O: YES I: NO	S: MODERATE R: NO REASONABLE POSSIBILITY A: NONE O: NONE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: WITHDRAWAL OF STEROIDS A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE								
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:102.2 KG							
	DB1	1 TO 55	44	44	R: FEVERISH INFECTION S: INFECTIONS AND INFESTATIONS P: 感染 L: INFECTION	O: YES I: NO	S: MODERATE R: NO REASONABLE POSSIBILITY A: NONE O: NONE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: WITHDRAWAL OF STEROIDS A: NO REASONABLE POSSIBILITY
[redacted]	AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:54.2 KG							
	DB1	1 TO 55	47	47 &	R: WORSENING OF HAEMORRHOIDS S: GASTROINTESTINAL DISORDERS P: 痔核 L: HEMORRHOIDS AGGRAVATED	E: 97 L: 51 DAYS I: NO	S: MODERATE R: NO REASONABLE POSSIBILITY A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: MILLIGAN MORGAN PROCEDURE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: HAMORROIDS ALREADY EXISTED PRIOR TO STUDY ENTRY (MED HISTORY!) A: NO REASONABLE POSSIBILITY

表 2.7.4.7-18.　　重篤な有害事象の一覧（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）

DB1 = Double blind induction study.
# Subject prematurely discontinued.
& Date is estimated.

Cross reference: M14-033 Induction Main-study Final CSR Table 14.3__2.5.1.1

表 2.7.4.7-19. 重篤な有害事象（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	2 (5.1)	3 (4.9)	5 (5.0)	19 (5.0)	22 (3.8)	41 (4.3)	17 (5.0)	19 (3.7)	36 (4.2)
血液およびリンパ系障害									
貧血	0	0	0	3 (0.8)	2 (0.3)	5 (0.5)	3 (0.9)	2 (0.4)	5 (0.6)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	3 (0.8)	2 (0.3)	5 (0.5)	3 (0.9)	2 (0.4)	5 (0.6)
心臓障害									
心停止	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)
胃腸障害									
腹痛	0	1 (1.6)	1 (1.0)	1 (0.3)	1 (0.2)	2 (0.2)	1 (0.3)	0	1 (0.1)
大腸炎	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
潰瘍性大腸炎	2 (5.1)	2 (3.3)	4 (4.0)	12 (3.2)	13 (2.3)	25 (2.6)	10 (2.9)	11 (2.1)	21 (2.5)
下痢	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)

表 2.7.4.7-19. 重篤な有害事象（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.)									
痔核	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
大腸狭窄	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
急性膵炎	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)	13 (3.4)	17 (3.0)	30 (3.2)	11 (3.2)	14 (2.7)	25 (2.9)
一般・全身障害および投与部位の状態									
発熱	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)
肝胆道系障害									
肝炎	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 2.7.4.7-19. 重篤な有害事象（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									
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)
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)
丹毒	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
帯状疱疹	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
感染	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
肺炎	1 (2.6)	0	1 (1.0)	1 (0.3)	0	1 (0.1)	0	0	0
水痘	0	1 (1.6)	1 (1.0)	0	1 (0.2)	1 (0.1)	0	0	0
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.6)	1 (1.6)	2 (2.0)	3 (0.8)	4 (0.7)	7 (0.7)	2 (0.6)	3 (0.6)	5 (0.6)
代謝および栄養障害									
血液量減少症	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 2.7.4.7-19. 重篤な有害事象（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									
四肢痛	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)
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）									
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)
子宮頚部扁平上皮癌	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									
腎不全	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 2.7.4.7-19. 重篤な有害事象（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 (%)
外科および内科処置									
創部ドレナージ	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)

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.

Cross reference: M14-033 Induction Japan Sub-study Final CSR Table 14.3__2.1.1_J

表 2.7.4.7-20. 治験薬と関連ありの重篤な有害事象（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	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)
感染症および寄生虫症									
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)
帯状疱疹	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
肺炎	1 (2.6)	0	1 (1.0)	1 (0.3)	0	1 (0.1)	0	0	0
SUBJECTS WITH ONE OR MORE EVENTS	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)
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）									
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)	0	1 (0.1)	1 (0.3)	0	1 (0.1)

表 2.7.4.7-20. 治験薬と関連ありの重篤な有害事象（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）

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__2.1.2_J

表 2.7.4.7-21. 重篤な有害事象の一覧（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）

SUBJECT NUMBER	---------- NAME	-- EPOCH -- INTERVAL	------- DAY	RX DAY OF ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 22.0 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AT END OF STUDY? L:LENGTH I:INTERMITTENT?	S:SEVERITY R:RELATIONSHIP TO STUDY DRUG A:ACTION TAKEN O:OTHER ACTIONS TAKEN	M:MALIGNANCY? S:SERIOUS AE? O:OTHER CAUSE OF EVENT A:ABBVIE OPINION OF CAUSALITY
INV [redacted] ([redacted])								
TRT:ADALIMUMAB STANDARD INDUCTION DOSE								
[redacted]	AGE:4[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:53.8 KG							
	POST	17 TO	9	25	R:UC AGGRAVATION S:GASTROINTESTINAL DISORDERS P:潰瘍性大腸炎 L:COLITIS ULCERATIVE AGGRAVATED	E:56 L:32 DAYS I:NO	S:MODERATE R:NO REASONABLE POSSIBILITY A:DISCONT. STUDY DRUG O:CONCOMITANT MEDICATION PRESCRIBED	S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:NATURAL PROGRESS OF THE UNDERLYING DISEASE,INSUFFICIENCY EFFICACY OF STUDY DRUG A:NO REASONABLE POSSIBILITY

表 2.7.4.7-21. 重篤な有害事象の一覧（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）（続き）

SUBJECT NUMBER	---------- NAME	-- EPOCH -- INTERVAL	------- DAY	RX DAY OF ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 22.0 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AT END OF STUDY? L:LENGTH I:INTERMITTENT?	S:SEVERITY R:RELATIONSHIP TO STUDY DRUG A:ACTION TAKEN O:OTHER ACTIONS TAKEN	M:MALIGNANCY? S:SERIOUS AE? O:OTHER CAUSE OF EVENT A:ABBVIE OPINION OF CAUSALITY
INV[redacted] ([redacted]) TRT:ADALIMUMAB STANDARD INDUCTION DOSE [redacted] AGE:2[redacted] SEX:MALE RACE:ASIAN WEIGHT:67.9 KG								
	DB1	1 TO 43	33	33	R:WORSENING OF ULCERATIVE COLITIS S:GASTROINTESTINAL DISORDERS P:潰瘍性大腸炎 L:COLITIS ULCERATIVE AGGRAVATED	E:127 L:95 DAYS I:NO	S:MODERATE R:NO REASONABLE POSSIBILITY A:DISCONT. STUDY DRUG O:CONCOMITANT MEDICATION PRESCRIBED	M:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:NATURAL COURSE OF UC A:NO REASONABLE POSSIBILITY
	POST	44 TO	24	67	R:PNEUMONIA S:INFECTIONS AND INFESTATIONS P:肺炎 L:PNEUMONIA	E:144 L:78 DAYS I:NO	S:SEVERE R:REASONABLE POSSIBILITY A:OTHER: NOT APPLICABLE O:CONCOMITANT MEDICATION PRESCRIBED	M:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A:REASONABLE POSSIBILITY

表 2.7.4.7-21. 重篤な有害事象の一覧（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）（続き）

SUBJECT NUMBER	---------- NAME	-- EPOCH -- INTERVAL	------- DAY	RX DAY OF ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 22.0 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AT END OF STUDY? L:LENGTH I:INTERMITTENT?	S:SEVERITY R:RELATIONSHIP TO STUDY DRUG A:ACTION TAKEN O:OTHER ACTIONS TAKEN	M:MALIGNANCY? S:SERIOUS AE? O:OTHER CAUSE OF EVENT A:ABBVIE OPINION OF CAUSALITY
INV[redacted] ([redacted]) TRT:ADALIMUMAB HIGHER INDUCTION DOSE [redacted] AGE:2[redacted] SEX:MALE RACE:ASIAN WEIGHT:94.8 KG								
	POST	24 TO	20	43	R:WORSENING OF ULCERATIVE COLITIS S:GASTROINTESTINAL DISORDERS P:潰瘍性大腸炎 L:COLITIS ULCERATIVE AGGRAVATED	E:63 L:21 DAYS I:NO	S:MODERATE R:NO REASONABLE POSSIBILITY A:NONE O:CONCOMITANT MEDICATION PRESCRIBED	M:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:NATURAL COUSE OF UC A:NO REASONABLE POSSIBILITY

表 2.7.4.7-21. 重篤な有害事象の一覧（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）（続き）

SUBJECT NUMBER	---------- NAME	-- EPOCH -- INTERVAL	------- DAY	RX DAY OF ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 22.0 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AT END OF STUDY? L:LENGTH I:INTERMITTENT?	S:SEVERITY R:RELATIONSHIP TO STUDY DRUG A:ACTION TAKEN O:OTHER ACTIONS TAKEN	M:MALIGNANCY? S:SERIOUS AE? O:OTHER CAUSE OF EVENT A:ABBVIE OPINION OF CAUSALITY
INV[redacted] ([redacted])								
TRT:ADALIMUMAB HIGHER INDUCTION DOSE								
[redacted] AGE:6[redacted]	SEX:MALE	RACE:ASIAN	WEIGHT:44.7 KG					
	DB1	1 TO 57	56	56	R:ABDOMINAL PAIN S:GASTROINTESTINAL DISORDERS P:腹痛 L:ABDOMINAL PAIN	E:61 L:6 DAYS I:NO	S:MODERATE R:NO REASONABLE POSSIBILITY A:NONE O:CONCOMITANT MEDICATION DISCONTINUED O:CONCOMITANT MEDICATION PRESCRIBED	S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:COLON BIOPSY A:NO REASONABLE POSSIBILITY

表 2.7.4.7-21. 重篤な有害事象の一覧（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）（続き）

SUBJECT NUMBER	---------- NAME	-- EPOCH -- INTERVAL	------- DAY	RX DAY OF ONSET	R:REPORTED TERM S:SYSTEM ORGAN CLASS P:MEDDRA 22.0 PREFERRED TERM L:LOWER LEVEL TERM	E:RX DAY ENDED O:ONGOING AT END OF STUDY? L:LENGTH I:INTERMITTENT?	S:SEVERITY R:RELATIONSHIP TO STUDY DRUG A:ACTION TAKEN O:OTHER ACTIONS TAKEN	M:MALIGNANCY? S:SERIOUS AE? O:OTHER CAUSE OF EVENT A:ABBVIE OPINION OF CAUSALITY
INV [redacted] ([redacted])								
TRT:ADALIMUMAB HIGHER INDUCTION DOSE								
[redacted] AGE:2[redacted] SEX:MALE RACE:ASIAN WEIGHT:78.3 KG								
	POST	30 TO	1	30	R:ULCERATIVE COLITIS DEVELOPMENT S:GASTROINTESTINAL DISORDERS P:潰瘍性大腸炎 L:ULCERATIVE COLITIS	E:73 L:44 DAYS I:NO	S:SEVERE R:NO REASONABLE POSSIBILITY A:NONE O:CONCOMITANT MEDICATION PRESCRIBED O:OTHER: FASTING, REST	M:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY O:ULCERATIVE COLITIS DEVELOPMENT A:NO REASONABLE POSSIBILITY
			22	51	R:VARICELLA S:INFECTIONS AND INFESTATIONS P:水痘 L:VARICELLA	E:61 L:11 DAYS I:NO	S:MODERATE R:NO REASONABLE POSSIBILITY A:OTHER: NOT APPLICABLE O:CONCOMITANT MEDICATION DISCONTINUED O:CONCOMITANT MEDICATION PRESCRIBED	M:NO S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:TACROLIMUS A:NO REASONABLE POSSIBILITY

DB1 = DOUBLE BLIND INDUCTION STUDY.
# SUBJECT PREMATURELY DISCONTINUED.

Cross reference: M14-033 Induction Japan Sub-study Final CSR Table 14.3__2.5.1.1_J

表 2.7.4.7-22. 重篤な有害事象（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	42 (13.9)	40 (13.2)	15 (9.9)	97 (12.8)
血液およびリンパ系障害	1 (0.3)	5 (1.6)	0	6 (0.8)
貧血	1 (0.3)	3 (1.0)	0	4 (0.5)
鉄欠乏性貧血	0	1 (0.3)	0	1 (0.1)
リンパ節症	0	1 (0.3)	0	1 (0.1)
血小板増加症	0	1 (0.3)	0	1 (0.1)
心臓障害	2 (0.7)	0	0	2 (0.3)
急性心筋梗塞	1 (0.3)	0	0	1 (0.1)
うっ血性心不全	1 (0.3)	0	0	1 (0.1)
冠動脈疾患	1 (0.3)	0	0	1 (0.1)
心筋虚血	1 (0.3)	0	0	1 (0.1)
眼障害	1 (0.3)	1 (0.3)	0	2 (0.3)
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)
胃腸障害	21 (7.0)	17 (5.6)	7 (4.6)	45 (5.9)
腹痛	1 (0.3)	0	0	1 (0.1)
上腹部痛	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-22. 重篤な有害事象（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.)				
肛門性器異形成	0	1 (0.3)	0	1 (0.1)
大腸炎	2 (0.7)	0	0	2 (0.3)
潰瘍性大腸炎	16 (5.3)	15 (4.9)	6 (4.0)	37 (4.9)
穿孔性十二指腸潰瘍	0	1 (0.3)	0	1 (0.1)
マロリー・ワイス症候群	0	0	1 (0.7)	1 (0.1)
悪心	1 (0.3)	0	0	1 (0.1)
急性膵炎	1 (0.3)	0	0	1 (0.1)
直腸出血	0	1 (0.3)	0	1 (0.1)
小腸閉塞	0	0	1 (0.7)	1 (0.1)
上部消化管出血	0	0	1 (0.7)	1 (0.1)
嘔吐	1 (0.3)	0	0	1 (0.1)
一般・全身障害および投与部位の状態	2 (0.7)	0	0	2 (0.3)
歩行障害	1 (0.3)	0	0	1 (0.1)
発熱	1 (0.3)	0	0	1 (0.1)
肝胆道系障害	0	0	2 (1.3)	2 (0.3)
胆管結石	0	0	1 (0.7)	1 (0.1)
門脈脾静脈腸間膜静脈血栓症	0	0	1 (0.7)	1 (0.1)

表 2.7.4.7-22. 重篤な有害事象（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	10 (3.3)	9 (3.0)	3 (2.0)	22 (2.9)
虫垂炎	0	1 (0.3)	0	1 (0.1)
気管支炎	0	0	1 (0.7)	1 (0.1)
クロストリジウム・ディフィシレ感染	3 (1.0)	0	0	3 (0.4)
外耳蜂巣炎	1 (0.3)	0	0	1 (0.1)
消化管感染	1 (0.3)	0	0	1 (0.1)
外耳炎	1 (0.3)	0	0	1 (0.1)
骨盤内炎症性疾患	0	1 (0.3)	0	1 (0.1)
会陰膿瘍	1 (0.3)	0	0	1 (0.1)
扁桃周囲膿瘍	0	1 (0.3)	0	1 (0.1)
肺炎	2 (0.7)	4 (1.3)	0	6 (0.8)
敗血症	0	0	1 (0.7)	1 (0.1)
胸骨炎	1 (0.3)	0	0	1 (0.1)
結核	0	1 (0.3)	1 (0.7)	2 (0.3)
胸腔内リンパ節結核	0	1 (0.3)	0	1 (0.1)
ウイルス感染	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-22. 重篤な有害事象（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 (%)
傷害、中毒および処置合併症	2 (0.7)	4 (1.3)	1 (0.7)	7 (0.9)
上腕骨骨折	0	1 (0.3)	0	1 (0.1)
半月板損傷	0	1 (0.3)	0	1 (0.1)
膝蓋骨骨折	0	1 (0.3)	0	1 (0.1)
処置後出血	0	0	1 (0.7)	1 (0.1)
橈骨骨折	0	1 (0.3)	0	1 (0.1)
肋骨骨折	1 (0.3)	0	0	1 (0.1)
上肢骨折	1 (0.3)	0	0	1 (0.1)
臨床検査	1 (0.3)	2 (0.7)	0	3 (0.4)
アラニンアミノトランスフェラーゼ増加	1 (0.3)	0	0	1 (0.1)
アスパラギン酸アミノトランスフェラーゼ増加	1 (0.3)	0	0	1 (0.1)
好中球数減少	0	1 (0.3)	0	1 (0.1)
体重減少	0	1 (0.3)	0	1 (0.1)
代謝および栄養障害	2 (0.7)	1 (0.3)	0	3 (0.4)
脱水	1 (0.3)	1 (0.3)	0	2 (0.3)
糖尿病	1 (0.3)	0	0	1 (0.1)
低ナトリウム血症	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-22. 重篤な有害事象（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 (%)
筋骨格系および結合組織障害	2 (0.7)	2 (0.7)	0	4 (0.5)
関節痛	1 (0.3)	2 (0.7)	0	3 (0.4)
変形性関節症	1 (0.3)	0	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）	1 (0.3)	5 (1.6)	0	6 (0.8)
膀胱癌	0	1 (0.3)	0	1 (0.1)
線維腫症	0	1 (0.3)	0	1 (0.1)
悪性黒色腫	0	1 (0.3)	0	1 (0.1)
非小細胞肺癌	1 (0.3)	0	0	1 (0.1)
食道腺癌	0	1 (0.3)	0	1 (0.1)
子宮平滑筋腫	0	1 (0.3)	0	1 (0.1)
神経系障害	0	1 (0.3)	2 (1.3)	3 (0.4)
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)
感覚鈍麻	0	1 (0.3)	0	1 (0.1)
虚血性脳卒中	0	0	1 (0.7)	1 (0.1)
単ニューロパチー	0	1 (0.3)	0	1 (0.1)
精神障害	0	1 (0.3)	1 (0.7)	2 (0.3)
むちゃ飲み	0	0	1 (0.7)	1 (0.1)
双極性障害	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-22. 重篤な有害事象（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 (%)
腎および尿路障害	2 (0.7)	0	1 (0.7)	3 (0.4)
血尿	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)
前立腺腫大	1 (0.3)	0	0	1 (0.1)
呼吸器、胸郭および縦隔障害	2 (0.7)	4 (1.3)	0	6 (0.8)
肺気腫	0	1 (0.3)	0	1 (0.1)
鼻茸	1 (0.3)	0	0	1 (0.1)
鼻中隔弯曲	0	1 (0.3)	0	1 (0.1)
肺塞栓症	1 (0.3)	2 (0.7)	0	3 (0.4)
副鼻腔ポリープ	1 (0.3)	0	0	1 (0.1)
皮膚および皮下組織障害	2 (0.7)	2 (0.7)	2 (1.3)	6 (0.8)
結節性紅斑	0	0	1 (0.7)	1 (0.1)
過剰皮膚	0	1 (0.3)	0	1 (0.1)
リニアIgA病	1 (0.3)	0	0	1 (0.1)
寝汗	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-22. 重篤な有害事象（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.)				
類天疱瘡	0	0	1 (0.7)	1 (0.1)
角層下膿疱性皮膚症	0	1 (0.3)	0	1 (0.1)
血管障害	1 (0.3)	0	0	1 (0.1)
高血圧	1 (0.3)	0	0	1 (0.1)

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.

Cross reference: M14-033 Maintenance Main-study Final CSR Table 14.3__2.1.1

表 2.7.4.7-23. 治験薬と関連ありの重篤な有害事象（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	8 (2.6)	9 (3.0)	4 (2.6)	21 (2.8)
血液およびリンパ系障害	0	2 (0.7)	0	2 (0.3)
貧血	0	1 (0.3)	0	1 (0.1)
リンパ節症	0	1 (0.3)	0	1 (0.1)
眼障害	1 (0.3)	1 (0.3)	0	2 (0.3)
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)
胃腸障害	2 (0.7)	1 (0.3)	1 (0.7)	4 (0.5)
上腹部痛	1 (0.3)	0	0	1 (0.1)
潰瘍性大腸炎	0	1 (0.3)	1 (0.7)	2 (0.3)
急性膵炎	1 (0.3)	0	0	1 (0.1)
感染症および寄生虫症	3 (1.0)	2 (0.7)	1 (0.7)	6 (0.8)
クロストリジウム・ディフィシレ感染	1 (0.3)	0	0	1 (0.1)
外耳蜂巣炎	1 (0.3)	0	0	1 (0.1)
外耳炎	1 (0.3)	0	0	1 (0.1)
肺炎	1 (0.3)	1 (0.3)	0	2 (0.3)
敗血症	0	0	1 (0.7)	1 (0.1)
結核	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-23. 治験薬と関連ありの重篤な有害事象（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 (%)
臨床検査	0	1 (0.3)	0	1 (0.1)
好中球数減少	0	1 (0.3)	0	1 (0.1)
筋骨格系および結合組織障害	0	1 (0.3)	0	1 (0.1)
関節痛	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	1 (0.3)	0	1 (0.1)
線維腫症	0	1 (0.3)	0	1 (0.1)
神経系障害	0	1 (0.3)	1 (0.7)	2 (0.3)
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)
感覚鈍麻	0	1 (0.3)	0	1 (0.1)
単ニューロパチー	0	1 (0.3)	0	1 (0.1)
腎および尿路障害	1 (0.3)	0	1 (0.7)	2 (0.3)
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)
呼吸器、胸郭および縦隔障害	0	1 (0.3)	0	1 (0.1)
肺気腫	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-23. 治験薬と関連ありの重篤な有害事象（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	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
リニアIgA病	1 (0.3)	0	0	1 (0.1)
類天疱瘡	0	0	1 (0.7)	1 (0.1)
角層下膿疱性皮膚症	0	1 (0.3)	0	1 (0.1)

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__2.1.2

表 2.7.4.7-24.　　重篤な有害事象の一覧（主試験安全性解析対象集団，M14-033 主試験の維持療法試験）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:80.0 KG							
	DB2	60 TO 379	276	335	R: POLYARTHRALGIAS S: MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS P: 関節痛 L: POLYARTHRALGIA	O: YES I: NO	S: Severe R: Reasonable possibility A: INTERRUPTION OF STUDY DRUG O: NONE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: No reasonable possibility
				335	R: BULLOUS PULMONARY EMPHYSEMA S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 肺気腫 L: EMPHYSEMATOUS BULLA	E: 365 L: 31 DAYS I: YES	S: Moderate R: Reasonable possibility A: INTERRUPTION OF STUDY DRUG O: NONE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: Reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:79.0 KG							
	OFF	89 TO	3	91	R: WORSENING OF UC S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 109 L: 19 DAYS I: NO	S: Severe R: No reasonable possibility A: DISCONT. STUDY DRUG O: OTHER: SURGERY	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: LACK OF EFFICACY A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:68.0 KG							
	DB2	57 TO 99	5	61	R: UC WORSENING S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 109 L: 49 DAYS I: NO	S: Moderate R: No reasonable possibility A: INTERRUPTION OF STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: ENDOSCOPY AND HOSPITALIZATION	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UC WORSENING A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK [redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:81.0 KG								
	DB2	57 TO 176	17	73 &	R: ENLARGED PROSTATE WORSENING S: REPRODUCTIVE SYSTEM AND BREAST DISORDERS P: 前立腺腫大 L: ENLARGED PROSTATE	E: 124 L: 52 DAYS I: NO	S: Moderate R: No reasonable possibility A: NONE O: OTHER: PROSTATECTOMY ON [redacted]–[redacted] 20[redacted]	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: MEDICAL HISTORY A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:81.0 KG							
	DB2	57 TO 176	93	149	R: ACUTE NON ST ELEVATION MYOCARDIAL INFRACTION S: CARDIAC DISORDERS P: 急性心筋梗塞 L: NON ST SEGMENT ELEVATION MYOCARDIAL INFARCTION	E: 152 L: 4 DAYS I: NO	S: Severe R: No reasonable possibility A: NONE O: OTHER: BLOOD TRANSFUSION	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: UNKNOWN A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:81.0 KG							
	DB2	57 TO 176	93	149	R: HEMATURIA S: RENAL AND URINARY DISORDERS P: 血尿 L: HEMATURIA	E: 156 L: 8 DAYS I: NO	S: Severe R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION DISCONTINUED O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: UROLIGIC WASHES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PROSTATECTOMY A: No reasonable possibility

表 2.7.4.7-24.　重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:81.0 KG							
	DB2	57 TO 176	96	152	R: CHRONIC ISCHEMIC HEART DESEASE - TRIPLE-VESSEL DISEASE S: CARDIAC DISORDERS P: 心筋虚血 L: CHRONIC ISCHEMIC HEART DISEASE, UNSPECIFIED	E: 248 L: 97 DAYS I: NO	S: Severe R: No reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: CORONARY ARTERIOGRAPHY USING TWO CATHETERS, (AORTO)CORONARY BYPASS OF ONE CORONARY ARTERY, DOUBLE INTERNAL MAMMARY-CORONARY ARTERY BYPASS, ACTION: CABGX3 LIMA TO LAD RIMA TO OM1 AND SV TO PDA...	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION, LIFE THREATENING O: INACTIVE ISCHEMIC HEART DISEASE IN MEDICAL HISTORY A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:81.0 KG							
	OFF	177 TO	18	194	R: INFECTION IN STERNUM S: INFECTIONS AND INFESTATIONS P: 胸骨炎 L: STERNITIS	E: 204 L: 11 DAYS I: NO	S: Moderate R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CAGB SURGERY A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:80.0 KG								
	DB2	60 TO 354	261	320	R: UPPER RIGHT SIDE TRANSVERSE ABDOMINAL PAIN S: GASTROINTESTINAL DISORDERS P: 上腹部痛 L: RIGHT UPPER QUADRANT PAIN	E: 323 L: 4 DAYS I: NO	S: Severe R: Reasonable possibility A: NONE O: NONE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:60.5 KG							
	OFF	125 TO	8	132	R: FLARE OF ULCERATIVE COLITIS S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 147 L: 16 DAYS I: NO	S: Moderate R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: LACK OF EFFICACY OF STUDY DRUG A: No reasonable possibility
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:49.8 KG							
	DB2	55 TO 357	85	139	R: FLARE OF UC S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 142 L: 4 DAYS I: YES	S: Severe R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POSSIBLE INFECTION A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB TDM								
[redacted]	AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:96.5 KG							
	DB2	57 TO 148	62	118	R: BULLOUS PEMPHIGOID ON BOTH LEGS, ARMS AND ABDOMEN S: SKIN AND SUBCUTANEOUS TISSUE DISORDERS P: 類天疱瘡 L: BULLOUS PEMPHIGOID	E: 148 L: 31 DAYS I: NO	S: Severe R: Reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION A: Reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:76.0 KG							
	DB2	57 TO 95	4	60	R: RIGHT SHOULDER FRACTURE S: INJURY, POISONING AND PROCEDURAL COMPLICATIONS P: 上肢骨折 L: SHOULDER FRACTURE	E: 61 L: 2 DAYS I: NO	S: Severe R: No reasonable possibility A: NONE O: OTHER: OPERATION OF RIGHT SHOULDER	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY O: ACCIDENT ONLY A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:76.0 KG							
	DB2	57 TO 95	36	92	R: EMBOLIA PULMONUM S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 肺塞栓症 L: PULMONARY EMBOLISM	E: 97 L: 6 DAYS I: NO	S: Severe R: No reasonable possibility A: DISCONT. STUDY DRUG O: OTHER: HOSPITALIZATION	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY, IMPORTANT MEDICAL OR SURGICAL INTERVENTION, LIFE THREATENING, DEATH OF SUBJECT O: POSSIBLE ALTERNATIVE ETIOLOGY FOR THE FATAL EVENT :RIGHT SHOULDER FRACTURE BUT NO AVAILABLE DOCUMENTATION/INFORMATION OF THE ETIOLOGY A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB TDM								
[redacted]	AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:61.4 KG							
	DB2	55 TO 217	54	108	R: URINARY RETENTION S: RENAL AND URINARY DISORDERS P: 尿閉 L: URINARY RETENTION	E: 128 L: 21 DAYS I: NO	S: Moderate R: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: INDWELLING CATHETER	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: Reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB TDM								
[redacted]	AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:61.4 KG							
	OFF	218 TO	3	220	R: WORSENING ULCERATIVE COLITIS S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 278 L: 59 DAYS I: NO	S: Severe R: No reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: WORSENING DISEASE A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:94.5 KG							
	DB2	56 TO 358	188	243	R: LEFT PATELLA FRACTURE S: INJURY, POISONING AND PROCEDURAL COMPLICATIONS P: 膝蓋骨骨折 L: PATELLA FRACTURE	E: 245 L: 3 DAYS I: NO	S: Severe R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FELL AND INJURED LEFT KNEE A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:55.8 KG							
	DB2	57 TO 316	190	246	R: ULCERATIVE COLITIS AGGRAVATED S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 325 L: 80 DAYS I: NO	S: Severe R: No reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: SURGICAL TREATMENT: COLECTOMY	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: AGGRAVATION OF ULCERATIVE COLITIS AFTER CORTICOSTEROIDS WITHDRAWAL A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

R: Reported Term
S: System Organ Class
P: MedDRA 22.0 Preferred Term
L: Lower Level Term
E: RX Day Ended+
O: Ongoing at End of Study?
L: Length
I: Intermittent?
S: Severity
R: Relationship to Study Drug
A: Actions Taken
O: Other Actions Taken
M: Malignancy?
S: Serious AE?
O: Other Cause of Event
A: Abbvie Opinion of Causality

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset+				
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK									
[redacted]	AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:104.0 KG								
		OFF	358 TO	9	366	R: SEVERE FLARE OF ULCERATIVE COLITIS S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 406 L: 41 DAYS I: NO	S: Severe R: No reasonable possibility A: OTHER: NOT APPLICABLE - AE OCCURED DURING FOLLOW-UP O: CONCOMITANT MEDICATION DISCONTINUED O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISCONTINUATION OF TREATMENT WITH STUDY DRUG A: No reasonable possibility

表 2.7.4.7-24.　　重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:104.0 KG							
	OFF	358 TO	13	370	R: EXCESSIVE AND REDUNDANT SKIN FOLLOWING WEIGHT LOSS S: INVESTIGATIONS P: 体重減少 L: WEIGHT LOSS	E: 372 L: 3 DAYS I: NO	S: Moderate R: No reasonable possibility A: OTHER: NOT APPLICABLE - AE OCCURED DURING FOLLOW-UP O: OTHER: SURGICAL ABDOMINOPLASTY	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: OBESITY IN PATIENT'S HISTORY A: No reasonable possibility
				370	R: EXCESSIVE AND REDUNDANT SKIN FOLLOWING WEIGHT LOSS S: SKIN AND SUBCUTANEOUS TISSUE DISORDERS P: 過剰皮膚 L: EXCESSIVE SKIN	E: 372 L: 3 DAYS I: NO	S: Moderate R: No reasonable possibility A: OTHER: NOT APPLICABLE - AE OCCURED DURING FOLLOW-UP O: OTHER: SURGICAL ABDOMINOPLASTY	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: OBESITY IN PATIENT'S HISTORY A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:57.0 KG							
	DB2	60 TO 256	54	113	R: CLINICALLY SIGNIFICANT ALT ELEVATION, MILD AST ELEVATION S: INVESTIGATIONS P: アラニンアミノトランスフェラーゼ増加 L: ALT INCREASED	E: 148 L: 36 DAYS I: NO	S: Moderate R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION DISCONTINUED O: OTHER: HBV DNA AND ANTY-HCV RETEST RECOMMENDED, BOTH TEST NEGATIVE. ALT=18 U/L, AST=21 U/L AT WEEK 24	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CONCOMITANT TREATMENT WITH MERCAPTOPURINE A: Reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:57.0 KG							
	DB2	60 TO 256	54	113	R: CLINICALLY SIGNIFICANT ALT ELEVATION, MILD AST ELEVATION S: INVESTIGATIONS P: アスパラギン酸アミノトランスフェラーゼ増加 L: AST INCREASED	E: 148 L: 36 DAYS I: NO	S: Moderate R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION DISCONTINUED O: OTHER: HBV DNA AND ANTY-HCV RETEST RECOMMENDED, BOTH TEST NEGATIVE. ALT=18 U/L, AST=21 U/L AT WEEK 24	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CONCOMITANT TREATMENT WITH MERCAPTOPURINE A: Reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:73.9 KG							
	DB2	57 TO 358	280	336	R: ULCERATIVE COLITIS AGGRAVATED S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	O: YES I: NO	S: Moderate R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CORTICOSTEROID DEPENDENT ULCERATIVE COLITIS; A NEW FLARE OD DISEASE AFTER CORTICOSTEROID THERAPY WITHDRAWAL A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:77.0 KG							
	DB2	57 TO 359	82	138	R: RIGHT-SIDED PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 246 L: 109 DAYS I: NO	S: Moderate R: Reasonable possibility A: INTERRUPTION OF STUDY DRUG O: CONCOMITANT MEDICATION DISCONTINUED O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: Reasonable possibility
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:93.0 KG							
	OFF	359 TO	31	389	R: ULCERATIVE COLITIS AGGRAVATED S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 406 L: 18 DAYS I: NO	S: Severe R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ULCERATIVE COLITIS AGGRAVATED A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB TDM								
[redacted]	AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:81.2 KG							
	DB2	59 TO 358	206	264	R: UPPER GASTROINTESTINAL BLEEDING AFTER BINGE DRINKING - MALLORY-WEISS SYNDROME S: GASTROINTESTINAL DISORDERS P: マロリー・ワイス症候群 L: MALLORY-WEISS SYNDROME	E: 267 L: 4 DAYS I: YES	S: Moderate R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: UPPER ENDOSCOPY SCHEDULDED FOR THE NEXT WEEK	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: VOMITTING AFTER BINGE DRINKING A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB TDM								
[redacted]	AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:81.2 KG							
	DB2	59 TO 358	206	264	R: UPPER GASTROINTESTINAL BLEEDING AFTER BINGE DRINKING - MALLORY-WEISS SYNDROME S: GASTROINTESTINAL DISORDERS P: 上部消化管出血 L: UPPER GASTROINTESTINAL HEMORRHAGE	E: 267 L: 4 DAYS I: YES	S: Moderate R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: UPPER ENDOSCOPY SCHEDULDED FOR THE NEXT WEEK	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: VOMITTING AFTER BINGE DRINKING A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB TDM								
[redacted]	AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:81.2 KG							
	DB2	59 TO 358	206	264	R: UPPER GASTROINTESTINAL BLEEDING AFTER BINGE DRINKING - MALLORY-WEISS SYNDROME S: PSYCHIATRIC DISORDERS P: むちゃ飲み L: BINGE DRINKING	E: 267 L: 4 DAYS I: YES	S: Moderate R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: UPPER ENDOSCOPY SCHEDULDED FOR THE NEXT WEEK	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: VOMITTING AFTER BINGE DRINKING A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted] AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:83.0 KG								
	DB2	61 TO 362	19	79	R: LEFT EXTERNAL OTITIS MEDIA WITH PERIAURICULAR CELLULITIS S: INFECTIONS AND INFESTATIONS P: 外耳蜂巣炎 L: EXTERNAL EAR CELLULITIS	E: 92 L: 14 DAYS I: NO	S: Severe R: Reasonable possibility A: INTERRUPTION OF STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: Reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted] AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:83.0 KG								
	DB2	61 TO 362	19	79	R: LEFT EXTERNAL OTITIS MEDIA WITH PERIAURICULAR CELLULITIS S: INFECTIONS AND INFESTATIONS P: 外耳炎 L: LEFT OTITIS EXTERNA	E: 92 L: 14 DAYS I: NO	S: Severe R: Reasonable possibility A: INTERRUPTION OF STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: Reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:122.0 KG							
	OFF	359 TO	52	410	R: ESOPHAGEAL INVASIVE ADENOSQUAMOUS CARCINOMA S: NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) P: 食道腺癌 L: OESOPHAGEAL ADENOCARCINOMA	E: 440 L: 31 DAYS I: NO	S: Severe R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY, IMPORTANT MEDICAL OR SURGICAL INTERVENTION, LIFE THREATENING, DEATH OF SUBJECT O: TO FOLLOW A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:98.0 KG							
	OFF	78 TO	7	84	R: WORSENING UC S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 152 L: 69 DAYS I: NO	S: Severe R: No reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INEFFECTIVE TREATMENT WITH STUDY MEDICATION. A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB TDM								
[redacted]	AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:79.0 KG							
	OFF	57 TO	4	60	R: UC WORSENING S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 65 L: 6 DAYS I: NO	S: Moderate R: No reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ULCERATIVE COLITIS FLARE A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:2[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:65.0 KG							
	OFF	148 TO	68	215	R: UC WORSENING S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 238 L: 24 DAYS I: NO	S: Severe R: No reasonable possibility A: OTHER: PATIENT ALREADY PERFORM A PD VISIT O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ULCERATIVE COLITIS FLARE A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:74.7 KG							
	OFF	360 TO	13	372	R: MELANOMA S: NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) P: 悪性黒色腫 L: MELANOMA	E: 393 L: 22 DAYS I: NO	S: Mild R: No reasonable possibility A: NONE O: OTHER: MEDICAL SURGERY ON 25-7	S: YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: THE SUN/OUTSIDE WORK. A: Reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:96.7 KG							
	OFF	142 TO	3	144	R: DISSEMINATED NON-SMALL CELL CARCINOMA PROBABLE PRIMARY LOCALISATION LUNG S: NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) P: 非小細胞肺癌 L: NON-SMALL CELL LUNG CANCER	E: 227 L: 84 DAYS I: NO	S: Severe R: No reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION, LIFE THREATENING, DEATH OF SUBJECT O: SMOKING A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:56.4 KG							
	DB2	52 TO 362	21	72	R: PELVIC INFLAMMATORY DISEASE S: INFECTIONS AND INFESTATIONS P: 骨盤内炎症性疾患 L: PELVIC INFLAMMATORY DISEASE	E: 83 L: 12 DAYS I: NO	S: Severe R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: UNKNOWN A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB TDM								
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:85.5 KG							
	DB2	55 TO 239	134	188	R: CHRONIC INFLAMMATORY DEMYELINATING POLYNEUROPATHY S: NERVOUS SYSTEM DISORDERS P: 慢性炎症性脱髄性多発根ニューロパチー L: CHRONIC INFLAMMATORY DEMYELINATING POLYNEUROPATHY	O: YES I: NO	S: Moderate R: Reasonable possibility A: DISCONT. STUDY DRUG O: OTHER: RESULT OF NEUROLOGIST CONSULTATION AND EMG: CIDP (CHRONIC INFLAMMATORY DEMYELINATING POLYNEUROPATHY)	S: YES, PERSISTENT OR SIGNIFICANT DISABILITY A: Reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:95.0 KG							
	DB2	57 TO 280	63	119	R: ANEMIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 貧血 L: ANEMIA	E: 126 L: 8 DAYS I: NO	S: Moderate R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THE PATIENT WAS ADMITTED TO THE HOSPITAL DUE TO VERY LOW LEVEL OF HEMOGLOBIN A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted] AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:95.0 KG								
	OFF	281 TO	8	288	R: EXACERBATION OF UC S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 326 L: 39 DAYS I: NO	S: Severe R: No reasonable possibility A: NONE O: OTHER: COLON RESECTION	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, LIFE THREATENING O: THE PATIENT WAS ADMITTED TO THE HOSPITAL DUE TO COLON RESECTION A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:91.0 KG							
	DB2	58 TO 115	14	71	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 140 L: 70 DAYS I: YES	S: Severe R: No reasonable possibility A: INTERRUPTION OF STUDY DRUG A: OTHER: THE PATIENT TOOK THE IMP 10 DAYS AFTER SCHEDULE TIME OF TAKING IMP DUE TO HOSPITALIZATION O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PATIENT WAS ADMITTED TO THE HOSPITAL DUE TO CHEST PAIN,DYSPONOEA AND FEVER. A: Reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:54.0 KG							
	DB2	59 TO 358	149	207	R: ANEMIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 貧血 L: ANEMIA	E: 211 L: 5 DAYS I: YES	S: Moderate R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THE PATIENT WAS ADMITTED TO THE HOSPOITAL DUE TO LOW SCORE OF HGB A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK [redacted] AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:54.0 KG								
	OFF	359 TO	32	390	R: DEEP SYMPTOMATIC ANEMIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 貧血 L: ANEMIA	E: 395 L: 6 DAYS I: NO	S: Severe R: No reasonable possibility A: OTHER: THE PATIENT HAS FINISHED A TREATMENT AND IS NOT USING A INVESTIGIONAL MEDICAL PRODUCT ANYMORE. AE HAPPEN DURING THE 70 DAYS FOLLOW UP PERIOD. O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THE PATIENT, AFTER UNSCHEDULED VISIT, WAS IMMEDIATELY REFERRED TO THE HOSPITAL BECAUSE OF THE DEPTH OF SYMPTOMATIC ANEMIA. THE INVESTIGATOR HAS BEEN INFORMED ABOUT ADVERSE EVENT ON [redacted] 20[redacted] A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:71.4 KG							
	OFF	149 TO	7	155	R: EXACERBATION OF ULCERATIVE COLITIS S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 167 L: 13 DAYS I: NO	S: Severe R: No reasonable possibility A: DISCONT. STUDY DRUG O: NONE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: EXACERBATION OF ULCERATIVE COLITIS REQUIRING COLECTOMY A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:86.0 KG							
	DB2	57 TO 189	117	173	R: CONGESTIVE HEART FAILURE S: CARDIAC DISORDERS P: うっ血性心不全 L: CONGESTIVE HEART FAILURE	E: 175 L: 3 DAYS I: NO	S: Severe R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: ECHOCARDIOGRAM	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: VENTRICULAR BLOCKAGE A: No reasonable possibility
	OFF	190 TO	6	195	R: DEHYDRATION S: METABOLISM AND NUTRITION DISORDERS P: 脱水 L: DEHYDRATION	E: 200 L: 6 DAYS I: NO	S: Severe R: No reasonable possibility A: INTERRUPTION OF STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DEHYDRATION CAUSING CHEST PAIN A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:86.0 KG							
	OFF	190 TO	28	217	R: CORONARY ARTERY DISEASE S: CARDIAC DISORDERS P: 冠動脈疾患 L: CORONARY ARTERY DISEASE	E: 220 L: 4 DAYS I: NO	S: Severe R: No reasonable possibility A: OTHER: DRUG HAD NOT BEEN REINTRODUCED FROM LAST SAE OF C-DIFF O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: ANGIOPLASTY PERFORMED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: UNSURE A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted] TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:4[redacted] SEX:FEMALE RACE:BLACK WEIGHT:84.0 KG							
	OFF	265 TO	3	267	R: PULMONARY EMBOLISM S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 肺塞栓症 L: PULMONARY EMBOLISM	E: 270 L: 4 DAYS I: NO	S: Severe R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POSSIBILITY OF SECONDARY TO ULCERATIVE COLITIS A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:81.2 KG							
	DB2	60 TO 361	277	336	R: FRACTURED RIBS S: INJURY, POISONING AND PROCEDURAL COMPLICATIONS P: 肋骨骨折 L: FRACTURED RIBS	O: YES I: NO	S: Moderate R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FALL FROM 3 METERS HEIGHT AT CONSTRUCTION AREA DURING WORK A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:81.2 KG							
	OFF	362 TO	12	373	R: COLITIS ULCEROSA S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE	E: 374 L: 2 DAYS I: NO	S: Mild R: No reasonable possibility A: NONE O: OTHER: PLANNED COLONOSCOPY	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: COLITIS ULCEROSA DISEASE A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:99.4 KG							
	DB2	58 TO 367	171	228	R: PERITONSILLAR ABSCESS S: INFECTIONS AND INFESTATIONS P: 扁桃周囲膿瘍 L: PERITONSILLAR ABSCESS	E: 243 L: 16 DAYS I: NO	S: Moderate R: No reasonable possibility A: INTERRUPTION OF STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: TONSILLECTOMY	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NO KNOWN CAUSE A: Reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:81.0 KG							
	DB2	58 TO 253	188	245	R: EXACERBATION OF ULCERATIVE COLITIS S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 349& L: 105 DAYS I: NO	S: Moderate R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: HISTORY OF ULCERATIVE COLITIS A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:78.0 KG							
	DB2	59 TO 358	183	241	R: ULCERATIVE COLITIS FLARE S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 252 L: 12 DAYS I: NO	S: Moderate R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: CT ABDOMEN AND PELVIS	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: HISTORY OF ULCERATIVE COLITIS A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:84.0 KG							
	OFF	198 TO	3	200	R: EXACERBATION OF ULCERATIVE COLITIS S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 207 L: 8 DAYS I: NO	S: Severe R: No reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: EXACERBATION OF ULCERATIVE COLITIS A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:60.5 KG							
	DB2	59 TO 267	124	182 &	R: AGGRESSIVE FIBROMATOSIS S: NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) P: 線維腫症 L: FIBROMATOSIS	E: 273 L: 92 DAYS I: NO	S: Moderate R: Reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: No reasonable possibility
	OFF	268 TO	23	290	R: AGGRESSIVA FIBROMATOSIS - BENIGN TUMOR OF THE OVARY S: NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) P: 線維腫症 L: FIBROMATOSIS	E: 298 L: 9 DAYS I: YES	S: Moderate R: Reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch	---- Interval	RX Day Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:60.5 KG							
	OFF	268 TO	33	300	R: AGGRESSIVE FIBROMATOSIS - A TUMOR IN THE SMALLER PELVIS S: NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) P: 線維腫症 L: FIBROMATOSIS	E: 313 L: 14 DAYS I: YES	S: Moderate R: Reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:60.5 KG							
	OFF	268 TO	66	333	R: A TUMOR IN THE SMALLER PELVIS (AGGRESSIVE FIBROMATOSIS) S: NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) P: 線維腫症 L: FIBROMATOSIS	E: 337 L: 5 DAYS I: YES	S: Moderate R: Reasonable possibility A: DISCONT. STUDY DRUG O: NONE	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:62.5 KG							
	DB2	60 TO 165	58	117	R: EXACERBATION OF UC. S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 119 L: 3 DAYS I: NO	S: Moderate R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ULCERATIVE COLITIS A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:2[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:62.5 KG				
	DB2	60 TO 165	101	160	R: CLOSTRIDIUM DIFFICILE INFECTION S: INFECTIONS AND INFESTATIONS P: クロストリジウム・ディフィシレ感染 L: CLOSTRIDIUM DIFFICILE INFECTION	E: 174 L: 15 DAYS I: NO	S: Moderate R: Reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: Reasonable possibility
[redacted]	AGE:2[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:54.8 KG				
	OFF	149 TO	1	149	R: EXACERBATION COLITIS ULCEROSA S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 155 L: 7 DAYS I: NO	S: Moderate R: No reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: EXACERBATION COLITIS ULCEROSA A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:65.0 KG							
	DB2	57 TO 361	161	217	R: CLOSTRIDIUM DIFFICILE INFECTION S: INFECTIONS AND INFESTATIONS P: クロストリジウム・ディフィシレ感染 L: CLOSTRIDIUM DIFFICILE INFECTION	E: 231 L: 15 DAYS I: YES	S: Moderate R: No reasonable possibility A: INTERRUPTION OF STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: HOSPITALIZATION DUE TO C.DIFFICILE INFECTION A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:55.9 KG							
	OFF	162 TO	13	174	R: TUBERCULOSIS S: INFECTIONS AND INFESTATIONS P: 結核 L: TUBERCULOSIS	E: 268 L: 95 DAYS I: NO	S: Severe R: Reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: Reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB TDM								
[redacted]	AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:64.0 KG							
	OFF	198 TO	3	200	R: EXACERBATION COLITIS ULCEROSA S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 211 L: 12 DAYS I: NO	S: Moderate R: No reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: EXACERBATION COLITIS ULCEROSA A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:67.0 KG							
	OFF	107 TO	3	109	R: ULCERATIVE COLITIS FLARE S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 114 L: 6 DAYS I: NO	S: Severe R: No reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: HOSPITALIZATION DUE TO UC FLARE A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:82.0 KG							
	DB2	55 TO 83	2	56	R: UTERINE FIBROID S: NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) P: 子宮平滑筋腫 L: UTERINE FIBROID	E: 57 L: 2 DAYS I: NO	S: Moderate R: No reasonable possibility A: INTERRUPTION OF STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: TOTAL LAPAROSCOPIC HYSTERECTOMY	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UTERINE FIBROIDS A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

R: Reported Term
S: System Organ Class
P: MedDRA 22.0 Preferred Term
L: Lower Level Term
E: RX Day Ended+
O: Ongoing at End of Study?
L: Length
I: Intermittent?
S: Severity
R: Relationship to Study Drug
A: Actions Taken
O: Other Actions Taken
M: Malignancy?
S: Serious AE?
O: Other Cause of Event
A: Abbvie Opinion of Causality

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+			
INV: [redacted] ([redacted])							
TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK							
[redacted]	AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:82.0 KG						
	OFF	84 TO	4	87	R: WORSENING ULCERATIVE COLITIS S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 109 L: 23 DAYS I: NO	S: Severe R: No reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: WORSENING ULCERATIVE COLITIS A: No reasonable possibility
[redacted]	AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:85.0 KG						
	OFF	361 TO	1	361	R: CHRONIC RIGHT SHOULDER JOINT PAIN S: MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS P: 関節痛 L: PAIN IN JOINT INVOLVING SHOULDER REGION	E: 362 L: 2 DAYS I: NO	S: Mild R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: CHRONIC JOINT PAIN A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:86.5 KG							
	DB2	58 TO 362	240	297	R: MEDIAL MENISCAL TEAR IN LEFT KNEE S: INJURY, POISONING AND PROCEDURAL COMPLICATIONS P: 半月板損傷 L: MENISCUS TEAR	E: 297 L: 1 DAY I: NO	S: Mild R: No reasonable possibility A: NONE O: NONE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NONE A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:69.1 KG							
	OFF	198 TO	10	207	R: INTESTINAL SURINFECTION S: INFECTIONS AND INFESTATIONS P: 消化管感染 L: GASTROINTESTINAL INFECTION	E: 229 L: 23 DAYS I: NO	S: Severe R: No reasonable possibility A: INTERRUPTION OF STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SUSPICION OF INTESTINAL SURINFECTION A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:54.2 KG							
	DB2	56 TO 148	45	100	R: DEVIATED NASAL SEPTUM S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 鼻中隔弯曲 L: DEVIATED NASAL SEPTUM	E: 102 L: 3 DAYS I: YES	S: Mild R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: SMR+TURBINECTOMY BY DIATHERMY FOR TREATMENT OF DEVIATED NASAL SEPTUM	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ELECTIVE SURGERY A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

R: Reported Term
S: System Organ Class
P: MedDRA 22.0 Preferred Term
L: Lower Level Term
E: RX Day Ended+
O: Ongoing at End of Study?
L: Length
I: Intermittent?
S: Severity
R: Relationship to Study Drug
A: Actions Taken
O: Other Actions Taken
M: Malignancy?
S: Serious AE?
O: Other Cause of Event
A: Abbvie Opinion of Causality

Subject Number	Name	Epoch	Day	RX Day of Onset+					
INV: [redacted] ([redacted])									
TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK									
[redacted]	AGE:6[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:54.2 KG					
	DB2	56 TO 148	58	113	R: SUBCORNEAL PUSTULAR DERMATOSIS S: SKIN AND SUBCUTANEOUS TISSUE DISORDERS P: 角層下膿疱性皮膚症 L: SUBCORNEAL PUSTULAR DERMATOSIS	O: YES I: NO	S: Severe R: Reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: Reasonable possibility	

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch	Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK									
[redacted]	AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:50.5 KG								
	OFF	269 TO	2	270		R: EXACERBATION OF UC S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 297 L: 28 DAYS I: NO	S: Moderate R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: INEFFICIENCY OF IMP TREATMENT A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB TDM								
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:64.4 KG							
	OFF	359 TO	4	362	R: ISCHEMIC STROKE S: NERVOUS SYSTEM DISORDERS P: 虚血性脳卒中 L: ISCHEMIC STROKE	E: 381 L: 20 DAYS I: NO	S: Severe R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNKNOWN BY THE MOMENT A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch	---- Interval	Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK [redacted] AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:108.0 KG									
	DB2	58 TO 357	74	131		R: ARTHRALGIA S: MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS P: 関節痛 L: ARTHRALGIA	O: YES I: NO	S: Severe R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: HSPITALISATION FOR DIAGNOSTIC AND TREATMENT BETWEEN [redacted]-[redacted]20[redacted]	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: HOSPITALISATION DUE TO ARTHRALGIA FOR DIAGNOSTIC AND TREATMENT BETWEEN [redacted]-[redacted]20[redacted] A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch	Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK [redacted] AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:108.0 KG									
	OFF	358 TO		63	420	R: UNCONTROLLED HYPERTENSION S: VASCULAR DISORDERS P: 高血圧 L: UNCONTROLLED HYPERTENSION	E: 426 L: 7 DAYS I: NO	S: Severe R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY, LIFE THREATENING O: HOSPITALISATION FOR DIAGNOSIS AND TREATMENT OPTIMALISATION A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch	---- Interval	Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK [redacted] AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:79.9 KG									
	DB2	57 TO 361	107	163		R: FRACTURE OF THE RIGHT HUMERUS S: INJURY, POISONING AND PROCEDURAL COMPLICATIONS P: 上腕骨骨折 L: HUMERUS FRACTURE	O: YES I: NO	S: Moderate R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: HOSPITALISATION FOR SURGERY TREATMENT [redacted]-[redacted]20[redacted]	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: HOSPITALISATION A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch	---- Interval	Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK [redacted] AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:79.9 KG									
	DB2	57 TO 361	245	301		R: FRACTURE OF THE LEFT HUMERUS S: INJURY, POISONING AND PROCEDURAL COMPLICATIONS P: 上腕骨骨折 L: HUMERUS FRACTURE	O: YES I: YES	S: Moderate R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: SURGERY TREATMENT	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: HOSPITALISATION WITH SURGERY TREATMENT A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted] AGE:5[redacted]	SEX:MALE	RACE:WHITE	WEIGHT:68.0 KG					
	OFF	184 TO	2	185	R: ULCERATIVE COLITIS WORSENING S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 196 L: 12 DAYS I: NO	S: Severe R: No reasonable possibility A: OTHER: PATIENT WAS WITHDRAWN BEFORE AE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: HOSPITALISATION	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PATIENT WAS WITHDRAWN FROM STUDY DUE TO PRIMARY NO RESPONSE FOR ADALIMUUMAB TREATMENT AND DIRECTED TO HOSPITALISATION A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:68.0 KG							
	OFF	184 TO	17	200	R: PNEUMONIA WORSENING S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA AGGRAVATED	E: 202 L: 3 DAYS I: NO	S: Severe R: No reasonable possibility A: OTHER: PATIENT PREVIOUSLY WITHDRAWN FROM THE STUDY O: CONCOMITANT MEDICATION DISCONTINUED O: OTHER: HOSPITALISATION	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, LIFE THREATENING, DEATH OF SUBJECT O: INFORMATION WILL BE UPDATED WHEN AVAILABLE A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] [redacted] TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK [redacted] AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:63.9 KG								
	DB2	57 TO 358	196	252	R: ULCER OF THE DUODENUM BULB WITH PERFORATION S: GASTROINTESTINAL DISORDERS P: 穿孔性十二指腸潰瘍 L: DUODENAL ULCER PERFORATION	E: 261 L: 10 DAYS I: NO	S: Severe R: No reasonable possibility A: INTERRUPTION OF STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: HOSPITALISATION FOR DIAGNOSTIC AND SURGERY TREATMENT	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION, LIFE THREATENING O: PATIENT WAS HOSPITALISED FOR DIAGNOSTIC SEVERE ABDOMINAL PAIN. ABDOMEN CT RESULT :SUSPICION OF GI PERFORATION. DURING DIAGNOSTIC LAPAROTOMY PERFORATION OF DUODENAL BULB WAS CONFIRMED AND RESOLVED. A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK [redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:66.6 KG								
	DB2	64 TO 358	162	225	R: SECONDARY ANEMIA INCREASING S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 貧血 L: ANEMIA AGGRAVATED	E: 232 L: 8 DAYS I: YES	S: Moderate R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: HOSPITALISATION WITH INTRAVENOUS FERRUM TREATMENT [redacted]-[redacted]/[redacted]/20[redacted]	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SYMPTOMATIC SECONDARY ANEMIA A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK [redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:66.6 KG								
	DB2	64 TO 358	272	335	R: SECONDARY ANEMIA INCREASE S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 貧血 L: SECONDARY ANEMIA	O: YES I: NO	S: Severe R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: HOSPITALISATION FOR INTRAVENOUS FERRUM INIECTION SINCE [redacted]-[redacted]/[redacted]/20[redacted]	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: SECONDARY ANEMIA DUE TO ULCETATIVE COLITIS MUCOSAL BLEEDING A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK [redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:66.6 KG								
	OFF	359 TO	66	424	R: ULCERATIVE COLITIS FLARE S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 427 L: 4 DAYS I: NO	S: Moderate R: No reasonable possibility A: OTHER: FOLLOW UP PEROID O: CONCOMITANT MEDICATION DISCONTINUED O: OTHER: HOSPITALISATION	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PANCOLECTOMY DUE TO FLARE OF COLITIS WITHOUT RESPONSE FOR STEROID, IMMUNOSUPRESANTS AND ANTYTNF TREATMENT A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

R: Reported Term
S: System Organ Class
P: MedDRA 22.0 Preferred Term
L: Lower Level Term
E: RX Day Ended+
O: Ongoing at End of Study?
L: Length
I: Intermittent?
S: Severity
R: Relationship to Study Drug
A: Actions Taken
O: Other Actions Taken
M: Malignancy?
S: Serious AE?
O: Other Cause of Event
A: Abbvie Opinion of Causality

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset+	R: Reported Term / S: System Organ Class / P: MedDRA 22.0 Preferred Term / L: Lower Level Term	E: RX Day Ended+ / O: Ongoing at End of Study? / L: Length / I: Intermittent?	S: Severity / R: Relationship to Study Drug / A: Actions Taken / O: Other Actions Taken	M: Malignancy? / S: Serious AE? / O: Other Cause of Event / A: Abbvie Opinion of Causality
INV: [redacted] ([redacted] TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK									
[redacted]	AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:96.7 KG								
	OFF	345 TO	4	348		R: ISOLATED ,IDIOPATIC MONONEUROPATHY IN THE REGION OF THE UPPER EYELID MUSCLE, RIGHT PTOSIS, HYPOAESTHESIA OF THE RIGHT EYEBROW S: EYE DISORDERS P: 眼瞼下垂 L: PTOSIS	O: YES I: NO	S: Severe R: Reasonable possibility A: DISCONT. STUDY DRUG O: OTHER: HOSPITALISATION IN NEUROLOGY DEPARTMENT BETWEEN [redacted]-[redacted]/[redacted]/20[redacted]	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY O: MAIN REASON WAS NOT UNRAVEL DURING HOSPITALISATION. ACCORDING TO NEUROLOGYST OPINION IT COULD BE IN RELATIONSHIP TO STUDY DRUG. IP WAS WITHDRAWN.EW VIST SCHEDULED ON [redacted]20[redacted] ISSUE NOT RESOLVED A: Reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

R: Reported Term
S: System Organ Class
P: MedDRA 22.0 Preferred Term
L: Lower Level Term
E: RX Day Ended+
O: Ongoing at End of Study?
L: Length
I: Intermittent?
S: Severity
R: Relationship to Study Drug
A: Actions Taken
O: Other Actions Taken
M: Malignancy?
S: Serious AE?
O: Other Cause of Event
A: Abbvie Opinion of Causality

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset+			
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:3[redacted]	SEX:MALE	RACE:WHITE	WEIGHT:96.7 KG				
	OFF	345 TO	4	348	R: ISOLATED ,IDIOPATIC MONONEUROPATHY IN THE REGION OF THE UPPER EYELID MUSCLE, RIGHT PTOSIS, HYPOAESTHESIA OF THE RIGHT EYEBROW S: NERVOUS SYSTEM DISORDERS P: 感覚鈍麻 L: HYPOESTHESIA	O: YES I: NO	S: Severe R: Reasonable possibility A: DISCONT. STUDY DRUG O: OTHER: HOSPITALISATION IN NEUROLOGY DEPARTMENT BETWEEN [redacted]-[redacted]/[redacted]/20[redacted]	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY O: MAIN REASON WAS NOT UNRAVEL DURING HOSPITALISATION. ACCORDING TO NEUROLOGYST OPINION IT COULD BE IN RELATIONSHIP TO STUDY DRUG. IP WAS WITHDRAWN.EW VIST SCHEDULED ON [redacted]20[redacted].ISSUE NOT RESOLVED A: Reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:96.7 KG							
	OFF	345 TO	4	348	R: ISOLATED ,IDIOPATIC MONONEUROPATHY IN THE REGION OF THE UPPER EYELID MUSCLE, RIGHT PTOSIS, HYPOAESTHESIA OF THE RIGHT EYEBROW S: NERVOUS SYSTEM DISORDERS P: 単ニューロパチー L: MONONEUROPATHY	O: YES I: NO	S: Severe R: Reasonable possibility A: DISCONT. STUDY DRUG O: OTHER: HOSPITALISATION IN NEUROLOGY DEPARTMENT BETWEEN [redacted]/[redacted]/20[redacted]	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY O: MAIN REASON WAS NOT UNRAVEL DURING HOSPITALISATION. ACCORDING TO NEUROLOGYST OPINION IT COULD BE IN RELATIONSHIP TO STUDY DRUG. IP WAS WITHDRAWN.EW VIST SCHEDULED ON [redacted]20[redacted].ISSUE NOT RESOLVED A: Reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:65.4 KG							
	OFF	100 TO	3	102	R: OTHER DISORDERS OF THE OPTIC NERVE (N. II) AND THE VISUAL PATH - ATROPHY OF THE OPTIC NERVE S: EYE DISORDERS P: 視神経萎縮 L: ATROPHY OPTIC NERVE	O: YES I: NO	S: Moderate R: Reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: CEREBROSPINAL FLUID PUNCTURE - RESULT IN NORMAL RANGE AND MRI OF HEAD AND NECK.	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY, IMPORTANT MEDICAL OR SURGICAL INTERVENTION A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:80.0 KG							
	OFF	67 TO	7	73	R: NEPHROTIC SYNDROME S: RENAL AND URINARY DISORDERS P: ネフローゼ症候群 L: NEPHROTIC SYNDROME	O: YES I: NO	S: Moderate R: Reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: NO RENAL, URETERIC, OR BLADDER CALCULI FOUND IN RENAL ULTRASOUND AND CT. PROTEIN AND HEMOGLOBIN FOUND IN URINE. ALBUMIN FOUND IN URINE. WBC, RBC, AND EPITHELIAL CELLS FOUND IN URINE.	S: YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:57.1 KG								
	DB2	57 TO 170	110	166	R: VIRAL INFECTION S: INFECTIONS AND INFESTATIONS P: ウイルス感染 L: VIRAL INFECTION	E: 169 L: 4 DAYS I: YES	S: Moderate R: No reasonable possibility A: NONE O: OTHER: ULTRA SOUND ABDOMEN, CHEST AND SINUS X-RAY	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: POSSIBLE VIRAL INFECTION A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:3[redacted]	SEX:MALE	RACE:WHITE	WEIGHT:95.0 KG				
	OFF	199 TO	1	199	R: WORSENING OF ULCERATIVE COLITIS S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 205 L: 7 DAYS I: NO	S: Moderate R: No reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: WORSENING OF DISEASE A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:66.1 KG							
	DB2	57 TO 358	26	82	R: LEFT DISTAL RADIUS FRACTURE S: INJURY, POISONING AND PROCEDURAL COMPLICATIONS P: 橈骨骨折 L: RADIUS FRACTURE	E: 152 L: 71 DAYS I: NO	S: Moderate R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: SURGERY	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NO A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB TDM								
[redacted]	AGE:5[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:77.6 KG				
	OFF	64 TO	1	64	R: WORSENING OF ULCERATIVE COLITIS S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 71 L: 8 DAYS I: NO	S: Moderate R: No reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE EXACERBATION A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB TDM								
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:77.6 KG							
	OFF	64 TO	14	77	R: SMALL BOWEL OBSTRUCTION S: GASTROINTESTINAL DISORDERS P: 小腸閉塞 L: SMALL BOWEL OBSTRUCTION	E: 90 L: 14 DAYS I: NO	S: Severe R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: HOSPITALIZATION, CON PROCEDURES, LABS	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: ULCERATIVE COLITIS A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB TDM								
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:77.6 KG							
	OFF	64 TO 14	77		R: PORTO MESENTERIC THROMBOSIS S: HEPATOBILIARY DISORDERS P: 門脈脾静脈腸間膜静脈血栓症 L: PORTOSPLENOMESENTERIC VENOUS THROMBOSIS	O: YES I: NO	S: Moderate R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: ULCERATIVE COLITIS A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:93.0 KG							
	OFF	332 TO	14	345	R: ACUTE PANCREATITIS S: GASTROINTESTINAL DISORDERS P: 急性膵炎 L: ACUTE PANCREATITIS	E: 360 L: 16 DAYS I: NO	S: Severe R: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:93.0 KG							
	OFF	332 TO	17	348	R: CLOSTRIDIUM DIFFICILE INFECTION S: INFECTIONS AND INFESTATIONS P: クロストリジウム・ディフィシレ感染 L: CLOSTRIDIUM DIFFICILE INFECTION	E: 360 L: 13 DAYS I: NO	S: Moderate R: No reasonable possibility A: NONE O: NONE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNKNOWN A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:2[redacted] SEX:FEMALE RACE:BLACK WEIGHT:103.0 KG							
	DB2	56 TO 358	152	207	R: WORSENING OF BIPOLAR DISORDER S: PSYCHIATRIC DISORDERS P: 双極性障害 L: BIPOLAR AFFECTIVE DISORDER AGGRAVATED	E: 208 L: 2 DAYS I: NO	S: Severe R: No reasonable possibility A: NONE O: OTHER: HOSPITALIZATION	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: HISTORY OF BIPOLAR WITH SUICIDAL IDEATION A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted] TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:73.5 KG							
	OFF	79 TO	4	82	R: UC EXACERBATION. S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 116 L: 35 DAYS I: YES	S: Severe R: Reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: PATIENT FINALLY WAS WITHDRAWN FROM THE STUDY	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:73.5 KG							
	OFF	79 TO	38	116	R: LYMPHADENOPATHY OF UNKNOWN ORIGIN OF THORACIC CAVITY S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: リンパ節症 L: LYMPHADENOPATHY	E: 147 L: 32 DAYS I: YES	S: Severe R: Reasonable possibility A: OTHER: BY THE MOMENT OF EVENT THE SUBJECT WAS NO LONGER IN THE STUDY O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY, IMPORTANT MEDICAL OR SURGICAL INTERVENTION, LIFE THREATENING A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK [redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:73.5 KG								
	OFF	79 TO	70	148	R: TUBERCULOSIS OF THE INTRATHORACIC LYMPH NODES S: INFECTIONS AND INFESTATIONS P: 胸腔内リンパ節結核 L: TUBERCULOSIS OF INTRATHORACIC LYMPH NODES	E: 382 L: 235 DAYS I: YES	S: Severe R: No reasonable possibility A: OTHER: HOSPITALIZATION TO DIAGNOSTIC DEPARTMENT OF TUBERCULOSIS HOSPITAL ON [redacted] 20[redacted]. THE PATIENT WAS MOVED TO THE DEPARTMENT OF OPENED TB FORMS ON [redacted] 20[redacted]. O: NONE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY, IMPORTANT MEDICAL OR SURGICAL INTERVENTION, LIFE THREATENING O: AT THE START OF EVENT THERE WAS A SUSPICION TUBERCULOSIS A: Reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:58.2 KG							
	DB2	57 TO 190	17	73	R: RIGHT SIDED COMMUNITY-ACQUIRED PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 89 L: 17 DAYS I: YES	S: Moderate R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AFTER HE CAUGHT IN THE RAIN,HE HAD SORE THROAT, NAZAL CONGESTION, T-39 C,DRY COUGH. A: Reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB TDM								
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:77.8 KG							
	DB2	55 TO 357	116	170	R: ACUTE BRONCHITIS S: INFECTIONS AND INFESTATIONS P: 気管支炎 L: ACUTE BRONCHITIS	E: 181 L: 12 DAYS I: NO	S: Moderate R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: COMMON COLD A: Reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:62.0 KG							
	DB2	56 TO 121	61	116	R: WORSENING OF ULCERATIVE COLITIS S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 129 L: 14 DAYS I: NO	S: Severe R: No reasonable possibility A: DISCONT. STUDY DRUG O: NONE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE UNDER STUDY A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK [redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:75.5 KG								
	OFF	198 TO	42	239	R: FEVER, NIGHT SWEATS S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 発熱 L: FEVER	E: 247 L: 9 DAYS I: NO	S: Moderate R: No reasonable possibility A: NONE O: NONE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: WORSENING OF UNDERLYING DISEASE IS THE MOST PROBABLE CAUSE A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:75.5 KG							
	OFF	198 TO	42	239	R: FEVER, NIGHT SWEATS S: SKIN AND SUBCUTANEOUS TISSUE DISORDERS P: 寝汗 L: NIGHT SWEATS	E: 247 L: 9 DAYS I: NO	S: Moderate R: No reasonable possibility A: NONE O: NONE	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: WORSENING OF UNDERLYING DISEASE IS THE MOST PROBABLE CAUSE A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:72.4 KG							
	DB2	57 TO 316	156	212	R: BILATERAL GONARTHROSIS S: MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS P: 変形性関節症 L: GONARTHROSIS	E: 215 L: 4 DAYS I: YES	S: Moderate R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: OSTEOPOROSIS A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:82.6 KG							
	DB2	56 TO 354	28	83	R: ACUTE APPENDICITIS S: INFECTIONS AND INFESTATIONS P: 虫垂炎 L: ACUTE APPENDICITIS	E: 86 L: 4 DAYS I: NO	S: Severe R: No reasonable possibility A: INTERRUPTION OF STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: APPENDECTOMY	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: [redacted]/[redacted]/20[redacted] ACUTE PAIN IN DOWN RIGHT PART OF ABDOMEN, WITH NUSEA AND VOMITTING, FEVER TO 39.0 DEGREE OF CELSIUS, HOSPITALIZED [redacted] [redacted]/20[redacted], SURGICAL PROCEDURE: APPENDECTOMY WAS PERFORMED. A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB TDM								
[redacted] AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:56.8 KG								
	OFF	359 TO	10	368	R: DIGESTIVE TRACT BLEEDING AFTER POLYPECTOMY S: INJURY, POISONING AND PROCEDURAL COMPLICATIONS P: 処置後出血 L: POSTOPERATIVE BLEEDING	E: 371 L: 4 DAYS I: NO	S: Moderate R: No reasonable possibility A: NONE O: OTHER: ENDOSCOPY	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: NO A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:69.8 KG							
	OFF	221 TO	3	223	R: LINEAR IGA BULLOUS DERMATOSIS S: SKIN AND SUBCUTANEOUS TISSUE DISORDERS P: リニアＩｇＡ病 L: LINEAR IGA BULLOUS DERMATOSIS	E: 240 L: 18 DAYS I: NO	S: Severe R: Reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB TDM								
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:58.3 KG							
	DB2	55 TO 294	224	278	R: CHOLEDOCHOLITHIASIS S: HEPATOBILIARY DISORDERS P: 胆管結石 L: CHOLEDOCHOLITHIASIS	E: 308 L: 31 DAYS I: NO	S: Moderate R: No reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION DISCONTINUED O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: USG SCAN ,LABORATORY, CHOLANGIO MRI EVALUATION , CHOLANGIO MRI	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: BILE LITHOGENICITY A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:94.0 KG							
	DB2	56 TO 210	101	156	R: DISCOVERY OF DIABETES S: METABOLISM AND NUTRITION DISORDERS P: 糖尿病 L: DIABETES	O: YES I: NO	S: Moderate R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNKNOWN A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted] AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:46.0 KG								
	OFF	308 TO	5	312	R: SEVERE ACUTE COLITIS S: GASTROINTESTINAL DISORDERS P: 大腸炎 L: COLITIS	E: 319 L: 8 DAYS I: NO	S: Severe R: No reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FLARE OF ULCERATIVE COLITIS DISEASE A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:63.5 KG							
	DB2	64 TO 232	39	102	R: RECTAL BLEEDING DUE TO FLARE OF ULVERATIVE COLITIS DISEASE S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 104 L: 3 DAYS I: YES	S: Moderate R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FLARE OF ULCERATIVE COLITIS DISEASE A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:4[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:63.5 KG				
	DB2	64 TO 232	39	102	R: RECTAL BLEEDING DUE TO FLARE OF ULVERATIVE COLITIS DISEASE S: GASTROINTESTINAL DISORDERS P: 直腸出血 L: RECTAL BLEEDING	E: 104 L: 3 DAYS I: YES	S: Moderate R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FLARE OF ULCERATIVE COLITIS DISEASE A: No reasonable possibility
	OFF	233 TO	2	234	R: ANEMIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 貧血 L: ANEMIA	E: 327 L: 94 DAYS I: YES	S: Severe R: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

R: Reported Term
S: System Organ Class
P: MedDRA 22.0 Preferred Term
L: Lower Level Term
E: RX Day Ended+
O: Ongoing at End of Study?
L: Length
I: Intermittent?
S: Severity
R: Relationship to Study Drug
A: Actions Taken
O: Other Actions Taken
M: Malignancy?
S: Serious AE?
O: Other Cause of Event
A: Abbvie Opinion of Causality

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset+				
INV: [redacted]([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK									
[redacted]	AGE:4[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:63.5 KG					
	OFF	233 TO		2	234	R: FLARE OF ULCERATIVE COLITIS S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 257 L: 24 DAYS I: NO	S: Severe R: No reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UC PROGRESSION A: No reasonable possibility
				5	237	R: PULMONARY EMBOLISM S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 肺塞栓症 L: PULMONARY EMBOLISM	E: 248 L: 12 DAYS I: NO	S: Severe R: No reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FAMILY HISTORY A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:84.0 KG							
	OFF	128 TO	2	129	R: DEHYDRATION, ULCERATIVE COLITIS - WORSENING S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 135 L: 7 DAYS I: NO	S: Severe R: No reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: WORSENING OF ULCERATIVE COLITIS A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:84.0 KG							
	OFF	128 TO	2	129	R: DEHYDRATION, ULCERATIVE COLITIS - WORSENING S: METABOLISM AND NUTRITION DISORDERS P: 脱水 L: DEHYDRATION	E: 135 L: 7 DAYS I: NO	S: Severe R: No reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: WORSENING OF ULCERATIVE COLITIS A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:84.0 KG							
	OFF	128 TO	35	162	R: WORSENING ULCERATIVE COLITIS, IRON DEFICIENCY ANEMIA, THROMBOCYTOSIS, HYPONATREMIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 鉄欠乏性貧血 L: IRON DEFICIENCY ANEMIA	E: 165 L: 4 DAYS I: NO	S: Severe R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: WORSENING OF ULCERATIVE COLITIS A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch	---- Interval	RX Day Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:84.0 KG							
	OFF	128 TO	35	162	R: WORSENING ULCERATIVE COLITIS, IRON DEFICIENCY ANEMIA, THROMBOCYTOSIS, HYPONATREMIA S: BLOOD AND LYMPHATIC SYSTEM DISORDERS P: 血小板増加症 L: THROMBOCYTOSIS	E: 165 L: 4 DAYS I: NO	S: Severe R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: WORSENING OF ULCERATIVE COLITIS A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:84.0 KG							
	OFF	128 TO	35	162	R: WORSENING ULCERATIVE COLITIS, IRON DEFICIENCY ANEMIA, THROMBOCYTOSIS, HYPONATREMIA S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 165 L: 4 DAYS I: NO	S: Severe R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: WORSENING OF ULCERATIVE COLITIS A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted] TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:6[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:84.0 KG				
	OFF	128 TO	35	162	R: WORSENING ULCERATIVE COLITIS, IRON DEFICIENCY ANEMIA, THROMBOCYTOSIS, HYPONATREMIA S: METABOLISM AND NUTRITION DISORDERS P: 低ナトリウム血症 L: HYPONATREMIA	E: 165 L: 4 DAYS I: NO	S: Severe R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: WORSENING OF ULCERATIVE COLITIS A: No reasonable possibility
			59	186	R: WORSENING OF ULCERATIVE COLITIS S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 200 L: 15 DAYS I: NO	S: Moderate R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DEHYDRATION A: No reasonable possibility

表 2.7.4.7-24.　　重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch	---- Interval	Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK									
[redacted]	AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:85.0 KG								
	DB2	57 TO 358	208	264		R: PERINEAL ABSCESS S: INFECTIONS AND INFESTATIONS P: 会陰膿瘍 L: PERINEAL ABSCESS	E: 264 L: 1 DAY I: NO	S: Moderate R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION DISCONTINUED O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: PERINEAL ABSCESS	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: NORMAL DISEASE PROGRESSION A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB TDM								
[redacted]	AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:114.0 KG							
	OFF	197 TO	4	200	R: FLARE OF ULCERATIVE COLITIS, SEPSIS SECONDARY TO ULCERATIVE COLITIS FLARE S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	O: YES I: NO	S: Severe R: Reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: HOSPITALIZATION	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB TDM								
[redacted]	AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:114.0 KG							
	OFF	197 TO	4	200	R: FLARE OF ULCERATIVE COLITIS, SEPSIS SECONDARY TO ULCERATIVE COLITIS FLARE S: INFECTIONS AND INFESTATIONS P: 敗血症 L: SEPSIS SECONDARY	O: YES I: NO	S: Severe R: Reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: HOSPITALIZATION	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION A: No reasonable possibility
INV: [redacted]([redacted] TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:71.0 KG							
	DB2	58 TO 261	74	131	R: PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 132 L: 2 DAYS I: NO	S: Moderate R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NO A: Reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:3[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:56.0 KG				
	OFF	56 TO	27	82	R: WORSING OF UC S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 90 L: 9 DAYS I: NO	S: Mild R: No reasonable possibility A: OTHER: PATIENT IS IN 70-DAY FOLLOW UP NO STUDY DRUG O: OTHER: PRE PLANED: COLECTOMY DUE TO WORSING OF ULEROSA COLITIS	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NO INFORMATION A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted] TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:4[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:61.1 KG				
	OFF	114 TO	1	114	R: LOW NEUTROPHILS S: INVESTIGATIONS P: 好中球数減少 L: NEUTROPHIL COUNT LOW	O: YES I: NO	S: Moderate R: Reasonable possibility A: INTERRUPTION OF STUDY DRUG O: OTHER: INCREASED BLOOD MONITORING WAS IMPLEMENTED HOWEVER NEUTROPENIA DID NOT RECOVER AND DISEASE CONTINUED TO FLARE REQUIRING A CHANGE IN TREATMENT MANAGEMENT AND STUDY DRUG WITHDRAWAL	S: YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: AE CHANGED TO A SAE ON [redacted]/[redacted]/20[redacted] PI DECISION A: Reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:105.9 KG							
	DB2	57 TO 161	69	125	R: INTRACTABLE ABDOMINAL PAIN S: GASTROINTESTINAL DISORDERS P: 腹痛 L: ABDOMINAL PAIN	E: 130 L: 6 DAYS I: YES	S: Severe R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: CT SCAN OF ABDOMEN AND PELVIS	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: GASTRITIS A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:105.9 KG							
	DB2	57 TO 161	69	125	R: INTRACTABLE NAUSEA AND VOMITING S: GASTROINTESTINAL DISORDERS P: 悪心 L: NAUSEA	E: 130 L: 6 DAYS I: YES	S: Severe R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: GASTRITIS A: No reasonable possibility
				125	R: INTRACTABLE NAUSEA AND VOMITING S: GASTROINTESTINAL DISORDERS P: 嘔吐 L: VOMITING	E: 130 L: 6 DAYS I: YES	S: Severe R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: GASTRITIS A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:92.2 KG							
	DB2	57 TO 358	297	353	R: RECURRENT NASAL AND PARANASAL SINUSES POLYPS S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 鼻茸 L: NASAL POLYPS	E: 355 L: 3 DAYS I: NO	S: Moderate R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: POLYPS IN THE NOSE A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted] TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK [redacted]AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:92.2 KG								
	DB2	57 TO 358	297	353	R: RECURRENT NASAL AND PARANASAL SINUSES POLYPS S: RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS P: 副鼻腔ポリープ L: SINUS POLYP	E: 355 L: 3 DAYS I: NO	S: Moderate R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: POLYPS IN THE NOSE A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB TDM								
[redacted]	AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:68.3 KG							
	DB2	58 TO 357	77	134	R: ERYTHEMA NODOSUM S: SKIN AND SUBCUTANEOUS TISSUE DISORDERS P: 結節性紅斑 L: ERYTHEMA NODOSUM	E: 142 L: 9 DAYS I: NO	S: Moderate R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNKNOWN.POSSIBLE RELATIONSHIP WITH STUDY DISEASE OR UPPER RESPIRATORY INFECTION A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:72.0 KG							
	OFF	72 TO	5	76	R: ACUTE SEVERE COLITIS S: GASTROINTESTINAL DISORDERS P: 大腸炎 L: COLITIS	E: 87 L: 12 DAYS I: NO	S: Severe R: No reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: DETERIORATION OF UC LEADING TO COLECTOMY A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:82.0 KG							
	OFF	289 TO	28	316	R: ONGOING UC S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE	E: 327 L: 12 DAYS I: NO	S: Severe R: No reasonable possibility A: NONE O: OTHER: PROCTOCOLECTOMY WITH FORMATION OF J POUCH AND ILEOSTOMY	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: HOSPITALIZATION A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:87.8 KG							
	DB2	57 TO 218	37	93	R: GAIT ABNORMALITIY S: GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS P: 歩行障害 L: ABNORMALITY OF GAIT	O: YES I: NO	S: Moderate R: No reasonable possibility A: NONE O: OTHER: HOSPITALISATION FOR DIAGNOSTIC WORK-UP	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: AS OF YET UNKNOWN, SUSPICION OF SPASTIC PARAPARESIS A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:102.2 KG							
	DB2	56 TO 61	1	56	R: LOW GRADE DYSPLASIA IN RECTUM S: GASTROINTESTINAL DISORDERS P: 肛門性器異形成 L: ANAL DYSPLASIA	E: 176 L: 121 DAYS I: NO	S: Moderate R: No reasonable possibility A: DISCONT. STUDY DRUG O: OTHER: POLYPECTOMIA PERFOMRED ON [redacted] [redacted] 20[redacted]	S: YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: ULCERATIVE COLITIS A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB TDM								
[redacted]	AGE:2[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:49.0 KG				
	OFF	88 TO	6	93	R: TUBERCULOSIS S: INFECTIONS AND INFESTATIONS P: 結核 L: TUBERCULOSIS	O: YES I: NO	S: Moderate R: No reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: PATIENTS WITH INCREASED RISK OF DEVELOPING TUBERCULOSIS. THE PATIENT WORKS IN PULMUNOLOGY HOSPITAL. A: Reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB STANDARD INDUCTION DOSE/ADALIMUMAB TDM								
[redacted]	AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:39.5 KG							
	DB2	57 TO 232	169	225	R: EXACERBATION OF ULCERATIVE COLITIS, S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 250 L: 26 DAYS I: NO	S: Severe R: No reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: LACK OF STUDY DRUG EFFICIENCY A: No reasonable possibility
TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:68.0 KG							
	DB2	55 TO 357	11	65	R: RIGHT SIDE PNEUMONIA S: INFECTIONS AND INFESTATIONS P: 肺炎 L: PNEUMONIA	E: 75 L: 11 DAYS I: NO	S: Moderate R: Reasonable possibility A: INTERRUPTION OF STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: Reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:86.0 KG							
	DB2	56 TO 147	65	120	R: BLADDER CANCER S: NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS) P: 膀胱癌 L: BLADDER CANCER	O: YES I: NO	S: Severe R: No reasonable possibility A: DISCONT. STUDY DRUG O: NONE	S: YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: NEW MEDICAL EVENT A: No reasonable possibility

表 2.7.4.7-24. 重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:5[redacted] SEX:MALE RACE:ASIAN WEIGHT:68.2 KG							
	DB2	58 TO 121	18	75	R: ULCERATIVE COLITIS FLARE S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	O: YES I: YES	S: Moderate R: No reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INCREASED BLEEDING POSSIBLY RELATED TO RECENT COLONOSCOPY WITH MULTIPLE BIOPSIES. A: No reasonable possibility

+ RX day relative to first dose of study drug during induction study.
DB2 = Double blind maintenance study.
# Subject prematurely discontinued.
& Date is estimated.

Cross reference: M14-033 Maintenance Main-study Final CSR Table 14.3__2.5.1.1

表 2.7.4.7-25. 重篤な有害事象（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	2 (4.7)	4 (8.7)	6 (6.7)	44 (12.8)	44 (12.6)	15 (9.9)	103 (12.2)
血液およびリンパ系障害	0	0	0	1 (0.3)	5 (1.4)	0	6 (0.7)
貧血	0	0	0	1 (0.3)	3 (0.9)	0	4 (0.5)
鉄欠乏性貧血	0	0	0	0	1 (0.3)	0	1 (0.1)
リンパ節症	0	0	0	0	1 (0.3)	0	1 (0.1)
血小板増加症	0	0	0	0	1 (0.3)	0	1 (0.1)
心臓障害	0	0	0	2 (0.6)	0	0	2 (0.2)
急性心筋梗塞	0	0	0	1 (0.3)	0	0	1 (0.1)
うっ血性心不全	0	0	0	1 (0.3)	0	0	1 (0.1)
冠動脈疾患	0	0	0	1 (0.3)	0	0	1 (0.1)
心筋虚血	0	0	0	1 (0.3)	0	0	1 (0.1)
眼障害	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
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)
胃腸障害	0	3 (6.5)	3 (3.4)	21 (6.1)	20 (5.7)	7 (4.6)	48 (5.7)
腹痛	0	0	0	1 (0.3)	0	0	1 (0.1)
上腹部痛	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-25. 重篤な有害事象（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.)							
肛門性器異形成	0	0	0	0	1 (0.3)	0	1 (0.1)
大腸炎	0	0	0	2 (0.6)	0	0	2 (0.2)
潰瘍性大腸炎	0	3 (6.5)	3 (3.4)	16 (4.6)	18 (5.1)	6 (4.0)	40 (4.7)
穿孔性十二指腸潰瘍	0	0	0	0	1 (0.3)	0	1 (0.1)
マロリー・ワイス症候群	0	0	0	0	0	1 (0.7)	1 (0.1)
悪心	0	0	0	1 (0.3)	0	0	1 (0.1)
急性膵炎	0	0	0	1 (0.3)	0	0	1 (0.1)
直腸出血	0	0	0	0	1 (0.3)	0	1 (0.1)
小腸閉塞	0	0	0	0	0	1 (0.7)	1 (0.1)
上部消化管出血	0	0	0	0	0	1 (0.7)	1 (0.1)
嘔吐	0	0	0	1 (0.3)	0	0	1 (0.1)
一般・全身障害および投与部位の状態	0	0	0	2 (0.6)	0	0	2 (0.2)
歩行障害	0	0	0	1 (0.3)	0	0	1 (0.1)
発熱	0	0	0	1 (0.3)	0	0	1 (0.1)
肝胆道系障害	0	0	0	0	0	2 (1.3)	2 (0.2)
胆管結石	0	0	0	0	0	1 (0.7)	1 (0.1)
門脈脾静脈腸間膜静脈血栓症	0	0	0	0	0	1 (0.7)	1 (0.1)

表 2.7.4.7-25. 重篤な有害事象（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 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 (%)
感染症および寄生虫症	1 (2.3)	0	1 (1.1)	11 (3.2)	9 (2.6)	3 (2.0)	23 (2.7)
虫垂炎	0	0	0	0	1 (0.3)	0	1 (0.1)
気管支炎	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	3 (0.9)	0	0	3 (0.4)
外耳蜂巣炎	0	0	0	1 (0.3)	0	0	1 (0.1)
胃腸炎	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
消化管感染	0	0	0	1 (0.3)	0	0	1 (0.1)
外耳炎	0	0	0	1 (0.3)	0	0	1 (0.1)
骨盤内炎症性疾患	0	0	0	0	1 (0.3)	0	1 (0.1)
会陰膿瘍	0	0	0	1 (0.3)	0	0	1 (0.1)
扁桃周囲膿瘍	0	0	0	0	1 (0.3)	0	1 (0.1)
肺炎	0	0	0	2 (0.6)	4 (1.1)	0	6 (0.7)
敗血症	0	0	0	0	0	1 (0.7)	1 (0.1)
胸骨炎	0	0	0	1 (0.3)	0	0	1 (0.1)
結核	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
胸腔内リンパ節結核	0	0	0	0	1 (0.3)	0	1 (0.1)
ウイルス感染	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-25. 重篤な有害事象（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 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 (%)
傷害、中毒および処置合併症	0	0	0	2 (0.6)	4 (1.1)	1 (0.7)	7 (0.8)
上腕骨骨折	0	0	0	0	1 (0.3)	0	1 (0.1)
半月板損傷	0	0	0	0	1 (0.3)	0	1 (0.1)
膝蓋骨骨折	0	0	0	0	1 (0.3)	0	1 (0.1)
処置後出血	0	0	0	0	0	1 (0.7)	1 (0.1)
橈骨骨折	0	0	0	0	1 (0.3)	0	1 (0.1)
肋骨骨折	0	0	0	1 (0.3)	0	0	1 (0.1)
上肢骨折	0	0	0	1 (0.3)	0	0	1 (0.1)
臨床検査	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)
アラニンアミノトランスフェラーゼ増加	0	0	0	1 (0.3)	0	0	1 (0.1)
アスパラギン酸アミノトランスフェラーゼ増加	0	0	0	1 (0.3)	0	0	1 (0.1)
好中球数減少	0	0	0	0	1 (0.3)	0	1 (0.1)
体重減少	0	0	0	0	1 (0.3)	0	1 (0.1)
代謝および栄養障害	0	0	0	2 (0.6)	1 (0.3)	0	3 (0.4)
脱水	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
糖尿病	0	0	0	1 (0.3)	0	0	1 (0.1)
低ナトリウム血症	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-25. 重篤な有害事象（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	0	0	0	2 (0.6)	2 (0.6)	0	4 (0.5)
関節痛	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)
変形性関節症	0	0	0	1 (0.3)	0	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	1 (0.3)	5 (1.4)	0	6 (0.7)
膀胱癌	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)
悪性黒色腫	0	0	0	0	1 (0.3)	0	1 (0.1)
非小細胞肺癌	0	0	0	1 (0.3)	0	0	1 (0.1)
食道腺癌	0	0	0	0	1 (0.3)	0	1 (0.1)
子宮平滑筋腫	0	0	0	0	1 (0.3)	0	1 (0.1)
神経系障害	1 (2.3)	0	1 (1.1)	1 (0.3)	1 (0.3)	2 (1.3)	4 (0.5)
意識変容状態	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
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)
感覚鈍麻	0	0	0	0	1 (0.3)	0	1 (0.1)
虚血性脳卒中	0	0	0	0	0	1 (0.7)	1 (0.1)
単ニューロパチー	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-25. 重篤な有害事象（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 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 (%)
精神障害	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
むちゃ飲み	0	0	0	0	0	1 (0.7)	1 (0.1)
双極性障害	0	0	0	0	1 (0.3)	0	1 (0.1)
腎および尿路障害	0	0	0	2 (0.6)	0	1 (0.7)	3 (0.4)
血尿	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)
前立腺腫大	0	0	0	1 (0.3)	0	0	1 (0.1)
呼吸器、胸郭および縦隔障害	0	0	0	2 (0.6)	4 (1.1)	0	6 (0.7)
肺気腫	0	0	0	0	1 (0.3)	0	1 (0.1)
鼻茸	0	0	0	1 (0.3)	0	0	1 (0.1)
鼻中隔弯曲	0	0	0	0	1 (0.3)	0	1 (0.1)
肺塞栓症	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)
副鼻腔ポリープ	0	0	0	1 (0.3)	0	0	1 (0.1)
皮膚および皮下組織障害	0	0	0	2 (0.6)	2 (0.6)	2 (1.3)	6 (0.7)
結節性紅斑	0	0	0	0	0	1 (0.7)	1 (0.1)
過剰皮膚	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-25. 重篤な有害事象（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.)							
リニアIgA病	0	0	0	1 (0.3)	0	0	1 (0.1)
寝汗	0	0	0	1 (0.3)	0	0	1 (0.1)
類天疱瘡	0	0	0	0	0	1 (0.7)	1 (0.1)
角層下膿疱性皮膚症	0	0	0	0	1 (0.3)	0	1 (0.1)
血管障害	0	1 (2.2)	1 (1.1)	1 (0.3)	1 (0.3)	0	2 (0.2)
高血圧	0	0	0	1 (0.3)	0	0	1 (0.1)
血栓性静脈炎	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)

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.

Cross reference: M14-033 Maintenance Japan Sub-study Final CSR Table 14.3__2.1.1_J

表 2.7.4.7-26. 治験薬と関連ありの重篤な有害事象（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 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 (%)
Any Adverse Event	1 (2.3)	0	1 (1.1)	9 (2.6)	9 (2.6)	4 (2.6)	22 (2.6)
血液およびリンパ系障害	0	0	0	0	2 (0.6)	0	2 (0.2)
貧血	0	0	0	0	1 (0.3)	0	1 (0.1)
リンパ節症	0	0	0	0	1 (0.3)	0	1 (0.1)
眼障害	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
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)
胃腸障害	0	0	0	2 (0.6)	1 (0.3)	1 (0.7)	4 (0.5)
上腹部痛	0	0	0	1 (0.3)	0	0	1 (0.1)
潰瘍性大腸炎	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
急性膵炎	0	0	0	1 (0.3)	0	0	1 (0.1)
感染症および寄生虫症	0	0	0	3 (0.9)	2 (0.6)	1 (0.7)	6 (0.7)
クロストリジウム・ディフィシレ感染	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)
外耳炎	0	0	0	1 (0.3)	0	0	1 (0.1)
肺炎	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
敗血症	0	0	0	0	0	1 (0.7)	1 (0.1)
結核	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-26. 治験薬と関連ありの重篤な有害事象（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 (%)
臨床検査	0	0	0	0	1 (0.3)	0	1 (0.1)
好中球数減少	0	0	0	0	1 (0.3)	0	1 (0.1)
筋骨格系および結合組織障害	0	0	0	0	1 (0.3)	0	1 (0.1)
関節痛	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	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)	0	1 (1.1)	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
意識変容状態	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
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)
感覚鈍麻	0	0	0	0	1 (0.3)	0	1 (0.1)
単ニューロパチー	0	0	0	0	1 (0.3)	0	1 (0.1)
腎および尿路障害	0	0	0	1 (0.3)	0	1 (0.7)	2 (0.2)
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)
呼吸器、胸郭および縦隔障害	0	0	0	0	1 (0.3)	0	1 (0.1)
肺気腫	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-26. 治験薬と関連ありの重篤な有害事象（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	0	0	0	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
リニアIgA病	0	0	0	1 (0.3)	0	0	1 (0.1)
類天疱瘡	0	0	0	0	0	1 (0.7)	1 (0.1)
角層下膿疱性皮膚症	0	0	0	0	1 (0.3)	0	1 (0.1)

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__2.1.2_J

表 2.7.4.7-27.　　重篤な有害事象の一覧（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）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:4[redacted] SEX:MALE RACE:ASIAN WEIGHT:63.5 KG							
	OFF	219 TO	7	225	R: UC AGGRAVATION S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	O: YES I: NO	S: Moderate R: No reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: LOSS OF RESPONSE A: No reasonable possibility

表 2.7.4.7-27. 重篤な有害事象の一覧（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）（続き）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK								
[redacted]	AGE:2[redacted] SEX:MALE RACE:ASIAN WEIGHT:66.0 KG							
	DB2	57 TO 358	74	130	R: INFECTIONS GASTROENTERO COLITIS S: INFECTIONS AND INFESTATIONS P: 胃腸炎 L: GASTROENTEROCOLITIS	E: 138 L: 9 DAYS I: NO	S: Moderate R: No reasonable possibility A: INTERRUPTION OF STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ACUTE INFECTIONS DISEASE BY STAPHYLOCOCCUS AUREUS A: No reasonable possibility

表 2.7.4.7-27. 重篤な有害事象の一覧（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）（続き）

R: Reported Term
S: System Organ Class
P: MedDRA 22.0 Preferred Term
L: Lower Level Term
E: RX Day Ended+
O: Ongoing at End of Study?
L: Length
I: Intermittent?
S: Severity
R: Relationship to Study Drug
A: Actions Taken
O: Other Actions Taken
M: Malignancy?
S: Serious AE?
O: Other Cause of Event
A: Abbvie Opinion of Causality

Subject Number	Name	Epoch	Interval	Day	RX Day of Onset+				
INV: [redacted] ([redacted])									
TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY OTHER WEEK									
[redacted] AGE:4[redacted] SEX:MALE RACE:ASIAN WEIGHT:87.6 KG									
	DB2	59 TO 162	52	110	R: DISTURBANCE OF CONSCIOUSNESS S: NERVOUS SYSTEM DISORDERS P: 意識変容状態 L: CONSCIOUSNESS DISTURBED	E: 113 L: 4 DAYS I: YES	S: Severe R: Reasonable possibility A: NONE O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: No reasonable possibility	

表 2.7.4.7-27. 重篤な有害事象の一覧（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）（続き）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:3[redacted] SEX:MALE RACE:ASIAN WEIGHT:64.1 KG							
	OFF	106 TO	7	112	R: WORSENING OF ULCERATIVE COLITIS S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 169 L: 58 DAYS I: NO	S: Severe R: No reasonable possibility A: DISCONT. STUDY DRUG O: CONCOMITANT MEDICATION DISCONTINUED O: CONCOMITANT MEDICATION PRESCRIBED	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UC A: No reasonable possibility

表 2.7.4.7-27. 重篤な有害事象の一覧（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）（続き）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:2[redacted] SEX:MALE RACE:ASIAN WEIGHT:70.2 KG							
	DB2	57 TO 360	127	183	R: LEFT SUBCLAVICULAR VENOUS THROMBOPHLEBITIS S: VASCULAR DISORDERS P: 血栓性静脈炎 L: VENOUS THROMBOPHLEBITIS	O: YES I: NO	S: Moderate R: No reasonable possibility A: INTERRUPTION OF STUDY DRUG O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UC HETERO TYPE PROTEIN C DEFICIENCY A: No reasonable possibility

表 2.7.4.7-27.　　重篤な有害事象の一覧（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）（続き）

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset+	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: RX Day Ended+ O: Ongoing at End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Actions Taken O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] TRT: ADALIMUMAB HIGHER INDUCTION DOSE/ADALIMUMAB 40 MG EVERY WEEK								
[redacted]	AGE:4[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:61.9 KG							
	OFF	211 TO	38	248	R: EXACERBATION OF UC S: GASTROINTESTINAL DISORDERS P: 潰瘍性大腸炎 L: COLITIS ULCERATIVE AGGRAVATED	E: 274 L: 27 DAYS I: NO	S: Severe R: No reasonable possibility A: OTHER: CLINICAL TRIAL WAS DISCONTINUED BEFORE APPEARANCE OF AE O: CONCOMITANT MEDICATION PRESCRIBED O: OTHER: HOSPITALIZATION	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INADEQUATE RESPONSE TO UC A: No reasonable possibility

+ RX day relative to first dose of study drug during induction study.
DB2 = Double blind maintenance study.
# Subject prematurely discontinued.

Cross reference: M14-033 Maintenance Japan Sub-study Final CSR Table 14.3__2.5.1.1_J

表 2.7.4.7-28. 治験薬投与の中止に至った有害事象（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）

	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 (%)
ANY ADVERSE EVENT	19 (5.6)	30 (5.9)	49 (5.8)
血液およびリンパ系障害			
貧血	2 (0.6)	0	2 (0.2)
SUBJECTS WITH ONE OR MORE EVENTS	2 (0.6)	0	2 (0.2)
心臓障害			
心停止	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (0.2)	1 (0.1)
胃腸障害			
大腸炎	1 (0.3)	1 (0.2)	2 (0.2)
潰瘍性大腸炎	12 (3.5)	17 (3.3)	29 (3.4)
下痢	0	1 (0.2)	1 (0.1)
大腸狭窄	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	13 (3.8)	20 (3.9)	33 (3.9)

表 2.7.4.7-28. 治験薬投与の中止に至った有害事象（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 (%)
一般・全身障害および投与部位の状態			
悪寒	0	1 (0.2)	1 (0.1)
注射部位過敏反応	0	1 (0.2)	1 (0.1)
注射部位疼痛	0	1 (0.2)	1 (0.1)
注射部位そう痒感	0	1 (0.2)	1 (0.1)
注射部位反応	0	1 (0.2)	1 (0.1)
注射部位腫脹	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	0	4 (0.8)	4 (0.5)
免疫系障害			
過敏症	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (0.2)	1 (0.1)
感染症および寄生虫症			
クロストリジウム・ディフィシレ感染	0	1 (0.2)	1 (0.1)
サイトメガロウイルス性大腸炎	0	1 (0.2)	1 (0.1)
丹毒	1 (0.3)	0	1 (0.1)
帯状疱疹	1 (0.3)	0	1 (0.1)
肺炎	0	1 (0.2)	1 (0.1)
結核	0	1 (0.2)	1 (0.1)

表 2.7.4.7-28. 治験薬投与の中止に至った有害事象（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 (%)
SUBJECTS WITH ONE OR MORE EVENTS	2 (0.6)	3 (0.6)	5 (0.6)
臨床検査			
クロストリジウム検査陽性	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (0.2)	1 (0.1)
代謝および栄養障害			
脱水	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (0.2)	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）			
基底細胞癌	1 (0.3)	0	1 (0.1)
表皮内悪性黒色腫	1 (0.3)	0	1 (0.1)
子宮頚部扁平上皮癌	1 (0.3)	0	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	3 (0.9)	0	3 (0.4)

表 2.7.4.7-28. 治験薬投与の中止に至った有害事象（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 (%)
皮膚および皮下組織障害			
脱毛症	1 (0.3)	0	1 (0.1)
血管浮腫	0	1 (0.2)	1 (0.1)
乾癬様皮膚炎	1 (0.3)	0	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	2 (0.6)	1 (0.2)	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 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__2.2.1

表 2.7.4.7-29. 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（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）

	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 (%)
ANY ADVERSE EVENT	3 (0.9)	10 (2.0)	13 (1.5)
胃腸障害			
潰瘍性大腸炎	0	1 (0.2)	1 (0.1)
下痢	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	0	2 (0.4)	2 (0.2)
一般・全身障害および投与部位の状態			
悪寒	0	1 (0.2)	1 (0.1)
注射部位過敏反応	0	1 (0.2)	1 (0.1)
注射部位疼痛	0	1 (0.2)	1 (0.1)
注射部位そう痒感	0	1 (0.2)	1 (0.1)
注射部位反応	0	1 (0.2)	1 (0.1)
注射部位腫脹	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	0	4 (0.8)	4 (0.5)
免疫系障害			
過敏症	0	1 (0.2)	1 (0.1)

表 2.7.4.7-29. 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（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 (%)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (0.2)	1 (0.1)
感染症および寄生虫症			
帯状疱疹	1 (0.3)	0	1 (0.1)
肺炎	0	1 (0.2)	1 (0.1)
結核	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	1 (0.3)	1 (0.2)	2 (0.2)
臨床検査			
クロストリジウム検査陽性	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (0.2)	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）			
表皮内悪性黒色腫	1 (0.3)	0	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	1 (0.3)	0	1 (0.1)

表 2.7.4.7-29. 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（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 (%)
皮膚および皮下組織障害			
血管浮腫	0	1 (0.2)	1 (0.1)
乾癬様皮膚炎	1 (0.3)	0	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	1 (0.3)	1 (0.2)	2 (0.2)

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__2.2.2

表 2.7.4.7-30. 治験薬投与の中止に至った有害事象（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	3 (7.7)	1 (1.6)	4 (4.0)	22 (5.8)	31 (5.4)	53 (5.6)	19 (5.6)	30 (5.9)	49 (5.8)
血液およびリンパ系障害									
貧血	0	0	0	2 (0.5)	0	2 (0.2)	2 (0.6)	0	2 (0.2)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	2 (0.5)	0	2 (0.2)	2 (0.6)	0	2 (0.2)
心臓障害									
心停止	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)
胃腸障害									
大腸炎	0	0	0	1 (0.3)	1 (0.2)	2 (0.2)	1 (0.3)	1 (0.2)	2 (0.2)
潰瘍性大腸炎	2 (5.1)	0	2 (2.0)	14 (3.7)	17 (3.0)	31 (3.3)	12 (3.5)	17 (3.3)	29 (3.4)
下痢	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
大腸狭窄	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)

表 2.7.4.7-30. 治験薬投与の中止に至った有害事象（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 (%)
SUBJECTS WITH ONE OR MORE EVENTS	2 (5.1)	0	2 (2.0)	15 (4.0)	20 (3.5)	35 (3.7)	13 (3.8)	20 (3.9)	33 (3.9)
一般・全身障害および投与部位の状態									
悪寒	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
注射部位紅斑	1 (2.6)	0	1 (1.0)	1 (0.3)	0	1 (0.1)	0	0	0
注射部位過敏反応	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	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
注射部位そう痒感	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
注射部位反応	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
注射部位腫脹	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)	0	1 (1.0)	1 (0.3)	4 (0.7)	5 (0.5)	0	4 (0.8)	4 (0.5)
免疫系障害									
過敏症	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 2.7.4.7-30. 治験薬投与の中止に至った有害事象（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									
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)
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)
丹毒	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
帯状疱疹	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
肺炎	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)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	2 (0.5)	3 (0.5)	5 (0.5)	2 (0.6)	3 (0.6)	5 (0.6)
臨床検査									
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)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
代謝および栄養障害									
脱水	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)

表 2.7.4.7-30. 治験薬投与の中止に至った有害事象（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 (%)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	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）									
基底細胞癌	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	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)
子宮頚部扁平上皮癌	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	3 (0.8)	0	3 (0.3)	3 (0.9)	0	3 (0.4)
皮膚および皮下組織障害									
脱毛症	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
血管浮腫	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
乾癬様皮膚炎	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)	0	1 (0.2)	1 (0.1)	0	0	0
SUBJECTS WITH ONE OR MORE EVENTS	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)

表 2.7.4.7-30. 治験薬投与の中止に至った有害事象（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）

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.

Cross reference: M14-033 Induction Japan Sub-study Final CSR Table 14.3__2.2.1_J

表 2.7.4.7-31. 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（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	1 (2.6)	1 (1.6)	2 (2.0)	4 (1.1)	11 (1.9)	15 (1.6)	3 (0.9)	10 (2.0)	13 (1.5)
胃腸障害									
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)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	0	2 (0.3)	2 (0.2)	0	2 (0.4)	2 (0.2)
一般・全身障害および投与部位の状態									
悪寒	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
注射部位紅斑	1 (2.6)	0	1 (1.0)	1 (0.3)	0	1 (0.1)	0	0	0
注射部位過敏反応	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	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
注射部位そう痒感	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
注射部位反応	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
注射部位腫脹	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)	0	1 (1.0)	1 (0.3)	4 (0.7)	5 (0.5)	0	4 (0.8)	4 (0.5)

表 2.7.4.7-31. 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（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									
過敏症	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)
感染症および寄生虫症									
帯状疱疹	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
肺炎	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)
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)
臨床検査									
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)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)

表 2.7.4.7-31. 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（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）									
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)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
皮膚および皮下組織障害									
血管浮腫	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
乾癬様皮膚炎	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)	0	1 (0.2)	1 (0.1)	0	0	0
SUBJECTS WITH ONE OR MORE EVENTS	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)

表 2.7.4.7-31.　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（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）

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__2.2.2_J

表 2.7.4.7-32. 治験薬投与の中止に至った有害事象（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	38 (12.6)	30 (9.9)	17 (11.3)	85 (11.2)
血液およびリンパ系障害	2 (0.7)	1 (0.3)	0	3 (0.4)
白血球減少症	1 (0.3)	1 (0.3)	0	2 (0.3)
血小板増加症	1 (0.3)	0	0	1 (0.1)
心臓障害	1 (0.3)	1 (0.3)	0	2 (0.3)
心房細動	0	1 (0.3)	0	1 (0.1)
心筋虚血	1 (0.3)	0	0	1 (0.1)
眼障害	1 (0.3)	1 (0.3)	0	2 (0.3)
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)
胃腸障害	22 (7.3)	18 (5.9)	7 (4.6)	47 (6.2)
肛門性器異形成	0	1 (0.3)	0	1 (0.1)
大腸炎	5 (1.7)	0	0	5 (0.7)
潰瘍性大腸炎	16 (5.3)	17 (5.6)	7 (4.6)	40 (5.3)
結腸異形成	1 (0.3)	0	0	1 (0.1)
小腸炎	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-32. 治験薬投与の中止に至った有害事象（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	1 (0.3)	0	1 (0.7)	2 (0.3)
異形成	0	0	1 (0.7)	1 (0.1)
限局性浮腫	1 (0.3)	0	0	1 (0.1)
ポリープ	0	0	1 (0.7)	1 (0.1)
肝胆道系障害	0	0	1 (0.7)	1 (0.1)
胆管結石	0	0	1 (0.7)	1 (0.1)
感染症および寄生虫症	3 (1.0)	3 (1.0)	4 (2.6)	10 (1.3)
クロストリジウム・ディフィシレ感染	2 (0.7)	0	0	2 (0.3)
肺炎	0	0	1 (0.7)	1 (0.1)
マイコプラズマ性肺炎	0	0	1 (0.7)	1 (0.1)
急性腎盂腎炎	0	1 (0.3)	0	1 (0.1)
敗血症	0	0	1 (0.7)	1 (0.1)
扁桃炎	0	1 (0.3)	0	1 (0.1)
結核	0	1 (0.3)	1 (0.7)	2 (0.3)
上気道感染	1 (0.3)	0	0	1 (0.1)
傷害、中毒および処置合併症	0	1 (0.3)	0	1 (0.1)
術後高血圧	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-32. 治験薬投与の中止に至った有害事象（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 (%)
臨床検査	3 (1.0)	0	2 (1.3)	5 (0.7)
血中クレアチニン増加	1 (0.3)	0	0	1 (0.1)
HIV検査陽性	0	0	1 (0.7)	1 (0.1)
肝機能検査値上昇	1 (0.3)	0	0	1 (0.1)
好中球数減少	1 (0.3)	0	0	1 (0.1)
白血球数減少	0	0	1 (0.7)	1 (0.1)
代謝および栄養障害	0	1 (0.3)	0	1 (0.1)
脱水	0	1 (0.3)	0	1 (0.1)
筋骨格系および結合組織障害	1 (0.3)	4 (1.3)	0	5 (0.7)
関節痛	0	3 (1.0)	0	3 (0.4)
筋炎	1 (0.3)	0	0	1 (0.1)
四肢痛	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）	1 (0.3)	2 (0.7)	0	3 (0.4)
膀胱癌	0	1 (0.3)	0	1 (0.1)
線維腫症	0	1 (0.3)	0	1 (0.1)
非小細胞肺癌	1 (0.3)	0	0	1 (0.1)
神経系障害	0	3 (1.0)	1 (0.7)	4 (0.5)
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)

表 2.7.4.7-32. 治験薬投与の中止に至った有害事象（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 (%)
神経系障害 (Cont.)				
浮動性めまい	0	1 (0.3)	0	1 (0.1)
頭部不快感	0	1 (0.3)	0	1 (0.1)
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	0	1 (0.3)	0	1 (0.1)
腎および尿路障害	1 (0.3)	0	0	1 (0.1)
ネフローゼ症候群	1 (0.3)	0	0	1 (0.1)
生殖系および乳房障害	1 (0.3)	0	0	1 (0.1)
卵巣嚢胞	1 (0.3)	0	0	1 (0.1)
呼吸器、胸郭および縦隔障害	1 (0.3)	1 (0.3)	0	2 (0.3)
肺塞栓症	1 (0.3)	1 (0.3)	0	2 (0.3)
皮膚および皮下組織障害	2 (0.7)	2 (0.7)	2 (1.3)	6 (0.8)
紅斑	1 (0.3)	0	0	1 (0.1)
リニアIgA病	1 (0.3)	0	0	1 (0.1)
類天疱瘡	0	0	1 (0.7)	1 (0.1)
発疹	0	1 (0.3)	1 (0.7)	2 (0.3)
角層下膿疱性皮膚症	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-32. 治験薬投与の中止に至った有害事象（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）

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.

Cross reference: M14-033 Maintenance Main-study Final CSR Table 14.3__2.2.1

表 2.7.4.7-33. 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（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	11 (3.6)	15 (4.9)	7 (4.6)	33 (4.4)
血液およびリンパ系障害	2 (0.7)	1 (0.3)	0	3 (0.4)
白血球減少症	1 (0.3)	1 (0.3)	0	2 (0.3)
血小板増加症	1 (0.3)	0	0	1 (0.1)
眼障害	1 (0.3)	1 (0.3)	0	2 (0.3)
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)
胃腸障害	1 (0.3)	3 (1.0)	2 (1.3)	6 (0.8)
潰瘍性大腸炎	1 (0.3)	3 (1.0)	2 (1.3)	6 (0.8)
一般・全身障害および投与部位の状態	1 (0.3)	0	0	1 (0.1)
限局性浮腫	1 (0.3)	0	0	1 (0.1)
感染症および寄生虫症	1 (0.3)	3 (1.0)	2 (1.3)	6 (0.8)
クロストリジウム・ディフィシレ感染	1 (0.3)	0	0	1 (0.1)
肺炎	0	0	1 (0.7)	1 (0.1)
急性腎盂腎炎	0	1 (0.3)	0	1 (0.1)
敗血症	0	0	1 (0.7)	1 (0.1)
扁桃炎	0	1 (0.3)	0	1 (0.1)
結核	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-33. 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（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 (%)
臨床検査	3 (1.0)	0	1 (0.7)	4 (0.5)
血中クレアチニン増加	1 (0.3)	0	0	1 (0.1)
肝機能検査値上昇	1 (0.3)	0	0	1 (0.1)
好中球数減少	1 (0.3)	0	0	1 (0.1)
白血球数減少	0	0	1 (0.7)	1 (0.1)
筋骨格系および結合組織障害	1 (0.3)	3 (1.0)	0	4 (0.5)
関節痛	0	2 (0.7)	0	2 (0.3)
筋炎	1 (0.3)	0	0	1 (0.1)
四肢痛	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	1 (0.3)	0	1 (0.1)
線維腫症	0	1 (0.3)	0	1 (0.1)
神経系障害	0	3 (1.0)	1 (0.7)	4 (0.5)
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)
浮動性めまい	0	1 (0.3)	0	1 (0.1)
頭部不快感	0	1 (0.3)	0	1 (0.1)
感覚鈍麻	0	2 (0.7)	0	2 (0.3)

表 2.7.4.7-33. 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（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 (%)
神経系障害 (Cont.)				
単ニューロパチー	0	1 (0.3)	0	1 (0.1)
錯感覚	0	1 (0.3)	0	1 (0.1)
腎および尿路障害	1 (0.3)	0	0	1 (0.1)
ネフローゼ症候群	1 (0.3)	0	0	1 (0.1)
皮膚および皮下組織障害	2 (0.7)	2 (0.7)	2 (1.3)	6 (0.8)
紅斑	1 (0.3)	0	0	1 (0.1)
リニアIgA病	1 (0.3)	0	0	1 (0.1)
類天疱瘡	0	0	1 (0.7)	1 (0.1)
発疹	0	1 (0.3)	1 (0.7)	2 (0.3)
角層下膿疱性皮膚症	0	1 (0.3)	0	1 (0.1)

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__2.2.2

表 2.7.4.7-34. 治験薬投与の中止に至った有害事象（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	2 (4.7)	5 (10.9)	7 (7.9)	40 (11.6)	35 (10.0)	17 (11.3)	92 (10.9)
血液およびリンパ系障害	0	0	0	2 (0.6)	1 (0.3)	0	3 (0.4)
白血球減少症	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
血小板増加症	0	0	0	1 (0.3)	0	0	1 (0.1)
心臓障害	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
心房細動	0	0	0	0	1 (0.3)	0	1 (0.1)
心筋虚血	0	0	0	1 (0.3)	0	0	1 (0.1)
眼障害	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
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)
胃腸障害	1 (2.3)	4 (8.7)	5 (5.6)	23 (6.7)	22 (6.3)	7 (4.6)	52 (6.1)
肛門性器異形成	0	0	0	0	1 (0.3)	0	1 (0.1)
大腸炎	0	0	0	5 (1.4)	0	0	5 (0.6)
潰瘍性大腸炎	1 (2.3)	4 (8.7)	5 (5.6)	17 (4.9)	21 (6.0)	7 (4.6)	45 (5.3)
結腸異形成	0	0	0	1 (0.3)	0	0	1 (0.1)
小腸炎	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-34. 治験薬投与の中止に至った有害事象（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	0	0	0	1 (0.3)	0	1 (0.7)	2 (0.2)
異形成	0	0	0	0	0	1 (0.7)	1 (0.1)
限局性浮腫	0	0	0	1 (0.3)	0	0	1 (0.1)
ポリープ	0	0	0	0	0	1 (0.7)	1 (0.1)
肝胆道系障害	1 (2.3)	0	1 (1.1)	1 (0.3)	0	1 (0.7)	2 (0.2)
胆管結石	0	0	0	0	0	1 (0.7)	1 (0.1)
肝胆道系疾患	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
感染症および寄生虫症	0	0	0	3 (0.9)	3 (0.9)	4 (2.6)	10 (1.2)
クロストリジウム・ディフィシレ感染	0	0	0	2 (0.6)	0	0	2 (0.2)
肺炎	0	0	0	0	0	1 (0.7)	1 (0.1)
マイコプラズマ性肺炎	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)
敗血症	0	0	0	0	0	1 (0.7)	1 (0.1)
扁桃炎	0	0	0	0	1 (0.3)	0	1 (0.1)
結核	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
上気道感染	0	0	0	1 (0.3)	0	0	1 (0.1)
傷害、中毒および処置合併症	0	0	0	0	1 (0.3)	0	1 (0.1)
術後高血圧	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-34. 治験薬投与の中止に至った有害事象（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 (%)
臨床検査	0	0	0	3 (0.9)	0	2 (1.3)	5 (0.6)
血中クレアチニン増加	0	0	0	1 (0.3)	0	0	1 (0.1)
HIV検査陽性	0	0	0	0	0	1 (0.7)	1 (0.1)
肝機能検査値上昇	0	0	0	1 (0.3)	0	0	1 (0.1)
好中球数減少	0	0	0	1 (0.3)	0	0	1 (0.1)
白血球数減少	0	0	0	0	0	1 (0.7)	1 (0.1)
代謝および栄養障害	0	0	0	0	1 (0.3)	0	1 (0.1)
脱水	0	0	0	0	1 (0.3)	0	1 (0.1)
筋骨格系および結合組織障害	0	1 (2.2)	1 (1.1)	1 (0.3)	5 (1.4)	0	6 (0.7)
関節痛	0	0	0	0	3 (0.9)	0	3 (0.4)
ループス様症候群	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)
筋炎	0	0	0	1 (0.3)	0	0	1 (0.1)
四肢痛	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	1 (0.3)	2 (0.6)	0	3 (0.4)
膀胱癌	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)
非小細胞肺癌	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-34. 治験薬投与の中止に至った有害事象（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 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 (%)
神経系障害	0	0	0	0	3 (0.9)	1 (0.7)	4 (0.5)
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)
浮動性めまい	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)
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	0	1 (0.3)	0	1 (0.1)
腎および尿路障害	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)
生殖系および乳房障害	0	0	0	1 (0.3)	0	0	1 (0.1)
卵巣嚢胞	0	0	0	1 (0.3)	0	0	1 (0.1)
呼吸器、胸郭および縦隔障害	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
肺塞栓症	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
皮膚および皮下組織障害	0	0	0	2 (0.6)	2 (0.6)	2 (1.3)	6 (0.7)
紅斑	0	0	0	1 (0.3)	0	0	1 (0.1)
リニアIgA病	0	0	0	1 (0.3)	0	0	1 (0.1)
類天疱瘡	0	0	0	0	0	1 (0.7)	1 (0.1)

表 2.7.4.7-34. 治験薬投与の中止に至った有害事象（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.)							
発疹	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
角層下膿疱性皮膚症	0	0	0	0	1 (0.3)	0	1 (0.1)

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.

Cross reference: M14-033 Maintenance Japan Sub-study Final CSR Table 14.3__2.2.1_J

表 2.7.4.7-35. 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（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	1 (2.3)	1 (2.2)	2 (2.2)	12 (3.5)	16 (4.6)	7 (4.6)	35 (4.1)
血液およびリンパ系障害	0	0	0	2 (0.6)	1 (0.3)	0	3 (0.4)
白血球減少症	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
血小板増加症	0	0	0	1 (0.3)	0	0	1 (0.1)
眼障害	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
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)
胃腸障害	0	0	0	1 (0.3)	3 (0.9)	2 (1.3)	6 (0.7)
潰瘍性大腸炎	0	0	0	1 (0.3)	3 (0.9)	2 (1.3)	6 (0.7)
一般・全身障害および投与部位の状態	0	0	0	1 (0.3)	0	0	1 (0.1)
限局性浮腫	0	0	0	1 (0.3)	0	0	1 (0.1)
肝胆道系障害	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
肝胆道系疾患	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
感染症および寄生虫症	0	0	0	1 (0.3)	3 (0.9)	2 (1.3)	6 (0.7)
クロストリジウム・ディフィシレ感染	0	0	0	1 (0.3)	0	0	1 (0.1)
肺炎	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)

表 2.7.4.7-35. 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（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 (%)
感染症および寄生虫症 (Cont.)							
敗血症	0	0	0	0	0	1 (0.7)	1 (0.1)
扁桃炎	0	0	0	0	1 (0.3)	0	1 (0.1)
結核	0	0	0	0	1 (0.3)	0	1 (0.1)
臨床検査	0	0	0	3 (0.9)	0	1 (0.7)	4 (0.5)
血中クレアチニン増加	0	0	0	1 (0.3)	0	0	1 (0.1)
肝機能検査値上昇	0	0	0	1 (0.3)	0	0	1 (0.1)
好中球数減少	0	0	0	1 (0.3)	0	0	1 (0.1)
白血球数減少	0	0	0	0	0	1 (0.7)	1 (0.1)
筋骨格系および結合組織障害	0	1 (2.2)	1 (1.1)	1 (0.3)	4 (1.1)	0	5 (0.6)
関節痛	0	0	0	0	2 (0.6)	0	2 (0.2)
ループス様症候群	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)
筋炎	0	0	0	1 (0.3)	0	0	1 (0.1)
四肢痛	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	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	0	0	0	0	3 (0.9)	1 (0.7)	4 (0.5)
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)

表 2.7.4.7-35. 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（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 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 (%)
神経系障害 (Cont.)							
浮動性めまい	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)
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	0	1 (0.3)	0	1 (0.1)
腎および尿路障害	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)
皮膚および皮下組織障害	0	0	0	2 (0.6)	2 (0.6)	2 (1.3)	6 (0.7)
紅斑	0	0	0	1 (0.3)	0	0	1 (0.1)
リニアIgA病	0	0	0	1 (0.3)	0	0	1 (0.1)
類天疱瘡	0	0	0	0	0	1 (0.7)	1 (0.1)
発疹	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
角層下膿疱性皮膚症	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-35.　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（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）

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__2.2.2_J

表 2.7.4.7-36. すべての感染症（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）

	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 (%)
ANY ADVERSE EVENT	58 (17.1)	69 (13.5)	127 (14.9)
感染症および寄生虫症			
膿瘍	1 (0.3)	0	1 (0.1)
四肢膿瘍	1 (0.3)	1 (0.2)	2 (0.2)
肛門膿瘍	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)
気管支炎	1 (0.3)	1 (0.2)	2 (0.2)
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)
蜂巣炎	1 (0.3)	0	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)
サイトメガロウイルス性大腸炎	0	1 (0.2)	1 (0.1)
耳感染	1 (0.3)	2 (0.4)	3 (0.4)
丹毒	1 (0.3)	0	1 (0.1)
真菌感染	0	1 (0.2)	1 (0.1)
胃腸炎	0	1 (0.2)	1 (0.1)
ウイルス性胃腸炎	1 (0.3)	2 (0.4)	3 (0.4)
ヘルペスウイルス感染	0	1 (0.2)	1 (0.1)
帯状疱疹	2 (0.6)	0	2 (0.2)
麦粒腫	0	1 (0.2)	1 (0.1)

表 2.7.4.7-36. すべての感染症（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 (%)
感染症および寄生虫症 (Cont.)			
膿痂疹	0	1 (0.2)	1 (0.1)
感染性嚢腫	0	1 (0.2)	1 (0.1)
感染	0	1 (0.2)	1 (0.1)
インフルエンザ	6 (1.8)	1 (0.2)	7 (0.8)
喉頭炎	1 (0.3)	0	1 (0.1)
限局性感染	0	1 (0.2)	1 (0.1)
上咽頭炎	14 (4.1)	19 (3.7)	33 (3.9)
食道カンジダ症	1 (0.3)	0	1 (0.1)
爪真菌症	0	1 (0.2)	1 (0.1)
口腔ヘルペス	2 (0.6)	2 (0.4)	4 (0.5)
中耳炎	1 (0.3)	0	1 (0.1)
咽頭炎	5 (1.5)	3 (0.6)	8 (0.9)
細菌性咽頭炎	1 (0.3)	0	1 (0.1)
レンサ球菌性咽頭炎	0	1 (0.2)	1 (0.1)
肺炎	2 (0.6)	1 (0.2)	3 (0.4)
腎盂腎炎	1 (0.3)	0	1 (0.1)
膿疱性皮疹	2 (0.6)	1 (0.2)	3 (0.4)
気道感染	0	1 (0.2)	1 (0.1)
鼻炎	3 (0.9)	2 (0.4)	5 (0.6)
副鼻腔炎	4 (1.2)	5 (1.0)	9 (1.1)
皮膚感染	0	1 (0.2)	1 (0.1)

表 2.7.4.7-36. すべての感染症（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 (%)
感染症および寄生虫症 (Cont.)			
白癬感染	0	2 (0.4)	2 (0.2)
歯感染	0	1 (0.2)	1 (0.1)
結核	0	1 (0.2)	1 (0.1)
上気道感染	3 (0.9)	6 (1.2)	9 (1.1)
尿路感染	5 (1.5)	6 (1.2)	11 (1.3)
腟感染	1 (0.3)	0	1 (0.1)
ウイルス感染	0	3 (0.6)	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	1 (0.3)	2 (0.4)	3 (0.4)
外陰腟真菌感染	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	58 (17.1)	68 (13.3)	126 (14.8)
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)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (0.2)	1 (0.1)

表 2.7.4.7-36.　　すべての感染症（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）

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.

Cross reference: M14-033 Induction Main-study Final CSR Table 14.3__2.4.1

表 2.7.4.7-37. すべての感染症（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	4 (10.3)	14 (23.0)	18 (18.0)	62 (16.4)	83 (14.5)	145 (15.2)	58 (17.1)	69 (13.5)	127 (14.9)
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)
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)
肛門膿瘍	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)
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)
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)
蜂巣炎	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・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)
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)
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
耳感染	0	0	0	1 (0.3)	2 (0.3)	3 (0.3)	1 (0.3)	2 (0.4)	3 (0.4)
丹毒	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	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 2.7.4.7-37. すべての感染症（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.)									
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)
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	2 (0.5)	0	2 (0.2)	2 (0.6)	0	2 (0.2)
麦粒腫	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
膿痂疹	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)
感染	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	1 (1.6)	1 (1.0)	6 (1.6)	2 (0.3)	8 (0.8)	6 (1.8)	1 (0.2)	7 (0.8)
喉頭炎	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	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)
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)
食道カンジダ症	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
爪真菌症	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
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)
中耳炎	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	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)

表 2.7.4.7-37. すべての感染症（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.)									
細菌性咽頭炎	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	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)
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)
腎盂腎炎	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	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)
気道感染	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
鼻炎	0	0	0	3 (0.8)	2 (0.3)	5 (0.5)	3 (0.9)	2 (0.4)	5 (0.6)
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)
皮膚感染	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
白癬感染	0	0	0	0	2 (0.3)	2 (0.2)	0	2 (0.4)	2 (0.2)
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)
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)
尿路感染	0	0	0	5 (1.3)	6 (1.0)	11 (1.2)	5 (1.5)	6 (1.2)	11 (1.3)
腟感染	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
水痘	0	1 (1.6)	1 (1.0)	0	1 (0.2)	1 (0.1)	0	0	0
ウイルス感染	0	0	0	0	3 (0.5)	3 (0.3)	0	3 (0.6)	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)

表 2.7.4.7-37. すべての感染症（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.)									
外陰部腟カンジダ症	0	0	0	1 (0.3)	2 (0.3)	3 (0.3)	1 (0.3)	2 (0.4)	3 (0.4)
外陰腟真菌感染	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	4 (10.3)	14 (23.0)	18 (18.0)	62 (16.4)	82 (14.3)	144 (15.1)	58 (17.1)	68 (13.3)	126 (14.8)
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)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)

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.

Cross reference: M14-033 Induction Japan Sub-study Final CSR Table 14.3__2.4.1_J

表 2.7.4.7-38.　すべての感染症（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	110 (36.4)	105 (34.5)	51 (33.8)	266 (35.1)
感染症および寄生虫症	110 (36.4)	104 (34.2)	51 (33.8)	265 (35.0)
四肢膿瘍	0	2 (0.7)	0	2 (0.3)
急性副鼻腔炎	0	2 (0.7)	0	2 (0.3)
肛門膿瘍	0	1 (0.3)	0	1 (0.1)
虫垂炎	0	1 (0.3)	0	1 (0.1)
無症候性細菌尿	0	1 (0.3)	0	1 (0.1)
細菌感染	1 (0.3)	0	0	1 (0.1)
細菌性膣症	0	1 (0.3)	0	1 (0.1)
気管支炎	4 (1.3)	1 (0.3)	3 (2.0)	8 (1.1)
カンジダ感染	1 (0.3)	2 (0.7)	1 (0.7)	4 (0.5)
蜂巣炎	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
クロストリジウム・ディフィシレ感染	4 (1.3)	2 (0.7)	0	6 (0.8)
膀胱炎	0	0	1 (0.7)	1 (0.1)
サイトメガロウイルス感染	1 (0.3)	0	0	1 (0.1)
憩室炎	0	1 (0.3)	0	1 (0.1)
耳感染	3 (1.0)	2 (0.7)	3 (2.0)	8 (1.1)

表 2.7.4.7-38. すべての感染症（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.)				
蟯虫症	0	2 (0.7)	0	2 (0.3)
エプスタイン・バーウイルス感染	2 (0.7)	0	0	2 (0.3)
外耳蜂巣炎	1 (0.3)	0	0	1 (0.1)
眼瞼感染	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)
せつ	1 (0.3)	0	0	1 (0.1)
胃腸炎	5 (1.7)	5 (1.6)	2 (1.3)	12 (1.6)
ウイルス性胃腸炎	1 (0.3)	2 (0.7)	0	3 (0.4)
消化管感染	1 (0.3)	0	0	1 (0.1)
性器カンジダ症	1 (0.3)	1 (0.3)	0	2 (0.3)
歯肉膿瘍	0	1 (0.3)	0	1 (0.1)
ヘリコバクター感染	1 (0.3)	0	0	1 (0.1)
ヘルペス眼感染	0	1 (0.3)	0	1 (0.1)
単純ヘルペス	2 (0.7)	0	0	2 (0.3)
帯状疱疹	3 (1.0)	3 (1.0)	1 (0.7)	7 (0.9)
麦粒腫	1 (0.3)	2 (0.7)	0	3 (0.4)

表 2.7.4.7-38. すべての感染症（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.)				
膿痂疹	1 (0.3)	1 (0.3)	0	2 (0.3)
インフルエンザ	13 (4.3)	11 (3.6)	5 (3.3)	29 (3.8)
喉頭炎	1 (0.3)	0	0	1 (0.1)
限局性感染	1 (0.3)	1 (0.3)	0	2 (0.3)
下気道感染	0	1 (0.3)	1 (0.7)	2 (0.3)
ライム病	1 (0.3)	0	0	1 (0.1)
伝染性軟属腫	0	1 (0.3)	0	1 (0.1)
鼓膜炎	0	0	1 (0.7)	1 (0.1)
上咽頭炎	31 (10.3)	30 (9.9)	11 (7.3)	72 (9.5)
口腔カンジダ症	1 (0.3)	0	1 (0.7)	2 (0.3)
口腔真菌感染	0	1 (0.3)	0	1 (0.1)
口腔ヘルペス	2 (0.7)	3 (1.0)	1 (0.7)	6 (0.8)
外耳炎	1 (0.3)	2 (0.7)	0	3 (0.4)
中耳炎	0	0	1 (0.7)	1 (0.1)
急性中耳炎	1 (0.3)	0	0	1 (0.1)
寄生虫性胃腸炎	0	0	1 (0.7)	1 (0.1)
爪囲炎	1 (0.3)	1 (0.3)	0	2 (0.3)

表 2.7.4.7-38. すべての感染症（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.)				
骨盤膿瘍	0	1 (0.3)	0	1 (0.1)
骨盤内感染	1 (0.3)	0	0	1 (0.1)
骨盤内炎症性疾患	0	1 (0.3)	0	1 (0.1)
会陰膿瘍	1 (0.3)	0	0	1 (0.1)
歯周炎	1 (0.3)	0	0	1 (0.1)
扁桃周囲膿瘍	0	1 (0.3)	0	1 (0.1)
咽頭炎	3 (1.0)	6 (2.0)	6 (4.0)	15 (2.0)
レンサ球菌性咽頭炎	4 (1.3)	0	1 (0.7)	5 (0.7)
咽頭扁桃炎	0	1 (0.3)	0	1 (0.1)
肺炎	3 (1.0)	7 (2.3)	1 (0.7)	11 (1.5)
マイコプラズマ性肺炎	0	0	1 (0.7)	1 (0.1)
処置後感染	0	1 (0.3)	0	1 (0.1)
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)
気道感染	0	0	1 (0.7)	1 (0.1)
ウイルス性気道感染	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-38.　すべての感染症（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.)				
鼻炎	3 (1.0)	3 (1.0)	0	6 (0.8)
敗血症	0	0	1 (0.7)	1 (0.1)
副鼻腔炎	13 (4.3)	9 (3.0)	7 (4.6)	29 (3.8)
皮膚カンジダ	0	1 (0.3)	0	1 (0.1)
皮膚感染	0	2 (0.7)	0	2 (0.3)
ブドウ球菌感染	0	1 (0.3)	0	1 (0.1)
胸骨炎	1 (0.3)	0	0	1 (0.1)
レンサ球菌感染	1 (0.3)	0	0	1 (0.1)
頭部白癬	1 (0.3)	0	0	1 (0.1)
癜風	1 (0.3)	0	1 (0.7)	2 (0.3)
扁桃炎	2 (0.7)	3 (1.0)	2 (1.3)	7 (0.9)
歯膿瘍	2 (0.7)	0	2 (1.3)	4 (0.5)
歯感染	2 (0.7)	4 (1.3)	0	6 (0.8)
結核	0	1 (0.3)	1 (0.7)	2 (0.3)
胸腔内リンパ節結核	0	1 (0.3)	0	1 (0.1)
上気道感染	21 (7.0)	17 (5.6)	9 (6.0)	47 (6.2)
尿路感染	8 (2.6)	4 (1.3)	4 (2.6)	16 (2.1)

表 2.7.4.7-38. すべての感染症（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.)				
膣感染	1 (0.3)	0	0	1 (0.1)
ウイルス感染	1 (0.3)	2 (0.7)	1 (0.7)	4 (0.5)
ウイルス性咽頭炎	0	2 (0.7)	0	2 (0.3)
外陰部膣カンジダ症	0	3 (1.0)	0	3 (0.4)
外陰膣真菌感染	1 (0.3)	2 (0.7)	1 (0.7)	4 (0.5)
外陰膣炎	0	0	1 (0.7)	1 (0.1)
エルシニア感染	1 (0.3)	1 (0.3)	0	2 (0.3)
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	1 (0.3)	0	1 (0.1)
肛門性器疣贅	0	1 (0.3)	0	1 (0.1)
生殖系および乳房障害	0	1 (0.3)	0	1 (0.1)
前立腺炎	0	1 (0.3)	0	1 (0.1)
呼吸器、胸郭および縦隔障害	1 (0.3)	0	0	1 (0.1)
鼻汁変色	1 (0.3)	0	0	1 (0.1)

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.

Cross reference: M14-033 Maintenance Main-study Final CSR Table 14.3__2.4.1

表 2.7.4.7-39. すべての感染症（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	22 (51.2)	25 (54.3)	47 (52.8)	132 (38.3)	130 (37.1)	51 (33.8)	313 (37.0)
感染症および寄生虫症	22 (51.2)	25 (54.3)	47 (52.8)	132 (38.3)	129 (36.9)	51 (33.8)	312 (36.9)
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	2 (0.6)	0	2 (0.2)
肛門膿瘍	0	0	0	0	1 (0.3)	0	1 (0.1)
虫垂炎	0	0	0	0	1 (0.3)	0	1 (0.1)
無症候性細菌尿	0	0	0	0	1 (0.3)	0	1 (0.1)
細菌感染	0	1 (2.2)	1 (1.1)	1 (0.3)	1 (0.3)	0	2 (0.2)
細菌性膣症	0	0	0	0	1 (0.3)	0	1 (0.1)
細菌性外陰膣炎	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
気管支炎	1 (2.3)	1 (2.2)	2 (2.2)	5 (1.4)	2 (0.6)	3 (2.0)	10 (1.2)
カンジダ感染	0	0	0	1 (0.3)	2 (0.6)	1 (0.7)	4 (0.5)
蜂巣炎	0	0	0	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
クロストリジウム・ディフィシレ感染	0	0	0	4 (1.2)	2 (0.6)	0	6 (0.7)
膀胱炎	0	0	0	0	0	1 (0.7)	1 (0.1)
サイトメガロウイルス感染	0	0	0	1 (0.3)	0	0	1 (0.1)
憩室炎	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-39. すべての感染症（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 (%)
感染症および寄生虫症 (Cont.)							
耳感染	0	0	0	3 (0.9)	2 (0.6)	3 (2.0)	8 (0.9)
蟯虫症	0	0	0	0	2 (0.6)	0	2 (0.2)
エプスタイン・バーウイルス感染	0	0	0	2 (0.6)	0	0	2 (0.2)
外耳蜂巣炎	0	0	0	1 (0.3)	0	0	1 (0.1)
眼瞼感染	0	0	0	0	1 (0.3)	0	1 (0.1)
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)
せつ	0	0	0	1 (0.3)	0	0	1 (0.1)
胃腸炎	1 (2.3)	0	1 (1.1)	6 (1.7)	5 (1.4)	2 (1.3)	13 (1.5)
細菌性胃腸炎	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)
ウイルス性胃腸炎	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)
消化管感染	0	0	0	1 (0.3)	0	0	1 (0.1)
性器カンジダ症	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
歯肉膿瘍	0	0	0	0	1 (0.3)	0	1 (0.1)
ヘリコバクター感染	0	0	0	1 (0.3)	0	0	1 (0.1)
ヘルペス眼感染	0	0	0	0	1 (0.3)	0	1 (0.1)
単純ヘルペス	0	0	0	2 (0.6)	0	0	2 (0.2)

表 2.7.4.7-39. すべての感染症（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 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 (%)
感染症および寄生虫症 (Cont.)							
帯状疱疹	0	0	0	3 (0.9)	3 (0.9)	1 (0.7)	7 (0.8)
麦粒腫	0	1 (2.2)	1 (1.1)	1 (0.3)	3 (0.9)	0	4 (0.5)
膿痂疹	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
インフルエンザ	3 (7.0)	4 (8.7)	7 (7.9)	16 (4.6)	15 (4.3)	5 (3.3)	36 (4.3)
喉頭炎	0	0	0	1 (0.3)	0	0	1 (0.1)
限局性感染	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
下気道感染	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
ライム病	0	0	0	1 (0.3)	0	0	1 (0.1)
伝染性軟属腫	0	0	0	0	1 (0.3)	0	1 (0.1)
鼓膜炎	0	0	0	0	0	1 (0.7)	1 (0.1)
上咽頭炎	16 (37.2)	16 (34.8)	32 (36.0)	47 (13.6)	46 (13.1)	11 (7.3)	104 (12.3)
口腔カンジダ症	1 (2.3)	0	1 (1.1)	2 (0.6)	0	1 (0.7)	3 (0.4)
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	2 (0.6)	3 (0.9)	1 (0.7)	6 (0.7)
外耳炎	0	0	0	1 (0.3)	2 (0.6)	0	3 (0.4)
中耳炎	0	0	0	0	0	1 (0.7)	1 (0.1)
急性中耳炎	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-39. すべての感染症（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 (%)
感染症および寄生虫症 (Cont.)							
寄生虫性胃腸炎	0	0	0	0	0	1 (0.7)	1 (0.1)
爪囲炎	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
骨盤膿瘍	0	0	0	0	1 (0.3)	0	1 (0.1)
骨盤内感染	0	0	0	1 (0.3)	0	0	1 (0.1)
骨盤内炎症性疾患	0	0	0	0	1 (0.3)	0	1 (0.1)
歯冠周囲炎	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)
会陰膿瘍	0	0	0	1 (0.3)	0	0	1 (0.1)
歯周炎	2 (4.7)	0	2 (2.2)	3 (0.9)	0	0	3 (0.4)
扁桃周囲膿瘍	0	0	0	0	1 (0.3)	0	1 (0.1)
咽頭炎	1 (2.3)	1 (2.2)	2 (2.2)	4 (1.2)	7 (2.0)	6 (4.0)	17 (2.0)
レンサ球菌性咽頭炎	0	0	0	4 (1.2)	0	1 (0.7)	5 (0.6)
咽頭扁桃炎	0	0	0	0	1 (0.3)	0	1 (0.1)
肺炎	1 (2.3)	0	1 (1.1)	4 (1.2)	7 (2.0)	1 (0.7)	12 (1.4)
マイコプラズマ性肺炎	0	0	0	0	0	1 (0.7)	1 (0.1)
処置後感染	0	0	0	0	1 (0.3)	0	1 (0.1)
化膿	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)
腎盂腎炎	0	0	0	0	0	1 (0.7)	1 (0.1)

表 2.7.4.7-39. すべての感染症（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 (%)
感染症および寄生虫症 (Cont.)							
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)
気道感染	0	0	0	0	0	1 (0.7)	1 (0.1)
ウイルス性気道感染	0	0	0	1 (0.3)	0	0	1 (0.1)
鼻炎	0	1 (2.2)	1 (1.1)	3 (0.9)	4 (1.1)	0	7 (0.8)
敗血症	0	0	0	0	0	1 (0.7)	1 (0.1)
副鼻腔炎	1 (2.3)	2 (4.3)	3 (3.4)	14 (4.1)	11 (3.1)	7 (4.6)	32 (3.8)
皮膚カンジダ	0	0	0	0	1 (0.3)	0	1 (0.1)
皮膚感染	0	0	0	0	2 (0.6)	0	2 (0.2)
ブドウ球菌感染	0	0	0	0	1 (0.3)	0	1 (0.1)
胸骨炎	0	0	0	1 (0.3)	0	0	1 (0.1)
レンサ球菌感染	0	0	0	1 (0.3)	0	0	1 (0.1)
頭部白癬	0	0	0	1 (0.3)	0	0	1 (0.1)
癜風	0	0	0	1 (0.3)	0	1 (0.7)	2 (0.2)
扁桃炎	1 (2.3)	0	1 (1.1)	3 (0.9)	3 (0.9)	2 (1.3)	8 (0.9)
歯膿瘍	0	0	0	2 (0.6)	0	2 (1.3)	4 (0.5)
歯感染	0	0	0	2 (0.6)	4 (1.1)	0	6 (0.7)

表 2.7.4.7-39. すべての感染症（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 (%)
感染症および寄生虫症 (Cont.)							
結核	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
胸腔内リンパ節結核	0	0	0	0	1 (0.3)	0	1 (0.1)
上気道感染	1 (2.3)	2 (4.3)	3 (3.4)	22 (6.4)	19 (5.4)	9 (6.0)	50 (5.9)
尿路感染	0	0	0	8 (2.3)	4 (1.1)	4 (2.6)	16 (1.9)
膣感染	0	0	0	1 (0.3)	0	0	1 (0.1)
ウイルス感染	0	0	0	1 (0.3)	2 (0.6)	1 (0.7)	4 (0.5)
ウイルス性咽頭炎	0	0	0	0	2 (0.6)	0	2 (0.2)
外陰部膣カンジダ症	0	0	0	0	3 (0.9)	0	3 (0.4)
外陰膣真菌感染	0	0	0	1 (0.3)	2 (0.6)	1 (0.7)	4 (0.5)
外陰膣炎	0	0	0	0	0	1 (0.7)	1 (0.1)
エルシニア感染	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
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	1 (0.3)	0	1 (0.1)
肛門性器疣贅	0	0	0	0	1 (0.3)	0	1 (0.1)
生殖系および乳房障害	1 (2.3)	0	1 (1.1)	1 (0.3)	1 (0.3)	0	2 (0.2)
前立腺炎	1 (2.3)	0	1 (1.1)	1 (0.3)	1 (0.3)	0	2 (0.2)
呼吸器、胸郭および縦隔障害	0	0	0	1 (0.3)	0	0	1 (0.1)
鼻汁変色	0	0	0	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-39.　すべての感染症（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）

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.

Cross reference: M14-033 Maintenance Japan Sub-study Final CSR Table 14.3__2.4.1_J

表 2.7.4.7-40. 重篤な感染症（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）

	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 (%)
ANY ADVERSE EVENT	2 (0.6)	3 (0.6)	5 (0.6)
感染症および寄生虫症			
クロストリジウム・ディフィシレ感染	0	1 (0.2)	1 (0.1)
サイトメガロウイルス性大腸炎	0	1 (0.2)	1 (0.1)
丹毒	1 (0.3)	0	1 (0.1)
帯状疱疹	1 (0.3)	0	1 (0.1)
感染	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	2 (0.6)	3 (0.6)	5 (0.6)

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.

Cross reference: M14-033 Induction Main-study Final CSR Table 14.3__2.4.2

表 2.7.4.7-41. 重篤な感染症（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	1 (2.6)	1 (1.6)	2 (2.0)	3 (0.8)	4 (0.7)	7 (0.7)	2 (0.6)	3 (0.6)	5 (0.6)
感染症および寄生虫症									
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)
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)
丹毒	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
帯状疱疹	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
感染	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
肺炎	1 (2.6)	0	1 (1.0)	1 (0.3)	0	1 (0.1)	0	0	0
水痘	0	1 (1.6)	1 (1.0)	0	1 (0.2)	1 (0.1)	0	0	0
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.6)	1 (1.6)	2 (2.0)	3 (0.8)	4 (0.7)	7 (0.7)	2 (0.6)	3 (0.6)	5 (0.6)

表 2.7.4.7-41. 重篤な感染症（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）

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.

Cross reference: M14-033 Induction Japan Sub-study Final CSR Table 14.3__2.4.2_J

表 2.7.4.7-42. 重篤な感染症（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	10 (3.3)	9 (3.0)	3 (2.0)	22 (2.9)
感染症および寄生虫症	10 (3.3)	9 (3.0)	3 (2.0)	22 (2.9)
虫垂炎	0	1 (0.3)	0	1 (0.1)
気管支炎	0	0	1 (0.7)	1 (0.1)
クロストリジウム・ディフィシレ感染	3 (1.0)	0	0	3 (0.4)
外耳蜂巣炎	1 (0.3)	0	0	1 (0.1)
消化管感染	1 (0.3)	0	0	1 (0.1)
外耳炎	1 (0.3)	0	0	1 (0.1)
骨盤内炎症性疾患	0	1 (0.3)	0	1 (0.1)
会陰膿瘍	1 (0.3)	0	0	1 (0.1)
扁桃周囲膿瘍	0	1 (0.3)	0	1 (0.1)
肺炎	2 (0.7)	4 (1.3)	0	6 (0.8)
敗血症	0	0	1 (0.7)	1 (0.1)
胸骨炎	1 (0.3)	0	0	1 (0.1)
結核	0	1 (0.3)	1 (0.7)	2 (0.3)
胸腔内リンパ節結核	0	1 (0.3)	0	1 (0.1)
ウイルス感染	1 (0.3)	0	0	1 (0.1)

表 2.7.4.7-42.　　重篤な感染症（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）

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.

Cross reference: M14-033 Maintenance Main-study Final CSR Table 14.3__2.4.2

表 2.7.4.7-43. 重篤な感染症（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	1 (2.3)	0	1 (1.1)	11 (3.2)	9 (2.6)	3 (2.0)	23 (2.7)
感染症および寄生虫症	1 (2.3)	0	1 (1.1)	11 (3.2)	9 (2.6)	3 (2.0)	23 (2.7)
虫垂炎	0	0	0	0	1 (0.3)	0	1 (0.1)
気管支炎	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	3 (0.9)	0	0	3 (0.4)
外耳蜂巣炎	0	0	0	1 (0.3)	0	0	1 (0.1)
胃腸炎	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
消化管感染	0	0	0	1 (0.3)	0	0	1 (0.1)
外耳炎	0	0	0	1 (0.3)	0	0	1 (0.1)
骨盤内炎症性疾患	0	0	0	0	1 (0.3)	0	1 (0.1)
会陰膿瘍	0	0	0	1 (0.3)	0	0	1 (0.1)
扁桃周囲膿瘍	0	0	0	0	1 (0.3)	0	1 (0.1)
肺炎	0	0	0	2 (0.6)	4 (1.1)	0	6 (0.7)
敗血症	0	0	0	0	0	1 (0.7)	1 (0.1)
胸骨炎	0	0	0	1 (0.3)	0	0	1 (0.1)
結核	0	0	0	0	1 (0.3)	1 (0.7)	2 (0.2)
胸腔内リンパ節結核	0	0	0	0	1 (0.3)	0	1 (0.1)

表 2.7.4.7-43. 重篤な感染症（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 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 (%)
感染症および寄生虫症 (Cont.)							
ウイルス感染	0	0	0	1 (0.3)	0	0	1 (0.1)

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.

Cross reference: M14-033 Maintenance Japan Sub-study Final CSR Table 14.3__2.4.2_J

表 2.7.4.7-44.　憩室炎（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	0	1 (0.3)	0	1 (0.1)
感染症および寄生虫症	0	1 (0.3)	0	1 (0.1)
憩室炎	0	1 (0.3)	0	1 (0.1)

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.

Cross reference: M14-033 Maintenance Main-study Final CSR Table 14.3__2.4.4

表 2.7.4.7-45. 口腔カンジダ症及び結核を除く日和見感染症（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）

	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 (%)
ANY ADVERSE EVENT	1 (0.3)	1 (0.2)	2 (0.2)
感染症および寄生虫症			
サイトメガロウイルス性大腸炎	0	1 (0.2)	1 (0.1)
食道カンジダ症	1 (0.3)	0	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	1 (0.3)	1 (0.2)	2 (0.2)

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.

Cross reference: M14-033 Induction Main-study Final CSR Table 14.3__2.4.5

表 2.7.4.7-46. 口腔カンジダ症（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	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
感染症および寄生虫症	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)
口腔カンジダ症	1 (0.3)	0	1 (0.7)	2 (0.3)
口腔真菌感染	0	1 (0.3)	0	1 (0.1)

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.

Cross reference: M14-033 Maintenance Main-study Final CSR Table 14.3__2.4.6

表 2.7.4.7-47. 口腔カンジダ症（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 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 (%)
Any Adverse Event	1 (2.3)	0	1 (1.1)	2 (0.6)	1 (0.3)	1 (0.7)	4 (0.5)
感染症および寄生虫症	1 (2.3)	0	1 (1.1)	2 (0.6)	1 (0.3)	1 (0.7)	4 (0.5)
口腔カンジダ症	1 (2.3)	0	1 (1.1)	2 (0.6)	0	1 (0.7)	3 (0.4)
口腔真菌感染	0	0	0	0	1 (0.3)	0	1 (0.1)

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.

Cross reference: M14-033 Maintenance Japan Sub-study Final CSR Table 14.3__2.4.4_J

表 2.7.4.7-48. 活動性結核（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）

	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 (%)
ANY ADVERSE EVENT	0	1 (0.2)	1 (0.1)
感染症および寄生虫症			
結核	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (0.2)	1 (0.1)

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.

Cross reference: M14-033 Induction Main-study Final CSR Table 14.3__2.4.8

表 2.7.4.7-49. 活動性結核（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	0	2 (0.7)	1 (0.7)	3 (0.4)
感染症および寄生虫症	0	2 (0.7)	1 (0.7)	3 (0.4)
結核	0	1 (0.3)	1 (0.7)	2 (0.3)
胸腔内リンパ節結核	0	1 (0.3)	0	1 (0.1)

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.

Cross reference: M14-033 Maintenance Main-study Final CSR Table 14.3__2.4.8

表 2.7.4.7-50. 寄生虫感染（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）

	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 (%)
ANY ADVERSE EVENT	0	1 (0.2)	1 (0.1)
感染症および寄生虫症			
ブラストシスティス感染	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (0.2)	1 (0.1)

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.

Cross reference: M14-033 Induction Main-study Final CSR Table 14.3__2.4.10

表 2.7.4.7-51. 寄生虫感染（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	0	2 (0.7)	1 (0.7)	3 (0.4)
感染症および寄生虫症	0	2 (0.7)	1 (0.7)	3 (0.4)
蟯虫症	0	2 (0.7)	0	2 (0.3)
寄生虫性胃腸炎	0	0	1 (0.7)	1 (0.1)

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.

Cross reference: M14-033 Maintenance Main-study Final CSR Table 14.3__2.4.10

表 2.7.4.7-52. 悪性腫瘍（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）

	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 (%)
ANY ADVERSE EVENT	3 (0.9)	0	3 (0.4)
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）			
基底細胞癌	1 (0.3)	0	1 (0.1)
表皮内悪性黒色腫	1 (0.3)	0	1 (0.1)
子宮頚部扁平上皮癌	1 (0.3)	0	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	3 (0.9)	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 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__2.4.13

表 2.7.4.7-53.　悪性腫瘍（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	2 (0.7)	4 (1.3)	0	6 (0.8)
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）	2 (0.7)	4 (1.3)	0	6 (0.8)
基底細胞癌	1 (0.3)	1 (0.3)	0	2 (0.3)
膀胱癌	0	1 (0.3)	0	1 (0.1)
悪性黒色腫	0	1 (0.3)	0	1 (0.1)
非小細胞肺癌	1 (0.3)	0	0	1 (0.1)
食道腺癌	0	1 (0.3)	0	1 (0.1)

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.

Cross reference: M14-033 Maintenance Main-study Final CSR Table 14.3__2.4.13

表 2.7.4.7-54. 血管浮腫 / アナフィラキシーを含むアレルギー反応（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）

	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 (%)
ANY ADVERSE EVENT	5 (1.5)	8 (1.6)	13 (1.5)
一般・全身障害および投与部位の状態			
注射部位蕁麻疹	1 (0.3)	1 (0.2)	2 (0.2)
SUBJECTS WITH ONE OR MORE EVENTS	1 (0.3)	1 (0.2)	2 (0.2)
免疫系障害			
薬物過敏症	1 (0.3)	1 (0.2)	2 (0.2)
過敏症	1 (0.3)	2 (0.4)	3 (0.4)
SUBJECTS WITH ONE OR MORE EVENTS	2 (0.6)	3 (0.6)	5 (0.6)
呼吸器、胸郭および縦隔障害			
喘息	0	2 (0.4)	2 (0.2)
SUBJECTS WITH ONE OR MORE EVENTS	0	2 (0.4)	2 (0.2)

表 2.7.4.7-54. 血管浮腫 / アナフィラキシーを含むアレルギー反応（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 (%)
皮膚および皮下組織障害			
血管浮腫	0	1 (0.2)	1 (0.1)
全身性そう痒症	0	1 (0.2)	1 (0.1)
発疹	1 (0.3)	0	1 (0.1)
蕁麻疹	1 (0.3)	0	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.

Cross reference: M14-033 Induction Main-study Final CSR Table 14.3__2.4.20

表 2.7.4.7-55. 血管浮腫 / アナフィラキシーを含むアレルギー反応（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----------			----INTEGRATED SAFETY SET-----			----------SAFETY SET----------		
	----------ADALIMUMAB----------			----------ADALIMUMAB----------			----------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	1 (2.6)	1 (1.6)	2 (2.0)	6 (1.6)	9 (1.6)	15 (1.6)	5 (1.5)	8 (1.6)	13 (1.5)
一般・全身障害および投与部位の状態									
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)
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)
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)
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)	2 (0.5)	4 (0.7)	6 (0.6)	2 (0.6)	3 (0.6)	5 (0.6)
呼吸器、胸郭および縦隔障害									
喘息	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	0	2 (0.3)	2 (0.2)	0	2 (0.4)	2 (0.2)

表 2.7.4.7-55. 血管浮腫 / アナフィラキシーを含むアレルギー反応（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----------			----INTEGRATED SAFETY SET-----			----------SAFETY SET----------		
	----------ADALIMUMAB----------			----------ADALIMUMAB----------			----------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									
血管浮腫	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
全身性そう痒症	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
発疹	0	0	0	1 (0.3)	0	1 (0.1)	1 (0.3)	0	1 (0.1)
蕁麻疹	1 (2.6)	0	1 (1.0)	2 (0.5)	0	2 (0.2)	1 (0.3)	0	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.6)	0	1 (1.0)	3 (0.8)	2 (0.3)	5 (0.5)	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.

Cross reference: M14-033 Induction Japan Sub-study Final CSR Table 14.3__2.4.3_J

表 2.7.4.7-56. 血管浮腫 / アナフィラキシーを含むアレルギー反応（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	4 (1.3)	6 (2.0)	0	10 (1.3)
眼障害	0	1 (0.3)	0	1 (0.1)
眼瞼腫脹	0	1 (0.3)	0	1 (0.1)
呼吸器、胸郭および縦隔障害	1 (0.3)	1 (0.3)	0	2 (0.3)
喘息	1 (0.3)	0	0	1 (0.1)
喘鳴	0	1 (0.3)	0	1 (0.1)
皮膚および皮下組織障害	3 (1.0)	4 (1.3)	0	7 (0.9)
血管浮腫	0	1 (0.3)	0	1 (0.1)
薬疹	0	1 (0.3)	0	1 (0.1)
発疹	2 (0.7)	0	0	2 (0.3)
蕁麻疹	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.

Cross reference: M14-033 Maintenance Main-study Final CSR Table 14.3__2.4.20

表 2.7.4.7-57. 血管浮腫 / アナフィラキシーを含むアレルギー反応（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	0	1 (2.2)	1 (1.1)	4 (1.2)	7 (2.0)	0	11 (1.3)
眼障害	0	0	0	0	1 (0.3)	0	1 (0.1)
眼瞼腫脹	0	0	0	0	1 (0.3)	0	1 (0.1)
呼吸器、胸郭および縦隔障害	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.2)
喘息	0	0	0	1 (0.3)	0	0	1 (0.1)
喘鳴	0	0	0	0	1 (0.3)	0	1 (0.1)
皮膚および皮下組織障害	0	1 (2.2)	1 (1.1)	3 (0.9)	5 (1.4)	0	8 (0.9)
血管浮腫	0	0	0	0	1 (0.3)	0	1 (0.1)
薬疹	0	0	0	0	1 (0.3)	0	1 (0.1)
発疹	0	0	0	2 (0.6)	0	0	2 (0.2)
蕁麻疹	0	1 (2.2)	1 (1.1)	1 (0.3)	3 (0.9)	0	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 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__2.4.12_J

表 2.7.4.7-58. ループス様反応及び全身性エリテマトーデス（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	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)
筋骨格系および結合組織障害	0	1 (2.2)	1 (1.1)	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)

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.

Cross reference: M14-033 Maintenance Japan Sub-study Final CSR Table 14.3__2.4.13_J

表 2.7.4.7-59. 血管炎（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	0	1 (0.3)	1 (0.7)	2 (0.3)
皮膚および皮下組織障害	0	0	1 (0.7)	1 (0.1)
過敏性血管炎	0	0	1 (0.7)	1 (0.1)
血管障害	0	1 (0.3)	0	1 (0.1)
動脈炎	0	1 (0.3)	0	1 (0.1)

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.

Cross reference: M14-033 Maintenance Main-study Final CSR Table 14.3__2.4.22

表 2.7.4.7-60. 心筋梗塞に関連する事象（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	1 (0.3)	0	0	1 (0.1)
心臓障害	1 (0.3)	0	0	1 (0.1)
急性心筋梗塞	1 (0.3)	0	0	1 (0.1)

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.

Cross reference: M14-033 Maintenance Main-study Final CSR Table 14.3__2.4.26

表 2.7.4.7-61. 脳血管発作に関連する事象（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	0	0	1 (0.7)	1 (0.1)
神経系障害	0	0	1 (0.7)	1 (0.1)
虚血性脳卒中	0	0	1 (0.7)	1 (0.1)

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.

Cross reference: M14-033 Maintenance Main-study Final CSR Table 14.3__2.4.27

表 2.7.4.7-62. うっ血性心不全に関連する事象（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	1 (0.3)	0	0	1 (0.1)
心臓障害	1 (0.3)	0	0	1 (0.1)
うっ血性心不全	1 (0.3)	0	0	1 (0.1)

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.

Cross reference: M14-033 Maintenance Main-study Final CSR Table 14.3__2.4.28

表 2.7.4.7-63. 肺塞栓症に関連する事象（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	1 (0.3)	3 (1.0)	0	4 (0.5)
呼吸器、胸郭および縦隔障害	1 (0.3)	3 (1.0)	0	4 (0.5)
肺塞栓症	1 (0.3)	3 (1.0)	0	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 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__2.4.29

表 2.7.4.7-64.　膵炎（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）

	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 (%)
ANY ADVERSE EVENT	0	1 (0.2)	1 (0.1)
胃腸障害			
急性膵炎	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (0.2)	1 (0.1)

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.

Cross reference: M14-033 Induction Main-study Final CSR Table 14.3__2.4.32

表 2.7.4.7-65. 膵炎（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	1 (0.3)	0	0	1 (0.1)
胃腸障害	1 (0.3)	0	0	1 (0.1)
急性膵炎	1 (0.3)	0	0	1 (0.1)

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.

Cross reference: M14-033 Maintenance Main-study Final CSR Table 14.3__2.4.32

表 2.7.4.7-66. 乾癬の悪化又は新規発症（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）

	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 (%)
ANY ADVERSE EVENT	2 (0.6)	1 (0.2)	3 (0.4)
皮膚および皮下組織障害			
乾癬様皮膚炎	1 (0.3)	0	1 (0.1)
乾癬	1 (0.3)	1 (0.2)	2 (0.2)
SUBJECTS WITH ONE OR MORE EVENTS	2 (0.6)	1 (0.2)	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 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__2.4.35

表 2.7.4.7-67. 乾癬の悪化又は新規発症（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	2 (0.7)	1 (0.3)	1 (0.7)	4 (0.5)
皮膚および皮下組織障害	2 (0.7)	1 (0.3)	1 (0.7)	4 (0.5)
乾癬	2 (0.7)	1 (0.3)	1 (0.7)	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 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__2.4.35

表 2.7.4.7-68. 脱髄疾患（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	0	0	1 (0.7)	1 (0.1)
神経系障害	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)

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.

Cross reference: M14-033 Maintenance Main-study Final CSR Table 14.3__2.4.36

表 2.7.4.7-69. 汎血球減少症を含む血液障害（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）

	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 (%)
ANY ADVERSE EVENT	16 (4.7)	22 (4.3)	38 (4.5)
血液およびリンパ系障害			
貧血	13 (3.8)	16 (3.1)	29 (3.4)
白血球減少症	1 (0.3)	3 (0.6)	4 (0.5)
リンパ球減少症	1 (0.3)	1 (0.2)	2 (0.2)
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	16 (4.7)	22 (4.3)	38 (4.5)

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.

Cross reference: M14-033 Induction Main-study Final CSR Table 14.3__2.4.39

表 2.7.4.7-70. 汎血球減少症を含む血液障害（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----------			----INTEGRATED SAFETY SET-----			----------SAFETY SET----------		
	----------ADALIMUMAB----------			----------ADALIMUMAB----------			----------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	2 (5.1)	4 (6.6)	6 (6.0)	18 (4.7)	26 (4.5)	44 (4.6)	16 (4.7)	22 (4.3)	38 (4.5)
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)
大球性貧血	0	1 (1.6)	1 (1.0)	0	1 (0.2)	1 (0.1)	0	0	0
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)
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)
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	2 (5.1)	4 (6.6)	6 (6.0)	18 (4.7)	26 (4.5)	44 (4.6)	16 (4.7)	22 (4.3)	38 (4.5)

表 2.7.4.7-70.　汎血球減少症を含む血液障害（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）

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.

Cross reference: M14-033 Induction Japan Sub-study Final CSR Table 14.3__2.4.4_J

表 2.7.4.7-71. 汎血球減少症を含む血液障害（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	14 (4.6)	17 (5.6)	8 (5.3)	39 (5.2)
血液およびリンパ系障害	14 (4.6)	17 (5.6)	8 (5.3)	39 (5.2)
貧血	12 (4.0)	13 (4.3)	5 (3.3)	30 (4.0)
白血球減少症	1 (0.3)	4 (1.3)	0	5 (0.7)
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)

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.

Cross reference: M14-033 Maintenance Main-study Final CSR Table 14.3__2.4.39

表 2.7.4.7-72. 汎血球減少症を含む血液障害（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	3 (7.0)	6 (13.0)	9 (10.1)	17 (4.9)	23 (6.6)	8 (5.3)	48 (5.7)
血液およびリンパ系障害	3 (7.0)	6 (13.0)	9 (10.1)	17 (4.9)	23 (6.6)	8 (5.3)	48 (5.7)
貧血	3 (7.0)	5 (10.9)	8 (9.0)	15 (4.3)	18 (5.1)	5 (3.3)	38 (4.5)
白血球減少症	0	1 (2.2)	1 (1.1)	1 (0.3)	5 (1.4)	0	6 (0.7)
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)

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.

Cross reference: M14-033 Maintenance Japan Sub-study Final CSR Table 14.3__2.4.24_J

表 2.7.4.7-73. 肝不全及びその他の肝臓関連事象（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）

	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 (%)
ANY ADVERSE EVENT	0	2 (0.4)	2 (0.2)
肝胆道系障害			
脂肪肝	0	1 (0.2)	1 (0.1)
肝炎	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	0	2 (0.4)	2 (0.2)

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.

Cross reference: M14-033 Induction Main-study Final CSR Table 14.3__2.4.40

表 2.7.4.7-74. 肝不全及びその他の肝臓関連事象（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	1 (0.3)	1 (0.3)	0	2 (0.3)
肝胆道系障害	1 (0.3)	1 (0.3)	0	2 (0.3)
脂肪肝	0	1 (0.3)	0	1 (0.1)
非アルコール性脂肪性肝炎	1 (0.3)	0	0	1 (0.1)

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.

Cross reference: M14-033 Maintenance Main-study Final CSR Table 14.3__2.4.40

表 2.7.4.7-75. 肝不全及びその他の肝臓関連事象（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 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 (%)
Any Adverse Event	1 (2.3)	1 (2.2)	2 (2.2)	2 (0.6)	2 (0.6)	0	4 (0.5)
肝胆道系障害	1 (2.3)	1 (2.2)	2 (2.2)	2 (0.6)	2 (0.6)	0	4 (0.5)
肝機能異常	0	1 (2.2)	1 (1.1)	0	1 (0.3)	0	1 (0.1)
脂肪肝	0	0	0	0	1 (0.3)	0	1 (0.1)
肝胆道系疾患	1 (2.3)	0	1 (1.1)	1 (0.3)	0	0	1 (0.1)
非アルコール性脂肪性肝炎	0	0	0	1 (0.3)	0	0	1 (0.1)

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.

Cross reference: M14-033 Maintenance Japan Sub-study Final CSR Table 14.3__2.4.25_J

表 2.7.4.7-76. 注射部位反応（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	13 (3.8)	62 (12.1)	75 (8.8)
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)
注射部位内出血	3 (0.9)	4 (0.8)	7 (0.8)
注射部位紅斑	2 (0.6)	14 (2.7)	16 (1.9)
注射部位血腫	0	1 (0.2)	1 (0.1)
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)
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)
SUBJECTS WITH ONE OR MORE EVENTS	13 (3.8)	61 (11.9)	74 (8.7)

表 2.7.4.7-76. 注射部位反応（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			
注射に伴う反応	0	1 (0.2)	1 (0.1)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (0.2)	1 (0.1)

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.

Cross reference: M14-033 Induction Main-study Final CSR Table 14.3__2.4.42

表 2.7.4.7-77. 注射部位反応（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----------			----INTEGRATED SAFETY SET-----			----------SAFETY SET----------		
	----------ADALIMUMAB----------			----------ADALIMUMAB----------			----------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	3 (7.7)	7 (11.5)	10 (10.0)	16 (4.2)	69 (12.0)	85 (8.9)	13 (3.8)	62 (12.1)	75 (8.8)
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)
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)
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)
注射部位血腫	0	0	0	0	1 (0.2)	1 (0.1)	0	1 (0.2)	1 (0.1)
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)
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)	6 (9.8)	8 (8.0)	3 (0.8)	25 (4.4)	28 (2.9)	1 (0.3)	19 (3.7)	20 (2.3)

表 2.7.4.7-77. 注射部位反応（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----------			----INTEGRATED SAFETY SET-----			----------SAFETY SET----------		
	----------ADALIMUMAB----------			----------ADALIMUMAB----------			----------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)
SUBJECTS WITH ONE OR MORE EVENTS	3 (7.7)	6 (9.8)	9 (9.0)	16 (4.2)	67 (11.7)	83 (8.7)	13 (3.8)	61 (11.9)	74 (8.7)
傷害、中毒および処置合併症									
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	2 (0.3)	2 (0.2)	0	1 (0.2)	1 (0.1)

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.

Cross reference: M14-033 Induction Japan Sub-study Final CSR Table 14.3__2.4.5_J

表 2.7.4.7-78. 注射部位反応（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	8 (2.6)	14 (4.6)	5 (3.3)	27 (3.6)
一般・全身障害および投与部位の状態	8 (2.6)	14 (4.6)	4 (2.6)	26 (3.4)
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)	2 (0.7)	0	4 (0.5)
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)
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)

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.

Cross reference: M14-033 Maintenance Main-study Final CSR Table 14.3__2.4.42

表 2.7.4.7-79. 注射部位反応（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	0	2 (4.3)	2 (2.2)	8 (2.3)	16 (4.6)	5 (3.3)	29 (3.4)
一般・全身障害および投与部位の状態	0	1 (2.2)	1 (1.1)	8 (2.3)	15 (4.3)	4 (2.6)	27 (3.2)
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)	2 (0.6)	0	4 (0.5)
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)
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)

表 2.7.4.7-79.　注射部位反応（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）

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.

Cross reference: M14-033 Maintenance Japan Sub-study Final CSR Table 14.3__2.4.26_J

表 2.7.4.7-80. 性別の有害事象の概要（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）

	Male			Female		
	Adalimumab			Adalimumab		
	Standard Induction Dose (N=213) n (%)	Higher Induction Dose (N=334) n (%)	Total (N=547) n (%)	Standard Induction Dose (N=166) n (%)	Higher Induction Dose (N=239) n (%)	Total (N=405) n (%)
Subjects with:						
Any adverse event (AE)	106 (49.8)	168 (50.3)	274 (50.1)	94 (56.6)	137 (57.3)	231 (57.0)
Any AE with reasonable possibility of being related to study drug$	32 (15.0)	70 (21.0)	102 (18.6)	51 (30.7)	79 (33.1)	130 (32.1)
Any severe AE	9 (4.2)	15 (4.5)	24 (4.4)	8 (4.8)	9 (3.8)	17 (4.2)
Any serious AE	12 (5.6)	16 (4.8)	28 (5.1)	7 (4.2)	6 (2.5)	13 (3.2)
Any AE leading to discontinuation of study drug	14 (6.6)	23 (6.9)	37 (6.8)	8 (4.8)	8 (3.3)	16 (4.0)
Any AE leading to death	0	1 (0.3)	1 (0.2)	0	0	0
Any infection	27 (12.7)	44 (13.2)	71 (13.0)	35 (21.1)	39 (16.3)	74 (18.3)
Any serious infection	2 (0.9)	3 (0.9)	5 (0.9)	1 (0.6)	1 (0.4)	2 (0.5)
Any legionella infection	0	0	0	0	0	0
Any diverticulitis infection	0	0	0	0	0	0
Any opportunistic INF. EXCL. oral candidiasis and TB	1 (0.5)	1 (0.3)	2 (0.4)	0	0	0
Any oral candidiasis	0	0	0	0	0	0
Any tuberculosis	0	0	0	0	1 (0.4)	1 (0.2)
Any active tuberculosis	0	0	0	0	1 (0.4)	1 (0.2)
Any latent tuberculosis	0	0	0	0	0	0
Any parasitic infection	0	1 (0.3)	1 (0.2)	0	0	0
Any reactivation of hepatitis B	0	0	0	0	0	0
Any progressive multifocal leukoencephalopathy (PML)	0	0	0	0	0	0

表 2.7.4.7-80. 性別の有害事象の概要（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）（続き）

	Male			Female		
	Adalimumab			Adalimumab		
	Standard Induction Dose (N=213) n (%)	Higher Induction Dose (N=334) n (%)	Total (N=547) n (%)	Standard Induction Dose (N=166) n (%)	Higher Induction Dose (N=239) n (%)	Total (N=405) n (%)
Any malignancy	0	0	0	3 (1.8)	0	3 (0.7)
Any lymphoma	0	0	0	0	0	0
Any hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0	0	0
Any non-melanoma skin cancer (NMSC)	0	0	0	1 (0.6)	0	1 (0.2)
Any melanoma	0	0	0	1 (0.6)	0	1 (0.2)
Any leukemia	0	0	0	0	0	0
Any malignancy other than NMSC, melanoma, lymphoma, HSTCL, and leukemia	0	0	0	1 (0.6)	0	1 (0.2)
Any allergic reaction (including angioedema/anaphylaxis)	1 (0.5)	1 (0.3)	2 (0.4)	5 (3.0)	8 (3.3)	13 (3.2)
Any lupus-like reactions and systemic lupus erythematosus	0	0	0	0	0	0
Any vasculitis	0	0	0	0	0	0
Any cutaneous vasculitis	0	0	0	0	0	0
Any non-cutaneous vasculitis	0	0	0	0	0	0
Any sarcoidosis	0	0	0	0	0	0
Any autoimmune hepatitis	0	0	0	0	0	0
Any myocardial infarction related	0	0	0	0	0	0
Any cerebrovascular accident related	0	0	0	0	0	0
Any congestive heart failure related	0	0	0	0	0	0
Any pulmonary embolism related	0	0	0	0	0	0

表 2.7.4.7-80. 性別の有害事象の概要（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）（続き）

	Male			Female		
	Adalimumab			Adalimumab		
	Standard Induction Dose (N=213) n (%)	Higher Induction Dose (N=334) n (%)	Total (N=547) n (%)	Standard Induction Dose (N=166) n (%)	Higher Induction Dose (N=239) n (%)	Total (N=405) n (%)
Any interstitial lung disease	0	0	0	0	0	0
Any intestinal perforation	0	0	0	0	0	0
Any pancreatitis	0	0	0	0	1 (0.4)	1 (0.2)
Any stevens-johnson syndrome	0	0	0	0	0	0
Any erythema multiforme related	0	0	0	0	0	0
Any worsening/new onset of psoriasis	0	0	0	2 (1.2)	1 (0.4)	3 (0.7)
Any demyelinating disorder	0	0	0	0	0	0
Any amyotrophic lateral sclerosis	0	0	0	0	0	0
Any reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0	0	0
Any hematologic disorders (including pancytopenia)	10 (4.7)	11 (3.3)	21 (3.8)	8 (4.8)	15 (6.3)	23 (5.7)
Any liver failure and other liver event (except gall bladder related)	0	1 (0.3)	1 (0.2)	0	1 (0.4)	1 (0.2)
Any humira administration related medication errors	0	0	0	0	0	0
Any injection site reaction	7 (3.3)	30 (9.0)	37 (6.8)	9 (5.4)	39 (16.3)	48 (11.9)
All deaths	0	2 (0.6)	2 (0.4)	0	0	0
Occurring <=70 days after last dose	0	1 (0.3)	1 (0.2)	0	0	0
Occurring >70 days after last dose	0	1 (0.3)	1 (0.2)	0	0	0

表 2.7.4.7-80.　　性別の有害事象の概要（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）（続き）

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. Event with unknown severity is being counted as severe. Event with unknown relationship to study drug is being counted as drug-related.
$ As assessed by investigator.

Cross reference: 追加解析レポート JCSS TABLE 2.7.4__1.5.1_J

表 2.7.4.7-81. 年齢区分別の有害事象の概要（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）

	<= 38 years			> 38 years		
	Adalimumab			Adalimumab		
	Standard Induction Dose (N=186) n (%)	Higher Induction Dose (N=277) n (%)	Total (N=463) n (%)	Standard Induction Dose (N=193) n (%)	Higher Induction Dose (N=296) n (%)	Total (N=489) n (%)
Subjects with:						
Any adverse event (AE)	105 (56.5)	140 (50.5)	245 (52.9)	95 (49.2)	165 (55.7)	260 (53.2)
Any AE with reasonable possibility of being related to study drug$	38 (20.4)	69 (24.9)	107 (23.1)	45 (23.3)	80 (27.0)	125 (25.6)
Any severe AE	10 (5.4)	11 (4.0)	21 (4.5)	7 (3.6)	13 (4.4)	20 (4.1)
Any serious AE	8 (4.3)	13 (4.7)	21 (4.5)	11 (5.7)	9 (3.0)	20 (4.1)
Any AE leading to discontinuation of study drug	10 (5.4)	17 (6.1)	27 (5.8)	12 (6.2)	14 (4.7)	26 (5.3)
Any AE leading to death	0	1 (0.4)	1 (0.2)	0	0	0
Any infection	37 (19.9)	38 (13.7)	75 (16.2)	25 (13.0)	45 (15.2)	70 (14.3)
Any serious infection	1 (0.5)	2 (0.7)	3 (0.6)	2 (1.0)	2 (0.7)	4 (0.8)
Any legionella infection	0	0	0	0	0	0
Any diverticulitis infection	0	0	0	0	0	0
Any opportunistic INF. EXCL. oral candidiasis and TB	0	0	0	1 (0.5)	1 (0.3)	2 (0.4)
Any oral candidiasis	0	0	0	0	0	0
Any tuberculosis	0	0	0	0	1 (0.3)	1 (0.2)
Any active tuberculosis	0	0	0	0	1 (0.3)	1 (0.2)
Any latent tuberculosis	0	0	0	0	0	0
Any parasitic infection	0	0	0	0	1 (0.3)	1 (0.2)
Any reactivation of hepatitis B	0	0	0	0	0	0
Any progressive multifocal leukoencephalopathy (PML)	0	0	0	0	0	0

表 2.7.4.7-81. 年齢区分別の有害事象の概要（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）（続き）

	<= 38 years			> 38 years		
	Adalimumab			Adalimumab		
	Standard Induction Dose (N=186) n (%)	Higher Induction Dose (N=277) n (%)	Total (N=463) n (%)	Standard Induction Dose (N=193) n (%)	Higher Induction Dose (N=296) n (%)	Total (N=489) n (%)
Any malignancy	1 (0.5)	0	1 (0.2)	2 (1.0)	0	2 (0.4)
Any lymphoma	0	0	0	0	0	0
Any hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0	0	0
Any non-melanoma skin cancer (NMSC)	0	0	0	1 (0.5)	0	1 (0.2)
Any melanoma	0	0	0	1 (0.5)	0	1 (0.2)
Any leukemia	0	0	0	0	0	0
Any malignancy other than NMSC, melanoma, lymphoma, HSTCL, and leukemia	1 (0.5)	0	1 (0.2)	0	0	0
Any allergic reaction (including angioedema/anaphylaxis)	3 (1.6)	5 (1.8)	8 (1.7)	3 (1.6)	4 (1.4)	7 (1.4)
Any lupus-like reactions and systemic lupus erythematosus	0	0	0	0	0	0
Any vasculitis	0	0	0	0	0	0
Any cutaneous vasculitis	0	0	0	0	0	0
Any non-cutaneous vasculitis	0	0	0	0	0	0
Any sarcoidosis	0	0	0	0	0	0
Any autoimmune hepatitis	0	0	0	0	0	0
Any myocardial infarction related	0	0	0	0	0	0
Any cerebrovascular accident related	0	0	0	0	0	0
Any congestive heart failure related	0	0	0	0	0	0
Any pulmonary embolism related	0	0	0	0	0	0

表 2.7.4.7-81. 年齢区分別の有害事象の概要（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）（続き）

	<= 38 years			> 38 years		
	Adalimumab			Adalimumab		
	Standard Induction Dose (N=186) n (%)	Higher Induction Dose (N=277) n (%)	Total (N=463) n (%)	Standard Induction Dose (N=193) n (%)	Higher Induction Dose (N=296) n (%)	Total (N=489) n (%)
Any interstitial lung disease	0	0	0	0	0	0
Any intestinal perforation	0	0	0	0	0	0
Any pancreatitis	0	1 (0.4)	1 (0.2)	0	0	0
Any stevens-johnson syndrome	0	0	0	0	0	0
Any erythema multiforme related	0	0	0	0	0	0
Any worsening/new onset of psoriasis	0	1 (0.4)	1 (0.2)	2 (1.0)	0	2 (0.4)
Any demyelinating disorder	0	0	0	0	0	0
Any amyotrophic lateral sclerosis	0	0	0	0	0	0
Any reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0	0	0
Any hematologic disorders (including pancytopenia)	8 (4.3)	10 (3.6)	18 (3.9)	10 (5.2)	16 (5.4)	26 (5.3)
Any liver failure and other liver event (except gall bladder related)	0	2 (0.7)	2 (0.4)	0	0	0
Any humira administration related medication errors	0	0	0	0	0	0
Any injection site reaction	7 (3.8)	35 (12.6)	42 (9.1)	9 (4.7)	34 (11.5)	43 (8.8)
All deaths	0	1 (0.4)	1 (0.2)	0	1 (0.3)	1 (0.2)
Occurring <=70 days after last dose	0	1 (0.4)	1 (0.2)	0	0	0
Occurring >70 days after last dose	0	0	0	0	1 (0.3)	1 (0.2)

表 2.7.4.7-81.　　年齢区分別の有害事象の概要（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）（続き）

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. Event with unknown severity is being counted as severe. Event with unknown relationship to study drug is being counted as drug-related.
$ As assessed by investigator.

Cross reference: 追加解析レポート JCSS TABLE 2.7.4__1.5.2_J

表 2.7.4.7-82. 人種別の有害事象の概要（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）

	White			Non-White			Missing
	Adalimumab			Adalimumab			Adalimumab
	Standard Induction Dose (N=327) n (%)	Higher Induction Dose (N=484) n (%)	Total (N=811) n (%)	Standard Induction Dose (N=52) n (%)	Higher Induction Dose (N=88) n (%)	Total (N=140) n (%)	Higher Induction Dose (N=1) n (%)
Subjects with:							
Any adverse event (AE)	179 (54.7)	253 (52.3)	432 (53.3)	21 (40.4)	51 (58.0)	72 (51.4)	1 (100)
Any AE with reasonable possibility of being related to study drug$	75 (22.9)	132 (27.3)	207 (25.5)	8 (15.4)	17 (19.3)	25 (17.9)	0
Any severe AE	16 (4.9)	21 (4.3)	37 (4.6)	1 (1.9)	3 (3.4)	4 (2.9)	0
Any serious AE	17 (5.2)	18 (3.7)	35 (4.3)	2 (3.8)	4 (4.5)	6 (4.3)	0
Any AE leading to discontinuation of study drug	18 (5.5)	28 (5.8)	46 (5.7)	4 (7.7)	3 (3.4)	7 (5.0)	0
Any AE leading to death	0	1 (0.2)	1 (0.1)	0	0	0	0
Any infection	55 (16.8)	64 (13.2)	119 (14.7)	7 (13.5)	19 (21.6)	26 (18.6)	0
Any serious infection	2 (0.6)	3 (0.6)	5 (0.6)	1 (1.9)	1 (1.1)	2 (1.4)	0
Any legionella infection	0	0	0	0	0	0	0
Any diverticulitis infection	0	0	0	0	0	0	0
Any opportunistic INF. EXCL. oral candidiasis and TB	1 (0.3)	1 (0.2)	2 (0.2)	0	0	0	0
Any oral candidiasis	0	0	0	0	0	0	0
Any tuberculosis	0	1 (0.2)	1 (0.1)	0	0	0	0
Any active tuberculosis	0	1 (0.2)	1 (0.1)	0	0	0	0
Any latent tuberculosis	0	0	0	0	0	0	0
Any parasitic infection	0	1 (0.2)	1 (0.1)	0	0	0	0
Any reactivation of hepatitis B	0	0	0	0	0	0	0
Any progressive multifocal leukoencephalopathy (PML)	0	0	0	0	0	0	0

表 2.7.4.7-82. 人種別の有害事象の概要（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）（続き）

	White			Non-White			Missing
	Adalimumab			Adalimumab			Adalimumab
	Standard Induction Dose (N=327) n (%)	Higher Induction Dose (N=484) n (%)	Total (N=811) n (%)	Standard Induction Dose (N=52) n (%)	Higher Induction Dose (N=88) n (%)	Total (N=140) n (%)	Higher Induction Dose (N=1) n (%)
Any malignancy	3 (0.9)	0	3 (0.4)	0	0	0	0
Any lymphoma	0	0	0	0	0	0	0
Any hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0	0	0	0
Any non-melanoma skin cancer (NMSC)	1 (0.3)	0	1 (0.1)	0	0	0	0
Any melanoma	1 (0.3)	0	1 (0.1)	0	0	0	0
Any leukemia	0	0	0	0	0	0	0
Any malignancy other than NMSC, melanoma, lymphoma, HSTCL, and leukemia	1 (0.3)	0	1 (0.1)	0	0	0	0
Any allergic reaction (including angioedema/anaphylaxis)	5 (1.5)	8 (1.7)	13 (1.6)	1 (1.9)	1 (1.1)	2 (1.4)	0
Any lupus-like reactions and systemic lupus erythematosus	0	0	0	0	0	0	0
Any vasculitis	0	0	0	0	0	0	0
Any cutaneous vasculitis	0	0	0	0	0	0	0
Any non-cutaneous vasculitis	0	0	0	0	0	0	0
Any sarcoidosis	0	0	0	0	0	0	0
Any autoimmune hepatitis	0	0	0	0	0	0	0
Any myocardial infarction related	0	0	0	0	0	0	0
Any cerebrovascular accident related	0	0	0	0	0	0	0
Any congestive heart failure related	0	0	0	0	0	0	0
Any pulmonary embolism related	0	0	0	0	0	0	0

表 2.7.4.7-82. 人種別の有害事象の概要（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）（続き）

	White			Non-White			-- Missing --
	Adalimumab			Adalimumab			Adalimumab
	Standard Induction Dose (N=327) n (%)	Higher Induction Dose (N=484) n (%)	Total (N=811) n (%)	Standard Induction Dose (N=52) n (%)	Higher Induction Dose (N=88) n (%)	Total (N=140) n (%)	Higher Induction Dose (N=1) n (%)
Any interstitial lung disease	0	0	0	0	0	0	0
Any intestinal perforation	0	0	0	0	0	0	0
Any pancreatitis	0	1 (0.2)	1 (0.1)	0	0	0	0
Any stevens-johnson syndrome	0	0	0	0	0	0	0
Any erythema multiforme related	0	0	0	0	0	0	0
Any worsening/new onset of psoriasis	2 (0.6)	1 (0.2)	3 (0.4)	0	0	0	0
Any demyelinating disorder	0	0	0	0	0	0	0
Any amyotrophic lateral sclerosis	0	0	0	0	0	0	0
Any reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0	0	0	0
Any hematologic disorders (including pancytopenia)	15 (4.6)	21 (4.3)	36 (4.4)	3 (5.8)	5 (5.7)	8 (5.7)	0
Any liver failure and other liver event (except gall bladder related)	0	2 (0.4)	2 (0.2)	0	0	0	0
Any humira administration related medication errors	0	0	0	0	0	0	0
Any injection site reaction	13 (4.0)	60 (12.4)	73 (9.0)	3 (5.8)	9 (10.2)	12 (8.6)	0
All deaths	0	2 (0.4)	2 (0.2)	0	0	0	0
Occurring <=70 days after last dose	0	1 (0.2)	1 (0.1)	0	0	0	0
Occurring >70 days after last dose	0	1 (0.2)	1 (0.1)	0	0	0	0

表 2.7.4.7-82.　人種別の有害事象の概要（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）（続き）

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. Event with unknown severity is being counted as severe. Event with unknown relationship to study drug is being counted as drug-related.
$ As assessed by investigator.

Cross reference: 追加解析レポート JCSS TABLE 2.7.4__1.5.3_J

表 2.7.4.7-83.　体重区分別の有害事象の概要（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）

	<= 73 kg			> 73 kg		
	Adalimumab			Adalimumab		
	Standard Induction Dose (N=202) n (%)	Higher Induction Dose (N=292) n (%)	Total (N=494) n (%)	Standard Induction Dose (N=177) n (%)	Higher Induction Dose (N=281) n (%)	Total (N=458) n (%)
Subjects with:						
Any adverse event (AE)	107 (53.0)	156 (53.4)	263 (53.2)	93 (52.5)	149 (53.0)	242 (52.8)
Any AE with reasonable possibility of being related to study drug$	44 (21.8)	86 (29.5)	130 (26.3)	39 (22.0)	63 (22.4)	102 (22.3)
Any severe AE	11 (5.4)	14 (4.8)	25 (5.1)	6 (3.4)	10 (3.6)	16 (3.5)
Any serious AE	11 (5.4)	9 (3.1)	20 (4.0)	8 (4.5)	13 (4.6)	21 (4.6)
Any AE leading to discontinuation of study drug	16 (7.9)	15 (5.1)	31 (6.3)	6 (3.4)	16 (5.7)	22 (4.8)
Any AE leading to death	0	0	0	0	1 (0.4)	1 (0.2)
Any infection	30 (14.9)	46 (15.8)	76 (15.4)	32 (18.1)	37 (13.2)	69 (15.1)
Any serious infection	2 (1.0)	1 (0.3)	3 (0.6)	1 (0.6)	3 (1.1)	4 (0.9)
Any legionella infection	0	0	0	0	0	0
Any diverticulitis infection	0	0	0	0	0	0
Any opportunistic INF. EXCL. oral candidiasis and TB	1 (0.5)	0	1 (0.2)	0	1 (0.4)	1 (0.2)
Any oral candidiasis	0	0	0	0	0	0
Any tuberculosis	0	1 (0.3)	1 (0.2)	0	0	0
Any active tuberculosis	0	1 (0.3)	1 (0.2)	0	0	0
Any latent tuberculosis	0	0	0	0	0	0
Any parasitic infection	0	0	0	0	1 (0.4)	1 (0.2)
Any reactivation of hepatitis B	0	0	0	0	0	0
Any progressive multifocal leukoencephalopathy (PML)	0	0	0	0	0	0

表 2.7.4.7-83. 体重区分別の有害事象の概要（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）（続き）

	<= 73 kg			> 73 kg		
	Adalimumab			Adalimumab		
	Standard Induction Dose (N=202) n (%)	Higher Induction Dose (N=292) n (%)	Total (N=494) n (%)	Standard Induction Dose (N=177) n (%)	Higher Induction Dose (N=281) n (%)	Total (N=458) n (%)
Any malignancy	3 (1.5)	0	3 (0.6)	0	0	0
Any lymphoma	0	0	0	0	0	0
Any hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0	0	0
Any non-melanoma skin cancer (NMSC)	1 (0.5)	0	1 (0.2)	0	0	0
Any melanoma	1 (0.5)	0	1 (0.2)	0	0	0
Any leukemia	0	0	0	0	0	0
Any malignancy other than NMSC, melanoma, lymphoma, HSTCL, and leukemia	1 (0.5)	0	1 (0.2)	0	0	0
Any allergic reaction (including angioedema/anaphylaxis)	3 (1.5)	6 (2.1)	9 (1.8)	3 (1.7)	3 (1.1)	6 (1.3)
Any lupus-like reactions and systemic lupus erythematosus	0	0	0	0	0	0
Any vasculitis	0	0	0	0	0	0
Any cutaneous vasculitis	0	0	0	0	0	0
Any non-cutaneous vasculitis	0	0	0	0	0	0
Any sarcoidosis	0	0	0	0	0	0
Any autoimmune hepatitis	0	0	0	0	0	0
Any myocardial infarction related	0	0	0	0	0	0
Any cerebrovascular accident related	0	0	0	0	0	0
Any congestive heart failure related	0	0	0	0	0	0
Any pulmonary embolism related	0	0	0	0	0	0

表 2.7.4.7-83. 体重区分別の有害事象の概要（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）（続き）

	<= 73 kg			> 73 kg		
	Adalimumab			Adalimumab		
	Standard Induction Dose (N=202) n (%)	Higher Induction Dose (N=292) n (%)	Total (N=494) n (%)	Standard Induction Dose (N=177) n (%)	Higher Induction Dose (N=281) n (%)	Total (N=458) n (%)
Any interstitial lung disease	0	0	0	0	0	0
Any intestinal perforation	0	0	0	0	0	0
Any pancreatitis	0	1 (0.3)	1 (0.2)	0	0	0
Any stevens-johnson syndrome	0	0	0	0	0	0
Any erythema multiforme related	0	0	0	0	0	0
Any worsening/new onset of psoriasis	1 (0.5)	1 (0.3)	2 (0.4)	1 (0.6)	0	1 (0.2)
Any demyelinating disorder	0	0	0	0	0	0
Any amyotrophic lateral sclerosis	0	0	0	0	0	0
Any reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0	0	0
Any hematologic disorders (including pancytopenia)	10 (5.0)	19 (6.5)	29 (5.9)	8 (4.5)	7 (2.5)	15 (3.3)
Any liver failure and other liver event (except gall bladder related)	0	1 (0.3)	1 (0.2)	0	1 (0.4)	1 (0.2)
Any humira administration related medication errors	0	0	0	0	0	0
Any injection site reaction	8 (4.0)	41 (14.0)	49 (9.9)	8 (4.5)	28 (10.0)	36 (7.9)
All deaths	0	1 (0.3)	1 (0.2)	0	1 (0.4)	1 (0.2)
Occurring <=70 days after last dose	0	0	0	0	1 (0.4)	1 (0.2)
Occurring >70 days after last dose	0	1 (0.3)	1 (0.2)	0	0	0

表 2.7.4.7-83.　　体重区分別の有害事象の概要（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）（続き）

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. Event with unknown severity is being counted as severe. Event with unknown relationship to study drug is being counted as drug-related.
$ As assessed by investigator.

Cross reference: 追加解析レポート JCSS TABLE 2.7.4__1.5.4_J

表 2.7.4.7-84.　性別の有害事象の概要（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）

	Male				Female			
	Adalimumab				Adalimumab			
	40mg EOW (N=198) n (%)	40mg EW (N=200) n (%)	TDM Regimen (N=81) n (%)	Total (N=479) n (%)	40mg EOW (N=147) n (%)	40mg EW (N=150) n (%)	TDM Regimen (N=70) n (%)	Total (N=367) n (%)
Subjects with:								
Any adverse event (AE)	141 (71.2)	147 (73.5)	54 (66.7)	342 (71.4)	116 (78.9)	116 (77.3)	42 (60.0)	274 (74.7)
Any AE with reasonable possibility of being related to study drug$	45 (22.7)	68 (34.0)	24 (29.6)	137 (28.6)	44 (29.9)	49 (32.7)	25 (35.7)	118 (32.2)
Any severe AE	18 (9.1)	23 (11.5)	5 (6.2)	46 (9.6)	11 (7.5)	18 (12.0)	5 (7.1)	34 (9.3)
Any serious AE	24 (12.1)	27 (13.5)	6 (7.4)	57 (11.9)	20 (13.6)	17 (11.3)	9 (12.9)	46 (12.5)
Any AE leading to discontinuation of study drug	20 (10.1)	21 (10.5)	6 (7.4)	47 (9.8)	20 (13.6)	14 (9.3)	11 (15.7)	45 (12.3)
Any AE leading to death	1 (0.5)	2 (1.0)	0	3 (0.6)	1 (0.7)	0	0	1 (0.3)
Any infection	69 (34.8)	74 (37.0)	32 (39.5)	175 (36.5)	63 (42.9)	56 (37.3)	19 (27.1)	138 (37.6)
Any serious infection	8 (4.0)	6 (3.0)	2 (2.5)	16 (3.3)	3 (2.0)	3 (2.0)	1 (1.4)	7 (1.9)
Any legionella infection	0	0	0	0	0	0	0	0
Any diverticulitis infection	0	0	0	0	0	1 (0.7)	0	1 (0.3)
Any opportunistic INF. EXCL. oral candidiasis and TB	0	0	0	0	0	0	0	0
Any oral candidiasis	2 (1.0)	0	0	2 (0.4)	0	1 (0.7)	1 (1.4)	2 (0.5)
Any tuberculosis	0	1 (0.5)	0	1 (0.2)	0	1 (0.7)	1 (1.4)	2 (0.5)
Any active tuberculosis	0	1 (0.5)	0	1 (0.2)	0	1 (0.7)	1 (1.4)	2 (0.5)
Any latent tuberculosis	0	0	0	0	0	0	0	0
Any parasitic infection	0	1 (0.5)	0	1 (0.2)	0	1 (0.7)	1 (1.4)	2 (0.5)
Any reactivation of hepatitis B	0	0	0	0	0	0	0	0
Any progressive multifocal leukoencephalopathy (PML)	0	0	0	0	0	0	0	0

表 2.7.4.7-84. 性別の有害事象の概要（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）

	Male				Female			
	Adalimumab				Adalimumab			
	40mg EOW (N=198) n (%)	40mg EW (N=200) n (%)	TDM Regimen (N=81) n (%)	Total (N=479) n (%)	40mg EOW (N=147) n (%)	40mg EW (N=150) n (%)	TDM Regimen (N=70) n (%)	Total (N=367) n (%)
Any malignancy	2 (1.0)	3 (1.5)	0	5 (1.0)	0	1 (0.7)	0	1 (0.3)
Any lymphoma	0	0	0	0	0	0	0	0
Any hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0	0	0	0	0
Any non-melanoma skin cancer (NMSC)	1 (0.5)	0	0	1 (0.2)	0	1 (0.7)	0	1 (0.3)
Any melanoma	0	1 (0.5)	0	1 (0.2)	0	0	0	0
Any leukemia	0	0	0	0	0	0	0	0
Any malignancy other than NMSC, melanoma, lymphoma, HSTCL, and leukemia	1 (0.5)	2 (1.0)	0	3 (0.6)	0	0	0	0
Any allergic reaction (including angioedema/anaphylaxis)	1 (0.5)	2 (1.0)	0	3 (0.6)	3 (2.0)	5 (3.3)	0	8 (2.2)
Any lupus-like reactions and systemic lupus erythematosus	0	1 (0.5)	0	1 (0.2)	0	0	0	0
Any vasculitis	0	1 (0.5)	1 (1.2)	2 (0.4)	0	0	0	0
Any cutaneous vasculitis	0	0	1 (1.2)	1 (0.2)	0	0	0	0
Any non-cutaneous vasculitis	0	1 (0.5)	0	1 (0.2)	0	0	0	0
Any sarcoidosis	0	0	0	0	0	0	0	0
Any autoimmune hepatitis	0	0	0	0	0	0	0	0
Any myocardial infarction related	1 (0.5)	0	0	1 (0.2)	0	0	0	0
Any cerebrovascular accident related	0	0	1 (1.2)	1 (0.2)	0	0	0	0
Any congestive heart failure related	1 (0.5)	0	0	1 (0.2)	0	0	0	0
Any pulmonary embolism related	0	1 (0.5)	0	1 (0.2)	1 (0.7)	2 (1.3)	0	3 (0.8)

表 2.7.4.7-84. 性別の有害事象の概要（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）

	Male				Female			
	Adalimumab				Adalimumab			
	40mg EOW (N=198) n (%)	40mg EW (N=200) n (%)	TDM Regimen (N=81) n (%)	Total (N=479) n (%)	40mg EOW (N=147) n (%)	40mg EW (N=150) n (%)	TDM Regimen (N=70) n (%)	Total (N=367) n (%)
Any interstitial lung disease	0	0	0	0	0	0	0	0
Any intestinal perforation	0	0	0	0	0	0	0	0
Any pancreatitis	1 (0.5)	0	0	1 (0.2)	0	0	0	0
Any stevens-johnson syndrome	0	0	0	0	0	0	0	0
Any erythema multiforme related	0	0	0	0	0	0	0	0
Any worsening/new onset of psoriasis	1 (0.5)	1 (0.5)	0	2 (0.4)	1 (0.7)	0	1 (1.4)	2 (0.5)
Any demyelinating disorder	0	0	0	0	0	0	1 (1.4)	1 (0.3)
Any amyotrophic lateral sclerosis	0	0	0	0	0	0	0	0
Any reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0	0	0	0	0
Any hematologic disorders (including pancytopenia)	9 (4.5)	11 (5.5)	5 (6.2)	25 (5.2)	8 (5.4)	12 (8.0)	3 (4.3)	23 (6.3)
Any liver failure and other liver event (except gall bladder related)	0	1 (0.5)	0	1 (0.2)	2 (1.4)	1 (0.7)	0	3 (0.8)
Any humira administration related medication errors	0	0	0	0	0	0	0	0
Any injection site reaction	4 (2.0)	7 (3.5)	2 (2.5)	13 (2.7)	4 (2.7)	9 (6.0)	3 (4.3)	16 (4.4)
All deaths	1 (0.5)	2 (1.0)	0	3 (0.6)	1 (0.7)	0	0	1 (0.3)
Occurring <=70 days after last dose	0	1 (0.5)	0	1 (0.2)	1 (0.7)	0	0	1 (0.3)
Occurring >70 days after last dose	1 (0.5)	1 (0.5)	0	2 (0.4)	0	0	0	0

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. Event with unknown severity is being counted as severe. Event with unknown relationship to study drug is being counted as drug-related.
$ As assessed by investigator.

Cross reference: 追加解析レポート JCSS TABLE 2.7.4__1.6.1_J

表 2.7.4.7-85. 年齢区分別の有害事象の概要（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）

	<= 38 years				> 38 years			
	Adalimumab				Adalimumab			
	40mg EOW (N=175) n (%)	40mg EW (N=159) n (%)	TDM Regimen (N=72) n (%)	Total (N=406) n (%)	40mg EOW (N=170) n (%)	40mg EW (N=191) n (%)	TDM Regimen (N=79) n (%)	Total (N=440) n (%)
Subjects with:								
Any adverse event (AE)	135 (77.1)	117 (73.6)	45 (62.5)	297 (73.2)	122 (71.8)	146 (76.4)	51 (64.6)	319 (72.5)
Any AE with reasonable possibility of being related to study drug$	39 (22.3)	48 (30.2)	23 (31.9)	110 (27.1)	50 (29.4)	69 (36.1)	26 (32.9)	145 (33.0)
Any severe AE	16 (9.1)	16 (10.1)	5 (6.9)	37 (9.1)	13 (7.6)	25 (13.1)	5 (6.3)	43 (9.8)
Any serious AE	23 (13.1)	19 (11.9)	7 (9.7)	49 (12.1)	21 (12.4)	25 (13.1)	8 (10.1)	54 (12.3)
Any AE leading to discontinuation of study drug	18 (10.3)	11 (6.9)	9 (12.5)	38 (9.4)	22 (12.9)	24 (12.6)	8 (10.1)	54 (12.3)
Any AE leading to death	0	0	0	0	2 (1.2)	2 (1.0)	0	4 (0.9)
Any infection	75 (42.9)	60 (37.7)	26 (36.1)	161 (39.7)	57 (33.5)	70 (36.6)	25 (31.6)	152 (34.5)
Any serious infection	7 (4.0)	6 (3.8)	1 (1.4)	14 (3.4)	4 (2.4)	3 (1.6)	2 (2.5)	9 (2.0)
Any legionella infection	0	0	0	0	0	0	0	0
Any diverticulitis infection	0	0	0	0	0	1 (0.5)	0	1 (0.2)
Any opportunistic INF. EXCL. oral candidiasis and TB	0	0	0	0	0	0	0	0
Any oral candidiasis	0	1 (0.6)	1 (1.4)	2 (0.5)	2 (1.2)	0	0	2 (0.5)
Any tuberculosis	0	1 (0.6)	1 (1.4)	2 (0.5)	0	1 (0.5)	0	1 (0.2)
Any active tuberculosis	0	1 (0.6)	1 (1.4)	2 (0.5)	0	1 (0.5)	0	1 (0.2)
Any latent tuberculosis	0	0	0	0	0	0	0	0
Any parasitic infection	0	1 (0.6)	1 (1.4)	2 (0.5)	0	1 (0.5)	0	1 (0.2)
Any reactivation of hepatitis B	0	0	0	0	0	0	0	0
Any progressive multifocal leukoencephalopathy (PML)	0	0	0	0	0	0	0	0

表 2.7.4.7-85. 年齢区分別の有害事象の概要（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）

	<= 38 years				> 38 years			
	Adalimumab				Adalimumab			
	40mg EOW (N=175) n (%)	40mg EW (N=159) n (%)	TDM Regimen (N=72) n (%)	Total (N=406) n (%)	40mg EOW (N=170) n (%)	40mg EW (N=191) n (%)	TDM Regimen (N=79) n (%)	Total (N=440) n (%)
Any malignancy	0	0	0	0	2 (1.2)	4 (2.1)	0	6 (1.4)
Any lymphoma	0	0	0	0	0	0	0	0
Any hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0	0	0	0	0
Any non-melanoma skin cancer (NMSC)	0	0	0	0	1 (0.6)	1 (0.5)	0	2 (0.5)
Any melanoma	0	0	0	0	0	1 (0.5)	0	1 (0.2)
Any leukemia	0	0	0	0	0	0	0	0
Any malignancy other than NMSC, melanoma, lymphoma, HSTCL, and leukemia	0	0	0	0	1 (0.6)	2 (1.0)	0	3 (0.7)
Any allergic reaction (including angioedema/anaphylaxis)	2 (1.1)	4 (2.5)	0	6 (1.5)	2 (1.2)	3 (1.6)	0	5 (1.1)
Any lupus-like reactions and systemic lupus erythematosus	0	1 (0.6)	0	1 (0.2)	0	0	0	0
Any vasculitis	0	0	0	0	0	1 (0.5)	1 (1.3)	2 (0.5)
Any cutaneous vasculitis	0	0	0	0	0	0	1 (1.3)	1 (0.2)
Any non-cutaneous vasculitis	0	0	0	0	0	1 (0.5)	0	1 (0.2)
Any sarcoidosis	0	0	0	0	0	0	0	0
Any autoimmune hepatitis	0	0	0	0	0	0	0	0
Any myocardial infarction related	0	0	0	0	1 (0.6)	0	0	1 (0.2)
Any cerebrovascular accident related	0	0	0	0	0	0	1 (1.3)	1 (0.2)
Any congestive heart failure related	0	0	0	0	1 (0.6)	0	0	1 (0.2)
Any pulmonary embolism related	0	0	0	0	1 (0.6)	3 (1.6)	0	4 (0.9)

表 2.7.4.7-85. 年齢区分別の有害事象の概要（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）

	<= 38 years				> 38 years			
	Adalimumab				Adalimumab			
	40mg EOW (N=175) n (%)	40mg EW (N=159) n (%)	TDM Regimen (N=72) n (%)	Total (N=406) n (%)	40mg EOW (N=170) n (%)	40mg EW (N=191) n (%)	TDM Regimen (N=79) n (%)	Total (N=440) n (%)
Any interstitial lung disease	0	0	0	0	0	0	0	0
Any intestinal perforation	0	0	0	0	0	0	0	0
Any pancreatitis	1 (0.6)	0	0	1 (0.2)	0	0	0	0
Any stevens-johnson syndrome	0	0	0	0	0	0	0	0
Any erythema multiforme related	0	0	0	0	0	0	0	0
Any worsening/new onset of psoriasis	0	1 (0.6)	1 (1.4)	2 (0.5)	2 (1.2)	0	0	2 (0.5)
Any demyelinating disorder	0	0	0	0	0	0	1 (1.3)	1 (0.2)
Any amyotrophic lateral sclerosis	0	0	0	0	0	0	0	0
Any reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0	0	0	0	0
Any hematologic disorders (including pancytopenia)	10 (5.7)	10 (6.3)	7 (9.7)	27 (6.7)	7 (4.1)	13 (6.8)	1 (1.3)	21 (4.8)
Any liver failure and other liver event (except gall bladder related)	1 (0.6)	1 (0.6)	0	2 (0.5)	1 (0.6)	1 (0.5)	0	2 (0.5)
Any humira administration related medication errors	0	0	0	0	0	0	0	0
Any injection site reaction	4 (2.3)	7 (4.4)	2 (2.8)	13 (3.2)	4 (2.4)	9 (4.7)	3 (3.8)	16 (3.6)
All deaths	0	0	0	0	2 (1.2)	2 (1.0)	0	4 (0.9)
Occurring <=70 days after last dose	0	0	0	0	1 (0.6)	1 (0.5)	0	2 (0.5)
Occurring >70 days after last dose	0	0	0	0	1 (0.6)	1 (0.5)	0	2 (0.5)

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. Event with unknown severity is being counted as severe. Event with unknown relationship to study drug is being counted as drug-related.
$ As assessed by investigator.

Cross reference: 追加解析レポート JCSS TABLE 2.7.4__1.6.2_J

表 2.7.4.7-86.　人種別の有害事象の概要（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）

	White				Non-White			
	Adalimumab				Adalimumab			
	40mg EOW (N=287) n (%)	40mg EW (N=290) n (%)	TDM Regimen (N=143) n (%)	Total (N=720) n (%)	40mg EOW (N=58) n (%)	40mg EW (N=60) n (%)	TDM Regimen (N=8) n (%)	Total (N=126) n (%)
Subjects with:								
Any adverse event (AE)	207 (72.1)	211 (72.8)	91 (63.6)	509 (70.7)	50 (86.2)	52 (86.7)	5 (62.5)	107 (84.9)
Any AE with reasonable possibility of being related to study drug$	77 (26.8)	101 (34.8)	45 (31.5)	223 (31.0)	12 (20.7)	16 (26.7)	4 (50.0)	32 (25.4)
Any severe AE	25 (8.7)	35 (12.1)	10 (7.0)	70 (9.7)	4 (6.9)	6 (10.0)	0	10 (7.9)
Any serious AE	40 (13.9)	38 (13.1)	15 (10.5)	93 (12.9)	4 (6.9)	6 (10.0)	0	10 (7.9)
Any AE leading to discontinuation of study drug	35 (12.2)	28 (9.7)	17 (11.9)	80 (11.1)	5 (8.6)	7 (11.7)	0	12 (9.5)
Any AE leading to death	2 (0.7)	2 (0.7)	0	4 (0.6)	0	0	0	0
Any infection	103 (35.9)	100 (34.5)	49 (34.3)	252 (35.0)	29 (50.0)	30 (50.0)	2 (25.0)	61 (48.4)
Any serious infection	10 (3.5)	9 (3.1)	3 (2.1)	22 (3.1)	1 (1.7)	0	0	1 (0.8)
Any legionella infection	0	0	0	0	0	0	0	0
Any diverticulitis infection	0	0	0	0	0	1 (1.7)	0	1 (0.8)
Any opportunistic INF. EXCL. oral candidiasis and TB	0	0	0	0	0	0	0	0
Any oral candidiasis	1 (0.3)	1 (0.3)	1 (0.7)	3 (0.4)	1 (1.7)	0	0	1 (0.8)
Any tuberculosis	0	2 (0.7)	1 (0.7)	3 (0.4)	0	0	0	0
Any active tuberculosis	0	2 (0.7)	1 (0.7)	3 (0.4)	0	0	0	0
Any latent tuberculosis	0	0	0	0	0	0	0	0
Any parasitic infection	0	2 (0.7)	1 (0.7)	3 (0.4)	0	0	0	0
Any reactivation of hepatitis B	0	0	0	0	0	0	0	0
Any progressive multifocal leukoencephalopathy (PML)	0	0	0	0	0	0	0	0

表 2.7.4.7-86. 人種別の有害事象の概要（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）

	White				Non-White			
	Adalimumab				Adalimumab			
	40mg EOW (N=287) n (%)	40mg EW (N=290) n (%)	TDM Regimen (N=143) n (%)	Total (N=720) n (%)	40mg EOW (N=58) n (%)	40mg EW (N=60) n (%)	TDM Regimen (N=8) n (%)	Total (N=126) n (%)
Any malignancy	2 (0.7)	4 (1.4)	0	6 (0.8)	0	0	0	0
Any lymphoma	0	0	0	0	0	0	0	0
Any hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0	0	0	0	0
Any non-melanoma skin cancer (NMSC)	1 (0.3)	1 (0.3)	0	2 (0.3)	0	0	0	0
Any melanoma	0	1 (0.3)	0	1 (0.1)	0	0	0	0
Any leukemia	0	0	0	0	0	0	0	0
Any malignancy other than NMSC, melanoma, lymphoma, HSTCL, and leukemia	1 (0.3)	2 (0.7)	0	3 (0.4)	0	0	0	0
Any allergic reaction (including angioedema/anaphylaxis)	4 (1.4)	6 (2.1)	0	10 (1.4)	0	1 (1.7)	0	1 (0.8)
Any lupus-like reactions and systemic lupus erythematosus	0	0	0	0	0	1 (1.7)	0	1 (0.8)
Any vasculitis	0	1 (0.3)	0	1 (0.1)	0	0	1 (12.5)	1 (0.8)
Any cutaneous vasculitis	0	0	0	0	0	0	1 (12.5)	1 (0.8)
Any non-cutaneous vasculitis	0	1 (0.3)	0	1 (0.1)	0	0	0	0
Any sarcoidosis	0	0	0	0	0	0	0	0
Any autoimmune hepatitis	0	0	0	0	0	0	0	0
Any myocardial infarction related	1 (0.3)	0	0	1 (0.1)	0	0	0	0
Any cerebrovascular accident related	0	0	1 (0.7)	1 (0.1)	0	0	0	0
Any congestive heart failure related	1 (0.3)	0	0	1 (0.1)	0	0	0	0
Any pulmonary embolism related	1 (0.3)	2 (0.7)	0	3 (0.4)	0	1 (1.7)	0	1 (0.8)

表 2.7.4.7-86. 人種別の有害事象の概要（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）

	White				Non-White			
	Adalimumab				Adalimumab			
	40mg EOW (N=287) n (%)	40mg EW (N=290) n (%)	TDM Regimen (N=143) n (%)	Total (N=720) n (%)	40mg EOW (N=58) n (%)	40mg EW (N=60) n (%)	TDM Regimen (N=8) n (%)	Total (N=126) n (%)
Any interstitial lung disease	0	0	0	0	0	0	0	0
Any intestinal perforation	0	0	0	0	0	0	0	0
Any pancreatitis	1 (0.3)	0	0	1 (0.1)	0	0	0	0
Any stevens-johnson syndrome	0	0	0	0	0	0	0	0
Any erythema multiforme related	0	0	0	0	0	0	0	0
Any worsening/new onset of psoriasis	2 (0.7)	1 (0.3)	1 (0.7)	4 (0.6)	0	0	0	0
Any demyelinating disorder	0	0	1 (0.7)	1 (0.1)	0	0	0	0
Any amyotrophic lateral sclerosis	0	0	0	0	0	0	0	0
Any reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0	0	0	0	0
Any hematologic disorders (including pancytopenia)	13 (4.5)	17 (5.9)	7 (4.9)	37 (5.1)	4 (6.9)	6 (10.0)	1 (12.5)	11 (8.7)
Any liver failure and other liver event (except gall bladder related)	1 (0.3)	1 (0.3)	0	2 (0.3)	1 (1.7)	1 (1.7)	0	2 (1.6)
Any humira administration related medication errors	0	0	0	0	0	0	0	0
Any injection site reaction	8 (2.8)	14 (4.8)	5 (3.5)	27 (3.8)	0	2 (3.3)	0	2 (1.6)
All deaths	2 (0.7)	2 (0.7)	0	4 (0.6)	0	0	0	0
Occurring <=70 days after last dose	1 (0.3)	1 (0.3)	0	2 (0.3)	0	0	0	0
Occurring >70 days after last dose	1 (0.3)	1 (0.3)	0	2 (0.3)	0	0	0	0

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. Event with unknown severity is being counted as severe. Event with unknown relationship to study drug is being counted as drug-related.
$ As assessed by investigator.

Cross reference: 追加解析レポート JCSS TABLE 2.7.4__1.6.3_J

表 2.7.4.7-87.　体重区分別の有害事象の概要（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）

	<= 73 kg				> 73 kg			
	Adalimumab				Adalimumab			
	40mg EOW (N=195) n (%)	40mg EW (N=173) n (%)	TDM Regimen (N=73) n (%)	Total (N=441) n (%)	40mg EOW (N=150) n (%)	40mg EW (N=177) n (%)	TDM Regimen (N=78) n (%)	Total (N=405) n (%)
Subjects with:								
Any adverse event (AE)	148 (75.9)	132 (76.3)	44 (60.3)	324 (73.5)	109 (72.7)	131 (74.0)	52 (66.7)	292 (72.1)
Any AE with reasonable possibility of being related to study drug$	56 (28.7)	60 (34.7)	24 (32.9)	140 (31.7)	33 (22.0)	57 (32.2)	25 (32.1)	115 (28.4)
Any severe AE	15 (7.7)	17 (9.8)	6 (8.2)	38 (8.6)	14 (9.3)	24 (13.6)	4 (5.1)	42 (10.4)
Any serious AE	23 (11.8)	18 (10.4)	8 (11.0)	49 (11.1)	21 (14.0)	26 (14.7)	7 (9.0)	54 (13.3)
Any AE leading to discontinuation of study drug	24 (12.3)	20 (11.6)	10 (13.7)	54 (12.2)	16 (10.7)	15 (8.5)	7 (9.0)	38 (9.4)
Any AE leading to death	0	1 (0.6)	0	1 (0.2)	2 (1.3)	1 (0.6)	0	3 (0.7)
Any infection	75 (38.5)	64 (37.0)	23 (31.5)	162 (36.7)	57 (38.0)	66 (37.3)	28 (35.9)	151 (37.3)
Any serious infection	7 (3.6)	4 (2.3)	1 (1.4)	12 (2.7)	4 (2.7)	5 (2.8)	2 (2.6)	11 (2.7)
Any legionella infection	0	0	0	0	0	0	0	0
Any diverticulitis infection	0	0	0	0	0	1 (0.6)	0	1 (0.2)
Any opportunistic INF. EXCL. oral candidiasis and TB	0	0	0	0	0	0	0	0
Any oral candidiasis	1 (0.5)	0	1 (1.4)	2 (0.5)	1 (0.7)	1 (0.6)	0	2 (0.5)
Any tuberculosis	0	1 (0.6)	1 (1.4)	2 (0.5)	0	1 (0.6)	0	1 (0.2)
Any active tuberculosis	0	1 (0.6)	1 (1.4)	2 (0.5)	0	1 (0.6)	0	1 (0.2)
Any latent tuberculosis	0	0	0	0	0	0	0	0
Any parasitic infection	0	2 (1.2)	1 (1.4)	3 (0.7)	0	0	0	0
Any reactivation of hepatitis B	0	0	0	0	0	0	0	0
Any progressive multifocal leukoencephalopathy (PML)	0	0	0	0	0	0	0	0

表 2.7.4.7-87. 体重区分別の有害事象の概要（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）

	<= 73 kg				> 73 kg			
	Adalimumab				Adalimumab			
	40mg EOW (N=195) n (%)	40mg EW (N=173) n (%)	TDM Regimen (N=73) n (%)	Total (N=441) n (%)	40mg EOW (N=150) n (%)	40mg EW (N=177) n (%)	TDM Regimen (N=78) n (%)	Total (N=405) n (%)
Any malignancy	1 (0.5)	1 (0.6)	0	2 (0.5)	1 (0.7)	3 (1.7)	0	4 (1.0)
Any lymphoma	0	0	0	0	0	0	0	0
Any hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0	0	0	0	0
Any non-melanoma skin cancer (NMSC)	1 (0.5)	1 (0.6)	0	2 (0.5)	0	0	0	0
Any melanoma	0	0	0	0	0	1 (0.6)	0	1 (0.2)
Any leukemia	0	0	0	0	0	0	0	0
Any malignancy other than NMSC, melanoma, lymphoma, HSTCL, and leukemia	0	0	0	0	1 (0.7)	2 (1.1)	0	3 (0.7)
Any allergic reaction (including angioedema/anaphylaxis)	2 (1.0)	3 (1.7)	0	5 (1.1)	2 (1.3)	4 (2.3)	0	6 (1.5)
Any lupus-like reactions and systemic lupus erythematosus	0	1 (0.6)	0	1 (0.2)	0	0	0	0
Any vasculitis	0	1 (0.6)	0	1 (0.2)	0	0	1 (1.3)	1 (0.2)
Any cutaneous vasculitis	0	0	0	0	0	0	1 (1.3)	1 (0.2)
Any non-cutaneous vasculitis	0	1 (0.6)	0	1 (0.2)	0	0	0	0
Any sarcoidosis	0	0	0	0	0	0	0	0
Any autoimmune hepatitis	0	0	0	0	0	0	0	0
Any myocardial infarction related	0	0	0	0	1 (0.7)	0	0	1 (0.2)
Any cerebrovascular accident related	0	0	1 (1.4)	1 (0.2)	0	0	0	0
Any congestive heart failure related	0	0	0	0	1 (0.7)	0	0	1 (0.2)
Any pulmonary embolism related	0	1 (0.6)	0	1 (0.2)	1 (0.7)	2 (1.1)	0	3 (0.7)

表 2.7.4.7-87. 体重区分別の有害事象の概要（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）

	<= 73 kg				> 73 kg			
	Adalimumab				Adalimumab			
	40mg EOW (N=195) n (%)	40mg EW (N=173) n (%)	TDM Regimen (N=73) n (%)	Total (N=441) n (%)	40mg EOW (N=150) n (%)	40mg EW (N=177) n (%)	TDM Regimen (N=78) n (%)	Total (N=405) n (%)
Any interstitial lung disease	0	0	0	0	0	0	0	0
Any intestinal perforation	0	0	0	0	0	0	0	0
Any pancreatitis	0	0	0	0	1 (0.7)	0	0	1 (0.2)
Any stevens-johnson syndrome	0	0	0	0	0	0	0	0
Any erythema multiforme related	0	0	0	0	0	0	0	0
Any worsening/new onset of psoriasis	1 (0.5)	0	1 (1.4)	2 (0.5)	1 (0.7)	1 (0.6)	0	2 (0.5)
Any demyelinating disorder	0	0	0	0	0	0	1 (1.3)	1 (0.2)
Any amyotrophic lateral sclerosis	0	0	0	0	0	0	0	0
Any reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0	0	0	0	0
Any hematologic disorders (including pancytopenia)	16 (8.2)	13 (7.5)	4 (5.5)	33 (7.5)	1 (0.7)	10 (5.6)	4 (5.1)	15 (3.7)
Any liver failure and other liver event (except gall bladder related)	2 (1.0)	2 (1.2)	0	4 (0.9)	0	0	0	0
Any humira administration related medication errors	0	0	0	0	0	0	0	0
Any injection site reaction	5 (2.6)	9 (5.2)	2 (2.7)	16 (3.6)	3 (2.0)	7 (4.0)	3 (3.8)	13 (3.2)
All deaths	0	1 (0.6)	0	1 (0.2)	2 (1.3)	1 (0.6)	0	3 (0.7)
Occurring <=70 days after last dose	0	1 (0.6)	0	1 (0.2)	1 (0.7)	0	0	1 (0.2)
Occurring >70 days after last dose	0	0	0	0	1 (0.7)	1 (0.6)	0	2 (0.5)

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. Event with unknown severity is being counted as severe. Event with unknown relationship to study drug is being counted as drug-related.
$ As assessed by investigator.

Cross reference: 追加解析レポート JCSS TABLE 2.7.4__1.6.4_J

表 2.7.4.7-88. 性別の有害事象の 100 人年あたりの発現頻度の概要（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）

	Male			Female		
	Adalimumab			Adalimumab		
	Standard Induction Dose (N=213) (PYS=31.9) Events (E/100PY)	Higher Induction Dose (N=334) (PYS=50.2) Events (E/100PY)	Total (N=547) (PYS=82.2) Events (E/100PY)	Standard Induction Dose (N=166) (PYS=27.7) Events (E/100PY)	Higher Induction Dose (N=239) (PYS=36.1) Events (E/100PY)	Total (N=405) (PYS=63.8) Events (E/100PY)
Any adverse event (AE)	247 (774.3)	386 (768.9)	633 (770.1)	243 (877.3)	387 (1072.0)	630 (987.5)
Any AE with reasonable possibility of being related to study drug$	67 (210.0)	140 (278.9)	207 (251.8)	89 (321.3)	149 (412.7)	238 (373.0)
Any severe AE	14 (43.9)	22 (43.8)	36 (43.8)	10 (36.1)	12 (33.2)	22 (34.5)
Any serious AE	19 (59.6)	23 (45.8)	42 (51.1)	8 (28.9)	8 (22.2)	16 (25.1)
Any AE leading to discontinuation of study drug	15 (47.0)	26 (51.8)	41 (49.9)	10 (36.1)	10 (27.7)	20 (31.3)
Any AE leading to death	0	1 (2.0)	1 (1.2)	0	0	0
Any infection	31 (97.2)	54 (107.6)	85 (103.4)	40 (144.4)	46 (127.4)	86 (134.8)
Any serious infection	2 (6.3)	3 (6.0)	5 (6.1)	1 (3.6)	1 (2.8)	2 (3.1)
Any legionella infection	0	0	0	0	0	0
Any diverticulitis infection	0	0	0	0	0	0
Any opportunistic INF. EXCL. oral candidiasis and TB	1 (3.1)	1 (2.0)	2 (2.4)	0	0	0
Any oral candidiasis	0	0	0	0	0	0
Any tuberculosis	0	0	0	0	1 (2.8)	1 (1.6)
Any active tuberculosis	0	0	0	0	1 (2.8)	1 (1.6)
Any latent tuberculosis	0	0	0	0	0	0
Any parasitic infection	0	1 (2.0)	1 (1.2)	0	0	0
Any reactivation of hepatitis B	0	0	0	0	0	0
Any progressive multifocal leukoencephalopathy (PML)	0	0	0	0	0	0

表 2.7.4.7-88. 性別の有害事象の 100 人年あたりの発現頻度の概要（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）（続き）

	Male			Female		
	Adalimumab			Adalimumab		
	Standard Induction Dose (N=213) (PYS=31.9) Events (E/100PY)	Higher Induction Dose (N=334) (PYS=50.2) Events (E/100PY)	Total (N=547) (PYS=82.2) Events (E/100PY)	Standard Induction Dose (N=166) (PYS=27.7) Events (E/100PY)	Higher Induction Dose (N=239) (PYS=36.1) Events (E/100PY)	Total (N=405) (PYS=63.8) Events (E/100PY)
Any malignancy	0	0	0	3 (10.8)	0	3 (4.7)
Any lymphoma	0	0	0	0	0	0
Any hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0	0	0
Any non-melanoma skin cancer (NMSC)	0	0	0	1 (3.6)	0	1 (1.6)
Any melanoma	0	0	0	1 (3.6)	0	1 (1.6)
Any leukemia	0	0	0	0	0	0
Any malignancy other than NMSC, melanoma, lymphoma, HSTCL, and leukemia	0	0	0	1 (3.6)	0	1 (1.6)
Any allergic reaction (including angioedema/anaphylaxis)	1 (3.1)	1 (2.0)	2 (2.4)	5 (18.1)	8 (22.2)	13 (20.4)
Any lupus-like reactions and systemic lupus erythematosus	0	0	0	0	0	0
Any vasculitis	0	0	0	0	0	0
Any cutaneous vasculitis	0	0	0	0	0	0
Any non-cutaneous vasculitis	0	0	0	0	0	0
Any sarcoidosis	0	0	0	0	0	0
Any autoimmune hepatitis	0	0	0	0	0	0
Any myocardial infarction related	0	0	0	0	0	0
Any cerebrovascular accident related	0	0	0	0	0	0
Any congestive heart failure related	0	0	0	0	0	0
Any pulmonary embolism related	0	0	0	0	0	0

表 2.7.4.7-88. 性別の有害事象の 100 人年あたりの発現頻度の概要（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）（続き）

	Male			Female		
	Adalimumab			Adalimumab		
	Standard Induction Dose (N=213) (PYS=31.9) Events (E/100PY)	Higher Induction Dose (N=334) (PYS=50.2) Events (E/100PY)	Total (N=547) (PYS=82.2) Events (E/100PY)	Standard Induction Dose (N=166) (PYS=27.7) Events (E/100PY)	Higher Induction Dose (N=239) (PYS=36.1) Events (E/100PY)	Total (N=405) (PYS=63.8) Events (E/100PY)
Any interstitial lung disease	0	0	0	0	0	0
Any intestinal perforation	0	0	0	0	0	0
Any pancreatitis	0	0	0	0	1 (2.8)	1 (1.6)
Any stevens-johnson syndrome	0	0	0	0	0	0
Any erythema multiforme related	0	0	0	0	0	0
Any worsening/new onset of psoriasis	0	0	0	2 (7.2)	1 (2.8)	3 (4.7)
Any demyelinating disorder	0	0	0	0	0	0
Any amyotrophic lateral sclerosis	0	0	0	0	0	0
Any reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0	0	0
Any hematologic disorders (including pancytopenia)	10 (31.3)	11 (21.9)	21 (25.5)	8 (28.9)	15 (41.6)	23 (36.1)
Any liver failure and other liver event (except gall bladder related)	0	1 (2.0)	1 (1.2)	0	1 (2.8)	1 (1.6)
Any humira administration related medication errors	0	0	0	0	0	0
Any injection site reaction	13 (40.8)	44 (87.6)	57 (69.3)	14 (50.5)	65 (180.1)	79 (123.8)
All deaths	0	2 (4.0)	2 (2.4)	0	0	0
Occurring <=70 days after last dose	0	1 (2.0)	1 (1.2)	0	0	0
Occurring >70 days after last dose	0	1 (2.0)	1 (1.2)	0	0	0

表 2.7.4.7-88.　　性別の有害事象の 100 人年あたりの発現頻度の概要（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）（続き）

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. Event with unknown severity is being counted as severe. Event with unknown relationship to study drug is being counted as drug-related.
E/100PY = Events per 100 patient-years.
$ As assessed by investigator.

Cross reference: 追加解析レポート JCSS TABLE 2.7.4__1.7.1_J

表 2.7.4.7-89. 年齢区分別の有害事象の 100 人年あたりの発現頻度の概要
（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）

	<= 38 years			> 38 years		
	Adalimumab			Adalimumab		
	Standard Induction Dose (N=186) (PYS=27.8) Events (E/100PY)	Higher Induction Dose (N=277) (PYS=41.6) Events (E/100PY)	Total (N=463) (PYS=69.3) Events (E/100PY)	Standard Induction Dose (N=193) (PYS=31.9) Events (E/100PY)	Higher Induction Dose (N=296) (PYS=44.8) Events (E/100PY)	Total (N=489) (PYS=76.7) Events (E/100PY)
Any adverse event (AE)	260 (935.3)	359 (863.0)	619 (893.2)	230 (721.0)	414 (924.1)	644 (839.6)
Any AE with reasonable possibility of being related to study drug$	69 (248.2)	136 (326.9)	205 (295.8)	87 (272.7)	153 (341.5)	240 (312.9)
Any severe AE	15 (54.0)	18 (43.3)	33 (47.6)	9 (28.2)	16 (35.7)	25 (32.6)
Any serious AE	13 (46.8)	17 (40.9)	30 (43.3)	14 (43.9)	14 (31.3)	28 (36.5)
Any AE leading to discontinuation of study drug	13 (46.8)	20 (48.1)	33 (47.6)	12 (37.6)	16 (35.7)	28 (36.5)
Any AE leading to death	0	1 (2.4)	1 (1.4)	0	0	0
Any infection	44 (158.3)	45 (108.2)	89 (128.4)	27 (84.6)	55 (122.8)	82 (106.9)
Any serious infection	1 (3.6)	2 (4.8)	3 (4.3)	2 (6.3)	2 (4.5)	4 (5.2)
Any legionella infection	0	0	0	0	0	0
Any diverticulitis infection	0	0	0	0	0	0
Any opportunistic INF. EXCL. oral candidiasis and TB	0	0	0	1 (3.1)	1 (2.2)	2 (2.6)
Any oral candidiasis	0	0	0	0	0	0
Any tuberculosis	0	0	0	0	1 (2.2)	1 (1.3)
Any active tuberculosis	0	0	0	0	1 (2.2)	1 (1.3)
Any latent tuberculosis	0	0	0	0	0	0
Any parasitic infection	0	0	0	0	1 (2.2)	1 (1.3)
Any reactivation of hepatitis B	0	0	0	0	0	0
Any progressive multifocal leukoencephalopathy (PML)	0	0	0	0	0	0

表 2.7.4.7-89. 年齢区分別の有害事象の 100 人年あたりの発現頻度の概要
（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）（続き）

	<= 38 years			> 38 years		
	Adalimumab			Adalimumab		
	Standard Induction Dose (N=186) (PYS=27.8) Events (E/100PY)	Higher Induction Dose (N=277) (PYS=41.6) Events (E/100PY)	Total (N=463) (PYS=69.3) Events (E/100PY)	Standard Induction Dose (N=193) (PYS=31.9) Events (E/100PY)	Higher Induction Dose (N=296) (PYS=44.8) Events (E/100PY)	Total (N=489) (PYS=76.7) Events (E/100PY)
Any malignancy	1 (3.6)	0	1 (1.4)	2 (6.3)	0	2 (2.6)
Any lymphoma	0	0	0	0	0	0
Any hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0	0	0
Any non-melanoma skin cancer (NMSC)	0	0	0	1 (3.1)	0	1 (1.3)
Any melanoma	0	0	0	1 (3.1)	0	1 (1.3)
Any leukemia	0	0	0	0	0	0
Any malignancy other than NMSC, melanoma, lymphoma, HSTCL, and leukemia	1 (3.6)	0	1 (1.4)	0	0	0
Any allergic reaction (including angioedema/anaphylaxis)	3 (10.8)	5 (12.0)	8 (11.5)	3 (9.4)	4 (8.9)	7 (9.1)
Any lupus-like reactions and systemic lupus erythematosus	0	0	0	0	0	0
Any vasculitis	0	0	0	0	0	0
Any cutaneous vasculitis	0	0	0	0	0	0
Any non-cutaneous vasculitis	0	0	0	0	0	0
Any sarcoidosis	0	0	0	0	0	0
Any autoimmune hepatitis	0	0	0	0	0	0
Any myocardial infarction related	0	0	0	0	0	0
Any cerebrovascular accident related	0	0	0	0	0	0
Any congestive heart failure related	0	0	0	0	0	0
Any pulmonary embolism related	0	0	0	0	0	0

表 2.7.4.7-89. 年齢区分別の有害事象の 100 人年あたりの発現頻度の概要
（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）（続き）

	<= 38 years			> 38 years		
	Adalimumab			Adalimumab		
	Standard Induction Dose (N=186) (PYS=27.8) Events (E/100PY)	Higher Induction Dose (N=277) (PYS=41.6) Events (E/100PY)	Total (N=463) (PYS=69.3) Events (E/100PY)	Standard Induction Dose (N=193) (PYS=31.9) Events (E/100PY)	Higher Induction Dose (N=296) (PYS=44.8) Events (E/100PY)	Total (N=489) (PYS=76.7) Events (E/100PY)
Any interstitial lung disease	0	0	0	0	0	0
Any intestinal perforation	0	0	0	0	0	0
Any pancreatitis	0	1 (2.4)	1 (1.4)	0	0	0
Any stevens-johnson syndrome	0	0	0	0	0	0
Any erythema multiforme related	0	0	0	0	0	0
Any worsening/new onset of psoriasis	0	1 (2.4)	1 (1.4)	2 (6.3)	0	2 (2.6)
Any demyelinating disorder	0	0	0	0	0	0
Any amyotrophic lateral sclerosis	0	0	0	0	0	0
Any reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0	0	0
Any hematologic disorders (including pancytopenia)	8 (28.8)	10 (24.0)	18 (26.0)	10 (31.3)	16 (35.7)	26 (33.9)
Any liver failure and other liver event (except gall bladder related)	0	2 (4.8)	2 (2.9)	0	0	0
Any humira administration related medication errors	0	0	0	0	0	0
Any injection site reaction	16 (57.6)	55 (132.2)	71 (102.5)	11 (34.5)	54 (120.5)	65 (84.7)
All deaths	0	1 (2.4)	1 (1.4)	0	1 (2.2)	1 (1.3)
Occurring <=70 days after last dose	0	1 (2.4)	1 (1.4)	0	0	0
Occurring >70 days after last dose	0	0	0	0	1 (2.2)	1 (1.3)

表 2.7.4.7-89.　年齢区分別の有害事象の 100 人年あたりの発現頻度の概要
（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）（続き）

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. Event with unknown severity is being counted as severe. Event with unknown relationship to study drug is being counted as drug-related.
E/100PY = Events per 100 patient-years.
$ As assessed by investigator.

Cross reference: 追加解析レポート JCSS TABLE 2.7.4__1.7.2_J

表 2.7.4.7-90. 人種別の有害事象の 100 人年あたりの発現頻度の概要（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）

	White			Non-White			Missing
	Adalimumab			Adalimumab			Adalimumab
	Standard Induction Dose (N=327) (PYS=52.0) Events (E/100PY)	Higher Induction Dose (N=484) (PYS=72.9) Events (E/100PY)	Total (N=811) (PYS=124.9) Events (E/100PY)	Standard Induction Dose (N=52) (PYS=7.7) Events (E/100PY)	Higher Induction Dose (N=88) (PYS=13.3) Events (E/100PY)	Total (N=140) (PYS=20.9) Events (E/100PY)	Higher Induction Dose (N=1) (PYS=0.2) Events (E/100PY)
Any adverse event (AE)	442 (850.0)	650 (891.6)	1092 (874.3)	48 (623.4)	118 (887.2)	166 (794.3)	5 (2500.0)
Any AE with reasonable possibility of being related to study drug$	144 (276.9)	253 (347.1)	397 (317.9)	12 (155.8)	36 (270.7)	48 (229.7)	0
Any severe AE	23 (44.2)	31 (42.5)	54 (43.2)	1 (13.0)	3 (22.6)	4 (19.1)	0
Any serious AE	24 (46.2)	24 (32.9)	48 (38.4)	3 (39.0)	7 (52.6)	10 (47.8)	0
Any AE leading to discontinuation of study drug	21 (40.4)	33 (45.3)	54 (43.2)	4 (51.9)	3 (22.6)	7 (33.5)	0
Any AE leading to death	0	1 (1.4)	1 (0.8)	0	0	0	0
Any infection	63 (121.2)	79 (108.4)	142 (113.7)	8 (103.9)	21 (157.9)	29 (138.8)	0
Any serious infection	2 (3.8)	3 (4.1)	5 (4.0)	1 (13.0)	1 (7.5)	2 (9.6)	0
Any legionella infection	0	0	0	0	0	0	0
Any diverticulitis infection	0	0	0	0	0	0	0
Any opportunistic INF. EXCL. oral candidiasis and TB	1 (1.9)	1 (1.4)	2 (1.6)	0	0	0	0
Any oral candidiasis	0	0	0	0	0	0	0
Any tuberculosis	0	1 (1.4)	1 (0.8)	0	0	0	0
Any active tuberculosis	0	1 (1.4)	1 (0.8)	0	0	0	0
Any latent tuberculosis	0	0	0	0	0	0	0

表 2.7.4.7-90. 人種別の有害事象の 100 人年あたりの発現頻度の概要（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）（続き）

	White			Non-White			Missing
	Adalimumab			Adalimumab			Adalimumab
	Standard Induction Dose (N=327) (PYS=52.0) Events (E/100PY)	Higher Induction Dose (N=484) (PYS=72.9) Events (E/100PY)	Total (N=811) (PYS=124.9) Events (E/100PY)	Standard Induction Dose (N=52) (PYS=7.7) Events (E/100PY)	Higher Induction Dose (N=88) (PYS=13.3) Events (E/100PY)	Total (N=140) (PYS=20.9) Events (E/100PY)	Higher Induction Dose (N=1) (PYS=0.2) Events (E/100PY)
Any parasitic infection	0	1 (1.4)	1 (0.8)	0	0	0	0
Any reactivation of hepatitis B	0	0	0	0	0	0	0
Any progressive multifocal leukoencephalopathy (PML)	0	0	0	0	0	0	0
Any malignancy	3 (5.8)	0	3 (2.4)	0	0	0	0
Any lymphoma	0	0	0	0	0	0	0
Any hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0	0	0	0
Any non-melanoma skin cancer (NMSC)	1 (1.9)	0	1 (0.8)	0	0	0	0
Any melanoma	1 (1.9)	0	1 (0.8)	0	0	0	0
Any leukemia	0	0	0	0	0	0	0
Any malignancy other than NMSC, melanoma, lymphoma, HSTCL, and leukemia	1 (1.9)	0	1 (0.8)	0	0	0	0
Any allergic reaction (including angioedema/anaphylaxis)	5 (9.6)	8 (11.0)	13 (10.4)	1 (13.0)	1 (7.5)	2 (9.6)	0
Any lupus-like reactions and systemic lupus erythematosus	0	0	0	0	0	0	0
Any vasculitis	0	0	0	0	0	0	0
Any cutaneous vasculitis	0	0	0	0	0	0	0
Any non-cutaneous vasculitis	0	0	0	0	0	0	0

表 2.7.4.7-90. 人種別の有害事象の 100 人年あたりの発現頻度の概要（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）（続き）

	White			Non-White			Missing
	Adalimumab			Adalimumab			Adalimumab
	Standard Induction Dose (N=327) (PYS=52.0) Events (E/100PY)	Higher Induction Dose (N=484) (PYS=72.9) Events (E/100PY)	Total (N=811) (PYS=124.9) Events (E/100PY)	Standard Induction Dose (N=52) (PYS=7.7) Events (E/100PY)	Higher Induction Dose (N=88) (PYS=13.3) Events (E/100PY)	Total (N=140) (PYS=20.9) Events (E/100PY)	Higher Induction Dose (N=1) (PYS=0.2) Events (E/100PY)
Any sarcoidosis	0	0	0	0	0	0	0
Any autoimmune hepatitis	0	0	0	0	0	0	0
Any myocardial infarction related	0	0	0	0	0	0	0
Any cerebrovascular accident related	0	0	0	0	0	0	0
Any congestive heart failure related	0	0	0	0	0	0	0
Any pulmonary embolism related	0	0	0	0	0	0	0
Any interstitial lung disease	0	0	0	0	0	0	0
Any intestinal perforation	0	0	0	0	0	0	0
Any pancreatitis	0	1 (1.4)	1 (0.8)	0	0	0	0
Any stevens-johnson syndrome	0	0	0	0	0	0	0
Any erythema multiforme related	0	0	0	0	0	0	0
Any worsening/new onset of psoriasis	2 (3.8)	1 (1.4)	3 (2.4)	0	0	0	0
Any demyelinating disorder	0	0	0	0	0	0	0
Any amyotrophic lateral sclerosis	0	0	0	0	0	0	0
Any reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0	0	0	0

表 2.7.4.7-90. 人種別の有害事象の 100 人年あたりの発現頻度の概要（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）（続き）

	White			Non-White			Missing
	Adalimumab			Adalimumab			Adalimumab
	Standard Induction Dose (N=327) (PYS=52.0) Events (E/100PY)	Higher Induction Dose (N=484) (PYS=72.9) Events (E/100PY)	Total (N=811) (PYS=124.9) Events (E/100PY)	Standard Induction Dose (N=52) (PYS=7.7) Events (E/100PY)	Higher Induction Dose (N=88) (PYS=13.3) Events (E/100PY)	Total (N=140) (PYS=20.9) Events (E/100PY)	Higher Induction Dose (N=1) (PYS=0.2) Events (E/100PY)
Any hematologic disorders (including pancytopenia)	15 (28.8)	21 (28.8)	36 (28.8)	3 (39.0)	5 (37.6)	8 (38.3)	0
Any liver failure and other liver event (except gall bladder related)	0	2 (2.7)	2 (1.6)	0	0	0	0
Any humira administration related medication errors	0	0	0	0	0	0	0
Any injection site reaction	24 (46.2)	99 (135.8)	123 (98.5)	3 (39.0)	10 (75.2)	13 (62.2)	0
All deaths	0	2 (2.7)	2 (1.6)	0	0	0	0
Occurring <=70 days after last dose	0	1 (1.4)	1 (0.8)	0	0	0	0
Occurring >70 days after last dose	0	1 (1.4)	1 (0.8)	0	0	0	0

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. Event with unknown severity is being counted as severe. Event with unknown relationship to study drug is being counted as drug-related.
E/100PY = Events per 100 patient-years.
$ As assessed by investigator.

Cross reference: 追加解析レポート JCSS TABLE 2.7.4__1.7.3_J

表 2.7.4.7-91. 体重区分別の有害事象の 100 人年あたりの発現頻度の概要（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）

	<= 73 kg			> 73 kg		
	Adalimumab			Adalimumab		
	Standard Induction Dose (N=202) (PYS=32.8) Events (E/100PY)	Higher Induction Dose (N=292) (PYS=43.9) Events (E/100PY)	Total (N=494) (PYS=76.7) Events (E/100PY)	Standard Induction Dose (N=177) (PYS=26.9) Events (E/100PY)	Higher Induction Dose (N=281) (PYS=42.5) Events (E/100PY)	Total (N=458) (PYS=69.3) Events (E/100PY)
Any adverse event (AE)	265 (807.9)	396 (902.1)	661 (861.8)	225 (836.4)	377 (887.1)	602 (868.7)
Any AE with reasonable possibility of being related to study drug$	86 (262.2)	157 (357.6)	243 (316.8)	70 (260.2)	132 (310.6)	202 (291.5)
Any severe AE	14 (42.7)	18 (41.0)	32 (41.7)	10 (37.2)	16 (37.6)	26 (37.5)
Any serious AE	14 (42.7)	12 (27.3)	26 (33.9)	13 (48.3)	19 (44.7)	32 (46.2)
Any AE leading to discontinuation of study drug	18 (54.9)	17 (38.7)	35 (45.6)	7 (26.0)	19 (44.7)	26 (37.5)
Any AE leading to death	0	0	0	0	1 (2.4)	1 (1.4)
Any infection	36 (109.8)	54 (123.0)	90 (117.3)	35 (130.1)	46 (108.2)	81 (116.9)
Any serious infection	2 (6.1)	1 (2.3)	3 (3.9)	1 (3.7)	3 (7.1)	4 (5.8)
Any legionella infection	0	0	0	0	0	0
Any diverticulitis infection	0	0	0	0	0	0
Any opportunistic INF. EXCL. oral candidiasis and TB	1 (3.0)	0	1 (1.3)	0	1 (2.4)	1 (1.4)
Any oral candidiasis	0	0	0	0	0	0
Any tuberculosis	0	1 (2.3)	1 (1.3)	0	0	0
Any active tuberculosis	0	1 (2.3)	1 (1.3)	0	0	0
Any latent tuberculosis	0	0	0	0	0	0
Any parasitic infection	0	0	0	0	1 (2.4)	1 (1.4)
Any reactivation of hepatitis B	0	0	0	0	0	0
Any progressive multifocal leukoencephalopathy (PML)	0	0	0	0	0	0

表 2.7.4.7-91.　体重区分別の有害事象の 100 人年あたりの発現頻度の概要（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）（続き）

	<= 73 kg			> 73 kg		
	Adalimumab			Adalimumab		
	Standard Induction Dose (N=202) (PYS=32.8) Events (E/100PY)	Higher Induction Dose (N=292) (PYS=43.9) Events (E/100PY)	Total (N=494) (PYS=76.7) Events (E/100PY)	Standard Induction Dose (N=177) (PYS=26.9) Events (E/100PY)	Higher Induction Dose (N=281) (PYS=42.5) Events (E/100PY)	Total (N=458) (PYS=69.3) Events (E/100PY)
Any malignancy	3 (9.1)	0	3 (3.9)	0	0	0
Any lymphoma	0	0	0	0	0	0
Any hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0	0	0
Any non-melanoma skin cancer (NMSC)	1 (3.0)	0	1 (1.3)	0	0	0
Any melanoma	1 (3.0)	0	1 (1.3)	0	0	0
Any leukemia	0	0	0	0	0	0
Any malignancy other than NMSC, melanoma, lymphoma, HSTCL, and leukemia	1 (3.0)	0	1 (1.3)	0	0	0
Any allergic reaction (including angioedema/anaphylaxis)	3 (9.1)	6 (13.7)	9 (11.7)	3 (11.2)	3 (7.1)	6 (8.7)
Any lupus-like reactions and systemic lupus erythematosus	0	0	0	0	0	0
Any vasculitis	0	0	0	0	0	0
Any cutaneous vasculitis	0	0	0	0	0	0
Any non-cutaneous vasculitis	0	0	0	0	0	0
Any sarcoidosis	0	0	0	0	0	0
Any autoimmune hepatitis	0	0	0	0	0	0
Any myocardial infarction related	0	0	0	0	0	0
Any cerebrovascular accident related	0	0	0	0	0	0
Any congestive heart failure related	0	0	0	0	0	0
Any pulmonary embolism related	0	0	0	0	0	0

表 2.7.4.7-91. 体重区分別の有害事象の 100 人年あたりの発現頻度の概要（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）（続き）

	<= 73 kg Adalimumab			> 73 kg Adalimumab		
	Standard Induction Dose (N=202) (PYS=32.8) Events (E/100PY)	Higher Induction Dose (N=292) (PYS=43.9) Events (E/100PY)	Total (N=494) (PYS=76.7) Events (E/100PY)	Standard Induction Dose (N=177) (PYS=26.9) Events (E/100PY)	Higher Induction Dose (N=281) (PYS=42.5) Events (E/100PY)	Total (N=458) (PYS=69.3) Events (E/100PY)
Any interstitial lung disease	0	0	0	0	0	0
Any intestinal perforation	0	0	0	0	0	0
Any pancreatitis	0	1 (2.3)	1 (1.3)	0	0	0
Any stevens-johnson syndrome	0	0	0	0	0	0
Any erythema multiforme related	0	0	0	0	0	0
Any worsening/new onset of psoriasis	1 (3.0)	1 (2.3)	2 (2.6)	1 (3.7)	0	1 (1.4)
Any demyelinating disorder	0	0	0	0	0	0
Any amyotrophic lateral sclerosis	0	0	0	0	0	0
Any reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0	0	0
Any hematologic disorders (including pancytopenia)	10 (30.5)	19 (43.3)	29 (37.8)	8 (29.7)	7 (16.5)	15 (21.6)
Any liver failure and other liver event (except gall bladder related)	0	1 (2.3)	1 (1.3)	0	1 (2.4)	1 (1.4)
Any humira administration related medication errors	0	0	0	0	0	0
Any injection site reaction	18 (54.9)	68 (154.9)	86 (112.1)	9 (33.5)	41 (96.5)	50 (72.2)
All deaths	0	1 (2.3)	1 (1.3)	0	1 (2.4)	1 (1.4)
Occurring <=70 days after last dose	0	0	0	0	1 (2.4)	1 (1.4)
Occurring >70 days after last dose	0	1 (2.3)	1 (1.3)	0	0	0

表 2.7.4.7-91.　体重区分別の有害事象の 100 人年あたりの発現頻度の概要（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）（続き）

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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. Event with unknown
      severity is being counted as severe. Event with unknown relationship to study drug is being counted as drug-related.
      E/100PY = Events per 100 patient-years.
$ As assessed by investigator.
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Cross reference: 追加解析レポート JCSS TABLE 2.7.4__1.7.4_J

表 2.7.4.7-92. 性別の有害事象の 100 人年あたりの発現頻度の概要（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）

	Male				Female			
	Adalimumab				Adalimumab			
	40mg EOW (N=198) (PYS=135.1) Events (E/100PY)	40mg EW (N=200) (PYS=143.3) Events (E/100PY)	TDM Regimen (N=81) (PYS=59.5) Events (E/100PY)	Total (N=479) (PYS=337.8) Events (E/100PY)	40mg EOW (N=147) (PYS=102.4) Events (E/100PY)	40mg EW (N=150) (PYS=108.9) Events (E/100PY)	TDM Regimen (N=70) (PYS=46.3) Events (E/100PY)	Total (N=367) (PYS=257.6) Events (E/100PY)
Any adverse event (AE)	521 (385.6)	520 (362.9)	184 (309.2)	1225 (362.6)	411 (401.4)	565 (518.8)	157 (339.1)	1133 (439.8)
Any AE with reasonable possibility of being related to study drug$	99 (73.3)	140 (97.7)	50 (84.0)	289 (85.6)	76 (74.2)	140 (128.6)	47 (101.5)	263 (102.1)
Any severe AE	28 (20.7)	33 (23.0)	6 (10.1)	67 (19.8)	14 (13.7)	27 (24.8)	5 (10.8)	46 (17.9)
Any serious AE	37 (27.4)	37 (25.8)	9 (15.1)	83 (24.6)	26 (25.4)	33 (30.3)	12 (25.9)	71 (27.6)
Any AE leading to discontinuation of study drug	22 (16.3)	25 (17.4)	8 (13.4)	55 (16.3)	20 (19.5)	26 (23.9)	11 (23.8)	57 (22.1)
Any AE leading to death	1 (0.7)	2 (1.4)	0	3 (0.9)	1 (1.0)	0	0	1 (0.4)
Any infection	117 (86.6)	110 (76.8)	49 (82.4)	276 (81.7)	109 (106.4)	110 (101.0)	43 (92.9)	262 (101.7)
Any serious infection	9 (6.7)	6 (4.2)	2 (3.4)	17 (5.0)	3 (2.9)	3 (2.8)	1 (2.2)	7 (2.7)
Any legionella infection	0	0	0	0	0	0	0	0
Any diverticulitis infection	0	0	0	0	0	1 (0.9)	0	1 (0.4)
Any opportunistic INF. EXCL. oral candidiasis and TB	0	0	0	0	0	0	0	0
Any oral candidiasis	2 (1.5)	0	0	2 (0.6)	0	1 (0.9)	1 (2.2)	2 (0.8)
Any tuberculosis	0	1 (0.7)	0	1 (0.3)	0	1 (0.9)	1 (2.2)	2 (0.8)
Any active tuberculosis	0	1 (0.7)	0	1 (0.3)	0	1 (0.9)	1 (2.2)	2 (0.8)
Any latent tuberculosis	0	0	0	0	0	0	0	0
Any parasitic infection	0	1 (0.7)	0	1 (0.3)	0	1 (0.9)	1 (2.2)	2 (0.8)
Any reactivation of hepatitis B	0	0	0	0	0	0	0	0
Any progressive multifocal leukoencephalopathy (PML)	0	0	0	0	0	0	0	0

表 2.7.4.7-92. 性別の有害事象の 100 人年あたりの発現頻度の概要（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）

	Male				Female			
	Adalimumab				Adalimumab			
	40mg EOW (N=198) (PYS=135.1) Events (E/100PY)	40mg EW (N=200) (PYS=143.3) Events (E/100PY)	TDM Regimen (N=81) (PYS=59.5) Events (E/100PY)	Total (N=479) (PYS=337.8) Events (E/100PY)	40mg EOW (N=147) (PYS=102.4) Events (E/100PY)	40mg EW (N=150) (PYS=108.9) Events (E/100PY)	TDM Regimen (N=70) (PYS=46.3) Events (E/100PY)	Total (N=367) (PYS=257.6) Events (E/100PY)
Any malignancy	2 (1.5)	3 (2.1)	0	5 (1.5)	0	1 (0.9)	0	1 (0.4)
Any lymphoma	0	0	0	0	0	0	0	0
Any hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0	0	0	0	0
Any non-melanoma skin cancer (NMSC)	1 (0.7)	0	0	1 (0.3)	0	1 (0.9)	0	1 (0.4)
Any melanoma	0	1 (0.7)	0	1 (0.3)	0	0	0	0
Any leukemia	0	0	0	0	0	0	0	0
Any malignancy other than NMSC, melanoma, lymphoma, HSTCL, and leukemia	1 (0.7)	2 (1.4)	0	3 (0.9)	0	0	0	0
Any allergic reaction (including angioedema/anaphylaxis)	1 (0.7)	2 (1.4)	0	3 (0.9)	3 (2.9)	5 (4.6)	0	8 (3.1)
Any lupus-like reactions and systemic lupus erythematosus	0	1 (0.7)	0	1 (0.3)	0	0	0	0
Any vasculitis	0	1 (0.7)	1 (1.7)	2 (0.6)	0	0	0	0
Any cutaneous vasculitis	0	0	1 (1.7)	1 (0.3)	0	0	0	0
Any non-cutaneous vasculitis	0	1 (0.7)	0	1 (0.3)	0	0	0	0
Any sarcoidosis	0	0	0	0	0	0	0	0
Any autoimmune hepatitis	0	0	0	0	0	0	0	0
Any myocardial infarction related	1 (0.7)	0	0	1 (0.3)	0	0	0	0
Any cerebrovascular accident related	0	0	1 (1.7)	1 (0.3)	0	0	0	0
Any congestive heart failure related	1 (0.7)	0	0	1 (0.3)	0	0	0	0
Any pulmonary embolism related	0	1 (0.7)	0	1 (0.3)	1 (1.0)	2 (1.8)	0	3 (1.2)

表 2.7.4.7-92. 性別の有害事象の 100 人年あたりの発現頻度の概要（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）

	Male				Female			
	Adalimumab				Adalimumab			
	40mg EOW (N=198) (PYS=135.1) Events (E/100PY)	40mg EW (N=200) (PYS=143.3) Events (E/100PY)	TDM Regimen (N=81) (PYS=59.5) Events (E/100PY)	Total (N=479) (PYS=337.8) Events (E/100PY)	40mg EOW (N=147) (PYS=102.4) Events (E/100PY)	40mg EW (N=150) (PYS=108.9) Events (E/100PY)	TDM Regimen (N=70) (PYS=46.3) Events (E/100PY)	Total (N=367) (PYS=257.6) Events (E/100PY)
Any interstitial lung disease	0	0	0	0	0	0	0	0
Any intestinal perforation	0	0	0	0	0	0	0	0
Any pancreatitis	1 (0.7)	0	0	1 (0.3)	0	0	0	0
Any stevens-johnson syndrome	0	0	0	0	0	0	0	0
Any erythema multiforme related	0	0	0	0	0	0	0	0
Any worsening/new onset of psoriasis	1 (0.7)	1 (0.7)	0	2 (0.6)	1 (1.0)	0	1 (2.2)	2 (0.8)
Any demyelinating disorder	0	0	0	0	0	0	1 (2.2)	1 (0.4)
Any amyotrophic lateral sclerosis	0	0	0	0	0	0	0	0
Any reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0	0	0	0	0
Any hematologic disorders (including pancytopenia)	11 (8.1)	14 (9.8)	5 (8.4)	30 (8.9)	8 (7.8)	14 (12.9)	3 (6.5)	25 (9.7)
Any liver failure and other liver event (except gall bladder related)	0	1 (0.7)	0	1 (0.3)	2 (2.0)	1 (0.9)	0	3 (1.2)
Any humira administration related medication errors	0	0	0	0	0	0	0	0
Any injection site reaction	6 (4.4)	7 (4.9)	4 (6.7)	17 (5.0)	12 (11.7)	26 (23.9)	5 (10.8)	43 (16.7)
All deaths	1 (0.7)	2 (1.4)	0	3 (0.9)	1 (1.0)	0	0	1 (0.4)
Occurring <=70 days after last dose	0	1 (0.7)	0	1 (0.3)	1 (1.0)	0	0	1 (0.4)
Occurring >70 days after last dose	1 (0.7)	1 (0.7)	0	2 (0.6)	0	0	0	0

表 2.7.4.7-92.　　性別の有害事象の 100 人年あたりの発現頻度の概要（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. Event with unknown severity is being counted as severe. Event with unknown relationship to study drug is being counted as drug-related.
E/100PY = Events per 100 patient-years.
$ As assessed by investigator.

Cross reference: 追加解析レポート JCSS TABLE 2.7.4__1.8.1_J

表 2.7.4.7-93. 年齢区分別の有害事象の 100 人年あたりの発現頻度の概要（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）

	<= 38 years				> 38 years			
	Adalimumab				Adalimumab			
	40mg EOW (N=175) (PYS=116.7) Events (E/100PY)	40mg EW (N=159) (PYS=114.4) Events (E/100PY)	TDM Regimen (N=72) (PYS=50.4) Events (E/100PY)	Total (N=406) (PYS=281.6) Events (E/100PY)	40mg EOW (N=170) (PYS=120.8) Events (E/100PY)	40mg EW (N=191) (PYS=137.7) Events (E/100PY)	TDM Regimen (N=79) (PYS=55.4) Events (E/100PY)	Total (N=440) (PYS=313.9) Events (E/100PY)
Any adverse event (AE)	532 (455.9)	472 (412.6)	183 (363.1)	1187 (421.5)	400 (331.1)	613 (445.2)	158 (285.2)	1171 (373.0)
Any AE with reasonable possibility of being related to study drug$	88 (75.4)	123 (107.5)	54 (107.1)	265 (94.1)	87 (72.0)	157 (114.0)	43 (77.6)	287 (91.4)
Any severe AE	22 (18.9)	20 (17.5)	5 (9.9)	47 (16.7)	20 (16.6)	40 (29.0)	6 (10.8)	66 (21.0)
Any serious AE	33 (28.3)	27 (23.6)	10 (19.8)	70 (24.9)	30 (24.8)	43 (31.2)	11 (19.9)	84 (26.8)
Any AE leading to discontinuation of study drug	18 (15.4)	16 (14.0)	9 (17.9)	43 (15.3)	24 (19.9)	35 (25.4)	10 (18.1)	69 (22.0)
Any AE leading to death	0	0	0	0	2 (1.7)	2 (1.5)	0	4 (1.3)
Any infection	134 (114.8)	110 (96.2)	58 (115.1)	302 (107.2)	92 (76.2)	110 (79.9)	34 (61.4)	236 (75.2)
Any serious infection	8 (6.9)	6 (5.2)	1 (2.0)	15 (5.3)	4 (3.3)	3 (2.2)	2 (3.6)	9 (2.9)
Any legionella infection	0	0	0	0	0	0	0	0
Any diverticulitis infection	0	0	0	0	0	1 (0.7)	0	1 (0.3)
Any opportunistic INF. EXCL. oral candidiasis and TB	0	0	0	0	0	0	0	0
Any oral candidiasis	0	1 (0.9)	1 (2.0)	2 (0.7)	2 (1.7)	0	0	2 (0.6)
Any tuberculosis	0	1 (0.9)	1 (2.0)	2 (0.7)	0	1 (0.7)	0	1 (0.3)
Any active tuberculosis	0	1 (0.9)	1 (2.0)	2 (0.7)	0	1 (0.7)	0	1 (0.3)
Any latent tuberculosis	0	0	0	0	0	0	0	0
Any parasitic infection	0	1 (0.9)	1 (2.0)	2 (0.7)	0	1 (0.7)	0	1 (0.3)
Any reactivation of hepatitis B	0	0	0	0	0	0	0	0
Any progressive multifocal leukoencephalopathy (PML)	0	0	0	0	0	0	0	0

表 2.7.4.7-93. 年齢区分別の有害事象の 100 人年あたりの発現頻度の概要（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）

	<= 38 years				> 38 years			
	Adalimumab				Adalimumab			
	40mg EOW (N=175) (PYS=116.7) Events (E/100PY)	40mg EW (N=159) (PYS=114.4) Events (E/100PY)	TDM Regimen (N=72) (PYS=50.4) Events (E/100PY)	Total (N=406) (PYS=281.6) Events (E/100PY)	40mg EOW (N=170) (PYS=120.8) Events (E/100PY)	40mg EW (N=191) (PYS=137.7) Events (E/100PY)	TDM Regimen (N=79) (PYS=55.4) Events (E/100PY)	Total (N=440) (PYS=313.9) Events (E/100PY)
Any malignancy	0	0	0	0	2 (1.7)	4 (2.9)	0	6 (1.9)
Any lymphoma	0	0	0	0	0	0	0	0
Any hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0	0	0	0	0
Any non-melanoma skin cancer (NMSC)	0	0	0	0	1 (0.8)	1 (0.7)	0	2 (0.6)
Any melanoma	0	0	0	0	0	1 (0.7)	0	1 (0.3)
Any leukemia	0	0	0	0	0	0	0	0
Any malignancy other than NMSC, melanoma, lymphoma, HSTCL, and leukemia	0	0	0	0	1 (0.8)	2 (1.5)	0	3 (1.0)
Any allergic reaction (including angioedema/anaphylaxis)	2 (1.7)	4 (3.5)	0	6 (2.1)	2 (1.7)	3 (2.2)	0	5 (1.6)
Any lupus-like reactions and systemic lupus erythematosus	0	1 (0.9)	0	1 (0.4)	0	0	0	0
Any vasculitis	0	0	0	0	0	1 (0.7)	1 (1.8)	2 (0.6)
Any cutaneous vasculitis	0	0	0	0	0	0	1 (1.8)	1 (0.3)
Any non-cutaneous vasculitis	0	0	0	0	0	1 (0.7)	0	1 (0.3)
Any sarcoidosis	0	0	0	0	0	0	0	0
Any autoimmune hepatitis	0	0	0	0	0	0	0	0
Any myocardial infarction related	0	0	0	0	1 (0.8)	0	0	1 (0.3)
Any cerebrovascular accident related	0	0	0	0	0	0	1 (1.8)	1 (0.3)
Any congestive heart failure related	0	0	0	0	1 (0.8)	0	0	1 (0.3)
Any pulmonary embolism related	0	0	0	0	1 (0.8)	3 (2.2)	0	4 (1.3)

表 2.7.4.7-93. 年齢区分別の有害事象の 100 人年あたりの発現頻度の概要（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）

	<= 38 years				> 38 years			
	Adalimumab				Adalimumab			
	40mg EOW (N=175) (PYS=116.7) Events (E/100PY)	40mg EW (N=159) (PYS=114.4) Events (E/100PY)	TDM Regimen (N=72) (PYS=50.4) Events (E/100PY)	Total (N=406) (PYS=281.6) Events (E/100PY)	40mg EOW (N=170) (PYS=120.8) Events (E/100PY)	40mg EW (N=191) (PYS=137.7) Events (E/100PY)	TDM Regimen (N=79) (PYS=55.4) Events (E/100PY)	Total (N=440) (PYS=313.9) Events (E/100PY)
Any interstitial lung disease	0	0	0	0	0	0	0	0
Any intestinal perforation	0	0	0	0	0	0	0	0
Any pancreatitis	1 (0.9)	0	0	1 (0.4)	0	0	0	0
Any stevens-johnson syndrome	0	0	0	0	0	0	0	0
Any erythema multiforme related	0	0	0	0	0	0	0	0
Any worsening/new onset of psoriasis	0	1 (0.9)	1 (2.0)	2 (0.7)	2 (1.7)	0	0	2 (0.6)
Any demyelinating disorder	0	0	0	0	0	0	1 (1.8)	1 (0.3)
Any amyotrophic lateral sclerosis	0	0	0	0	0	0	0	0
Any reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0	0	0	0	0
Any hematologic disorders (including pancytopenia)	12 (10.3)	13 (11.4)	7 (13.9)	32 (11.4)	7 (5.8)	15 (10.9)	1 (1.8)	23 (7.3)
Any liver failure and other liver event (except gall bladder related)	1 (0.9)	1 (0.9)	0	2 (0.7)	1 (0.8)	1 (0.7)	0	2 (0.6)
Any humira administration related medication errors	0	0	0	0	0	0	0	0
Any injection site reaction	6 (5.1)	19 (16.6)	4 (7.9)	29 (10.3)	12 (9.9)	14 (10.2)	5 (9.0)	31 (9.9)
All deaths	0	0	0	0	2 (1.7)	2 (1.5)	0	4 (1.3)
Occurring <=70 days after last dose	0	0	0	0	1 (0.8)	1 (0.7)	0	2 (0.6)
Occurring >70 days after last dose	0	0	0	0	1 (0.8)	1 (0.7)	0	2 (0.6)

表 2.7.4.7-93.　年齢区分別の有害事象の 100 人年あたりの発現頻度の概要（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. Event with unknown severity is being counted as severe. Event with unknown relationship to study drug is being counted as drug-related.
E/100PY = Events per 100 patient-years.
$ As assessed by investigator.

Cross reference: 追加解析レポート JCSS TABLE 2.7.4__1.8.2_J

表 2.7.4.7-94. 人種別の有害事象の 100 人年あたりの発現頻度の概要（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）

	White				Non-White			
	Adalimumab				Adalimumab			
	40mg EOW (N=287) (PYS=197.5) Events (E/100PY)	40mg EW (N=290) (PYS=209.6) Events (E/100PY)	TDM Regimen (N=143) (PYS=99.5) Events (E/100PY)	Total (N=720) (PYS=506.7) Events (E/100PY)	40mg EOW (N=58) (PYS=40.0) Events (E/100PY)	40mg EW (N=60) (PYS=42.6) Events (E/100PY)	TDM Regimen (N=8) (PYS=6.3) Events (E/100PY)	Total (N=126) (PYS=88.8) Events (E/100PY)
Any adverse event (AE)	782 (395.9)	919 (438.5)	328 (329.6)	2029 (400.4)	150 (375.0)	166 (389.7)	13 (206.3)	329 (370.5)
Any AE with reasonable possibility of being related to study drug$	157 (79.5)	260 (124.0)	92 (92.5)	509 (100.5)	18 (45.0)	20 (46.9)	5 (79.4)	43 (48.4)
Any severe AE	38 (19.2)	52 (24.8)	11 (11.1)	101 (19.9)	4 (10.0)	8 (18.8)	0	12 (13.5)
Any serious AE	59 (29.9)	64 (30.5)	21 (21.1)	144 (28.4)	4 (10.0)	6 (14.1)	0	10 (11.3)
Any AE leading to discontinuation of study drug	37 (18.7)	44 (21.0)	19 (19.1)	100 (19.7)	5 (12.5)	7 (16.4)	0	12 (13.5)
Any AE leading to death	2 (1.0)	2 (1.0)	0	4 (0.8)	0	0	0	0
Any infection	179 (90.6)	175 (83.5)	89 (89.4)	443 (87.4)	47 (117.5)	45 (105.6)	3 (47.6)	95 (107.0)
Any serious infection	11 (5.6)	9 (4.3)	3 (3.0)	23 (4.5)	1 (2.5)	0	0	1 (1.1)
Any legionella infection	0	0	0	0	0	0	0	0
Any diverticulitis infection	0	0	0	0	0	1 (2.3)	0	1 (1.1)
Any opportunistic INF. EXCL. oral candidiasis and TB	0	0	0	0	0	0	0	0
Any oral candidiasis	1 (0.5)	1 (0.5)	1 (1.0)	3 (0.6)	1 (2.5)	0	0	1 (1.1)
Any tuberculosis	0	2 (1.0)	1 (1.0)	3 (0.6)	0	0	0	0
Any active tuberculosis	0	2 (1.0)	1 (1.0)	3 (0.6)	0	0	0	0
Any latent tuberculosis	0	0	0	0	0	0	0	0
Any parasitic infection	0	2 (1.0)	1 (1.0)	3 (0.6)	0	0	0	0
Any reactivation of hepatitis B	0	0	0	0	0	0	0	0
Any progressive multifocal leukoencephalopathy (PML)	0	0	0	0	0	0	0	0

表 2.7.4.7-94. 人種別の有害事象の 100 人年あたりの発現頻度の概要（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）

	White				Non-White			
	Adalimumab				Adalimumab			
	40mg EOW (N=287) (PYS=197.5) Events (E/100PY)	40mg EW (N=290) (PYS=209.6) Events (E/100PY)	TDM Regimen (N=143) (PYS=99.5) Events (E/100PY)	Total (N=720) (PYS=506.7) Events (E/100PY)	40mg EOW (N=58) (PYS=40.0) Events (E/100PY)	40mg EW (N=60) (PYS=42.6) Events (E/100PY)	TDM Regimen (N=8) (PYS=6.3) Events (E/100PY)	Total (N=126) (PYS=88.8) Events (E/100PY)
Any malignancy	2 (1.0)	4 (1.9)	0	6 (1.2)	0	0	0	0
Any lymphoma	0	0	0	0	0	0	0	0
Any hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0	0	0	0	0
Any non-melanoma skin cancer (NMSC)	1 (0.5)	1 (0.5)	0	2 (0.4)	0	0	0	0
Any melanoma	0	1 (0.5)	0	1 (0.2)	0	0	0	0
Any leukemia	0	0	0	0	0	0	0	0
Any malignancy other than NMSC, melanoma, lymphoma, HSTCL, and leukemia	1 (0.5)	2 (1.0)	0	3 (0.6)	0	0	0	0
Any allergic reaction (including angioedema/anaphylaxis)	4 (2.0)	6 (2.9)	0	10 (2.0)	0	1 (2.3)	0	1 (1.1)
Any lupus-like reactions and systemic lupus erythematosus	0	0	0	0	0	1 (2.3)	0	1 (1.1)
Any vasculitis	0	1 (0.5)	0	1 (0.2)	0	0	1 (15.9)	1 (1.1)
Any cutaneous vasculitis	0	0	0	0	0	0	1 (15.9)	1 (1.1)
Any non-cutaneous vasculitis	0	1 (0.5)	0	1 (0.2)	0	0	0	0
Any sarcoidosis	0	0	0	0	0	0	0	0
Any autoimmune hepatitis	0	0	0	0	0	0	0	0
Any myocardial infarction related	1 (0.5)	0	0	1 (0.2)	0	0	0	0
Any cerebrovascular accident related	0	0	1 (1.0)	1 (0.2)	0	0	0	0
Any congestive heart failure related	1 (0.5)	0	0	1 (0.2)	0	0	0	0
Any pulmonary embolism related	1 (0.5)	2 (1.0)	0	3 (0.6)	0	1 (2.3)	0	1 (1.1)

表 2.7.4.7-94. 人種別の有害事象の 100 人年あたりの発現頻度の概要（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）

	White				Non-White			
	Adalimumab				Adalimumab			
	40mg EOW (N=287) (PYS=197.5) Events (E/100PY)	40mg EW (N=290) (PYS=209.6) Events (E/100PY)	TDM Regimen (N=143) (PYS=99.5) Events (E/100PY)	Total (N=720) (PYS=506.7) Events (E/100PY)	40mg EOW (N=58) (PYS=40.0) Events (E/100PY)	40mg EW (N=60) (PYS=42.6) Events (E/100PY)	TDM Regimen (N=8) (PYS=6.3) Events (E/100PY)	Total (N=126) (PYS=88.8) Events (E/100PY)
Any interstitial lung disease	0	0	0	0	0	0	0	0
Any intestinal perforation	0	0	0	0	0	0	0	0
Any pancreatitis	1 (0.5)	0	0	1 (0.2)	0	0	0	0
Any stevens-johnson syndrome	0	0	0	0	0	0	0	0
Any erythema multiforme related	0	0	0	0	0	0	0	0
Any worsening/new onset of psoriasis	2 (1.0)	1 (0.5)	1 (1.0)	4 (0.8)	0	0	0	0
Any demyelinating disorder	0	0	1 (1.0)	1 (0.2)	0	0	0	0
Any amyotrophic lateral sclerosis	0	0	0	0	0	0	0	0
Any reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0	0	0	0	0
Any hematologic disorders (including pancytopenia)	15 (7.6)	22 (10.5)	7 (7.0)	44 (8.7)	4 (10.0)	6 (14.1)	1 (15.9)	11 (12.4)
Any liver failure and other liver event (except gall bladder related)	1 (0.5)	1 (0.5)	0	2 (0.4)	1 (2.5)	1 (2.3)	0	2 (2.3)
Any humira administration related medication errors	0	0	0	0	0	0	0	0
Any injection site reaction	18 (9.1)	31 (14.8)	9 (9.0)	58 (11.4)	0	2 (4.7)	0	2 (2.3)
All deaths	2 (1.0)	2 (1.0)	0	4 (0.8)	0	0	0	0
Occurring <=70 days after last dose	1 (0.5)	1 (0.5)	0	2 (0.4)	0	0	0	0
Occurring >70 days after last dose	1 (0.5)	1 (0.5)	0	2 (0.4)	0	0	0	0

表 2.7.4.7-94.　人種別の有害事象の 100 人年あたりの発現頻度の概要（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. Event with unknown severity is being counted as severe. Event with unknown relationship to study drug is being counted as drug-related.
E/100PY = Events per 100 patient-years.
$ As assessed by investigator.

Cross reference: 追加解析レポート JCSS TABLE 2.7.4__1.8.3_J

表 2.7.4.7-95. 体重区分別の有害事象の 100 人年あたりの発現頻度の概要
（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）

	<= 73 kg				> 73 kg			
	Adalimumab				Adalimumab			
	40mg EOW (N=195) (PYS=134.7) Events (E/100PY)	40mg EW (N=173) (PYS=124.4) Events (E/100PY)	TDM Regimen (N=73) (PYS=50.2) Events (E/100PY)	Total (N=441) (PYS=309.2) Events (E/100PY)	40mg EOW (N=150) (PYS=102.9) Events (E/100PY)	40mg EW (N=177) (PYS=127.8) Events (E/100PY)	TDM Regimen (N=78) (PYS=55.6) Events (E/100PY)	Total (N=405) (PYS=286.3) Events (E/100PY)
Any adverse event (AE)	517 (383.8)	536 (430.9)	166 (330.7)	1219 (394.2)	415 (403.3)	549 (429.6)	175 (314.7)	1139 (397.8)
Any AE with reasonable possibility of being related to study drug$	101 (75.0)	147 (118.2)	46 (91.6)	294 (95.1)	74 (71.9)	133 (104.1)	51 (91.7)	258 (90.1)
Any severe AE	16 (11.9)	22 (17.7)	6 (12.0)	44 (14.2)	26 (25.3)	38 (29.7)	5 (9.0)	69 (24.1)
Any serious AE	27 (20.0)	28 (22.5)	9 (17.9)	64 (20.7)	36 (35.0)	42 (32.9)	12 (21.6)	90 (31.4)
Any AE leading to discontinuation of study drug	25 (18.6)	28 (22.5)	10 (19.9)	63 (20.4)	17 (16.5)	23 (18.0)	9 (16.2)	49 (17.1)
Any AE leading to death	0	1 (0.8)	0	1 (0.3)	2 (1.9)	1 (0.8)	0	3 (1.0)
Any infection	125 (92.8)	104 (83.6)	52 (103.6)	281 (90.9)	101 (98.2)	116 (90.8)	40 (71.9)	257 (89.8)
Any serious infection	7 (5.2)	4 (3.2)	1 (2.0)	12 (3.9)	5 (4.9)	5 (3.9)	2 (3.6)	12 (4.2)
Any legionella infection	0	0	0	0	0	0	0	0
Any diverticulitis infection	0	0	0	0	0	1 (0.8)	0	1 (0.3)
Any opportunistic INF. EXCL. oral candidiasis and TB	0	0	0	0	0	0	0	0
Any oral candidiasis	1 (0.7)	0	1 (2.0)	2 (0.6)	1 (1.0)	1 (0.8)	0	2 (0.7)
Any tuberculosis	0	1 (0.8)	1 (2.0)	2 (0.6)	0	1 (0.8)	0	1 (0.3)
Any active tuberculosis	0	1 (0.8)	1 (2.0)	2 (0.6)	0	1 (0.8)	0	1 (0.3)
Any latent tuberculosis	0	0	0	0	0	0	0	0
Any parasitic infection	0	2 (1.6)	1 (2.0)	3 (1.0)	0	0	0	0
Any reactivation of hepatitis B	0	0	0	0	0	0	0	0
Any progressive multifocal leukoencephalopathy (PML)	0	0	0	0	0	0	0	0

表 2.7.4.7-95. 体重区分別の有害事象の 100 人年あたりの発現頻度の概要
（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）

	<= 73 kg				> 73 kg			
	Adalimumab				Adalimumab			
	40mg EOW (N=195) (PYS=134.7) Events (E/100PY)	40mg EW (N=173) (PYS=124.4) Events (E/100PY)	TDM Regimen (N=73) (PYS=50.2) Events (E/100PY)	Total (N=441) (PYS=309.2) Events (E/100PY)	40mg EOW (N=150) (PYS=102.9) Events (E/100PY)	40mg EW (N=177) (PYS=127.8) Events (E/100PY)	TDM Regimen (N=78) (PYS=55.6) Events (E/100PY)	Total (N=405) (PYS=286.3) Events (E/100PY)
Any malignancy	1 (0.7)	1 (0.8)	0	2 (0.6)	1 (1.0)	3 (2.3)	0	4 (1.4)
Any lymphoma	0	0	0	0	0	0	0	0
Any hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0	0	0	0	0
Any non-melanoma skin cancer (NMSC)	1 (0.7)	1 (0.8)	0	2 (0.6)	0	0	0	0
Any melanoma	0	0	0	0	0	1 (0.8)	0	1 (0.3)
Any leukemia	0	0	0	0	0	0	0	0
Any malignancy other than NMSC, melanoma, lymphoma, HSTCL, and leukemia	0	0	0	0	1 (1.0)	2 (1.6)	0	3 (1.0)
Any allergic reaction (including angioedema/anaphylaxis)	2 (1.5)	3 (2.4)	0	5 (1.6)	2 (1.9)	4 (3.1)	0	6 (2.1)
Any lupus-like reactions and systemic lupus erythematosus	0	1 (0.8)	0	1 (0.3)	0	0	0	0
Any vasculitis	0	1 (0.8)	0	1 (0.3)	0	0	1 (1.8)	1 (0.3)
Any cutaneous vasculitis	0	0	0	0	0	0	1 (1.8)	1 (0.3)
Any non-cutaneous vasculitis	0	1 (0.8)	0	1 (0.3)	0	0	0	0
Any sarcoidosis	0	0	0	0	0	0	0	0
Any autoimmune hepatitis	0	0	0	0	0	0	0	0
Any myocardial infarction related	0	0	0	0	1 (1.0)	0	0	1 (0.3)
Any cerebrovascular accident related	0	0	1 (2.0)	1 (0.3)	0	0	0	0
Any congestive heart failure related	0	0	0	0	1 (1.0)	0	0	1 (0.3)
Any pulmonary embolism related	0	1 (0.8)	0	1 (0.3)	1 (1.0)	2 (1.6)	0	3 (1.0)

表 2.7.4.7-95. 体重区分別の有害事象の 100 人年あたりの発現頻度の概要
（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）

	<= 73 kg				> 73 kg			
	Adalimumab				Adalimumab			
	40mg EOW (N=195) (PYS=134.7) Events (E/100PY)	40mg EW (N=173) (PYS=124.4) Events (E/100PY)	TDM Regimen (N=73) (PYS=50.2) Events (E/100PY)	Total (N=441) (PYS=309.2) Events (E/100PY)	40mg EOW (N=150) (PYS=102.9) Events (E/100PY)	40mg EW (N=177) (PYS=127.8) Events (E/100PY)	TDM Regimen (N=78) (PYS=55.6) Events (E/100PY)	Total (N=405) (PYS=286.3) Events (E/100PY)
Any interstitial lung disease	0	0	0	0	0	0	0	0
Any intestinal perforation	0	0	0	0	0	0	0	0
Any pancreatitis	0	0	0	0	1 (1.0)	0	0	1 (0.3)
Any stevens-johnson syndrome	0	0	0	0	0	0	0	0
Any erythema multiforme related	0	0	0	0	0	0	0	0
Any worsening/new onset of psoriasis	1 (0.7)	0	1 (2.0)	2 (0.6)	1 (1.0)	1 (0.8)	0	2 (0.7)
Any demyelinating disorder	0	0	0	0	0	0	1 (1.8)	1 (0.3)
Any amyotrophic lateral sclerosis	0	0	0	0	0	0	0	0
Any reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0	0	0	0	0
Any hematologic disorders (including pancytopenia)	18 (13.4)	15 (12.1)	4 (8.0)	37 (12.0)	1 (1.0)	13 (10.2)	4 (7.2)	18 (6.3)
Any liver failure and other liver event (except gall bladder related)	2 (1.5)	2 (1.6)	0	4 (1.3)	0	0	0	0
Any humira administration related medication errors	0	0	0	0	0	0	0	0
Any injection site reaction	14 (10.4)	24 (19.3)	3 (6.0)	41 (13.3)	4 (3.9)	9 (7.0)	6 (10.8)	19 (6.6)
All deaths	0	1 (0.8)	0	1 (0.3)	2 (1.9)	1 (0.8)	0	3 (1.0)
Occurring <=70 days after last dose	0	1 (0.8)	0	1 (0.3)	1 (1.0)	0	0	1 (0.3)
Occurring >70 days after last dose	0	0	0	0	1 (1.0)	1 (0.8)	0	2 (0.7)

表 2.7.4.7-95.　体重区分別の有害事象の 100 人年あたりの発現頻度の概要
（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. Event with unknown severity is being counted as severe. Event with unknown relationship to study drug is being counted as drug-related.
E/100PY = Events per 100 patient-years.
$ As assessed by investigator.

Cross reference: 追加解析レポート JCSS TABLE 2.7.4__1.8.4_J

表 2.7.4.7-96. 抗 TNF 製剤の投与経験の有無別の有害事象の概要（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）

	Yes			No		
	Adalimumab			Adalimumab		
	Standard Induction Dose (N=53) n (%)	Higher Induction Dose (N=82) n (%)	Total (N=135) n (%)	Standard Induction Dose (N=326) n (%)	Higher Induction Dose (N=491) n (%)	Total (N=817) n (%)
Subjects with:						
Any adverse event (AE)	34 (64.2)	48 (58.5)	82 (60.7)	166 (50.9)	257 (52.3)	423 (51.8)
Any AE with reasonable possibility of being related to study drug$	11 (20.8)	19 (23.2)	30 (22.2)	72 (22.1)	130 (26.5)	202 (24.7)
Any severe AE	5 (9.4)	5 (6.1)	10 (7.4)	12 (3.7)	19 (3.9)	31 (3.8)
Any serious AE	6 (11.3)	4 (4.9)	10 (7.4)	13 (4.0)	18 (3.7)	31 (3.8)
Any AE leading to discontinuation of study drug	7 (13.2)	6 (7.3)	13 (9.6)	15 (4.6)	25 (5.1)	40 (4.9)
Any AE leading to death	0	0	0	0	1 (0.2)	1 (0.1)
Any infection	10 (18.9)	15 (18.3)	25 (18.5)	52 (16.0)	68 (13.8)	120 (14.7)
Any serious infection	1 (1.9)	2 (2.4)	3 (2.2)	2 (0.6)	2 (0.4)	4 (0.5)
Any legionella infection	0	0	0	0	0	0
Any diverticulitis infection	0	0	0	0	0	0
Any opportunistic INF. EXCL. oral candidiasis and TB	1 (1.9)	1 (1.2)	2 (1.5)	0	0	0
Any oral candidiasis	0	0	0	0	0	0
Any tuberculosis	0	0	0	0	1 (0.2)	1 (0.1)
Any active tuberculosis	0	0	0	0	1 (0.2)	1 (0.1)
Any latent tuberculosis	0	0	0	0	0	0
Any parasitic infection	0	0	0	0	1 (0.2)	1 (0.1)
Any reactivation of hepatitis B	0	0	0	0	0	0
Any progressive multifocal leukoencephalopathy (PML)	0	0	0	0	0	0

表 2.7.4.7-96. 抗 TNF 製剤の投与経験の有無別の有害事象の概要（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）（続き）

	Yes			No		
	Adalimumab			Adalimumab		
	Standard Induction Dose (N=53) n (%)	Higher Induction Dose (N=82) n (%)	Total (N=135) n (%)	Standard Induction Dose (N=326) n (%)	Higher Induction Dose (N=491) n (%)	Total (N=817) n (%)
Any malignancy	1 (1.9)	0	1 (0.7)	2 (0.6)	0	2 (0.2)
Any lymphoma	0	0	0	0	0	0
Any hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0	0	0
Any non-melanoma skin cancer (NMSC)	0	0	0	1 (0.3)	0	1 (0.1)
Any melanoma	1 (1.9)	0	1 (0.7)	0	0	0
Any leukemia	0	0	0	0	0	0
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 (1.9)	0	1 (0.7)	5 (1.5)	9 (1.8)	14 (1.7)
Any lupus-like reactions and systemic lupus erythematosus	0	0	0	0	0	0
Any vasculitis	0	0	0	0	0	0
Any cutaneous vasculitis	0	0	0	0	0	0
Any non-cutaneous vasculitis	0	0	0	0	0	0
Any sarcoidosis	0	0	0	0	0	0
Any autoimmune hepatitis	0	0	0	0	0	0
Any myocardial infarction related	0	0	0	0	0	0
Any cerebrovascular accident related	0	0	0	0	0	0
Any congestive heart failure related	0	0	0	0	0	0
Any pulmonary embolism related	0	0	0	0	0	0

表 2.7.4.7-96. 抗 TNF 製剤の投与経験の有無別の有害事象の概要（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）（続き）

	Yes			No		
	Adalimumab			Adalimumab		
	Standard Induction Dose (N=53) n (%)	Higher Induction Dose (N=82) n (%)	Total (N=135) n (%)	Standard Induction Dose (N=326) n (%)	Higher Induction Dose (N=491) n (%)	Total (N=817) n (%)
Any interstitial lung disease	0	0	0	0	0	0
Any intestinal perforation	0	0	0	0	0	0
Any pancreatitis	0	0	0	0	1 (0.2)	1 (0.1)
Any stevens-johnson syndrome	0	0	0	0	0	0
Any erythema multiforme related	0	0	0	0	0	0
Any worsening/new onset of psoriasis	1 (1.9)	0	1 (0.7)	1 (0.3)	1 (0.2)	2 (0.2)
Any demyelinating disorder	0	0	0	0	0	0
Any amyotrophic lateral sclerosis	0	0	0	0	0	0
Any reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0	0	0
Any hematologic disorders (including pancytopenia)	3 (5.7)	3 (3.7)	6 (4.4)	15 (4.6)	23 (4.7)	38 (4.7)
Any liver failure and other liver event (except gall bladder related)	0	0	0	0	2 (0.4)	2 (0.2)
Any humira administration related medication errors	0	0	0	0	0	0
Any injection site reaction	2 (3.8)	12 (14.6)	14 (10.4)	14 (4.3)	57 (11.6)	71 (8.7)
All deaths	0	0	0	0	2 (0.4)	2 (0.2)
Occurring <=70 days after last dose	0	0	0	0	1 (0.2)	1 (0.1)
Occurring >70 days after last dose	0	0	0	0	1 (0.2)	1 (0.1)

表 2.7.4.7-96.　抗 TNF 製剤の投与経験の有無別の有害事象の概要（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）（続き）

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. Event with unknown severity is being counted as severe. Event with unknown relationship to study drug is being counted as drug-related.
$ As assessed by investigator.

Cross reference: 追加解析レポート JCSS TABLE 2.7.4__1.5.5_J

表 2.7.4.7-97. 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別の有害事象の概要
（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）

	Yes			No		
	Adalimumab			Adalimumab		
	Standard Induction Dose (N=227) n (%)	Higher Induction Dose (N=328) n (%)	Total (N=555) n (%)	Standard Induction Dose (N=152) n (%)	Higher Induction Dose (N=245) n (%)	Total (N=397) n (%)
Subjects with:						
Any adverse event (AE)	113 (49.8)	157 (47.9)	270 (48.6)	87 (57.2)	148 (60.4)	235 (59.2)
Any AE with reasonable possibility of being related to study drug$	39 (17.2)	71 (21.6)	110 (19.8)	44 (28.9)	78 (31.8)	122 (30.7)
Any severe AE	10 (4.4)	16 (4.9)	26 (4.7)	7 (4.6)	8 (3.3)	15 (3.8)
Any serious AE	12 (5.3)	13 (4.0)	25 (4.5)	7 (4.6)	9 (3.7)	16 (4.0)
Any AE leading to discontinuation of study drug	11 (4.8)	20 (6.1)	31 (5.6)	11 (7.2)	11 (4.5)	22 (5.5)
Any AE leading to death	0	1 (0.3)	1 (0.2)	0	0	0
Any infection	30 (13.2)	47 (14.3)	77 (13.9)	32 (21.1)	36 (14.7)	68 (17.1)
Any serious infection	1 (0.4)	2 (0.6)	3 (0.5)	2 (1.3)	2 (0.8)	4 (1.0)
Any legionella infection	0	0	0	0	0	0
Any diverticulitis infection	0	0	0	0	0	0
Any opportunistic INF. EXCL. oral candidiasis and TB	0	0	0	1 (0.7)	1 (0.4)	2 (0.5)
Any oral candidiasis	0	0	0	0	0	0
Any tuberculosis	0	1 (0.3)	1 (0.2)	0	0	0
Any active tuberculosis	0	1 (0.3)	1 (0.2)	0	0	0
Any latent tuberculosis	0	0	0	0	0	0
Any parasitic infection	0	1 (0.3)	1 (0.2)	0	0	0
Any reactivation of hepatitis B	0	0	0	0	0	0
Any progressive multifocal leukoencephalopathy (PML)	0	0	0	0	0	0

表 2.7.4.7-97. 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別の有害事象の概要
（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）（続き）

	Yes			No		
	Adalimumab			Adalimumab		
	Standard Induction Dose (N=227) n (%)	Higher Induction Dose (N=328) n (%)	Total (N=555) n (%)	Standard Induction Dose (N=152) n (%)	Higher Induction Dose (N=245) n (%)	Total (N=397) n (%)
Any malignancy	1 (0.4)	0	1 (0.2)	2 (1.3)	0	2 (0.5)
Any lymphoma	0	0	0	0	0	0
Any hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0	0	0
Any non-melanoma skin cancer (NMSC)	0	0	0	1 (0.7)	0	1 (0.3)
Any melanoma	0	0	0	1 (0.7)	0	1 (0.3)
Any leukemia	0	0	0	0	0	0
Any malignancy other than NMSC, melanoma, lymphoma, HSTCL, and leukemia	1 (0.4)	0	1 (0.2)	0	0	0
Any allergic reaction (including angioedema/anaphylaxis)	3 (1.3)	4 (1.2)	7 (1.3)	3 (2.0)	5 (2.0)	8 (2.0)
Any lupus-like reactions and systemic lupus erythematosus	0	0	0	0	0	0
Any vasculitis	0	0	0	0	0	0
Any cutaneous vasculitis	0	0	0	0	0	0
Any non-cutaneous vasculitis	0	0	0	0	0	0
Any sarcoidosis	0	0	0	0	0	0
Any autoimmune hepatitis	0	0	0	0	0	0
Any myocardial infarction related	0	0	0	0	0	0
Any cerebrovascular accident related	0	0	0	0	0	0
Any congestive heart failure related	0	0	0	0	0	0
Any pulmonary embolism related	0	0	0	0	0	0

表 2.7.4.7-97. 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別の有害事象の概要
（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）（続き）

	Yes			No		
	Adalimumab			Adalimumab		
	Standard Induction Dose (N=227) n (%)	Higher Induction Dose (N=328) n (%)	Total (N=555) n (%)	Standard Induction Dose (N=152) n (%)	Higher Induction Dose (N=245) n (%)	Total (N=397) n (%)
Any interstitial lung disease	0	0	0	0	0	0
Any intestinal perforation	0	0	0	0	0	0
Any pancreatitis	0	1 (0.3)	1 (0.2)	0	0	0
Any stevens-johnson syndrome	0	0	0	0	0	0
Any erythema multiforme related	0	0	0	0	0	0
Any worsening/new onset of psoriasis	2 (0.9)	0	2 (0.4)	0	1 (0.4)	1 (0.3)
Any demyelinating disorder	0	0	0	0	0	0
Any amyotrophic lateral sclerosis	0	0	0	0	0	0
Any reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0	0	0
Any hematologic disorders (including pancytopenia)	11 (4.8)	11 (3.4)	22 (4.0)	7 (4.6)	15 (6.1)	22 (5.5)
Any liver failure and other liver event (except gall bladder related)	0	1 (0.3)	1 (0.2)	0	1 (0.4)	1 (0.3)
Any humira administration related medication errors	0	0	0	0	0	0
Any injection site reaction	8 (3.5)	27 (8.2)	35 (6.3)	8 (5.3)	42 (17.1)	50 (12.6)
All deaths	0	2 (0.6)	2 (0.4)	0	0	0
Occurring <=70 days after last dose	0	1 (0.3)	1 (0.2)	0	0	0
Occurring >70 days after last dose	0	1 (0.3)	1 (0.2)	0	0	0

表 2.7.4.7-97.　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別の有害事象の概要
（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）（続き）

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. Event with unknown severity is being counted as severe. Event with unknown relationship to study drug is being counted as drug-related.
$ As assessed by investigator.

Cross reference: 追加解析レポート JCSS TABLE 2.7.4__1.5.6_J

表 2.7.4.7-98. ベースラインにおける免疫抑制剤の使用の有無別の有害事象の概要
（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）

	Yes			No		
	Adalimumab			Adalimumab		
	Standard Induction Dose (N=104) n (%)	Higher Induction Dose (N=164) n (%)	Total (N=268) n (%)	Standard Induction Dose (N=275) n (%)	Higher Induction Dose (N=409) n (%)	Total (N=684) n (%)
Subjects with:						
Any adverse event (AE)	52 (50.0)	86 (52.4)	138 (51.5)	148 (53.8)	219 (53.5)	367 (53.7)
Any AE with reasonable possibility of being related to study drug$	15 (14.4)	38 (23.2)	53 (19.8)	68 (24.7)	111 (27.1)	179 (26.2)
Any severe AE	2 (1.9)	8 (4.9)	10 (3.7)	15 (5.5)	16 (3.9)	31 (4.5)
Any serious AE	2 (1.9)	8 (4.9)	10 (3.7)	17 (6.2)	14 (3.4)	31 (4.5)
Any AE leading to discontinuation of study drug	3 (2.9)	3 (1.8)	6 (2.2)	19 (6.9)	28 (6.8)	47 (6.9)
Any AE leading to death	0	0	0	0	1 (0.2)	1 (0.1)
Any infection	11 (10.6)	28 (17.1)	39 (14.6)	51 (18.5)	55 (13.4)	106 (15.5)
Any serious infection	0	1 (0.6)	1 (0.4)	3 (1.1)	3 (0.7)	6 (0.9)
Any legionella infection	0	0	0	0	0	0
Any diverticulitis infection	0	0	0	0	0	0
Any opportunistic INF. EXCL. oral candidiasis and TB	0	0	0	1 (0.4)	1 (0.2)	2 (0.3)
Any oral candidiasis	0	0	0	0	0	0
Any tuberculosis	0	0	0	0	1 (0.2)	1 (0.1)
Any active tuberculosis	0	0	0	0	1 (0.2)	1 (0.1)
Any latent tuberculosis	0	0	0	0	0	0
Any parasitic infection	0	1 (0.6)	1 (0.4)	0	0	0
Any reactivation of hepatitis B	0	0	0	0	0	0
Any progressive multifocal leukoencephalopathy (PML)	0	0	0	0	0	0

表 2.7.4.7-98. ベースラインにおける免疫抑制剤の使用の有無別の有害事象の概要
（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）（続き）

	Yes			No		
	Adalimumab			Adalimumab		
	Standard Induction Dose (N=104) n (%)	Higher Induction Dose (N=164) n (%)	Total (N=268) n (%)	Standard Induction Dose (N=275) n (%)	Higher Induction Dose (N=409) n (%)	Total (N=684) n (%)
Any malignancy	1 (1.0)	0	1 (0.4)	2 (0.7)	0	2 (0.3)
Any lymphoma	0	0	0	0	0	0
Any hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0	0	0
Any non-melanoma skin cancer (NMSC)	0	0	0	1 (0.4)	0	1 (0.1)
Any melanoma	0	0	0	1 (0.4)	0	1 (0.1)
Any leukemia	0	0	0	0	0	0
Any malignancy other than NMSC, melanoma, lymphoma, HSTCL, and leukemia	1 (1.0)	0	1 (0.4)	0	0	0
Any allergic reaction (including angioedema/anaphylaxis)	1 (1.0)	2 (1.2)	3 (1.1)	5 (1.8)	7 (1.7)	12 (1.8)
Any lupus-like reactions and systemic lupus erythematosus	0	0	0	0	0	0
Any vasculitis	0	0	0	0	0	0
Any cutaneous vasculitis	0	0	0	0	0	0
Any non-cutaneous vasculitis	0	0	0	0	0	0
Any sarcoidosis	0	0	0	0	0	0
Any autoimmune hepatitis	0	0	0	0	0	0
Any myocardial infarction related	0	0	0	0	0	0
Any cerebrovascular accident related	0	0	0	0	0	0
Any congestive heart failure related	0	0	0	0	0	0
Any pulmonary embolism related	0	0	0	0	0	0

表 2.7.4.7-98. ベースラインにおける免疫抑制剤の使用の有無別の有害事象の概要
（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）（続き）

	Yes			No		
	Adalimumab			Adalimumab		
	Standard Induction Dose (N=104) n (%)	Higher Induction Dose (N=164) n (%)	Total (N=268) n (%)	Standard Induction Dose (N=275) n (%)	Higher Induction Dose (N=409) n (%)	Total (N=684) n (%)
Any interstitial lung disease	0	0	0	0	0	0
Any intestinal perforation	0	0	0	0	0	0
Any pancreatitis	0	0	0	0	1 (0.2)	1 (0.1)
Any stevens-johnson syndrome	0	0	0	0	0	0
Any erythema multiforme related	0	0	0	0	0	0
Any worsening/new onset of psoriasis	0	0	0	2 (0.7)	1 (0.2)	3 (0.4)
Any demyelinating disorder	0	0	0	0	0	0
Any amyotrophic lateral sclerosis	0	0	0	0	0	0
Any reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0	0	0
Any hematologic disorders (including pancytopenia)	3 (2.9)	10 (6.1)	13 (4.9)	15 (5.5)	16 (3.9)	31 (4.5)
Any liver failure and other liver event (except gall bladder related)	0	1 (0.6)	1 (0.4)	0	1 (0.2)	1 (0.1)
Any humira administration related medication errors	0	0	0	0	0	0
Any injection site reaction	5 (4.8)	15 (9.1)	20 (7.5)	11 (4.0)	54 (13.2)	65 (9.5)
All deaths	0	0	0	0	2 (0.5)	2 (0.3)
Occurring <=70 days after last dose	0	0	0	0	1 (0.2)	1 (0.1)
Occurring >70 days after last dose	0	0	0	0	1 (0.2)	1 (0.1)

表 2.7.4.7-98.　ベースラインにおける免疫抑制剤の使用の有無別の有害事象の概要
（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）（続き）

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. Event with unknown severity is being counted as severe. Event with unknown relationship to study drug is being counted as drug-related.
$ As assessed by investigator.

Cross reference: 追加解析レポート JCSS TABLE 2.7.4__1.5.7_J

表 2.7.4.7-99. Mayo スコアに基づく疾患重症度別の有害事象の概要（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）

	<= 9 Adalimumab Standard Induction Dose (N=244) n (%)	<= 9 Adalimumab Higher Induction Dose (N=325) n (%)	<= 9 Total (N=569) n (%)	> 9 Adalimumab Standard Induction Dose (N=135) n (%)	> 9 Adalimumab Higher Induction Dose (N=245) n (%)	> 9 Total (N=380) n (%)	-- Missing -- Adalimumab Higher Induction Dose (N=3) n (%)
Subjects with:							
Any adverse event (AE)	123 (50.4)	176 (54.2)	299 (52.5)	77 (57.0)	128 (52.2)	205 (53.9)	1 (33.3)
Any AE with reasonable possibility of being related to study drug$	51 (20.9)	93 (28.6)	144 (25.3)	32 (23.7)	56 (22.9)	88 (23.2)	0
Any severe AE	8 (3.3)	11 (3.4)	19 (3.3)	9 (6.7)	13 (5.3)	22 (5.8)	0
Any serious AE	8 (3.3)	9 (2.8)	17 (3.0)	11 (8.1)	13 (5.3)	24 (6.3)	0
Any AE leading to discontinuation of study drug	15 (6.1)	15 (4.6)	30 (5.3)	7 (5.2)	16 (6.5)	23 (6.1)	0
Any AE leading to death	0	1 (0.3)	1 (0.2)	0	0	0	0
Any infection	33 (13.5)	42 (12.9)	75 (13.2)	29 (21.5)	41 (16.7)	70 (18.4)	0
Any serious infection	3 (1.2)	1 (0.3)	4 (0.7)	0	3 (1.2)	3 (0.8)	0
Any legionella infection	0	0	0	0	0	0	0
Any diverticulitis infection	0	0	0	0	0	0	0
Any opportunistic INF. EXCL. oral candidiasis and TB	0	0	0	1 (0.7)	1 (0.4)	2 (0.5)	0
Any oral candidiasis	0	0	0	0	0	0	0
Any tuberculosis	0	1 (0.3)	1 (0.2)	0	0	0	0
Any active tuberculosis	0	1 (0.3)	1 (0.2)	0	0	0	0
Any latent tuberculosis	0	0	0	0	0	0	0
Any parasitic infection	0	1 (0.3)	1 (0.2)	0	0	0	0
Any reactivation of hepatitis B	0	0	0	0	0	0	0
Any progressive multifocal leukoencephalopathy (PML)	0	0	0	0	0	0	0

表 2.7.4.7-99. Mayo スコアに基づく疾患重症度別の有害事象の概要（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）（続き）

	<= 9			> 9			-- Missing --
	Adalimumab			Adalimumab			Adalimumab
	Standard Induction Dose (N=244) n (%)	Higher Induction Dose (N=325) n (%)	Total (N=569) n (%)	Standard Induction Dose (N=135) n (%)	Higher Induction Dose (N=245) n (%)	Total (N=380) n (%)	Higher Induction Dose (N=3) n (%)
Any malignancy	3 (1.2)	0	3 (0.5)	0	0	0	0
Any lymphoma	0	0	0	0	0	0	0
Any hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0	0	0	0
Any non-melanoma skin cancer (NMSC)	1 (0.4)	0	1 (0.2)	0	0	0	0
Any melanoma	1 (0.4)	0	1 (0.2)	0	0	0	0
Any leukemia	0	0	0	0	0	0	0
Any malignancy other than NMSC, melanoma, lymphoma, HSTCL, and leukemia	1 (0.4)	0	1 (0.2)	0	0	0	0
Any allergic reaction (including angioedema/anaphylaxis)	3 (1.2)	6 (1.8)	9 (1.6)	3 (2.2)	3 (1.2)	6 (1.6)	0
Any lupus-like reactions and systemic lupus erythematosus	0	0	0	0	0	0	0
Any vasculitis	0	0	0	0	0	0	0
Any cutaneous vasculitis	0	0	0	0	0	0	0
Any non-cutaneous vasculitis	0	0	0	0	0	0	0
Any sarcoidosis	0	0	0	0	0	0	0
Any autoimmune hepatitis	0	0	0	0	0	0	0
Any myocardial infarction related	0	0	0	0	0	0	0
Any cerebrovascular accident related	0	0	0	0	0	0	0
Any congestive heart failure related	0	0	0	0	0	0	0
Any pulmonary embolism related	0	0	0	0	0	0	0

表 2.7.4.7-99. Mayo スコアに基づく疾患重症度別の有害事象の概要（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）（続き）

	<= 9			> 9			-- Missing --
	Adalimumab			Adalimumab			Adalimumab
	Standard Induction Dose (N=244) n (%)	Higher Induction Dose (N=325) n (%)	Total (N=569) n (%)	Standard Induction Dose (N=135) n (%)	Higher Induction Dose (N=245) n (%)	Total (N=380) n (%)	Higher Induction Dose (N=3) n (%)
Any interstitial lung disease	0	0	0	0	0	0	0
Any intestinal perforation	0	0	0	0	0	0	0
Any pancreatitis	0	1 (0.3)	1 (0.2)	0	0	0	0
Any stevens-johnson syndrome	0	0	0	0	0	0	0
Any erythema multiforme related	0	0	0	0	0	0	0
Any worsening/new onset of psoriasis	1 (0.4)	1 (0.3)	2 (0.4)	1 (0.7)	0	1 (0.3)	0
Any demyelinating disorder	0	0	0	0	0	0	0
Any amyotrophic lateral sclerosis	0	0	0	0	0	0	0
Any reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0	0	0	0
Any hematologic disorders (including pancytopenia)	8 (3.3)	13 (4.0)	21 (3.7)	10 (7.4)	13 (5.3)	23 (6.1)	0
Any liver failure and other liver event (except gall bladder related)	0	1 (0.3)	1 (0.2)	0	1 (0.4)	1 (0.3)	0
Any humira administration related medication errors	0	0	0	0	0	0	0
Any injection site reaction	12 (4.9)	45 (13.8)	57 (10.0)	4 (3.0)	24 (9.8)	28 (7.4)	0
All deaths	0	1 (0.3)	1 (0.2)	0	1 (0.4)	1 (0.3)	0
Occurring <=70 days after last dose	0	1 (0.3)	1 (0.2)	0	0	0	0
Occurring >70 days after last dose	0	0	0	0	1 (0.4)	1 (0.3)	0

表 2.7.4.7-99.　　Mayo スコアに基づく疾患重症度別の有害事象の概要（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）（続き）

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. Event with unknown severity is being counted as severe. Event with unknown relationship to study drug is being counted as drug-related.
$ As assessed by investigator.

Cross reference: 追加解析レポート JCSS TABLE 2.7.4__1.5.8_J

表 2.7.4.7-100. 抗 TNF 製剤の投与経験の有無別の有害事象の概要（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）

	Yes				No			
	Adalimumab				Adalimumab			
	40mg EOW (N=54) n (%)	40mg EW (N=47) n (%)	TDM Regimen (N=16) n (%)	Total (N=117) n (%)	40mg EOW (N=291) n (%)	40mg EW (N=303) n (%)	TDM Regimen (N=135) n (%)	Total (N=729) n (%)
Subjects with:								
Any adverse event (AE)	44 (81.5)	38 (80.9)	12 (75.0)	94 (80.3)	213 (73.2)	225 (74.3)	84 (62.2)	522 (71.6)
Any AE with reasonable possibility of being related to study drug$	19 (35.2)	14 (29.8)	7 (43.8)	40 (34.2)	70 (24.1)	103 (34.0)	42 (31.1)	215 (29.5)
Any severe AE	4 (7.4)	2 (4.3)	2 (12.5)	8 (6.8)	25 (8.6)	39 (12.9)	8 (5.9)	72 (9.9)
Any serious AE	6 (11.1)	5 (10.6)	3 (18.8)	14 (12.0)	38 (13.1)	39 (12.9)	12 (8.9)	89 (12.2)
Any AE leading to discontinuation of study drug	8 (14.8)	5 (10.6)	4 (25.0)	17 (14.5)	32 (11.0)	30 (9.9)	13 (9.6)	75 (10.3)
Any AE leading to death	0	0	0	0	2 (0.7)	2 (0.7)	0	4 (0.5)
Any infection	23 (42.6)	20 (42.6)	5 (31.3)	48 (41.0)	109 (37.5)	110 (36.3)	46 (34.1)	265 (36.4)
Any serious infection	0	2 (4.3)	1 (6.3)	3 (2.6)	11 (3.8)	7 (2.3)	2 (1.5)	20 (2.7)
Any legionella infection	0	0	0	0	0	0	0	0
Any diverticulitis infection	0	0	0	0	0	1 (0.3)	0	1 (0.1)
Any opportunistic INF. EXCL. oral candidiasis and TB	0	0	0	0	0	0	0	0
Any oral candidiasis	1 (1.9)	0	1 (6.3)	2 (1.7)	1 (0.3)	1 (0.3)	0	2 (0.3)
Any tuberculosis	0	1 (2.1)	0	1 (0.9)	0	1 (0.3)	1 (0.7)	2 (0.3)
Any active tuberculosis	0	1 (2.1)	0	1 (0.9)	0	1 (0.3)	1 (0.7)	2 (0.3)
Any latent tuberculosis	0	0	0	0	0	0	0	0
Any parasitic infection	0	0	1 (6.3)	1 (0.9)	0	2 (0.7)	0	2 (0.3)
Any reactivation of hepatitis B	0	0	0	0	0	0	0	0
Any progressive multifocal leukoencephalopathy (PML)	0	0	0	0	0	0	0	0

表 2.7.4.7-100. 抗 TNF 製剤の投与経験の有無別の有害事象の概要（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）

	Yes				No			
	Adalimumab				Adalimumab			
	40mg EOW (N=54) n (%)	40mg EW (N=47) n (%)	TDM Regimen (N=16) n (%)	Total (N=117) n (%)	40mg EOW (N=291) n (%)	40mg EW (N=303) n (%)	TDM Regimen (N=135) n (%)	Total (N=729) n (%)
Any malignancy	0	0	0	0	2 (0.7)	4 (1.3)	0	6 (0.8)
Any lymphoma	0	0	0	0	0	0	0	0
Any hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0	0	0	0	0
Any non-melanoma skin cancer (NMSC)	0	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.3)
Any melanoma	0	0	0	0	0	1 (0.3)	0	1 (0.1)
Any leukemia	0	0	0	0	0	0	0	0
Any malignancy other than NMSC, melanoma, lymphoma, HSTCL, and leukemia	0	0	0	0	1 (0.3)	2 (0.7)	0	3 (0.4)
Any allergic reaction (including angioedema/anaphylaxis)	1 (1.9)	0	0	1 (0.9)	3 (1.0)	7 (2.3)	0	10 (1.4)
Any lupus-like reactions and systemic lupus erythematosus	0	0	0	0	0	1 (0.3)	0	1 (0.1)
Any vasculitis	0	1 (2.1)	0	1 (0.9)	0	0	1 (0.7)	1 (0.1)
Any cutaneous vasculitis	0	0	0	0	0	0	1 (0.7)	1 (0.1)
Any non-cutaneous vasculitis	0	1 (2.1)	0	1 (0.9)	0	0	0	0
Any sarcoidosis	0	0	0	0	0	0	0	0
Any autoimmune hepatitis	0	0	0	0	0	0	0	0
Any myocardial infarction related	0	0	0	0	1 (0.3)	0	0	1 (0.1)
Any cerebrovascular accident related	0	0	0	0	0	0	1 (0.7)	1 (0.1)
Any congestive heart failure related	0	0	0	0	1 (0.3)	0	0	1 (0.1)
Any pulmonary embolism related	0	0	0	0	1 (0.3)	3 (1.0)	0	4 (0.5)

表 2.7.4.7-100. 抗 TNF 製剤の投与経験の有無別の有害事象の概要（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）

	Yes				No			
	Adalimumab				Adalimumab			
	40mg EOW (N=54) n (%)	40mg EW (N=47) n (%)	TDM Regimen (N=16) n (%)	Total (N=117) n (%)	40mg EOW (N=291) n (%)	40mg EW (N=303) n (%)	TDM Regimen (N=135) n (%)	Total (N=729) n (%)
Any interstitial lung disease	0	0	0	0	0	0	0	0
Any intestinal perforation	0	0	0	0	0	0	0	0
Any pancreatitis	0	0	0	0	1 (0.3)	0	0	1 (0.1)
Any stevens-johnson syndrome	0	0	0	0	0	0	0	0
Any erythema multiforme related	0	0	0	0	0	0	0	0
Any worsening/new onset of psoriasis	0	0	0	0	2 (0.7)	1 (0.3)	1 (0.7)	4 (0.5)
Any demyelinating disorder	0	0	0	0	0	0	1 (0.7)	1 (0.1)
Any amyotrophic lateral sclerosis	0	0	0	0	0	0	0	0
Any reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0	0	0	0	0
Any hematologic disorders (including pancytopenia)	3 (5.6)	4 (8.5)	1 (6.3)	8 (6.8)	14 (4.8)	19 (6.3)	7 (5.2)	40 (5.5)
Any liver failure and other liver event (except gall bladder related)	0	0	0	0	2 (0.7)	2 (0.7)	0	4 (0.5)
Any humira administration related medication errors	0	0	0	0	0	0	0	0
Any injection site reaction	2 (3.7)	2 (4.3)	0	4 (3.4)	6 (2.1)	14 (4.6)	5 (3.7)	25 (3.4)
All deaths	0	0	0	0	2 (0.7)	2 (0.7)	0	4 (0.5)
Occurring <=70 days after last dose	0	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.3)
Occurring >70 days after last dose	0	0	0	0	1 (0.3)	1 (0.3)	0	2 (0.3)

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. Event with unknown severity is being counted as severe. Event with unknown relationship to study drug is being counted as drug-related.
$ As assessed by investigator.

Cross reference: 追加解析レポート JCSS TABLE 2.7.4__1.6.5_J

表 2.7.4.7-101. 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別の有害事象の概要
（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）

	Yes				No			
	Adalimumab				Adalimumab			
	40mg EOW (N=208) n (%)	40mg EW (N=208) n (%)	TDM Regimen (N=88) n (%)	Total (N=504) n (%)	40mg EOW (N=137) n (%)	40mg EW (N=142) n (%)	TDM Regimen (N=63) n (%)	Total (N=342) n (%)
Subjects with:								
Any adverse event (AE)	150 (72.1)	153 (73.6)	54 (61.4)	357 (70.8)	107 (78.1)	110 (77.5)	42 (66.7)	259 (75.7)
Any AE with reasonable possibility of being related to study drug$	47 (22.6)	73 (35.1)	26 (29.5)	146 (29.0)	42 (30.7)	44 (31.0)	23 (36.5)	109 (31.9)
Any severe AE	18 (8.7)	26 (12.5)	6 (6.8)	50 (9.9)	11 (8.0)	15 (10.6)	4 (6.3)	30 (8.8)
Any serious AE	27 (13.0)	32 (15.4)	8 (9.1)	67 (13.3)	17 (12.4)	12 (8.5)	7 (11.1)	36 (10.5)
Any AE leading to discontinuation of study drug	25 (12.0)	22 (10.6)	10 (11.4)	57 (11.3)	15 (10.9)	13 (9.2)	7 (11.1)	35 (10.2)
Any AE leading to death	0	0	0	0	2 (1.5)	2 (1.4)	0	4 (1.2)
Any infection	69 (33.2)	72 (34.6)	27 (30.7)	168 (33.3)	63 (46.0)	58 (40.8)	24 (38.1)	145 (42.4)
Any serious infection	7 (3.4)	6 (2.9)	3 (3.4)	16 (3.2)	4 (2.9)	3 (2.1)	0	7 (2.0)
Any legionella infection	0	0	0	0	0	0	0	0
Any diverticulitis infection	0	0	0	0	0	1 (0.7)	0	1 (0.3)
Any opportunistic INF. EXCL. oral candidiasis and TB	0	0	0	0	0	0	0	0
Any oral candidiasis	1 (0.5)	0	1 (1.1)	2 (0.4)	1 (0.7)	1 (0.7)	0	2 (0.6)
Any tuberculosis	0	1 (0.5)	1 (1.1)	2 (0.4)	0	1 (0.7)	0	1 (0.3)
Any active tuberculosis	0	1 (0.5)	1 (1.1)	2 (0.4)	0	1 (0.7)	0	1 (0.3)
Any latent tuberculosis	0	0	0	0	0	0	0	0
Any parasitic infection	0	1 (0.5)	0	1 (0.2)	0	1 (0.7)	1 (1.6)	2 (0.6)
Any reactivation of hepatitis B	0	0	0	0	0	0	0	0
Any progressive multifocal leukoencephalopathy (PML)	0	0	0	0	0	0	0	0

表 2.7.4.7-101. 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別の有害事象の概要
（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）

	Yes				No			
	Adalimumab				Adalimumab			
	40mg EOW (N=208) n (%)	40mg EW (N=208) n (%)	TDM Regimen (N=88) n (%)	Total (N=504) n (%)	40mg EOW (N=137) n (%)	40mg EW (N=142) n (%)	TDM Regimen (N=63) n (%)	Total (N=342) n (%)
Any malignancy	0	2 (1.0)	0	2 (0.4)	2 (1.5)	2 (1.4)	0	4 (1.2)
Any lymphoma	0	0	0	0	0	0	0	0
Any hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0	0	0	0	0
Any non-melanoma skin cancer (NMSC)	0	0	0	0	1 (0.7)	1 (0.7)	0	2 (0.6)
Any melanoma	0	1 (0.5)	0	1 (0.2)	0	0	0	0
Any leukemia	0	0	0	0	0	0	0	0
Any malignancy other than NMSC, melanoma, lymphoma, HSTCL, and leukemia	0	1 (0.5)	0	1 (0.2)	1 (0.7)	1 (0.7)	0	2 (0.6)
Any allergic reaction (including angioedema/anaphylaxis)	2 (1.0)	3 (1.4)	0	5 (1.0)	2 (1.5)	4 (2.8)	0	6 (1.8)
Any lupus-like reactions and systemic lupus erythematosus	0	1 (0.5)	0	1 (0.2)	0	0	0	0
Any vasculitis	0	1 (0.5)	0	1 (0.2)	0	0	1 (1.6)	1 (0.3)
Any cutaneous vasculitis	0	0	0	0	0	0	1 (1.6)	1 (0.3)
Any non-cutaneous vasculitis	0	1 (0.5)	0	1 (0.2)	0	0	0	0
Any sarcoidosis	0	0	0	0	0	0	0	0
Any autoimmune hepatitis	0	0	0	0	0	0	0	0
Any myocardial infarction related	1 (0.5)	0	0	1 (0.2)	0	0	0	0
Any cerebrovascular accident related	0	0	1 (1.1)	1 (0.2)	0	0	0	0
Any congestive heart failure related	1 (0.5)	0	0	1 (0.2)	0	0	0	0
Any pulmonary embolism related	0	2 (1.0)	0	2 (0.4)	1 (0.7)	1 (0.7)	0	2 (0.6)

表 2.7.4.7-101. 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別の有害事象の概要
（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）

	Yes				No			
	Adalimumab				Adalimumab			
	40mg EOW (N=208) n (%)	40mg EW (N=208) n (%)	TDM Regimen (N=88) n (%)	Total (N=504) n (%)	40mg EOW (N=137) n (%)	40mg EW (N=142) n (%)	TDM Regimen (N=63) n (%)	Total (N=342) n (%)
Any interstitial lung disease	0	0	0	0	0	0	0	0
Any intestinal perforation	0	0	0	0	0	0	0	0
Any pancreatitis	1 (0.5)	0	0	1 (0.2)	0	0	0	0
Any stevens-johnson syndrome	0	0	0	0	0	0	0	0
Any erythema multiforme related	0	0	0	0	0	0	0	0
Any worsening/new onset of psoriasis	1 (0.5)	1 (0.5)	0	2 (0.4)	1 (0.7)	0	1 (1.6)	2 (0.6)
Any demyelinating disorder	0	0	0	0	0	0	1 (1.6)	1 (0.3)
Any amyotrophic lateral sclerosis	0	0	0	0	0	0	0	0
Any reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0	0	0	0	0
Any hematologic disorders (including pancytopenia)	11 (5.3)	14 (6.7)	6 (6.8)	31 (6.2)	6 (4.4)	9 (6.3)	2 (3.2)	17 (5.0)
Any liver failure and other liver event (except gall bladder related)	1 (0.5)	1 (0.5)	0	2 (0.4)	1 (0.7)	1 (0.7)	0	2 (0.6)
Any humira administration related medication errors	0	0	0	0	0	0	0	0
Any injection site reaction	3 (1.4)	8 (3.8)	2 (2.3)	13 (2.6)	5 (3.6)	8 (5.6)	3 (4.8)	16 (4.7)
All deaths	0	0	0	0	2 (1.5)	2 (1.4)	0	4 (1.2)
Occurring <=70 days after last dose	0	0	0	0	1 (0.7)	1 (0.7)	0	2 (0.6)
Occurring >70 days after last dose	0	0	0	0	1 (0.7)	1 (0.7)	0	2 (0.6)

表 2.7.4.7-101.　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別の有害事象の概要
（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. Event with unknown severity is being counted as severe. Event with unknown relationship to study drug is being counted as drug-related.
$ As assessed by investigator.

Cross reference: 追加解析レポート JCSS TABLE 2.7.4__1.6.6_J

表 2.7.4.7-102. ベースラインにおける免疫抑制剤の使用の有無別の有害事象の概要
（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）

	Yes				No			
	Adalimumab				Adalimumab			
	40mg EOW (N=107) n (%)	40mg EW (N=94) n (%)	TDM Regimen (N=45) n (%)	Total (N=246) n (%)	40mg EOW (N=238) n (%)	40mg EW (N=256) n (%)	TDM Regimen (N=106) n (%)	Total (N=600) n (%)
Subjects with:								
Any adverse event (AE)	86 (80.4)	73 (77.7)	34 (75.6)	193 (78.5)	171 (71.8)	190 (74.2)	62 (58.5)	423 (70.5)
Any AE with reasonable possibility of being related to study drug$	28 (26.2)	30 (31.9)	17 (37.8)	75 (30.5)	61 (25.6)	87 (34.0)	32 (30.2)	180 (30.0)
Any severe AE	8 (7.5)	5 (5.3)	6 (13.3)	19 (7.7)	21 (8.8)	36 (14.1)	4 (3.8)	61 (10.2)
Any serious AE	14 (13.1)	10 (10.6)	6 (13.3)	30 (12.2)	30 (12.6)	34 (13.3)	9 (8.5)	73 (12.2)
Any AE leading to discontinuation of study drug	7 (6.5)	5 (5.3)	7 (15.6)	19 (7.7)	33 (13.9)	30 (11.7)	10 (9.4)	73 (12.2)
Any AE leading to death	0	1 (1.1)	0	1 (0.4)	2 (0.8)	1 (0.4)	0	3 (0.5)
Any infection	58 (54.2)	46 (48.9)	16 (35.6)	120 (48.8)	74 (31.1)	84 (32.8)	35 (33.0)	193 (32.2)
Any serious infection	6 (5.6)	1 (1.1)	0	7 (2.8)	5 (2.1)	8 (3.1)	3 (2.8)	16 (2.7)
Any legionella infection	0	0	0	0	0	0	0	0
Any diverticulitis infection	0	0	0	0	0	1 (0.4)	0	1 (0.2)
Any opportunistic INF. EXCL. oral candidiasis and TB	0	0	0	0	0	0	0	0
Any oral candidiasis	2 (1.9)	1 (1.1)	1 (2.2)	4 (1.6)	0	0	0	0
Any tuberculosis	0	0	0	0	0	2 (0.8)	1 (0.9)	3 (0.5)
Any active tuberculosis	0	0	0	0	0	2 (0.8)	1 (0.9)	3 (0.5)
Any latent tuberculosis	0	0	0	0	0	0	0	0
Any parasitic infection	0	0	0	0	0	2 (0.8)	1 (0.9)	3 (0.5)
Any reactivation of hepatitis B	0	0	0	0	0	0	0	0
Any progressive multifocal leukoencephalopathy (PML)	0	0	0	0	0	0	0	0

表 2.7.4.7-102. ベースラインにおける免疫抑制剤の使用の有無別の有害事象の概要
（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）

	Yes				No			
	Adalimumab				Adalimumab			
	40mg EOW (N=107) n (%)	40mg EW (N=94) n (%)	TDM Regimen (N=45) n (%)	Total (N=246) n (%)	40mg EOW (N=238) n (%)	40mg EW (N=256) n (%)	TDM Regimen (N=106) n (%)	Total (N=600) n (%)
Any malignancy	0	2 (2.1)	0	2 (0.8)	2 (0.8)	2 (0.8)	0	4 (0.7)
Any lymphoma	0	0	0	0	0	0	0	0
Any hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0	0	0	0	0
Any non-melanoma skin cancer (NMSC)	0	0	0	0	1 (0.4)	1 (0.4)	0	2 (0.3)
Any melanoma	0	1 (1.1)	0	1 (0.4)	0	0	0	0
Any leukemia	0	0	0	0	0	0	0	0
Any malignancy other than NMSC, melanoma, lymphoma, HSTCL, and leukemia	0	1 (1.1)	0	1 (0.4)	1 (0.4)	1 (0.4)	0	2 (0.3)
Any allergic reaction (including angioedema/anaphylaxis)	1 (0.9)	1 (1.1)	0	2 (0.8)	3 (1.3)	6 (2.3)	0	9 (1.5)
Any lupus-like reactions and systemic lupus erythematosus	0	0	0	0	0	1 (0.4)	0	1 (0.2)
Any vasculitis	0	0	0	0	0	1 (0.4)	1 (0.9)	2 (0.3)
Any cutaneous vasculitis	0	0	0	0	0	0	1 (0.9)	1 (0.2)
Any non-cutaneous vasculitis	0	0	0	0	0	1 (0.4)	0	1 (0.2)
Any sarcoidosis	0	0	0	0	0	0	0	0
Any autoimmune hepatitis	0	0	0	0	0	0	0	0
Any myocardial infarction related	0	0	0	0	1 (0.4)	0	0	1 (0.2)
Any cerebrovascular accident related	0	0	0	0	0	0	1 (0.9)	1 (0.2)
Any congestive heart failure related	1 (0.9)	0	0	1 (0.4)	0	0	0	0
Any pulmonary embolism related	0	2 (2.1)	0	2 (0.8)	1 (0.4)	1 (0.4)	0	2 (0.3)

表 2.7.4.7-102. ベースラインにおける免疫抑制剤の使用の有無別の有害事象の概要
（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）

	Yes				No			
	Adalimumab				Adalimumab			
	40mg EOW (N=107) n (%)	40mg EW (N=94) n (%)	TDM Regimen (N=45) n (%)	Total (N=246) n (%)	40mg EOW (N=238) n (%)	40mg EW (N=256) n (%)	TDM Regimen (N=106) n (%)	Total (N=600) n (%)
Any interstitial lung disease	0	0	0	0	0	0	0	0
Any intestinal perforation	0	0	0	0	0	0	0	0
Any pancreatitis	0	0	0	0	1 (0.4)	0	0	1 (0.2)
Any stevens-johnson syndrome	0	0	0	0	0	0	0	0
Any erythema multiforme related	0	0	0	0	0	0	0	0
Any worsening/new onset of psoriasis	0	0	0	0	2 (0.8)	1 (0.4)	1 (0.9)	4 (0.7)
Any demyelinating disorder	0	0	0	0	0	0	1 (0.9)	1 (0.2)
Any amyotrophic lateral sclerosis	0	0	0	0	0	0	0	0
Any reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0	0	0	0	0
Any hematologic disorders (including pancytopenia)	3 (2.8)	13 (13.8)	3 (6.7)	19 (7.7)	14 (5.9)	10 (3.9)	5 (4.7)	29 (4.8)
Any liver failure and other liver event (except gall bladder related)	1 (0.9)	2 (2.1)	0	3 (1.2)	1 (0.4)	0	0	1 (0.2)
Any humira administration related medication errors	0	0	0	0	0	0	0	0
Any injection site reaction	2 (1.9)	4 (4.3)	0	6 (2.4)	6 (2.5)	12 (4.7)	5 (4.7)	23 (3.8)
All deaths	0	1 (1.1)	0	1 (0.4)	2 (0.8)	1 (0.4)	0	3 (0.5)
Occurring <=70 days after last dose	0	0	0	0	1 (0.4)	1 (0.4)	0	2 (0.3)
Occurring >70 days after last dose	0	1 (1.1)	0	1 (0.4)	1 (0.4)	0	0	1 (0.2)

表 2.7.4.7-102.　ベースラインにおける免疫抑制剤の使用の有無別の有害事象の概要
（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. Event with unknown severity is being counted as severe. Event with unknown relationship to study drug is being counted as drug-related.
$ As assessed by investigator.

Cross reference: 追加解析レポート JCSS TABLE 2.7.4__1.6.7_J

表 2.7.4.7-103. Mayo スコアに基づく疾患重症度別の有害事象の概要（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）

	<= 9 Adalimumab				> 9 Adalimumab				Missing -- Adalimumab --		
	40mg EOW (N=218) n (%)	40mg EW (N=206) n (%)	TDM Regimen (N=92) n (%)	Total (N=516) n (%)	40mg EOW (N=125) n (%)	40mg EW (N=143) n (%)	TDM Regimen (N=59) n (%)	Total (N=327) n (%)	40mg EOW (N=2) n (%)	40mg EW (N=1) n (%)	Total (N=3) n (%)
Subjects with:											
Any adverse event (AE)	157 (72.0)	154 (74.8)	60 (65.2)	371 (71.9)	98 (78.4)	109 (76.2)	36 (61.0)	243 (74.3)	2 (100)	0	2 (66.7)
Any AE with reasonable possibility of being related to study drug$	52 (23.9)	66 (32.0)	30 (32.6)	148 (28.7)	37 (29.6)	51 (35.7)	19 (32.2)	107 (32.7)	0	0	0
Any severe AE	18 (8.3)	27 (13.1)	7 (7.6)	52 (10.1)	10 (8.0)	14 (9.8)	3 (5.1)	27 (8.3)	1 (50.0)	0	1 (33.3)
Any serious AE	23 (10.6)	27 (13.1)	9 (9.8)	59 (11.4)	20 (16.0)	17 (11.9)	6 (10.2)	43 (13.1)	1 (50.0)	0	1 (33.3)
Any AE leading to discontinuation of study drug	22 (10.1)	19 (9.2)	12 (13.0)	53 (10.3)	17 (13.6)	16 (11.2)	5 (8.5)	38 (11.6)	1 (50.0)	0	1 (33.3)
Any AE leading to death	1 (0.5)	0	0	1 (0.2)	0	2 (1.4)	0	2 (0.6)	1 (50.0)	0	1 (33.3)
Any infection	83 (38.1)	81 (39.3)	31 (33.7)	195 (37.8)	49 (39.2)	49 (34.3)	20 (33.9)	118 (36.1)	0	0	0
Any serious infection	6 (2.8)	5 (2.4)	1 (1.1)	12 (2.3)	5 (4.0)	4 (2.8)	2 (3.4)	11 (3.4)	0	0	0
Any legionella infection	0	0	0	0	0	0	0	0	0	0	0

表 2.7.4.7-103. Mayo スコアに基づく疾患重症度別の有害事象の概要（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）

	<= 9 Adalimumab				> 9 Adalimumab				Missing -- Adalimumab --		
	40mg EOW (N=218) n (%)	40mg EW (N=206) n (%)	TDM Regimen (N=92) n (%)	Total (N=516) n (%)	40mg EOW (N=125) n (%)	40mg EW (N=143) n (%)	TDM Regimen (N=59) n (%)	Total (N=327) n (%)	40mg EOW (N=2) n (%)	40mg EW (N=1) n (%)	Total (N=3) n (%)
Any diverticulitis infection	0	0	0	0	0	1 (0.7)	0	1 (0.3)	0	0	0
Any opportunistic INF. EXCL. oral candidiasis and TB	0	0	0	0	0	0	0	0	0	0	0
Any oral candidiasis	2 (0.9)	1 (0.5)	1 (1.1)	4 (0.8)	0	0	0	0	0	0	0
Any tuberculosis	0	1 (0.5)	1 (1.1)	2 (0.4)	0	1 (0.7)	0	1 (0.3)	0	0	0
Any active tuberculosis	0	1 (0.5)	1 (1.1)	2 (0.4)	0	1 (0.7)	0	1 (0.3)	0	0	0
Any latent tuberculosis	0	0	0	0	0	0	0	0	0	0	0
Any parasitic infection	0	2 (1.0)	1 (1.1)	3 (0.6)	0	0	0	0	0	0	0
Any reactivation of hepatitis B	0	0	0	0	0	0	0	0	0	0	0
Any progressive multifocal leukoencephalopathy (PML)	0	0	0	0	0	0	0	0	0	0	0

表 2.7.4.7-103. Mayo スコアに基づく疾患重症度別の有害事象の概要（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）

	<= 9 Adalimumab				> 9 Adalimumab				Missing -- Adalimumab --		
	40mg EOW (N=218) n (%)	40mg EW (N=206) n (%)	TDM Regimen (N=92) n (%)	Total (N=516) n (%)	40mg EOW (N=125) n (%)	40mg EW (N=143) n (%)	TDM Regimen (N=59) n (%)	Total (N=327) n (%)	40mg EOW (N=2) n (%)	40mg EW (N=1) n (%)	Total (N=3) n (%)
Any malignancy	2 (0.9)	2 (1.0)	0	4 (0.8)	0	2 (1.4)	0	2 (0.6)	0	0	0
Any lymphoma	0	0	0	0	0	0	0	0	0	0	0
Any hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0	0	0	0	0	0	0	0
Any non-melanoma skin cancer (NMSC)	1 (0.5)	1 (0.5)	0	2 (0.4)	0	0	0	0	0	0	0
Any melanoma	0	1 (0.5)	0	1 (0.2)	0	0	0	0	0	0	0
Any leukemia	0	0	0	0	0	0	0	0	0	0	0
Any malignancy other than NMSC, melanoma, lymphoma, HSTCL, and leukemia	1 (0.5)	0	0	1 (0.2)	0	2 (1.4)	0	2 (0.6)	0	0	0
Any allergic reaction (including angioedema/anaphylaxis)	1 (0.5)	3 (1.5)	0	4 (0.8)	2 (1.6)	4 (2.8)	0	6 (1.8)	1 (50.0)	0	1 (33.3)
Any lupus-like reactions and systemic lupus erythematosus	0	0	0	0	0	1 (0.7)	0	1 (0.3)	0	0	0

表 2.7.4.7-103. Mayo スコアに基づく疾患重症度別の有害事象の概要（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）

	<= 9 Adalimumab				> 9 Adalimumab				Missing -- Adalimumab --		
	40mg EOW (N=218) n (%)	40mg EW (N=206) n (%)	TDM Regimen (N=92) n (%)	Total (N=516) n (%)	40mg EOW (N=125) n (%)	40mg EW (N=143) n (%)	TDM Regimen (N=59) n (%)	Total (N=327) n (%)	40mg EOW (N=2) n (%)	40mg EW (N=1) n (%)	Total (N=3) n (%)
Any vasculitis	0	1 (0.5)	1 (1.1)	2 (0.4)	0	0	0	0	0	0	0
Any cutaneous vasculitis	0	0	1 (1.1)	1 (0.2)	0	0	0	0	0	0	0
Any non-cutaneous vasculitis	0	1 (0.5)	0	1 (0.2)	0	0	0	0	0	0	0
Any sarcoidosis	0	0	0	0	0	0	0	0	0	0	0
Any autoimmune hepatitis	0	0	0	0	0	0	0	0	0	0	0
Any myocardial infarction related	1 (0.5)	0	0	1 (0.2)	0	0	0	0	0	0	0
Any cerebrovascular accident related	0	0	1 (1.1)	1 (0.2)	0	0	0	0	0	0	0
Any congestive heart failure related	0	0	0	0	1 (0.8)	0	0	1 (0.3)	0	0	0
Any pulmonary embolism related	0	2 (1.0)	0	2 (0.4)	0	1 (0.7)	0	1 (0.3)	1 (50.0)	0	1 (33.3)

表 2.7.4.7-103. Mayo スコアに基づく疾患重症度別の有害事象の概要（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）

	<= 9 Adalimumab				> 9 Adalimumab				Missing -- Adalimumab --		
	40mg EOW (N=218) n (%)	40mg EW (N=206) n (%)	TDM Regimen (N=92) n (%)	Total (N=516) n (%)	40mg EOW (N=125) n (%)	40mg EW (N=143) n (%)	TDM Regimen (N=59) n (%)	Total (N=327) n (%)	40mg EOW (N=2) n (%)	40mg EW (N=1) n (%)	Total (N=3) n (%)
Any interstitial lung disease	0	0	0	0	0	0	0	0	0	0	0
Any intestinal perforation	0	0	0	0	0	0	0	0	0	0	0
Any pancreatitis	1 (0.5)	0	0	1 (0.2)	0	0	0	0	0	0	0
Any stevens-johnson syndrome	0	0	0	0	0	0	0	0	0	0	0
Any erythema multiforme related	0	0	0	0	0	0	0	0	0	0	0
Any worsening/new onset of psoriasis	1 (0.5)	1 (0.5)	0	2 (0.4)	1 (0.8)	0	1 (1.7)	2 (0.6)	0	0	0
Any demyelinating disorder	0	0	1 (1.1)	1 (0.2)	0	0	0	0	0	0	0
Any amyotrophic lateral sclerosis	0	0	0	0	0	0	0	0	0	0	0
Any reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0	0	0	0	0	0	0	0

表 2.7.4.7-103. Mayo スコアに基づく疾患重症度別の有害事象の概要（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）

	<= 9 Adalimumab				> 9 Adalimumab				Missing -- Adalimumab --		
	40mg EOW (N=218) n (%)	40mg EW (N=206) n (%)	TDM Regimen (N=92) n (%)	Total (N=516) n (%)	40mg EOW (N=125) n (%)	40mg EW (N=143) n (%)	TDM Regimen (N=59) n (%)	Total (N=327) n (%)	40mg EOW (N=2) n (%)	40mg EW (N=1) n (%)	Total (N=3) n (%)
Any hematologic disorders (including pancytopenia)	10 (4.6)	13 (6.3)	5 (5.4)	28 (5.4)	7 (5.6)	10 (7.0)	3 (5.1)	20 (6.1)	0	0	0
Any liver failure and other liver event (except gall bladder related)	0	1 (0.5)	0	1 (0.2)	2 (1.6)	1 (0.7)	0	3 (0.9)	0	0	0
Any humira administration related medication errors	0	0	0	0	0	0	0	0	0	0	0
Any injection site reaction	6 (2.8)	10 (4.9)	2 (2.2)	18 (3.5)	2 (1.6)	6 (4.2)	3 (5.1)	11 (3.4)	0	0	0
All deaths	1 (0.5)	0	0	1 (0.2)	0	2 (1.4)	0	2 (0.6)	1 (50.0)	0	1 (33.3)
Occurring <=70 days after last dose	0	0	0	0	0	1 (0.7)	0	1 (0.3)	1 (50.0)	0	1 (33.3)
Occurring >70 days after last dose	1 (0.5)	0	0	1 (0.2)	0	1 (0.7)	0	1 (0.3)	0	0	0

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. Event with unknown severity is being counted as severe. Event with unknown relationship to study drug is being counted as drug-related.
$ As assessed by investigator.

Cross reference: 追加解析レポート JCSS TABLE 2.7.4__1.6.8_J

表 2.7.4.7-104. 抗 TNF 製剤の投与経験の有無別の有害事象の 100 人年あたりの発現頻度の概要
（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）

	Yes			No		
	Adalimumab			Adalimumab		
	Standard Induction Dose (N=53) (PYS=7.8) Events (E/100PY)	Higher Induction Dose (N=82) (PYS=12.3) Events (E/100PY)	Total (N=135) (PYS=20.1) Events (E/100PY)	Standard Induction Dose (N=326) (PYS=51.9) Events (E/100PY)	Higher Induction Dose (N=491) (PYS=74.0) Events (E/100PY)	Total (N=817) (PYS=125.9) Events (E/100PY)
Any adverse event (AE)	74 (948.7)	128 (1040.7)	202 (1005.0)	416 (801.5)	645 (871.6)	1061 (842.7)
Any AE with reasonable possibility of being related to study drug$	21 (269.2)	47 (382.1)	68 (338.3)	135 (260.1)	242 (327.0)	377 (299.4)
Any severe AE	7 (89.7)	8 (65.0)	15 (74.6)	17 (32.8)	26 (35.1)	43 (34.2)
Any serious AE	9 (115.4)	8 (65.0)	17 (84.6)	18 (34.7)	23 (31.1)	41 (32.6)
Any AE leading to discontinuation of study drug	8 (102.6)	8 (65.0)	16 (79.6)	17 (32.8)	28 (37.8)	45 (35.7)
Any AE leading to death	0	0	0	0	1 (1.4)	1 (0.8)
Any infection	11 (141.0)	20 (162.6)	31 (154.2)	60 (115.6)	80 (108.1)	140 (111.2)
Any serious infection	1 (12.8)	2 (16.3)	3 (14.9)	2 (3.9)	2 (2.7)	4 (3.2)
Any legionella infection	0	0	0	0	0	0
Any diverticulitis infection	0	0	0	0	0	0
Any opportunistic INF. EXCL. oral candidiasis and TB	1 (12.8)	1 (8.1)	2 (10.0)	0	0	0
Any oral candidiasis	0	0	0	0	0	0
Any tuberculosis	0	0	0	0	1 (1.4)	1 (0.8)
Any active tuberculosis	0	0	0	0	1 (1.4)	1 (0.8)
Any latent tuberculosis	0	0	0	0	0	0
Any parasitic infection	0	0	0	0	1 (1.4)	1 (0.8)
Any reactivation of hepatitis B	0	0	0	0	0	0
Any progressive multifocal leukoencephalopathy (PML)	0	0	0	0	0	0

表 2.7.4.7-104. 抗 TNF 製剤の投与経験の有無別の有害事象の 100 人年あたりの発現頻度の概要
（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）（続き）

	Yes			No		
	Adalimumab			Adalimumab		
	Standard Induction Dose (N=53) (PYS=7.8) Events (E/100PY)	Higher Induction Dose (N=82) (PYS=12.3) Events (E/100PY)	Total (N=135) (PYS=20.1) Events (E/100PY)	Standard Induction Dose (N=326) (PYS=51.9) Events (E/100PY)	Higher Induction Dose (N=491) (PYS=74.0) Events (E/100PY)	Total (N=817) (PYS=125.9) Events (E/100PY)
Any malignancy	1 (12.8)	0	1 (5.0)	2 (3.9)	0	2 (1.6)
Any lymphoma	0	0	0	0	0	0
Any hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0	0	0
Any non-melanoma skin cancer (NMSC)	0	0	0	1 (1.9)	0	1 (0.8)
Any melanoma	1 (12.8)	0	1 (5.0)	0	0	0
Any leukemia	0	0	0	0	0	0
Any malignancy other than NMSC, melanoma, lymphoma, HSTCL, and leukemia	0	0	0	1 (1.9)	0	1 (0.8)
Any allergic reaction (including angioedema/anaphylaxis)	1 (12.8)	0	1 (5.0)	5 (9.6)	9 (12.2)	14 (11.1)
Any lupus-like reactions and systemic lupus erythematosus	0	0	0	0	0	0
Any vasculitis	0	0	0	0	0	0
Any cutaneous vasculitis	0	0	0	0	0	0
Any non-cutaneous vasculitis	0	0	0	0	0	0
Any sarcoidosis	0	0	0	0	0	0
Any autoimmune hepatitis	0	0	0	0	0	0
Any myocardial infarction related	0	0	0	0	0	0
Any cerebrovascular accident related	0	0	0	0	0	0
Any congestive heart failure related	0	0	0	0	0	0
Any pulmonary embolism related	0	0	0	0	0	0

表 2.7.4.7-104. 抗 TNF 製剤の投与経験の有無別の有害事象の 100 人年あたりの発現頻度の概要
（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）（続き）

	Yes			No		
	Adalimumab			Adalimumab		
	Standard Induction Dose (N=53) (PYS=7.8) Events (E/100PY)	Higher Induction Dose (N=82) (PYS=12.3) Events (E/100PY)	Total (N=135) (PYS=20.1) Events (E/100PY)	Standard Induction Dose (N=326) (PYS=51.9) Events (E/100PY)	Higher Induction Dose (N=491) (PYS=74.0) Events (E/100PY)	Total (N=817) (PYS=125.9) Events (E/100PY)
Any interstitial lung disease	0	0	0	0	0	0
Any intestinal perforation	0	0	0	0	0	0
Any pancreatitis	0	0	0	0	1 (1.4)	1 (0.8)
Any stevens-johnson syndrome	0	0	0	0	0	0
Any erythema multiforme related	0	0	0	0	0	0
Any worsening/new onset of psoriasis	1 (12.8)	0	1 (5.0)	1 (1.9)	1 (1.4)	2 (1.6)
Any demyelinating disorder	0	0	0	0	0	0
Any amyotrophic lateral sclerosis	0	0	0	0	0	0
Any reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0	0	0
Any hematologic disorders (including pancytopenia)	3 (38.5)	3 (24.4)	6 (29.9)	15 (28.9)	23 (31.1)	38 (30.2)
Any liver failure and other liver event (except gall bladder related)	0	0	0	0	2 (2.7)	2 (1.6)
Any humira administration related medication errors	0	0	0	0	0	0
Any injection site reaction	2 (25.6)	23 (187.0)	25 (124.4)	25 (48.2)	86 (116.2)	111 (88.2)
All deaths	0	0	0	0	2 (2.7)	2 (1.6)
Occurring <=70 days after last dose	0	0	0	0	1 (1.4)	1 (0.8)
Occurring >70 days after last dose	0	0	0	0	1 (1.4)	1 (0.8)

表 2.7.4.7-104.　抗 TNF 製剤の投与経験の有無別の有害事象の 100 人年あたりの発現頻度の概要
（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）（続き）

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. Event with unknown severity is being counted as severe. Event with unknown relationship to study drug is being counted as drug-related.
E/100PY = Events per 100 patient-years.
$ As assessed by investigator.

Cross reference: 追加解析レポート JCSS TABLE 2.7.4__1.7.5_J

表 2.7.4.7-105. 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別の有害事象の 100 人年あたりの発現頻度の概要
（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）

	Yes			No		
	Adalimumab			Adalimumab		
	Standard Induction Dose (N=227) (PYS=34.2) Events (E/100PY)	Higher Induction Dose (N=328) (PYS=49.2) Events (E/100PY)	Total (N=555) (PYS=83.5) Events (E/100PY)	Standard Induction Dose (N=152) (PYS=25.5) Events (E/100PY)	Higher Induction Dose (N=245) (PYS=37.1) Events (E/100PY)	Total (N=397) (PYS=62.6) Events (E/100PY)
Any adverse event (AE)	268 (783.6)	372 (756.1)	640 (766.5)	222 (870.6)	401 (1080.9)	623 (995.2)
Any AE with reasonable possibility of being related to study drug$	69 (201.8)	132 (268.3)	201 (240.7)	87 (341.2)	157 (423.2)	244 (389.8)
Any severe AE	15 (43.9)	22 (44.7)	37 (44.3)	9 (35.3)	12 (32.3)	21 (33.5)
Any serious AE	18 (52.6)	20 (40.7)	38 (45.5)	9 (35.3)	11 (29.6)	20 (31.9)
Any AE leading to discontinuation of study drug	12 (35.1)	22 (44.7)	34 (40.7)	13 (51.0)	14 (37.7)	27 (43.1)
Any AE leading to death	0	1 (2.0)	1 (1.2)	0	0	0
Any infection	35 (102.3)	53 (107.7)	88 (105.4)	36 (141.2)	47 (126.7)	83 (132.6)
Any serious infection	1 (2.9)	2 (4.1)	3 (3.6)	2 (7.8)	2 (5.4)	4 (6.4)
Any legionella infection	0	0	0	0	0	0
Any diverticulitis infection	0	0	0	0	0	0
Any opportunistic INF. EXCL. oral candidiasis and TB	0	0	0	1 (3.9)	1 (2.7)	2 (3.2)
Any oral candidiasis	0	0	0	0	0	0
Any tuberculosis	0	1 (2.0)	1 (1.2)	0	0	0
Any active tuberculosis	0	1 (2.0)	1 (1.2)	0	0	0
Any latent tuberculosis	0	0	0	0	0	0
Any parasitic infection	0	1 (2.0)	1 (1.2)	0	0	0
Any reactivation of hepatitis B	0	0	0	0	0	0
Any progressive multifocal leukoencephalopathy (PML)	0	0	0	0	0	0

表 2.7.4.7-105. 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別の有害事象の 100 人年あたりの発現頻度の概要
（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）（続き）

	Yes			No		
	Adalimumab			Adalimumab		
	Standard Induction Dose (N=227) (PYS=34.2) Events (E/100PY)	Higher Induction Dose (N=328) (PYS=49.2) Events (E/100PY)	Total (N=555) (PYS=83.5) Events (E/100PY)	Standard Induction Dose (N=152) (PYS=25.5) Events (E/100PY)	Higher Induction Dose (N=245) (PYS=37.1) Events (E/100PY)	Total (N=397) (PYS=62.6) Events (E/100PY)
Any malignancy	1 (2.9)	0	1 (1.2)	2 (7.8)	0	2 (3.2)
Any lymphoma	0	0	0	0	0	0
Any hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0	0	0
Any non-melanoma skin cancer (NMSC)	0	0	0	1 (3.9)	0	1 (1.6)
Any melanoma	0	0	0	1 (3.9)	0	1 (1.6)
Any leukemia	0	0	0	0	0	0
Any malignancy other than NMSC, melanoma, lymphoma, HSTCL, and leukemia	1 (2.9)	0	1 (1.2)	0	0	0
Any allergic reaction (including angioedema/anaphylaxis)	3 (8.8)	4 (8.1)	7 (8.4)	3 (11.8)	5 (13.5)	8 (12.8)
Any lupus-like reactions and systemic lupus erythematosus	0	0	0	0	0	0
Any vasculitis	0	0	0	0	0	0
Any cutaneous vasculitis	0	0	0	0	0	0
Any non-cutaneous vasculitis	0	0	0	0	0	0
Any sarcoidosis	0	0	0	0	0	0
Any autoimmune hepatitis	0	0	0	0	0	0
Any myocardial infarction related	0	0	0	0	0	0
Any cerebrovascular accident related	0	0	0	0	0	0
Any congestive heart failure related	0	0	0	0	0	0
Any pulmonary embolism related	0	0	0	0	0	0

表 2.7.4.7-105. 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別の有害事象の 100 人年あたりの発現頻度の概要
（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）（続き）

	Yes			No		
	Adalimumab			Adalimumab		
	Standard Induction Dose (N=227) (PYS=34.2) Events (E/100PY)	Higher Induction Dose (N=328) (PYS=49.2) Events (E/100PY)	Total (N=555) (PYS=83.5) Events (E/100PY)	Standard Induction Dose (N=152) (PYS=25.5) Events (E/100PY)	Higher Induction Dose (N=245) (PYS=37.1) Events (E/100PY)	Total (N=397) (PYS=62.6) Events (E/100PY)
Any interstitial lung disease	0	0	0	0	0	0
Any intestinal perforation	0	0	0	0	0	0
Any pancreatitis	0	1 (2.0)	1 (1.2)	0	0	0
Any stevens-johnson syndrome	0	0	0	0	0	0
Any erythema multiforme related	0	0	0	0	0	0
Any worsening/new onset of psoriasis	2 (5.8)	0	2 (2.4)	0	1 (2.7)	1 (1.6)
Any demyelinating disorder	0	0	0	0	0	0
Any amyotrophic lateral sclerosis	0	0	0	0	0	0
Any reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0	0	0
Any hematologic disorders (including pancytopenia)	11 (32.2)	11 (22.4)	22 (26.3)	7 (27.5)	15 (40.4)	22 (35.1)
Any liver failure and other liver event (except gall bladder related)	0	1 (2.0)	1 (1.2)	0	1 (2.7)	1 (1.6)
Any humira administration related medication errors	0	0	0	0	0	0
Any injection site reaction	8 (23.4)	47 (95.5)	55 (65.9)	19 (74.5)	62 (167.1)	81 (129.4)
All deaths	0	2 (4.1)	2 (2.4)	0	0	0
Occurring <=70 days after last dose	0	1 (2.0)	1 (1.2)	0	0	0
Occurring >70 days after last dose	0	1 (2.0)	1 (1.2)	0	0	0

表 2.7.4.7-105.　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別の有害事象の 100 人年あたりの発現頻度の概要
（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）（続き）

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. Event with unknown severity is being counted as severe. Event with unknown relationship to study drug is being counted as drug-related.
E/100PY = Events per 100 patient-years.
$ As assessed by investigator.

Cross reference: 追加解析レポート JCSS TABLE 2.7.4__1.7.6_J

表 2.7.4.7-106. ベースラインにおける免疫抑制剤の使用の有無別の有害事象の 100 人年あたりの発現頻度の概要（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）

	Yes			No		
	Adalimumab			Adalimumab		
	Standard Induction Dose (N=104) (PYS=15.7) Events (E/100PY)	Higher Induction Dose (N=164) (PYS=24.9) Events (E/100PY)	Total (N=268) (PYS=40.6) Events (E/100PY)	Standard Induction Dose (N=275) (PYS=44.0) Events (E/100PY)	Higher Induction Dose (N=409) (PYS=61.4) Events (E/100PY)	Total (N=684) (PYS=105.4) Events (E/100PY)
Any adverse event (AE)	115 (732.5)	216 (867.5)	331 (815.3)	375 (852.3)	557 (907.2)	932 (884.3)
Any AE with reasonable possibility of being related to study drug$	27 (172.0)	60 (241.0)	87 (214.3)	129 (293.2)	229 (373.0)	358 (339.7)
Any severe AE	3 (19.1)	12 (48.2)	15 (36.9)	21 (47.7)	22 (35.8)	43 (40.8)
Any serious AE	3 (19.1)	11 (44.2)	14 (34.5)	24 (54.5)	20 (32.6)	44 (41.7)
Any AE leading to discontinuation of study drug	3 (19.1)	3 (12.0)	6 (14.8)	22 (50.0)	33 (53.7)	55 (52.2)
Any AE leading to death	0	0	0	0	1 (1.6)	1 (0.9)
Any infection	12 (76.4)	34 (136.5)	46 (113.3)	59 (134.1)	66 (107.5)	125 (118.6)
Any serious infection	0	1 (4.0)	1 (2.5)	3 (6.8)	3 (4.9)	6 (5.7)
Any legionella infection	0	0	0	0	0	0
Any diverticulitis infection	0	0	0	0	0	0
Any opportunistic INF. EXCL. oral candidiasis and TB	0	0	0	1 (2.3)	1 (1.6)	2 (1.9)
Any oral candidiasis	0	0	0	0	0	0
Any tuberculosis	0	0	0	0	1 (1.6)	1 (0.9)
Any active tuberculosis	0	0	0	0	1 (1.6)	1 (0.9)
Any latent tuberculosis	0	0	0	0	0	0
Any parasitic infection	0	1 (4.0)	1 (2.5)	0	0	0
Any reactivation of hepatitis B	0	0	0	0	0	0
Any progressive multifocal leukoencephalopathy (PML)	0	0	0	0	0	0

表 2.7.4.7-106. ベースラインにおける免疫抑制剤の使用の有無別の有害事象の 100 人年あたりの発現頻度の概要（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）（続き）

	Yes			No		
	Adalimumab			Adalimumab		
	Standard Induction Dose (N=104) (PYS=15.7) Events (E/100PY)	Higher Induction Dose (N=164) (PYS=24.9) Events (E/100PY)	Total (N=268) (PYS=40.6) Events (E/100PY)	Standard Induction Dose (N=275) (PYS=44.0) Events (E/100PY)	Higher Induction Dose (N=409) (PYS=61.4) Events (E/100PY)	Total (N=684) (PYS=105.4) Events (E/100PY)
Any malignancy	1 (6.4)	0	1 (2.5)	2 (4.5)	0	2 (1.9)
Any lymphoma	0	0	0	0	0	0
Any hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0	0	0
Any non-melanoma skin cancer (NMSC)	0	0	0	1 (2.3)	0	1 (0.9)
Any melanoma	0	0	0	1 (2.3)	0	1 (0.9)
Any leukemia	0	0	0	0	0	0
Any malignancy other than NMSC, melanoma, lymphoma, HSTCL, and leukemia	1 (6.4)	0	1 (2.5)	0	0	0
Any allergic reaction (including angioedema/anaphylaxis)	1 (6.4)	2 (8.0)	3 (7.4)	5 (11.4)	7 (11.4)	12 (11.4)
Any lupus-like reactions and systemic lupus erythematosus	0	0	0	0	0	0
Any vasculitis	0	0	0	0	0	0
Any cutaneous vasculitis	0	0	0	0	0	0
Any non-cutaneous vasculitis	0	0	0	0	0	0
Any sarcoidosis	0	0	0	0	0	0
Any autoimmune hepatitis	0	0	0	0	0	0
Any myocardial infarction related	0	0	0	0	0	0
Any cerebrovascular accident related	0	0	0	0	0	0
Any congestive heart failure related	0	0	0	0	0	0
Any pulmonary embolism related	0	0	0	0	0	0

表 2.7.4.7-106. ベースラインにおける免疫抑制剤の使用の有無別の有害事象の 100 人年あたりの発現頻度の概要（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）（続き）

	Yes			No		
	Adalimumab			Adalimumab		
	Standard Induction Dose (N=104) (PYS=15.7) Events (E/100PY)	Higher Induction Dose (N=164) (PYS=24.9) Events (E/100PY)	Total (N=268) (PYS=40.6) Events (E/100PY)	Standard Induction Dose (N=275) (PYS=44.0) Events (E/100PY)	Higher Induction Dose (N=409) (PYS=61.4) Events (E/100PY)	Total (N=684) (PYS=105.4) Events (E/100PY)
Any interstitial lung disease	0	0	0	0	0	0
Any intestinal perforation	0	0	0	0	0	0
Any pancreatitis	0	0	0	0	1 (1.6)	1 (0.9)
Any stevens-johnson syndrome	0	0	0	0	0	0
Any erythema multiforme related	0	0	0	0	0	0
Any worsening/new onset of psoriasis	0	0	0	2 (4.5)	1 (1.6)	3 (2.8)
Any demyelinating disorder	0	0	0	0	0	0
Any amyotrophic lateral sclerosis	0	0	0	0	0	0
Any reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0	0	0
Any hematologic disorders (including pancytopenia)	3 (19.1)	10 (40.2)	13 (32.0)	15 (34.1)	16 (26.1)	31 (29.4)
Any liver failure and other liver event (except gall bladder related)	0	1 (4.0)	1 (2.5)	0	1 (1.6)	1 (0.9)
Any humira administration related medication errors	0	0	0	0	0	0
Any injection site reaction	9 (57.3)	24 (96.4)	33 (81.3)	18 (40.9)	85 (138.4)	103 (97.7)
All deaths	0	0	0	0	2 (3.3)	2 (1.9)
Occurring <=70 days after last dose	0	0	0	0	1 (1.6)	1 (0.9)
Occurring >70 days after last dose	0	0	0	0	1 (1.6)	1 (0.9)

表 2.7.4.7-106. ベースラインにおける免疫抑制剤の使用の有無別の有害事象の 100 人年あたりの発現頻度の概要（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）（続き）

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. Event with unknown severity is being counted as severe. Event with unknown relationship to study drug is being counted as drug-related.
E/100PY = Events per 100 patient-years.
$ As assessed by investigator.

Cross reference: 追加解析レポート JCSS TABLE 2.7.4__1.7.7_J

表 2.7.4.7-107. Mayo スコアに基づく疾患重症度別の有害事象の 100 人年あたりの発現頻度の概要（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）

	<= 9			> 9			-- Missing --
	Adalimumab			Adalimumab			Adalimumab
	Standard Induction Dose (N=244) (PYS=37.0) Events (E/100PY)	Higher Induction Dose (N=325) (PYS=49.1) Events (E/100PY)	Total (N=569) (PYS=86.1) Events (E/100PY)	Standard Induction Dose (N=135) (PYS=22.7) Events (E/100PY)	Higher Induction Dose (N=245) (PYS=36.7) Events (E/100PY)	Total (N=380) (PYS=59.5) Events (E/100PY)	Higher Induction Dose (N=3) (PYS=0.5) Events (E/100PY)
Any adverse event (AE)	285 (770.3)	429 (873.7)	714 (829.3)	205 (903.1)	343 (934.6)	548 (921.0)	1 (200.0)
Any AE with reasonable possibility of being related to study drug$	97 (262.2)	175 (356.4)	272 (315.9)	59 (259.9)	114 (310.6)	173 (290.8)	0
Any severe AE	9 (24.3)	16 (32.6)	25 (29.0)	15 (66.1)	18 (49.0)	33 (55.5)	0
Any serious AE	11 (29.7)	12 (24.4)	23 (26.7)	16 (70.5)	19 (51.8)	35 (58.8)	0
Any AE leading to discontinuation of study drug	16 (43.2)	17 (34.6)	33 (38.3)	9 (39.6)	19 (51.8)	28 (47.1)	0
Any AE leading to death	0	1 (2.0)	1 (1.2)	0	0	0	0
Any infection	39 (105.4)	50 (101.8)	89 (103.4)	32 (141.0)	50 (136.2)	82 (137.8)	0
Any serious infection	3 (8.1)	1 (2.0)	4 (4.6)	0	3 (8.2)	3 (5.0)	0
Any legionella infection	0	0	0	0	0	0	0
Any diverticulitis infection	0	0	0	0	0	0	0
Any opportunistic INF. EXCL. oral candidiasis and TB	0	0	0	1 (4.4)	1 (2.7)	2 (3.4)	0
Any oral candidiasis	0	0	0	0	0	0	0
Any tuberculosis	0	1 (2.0)	1 (1.2)	0	0	0	0
Any active tuberculosis	0	1 (2.0)	1 (1.2)	0	0	0	0
Any latent tuberculosis	0	0	0	0	0	0	0

表 2.7.4.7-107. Mayo スコアに基づく疾患重症度別の有害事象の 100 人年あたりの発現頻度の概要（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）（続き）

	<= 9			> 9			-- Missing --
	Adalimumab			Adalimumab			Adalimumab
	Standard Induction Dose (N=244) (PYS=37.0) Events (E/100PY)	Higher Induction Dose (N=325) (PYS=49.1) Events (E/100PY)	Total (N=569) (PYS=86.1) Events (E/100PY)	Standard Induction Dose (N=135) (PYS=22.7) Events (E/100PY)	Higher Induction Dose (N=245) (PYS=36.7) Events (E/100PY)	Total (N=380) (PYS=59.5) Events (E/100PY)	Higher Induction Dose (N=3) (PYS=0.5) Events (E/100PY)
Any parasitic infection	0	1 (2.0)	1 (1.2)	0	0	0	0
Any reactivation of hepatitis B	0	0	0	0	0	0	0
Any progressive multifocal leukoencephalopathy (PML)	0	0	0	0	0	0	0
Any malignancy	3 (8.1)	0	3 (3.5)	0	0	0	0
Any lymphoma	0	0	0	0	0	0	0
Any hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0	0	0	0
Any non-melanoma skin cancer (NMSC)	1 (2.7)	0	1 (1.2)	0	0	0	0
Any melanoma	1 (2.7)	0	1 (1.2)	0	0	0	0
Any leukemia	0	0	0	0	0	0	0
Any malignancy other than NMSC, melanoma, lymphoma, HSTCL, and leukemia	1 (2.7)	0	1 (1.2)	0	0	0	0
Any allergic reaction (including angioedema/anaphylaxis)	3 (8.1)	6 (12.2)	9 (10.5)	3 (13.2)	3 (8.2)	6 (10.1)	0
Any lupus-like reactions and systemic lupus erythematosus	0	0	0	0	0	0	0
Any vasculitis	0	0	0	0	0	0	0
Any cutaneous vasculitis	0	0	0	0	0	0	0
Any non-cutaneous vasculitis	0	0	0	0	0	0	0

表 2.7.4.7-107. Mayo スコアに基づく疾患重症度別の有害事象の 100 人年あたりの発現頻度の概要（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）（続き）

	<= 9 Adalimumab Standard Induction Dose (N=244) (PYS=37.0) Events (E/100PY)	<= 9 Adalimumab Higher Induction Dose (N=325) (PYS=49.1) Events (E/100PY)	<= 9 Total (N=569) (PYS=86.1) Events (E/100PY)	> 9 Adalimumab Standard Induction Dose (N=135) (PYS=22.7) Events (E/100PY)	> 9 Adalimumab Higher Induction Dose (N=245) (PYS=36.7) Events (E/100PY)	> 9 Total (N=380) (PYS=59.5) Events (E/100PY)	-- Missing -- Adalimumab Higher Induction Dose (N=3) (PYS=0.5) Events (E/100PY)
Any sarcoidosis	0	0	0	0	0	0	0
Any autoimmune hepatitis	0	0	0	0	0	0	0
Any myocardial infarction related	0	0	0	0	0	0	0
Any cerebrovascular accident related	0	0	0	0	0	0	0
Any congestive heart failure related	0	0	0	0	0	0	0
Any pulmonary embolism related	0	0	0	0	0	0	0
Any interstitial lung disease	0	0	0	0	0	0	0
Any intestinal perforation	0	0	0	0	0	0	0
Any pancreatitis	0	1 (2.0)	1 (1.2)	0	0	0	0
Any stevens-johnson syndrome	0	0	0	0	0	0	0
Any erythema multiforme related	0	0	0	0	0	0	0
Any worsening/new onset of psoriasis	1 (2.7)	1 (2.0)	2 (2.3)	1 (4.4)	0	1 (1.7)	0
Any demyelinating disorder	0	0	0	0	0	0	0
Any amyotrophic lateral sclerosis	0	0	0	0	0	0	0
Any reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0	0	0	0

表 2.7.4.7-107. Mayo スコアに基づく疾患重症度別の有害事象の 100 人年あたりの発現頻度の概要（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）（続き）

	<= 9			> 9			-- Missing --
	Adalimumab			Adalimumab			Adalimumab
	Standard Induction Dose (N=244) (PYS=37.0) Events (E/100PY)	Higher Induction Dose (N=325) (PYS=49.1) Events (E/100PY)	Total (N=569) (PYS=86.1) Events (E/100PY)	Standard Induction Dose (N=135) (PYS=22.7) Events (E/100PY)	Higher Induction Dose (N=245) (PYS=36.7) Events (E/100PY)	Total (N=380) (PYS=59.5) Events (E/100PY)	Higher Induction Dose (N=3) (PYS=0.5) Events (E/100PY)
Any hematologic disorders (including pancytopenia)	8 (21.6)	13 (26.5)	21 (24.4)	10 (44.1)	13 (35.4)	23 (38.7)	0
Any liver failure and other liver event (except gall bladder related)	0	1 (2.0)	1 (1.2)	0	1 (2.7)	1 (1.7)	0
Any humira administration related medication errors	0	0	0	0	0	0	0
Any injection site reaction	19 (51.4)	70 (142.6)	89 (103.4)	8 (35.2)	39 (106.3)	47 (79.0)	0
All deaths	0	1 (2.0)	1 (1.2)	0	1 (2.7)	1 (1.7)	0
Occurring <=70 days after last dose	0	1 (2.0)	1 (1.2)	0	0	0	0
Occurring >70 days after last dose	0	0	0	0	1 (2.7)	1 (1.7)	0

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. Event with unknown severity is being counted as severe. Event with unknown relationship to study drug is being counted as drug-related.
E/100PY = Events per 100 patient-years.
$ As assessed by investigator.

Cross reference: 追加解析レポート JCSS TABLE 2.7.4__1.7.8_J

表 2.7.4.7-108. 抗 TNF 製剤の投与経験の有無別の有害事象の 100 人年あたりの発現頻度の概要
（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）

	Yes				No			
	Adalimumab				Adalimumab			
	40mg EOW (N=54) (PYS=31.6) Events (E/100PY)	40mg EW (N=47) (PYS=31.5) Events (E/100PY)	TDM Regimen (N=16) (PYS=7.5) Events (E/100PY)	Total (N=117) (PYS=70.5) Events (E/100PY)	40mg EOW (N=291) (PYS=205.9) Events (E/100PY)	40mg EW (N=303) (PYS=220.7) Events (E/100PY)	TDM Regimen (N=135) (PYS=98.3) Events (E/100PY)	Total (N=729) (PYS=524.9) Events (E/100PY)
Any adverse event (AE)	173 (547.5)	118 (374.6)	40 (533.3)	331 (469.5)	759 (368.6)	967 (438.2)	301 (306.2)	2027 (386.2)
Any AE with reasonable possibility of being related to study drug$	45 (142.4)	23 (73.0)	15 (200.0)	83 (117.7)	130 (63.1)	257 (116.4)	82 (83.4)	469 (89.4)
Any severe AE	4 (12.7)	2 (6.3)	3 (40.0)	9 (12.8)	38 (18.5)	58 (26.3)	8 (8.1)	104 (19.8)
Any serious AE	6 (19.0)	5 (15.9)	5 (66.7)	16 (22.7)	57 (27.7)	65 (29.5)	16 (16.3)	138 (26.3)
Any AE leading to discontinuation of study drug	8 (25.3)	6 (19.0)	5 (66.7)	19 (27.0)	34 (16.5)	45 (20.4)	14 (14.2)	93 (17.7)
Any AE leading to death	0	0	0	0	2 (1.0)	2 (0.9)	0	4 (0.8)
Any infection	42 (132.9)	27 (85.7)	14 (186.7)	83 (117.7)	184 (89.4)	193 (87.4)	78 (79.3)	455 (86.7)
Any serious infection	0	2 (6.3)	1 (13.3)	3 (4.3)	12 (5.8)	7 (3.2)	2 (2.0)	21 (4.0)
Any legionella infection	0	0	0	0	0	0	0	0
Any diverticulitis infection	0	0	0	0	0	1 (0.5)	0	1 (0.2)
Any opportunistic INF. EXCL. oral candidiasis and TB	0	0	0	0	0	0	0	0
Any oral candidiasis	1 (3.2)	0	1 (13.3)	2 (2.8)	1 (0.5)	1 (0.5)	0	2 (0.4)
Any tuberculosis	0	1 (3.2)	0	1 (1.4)	0	1 (0.5)	1 (1.0)	2 (0.4)
Any active tuberculosis	0	1 (3.2)	0	1 (1.4)	0	1 (0.5)	1 (1.0)	2 (0.4)
Any latent tuberculosis	0	0	0	0	0	0	0	0
Any parasitic infection	0	0	1 (13.3)	1 (1.4)	0	2 (0.9)	0	2 (0.4)
Any reactivation of hepatitis B	0	0	0	0	0	0	0	0
Any progressive multifocal leukoencephalopathy (PML)	0	0	0	0	0	0	0	0

表 2.7.4.7-108. 抗 TNF 製剤の投与経験の有無別の有害事象の 100 人年あたりの発現頻度の概要
（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）

	Yes				No			
	Adalimumab				Adalimumab			
	40mg EOW (N=54) (PYS=31.6) Events (E/100PY)	40mg EW (N=47) (PYS=31.5) Events (E/100PY)	TDM Regimen (N=16) (PYS=7.5) Events (E/100PY)	Total (N=117) (PYS=70.5) Events (E/100PY)	40mg EOW (N=291) (PYS=205.9) Events (E/100PY)	40mg EW (N=303) (PYS=220.7) Events (E/100PY)	TDM Regimen (N=135) (PYS=98.3) Events (E/100PY)	Total (N=729) (PYS=524.9) Events (E/100PY)
Any malignancy	0	0	0	0	2 (1.0)	4 (1.8)	0	6 (1.1)
Any lymphoma	0	0	0	0	0	0	0	0
Any hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0	0	0	0	0
Any non-melanoma skin cancer (NMSC)	0	0	0	0	1 (0.5)	1 (0.5)	0	2 (0.4)
Any melanoma	0	0	0	0	0	1 (0.5)	0	1 (0.2)
Any leukemia	0	0	0	0	0	0	0	0
Any malignancy other than NMSC, melanoma, lymphoma, HSTCL, and leukemia	0	0	0	0	1 (0.5)	2 (0.9)	0	3 (0.6)
Any allergic reaction (including angioedema/anaphylaxis)	1 (3.2)	0	0	1 (1.4)	3 (1.5)	7 (3.2)	0	10 (1.9)
Any lupus-like reactions and systemic lupus erythematosus	0	0	0	0	0	1 (0.5)	0	1 (0.2)
Any vasculitis	0	1 (3.2)	0	1 (1.4)	0	0	1 (1.0)	1 (0.2)
Any cutaneous vasculitis	0	0	0	0	0	0	1 (1.0)	1 (0.2)
Any non-cutaneous vasculitis	0	1 (3.2)	0	1 (1.4)	0	0	0	0
Any sarcoidosis	0	0	0	0	0	0	0	0
Any autoimmune hepatitis	0	0	0	0	0	0	0	0
Any myocardial infarction related	0	0	0	0	1 (0.5)	0	0	1 (0.2)
Any cerebrovascular accident related	0	0	0	0	0	0	1 (1.0)	1 (0.2)
Any congestive heart failure related	0	0	0	0	1 (0.5)	0	0	1 (0.2)
Any pulmonary embolism related	0	0	0	0	1 (0.5)	3 (1.4)	0	4 (0.8)

表 2.7.4.7-108. 抗 TNF 製剤の投与経験の有無別の有害事象の 100 人年あたりの発現頻度の概要
（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）

	Yes				No			
	Adalimumab				Adalimumab			
	40mg EOW (N=54) (PYS=31.6) Events (E/100PY)	40mg EW (N=47) (PYS=31.5) Events (E/100PY)	TDM Regimen (N=16) (PYS=7.5) Events (E/100PY)	Total (N=117) (PYS=70.5) Events (E/100PY)	40mg EOW (N=291) (PYS=205.9) Events (E/100PY)	40mg EW (N=303) (PYS=220.7) Events (E/100PY)	TDM Regimen (N=135) (PYS=98.3) Events (E/100PY)	Total (N=729) (PYS=524.9) Events (E/100PY)
Any interstitial lung disease	0	0	0	0	0	0	0	0
Any intestinal perforation	0	0	0	0	0	0	0	0
Any pancreatitis	0	0	0	0	1 (0.5)	0	0	1 (0.2)
Any stevens-johnson syndrome	0	0	0	0	0	0	0	0
Any erythema multiforme related	0	0	0	0	0	0	0	0
Any worsening/new onset of psoriasis	0	0	0	0	2 (1.0)	1 (0.5)	1 (1.0)	4 (0.8)
Any demyelinating disorder	0	0	0	0	0	0	1 (1.0)	1 (0.2)
Any amyotrophic lateral sclerosis	0	0	0	0	0	0	0	0
Any reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0	0	0	0	0
Any hematologic disorders (including pancytopenia)	3 (9.5)	4 (12.7)	1 (13.3)	8 (11.3)	16 (7.8)	24 (10.9)	7 (7.1)	47 (9.0)
Any liver failure and other liver event (except gall bladder related)	0	0	0	0	2 (1.0)	2 (0.9)	0	4 (0.8)
Any humira administration related medication errors	0	0	0	0	0	0	0	0
Any injection site reaction	9 (28.5)	2 (6.3)	0	11 (15.6)	9 (4.4)	31 (14.0)	9 (9.2)	49 (9.3)
All deaths	0	0	0	0	2 (1.0)	2 (0.9)	0	4 (0.8)
Occurring <=70 days after last dose	0	0	0	0	1 (0.5)	1 (0.5)	0	2 (0.4)
Occurring >70 days after last dose	0	0	0	0	1 (0.5)	1 (0.5)	0	2 (0.4)

表 2.7.4.7-108.　抗 TNF 製剤の投与経験の有無別の有害事象の 100 人年あたりの発現頻度の概要
（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. Event with unknown severity is being counted as severe. Event with unknown relationship to study drug is being counted as drug-related.
E/100PY = Events per 100 patient-years.
$ As assessed by investigator.

Cross reference: 追加解析レポート JCSS TABLE 2.7.4__1.8.5_J

表 2.7.4.7-109. 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別の有害事象の 100 人年あたりの発現頻度の概要
（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）

	Yes				No			
	Adalimumab				Adalimumab			
	40mg EOW (N=208) (PYS=145.7) Events (E/100PY)	40mg EW (N=208) (PYS=151.2) Events (E/100PY)	TDM Regimen (N=88) (PYS=64.6) Events (E/100PY)	Total (N=504) (PYS=361.4) Events (E/100PY)	40mg EOW (N=137) (PYS=91.9) Events (E/100PY)	40mg EW (N=142) (PYS=101.0) Events (E/100PY)	TDM Regimen (N=63) (PYS=41.2) Events (E/100PY)	Total (N=342) (PYS=234.1) Events (E/100PY)
Any adverse event (AE)	516 (354.2)	576 (381.0)	177 (274.0)	1269 (351.1)	416 (452.7)	509 (504.0)	164 (398.1)	1089 (465.2)
Any AE with reasonable possibility of being related to study drug$	99 (67.9)	154 (101.9)	56 (86.7)	309 (85.5)	76 (82.7)	126 (124.8)	41 (99.5)	243 (103.8)
Any severe AE	24 (16.5)	40 (26.5)	7 (10.8)	71 (19.6)	18 (19.6)	20 (19.8)	4 (9.7)	42 (17.9)
Any serious AE	40 (27.5)	56 (37.0)	10 (15.5)	106 (29.3)	23 (25.0)	14 (13.9)	11 (26.7)	48 (20.5)
Any AE leading to discontinuation of study drug	26 (17.8)	34 (22.5)	11 (17.0)	71 (19.6)	16 (17.4)	17 (16.8)	8 (19.4)	41 (17.5)
Any AE leading to death	0	0	0	0	2 (2.2)	2 (2.0)	0	4 (1.7)
Any infection	118 (81.0)	109 (72.1)	46 (71.2)	273 (75.5)	108 (117.5)	111 (109.9)	46 (111.7)	265 (113.2)
Any serious infection	7 (4.8)	6 (4.0)	3 (4.6)	16 (4.4)	5 (5.4)	3 (3.0)	0	8 (3.4)
Any legionella infection	0	0	0	0	0	0	0	0
Any diverticulitis infection	0	0	0	0	0	1 (1.0)	0	1 (0.4)
Any opportunistic INF. EXCL. oral candidiasis and TB	0	0	0	0	0	0	0	0
Any oral candidiasis	1 (0.7)	0	1 (1.5)	2 (0.6)	1 (1.1)	1 (1.0)	0	2 (0.9)
Any tuberculosis	0	1 (0.7)	1 (1.5)	2 (0.6)	0	1 (1.0)	0	1 (0.4)
Any active tuberculosis	0	1 (0.7)	1 (1.5)	2 (0.6)	0	1 (1.0)	0	1 (0.4)
Any latent tuberculosis	0	0	0	0	0	0	0	0
Any parasitic infection	0	1 (0.7)	0	1 (0.3)	0	1 (1.0)	1 (2.4)	2 (0.9)
Any reactivation of hepatitis B	0	0	0	0	0	0	0	0
Any progressive multifocal leukoencephalopathy (PML)	0	0	0	0	0	0	0	0

表 2.7.4.7-109. 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別の有害事象の 100 人年あたりの発現頻度の概要
（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）

	Yes				No			
	Adalimumab				Adalimumab			
	40mg EOW (N=208) (PYS=145.7) Events (E/100PY)	40mg EW (N=208) (PYS=151.2) Events (E/100PY)	TDM Regimen (N=88) (PYS=64.6) Events (E/100PY)	Total (N=504) (PYS=361.4) Events (E/100PY)	40mg EOW (N=137) (PYS=91.9) Events (E/100PY)	40mg EW (N=142) (PYS=101.0) Events (E/100PY)	TDM Regimen (N=63) (PYS=41.2) Events (E/100PY)	Total (N=342) (PYS=234.1) Events (E/100PY)
Any malignancy	0	2 (1.3)	0	2 (0.6)	2 (2.2)	2 (2.0)	0	4 (1.7)
Any lymphoma	0	0	0	0	0	0	0	0
Any hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0	0	0	0	0
Any non-melanoma skin cancer (NMSC)	0	0	0	0	1 (1.1)	1 (1.0)	0	2 (0.9)
Any melanoma	0	1 (0.7)	0	1 (0.3)	0	0	0	0
Any leukemia	0	0	0	0	0	0	0	0
Any malignancy other than NMSC, melanoma, lymphoma, HSTCL, and leukemia	0	1 (0.7)	0	1 (0.3)	1 (1.1)	1 (1.0)	0	2 (0.9)
Any allergic reaction (including angioedema/anaphylaxis)	2 (1.4)	3 (2.0)	0	5 (1.4)	2 (2.2)	4 (4.0)	0	6 (2.6)
Any lupus-like reactions and systemic lupus erythematosus	0	1 (0.7)	0	1 (0.3)	0	0	0	0
Any vasculitis	0	1 (0.7)	0	1 (0.3)	0	0	1 (2.4)	1 (0.4)
Any cutaneous vasculitis	0	0	0	0	0	0	1 (2.4)	1 (0.4)
Any non-cutaneous vasculitis	0	1 (0.7)	0	1 (0.3)	0	0	0	0
Any sarcoidosis	0	0	0	0	0	0	0	0
Any autoimmune hepatitis	0	0	0	0	0	0	0	0
Any myocardial infarction related	1 (0.7)	0	0	1 (0.3)	0	0	0	0
Any cerebrovascular accident related	0	0	1 (1.5)	1 (0.3)	0	0	0	0
Any congestive heart failure related	1 (0.7)	0	0	1 (0.3)	0	0	0	0
Any pulmonary embolism related	0	2 (1.3)	0	2 (0.6)	1 (1.1)	1 (1.0)	0	2 (0.9)

表 2.7.4.7-109. 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別の有害事象の 100 人年あたりの発現頻度の概要
（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）

	Yes				No			
	Adalimumab				Adalimumab			
	40mg EOW (N=208) (PYS=145.7) Events (E/100PY)	40mg EW (N=208) (PYS=151.2) Events (E/100PY)	TDM Regimen (N=88) (PYS=64.6) Events (E/100PY)	Total (N=504) (PYS=361.4) Events (E/100PY)	40mg EOW (N=137) (PYS=91.9) Events (E/100PY)	40mg EW (N=142) (PYS=101.0) Events (E/100PY)	TDM Regimen (N=63) (PYS=41.2) Events (E/100PY)	Total (N=342) (PYS=234.1) Events (E/100PY)
Any interstitial lung disease	0	0	0	0	0	0	0	0
Any intestinal perforation	0	0	0	0	0	0	0	0
Any pancreatitis	1 (0.7)	0	0	1 (0.3)	0	0	0	0
Any stevens-johnson syndrome	0	0	0	0	0	0	0	0
Any erythema multiforme related	0	0	0	0	0	0	0	0
Any worsening/new onset of psoriasis	1 (0.7)	1 (0.7)	0	2 (0.6)	1 (1.1)	0	1 (2.4)	2 (0.9)
Any demyelinating disorder	0	0	0	0	0	0	1 (2.4)	1 (0.4)
Any amyotrophic lateral sclerosis	0	0	0	0	0	0	0	0
Any reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0	0	0	0	0
Any hematologic disorders (including pancytopenia)	12 (8.2)	19 (12.6)	6 (9.3)	37 (10.2)	7 (7.6)	9 (8.9)	2 (4.9)	18 (7.7)
Any liver failure and other liver event (except gall bladder related)	1 (0.7)	1 (0.7)	0	2 (0.6)	1 (1.1)	1 (1.0)	0	2 (0.9)
Any humira administration related medication errors	0	0	0	0	0	0	0	0
Any injection site reaction	11 (7.5)	9 (6.0)	4 (6.2)	24 (6.6)	7 (7.6)	24 (23.8)	5 (12.1)	36 (15.4)
All deaths	0	0	0	0	2 (2.2)	2 (2.0)	0	4 (1.7)
Occurring <=70 days after last dose	0	0	0	0	1 (1.1)	1 (1.0)	0	2 (0.9)
Occurring >70 days after last dose	0	0	0	0	1 (1.1)	1 (1.0)	0	2 (0.9)

表 2.7.4.7-109.　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別の有害事象の 100 人年あたりの発現頻度の概要
（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. Event with unknown severity is being counted as severe. Event with unknown relationship to study drug is being counted as drug-related.
E/100PY = Events per 100 patient-years.
$ As assessed by investigator.

Cross reference: 追加解析レポート JCSS TABLE 2.7.4__1.8.6_J

表 2.7.4.7-110. ベースラインにおける免疫抑制剤の使用の有無別の有害事象の 100 人年あたりの発現頻度の概要
（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）

	Yes				No			
	Adalimumab				Adalimumab			
	40mg EOW (N=107) (PYS=76.1) Events (E/100PY)	40mg EW (N=94) (PYS=74.4) Events (E/100PY)	TDM Regimen (N=45) (PYS=31.3) Events (E/100PY)	Total (N=246) (PYS=181.8) Events (E/100PY)	40mg EOW (N=238) (PYS=161.5) Events (E/100PY)	40mg EW (N=256) (PYS=177.7) Events (E/100PY)	TDM Regimen (N=106) (PYS=74.5) Events (E/100PY)	Total (N=600) (PYS=413.7) Events (E/100PY)
Any adverse event (AE)	279 (366.6)	297 (399.2)	139 (444.1)	715 (393.3)	653 (404.3)	788 (443.4)	202 (271.1)	1643 (397.1)
Any AE with reasonable possibility of being related to study drug$	51 (67.0)	69 (92.7)	42 (134.2)	162 (89.1)	124 (76.8)	211 (118.7)	55 (73.8)	390 (94.3)
Any severe AE	15 (19.7)	10 (13.4)	6 (19.2)	31 (17.1)	27 (16.7)	50 (28.1)	5 (6.7)	82 (19.8)
Any serious AE	23 (30.2)	17 (22.8)	9 (28.8)	49 (27.0)	40 (24.8)	53 (29.8)	12 (16.1)	105 (25.4)
Any AE leading to discontinuation of study drug	7 (9.2)	7 (9.4)	8 (25.6)	22 (12.1)	35 (21.7)	44 (24.8)	11 (14.8)	90 (21.8)
Any AE leading to death	0	1 (1.3)	0	1 (0.6)	2 (1.2)	1 (0.6)	0	3 (0.7)
Any infection	105 (138.0)	73 (98.1)	34 (108.6)	212 (116.6)	121 (74.9)	147 (82.7)	58 (77.9)	326 (78.8)
Any serious infection	7 (9.2)	1 (1.3)	0	8 (4.4)	5 (3.1)	8 (4.5)	3 (4.0)	16 (3.9)
Any legionella infection	0	0	0	0	0	0	0	0
Any diverticulitis infection	0	0	0	0	0	1 (0.6)	0	1 (0.2)
Any opportunistic INF. EXCL. oral candidiasis and TB	0	0	0	0	0	0	0	0
Any oral candidiasis	2 (2.6)	1 (1.3)	1 (3.2)	4 (2.2)	0	0	0	0
Any tuberculosis	0	0	0	0	0	2 (1.1)	1 (1.3)	3 (0.7)
Any active tuberculosis	0	0	0	0	0	2 (1.1)	1 (1.3)	3 (0.7)
Any latent tuberculosis	0	0	0	0	0	0	0	0
Any parasitic infection	0	0	0	0	0	2 (1.1)	1 (1.3)	3 (0.7)
Any reactivation of hepatitis B	0	0	0	0	0	0	0	0
Any progressive multifocal leukoencephalopathy (PML)	0	0	0	0	0	0	0	0

表 2.7.4.7-110. ベースラインにおける免疫抑制剤の使用の有無別の有害事象の 100 人年あたりの発現頻度の概要
（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）

	Yes				No			
	Adalimumab				Adalimumab			
	40mg EOW (N=107) (PYS=76.1) Events (E/100PY)	40mg EW (N=94) (PYS=74.4) Events (E/100PY)	TDM Regimen (N=45) (PYS=31.3) Events (E/100PY)	Total (N=246) (PYS=181.8) Events (E/100PY)	40mg EOW (N=238) (PYS=161.5) Events (E/100PY)	40mg EW (N=256) (PYS=177.7) Events (E/100PY)	TDM Regimen (N=106) (PYS=74.5) Events (E/100PY)	Total (N=600) (PYS=413.7) Events (E/100PY)
Any malignancy	0	2 (2.7)	0	2 (1.1)	2 (1.2)	2 (1.1)	0	4 (1.0)
Any lymphoma	0	0	0	0	0	0	0	0
Any hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0	0	0	0	0
Any non-melanoma skin cancer (NMSC)	0	0	0	0	1 (0.6)	1 (0.6)	0	2 (0.5)
Any melanoma	0	1 (1.3)	0	1 (0.6)	0	0	0	0
Any leukemia	0	0	0	0	0	0	0	0
Any malignancy other than NMSC, melanoma, lymphoma, HSTCL, and leukemia	0	1 (1.3)	0	1 (0.6)	1 (0.6)	1 (0.6)	0	2 (0.5)
Any allergic reaction (including angioedema/anaphylaxis)	1 (1.3)	1 (1.3)	0	2 (1.1)	3 (1.9)	6 (3.4)	0	9 (2.2)
Any lupus-like reactions and systemic lupus erythematosus	0	0	0	0	0	1 (0.6)	0	1 (0.2)
Any vasculitis	0	0	0	0	0	1 (0.6)	1 (1.3)	2 (0.5)
Any cutaneous vasculitis	0	0	0	0	0	0	1 (1.3)	1 (0.2)
Any non-cutaneous vasculitis	0	0	0	0	0	1 (0.6)	0	1 (0.2)
Any sarcoidosis	0	0	0	0	0	0	0	0
Any autoimmune hepatitis	0	0	0	0	0	0	0	0
Any myocardial infarction related	0	0	0	0	1 (0.6)	0	0	1 (0.2)
Any cerebrovascular accident related	0	0	0	0	0	0	1 (1.3)	1 (0.2)
Any congestive heart failure related	1 (1.3)	0	0	1 (0.6)	0	0	0	0
Any pulmonary embolism related	0	2 (2.7)	0	2 (1.1)	1 (0.6)	1 (0.6)	0	2 (0.5)

表 2.7.4.7-110. ベースラインにおける免疫抑制剤の使用の有無別の有害事象の 100 人年あたりの発現頻度の概要
（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）

	Yes				No			
	Adalimumab				Adalimumab			
	40mg EOW (N=107) (PYS=76.1) Events (E/100PY)	40mg EW (N=94) (PYS=74.4) Events (E/100PY)	TDM Regimen (N=45) (PYS=31.3) Events (E/100PY)	Total (N=246) (PYS=181.8) Events (E/100PY)	40mg EOW (N=238) (PYS=161.5) Events (E/100PY)	40mg EW (N=256) (PYS=177.7) Events (E/100PY)	TDM Regimen (N=106) (PYS=74.5) Events (E/100PY)	Total (N=600) (PYS=413.7) Events (E/100PY)
Any interstitial lung disease	0	0	0	0	0	0	0	0
Any intestinal perforation	0	0	0	0	0	0	0	0
Any pancreatitis	0	0	0	0	1 (0.6)	0	0	1 (0.2)
Any stevens-johnson syndrome	0	0	0	0	0	0	0	0
Any erythema multiforme related	0	0	0	0	0	0	0	0
Any worsening/new onset of psoriasis	0	0	0	0	2 (1.2)	1 (0.6)	1 (1.3)	4 (1.0)
Any demyelinating disorder	0	0	0	0	0	0	1 (1.3)	1 (0.2)
Any amyotrophic lateral sclerosis	0	0	0	0	0	0	0	0
Any reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0	0	0	0	0
Any hematologic disorders (including pancytopenia)	4 (5.3)	13 (17.5)	3 (9.6)	20 (11.0)	15 (9.3)	15 (8.4)	5 (6.7)	35 (8.5)
Any liver failure and other liver event (except gall bladder related)	1 (1.3)	2 (2.7)	0	3 (1.7)	1 (0.6)	0	0	1 (0.2)
Any humira administration related medication errors	0	0	0	0	0	0	0	0
Any injection site reaction	3 (3.9)	5 (6.7)	0	8 (4.4)	15 (9.3)	28 (15.8)	9 (12.1)	52 (12.6)
All deaths	0	1 (1.3)	0	1 (0.6)	2 (1.2)	1 (0.6)	0	3 (0.7)
Occurring <=70 days after last dose	0	0	0	0	1 (0.6)	1 (0.6)	0	2 (0.5)
Occurring >70 days after last dose	0	1 (1.3)	0	1 (0.6)	1 (0.6)	0	0	1 (0.2)

表 2.7.4.7-110.　ベースラインにおける免疫抑制剤の使用の有無別の有害事象の 100 人年あたりの発現頻度の概要
（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. Event with unknown severity is being counted as severe. Event with unknown relationship to study drug is being counted as drug-related.
E/100PY = Events per 100 patient-years.
$ As assessed by investigator.

Cross reference: 追加解析レポート JCSS TABLE 2.7.4__1.8.7_J

表 2.7.4.7-111. Mayo スコアに基づく疾患重症度別の有害事象の 100 人年あたりの発現頻度の概要（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）

	<= 9				> 9				Missing		
	Adalimumab				Adalimumab				Adalimumab		
	40mg EOW (N=218) (PYS=154.3) Events (E/100PY)	40mg EW (N=206) (PYS=152.4) Events (E/100PY)	TDM Regimen (N=92) (PYS=64.7) Events (E/100PY)	Total (N=516) (PYS=371.4) Events (E/100PY)	40mg EOW (N=125) (PYS=82.2) Events (E/100PY)	40mg EW (N=143) (PYS=98.9) Events (E/100PY)	TDM Regimen (N=59) (PYS=41.1) Events (E/100PY)	Total (N=327) (PYS=222.2) Events (E/100PY)	40mg EOW (N=2) (PYS=1.0) Events (E/100PY)	40mg EW (N=1) (PYS=0.9) Events (E/100PY)	Total (N=3) (PYS=1.9) Events (E/100PY)
Any adverse event (AE)	608 (394.0)	625 (410.1)	188 (290.6)	1421 (382.6)	320 (389.3)	460 (465.1)	153 (372.3)	933 (419.9)	4 (400.0)	0	4 (210.5)
Any AE with reasonable possibility of being related to study drug$	124 (80.4)	152 (99.7)	58 (89.6)	334 (89.9)	51 (62.0)	128 (129.4)	39 (94.9)	218 (98.1)	0	0	0
Any severe AE	24 (15.6)	32 (21.0)	7 (10.8)	63 (17.0)	16 (19.5)	28 (28.3)	4 (9.7)	48 (21.6)	2 (200.0)	0	2 (105.3)
Any serious AE	35 (22.7)	40 (26.2)	12 (18.5)	87 (23.4)	26 (31.6)	30 (30.3)	9 (21.9)	65 (29.3)	2 (200.0)	0	2 (105.3)
Any AE leading to discontinuation of study drug	22 (14.3)	26 (17.1)	13 (20.1)	61 (16.4)	19 (23.1)	25 (25.3)	6 (14.6)	50 (22.5)	1 (100)	0	1 (52.6)
Any AE leading to death	1 (0.6)	0	0	1 (0.3)	0	2 (2.0)	0	2 (0.9)	1 (100)	0	1 (52.6)
Any infection	146 (94.6)	124 (81.4)	55 (85.0)	325 (87.5)	80 (97.3)	96 (97.1)	37 (90.0)	213 (95.9)	0	0	0
Any serious infection	7 (4.5)	5 (3.3)	1 (1.5)	13 (3.5)	5 (6.1)	4 (4.0)	2 (4.9)	11 (5.0)	0	0	0

表 2.7.4.7-111. Mayo スコアに基づく疾患重症度別の有害事象の 100 人年あたりの発現頻度の概要（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）

	<= 9				> 9				Missing		
	Adalimumab				Adalimumab				Adalimumab		
	40mg EOW (N=218) (PYS=154.3) Events (E/100PY)	40mg EW (N=206) (PYS=152.4) Events (E/100PY)	TDM Regimen (N=92) (PYS=64.7) Events (E/100PY)	Total (N=516) (PYS=371.4) Events (E/100PY)	40mg EOW (N=125) (PYS=82.2) Events (E/100PY)	40mg EW (N=143) (PYS=98.9) Events (E/100PY)	TDM Regimen (N=59) (PYS=41.1) Events (E/100PY)	Total (N=327) (PYS=222.2) Events (E/100PY)	40mg EOW (N=2) (PYS=1.0) Events (E/100PY)	40mg EW (N=1) (PYS=0.9) Events (E/100PY)	Total (N=3) (PYS=1.9) Events (E/100PY)
Any legionella infection	0	0	0	0	0	0	0	0	0	0	0
Any diverticulitis infection	0	0	0	0	0	1 (1.0)	0	1 (0.5)	0	0	0
Any opportunistic INF. EXCL. oral candidiasis and TB	0	0	0	0	0	0	0	0	0	0	0
Any oral candidiasis	2 (1.3)	1 (0.7)	1 (1.5)	4 (1.1)	0	0	0	0	0	0	0
Any tuberculosis	0	1 (0.7)	1 (1.5)	2 (0.5)	0	1 (1.0)	0	1 (0.5)	0	0	0
Any active tuberculosis	0	1 (0.7)	1 (1.5)	2 (0.5)	0	1 (1.0)	0	1 (0.5)	0	0	0
Any latent tuberculosis	0	0	0	0	0	0	0	0	0	0	0
Any parasitic infection	0	2 (1.3)	1 (1.5)	3 (0.8)	0	0	0	0	0	0	0

表 2.7.4.7-111. Mayo スコアに基づく疾患重症度別の有害事象の 100 人年あたりの発現頻度の概要（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）

	<= 9				> 9				Missing		
	Adalimumab				Adalimumab				Adalimumab		
	40mg EOW (N=218) (PYS=154.3) Events (E/100PY)	40mg EW (N=206) (PYS=152.4) Events (E/100PY)	TDM Regimen (N=92) (PYS=64.7) Events (E/100PY)	Total (N=516) (PYS=371.4) Events (E/100PY)	40mg EOW (N=125) (PYS=82.2) Events (E/100PY)	40mg EW (N=143) (PYS=98.9) Events (E/100PY)	TDM Regimen (N=59) (PYS=41.1) Events (E/100PY)	Total (N=327) (PYS=222.2) Events (E/100PY)	40mg EOW (N=2) (PYS=1.0) Events (E/100PY)	40mg EW (N=1) (PYS=0.9) Events (E/100PY)	Total (N=3) (PYS=1.9) Events (E/100PY)
Any reactivation of hepatitis B	0	0	0	0	0	0	0	0	0	0	0
Any progressive multifocal leukoencephalopathy (PML)	0	0	0	0	0	0	0	0	0	0	0
Any malignancy	2 (1.3)	2 (1.3)	0	4 (1.1)	0	2 (2.0)	0	2 (0.9)	0	0	0
Any lymphoma	0	0	0	0	0	0	0	0	0	0	0
Any hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0	0	0	0	0	0	0	0
Any non-melanoma skin cancer (NMSC)	1 (0.6)	1 (0.7)	0	2 (0.5)	0	0	0	0	0	0	0
Any melanoma	0	1 (0.7)	0	1 (0.3)	0	0	0	0	0	0	0
Any leukemia	0	0	0	0	0	0	0	0	0	0	0

表 2.7.4.7-111. Mayo スコアに基づく疾患重症度別の有害事象の 100 人年あたりの発現頻度の概要（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）

	<= 9				> 9				Missing		
	Adalimumab				Adalimumab				Adalimumab		
	40mg EOW (N=218) (PYS=154.3) Events (E/100PY)	40mg EW (N=206) (PYS=152.4) Events (E/100PY)	TDM Regimen (N=92) (PYS=64.7) Events (E/100PY)	Total (N=516) (PYS=371.4) Events (E/100PY)	40mg EOW (N=125) (PYS=82.2) Events (E/100PY)	40mg EW (N=143) (PYS=98.9) Events (E/100PY)	TDM Regimen (N=59) (PYS=41.1) Events (E/100PY)	Total (N=327) (PYS=222.2) Events (E/100PY)	40mg EOW (N=2) (PYS=1.0) Events (E/100PY)	40mg EW (N=1) (PYS=0.9) Events (E/100PY)	Total (N=3) (PYS=1.9) Events (E/100PY)
Any malignancy other than NMSC, melanoma, lymphoma, HSTCL, and leukemia	1 (0.6)	0	0	1 (0.3)	0	2 (2.0)	0	2 (0.9)	0	0	0
Any allergic reaction (including angioedema/anaphylaxis)	1 (0.6)	3 (2.0)	0	4 (1.1)	2 (2.4)	4 (4.0)	0	6 (2.7)	1 (100)	0	1 (52.6)
Any lupus-like reactions and systemic lupus erythematosus	0	0	0	0	0	1 (1.0)	0	1 (0.5)	0	0	0
Any vasculitis	0	1 (0.7)	1 (1.5)	2 (0.5)	0	0	0	0	0	0	0
Any cutaneous vasculitis	0	0	1 (1.5)	1 (0.3)	0	0	0	0	0	0	0
Any non-cutaneous vasculitis	0	1 (0.7)	0	1 (0.3)	0	0	0	0	0	0	0

表 2.7.4.7-111. Mayo スコアに基づく疾患重症度別の有害事象の 100 人年あたりの発現頻度の概要（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）

	<= 9				> 9				Missing		
	Adalimumab				Adalimumab				Adalimumab		
	40mg EOW (N=218) (PYS=154.3) Events (E/100PY)	40mg EW (N=206) (PYS=152.4) Events (E/100PY)	TDM Regimen (N=92) (PYS=64.7) Events (E/100PY)	Total (N=516) (PYS=371.4) Events (E/100PY)	40mg EOW (N=125) (PYS=82.2) Events (E/100PY)	40mg EW (N=143) (PYS=98.9) Events (E/100PY)	TDM Regimen (N=59) (PYS=41.1) Events (E/100PY)	Total (N=327) (PYS=222.2) Events (E/100PY)	40mg EOW (N=2) (PYS=1.0) Events (E/100PY)	40mg EW (N=1) (PYS=0.9) Events (E/100PY)	Total (N=3) (PYS=1.9) Events (E/100PY)
Any sarcoidosis	0	0	0	0	0	0	0	0	0	0	0
Any autoimmune hepatitis	0	0	0	0	0	0	0	0	0	0	0
Any myocardial infarction related	1 (0.6)	0	0	1 (0.3)	0	0	0	0	0	0	0
Any cerebrovascular accident related	0	0	1 (1.5)	1 (0.3)	0	0	0	0	0	0	0
Any congestive heart failure related	0	0	0	0	1 (1.2)	0	0	1 (0.5)	0	0	0
Any pulmonary embolism related	0	2 (1.3)	0	2 (0.5)	0	1 (1.0)	0	1 (0.5)	1 (100)	0	1 (52.6)

表 2.7.4.7-111. Mayo スコアに基づく疾患重症度別の有害事象の 100 人年あたりの発現頻度の概要（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）

	<= 9				> 9				Missing		
	Adalimumab				Adalimumab				Adalimumab		
	40mg EOW (N=218) (PYS=154.3) Events (E/100PY)	40mg EW (N=206) (PYS=152.4) Events (E/100PY)	TDM Regimen (N=92) (PYS=64.7) Events (E/100PY)	Total (N=516) (PYS=371.4) Events (E/100PY)	40mg EOW (N=125) (PYS=82.2) Events (E/100PY)	40mg EW (N=143) (PYS=98.9) Events (E/100PY)	TDM Regimen (N=59) (PYS=41.1) Events (E/100PY)	Total (N=327) (PYS=222.2) Events (E/100PY)	40mg EOW (N=2) (PYS=1.0) Events (E/100PY)	40mg EW (N=1) (PYS=0.9) Events (E/100PY)	Total (N=3) (PYS=1.9) Events (E/100PY)
Any interstitial lung disease	0	0	0	0	0	0	0	0	0	0	0
Any intestinal perforation	0	0	0	0	0	0	0	0	0	0	0
Any pancreatitis	1 (0.6)	0	0	1 (0.3)	0	0	0	0	0	0	0
Any stevens-johnson syndrome	0	0	0	0	0	0	0	0	0	0	0
Any erythema multiforme related	0	0	0	0	0	0	0	0	0	0	0
Any worsening/new onset of psoriasis	1 (0.6)	1 (0.7)	0	2 (0.5)	1 (1.2)	0	1 (2.4)	2 (0.9)	0	0	0

表 2.7.4.7-111. Mayo スコアに基づく疾患重症度別の有害事象の 100 人年あたりの発現頻度の概要（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）

	<= 9				> 9				Missing		
	Adalimumab				Adalimumab				-- Adalimumab --		
	40mg EOW (N=218) (PYS=154.3) Events (E/100PY)	40mg EW (N=206) (PYS=152.4) Events (E/100PY)	TDM Regimen (N=92) (PYS=64.7) Events (E/100PY)	Total (N=516) (PYS=371.4) Events (E/100PY)	40mg EOW (N=125) (PYS=82.2) Events (E/100PY)	40mg EW (N=143) (PYS=98.9) Events (E/100PY)	TDM Regimen (N=59) (PYS=41.1) Events (E/100PY)	Total (N=327) (PYS=222.2) Events (E/100PY)	40mg EOW (N=2) (PYS=1.0) Events (E/100PY)	40mg EW (N=1) (PYS=0.9) Events (E/100PY)	Total (N=3) (PYS=1.9) Events (E/100PY)
Any demyelinating disorder	0	0	1 (1.5)	1 (0.3)	0	0	0	0	0	0	0
Any amyotrophic lateral sclerosis	0	0	0	0	0	0	0	0	0	0	0
Any reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0	0	0	0	0	0	0	0
Any hematologic disorders (including pancytopenia)	12 (7.8)	18 (11.8)	5 (7.7)	35 (9.4)	7 (8.5)	10 (10.1)	3 (7.3)	20 (9.0)	0	0	0
Any liver failure and other liver event (except gall bladder related)	0	1 (0.7)	0	1 (0.3)	2 (2.4)	1 (1.0)	0	3 (1.4)	0	0	0
Any humira administration related medication errors	0	0	0	0	0	0	0	0	0	0	0

表 2.7.4.7-111. Mayo スコアに基づく疾患重症度別の有害事象の 100 人年あたりの発現頻度の概要（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）

	<= 9				> 9				Missing		
	Adalimumab				Adalimumab				Adalimumab		
	40mg EOW (N=218) (PYS=154.3) Events (E/100PY)	40mg EW (N=206) (PYS=152.4) Events (E/100PY)	TDM Regimen (N=92) (PYS=64.7) Events (E/100PY)	Total (N=516) (PYS=371.4) Events (E/100PY)	40mg EOW (N=125) (PYS=82.2) Events (E/100PY)	40mg EW (N=143) (PYS=98.9) Events (E/100PY)	TDM Regimen (N=59) (PYS=41.1) Events (E/100PY)	Total (N=327) (PYS=222.2) Events (E/100PY)	40mg EOW (N=2) (PYS=1.0) Events (E/100PY)	40mg EW (N=1) (PYS=0.9) Events (E/100PY)	Total (N=3) (PYS=1.9) Events (E/100PY)
Any injection site reaction	15 (9.7)	25 (16.4)	5 (7.7)	45 (12.1)	3 (3.6)	8 (8.1)	4 (9.7)	15 (6.8)	0	0	0
All deaths	1 (0.6)	0	0	1 (0.3)	0	2 (2.0)	0	2 (0.9)	1 (100)	0	1 (52.6)
Occurring <=70 days after last dose	0	0	0	0	0	1 (1.0)	0	1 (0.5)	1 (100)	0	1 (52.6)
Occurring >70 days after last dose	1 (0.6)	0	0	1 (0.3)	0	1 (1.0)	0	1 (0.5)	0	0	0

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. Event with unknown severity is being counted as severe. Event with unknown relationship to study drug is being counted as drug-related.
E/100PY = Events per 100 patient-years.
$ As assessed by investigator.

Cross reference: 追加解析レポート JCSS TABLE 2.7.4__1.8.8_J

2.7.4.7 小児 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
- 口腔カンジダ症及び結核を除く日和見感染症
- 結核（活動性結核 / 潜在性結核）
- 口腔カンジダ症
- レジオネラ感染
- 寄生虫感染
- 憩室炎
- 悪性腫瘍
- リンパ腫
- 肝脾 T 細胞リンパ腫
- 白血病
- 非黒色腫皮膚癌
- 黒色腫
- その他の悪性腫瘍（リンパ腫，肝脾 T 細胞リンパ腫，白血病，非黒色腫皮膚癌，黒色腫を除く）
- ループス様反応及び全身性エリテマトーデス
- 血管浮腫 / アナフィラキシーを含むアレルギー反応
- スティーブンス・ジョンソン症候群
- サルコイドーシス
- 血管炎（皮膚血管炎 / 皮膚以外の血管炎）
- 脱髄疾患
- 間質性肺疾患
- うっ血性心不全
- 心筋梗塞
- 脳血管発作
- 腸管穿孔
- 膵炎
- 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
- B 型肝炎再燃
- 自己免疫性肝炎

- 注射部位反応
- 多形紅斑
- 乾癬の悪化又は新規発症
- 肺塞栓症
- 進行性多巣性白質脳症
- 可逆性後白質脳症症候群
- 筋萎縮性側索硬化症
- ヒュミラ投与に関連した投薬過誤

表 2.7.4.7-2. 導入療法期中の治験薬の曝露期間（統合安全性解析対象集団，M11-290 試験）

	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 2.7.4.7-3. 維持療法期中の治験薬の曝露期間（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）

	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 2.7.4.7-4. 試験期間全体での治験薬の曝露期間（統合安全性解析対象集団，M11-290 試験）

	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 2.7.4.7-5. 導入療法期中の治験薬の曝露期間（日本人安全性解析対象集団，M11-290 試験）

	I-SD (N=2)	I-HD (N=4)	I-HD-OL (N=1)	Total (N=7)
Duration (day)				
n	2	4	1	7
Mean (SD)	35.0(29.70)	55.5(1.00)	57.0(NA)	49.9(15.84)
Median	35.0	56.0	57.0	56.0
Min, Max	14, 56	54, 56	57, 57	14, 57
Patient-Years of exposure	0.2	0.6	0.2	1.0

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.
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_J

表 2.7.4.7-6. 維持療法期中の治験薬の曝露期間
（維持療法期中に治験薬の投与を 1 回以上受けた日本人安全性解析対象集団の被験者，M11-290 試験）

	M-PL (N=0)	M-SD (N=2)	M-HD (N=3)	ADA-Total (N=5)	Total (N=5)
Duration (day)					
n	0	2	3	5	5
Mean (SD)		54.5(12.02)	247.0(105.70)	170.0(129.38)	170.0(129.38)
Median		54.5	305.0	125.0	125.0
Min, Max		46, 63	125, 311	46, 311	46, 311
Patient-Years of exposure		0.3	2.0	2.3	2.3

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.
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_J

表 2.7.4.7-7. 試験期間全体での治験薬の曝露期間（日本人安全性解析対象集団，M11-290 試験）

	Any ADA								
	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)
Duration (day)									
n	2	0	0	0	0	0	2	3	7
Mean (SD)	35.0(29.70)						315.0(69.30)	365.0(1.73)	256.4(155.98)
Median	35.0						315.0	364.0	364.0
Min, Max	14, 56						266, 364	364, 367	14, 367
Patient-Years of exposure	0.2						1.7	3.0	4.9

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.
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_J

表 2.7.4.7-8.　　M10-870 試験での治験薬の曝露期間（統合 FAS 集団，M10-870 試験）

	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 2.7.4.7-9. M11-290 試験及び M10-870 試験の合計での治験薬の曝露期間（統合 FAS 集団，M10-870 試験）

	Adalimumab (N=59)
Duration (days)	
n	59
Mean (SD)	859.1(384.46)
Median	785.0
Min, Max	321, 1736
Patient-Years of exposure	138.8

Note: Overall ADA exposure in Study M11-290 and Study M10-870 = ADA exposure in Study M10-870 + Overall ADA exposure in Study M11-290.

Cross reference: M10-870 Japan Sub-study CSR_Interim Table 14.1__7.2_A

表 2.7.4.7-10.　導入療法期中に発現したすべての有害事象（MedDRA SOC 及び PT 別）（統合安全性解析対象集団，M11-290 試験）

MedDRA 22.0 System Organ Class Preferred Term	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
Any adverse event	19 (59.4)	27 (52.9)	13 (76.5)	59 (59.0)
血液およびリンパ系障害	3 (9.4)	3 (5.9)	1 (5.9)	7 (7.0)
貧血	3 (9.4)	3 (5.9)	1 (5.9)	7 (7.0)
血小板増加症	0	0	1 (5.9)	1 (1.0)
心臓障害	1 (3.1)	0	0	1 (1.0)
心膜炎	1 (3.1)	0	0	1 (1.0)
内分泌障害	1 (3.1)	0	0	1 (1.0)
甲状腺腫	1 (3.1)	0	0	1 (1.0)
眼障害	1 (3.1)	1 (2.0)	0	2 (2.0)
眼瞼炎	0	1 (2.0)	0	1 (1.0)
角膜炎	1 (3.1)	0	0	1 (1.0)
胃腸障害	6 (18.8)	9 (17.6)	5 (29.4)	20 (20.0)
腹痛	0	2 (3.9)	2 (11.8)	4 (4.0)
上腹部痛	1 (3.1)	2 (3.9)	0	3 (3.0)
潰瘍性大腸炎	4 (12.5)	2 (3.9)	1 (5.9)	7 (7.0)
便秘	0	0	1 (5.9)	1 (1.0)
下痢	0	0	1 (5.9)	1 (1.0)
血性下痢	1 (3.1)	0	0	1 (1.0)
小腸炎	1 (3.1)	0	0	1 (1.0)
鼓腸	1 (3.1)	0	0	1 (1.0)

表 2.7.4.7-10. 導入療法期中に発現したすべての有害事象（MedDRA SOC 及び PT 別）（統合安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
胃腸障害 (Cont.)				
排便回数増加	0	1 (2.0)	0	1 (1.0)
胃食道逆流性疾患	0	1 (2.0)	1 (5.9)	2 (2.0)
血便排泄	0	2 (3.9)	0	2 (2.0)
悪心	0	3 (5.9)	1 (5.9)	4 (4.0)
膵炎	0	1 (2.0)	0	1 (1.0)
嘔吐	0	1 (2.0)	1 (5.9)	2 (2.0)
一般・全身障害および投与部位の状態	5 (15.6)	7 (13.7)	0	12 (12.0)
腋窩痛	0	1 (2.0)	0	1 (1.0)
胸痛	0	1 (2.0)	0	1 (1.0)
疲労	0	1 (2.0)	0	1 (1.0)
異常感	1 (3.1)	0	0	1 (1.0)
注射部位紅斑	0	1 (2.0)	0	1 (1.0)
注射部位疼痛	1 (3.1)	1 (2.0)	0	2 (2.0)
注射部位蕁麻疹	0	1 (2.0)	0	1 (1.0)
末梢腫脹	1 (3.1)	0	0	1 (1.0)
発熱	2 (6.3)	1 (2.0)	0	3 (3.0)
肝胆道系障害	1 (3.1)	0	0	1 (1.0)
高ビリルビン血症	1 (3.1)	0	0	1 (1.0)
感染症および寄生虫症	6 (18.8)	11 (21.6)	6 (35.3)	23 (23.0)
気管支炎	0	0	1 (5.9)	1 (1.0)

表 2.7.4.7-10. 導入療法期中に発現したすべての有害事象（MedDRA SOC 及び PT 別）（統合安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
感染症および寄生虫症 (Cont.)				
せつ	0	1 (2.0)	0	1 (1.0)
サルモネラ菌性胃腸炎	1 (3.1)	0	0	1 (1.0)
上咽頭炎	2 (6.3)	2 (3.9)	1 (5.9)	5 (5.0)
口腔ヘルペス	1 (3.1)	2 (3.9)	0	3 (3.0)
外耳炎	0	1 (2.0)	0	1 (1.0)
咽頭炎	2 (6.3)	1 (2.0)	1 (5.9)	4 (4.0)
レンサ球菌感染	0	0	1 (5.9)	1 (1.0)
上気道感染	0	3 (5.9)	0	3 (3.0)
尿路感染	1 (3.1)	0	0	1 (1.0)
水痘	0	1 (2.0)	0	1 (1.0)
ウイルス感染	0	0	1 (5.9)	1 (1.0)
ウイルス性上気道感染	0	1 (2.0)	0	1 (1.0)
外陰腟真菌感染	0	0	1 (5.9)	1 (1.0)
傷害、中毒および処置合併症	4 (12.5)	2 (3.9)	0	6 (6.0)
節足動物咬傷	1 (3.1)	0	0	1 (1.0)
転倒	1 (3.1)	0	0	1 (1.0)
注入に伴う反応	1 (3.1)	0	0	1 (1.0)
靭帯捻挫	1 (3.1)	0	0	1 (1.0)
処置による疼痛	0	1 (2.0)	0	1 (1.0)
手首関節骨折	0	1 (2.0)	0	1 (1.0)

表 2.7.4.7-10. 導入療法期中に発現したすべての有害事象（MedDRA SOC 及び PT 別）（統合安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
臨床検査	2 (6.3)	2 (3.9)	2 (11.8)	6 (6.0)
血圧上昇	0	1 (2.0)	0	1 (1.0)
C一反応性蛋白増加	0	1 (2.0)	0	1 (1.0)
ヘモグロビン減少	1 (3.1)	0	0	1 (1.0)
肝酵素上昇	0	0	1 (5.9)	1 (1.0)
単球数減少	0	0	1 (5.9)	1 (1.0)
好中球数減少	0	0	1 (5.9)	1 (1.0)
体重減少	1 (3.1)	1 (2.0)	0	2 (2.0)
白血球数減少	0	0	1 (5.9)	1 (1.0)
筋骨格系および結合組織障害	2 (6.3)	2 (3.9)	1 (5.9)	5 (5.0)
関節痛	1 (3.1)	0	1 (5.9)	2 (2.0)
背部痛	0	1 (2.0)	0	1 (1.0)
靱帯障害	0	1 (2.0)	0	1 (1.0)
四肢痛	1 (3.1)	0	0	1 (1.0)
神経系障害	6 (18.8)	5 (9.8)	4 (23.5)	15 (15.0)
頭痛	5 (15.6)	5 (9.8)	4 (23.5)	14 (14.0)
意識消失	1 (3.1)	0	0	1 (1.0)
片頭痛	1 (3.1)	0	0	1 (1.0)
錯感覚	1 (3.1)	0	0	1 (1.0)
振戦	0	1 (2.0)	1 (5.9)	2 (2.0)

表 2.7.4.7-10. 導入療法期中に発現したすべての有害事象（MedDRA SOC 及び PT 別）（統合安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
腎および尿路障害	0	0	1 (5.9)	1 (1.0)
糖尿	0	0	1 (5.9)	1 (1.0)
生殖系および乳房障害	0	1 (2.0)	0	1 (1.0)
乳房痛	0	1 (2.0)	0	1 (1.0)
呼吸器、胸郭および縦隔障害	1 (3.1)	3 (5.9)	3 (17.6)	7 (7.0)
咳嗽	0	1 (2.0)	0	1 (1.0)
鼻閉	0	1 (2.0)	0	1 (1.0)
口腔咽頭痛	1 (3.1)	1 (2.0)	2 (11.8)	4 (4.0)
鼻漏	0	1 (2.0)	1 (5.9)	2 (2.0)
皮膚および皮下組織障害	1 (3.1)	0	1 (5.9)	2 (2.0)
結節性紅斑	1 (3.1)	0	0	1 (1.0)
発疹	0	0	1 (5.9)	1 (1.0)

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
I-SD = induction standard dose group; I-HD = induction high dose group; I-HD-OL = induction high dose open-label group;
Note: 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_A

表 2.7.4.7-11.　維持療法期中に発現したすべての有害事象（MedDRA SOC 及び PT 別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）

MedDRA 22.0 System Organ Class Preferred Term	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
Any adverse event	21 (63.6)	25 (71.4)	46 (67.6)	10 (83.3)	56 (70.0)
血液およびリンパ系障害	4 (12.1)	1 (2.9)	5 (7.4)	2 (16.7)	7 (8.8)
貧血	3 (9.1)	1 (2.9)	4 (5.9)	1 (8.3)	5 (6.3)
リンパ節症	1 (3.0)	0	1 (1.5)	0	1 (1.3)
好中球減少症	0	0	0	1 (8.3)	1 (1.3)
耳および迷路障害	0	1 (2.9)	1 (1.5)	0	1 (1.3)
耳痛	0	1 (2.9)	1 (1.5)	0	1 (1.3)
眼障害	0	0	0	1 (8.3)	1 (1.3)
非感染性結膜炎	0	0	0	1 (8.3)	1 (1.3)
胃腸障害	9 (27.3)	10 (28.6)	19 (27.9)	3 (25.0)	22 (27.5)
腹痛	1 (3.0)	1 (2.9)	2 (2.9)	1 (8.3)	3 (3.8)
上腹部痛	0	2 (5.7)	2 (2.9)	0	2 (2.5)
アフタ性潰瘍	1 (3.0)	0	1 (1.5)	0	1 (1.3)
潰瘍性大腸炎	6 (18.2)	4 (11.4)	10 (14.7)	2 (16.7)	12 (15.0)
便秘	1 (3.0)	0	1 (1.5)	0	1 (1.3)
下痢	0	1 (2.9)	1 (1.5)	0	1 (1.3)
消化不良	0	1 (2.9)	1 (1.5)	0	1 (1.3)
小腸炎	2 (6.1)	1 (2.9)	3 (4.4)	0	3 (3.8)
胃食道逆流性疾患	0	1 (2.9)	1 (1.5)	0	1 (1.3)

表 2.7.4.7-11. 維持療法期中に発現したすべての有害事象（MedDRA SOC 及び PT 別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
一般・全身障害および投与部位の状態	5 (15.2)	3 (8.6)	8 (11.8)	1 (8.3)	9 (11.3)
胸痛	0	1 (2.9)	1 (1.5)	0	1 (1.3)
疲労	2 (6.1)	0	2 (2.9)	0	2 (2.5)
炎症	0	0	0	1 (8.3)	1 (1.3)
注射部位紅斑	0	1 (2.9)	1 (1.5)	0	1 (1.3)
注射部位炎症	1 (3.0)	0	1 (1.5)	0	1 (1.3)
注射部位浮腫	1 (3.0)	0	1 (1.5)	0	1 (1.3)
注射部位疼痛	1 (3.0)	0	1 (1.5)	0	1 (1.3)
注射部位そう痒感	0	1 (2.9)	1 (1.5)	0	1 (1.3)
注射部位腫脹	1 (3.0)	0	1 (1.5)	0	1 (1.3)
注射部位蕁麻疹	0	1 (2.9)	1 (1.5)	0	1 (1.3)
倦怠感	0	1 (2.9)	1 (1.5)	0	1 (1.3)
発熱	1 (3.0)	0	1 (1.5)	0	1 (1.3)
免疫系障害	0	1 (2.9)	1 (1.5)	0	1 (1.3)
薬物過敏症	0	1 (2.9)	1 (1.5)	0	1 (1.3)
感染症および寄生虫症	11 (33.3)	16 (45.7)	27 (39.7)	5 (41.7)	32 (40.0)
気管支炎	1 (3.0)	0	1 (1.5)	0	1 (1.3)
感染性腸炎	1 (3.0)	0	1 (1.5)	0	1 (1.3)
胃腸炎	2 (6.1)	0	2 (2.9)	1 (8.3)	3 (3.8)
膿痂疹	0	1 (2.9)	1 (1.5)	0	1 (1.3)
感染性嚢腫	0	1 (2.9)	1 (1.5)	0	1 (1.3)

表 2.7.4.7-11. 維持療法期中に発現したすべての有害事象（MedDRA SOC 及び PT 別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
感染症および寄生虫症 (Cont.)					
インフルエンザ	0	2 (5.7)	2 (2.9)	0	2 (2.5)
喉頭炎	0	1 (2.9)	1 (1.5)	0	1 (1.3)
無菌性髄膜炎	0	1 (2.9)	1 (1.5)	0	1 (1.3)
上咽頭炎	3 (9.1)	4 (11.4)	7 (10.3)	1 (8.3)	8 (10.0)
口腔ヘルペス	0	1 (2.9)	1 (1.5)	0	1 (1.3)
中耳炎	0	1 (2.9)	1 (1.5)	0	1 (1.3)
咽頭炎	2 (6.1)	2 (5.7)	4 (5.9)	1 (8.3)	5 (6.3)
気道感染	1 (3.0)	0	1 (1.5)	0	1 (1.3)
ウイルス性気道感染	0	0	0	1 (8.3)	1 (1.3)
鼻炎	1 (3.0)	0	1 (1.5)	0	1 (1.3)
癜風	1 (3.0)	0	1 (1.5)	0	1 (1.3)
歯膿瘍	0	0	0	1 (8.3)	1 (1.3)
気管炎	1 (3.0)	0	1 (1.5)	0	1 (1.3)
上気道感染	2 (6.1)	4 (11.4)	6 (8.8)	2 (16.7)	8 (10.0)
尿路感染	1 (3.0)	2 (5.7)	3 (4.4)	0	3 (3.8)
水痘	0	1 (2.9)	1 (1.5)	0	1 (1.3)
傷害、中毒および処置合併症	0	3 (8.6)	3 (4.4)	1 (8.3)	4 (5.0)
眼瞼挫傷	0	1 (2.9)	1 (1.5)	0	1 (1.3)
手骨折	0	2 (5.7)	2 (2.9)	0	2 (2.5)
関節損傷	0	0	0	1 (8.3)	1 (1.3)
靭帯捻挫	0	1 (2.9)	1 (1.5)	0	1 (1.3)

表 2.7.4.7-11. 維持療法期中に発現したすべての有害事象（MedDRA SOC 及び PT 別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
臨床検査	5 (15.2)	3 (8.6)	8 (11.8)	0	8 (10.0)
血中ビリルビン増加	1 (3.0)	1 (2.9)	2 (2.9)	0	2 (2.5)
血中カルシウム減少	1 (3.0)	0	1 (1.5)	0	1 (1.3)
血中ナトリウム減少	0	1 (2.9)	1 (1.5)	0	1 (1.3)
骨密度減少	1 (3.0)	0	1 (1.5)	0	1 (1.3)
C一反応性蛋白増加	3 (9.1)	0	3 (4.4)	0	3 (3.8)
好酸球数増加	0	1 (2.9)	1 (1.5)	0	1 (1.3)
リンパ節触知	1 (3.0)	0	1 (1.5)	0	1 (1.3)
結核菌群検査陽性	0	1 (2.9)	1 (1.5)	0	1 (1.3)
好中球数減少	1 (3.0)	0	1 (1.5)	0	1 (1.3)
白血球数減少	1 (3.0)	0	1 (1.5)	0	1 (1.3)
筋骨格系および結合組織障害	1 (3.0)	2 (5.7)	3 (4.4)	1 (8.3)	4 (5.0)
関節痛	0	1 (2.9)	1 (1.5)	0	1 (1.3)
背部痛	1 (3.0)	1 (2.9)	2 (2.9)	0	2 (2.5)
筋骨格痛	0	0	0	1 (8.3)	1 (1.3)
神経系障害	6 (18.2)	3 (8.6)	9 (13.2)	2 (16.7)	11 (13.8)
頭痛	6 (18.2)	2 (5.7)	8 (11.8)	2 (16.7)	10 (12.5)
感覚鈍麻	0	1 (2.9)	1 (1.5)	0	1 (1.3)
錯感覚	0	1 (2.9)	1 (1.5)	0	1 (1.3)

表 2.7.4.7-11. 維持療法期中に発現したすべての有害事象（MedDRA SOC 及び PT 別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
精神障害	1 (3.0)	1 (2.9)	2 (2.9)	0	2 (2.5)
うつ病	1 (3.0)	1 (2.9)	2 (2.9)	0	2 (2.5)
生殖系および乳房障害	0	1 (2.9)	1 (1.5)	0	1 (1.3)
月経困難症	0	1 (2.9)	1 (1.5)	0	1 (1.3)
呼吸器、胸郭および縦隔障害	4 (12.1)	5 (14.3)	9 (13.2)	3 (25.0)	12 (15.0)
喘息	1 (3.0)	0	1 (1.5)	0	1 (1.3)
咳嗽	0	2 (5.7)	2 (2.9)	0	2 (2.5)
鼻出血	0	0	0	2 (16.7)	2 (2.5)
鼻浮腫	1 (3.0)	0	1 (1.5)	0	1 (1.3)
口腔咽頭痛	2 (6.1)	1 (2.9)	3 (4.4)	0	3 (3.8)
アレルギー性鼻炎	0	2 (5.7)	2 (2.9)	0	2 (2.5)
鼻漏	1 (3.0)	0	1 (1.5)	0	1 (1.3)
喘鳴	0	0	0	1 (8.3)	1 (1.3)
皮膚および皮下組織障害	1 (3.0)	7 (20.0)	8 (11.8)	3 (25.0)	11 (13.8)
脱毛症	0	1 (2.9)	1 (1.5)	0	1 (1.3)
皮膚炎	0	1 (2.9)	1 (1.5)	1 (8.3)	2 (2.5)
紅斑	0	1 (2.9)	1 (1.5)	0	1 (1.3)
結節性紅斑	0	1 (2.9)	1 (1.5)	0	1 (1.3)
逆むけ	0	0	0	1 (8.3)	1 (1.3)
乾癬	0	0	0	1 (8.3)	1 (1.3)

表 2.7.4.7-11. 維持療法期中に発現したすべての有害事象（MedDRA SOC 及び PT 別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
皮膚および皮下組織障害 (Cont.)					
紫斑	0	1 (2.9)	1 (1.5)	0	1 (1.3)
発疹	1 (3.0)	2 (5.7)	3 (4.4)	0	3 (3.8)
痂皮	0	1 (2.9)	1 (1.5)	0	1 (1.3)
脂漏	1 (3.0)	0	1 (1.5)	0	1 (1.3)
皮膚病変	0	1 (2.9)	1 (1.5)	0	1 (1.3)

One patient ([redacted] who is ongoing study is excluded from interim analysis.
M-PL = maintenance placebo group; M-SD = maintenance standard dose group; M-HD = maintenance high dose group;
Note: 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_A

表 2.7.4.7-12.　すべての有害事象（MedDRA SOC 及び PT 別）（統合 FAS 集団，M10-870 試験）

MedDRA 22.0 System Organ Class Preferred Term	Adalimumab (N=59) n (%)
Any adverse event	40 (67.8)
血液およびリンパ系障害	6 (10.2)
貧血	4 (6.8)
失血性貧血	1 (1.7)
鉄欠乏性貧血	1 (1.7)
リンパ節炎	1 (1.7)
眼障害	1 (1.7)
近視	1 (1.7)
胃腸障害	23 (39.0)
腹部不快感	1 (1.7)
腹痛	1 (1.7)
上腹部痛	2 (3.4)
口唇症	1 (1.7)
潰瘍性大腸炎	12 (20.3)
便秘	1 (1.7)
下痢	1 (1.7)
消化不良	2 (3.4)
腸炎	1 (1.7)
胃炎	3 (5.1)
血便排泄	2 (3.4)
大腸ポリープ	1 (1.7)
悪心	2 (3.4)
直腸出血	1 (1.7)

表 2.7.4.7-12. すべての有害事象（MedDRA SOC 及び PT 別）（統合 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	Adalimumab (N=59) n (%)
胃腸障害 (Cont.)	
口内炎	1 (1.7)
嘔吐	1 (1.7)
一般・全身障害および投与部位の状態	4 (6.8)
倦怠感	1 (1.7)
末梢性浮腫	1 (1.7)
発熱	2 (3.4)
肝胆道系障害	1 (1.7)
胆嚢炎	1 (1.7)
免疫系障害	1 (1.7)
季節性アレルギー	1 (1.7)
感染症および寄生虫症	24 (40.7)
肛門膿瘍	1 (1.7)
気管支炎	3 (5.1)
ウイルス性胃腸炎	2 (3.4)
帯状疱疹	2 (3.4)
膿痂疹	1 (1.7)
上咽頭炎	5 (8.5)
口腔ヘルペス	1 (1.7)
中耳炎	1 (1.7)
咽頭炎	4 (6.8)

表 2.7.4.7-12. すべての有害事象（MedDRA SOC 及び PT 別）（統合 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	Adalimumab (N=59) n (%)
感染症および寄生虫症 (Cont.)	
敗血症	1 (1.7)
副鼻腔炎	1 (1.7)
レンサ球菌感染	1 (1.7)
歯膿瘍	1 (1.7)
上気道感染	7 (11.9)
尿路感染	2 (3.4)
ウイルス感染	2 (3.4)
ウイルス性上気道感染	2 (3.4)
外陰腟炎	1 (1.7)
傷害、中毒および処置合併症	5 (8.5)
足関節部骨折	1 (1.7)
手骨折	1 (1.7)
四肢損傷	1 (1.7)
上肢骨折	1 (1.7)
手首関節骨折	1 (1.7)
臨床検査	6 (10.2)
血中アルカリホスファターゼ増加	1 (1.7)
体温上昇	1 (1.7)
結核菌群検査陽性	4 (6.8)
代謝および栄養障害	1 (1.7)
食欲減退	1 (1.7)

表 2.7.4.7-12. すべての有害事象（MedDRA SOC 及び PT 別）（統合 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	Adalimumab (N=59) n (%)
筋骨格系および結合組織障害	7 (11.9)
関節痛	4 (6.8)
背部痛	1 (1.7)
成長不全	1 (1.7)
若年性特発性関節炎	1 (1.7)
脊椎痛	1 (1.7)
神経系障害	6 (10.2)
頭痛	5 (8.5)
傾眠	1 (1.7)
精神障害	2 (3.4)
うつ病	2 (3.4)
腎および尿路障害	3 (5.1)
血尿	1 (1.7)
腎結石症	1 (1.7)
腎仙痛	1 (1.7)
生殖系および乳房障害	3 (5.1)
月経困難症	1 (1.7)
卵巣嚢胞	2 (3.4)
呼吸器、胸郭および縦隔障害	4 (6.8)
喘息	1 (1.7)
鼻出血	1 (1.7)

表 2.7.4.7-12. すべての有害事象（MedDRA SOC 及び PT 別）（統合 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	Adalimumab (N=59) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)	
アレルギー性鼻炎	2 (3.4)
鼻漏	1 (1.7)
皮膚および皮下組織障害	5 (8.5)
皮膚炎	1 (1.7)
乾癬様皮膚炎	1 (1.7)
乾癬	1 (1.7)
発疹	1 (1.7)
皮膚障害	1 (1.7)
蕁麻疹	1 (1.7)
血管障害	1 (1.7)
高血圧	1 (1.7)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Cross reference: M10-870 Japan Sub-study CSR_Interim Table 14.3__1.2.1.1_A

表 2.7.4.7-13. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（統合安全性解析対象集団，M11-290 試験）

MedDRA 22.0 System Organ Class Preferred Term Relationship	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
Any adverse event	19 (59.4)	27 (52.9)	13 (76.5)	59 (59.0)
No Reasonable Possibility	14 (43.8)	19 (37.3)	11 (64.7)	44 (44.0)
Reasonable Possibility	5 (15.6)	8 (15.7)	2 (11.8)	15 (15.0)
血液およびリンパ系障害	3 (9.4)	3 (5.9)	1 (5.9)	7 (7.0)
No Reasonable Possibility	3 (9.4)	3 (5.9)	1 (5.9)	7 (7.0)
貧血	3 (9.4)	3 (5.9)	1 (5.9)	7 (7.0)
No Reasonable Possibility	3 (9.4)	3 (5.9)	1 (5.9)	7 (7.0)
血小板増加症	0	0	1 (5.9)	1 (1.0)
No Reasonable Possibility	0	0	1 (5.9)	1 (1.0)
心臓障害	1 (3.1)	0	0	1 (1.0)
Reasonable Possibility	1 (3.1)	0	0	1 (1.0)
心膜炎	1 (3.1)	0	0	1 (1.0)
Reasonable Possibility	1 (3.1)	0	0	1 (1.0)
内分泌障害	1 (3.1)	0	0	1 (1.0)
No Reasonable Possibility	1 (3.1)	0	0	1 (1.0)
甲状腺腫	1 (3.1)	0	0	1 (1.0)
No Reasonable Possibility	1 (3.1)	0	0	1 (1.0)

表 2.7.4.7-13. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（統合安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
眼障害	1 (3.1)	1 (2.0)	0	2 (2.0)
No Reasonable Possibility	1 (3.1)	1 (2.0)	0	2 (2.0)
眼瞼炎	0	1 (2.0)	0	1 (1.0)
No Reasonable Possibility	0	1 (2.0)	0	1 (1.0)
角膜炎	1 (3.1)	0	0	1 (1.0)
No Reasonable Possibility	1 (3.1)	0	0	1 (1.0)
胃腸障害	6 (18.8)	9 (17.6)	5 (29.4)	20 (20.0)
No Reasonable Possibility	6 (18.8)	6 (11.8)	4 (23.5)	16 (16.0)
Reasonable Possibility	0	3 (5.9)	1 (5.9)	4 (4.0)
腹痛	0	2 (3.9)	2 (11.8)	4 (4.0)
No Reasonable Possibility	0	2 (3.9)	2 (11.8)	4 (4.0)
上腹部痛	1 (3.1)	2 (3.9)	0	3 (3.0)
No Reasonable Possibility	1 (3.1)	2 (3.9)	0	3 (3.0)
潰瘍性大腸炎	4 (12.5)	2 (3.9)	1 (5.9)	7 (7.0)
No Reasonable Possibility	4 (12.5)	2 (3.9)	0	6 (6.0)
Reasonable Possibility	0	0	1 (5.9)	1 (1.0)
便秘	0	0	1 (5.9)	1 (1.0)
No Reasonable Possibility	0	0	1 (5.9)	1 (1.0)

表 2.7.4.7-13. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（統合安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
胃腸障害 (Cont.)				
下痢	0	0	1 (5.9)	1 (1.0)
No Reasonable Possibility	0	0	1 (5.9)	1 (1.0)
血性下痢	1 (3.1)	0	0	1 (1.0)
No Reasonable Possibility	1 (3.1)	0	0	1 (1.0)
小腸炎	1 (3.1)	0	0	1 (1.0)
No Reasonable Possibility	1 (3.1)	0	0	1 (1.0)
鼓腸	1 (3.1)	0	0	1 (1.0)
No Reasonable Possibility	1 (3.1)	0	0	1 (1.0)
排便回数増加	0	1 (2.0)	0	1 (1.0)
Reasonable Possibility	0	1 (2.0)	0	1 (1.0)
胃食道逆流性疾患	0	1 (2.0)	1 (5.9)	2 (2.0)
No Reasonable Possibility	0	1 (2.0)	1 (5.9)	2 (2.0)
血便排泄	0	2 (3.9)	0	2 (2.0)
No Reasonable Possibility	0	1 (2.0)	0	1 (1.0)
Reasonable Possibility	0	1 (2.0)	0	1 (1.0)
悪心	0	3 (5.9)	1 (5.9)	4 (4.0)
No Reasonable Possibility	0	2 (3.9)	1 (5.9)	3 (3.0)
Reasonable Possibility	0	1 (2.0)	0	1 (1.0)

表 2.7.4.7-13. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（統合安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
胃腸障害 (Cont.)				
膵炎	0	1 (2.0)	0	1 (1.0)
Reasonable Possibility	0	1 (2.0)	0	1 (1.0)
嘔吐	0	1 (2.0)	1 (5.9)	2 (2.0)
No Reasonable Possibility	0	0	1 (5.9)	1 (1.0)
Reasonable Possibility	0	1 (2.0)	0	1 (1.0)
一般・全身障害および投与部位の状態	5 (15.6)	7 (13.7)	0	12 (12.0)
No Reasonable Possibility	4 (12.5)	3 (5.9)	0	7 (7.0)
Reasonable Possibility	1 (3.1)	4 (7.8)	0	5 (5.0)
腋窩痛	0	1 (2.0)	0	1 (1.0)
No Reasonable Possibility	0	1 (2.0)	0	1 (1.0)
胸痛	0	1 (2.0)	0	1 (1.0)
No Reasonable Possibility	0	1 (2.0)	0	1 (1.0)
疲労	0	1 (2.0)	0	1 (1.0)
No Reasonable Possibility	0	1 (2.0)	0	1 (1.0)
異常感	1 (3.1)	0	0	1 (1.0)
No Reasonable Possibility	1 (3.1)	0	0	1 (1.0)
注射部位紅斑	0	1 (2.0)	0	1 (1.0)
Reasonable Possibility	0	1 (2.0)	0	1 (1.0)

表 2.7.4.7-13. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（統合安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
一般・全身障害および投与部位の状態 (Cont.)				
注射部位疼痛	1 (3.1)	1 (2.0)	0	2 (2.0)
Reasonable Possibility	1 (3.1)	1 (2.0)	0	2 (2.0)
注射部位蕁麻疹	0	1 (2.0)	0	1 (1.0)
Reasonable Possibility	0	1 (2.0)	0	1 (1.0)
末梢腫脹	1 (3.1)	0	0	1 (1.0)
No Reasonable Possibility	1 (3.1)	0	0	1 (1.0)
発熱	2 (6.3)	1 (2.0)	0	3 (3.0)
No Reasonable Possibility	2 (6.3)	0	0	2 (2.0)
Reasonable Possibility	0	1 (2.0)	0	1 (1.0)
肝胆道系障害	1 (3.1)	0	0	1 (1.0)
Reasonable Possibility	1 (3.1)	0	0	1 (1.0)
高ビリルビン血症	1 (3.1)	0	0	1 (1.0)
Reasonable Possibility	1 (3.1)	0	0	1 (1.0)
感染症および寄生虫症	6 (18.8)	11 (21.6)	6 (35.3)	23 (23.0)
No Reasonable Possibility	6 (18.8)	11 (21.6)	5 (29.4)	22 (22.0)
Reasonable Possibility	0	0	1 (5.9)	1 (1.0)
気管支炎	0	0	1 (5.9)	1 (1.0)
No Reasonable Possibility	0	0	1 (5.9)	1 (1.0)

表 2.7.4.7-13. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（統合安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
感染症および寄生虫症 (Cont.)				
せつ	0	1 (2.0)	0	1 (1.0)
No Reasonable Possibility	0	1 (2.0)	0	1 (1.0)
サルモネラ菌性胃腸炎	1 (3.1)	0	0	1 (1.0)
No Reasonable Possibility	1 (3.1)	0	0	1 (1.0)
上咽頭炎	2 (6.3)	2 (3.9)	1 (5.9)	5 (5.0)
No Reasonable Possibility	2 (6.3)	2 (3.9)	1 (5.9)	5 (5.0)
口腔ヘルペス	1 (3.1)	2 (3.9)	0	3 (3.0)
No Reasonable Possibility	1 (3.1)	2 (3.9)	0	3 (3.0)
外耳炎	0	1 (2.0)	0	1 (1.0)
No Reasonable Possibility	0	1 (2.0)	0	1 (1.0)
咽頭炎	2 (6.3)	1 (2.0)	1 (5.9)	4 (4.0)
No Reasonable Possibility	2 (6.3)	1 (2.0)	1 (5.9)	4 (4.0)
レンサ球菌感染	0	0	1 (5.9)	1 (1.0)
No Reasonable Possibility	0	0	1 (5.9)	1 (1.0)
上気道感染	0	3 (5.9)	0	3 (3.0)
No Reasonable Possibility	0	3 (5.9)	0	3 (3.0)

表 2.7.4.7-13. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（統合安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
感染症および寄生虫症 (Cont.)				
尿路感染	1 (3.1)	0	0	1 (1.0)
No Reasonable Possibility	1 (3.1)	0	0	1 (1.0)
水痘	0	1 (2.0)	0	1 (1.0)
No Reasonable Possibility	0	1 (2.0)	0	1 (1.0)
ウイルス感染	0	0	1 (5.9)	1 (1.0)
No Reasonable Possibility	0	0	1 (5.9)	1 (1.0)
ウイルス性上気道感染	0	1 (2.0)	0	1 (1.0)
No Reasonable Possibility	0	1 (2.0)	0	1 (1.0)
外陰腟真菌感染	0	0	1 (5.9)	1 (1.0)
Reasonable Possibility	0	0	1 (5.9)	1 (1.0)
傷害、中毒および処置合併症	4 (12.5)	2 (3.9)	0	6 (6.0)
No Reasonable Possibility	4 (12.5)	2 (3.9)	0	6 (6.0)
節足動物咬傷	1 (3.1)	0	0	1 (1.0)
No Reasonable Possibility	1 (3.1)	0	0	1 (1.0)
転倒	1 (3.1)	0	0	1 (1.0)
No Reasonable Possibility	1 (3.1)	0	0	1 (1.0)

表 2.7.4.7-13. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（統合安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
傷害、中毒および処置合併症 (Cont.)				
注入に伴う反応	1 (3.1)	0	0	1 (1.0)
No Reasonable Possibility	1 (3.1)	0	0	1 (1.0)
靭帯捻挫	1 (3.1)	0	0	1 (1.0)
No Reasonable Possibility	1 (3.1)	0	0	1 (1.0)
処置による疼痛	0	1 (2.0)	0	1 (1.0)
No Reasonable Possibility	0	1 (2.0)	0	1 (1.0)
手首関節骨折	0	1 (2.0)	0	1 (1.0)
No Reasonable Possibility	0	1 (2.0)	0	1 (1.0)
臨床検査	2 (6.3)	2 (3.9)	2 (11.8)	6 (6.0)
No Reasonable Possibility	2 (6.3)	1 (2.0)	1 (5.9)	4 (4.0)
Reasonable Possibility	0	1 (2.0)	1 (5.9)	2 (2.0)
血圧上昇	0	1 (2.0)	0	1 (1.0)
No Reasonable Possibility	0	1 (2.0)	0	1 (1.0)
C－反応性蛋白増加	0	1 (2.0)	0	1 (1.0)
Reasonable Possibility	0	1 (2.0)	0	1 (1.0)
ヘモグロビン減少	1 (3.1)	0	0	1 (1.0)
No Reasonable Possibility	1 (3.1)	0	0	1 (1.0)

表 2.7.4.7-13. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（統合安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
臨床検査 (Cont.)				
肝酵素上昇	0	0	1 (5.9)	1 (1.0)
No Reasonable Possibility	0	0	1 (5.9)	1 (1.0)
単球数減少	0	0	1 (5.9)	1 (1.0)
Reasonable Possibility	0	0	1 (5.9)	1 (1.0)
好中球数減少	0	0	1 (5.9)	1 (1.0)
Reasonable Possibility	0	0	1 (5.9)	1 (1.0)
体重減少	1 (3.1)	1 (2.0)	0	2 (2.0)
No Reasonable Possibility	1 (3.1)	0	0	1 (1.0)
Reasonable Possibility	0	1 (2.0)	0	1 (1.0)
白血球数減少	0	0	1 (5.9)	1 (1.0)
Reasonable Possibility	0	0	1 (5.9)	1 (1.0)
筋骨格系および結合組織障害	2 (6.3)	2 (3.9)	1 (5.9)	5 (5.0)
No Reasonable Possibility	1 (3.1)	2 (3.9)	1 (5.9)	4 (4.0)
Reasonable Possibility	1 (3.1)	0	0	1 (1.0)
関節痛	1 (3.1)	0	1 (5.9)	2 (2.0)
No Reasonable Possibility	1 (3.1)	0	1 (5.9)	2 (2.0)
背部痛	0	1 (2.0)	0	1 (1.0)
No Reasonable Possibility	0	1 (2.0)	0	1 (1.0)

表 2.7.4.7-13. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（統合安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
筋骨格系および結合組織障害 (Cont.)				
靭帯障害	0	1 (2.0)	0	1 (1.0)
No Reasonable Possibility	0	1 (2.0)	0	1 (1.0)
四肢痛	1 (3.1)	0	0	1 (1.0)
Reasonable Possibility	1 (3.1)	0	0	1 (1.0)
神経系障害	6 (18.8)	5 (9.8)	4 (23.5)	15 (15.0)
No Reasonable Possibility	4 (12.5)	3 (5.9)	4 (23.5)	11 (11.0)
Reasonable Possibility	2 (6.3)	2 (3.9)	0	4 (4.0)
頭痛	5 (15.6)	5 (9.8)	4 (23.5)	14 (14.0)
No Reasonable Possibility	4 (12.5)	3 (5.9)	4 (23.5)	11 (11.0)
Reasonable Possibility	1 (3.1)	2 (3.9)	0	3 (3.0)
意識消失	1 (3.1)	0	0	1 (1.0)
Reasonable Possibility	1 (3.1)	0	0	1 (1.0)
片頭痛	1 (3.1)	0	0	1 (1.0)
Reasonable Possibility	1 (3.1)	0	0	1 (1.0)
錯感覚	1 (3.1)	0	0	1 (1.0)
Reasonable Possibility	1 (3.1)	0	0	1 (1.0)
振戦	0	1 (2.0)	1 (5.9)	2 (2.0)
No Reasonable Possibility	0	1 (2.0)	1 (5.9)	2 (2.0)

表 2.7.4.7-13. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（統合安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
腎および尿路障害	0	0	1 (5.9)	1 (1.0)
No Reasonable Possibility	0	0	1 (5.9)	1 (1.0)
糖尿	0	0	1 (5.9)	1 (1.0)
No Reasonable Possibility	0	0	1 (5.9)	1 (1.0)
生殖系および乳房障害	0	1 (2.0)	0	1 (1.0)
No Reasonable Possibility	0	1 (2.0)	0	1 (1.0)
乳房痛	0	1 (2.0)	0	1 (1.0)
No Reasonable Possibility	0	1 (2.0)	0	1 (1.0)
呼吸器、胸郭および縦隔障害	1 (3.1)	3 (5.9)	3 (17.6)	7 (7.0)
No Reasonable Possibility	1 (3.1)	3 (5.9)	3 (17.6)	7 (7.0)
咳嗽	0	1 (2.0)	0	1 (1.0)
No Reasonable Possibility	0	1 (2.0)	0	1 (1.0)
鼻閉	0	1 (2.0)	0	1 (1.0)
No Reasonable Possibility	0	1 (2.0)	0	1 (1.0)
口腔咽頭痛	1 (3.1)	1 (2.0)	2 (11.8)	4 (4.0)
No Reasonable Possibility	1 (3.1)	1 (2.0)	2 (11.8)	4 (4.0)

表 2.7.4.7-13. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（統合安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)				
鼻漏	0	1 (2.0)	1 (5.9)	2 (2.0)
No Reasonable Possibility	0	1 (2.0)	1 (5.9)	2 (2.0)
皮膚および皮下組織障害	1 (3.1)	0	1 (5.9)	2 (2.0)
No Reasonable Possibility	1 (3.1)	0	1 (5.9)	2 (2.0)
結節性紅斑	1 (3.1)	0	0	1 (1.0)
No Reasonable Possibility	1 (3.1)	0	0	1 (1.0)
発疹	0	0	1 (5.9)	1 (1.0)
No Reasonable Possibility	0	0	1 (5.9)	1 (1.0)

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
I-SD = induction standard dose group; I-HD = induction high dose group; I-HD-OL = induction high dose open-label group;
Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
If a subject has an AE with unknown relationship, then the subject will be counted in the relationship category of "unknown," unless the subject has another occurrence of the same AE with a relationship assessment of "Reasonable Possibility."

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.3__1.3.1.1_A

表 2.7.4.7-14.　導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（日本人安全性解析対象集団，M11-290 試験）

MedDRA 22.0 System Organ Class Preferred Term Relationship	I-SD (N=2) n (%)	I-HD (N=4) n (%)	I-HD-OL (N=1) n (%)	Total (N=7) n (%)
Any adverse event	2 (100)	4 (100)	1 (100)	7 (100)
No Reasonable Possibility	1 (50.0)	3 (75.0)	0	4 (57.1)
Reasonable Possibility	1 (50.0)	1 (25.0)	1 (100)	3 (42.9)
眼障害	0	1 (25.0)	0	1 (14.3)
No Reasonable Possibility	0	1 (25.0)	0	1 (14.3)
眼瞼炎	0	1 (25.0)	0	1 (14.3)
No Reasonable Possibility	0	1 (25.0)	0	1 (14.3)
一般・全身障害および投与部位の状態	2 (100)	1 (25.0)	0	3 (42.9)
No Reasonable Possibility	1 (50.0)	0	0	1 (14.3)
Reasonable Possibility	1 (50.0)	1 (25.0)	0	2 (28.6)
異常感	1 (50.0)	0	0	1 (14.3)
No Reasonable Possibility	1 (50.0)	0	0	1 (14.3)
注射部位紅斑	0	1 (25.0)	0	1 (14.3)
Reasonable Possibility	0	1 (25.0)	0	1 (14.3)
注射部位疼痛	1 (50.0)	0	0	1 (14.3)
Reasonable Possibility	1 (50.0)	0	0	1 (14.3)
感染症および寄生虫症	0	3 (75.0)	0	3 (42.9)
No Reasonable Possibility	0	3 (75.0)	0	3 (42.9)

表 2.7.4.7-14. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（日本人安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	I-SD (N=2) n (%)	I-HD (N=4) n (%)	I-HD-OL (N=1) n (%)	Total (N=7) n (%)
感染症および寄生虫症 (Cont.)				
外耳炎	0	1 (25.0)	0	1 (14.3)
No Reasonable Possibility	0	1 (25.0)	0	1 (14.3)
上気道感染	0	2 (50.0)	0	2 (28.6)
No Reasonable Possibility	0	2 (50.0)	0	2 (28.6)
臨床検査	0	0	1 (100)	1 (14.3)
Reasonable Possibility	0	0	1 (100)	1 (14.3)
単球数減少	0	0	1 (100)	1 (14.3)
Reasonable Possibility	0	0	1 (100)	1 (14.3)
好中球数減少	0	0	1 (100)	1 (14.3)
Reasonable Possibility	0	0	1 (100)	1 (14.3)
白血球数減少	0	0	1 (100)	1 (14.3)
Reasonable Possibility	0	0	1 (100)	1 (14.3)
神経系障害	1 (50.0)	0	0	1 (14.3)
No Reasonable Possibility	1 (50.0)	0	0	1 (14.3)
頭痛	1 (50.0)	0	0	1 (14.3)
No Reasonable Possibility	1 (50.0)	0	0	1 (14.3)

表 2.7.4.7-14. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（日本人安全性解析対象集団，M11-290 試験）（続き）

One patient ([redacted] who is ongoing study is excluded from interim analysis.
I-SD = induction standard dose group; I-HD = induction high dose group; I-HD-OL = induction high dose open-label group;
Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
If a subject has an AE with unknown relationship, then the subject will be counted in the relationship category of "unknown," unless the subject has another occurrence of the same AE with a relationship assessment of "Reasonable Possibility."

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.3__1.3.1.1_J

表 2.7.4.7-15. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）

MedDRA 22.0 System Organ Class Preferred Term Relationship	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
Any adverse event	21 (63.6)	25 (71.4)	46 (67.6)	10 (83.3)	56 (70.0)
No Reasonable Possibility	13 (39.4)	14 (40.0)	27 (39.7)	5 (41.7)	32 (40.0)
Reasonable Possibility	8 (24.2)	11 (31.4)	19 (27.9)	5 (41.7)	24 (30.0)
血液およびリンパ系障害	4 (12.1)	1 (2.9)	5 (7.4)	2 (16.7)	7 (8.8)
No Reasonable Possibility	3 (9.1)	1 (2.9)	4 (5.9)	0	4 (5.0)
Reasonable Possibility	1 (3.0)	0	1 (1.5)	2 (16.7)	3 (3.8)
貧血	3 (9.1)	1 (2.9)	4 (5.9)	1 (8.3)	5 (6.3)
No Reasonable Possibility	2 (6.1)	1 (2.9)	3 (4.4)	0	3 (3.8)
Reasonable Possibility	1 (3.0)	0	1 (1.5)	1 (8.3)	2 (2.5)
リンパ節症	1 (3.0)	0	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	1 (3.0)	0	1 (1.5)	0	1 (1.3)
好中球減少症	0	0	0	1 (8.3)	1 (1.3)
Reasonable Possibility	0	0	0	1 (8.3)	1 (1.3)
耳および迷路障害	0	1 (2.9)	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)
耳痛	0	1 (2.9)	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)
眼障害	0	0	0	1 (8.3)	1 (1.3)
No Reasonable Possibility	0	0	0	1 (8.3)	1 (1.3)

表 2.7.4.7-15. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
眼障害 (Cont.)					
非感染性結膜炎	0	0	0	1 (8.3)	1 (1.3)
No Reasonable Possibility	0	0	0	1 (8.3)	1 (1.3)
胃腸障害	9 (27.3)	10 (28.6)	19 (27.9)	3 (25.0)	22 (27.5)
No Reasonable Possibility	7 (21.2)	7 (20.0)	14 (20.6)	3 (25.0)	17 (21.3)
Reasonable Possibility	2 (6.1)	3 (8.6)	5 (7.4)	0	5 (6.3)
腹痛	1 (3.0)	1 (2.9)	2 (2.9)	1 (8.3)	3 (3.8)
No Reasonable Possibility	1 (3.0)	1 (2.9)	2 (2.9)	1 (8.3)	3 (3.8)
上腹部痛	0	2 (5.7)	2 (2.9)	0	2 (2.5)
No Reasonable Possibility	0	2 (5.7)	2 (2.9)	0	2 (2.5)
アフタ性潰瘍	1 (3.0)	0	1 (1.5)	0	1 (1.3)
Reasonable Possibility	1 (3.0)	0	1 (1.5)	0	1 (1.3)
潰瘍性大腸炎	6 (18.2)	4 (11.4)	10 (14.7)	2 (16.7)	12 (15.0)
No Reasonable Possibility	5 (15.2)	2 (5.7)	7 (10.3)	2 (16.7)	9 (11.3)
Reasonable Possibility	1 (3.0)	2 (5.7)	3 (4.4)	0	3 (3.8)
便秘	1 (3.0)	0	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	1 (3.0)	0	1 (1.5)	0	1 (1.3)
下痢	0	1 (2.9)	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)

表 2.7.4.7-15. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
胃腸障害 (Cont.)					
消化不良	0	1 (2.9)	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)
小腸炎	2 (6.1)	1 (2.9)	3 (4.4)	0	3 (3.8)
No Reasonable Possibility	2 (6.1)	0	2 (2.9)	0	2 (2.5)
Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)
胃食道逆流性疾患	0	1 (2.9)	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)
一般・全身障害および投与部位の状態	5 (15.2)	3 (8.6)	8 (11.8)	1 (8.3)	9 (11.3)
No Reasonable Possibility	1 (3.0)	1 (2.9)	2 (2.9)	0	2 (2.5)
Reasonable Possibility	4 (12.1)	2 (5.7)	6 (8.8)	1 (8.3)	7 (8.8)
胸痛	0	1 (2.9)	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)
疲労	2 (6.1)	0	2 (2.9)	0	2 (2.5)
Reasonable Possibility	2 (6.1)	0	2 (2.9)	0	2 (2.5)
炎症	0	0	0	1 (8.3)	1 (1.3)
Reasonable Possibility	0	0	0	1 (8.3)	1 (1.3)
注射部位紅斑	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)

表 2.7.4.7-15. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
一般・全身障害および投与部位の状態 (Cont.)					
注射部位炎症	1 (3.0)	0	1 (1.5)	0	1 (1.3)
Reasonable Possibility	1 (3.0)	0	1 (1.5)	0	1 (1.3)
注射部位浮腫	1 (3.0)	0	1 (1.5)	0	1 (1.3)
Reasonable Possibility	1 (3.0)	0	1 (1.5)	0	1 (1.3)
注射部位疼痛	1 (3.0)	0	1 (1.5)	0	1 (1.3)
Reasonable Possibility	1 (3.0)	0	1 (1.5)	0	1 (1.3)
注射部位そう痒感	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)
注射部位腫脹	1 (3.0)	0	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	1 (3.0)	0	1 (1.5)	0	1 (1.3)
注射部位蕁麻疹	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)
倦怠感	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)
発熱	1 (3.0)	0	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	1 (3.0)	0	1 (1.5)	0	1 (1.3)

表 2.7.4.7-15. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
免疫系障害	0	1 (2.9)	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)
薬物過敏症	0	1 (2.9)	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)
感染症および寄生虫症	11 (33.3)	16 (45.7)	27 (39.7)	5 (41.7)	32 (40.0)
No Reasonable Possibility	11 (33.3)	14 (40.0)	25 (36.8)	5 (41.7)	30 (37.5)
Reasonable Possibility	0	2 (5.7)	2 (2.9)	0	2 (2.5)
気管支炎	1 (3.0)	0	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	1 (3.0)	0	1 (1.5)	0	1 (1.3)
感染性腸炎	1 (3.0)	0	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	1 (3.0)	0	1 (1.5)	0	1 (1.3)
胃腸炎	2 (6.1)	0	2 (2.9)	1 (8.3)	3 (3.8)
No Reasonable Possibility	2 (6.1)	0	2 (2.9)	1 (8.3)	3 (3.8)
膿痂疹	0	1 (2.9)	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)
感染性嚢腫	0	1 (2.9)	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)

表 2.7.4.7-15. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
感染症および寄生虫症 (Cont.)					
インフルエンザ	0	2 (5.7)	2 (2.9)	0	2 (2.5)
No Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)
喉頭炎	0	1 (2.9)	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)
無菌性髄膜炎	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)
上咽頭炎	3 (9.1)	4 (11.4)	7 (10.3)	1 (8.3)	8 (10.0)
No Reasonable Possibility	3 (9.1)	4 (11.4)	7 (10.3)	1 (8.3)	8 (10.0)
口腔ヘルペス	0	1 (2.9)	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)
中耳炎	0	1 (2.9)	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)
咽頭炎	2 (6.1)	2 (5.7)	4 (5.9)	1 (8.3)	5 (6.3)
No Reasonable Possibility	2 (6.1)	2 (5.7)	4 (5.9)	1 (8.3)	5 (6.3)
気道感染	1 (3.0)	0	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	1 (3.0)	0	1 (1.5)	0	1 (1.3)

表 2.7.4.7-15. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
感染症および寄生虫症 (Cont.)					
ウイルス性気道感染	0	0	0	1 (8.3)	1 (1.3)
No Reasonable Possibility	0	0	0	1 (8.3)	1 (1.3)
鼻炎	1 (3.0)	0	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	1 (3.0)	0	1 (1.5)	0	1 (1.3)
癜風	1 (3.0)	0	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	1 (3.0)	0	1 (1.5)	0	1 (1.3)
歯膿瘍	0	0	0	1 (8.3)	1 (1.3)
No Reasonable Possibility	0	0	0	1 (8.3)	1 (1.3)
気管炎	1 (3.0)	0	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	1 (3.0)	0	1 (1.5)	0	1 (1.3)
上気道感染	2 (6.1)	4 (11.4)	6 (8.8)	2 (16.7)	8 (10.0)
No Reasonable Possibility	2 (6.1)	4 (11.4)	6 (8.8)	2 (16.7)	8 (10.0)
尿路感染	1 (3.0)	2 (5.7)	3 (4.4)	0	3 (3.8)
No Reasonable Possibility	1 (3.0)	2 (5.7)	3 (4.4)	0	3 (3.8)
水痘	0	1 (2.9)	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)

表 2.7.4.7-15. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
傷害、中毒および処置合併症	0	3 (8.6)	3 (4.4)	1 (8.3)	4 (5.0)
No Reasonable Possibility	0	3 (8.6)	3 (4.4)	1 (8.3)	4 (5.0)
眼瞼挫傷	0	1 (2.9)	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)
手骨折	0	2 (5.7)	2 (2.9)	0	2 (2.5)
No Reasonable Possibility	0	2 (5.7)	2 (2.9)	0	2 (2.5)
関節損傷	0	0	0	1 (8.3)	1 (1.3)
No Reasonable Possibility	0	0	0	1 (8.3)	1 (1.3)
靭帯捻挫	0	1 (2.9)	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)
臨床検査	5 (15.2)	3 (8.6)	8 (11.8)	0	8 (10.0)
No Reasonable Possibility	4 (12.1)	1 (2.9)	5 (7.4)	0	5 (6.3)
Reasonable Possibility	1 (3.0)	2 (5.7)	3 (4.4)	0	3 (3.8)
血中ビリルビン増加	1 (3.0)	1 (2.9)	2 (2.9)	0	2 (2.5)
No Reasonable Possibility	1 (3.0)	0	1 (1.5)	0	1 (1.3)
Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)
血中カルシウム減少	1 (3.0)	0	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	1 (3.0)	0	1 (1.5)	0	1 (1.3)

表 2.7.4.7-15. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
臨床検査 (Cont.)					
血中ナトリウム減少	0	1 (2.9)	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)
骨密度減少	1 (3.0)	0	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	1 (3.0)	0	1 (1.5)	0	1 (1.3)
C－反応性蛋白増加	3 (9.1)	0	3 (4.4)	0	3 (3.8)
No Reasonable Possibility	2 (6.1)	0	2 (2.9)	0	2 (2.5)
Reasonable Possibility	1 (3.0)	0	1 (1.5)	0	1 (1.3)
好酸球数増加	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)
リンパ節触知	1 (3.0)	0	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	1 (3.0)	0	1 (1.5)	0	1 (1.3)
結核菌群検査陽性	0	1 (2.9)	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)
好中球数減少	1 (3.0)	0	1 (1.5)	0	1 (1.3)
Reasonable Possibility	1 (3.0)	0	1 (1.5)	0	1 (1.3)
白血球数減少	1 (3.0)	0	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	1 (3.0)	0	1 (1.5)	0	1 (1.3)

表 2.7.4.7-15. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
筋骨格系および結合組織障害	1 (3.0)	2 (5.7)	3 (4.4)	1 (8.3)	4 (5.0)
No Reasonable Possibility	1 (3.0)	1 (2.9)	2 (2.9)	1 (8.3)	3 (3.8)
Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)
関節痛	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)
背部痛	1 (3.0)	1 (2.9)	2 (2.9)	0	2 (2.5)
No Reasonable Possibility	1 (3.0)	1 (2.9)	2 (2.9)	0	2 (2.5)
筋骨格痛	0	0	0	1 (8.3)	1 (1.3)
No Reasonable Possibility	0	0	0	1 (8.3)	1 (1.3)
神経系障害	6 (18.2)	3 (8.6)	9 (13.2)	2 (16.7)	11 (13.8)
No Reasonable Possibility	4 (12.1)	2 (5.7)	6 (8.8)	1 (8.3)	7 (8.8)
Reasonable Possibility	2 (6.1)	1 (2.9)	3 (4.4)	1 (8.3)	4 (5.0)
頭痛	6 (18.2)	2 (5.7)	8 (11.8)	2 (16.7)	10 (12.5)
No Reasonable Possibility	4 (12.1)	2 (5.7)	6 (8.8)	1 (8.3)	7 (8.8)
Reasonable Possibility	2 (6.1)	0	2 (2.9)	1 (8.3)	3 (3.8)
感覚鈍麻	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)
錯感覚	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)

表 2.7.4.7-15. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
精神障害	1 (3.0)	1 (2.9)	2 (2.9)	0	2 (2.5)
No Reasonable Possibility	1 (3.0)	1 (2.9)	2 (2.9)	0	2 (2.5)
うつ病	1 (3.0)	1 (2.9)	2 (2.9)	0	2 (2.5)
No Reasonable Possibility	1 (3.0)	1 (2.9)	2 (2.9)	0	2 (2.5)
生殖系および乳房障害	0	1 (2.9)	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)
月経困難症	0	1 (2.9)	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)
呼吸器、胸郭および縦隔障害	4 (12.1)	5 (14.3)	9 (13.2)	3 (25.0)	12 (15.0)
No Reasonable Possibility	4 (12.1)	5 (14.3)	9 (13.2)	3 (25.0)	12 (15.0)
喘息	1 (3.0)	0	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	1 (3.0)	0	1 (1.5)	0	1 (1.3)
咳嗽	0	2 (5.7)	2 (2.9)	0	2 (2.5)
No Reasonable Possibility	0	2 (5.7)	2 (2.9)	0	2 (2.5)
鼻出血	0	0	0	2 (16.7)	2 (2.5)
No Reasonable Possibility	0	0	0	2 (16.7)	2 (2.5)

表 2.7.4.7-15. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)					
鼻浮腫	1 (3.0)	0	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	1 (3.0)	0	1 (1.5)	0	1 (1.3)
口腔咽頭痛	2 (6.1)	1 (2.9)	3 (4.4)	0	3 (3.8)
No Reasonable Possibility	2 (6.1)	1 (2.9)	3 (4.4)	0	3 (3.8)
アレルギー性鼻炎	0	2 (5.7)	2 (2.9)	0	2 (2.5)
No Reasonable Possibility	0	2 (5.7)	2 (2.9)	0	2 (2.5)
鼻漏	1 (3.0)	0	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	1 (3.0)	0	1 (1.5)	0	1 (1.3)
喘鳴	0	0	0	1 (8.3)	1 (1.3)
No Reasonable Possibility	0	0	0	1 (8.3)	1 (1.3)
皮膚および皮下組織障害	1 (3.0)	7 (20.0)	8 (11.8)	3 (25.0)	11 (13.8)
No Reasonable Possibility	1 (3.0)	2 (5.7)	3 (4.4)	1 (8.3)	4 (5.0)
Reasonable Possibility	0	5 (14.3)	5 (7.4)	2 (16.7)	7 (8.8)
脱毛症	0	1 (2.9)	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)
皮膚炎	0	1 (2.9)	1 (1.5)	1 (8.3)	2 (2.5)
No Reasonable Possibility	0	0	0	1 (8.3)	1 (1.3)
Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)

表 2.7.4.7-15. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
皮膚および皮下組織障害 (Cont.)					
紅斑	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)
結節性紅斑	0	1 (2.9)	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)
逆むけ	0	0	0	1 (8.3)	1 (1.3)
Reasonable Possibility	0	0	0	1 (8.3)	1 (1.3)
乾癬	0	0	0	1 (8.3)	1 (1.3)
Reasonable Possibility	0	0	0	1 (8.3)	1 (1.3)
紫斑	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)
発疹	1 (3.0)	2 (5.7)	3 (4.4)	0	3 (3.8)
No Reasonable Possibility	1 (3.0)	0	1 (1.5)	0	1 (1.3)
Reasonable Possibility	0	2 (5.7)	2 (2.9)	0	2 (2.5)
痂皮	0	1 (2.9)	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)
脂漏	1 (3.0)	0	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	1 (3.0)	0	1 (1.5)	0	1 (1.3)

表 2.7.4.7-15. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
皮膚および皮下組織障害 (Cont.)					
皮膚病変	0	1 (2.9)	1 (1.5)	0	1 (1.3)
No Reasonable Possibility	0	1 (2.9)	1 (1.5)	0	1 (1.3)

One patient ([redacted] who is ongoing study is excluded from interim analysis.
M-PL = maintenance placebo group; M-SD = maintenance standard dose group; M-HD = maintenance high dose group;
Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
If a subject has an AE with unknown relationship, then the subject will be counted in the relationship category of "unknown," unless the subject has another occurrence of the same AE with a relationship assessment of "Reasonable Possibility."

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.3__1.3.1.2_A

表 2.7.4.7-16. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）
（維持療法期中に治験薬の投与を 1 回以上受けた日本人安全性解析対象集団の被験者，M11-290 試験）

MedDRA 22.0 System Organ Class Preferred Term Relationship	M-SD (N=2) n (%)	M-HD (N=3) n (%)	Total-ADA (N=5) n (%)	M-PL (N=0) n (%)	Total (N=5) n (%)
Any adverse event	1 (50.0)	3 (100)	4 (80.0)	0	4 (80.0)
No Reasonable Possibility	1 (50.0)	2 (66.7)	3 (60.0)	0	3 (60.0)
Reasonable Possibility	0	1 (33.3)	1 (20.0)	0	1 (20.0)
感染症および寄生虫症	1 (50.0)	3 (100)	4 (80.0)	0	4 (80.0)
No Reasonable Possibility	1 (50.0)	2 (66.7)	3 (60.0)	0	3 (60.0)
Reasonable Possibility	0	1 (33.3)	1 (20.0)	0	1 (20.0)
感染性腸炎	1 (50.0)	0	1 (20.0)	0	1 (20.0)
No Reasonable Possibility	1 (50.0)	0	1 (20.0)	0	1 (20.0)
膿痂疹	0	1 (33.3)	1 (20.0)	0	1 (20.0)
No Reasonable Possibility	0	1 (33.3)	1 (20.0)	0	1 (20.0)
インフルエンザ	0	1 (33.3)	1 (20.0)	0	1 (20.0)
Reasonable Possibility	0	1 (33.3)	1 (20.0)	0	1 (20.0)
上気道感染	0	1 (33.3)	1 (20.0)	0	1 (20.0)
No Reasonable Possibility	0	1 (33.3)	1 (20.0)	0	1 (20.0)
傷害、中毒および処置合併症	0	2 (66.7)	2 (40.0)	0	2 (40.0)
No Reasonable Possibility	0	2 (66.7)	2 (40.0)	0	2 (40.0)
眼瞼挫傷	0	1 (33.3)	1 (20.0)	0	1 (20.0)
No Reasonable Possibility	0	1 (33.3)	1 (20.0)	0	1 (20.0)

表 2.7.4.7-16. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）
（維持療法期中に治験薬の投与を 1 回以上受けた日本人安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	M-SD (N=2) n (%)	M-HD (N=3) n (%)	Total-ADA (N=5) n (%)	M-PL (N=0) n (%)	Total (N=5) n (%)
傷害、中毒および処置合併症 (Cont.)					
手骨折	0	1 (33.3)	1 (20.0)	0	1 (20.0)
No Reasonable Possibility	0	1 (33.3)	1 (20.0)	0	1 (20.0)
靭帯捻挫	0	1 (33.3)	1 (20.0)	0	1 (20.0)
No Reasonable Possibility	0	1 (33.3)	1 (20.0)	0	1 (20.0)
皮膚および皮下組織障害	0	1 (33.3)	1 (20.0)	0	1 (20.0)
Reasonable Possibility	0	1 (33.3)	1 (20.0)	0	1 (20.0)
紫斑	0	1 (33.3)	1 (20.0)	0	1 (20.0)
Reasonable Possibility	0	1 (33.3)	1 (20.0)	0	1 (20.0)

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
M-PL = maintenance placebo group; M-SD = maintenance standard dose group; M-HD = maintenance high dose group;
Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
If a subject has an AE with unknown relationship, then the subject will be counted in the relationship category of "unknown," unless the subject has another occurrence of the same AE with a relationship assessment of "Reasonable Possibility."

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.3__1.3.1.2_J

表 2.7.4.7-17.　すべての有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（統合 FAS 集団，M10-870 試験）

MedDRA 22.0 System Organ Class Preferred Term Relationship	Adalimumab (N=59) n (%)
Any adverse event	40 (67.8)
No Reasonable Possibility	27 (45.8)
Reasonable Possibility	13 (22.0)
血液およびリンパ系障害	6 (10.2)
No Reasonable Possibility	6 (10.2)
貧血	4 (6.8)
No Reasonable Possibility	4 (6.8)
失血性貧血	1 (1.7)
No Reasonable Possibility	1 (1.7)
鉄欠乏性貧血	1 (1.7)
No Reasonable Possibility	1 (1.7)
リンパ節炎	1 (1.7)
No Reasonable Possibility	1 (1.7)
眼障害	1 (1.7)
No Reasonable Possibility	1 (1.7)
近視	1 (1.7)
No Reasonable Possibility	1 (1.7)

表 2.7.4.7-17. すべての有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（統合 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	Adalimumab (N=59) n (%)
胃腸障害	23 (39.0)
No Reasonable Possibility	21 (35.6)
Reasonable Possibility	2 (3.4)
腹部不快感	1 (1.7)
No Reasonable Possibility	1 (1.7)
腹痛	1 (1.7)
No Reasonable Possibility	1 (1.7)
上腹部痛	2 (3.4)
No Reasonable Possibility	2 (3.4)
口唇症	1 (1.7)
No Reasonable Possibility	1 (1.7)
潰瘍性大腸炎	12 (20.3)
No Reasonable Possibility	11 (18.6)
Reasonable Possibility	1 (1.7)
便秘	1 (1.7)
No Reasonable Possibility	1 (1.7)
下痢	1 (1.7)
No Reasonable Possibility	1 (1.7)

表 2.7.4.7-17. すべての有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（統合 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	Adalimumab (N=59) n (%)
胃腸障害 (Cont.)	
消化不良	2 (3.4)
No Reasonable Possibility	2 (3.4)
腸炎	1 (1.7)
No Reasonable Possibility	1 (1.7)
胃炎	3 (5.1)
No Reasonable Possibility	2 (3.4)
Reasonable Possibility	1 (1.7)
血便排泄	2 (3.4)
No Reasonable Possibility	2 (3.4)
大腸ポリープ	1 (1.7)
No Reasonable Possibility	1 (1.7)
悪心	2 (3.4)
No Reasonable Possibility	2 (3.4)
直腸出血	1 (1.7)
No Reasonable Possibility	1 (1.7)
口内炎	1 (1.7)
No Reasonable Possibility	1 (1.7)

表 2.7.4.7-17.　すべての有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（統合 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	Adalimumab (N=59) n (%)
胃腸障害 (Cont.)	
嘔吐	1 (1.7)
No Reasonable Possibility	1 (1.7)
一般・全身障害および投与部位の状態	4 (6.8)
No Reasonable Possibility	3 (5.1)
Reasonable Possibility	1 (1.7)
倦怠感	1 (1.7)
No Reasonable Possibility	1 (1.7)
末梢性浮腫	1 (1.7)
No Reasonable Possibility	1 (1.7)
発熱	2 (3.4)
No Reasonable Possibility	1 (1.7)
Reasonable Possibility	1 (1.7)
肝胆道系障害	1 (1.7)
Reasonable Possibility	1 (1.7)
胆嚢炎	1 (1.7)
Reasonable Possibility	1 (1.7)
免疫系障害	1 (1.7)
No Reasonable Possibility	1 (1.7)

表 2.7.4.7-17.　すべての有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（統合 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	Adalimumab (N=59) n (%)
免疫系障害 (Cont.)	
季節性アレルギー	1 (1.7)
No Reasonable Possibility	1 (1.7)
感染症および寄生虫症	24 (40.7)
No Reasonable Possibility	19 (32.2)
Reasonable Possibility	5 (8.5)
肛門膿瘍	1 (1.7)
Reasonable Possibility	1 (1.7)
気管支炎	3 (5.1)
No Reasonable Possibility	3 (5.1)
ウイルス性胃腸炎	2 (3.4)
No Reasonable Possibility	2 (3.4)
帯状疱疹	2 (3.4)
Reasonable Possibility	2 (3.4)
膿痂疹	1 (1.7)
No Reasonable Possibility	1 (1.7)
上咽頭炎	5 (8.5)
No Reasonable Possibility	5 (8.5)

表 2.7.4.7-17.　すべての有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（統合 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	Adalimumab (N=59) n (%)
感染症および寄生虫症 (Cont.)	
口腔ヘルペス	1 (1.7)
No Reasonable Possibility	1 (1.7)
中耳炎	1 (1.7)
No Reasonable Possibility	1 (1.7)
咽頭炎	4 (6.8)
No Reasonable Possibility	4 (6.8)
敗血症	1 (1.7)
No Reasonable Possibility	1 (1.7)
副鼻腔炎	1 (1.7)
No Reasonable Possibility	1 (1.7)
レンサ球菌感染	1 (1.7)
No Reasonable Possibility	1 (1.7)
歯膿瘍	1 (1.7)
No Reasonable Possibility	1 (1.7)
上気道感染	7 (11.9)
No Reasonable Possibility	5 (8.5)
Reasonable Possibility	2 (3.4)

表 2.7.4.7-17.　すべての有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（統合 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	Adalimumab (N=59) n (%)
感染症および寄生虫症 (Cont.)	
尿路感染	2 (3.4)
No Reasonable Possibility	2 (3.4)
ウイルス感染	2 (3.4)
No Reasonable Possibility	2 (3.4)
ウイルス性上気道感染	2 (3.4)
No Reasonable Possibility	2 (3.4)
外陰膣炎	1 (1.7)
No Reasonable Possibility	1 (1.7)
傷害、中毒および処置合併症	5 (8.5)
No Reasonable Possibility	5 (8.5)
足関節部骨折	1 (1.7)
No Reasonable Possibility	1 (1.7)
手骨折	1 (1.7)
No Reasonable Possibility	1 (1.7)
四肢損傷	1 (1.7)
No Reasonable Possibility	1 (1.7)

表 2.7.4.7-17.　すべての有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（統合 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	Adalimumab (N=59) n (%)
傷害、中毒および処置合併症 (Cont.)	
上肢骨折	1 (1.7)
No Reasonable Possibility	1 (1.7)
手首関節骨折	1 (1.7)
No Reasonable Possibility	1 (1.7)
臨床検査	6 (10.2)
No Reasonable Possibility	5 (8.5)
Reasonable Possibility	1 (1.7)
血中アルカリホスファターゼ増加	1 (1.7)
No Reasonable Possibility	1 (1.7)
体温上昇	1 (1.7)
No Reasonable Possibility	1 (1.7)
結核菌群検査陽性	4 (6.8)
No Reasonable Possibility	3 (5.1)
Reasonable Possibility	1 (1.7)
代謝および栄養障害	1 (1.7)
No Reasonable Possibility	1 (1.7)
食欲減退	1 (1.7)
No Reasonable Possibility	1 (1.7)

表 2.7.4.7-17.　すべての有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（統合 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	Adalimumab (N=59) n (%)
筋骨格系および結合組織障害	7 (11.9)
No Reasonable Possibility	5 (8.5)
Reasonable Possibility	2 (3.4)
関節痛	4 (6.8)
No Reasonable Possibility	2 (3.4)
Reasonable Possibility	2 (3.4)
背部痛	1 (1.7)
No Reasonable Possibility	1 (1.7)
成長不全	1 (1.7)
No Reasonable Possibility	1 (1.7)
若年性特発性関節炎	1 (1.7)
No Reasonable Possibility	1 (1.7)
脊椎痛	1 (1.7)
No Reasonable Possibility	1 (1.7)
神経系障害	6 (10.2)
No Reasonable Possibility	6 (10.2)
頭痛	5 (8.5)
No Reasonable Possibility	5 (8.5)

表 2.7.4.7-17.　すべての有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（統合 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	Adalimumab (N=59) n (%)
神経系障害 (Cont.)	
傾眠	1 (1.7)
No Reasonable Possibility	1 (1.7)
精神障害	2 (3.4)
No Reasonable Possibility	2 (3.4)
うつ病	2 (3.4)
No Reasonable Possibility	2 (3.4)
腎および尿路障害	3 (5.1)
No Reasonable Possibility	2 (3.4)
Reasonable Possibility	1 (1.7)
血尿	1 (1.7)
No Reasonable Possibility	1 (1.7)
腎結石症	1 (1.7)
Reasonable Possibility	1 (1.7)
腎仙痛	1 (1.7)
No Reasonable Possibility	1 (1.7)
生殖系および乳房障害	3 (5.1)
No Reasonable Possibility	2 (3.4)
Reasonable Possibility	1 (1.7)

表 2.7.4.7-17.　すべての有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（統合 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	Adalimumab (N=59) n (%)
生殖系および乳房障害 (Cont.)	
月経困難症	1 (1.7)
No Reasonable Possibility	1 (1.7)
卵巣嚢胞	2 (3.4)
No Reasonable Possibility	1 (1.7)
Reasonable Possibility	1 (1.7)
呼吸器、胸郭および縦隔障害	4 (6.8)
No Reasonable Possibility	4 (6.8)
喘息	1 (1.7)
No Reasonable Possibility	1 (1.7)
鼻出血	1 (1.7)
No Reasonable Possibility	1 (1.7)
アレルギー性鼻炎	2 (3.4)
No Reasonable Possibility	2 (3.4)
鼻漏	1 (1.7)
No Reasonable Possibility	1 (1.7)
皮膚および皮下組織障害	5 (8.5)
No Reasonable Possibility	2 (3.4)
Reasonable Possibility	3 (5.1)

表 2.7.4.7-17.　すべての有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（統合 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	Adalimumab (N=59) n (%)
皮膚および皮下組織障害 (Cont.)	
皮膚炎	1 (1.7)
No Reasonable Possibility	1 (1.7)
乾癬様皮膚炎	1 (1.7)
Reasonable Possibility	1 (1.7)
乾癬	1 (1.7)
Reasonable Possibility	1 (1.7)
発疹	1 (1.7)
No Reasonable Possibility	1 (1.7)
皮膚障害	1 (1.7)
Reasonable Possibility	1 (1.7)
蕁麻疹	1 (1.7)
No Reasonable Possibility	1 (1.7)
血管障害	1 (1.7)
No Reasonable Possibility	1 (1.7)
高血圧	1 (1.7)
No Reasonable Possibility	1 (1.7)

表 2.7.4.7-17.　　すべての有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（統合 FAS 集団，M10-870 試験）（続き）

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Cross reference: M10-870 Japan Sub-study CSR_Interim Table 14.3__1.3.1_A

表 2.7.4.7-18. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）（統合安全性解析対象集団，M11-290 試験）

MedDRA 22.0 System Organ Class Preferred Term Severity	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
Any adverse event	19 (59.4)	27 (52.9)	13 (76.5)	59 (59.0)
Mild	12 (37.5)	19 (37.3)	11 (64.7)	42 (42.0)
Moderate	3 (9.4)	7 (13.7)	2 (11.8)	12 (12.0)
Severe	4 (12.5)	1 (2.0)	0	5 (5.0)
血液およびリンパ系障害	3 (9.4)	3 (5.9)	1 (5.9)	7 (7.0)
Mild	1 (3.1)	1 (2.0)	1 (5.9)	3 (3.0)
Moderate	1 (3.1)	2 (3.9)	0	3 (3.0)
Severe	1 (3.1)	0	0	1 (1.0)
貧血	3 (9.4)	3 (5.9)	1 (5.9)	7 (7.0)
Mild	1 (3.1)	1 (2.0)	1 (5.9)	3 (3.0)
Moderate	1 (3.1)	2 (3.9)	0	3 (3.0)
Severe	1 (3.1)	0	0	1 (1.0)
血小板増加症	0	0	1 (5.9)	1 (1.0)
Mild	0	0	1 (5.9)	1 (1.0)
心臓障害	1 (3.1)	0	0	1 (1.0)
Severe	1 (3.1)	0	0	1 (1.0)

表 2.7.4.7-18. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）（統合安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
心臓障害 (Cont.)				
心膜炎	1 (3.1)	0	0	1 (1.0)
Severe	1 (3.1)	0	0	1 (1.0)
内分泌障害	1 (3.1)	0	0	1 (1.0)
Mild	1 (3.1)	0	0	1 (1.0)
甲状腺腫	1 (3.1)	0	0	1 (1.0)
Mild	1 (3.1)	0	0	1 (1.0)
眼障害	1 (3.1)	1 (2.0)	0	2 (2.0)
Mild	1 (3.1)	1 (2.0)	0	2 (2.0)
眼瞼炎	0	1 (2.0)	0	1 (1.0)
Mild	0	1 (2.0)	0	1 (1.0)

表 2.7.4.7-18. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）（統合安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
眼障害 (Cont.)				
角膜炎	1 (3.1)	0	0	1 (1.0)
Mild	1 (3.1)	0	0	1 (1.0)
胃腸障害	6 (18.8)	9 (17.6)	5 (29.4)	20 (20.0)
Mild	2 (6.3)	4 (7.8)	4 (23.5)	10 (10.0)
Moderate	2 (6.3)	4 (7.8)	1 (5.9)	7 (7.0)
Severe	2 (6.3)	1 (2.0)	0	3 (3.0)
腹痛	0	2 (3.9)	2 (11.8)	4 (4.0)
Mild	0	2 (3.9)	2 (11.8)	4 (4.0)
上腹部痛	1 (3.1)	2 (3.9)	0	3 (3.0)
Mild	1 (3.1)	1 (2.0)	0	2 (2.0)
Moderate	0	1 (2.0)	0	1 (1.0)
潰瘍性大腸炎	4 (12.5)	2 (3.9)	1 (5.9)	7 (7.0)
Mild	0	0	1 (5.9)	1 (1.0)
Moderate	2 (6.3)	1 (2.0)	0	3 (3.0)
Severe	2 (6.3)	1 (2.0)	0	3 (3.0)

表 2.7.4.7-18. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）（統合安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
胃腸障害 (Cont.)				
便秘	0	0	1 (5.9)	1 (1.0)
Mild	0	0	1 (5.9)	1 (1.0)
下痢	0	0	1 (5.9)	1 (1.0)
Mild	0	0	1 (5.9)	1 (1.0)
血性下痢	1 (3.1)	0	0	1 (1.0)
Mild	1 (3.1)	0	0	1 (1.0)
小腸炎	1 (3.1)	0	0	1 (1.0)
Mild	1 (3.1)	0	0	1 (1.0)
鼓腸	1 (3.1)	0	0	1 (1.0)
Mild	1 (3.1)	0	0	1 (1.0)

表 2.7.4.7-18. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）（統合安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
胃腸障害 (Cont.)				
排便回数増加	0	1 (2.0)	0	1 (1.0)
Moderate	0	1 (2.0)	0	1 (1.0)
胃食道逆流性疾患	0	1 (2.0)	1 (5.9)	2 (2.0)
Mild	0	1 (2.0)	1 (5.9)	2 (2.0)
血便排泄	0	2 (3.9)	0	2 (2.0)
Mild	0	1 (2.0)	0	1 (1.0)
Moderate	0	1 (2.0)	0	1 (1.0)
悪心	0	3 (5.9)	1 (5.9)	4 (4.0)
Mild	0	3 (5.9)	1 (5.9)	4 (4.0)
膵炎	0	1 (2.0)	0	1 (1.0)
Moderate	0	1 (2.0)	0	1 (1.0)

表 2.7.4.7-18. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）（統合安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
胃腸障害 (Cont.)				
嘔吐	0	1 (2.0)	1 (5.9)	2 (2.0)
Mild	0	1 (2.0)	0	1 (1.0)
Moderate	0	0	1 (5.9)	1 (1.0)
一般・全身障害および投与部位の状態	5 (15.6)	7 (13.7)	0	12 (12.0)
Mild	3 (9.4)	6 (11.8)	0	9 (9.0)
Moderate	2 (6.3)	1 (2.0)	0	3 (3.0)
腋窩痛	0	1 (2.0)	0	1 (1.0)
Mild	0	1 (2.0)	0	1 (1.0)
胸痛	0	1 (2.0)	0	1 (1.0)
Mild	0	1 (2.0)	0	1 (1.0)
疲労	0	1 (2.0)	0	1 (1.0)
Mild	0	1 (2.0)	0	1 (1.0)

表 2.7.4.7-18. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）（統合安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
一般・全身障害および投与部位の状態 (Cont.)				
異常感	1 (3.1)	0	0	1 (1.0)
Mild	1 (3.1)	0	0	1 (1.0)
注射部位紅斑	0	1 (2.0)	0	1 (1.0)
Mild	0	1 (2.0)	0	1 (1.0)
注射部位疼痛	1 (3.1)	1 (2.0)	0	2 (2.0)
Moderate	1 (3.1)	1 (2.0)	0	2 (2.0)
注射部位蕁麻疹	0	1 (2.0)	0	1 (1.0)
Mild	0	1 (2.0)	0	1 (1.0)
末梢腫脹	1 (3.1)	0	0	1 (1.0)
Mild	1 (3.1)	0	0	1 (1.0)

表 2.7.4.7-18. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）（統合安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
一般・全身障害および投与部位の状態 (Cont.)				
発熱	2 (6.3)	1 (2.0)	0	3 (3.0)
Mild	1 (3.1)	1 (2.0)	0	2 (2.0)
Moderate	1 (3.1)	0	0	1 (1.0)
肝胆道系障害	1 (3.1)	0	0	1 (1.0)
Mild	1 (3.1)	0	0	1 (1.0)
高ビリルビン血症	1 (3.1)	0	0	1 (1.0)
Mild	1 (3.1)	0	0	1 (1.0)
感染症および寄生虫症	6 (18.8)	11 (21.6)	6 (35.3)	23 (23.0)
Mild	5 (15.6)	11 (21.6)	5 (29.4)	21 (21.0)
Moderate	0	0	1 (5.9)	1 (1.0)
Severe	1 (3.1)	0	0	1 (1.0)
気管支炎	0	0	1 (5.9)	1 (1.0)
Moderate	0	0	1 (5.9)	1 (1.0)

表 2.7.4.7-18. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）（統合安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
感染症および寄生虫症 (Cont.)				
せつ	0	1 (2.0)	0	1 (1.0)
Mild	0	1 (2.0)	0	1 (1.0)
サルモネラ菌性胃腸炎	1 (3.1)	0	0	1 (1.0)
Severe	1 (3.1)	0	0	1 (1.0)
上咽頭炎	2 (6.3)	2 (3.9)	1 (5.9)	5 (5.0)
Mild	2 (6.3)	2 (3.9)	1 (5.9)	5 (5.0)
口腔ヘルペス	1 (3.1)	2 (3.9)	0	3 (3.0)
Mild	1 (3.1)	2 (3.9)	0	3 (3.0)
外耳炎	0	1 (2.0)	0	1 (1.0)
Mild	0	1 (2.0)	0	1 (1.0)

表 2.7.4.7-18. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）（統合安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
感染症および寄生虫症 (Cont.)				
咽頭炎	2 (6.3)	1 (2.0)	1 (5.9)	4 (4.0)
Mild	2 (6.3)	1 (2.0)	1 (5.9)	4 (4.0)
レンサ球菌感染	0	0	1 (5.9)	1 (1.0)
Mild	0	0	1 (5.9)	1 (1.0)
上気道感染	0	3 (5.9)	0	3 (3.0)
Mild	0	3 (5.9)	0	3 (3.0)
尿路感染	1 (3.1)	0	0	1 (1.0)
Mild	1 (3.1)	0	0	1 (1.0)
水痘	0	1 (2.0)	0	1 (1.0)
Mild	0	1 (2.0)	0	1 (1.0)

表 2.7.4.7-18. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）（統合安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
感染症および寄生虫症 (Cont.)				
ウイルス感染	0	0	1 (5.9)	1 (1.0)
Mild	0	0	1 (5.9)	1 (1.0)
ウイルス性上気道感染	0	1 (2.0)	0	1 (1.0)
Mild	0	1 (2.0)	0	1 (1.0)
外陰腟真菌感染	0	0	1 (5.9)	1 (1.0)
Mild	0	0	1 (5.9)	1 (1.0)
傷害、中毒および処置合併症	4 (12.5)	2 (3.9)	0	6 (6.0)
Mild	4 (12.5)	1 (2.0)	0	5 (5.0)
Moderate	0	1 (2.0)	0	1 (1.0)
節足動物咬傷	1 (3.1)	0	0	1 (1.0)
Mild	1 (3.1)	0	0	1 (1.0)

表 2.7.4.7-18. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）（統合安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
傷害、中毒および処置合併症 (Cont.)				
転倒	1 (3.1)	0	0	1 (1.0)
Mild	1 (3.1)	0	0	1 (1.0)
注入に伴う反応	1 (3.1)	0	0	1 (1.0)
Mild	1 (3.1)	0	0	1 (1.0)
靭帯捻挫	1 (3.1)	0	0	1 (1.0)
Mild	1 (3.1)	0	0	1 (1.0)
処置による疼痛	0	1 (2.0)	0	1 (1.0)
Mild	0	1 (2.0)	0	1 (1.0)
手首関節骨折	0	1 (2.0)	0	1 (1.0)
Moderate	0	1 (2.0)	0	1 (1.0)

表 2.7.4.7-18. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）（統合安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
臨床検査	2 (6.3)	2 (3.9)	2 (11.8)	6 (6.0)
Mild	2 (6.3)	1 (2.0)	2 (11.8)	5 (5.0)
Moderate	0	1 (2.0)	0	1 (1.0)
血圧上昇	0	1 (2.0)	0	1 (1.0)
Mild	0	1 (2.0)	0	1 (1.0)
C一反応性蛋白増加	0	1 (2.0)	0	1 (1.0)
Moderate	0	1 (2.0)	0	1 (1.0)
ヘモグロビン減少	1 (3.1)	0	0	1 (1.0)
Mild	1 (3.1)	0	0	1 (1.0)
肝酵素上昇	0	0	1 (5.9)	1 (1.0)
Mild	0	0	1 (5.9)	1 (1.0)

表 2.7.4.7-18. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）（統合安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
臨床検査 (Cont.)				
単球数減少	0	0	1 (5.9)	1 (1.0)
Mild	0	0	1 (5.9)	1 (1.0)
好中球数減少	0	0	1 (5.9)	1 (1.0)
Mild	0	0	1 (5.9)	1 (1.0)
体重減少	1 (3.1)	1 (2.0)	0	2 (2.0)
Mild	1 (3.1)	0	0	1 (1.0)
Moderate	0	1 (2.0)	0	1 (1.0)
白血球数減少	0	0	1 (5.9)	1 (1.0)
Mild	0	0	1 (5.9)	1 (1.0)
筋骨格系および結合組織障害	2 (6.3)	2 (3.9)	1 (5.9)	5 (5.0)
Mild	2 (6.3)	2 (3.9)	1 (5.9)	5 (5.0)

表 2.7.4.7-18. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）（統合安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
筋骨格系および結合組織障害 (Cont.)				
関節痛	1 (3.1)	0	1 (5.9)	2 (2.0)
Mild	1 (3.1)	0	1 (5.9)	2 (2.0)
背部痛	0	1 (2.0)	0	1 (1.0)
Mild	0	1 (2.0)	0	1 (1.0)
靱帯障害	0	1 (2.0)	0	1 (1.0)
Mild	0	1 (2.0)	0	1 (1.0)
四肢痛	1 (3.1)	0	0	1 (1.0)
Mild	1 (3.1)	0	0	1 (1.0)
神経系障害	6 (18.8)	5 (9.8)	4 (23.5)	15 (15.0)
Mild	5 (15.6)	5 (9.8)	4 (23.5)	14 (14.0)
Moderate	1 (3.1)	0	0	1 (1.0)

表 2.7.4.7-18. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）（統合安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
神経系障害 (Cont.)				
頭痛	5 (15.6)	5 (9.8)	4 (23.5)	14 (14.0)
Mild	5 (15.6)	5 (9.8)	4 (23.5)	14 (14.0)
意識消失	1 (3.1)	0	0	1 (1.0)
Mild	1 (3.1)	0	0	1 (1.0)
片頭痛	1 (3.1)	0	0	1 (1.0)
Moderate	1 (3.1)	0	0	1 (1.0)
錯感覚	1 (3.1)	0	0	1 (1.0)
Moderate	1 (3.1)	0	0	1 (1.0)
振戦	0	1 (2.0)	1 (5.9)	2 (2.0)
Mild	0	1 (2.0)	1 (5.9)	2 (2.0)

表 2.7.4.7-18. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）（統合安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
腎および尿路障害	0	0	1 (5.9)	1 (1.0)
Mild	0	0	1 (5.9)	1 (1.0)
糖尿	0	0	1 (5.9)	1 (1.0)
Mild	0	0	1 (5.9)	1 (1.0)
生殖系および乳房障害	0	1 (2.0)	0	1 (1.0)
Mild	0	1 (2.0)	0	1 (1.0)
乳房痛	0	1 (2.0)	0	1 (1.0)
Mild	0	1 (2.0)	0	1 (1.0)
呼吸器、胸郭および縦隔障害	1 (3.1)	3 (5.9)	3 (17.6)	7 (7.0)
Mild	1 (3.1)	3 (5.9)	3 (17.6)	7 (7.0)

表 2.7.4.7-18. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）（統合安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)				
咳嗽	0	1 (2.0)	0	1 (1.0)
Mild	0	1 (2.0)	0	1 (1.0)
鼻閉	0	1 (2.0)	0	1 (1.0)
Mild	0	1 (2.0)	0	1 (1.0)
口腔咽頭痛	1 (3.1)	1 (2.0)	2 (11.8)	4 (4.0)
Mild	1 (3.1)	1 (2.0)	2 (11.8)	4 (4.0)
鼻漏	0	1 (2.0)	1 (5.9)	2 (2.0)
Mild	0	1 (2.0)	1 (5.9)	2 (2.0)
皮膚および皮下組織障害	1 (3.1)	0	1 (5.9)	2 (2.0)
Mild	0	0	1 (5.9)	1 (1.0)
Moderate	1 (3.1)	0	0	1 (1.0)

表 2.7.4.7-18. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）（統合安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
皮膚および皮下組織障害 (Cont.)				
結節性紅斑	1 (3.1)	0	0	1 (1.0)
Moderate	1 (3.1)	0	0	1 (1.0)
発疹	0	0	1 (5.9)	1 (1.0)
Mild	0	0	1 (5.9)	1 (1.0)

One patient ([redacted] who is ongoing study is excluded from interim analysis.
I-SD = induction standard dose group; I-HD = induction high dose group; I-HD-OL = induction high dose open-label group;
Note: Table depicts the most servere adverse event for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
If a subject has an AE with unknown severity, then the subject will be counted in the severity category of "unknown,"even if the subject has another occurrence of the same event with a severity present. The only exception is if the subject has another occurrence of the same AE with the most extreme severity - "Severe." In this case, the subject will be counted under the "Severe" category.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.3__1.3.2.1_A

表 2.7.4.7-19.　導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）（日本人安全性解析対象集団，M11-290 試験）

MedDRA 22.0 System Organ Class Preferred Term Severity	I-SD (N=2) n (%)	I-HD (N=4) n (%)	I-HD-OL (N=1) n (%)	Total (N=7) n (%)
Any adverse event	2 (100)	4 (100)	1 (100)	7 (100)
Mild	1 (50.0)	4 (100)	1 (100)	6 (85.7)
Moderate	1 (50.0)	0	0	1 (14.3)
眼障害	0	1 (25.0)	0	1 (14.3)
Mild	0	1 (25.0)	0	1 (14.3)
眼瞼炎	0	1 (25.0)	0	1 (14.3)
Mild	0	1 (25.0)	0	1 (14.3)
一般・全身障害および投与部位の状態	2 (100)	1 (25.0)	0	3 (42.9)
Mild	1 (50.0)	1 (25.0)	0	2 (28.6)
Moderate	1 (50.0)	0	0	1 (14.3)
異常感	1 (50.0)	0	0	1 (14.3)
Mild	1 (50.0)	0	0	1 (14.3)
注射部位紅斑	0	1 (25.0)	0	1 (14.3)
Mild	0	1 (25.0)	0	1 (14.3)
注射部位疼痛	1 (50.0)	0	0	1 (14.3)
Moderate	1 (50.0)	0	0	1 (14.3)

表 2.7.4.7-19. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）（日本人安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	I-SD (N=2) n (%)	I-HD (N=4) n (%)	I-HD-OL (N=1) n (%)	Total (N=7) n (%)
感染症および寄生虫症	0	3 (75.0)	0	3 (42.9)
Mild	0	3 (75.0)	0	3 (42.9)
外耳炎	0	1 (25.0)	0	1 (14.3)
Mild	0	1 (25.0)	0	1 (14.3)
上気道感染	0	2 (50.0)	0	2 (28.6)
Mild	0	2 (50.0)	0	2 (28.6)
臨床検査	0	0	1 (100)	1 (14.3)
Mild	0	0	1 (100)	1 (14.3)
単球数減少	0	0	1 (100)	1 (14.3)
Mild	0	0	1 (100)	1 (14.3)
好中球数減少	0	0	1 (100)	1 (14.3)
Mild	0	0	1 (100)	1 (14.3)
白血球数減少	0	0	1 (100)	1 (14.3)
Mild	0	0	1 (100)	1 (14.3)

表 2.7.4.7-19. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）（日本人安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	I-SD (N=2) n (%)	I-HD (N=4) n (%)	I-HD-OL (N=1) n (%)	Total (N=7) n (%)
神経系障害	1 (50.0)	0	0	1 (14.3)
Mild	1 (50.0)	0	0	1 (14.3)
頭痛	1 (50.0)	0	0	1 (14.3)
Mild	1 (50.0)	0	0	1 (14.3)

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
I-SD = induction standard dose group; I-HD = induction high dose group; I-HD-OL = induction high dose open-label group;
Note: Table depicts the most servere adverse event for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
If a subject has an AE with unknown severity, then the subject will be counted in the severity category of "unknown,"even if the subject has another occurrence of the same event with a severity present. The only exception is if the subject has another occurrence of the same AE with the most extreme severity - "Severe." In this case, the subject will be counted under the "Severe" category.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.3__1.3.2.1_J

表 2.7.4.7-20. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
Any adverse event	21 (63.6)	25 (71.4)	46 (67.6)	10 (83.3)	56 (70.0)
Mild	7 (21.2)	17 (48.6)	24 (35.3)	8 (66.7)	32 (40.0)
Moderate	11 (33.3)	7 (20.0)	18 (26.5)	2 (16.7)	20 (25.0)
Severe	3 (9.1)	1 (2.9)	4 (5.9)	0	4 (5.0)
血液およびリンパ系障害	4 (12.1)	1 (2.9)	5 (7.4)	2 (16.7)	7 (8.8)
Mild	1 (3.0)	1 (2.9)	2 (2.9)	1 (8.3)	3 (3.8)
Moderate	2 (6.1)	0	2 (2.9)	1 (8.3)	3 (3.8)
Severe	1 (3.0)	0	1 (1.5)	0	1 (1.3)
貧血	3 (9.1)	1 (2.9)	4 (5.9)	1 (8.3)	5 (6.3)
Mild	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Moderate	2 (6.1)	0	2 (2.9)	1 (8.3)	3 (3.8)
Severe	1 (3.0)	0	1 (1.5)	0	1 (1.3)
リンパ節症	1 (3.0)	0	1 (1.5)	0	1 (1.3)
Mild	1 (3.0)	0	1 (1.5)	0	1 (1.3)
好中球減少症	0	0	0	1 (8.3)	1 (1.3)
Mild	0	0	0	1 (8.3)	1 (1.3)

表 2.7.4.7-20. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
耳および迷路障害	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Mild	0	1 (2.9)	1 (1.5)	0	1 (1.3)
耳痛	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Mild	0	1 (2.9)	1 (1.5)	0	1 (1.3)
眼障害	0	0	0	1 (8.3)	1 (1.3)
Mild	0	0	0	1 (8.3)	1 (1.3)
非感染性結膜炎	0	0	0	1 (8.3)	1 (1.3)
Mild	0	0	0	1 (8.3)	1 (1.3)
胃腸障害	9 (27.3)	10 (28.6)	19 (27.9)	3 (25.0)	22 (27.5)
Mild	3 (9.1)	6 (17.1)	9 (13.2)	2 (16.7)	11 (13.8)
Moderate	3 (9.1)	4 (11.4)	7 (10.3)	1 (8.3)	8 (10.0)
Severe	3 (9.1)	0	3 (4.4)	0	3 (3.8)

表 2.7.4.7-20. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
胃腸障害 (Cont.)					
腹痛	1 (3.0)	1 (2.9)	2 (2.9)	1 (8.3)	3 (3.8)
Mild	1 (3.0)	1 (2.9)	2 (2.9)	1 (8.3)	3 (3.8)
上腹部痛	0	2 (5.7)	2 (2.9)	0	2 (2.5)
Mild	0	2 (5.7)	2 (2.9)	0	2 (2.5)
アフタ性潰瘍	1 (3.0)	0	1 (1.5)	0	1 (1.3)
Mild	1 (3.0)	0	1 (1.5)	0	1 (1.3)
潰瘍性大腸炎	6 (18.2)	4 (11.4)	10 (14.7)	2 (16.7)	12 (15.0)
Mild	1 (3.0)	0	1 (1.5)	1 (8.3)	2 (2.5)
Moderate	2 (6.1)	4 (11.4)	6 (8.8)	1 (8.3)	7 (8.8)
Severe	3 (9.1)	0	3 (4.4)	0	3 (3.8)
便秘	1 (3.0)	0	1 (1.5)	0	1 (1.3)
Mild	1 (3.0)	0	1 (1.5)	0	1 (1.3)

表 2.7.4.7-20. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
胃腸障害 (Cont.)					
下痢	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Mild	0	1 (2.9)	1 (1.5)	0	1 (1.3)
消化不良	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Mild	0	1 (2.9)	1 (1.5)	0	1 (1.3)
小腸炎	2 (6.1)	1 (2.9)	3 (4.4)	0	3 (3.8)
Mild	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Moderate	2 (6.1)	0	2 (2.9)	0	2 (2.5)
胃食道逆流性疾患	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Mild	0	1 (2.9)	1 (1.5)	0	1 (1.3)
一般・全身障害および投与部位の状態	5 (15.2)	3 (8.6)	8 (11.8)	1 (8.3)	9 (11.3)
Mild	3 (9.1)	2 (5.7)	5 (7.4)	1 (8.3)	6 (7.5)
Moderate	2 (6.1)	1 (2.9)	3 (4.4)	0	3 (3.8)

表 2.7.4.7-20. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
一般・全身障害および投与部位の状態 (Cont.)					
胸痛	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Mild	0	1 (2.9)	1 (1.5)	0	1 (1.3)
疲労	2 (6.1)	0	2 (2.9)	0	2 (2.5)
Mild	2 (6.1)	0	2 (2.9)	0	2 (2.5)
炎症	0	0	0	1 (8.3)	1 (1.3)
Mild	0	0	0	1 (8.3)	1 (1.3)
注射部位紅斑	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Mild	0	1 (2.9)	1 (1.5)	0	1 (1.3)
注射部位炎症	1 (3.0)	0	1 (1.5)	0	1 (1.3)
Moderate	1 (3.0)	0	1 (1.5)	0	1 (1.3)

表 2.7.4.7-20. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
一般・全身障害および投与部位の状態 (Cont.)					
注射部位浮腫	1 (3.0)	0	1 (1.5)	0	1 (1.3)
Mild	1 (3.0)	0	1 (1.5)	0	1 (1.3)
注射部位疼痛	1 (3.0)	0	1 (1.5)	0	1 (1.3)
Mild	1 (3.0)	0	1 (1.5)	0	1 (1.3)
注射部位そう痒感	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Mild	0	1 (2.9)	1 (1.5)	0	1 (1.3)
注射部位腫脹	1 (3.0)	0	1 (1.5)	0	1 (1.3)
Mild	1 (3.0)	0	1 (1.5)	0	1 (1.3)
注射部位蕁麻疹	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Mild	0	1 (2.9)	1 (1.5)	0	1 (1.3)

表 2.7.4.7-20. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
一般・全身障害および投与部位の状態 (Cont.)					
倦怠感	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Moderate	0	1 (2.9)	1 (1.5)	0	1 (1.3)
発熱	1 (3.0)	0	1 (1.5)	0	1 (1.3)
Moderate	1 (3.0)	0	1 (1.5)	0	1 (1.3)
免疫系障害	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Mild	0	1 (2.9)	1 (1.5)	0	1 (1.3)
薬物過敏症	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Mild	0	1 (2.9)	1 (1.5)	0	1 (1.3)
感染症および寄生虫症	11 (33.3)	16 (45.7)	27 (39.7)	5 (41.7)	32 (40.0)
Mild	5 (15.2)	13 (37.1)	18 (26.5)	5 (41.7)	23 (28.8)
Moderate	6 (18.2)	2 (5.7)	8 (11.8)	0	8 (10.0)
Severe	0	1 (2.9)	1 (1.5)	0	1 (1.3)

表 2.7.4.7-20. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
感染症および寄生虫症 (Cont.)					
気管支炎	1 (3.0)	0	1 (1.5)	0	1 (1.3)
Moderate	1 (3.0)	0	1 (1.5)	0	1 (1.3)
感染性腸炎	1 (3.0)	0	1 (1.5)	0	1 (1.3)
Mild	1 (3.0)	0	1 (1.5)	0	1 (1.3)
胃腸炎	2 (6.1)	0	2 (2.9)	1 (8.3)	3 (3.8)
Mild	0	0	0	1 (8.3)	1 (1.3)
Moderate	2 (6.1)	0	2 (2.9)	0	2 (2.5)
膿痂疹	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Mild	0	1 (2.9)	1 (1.5)	0	1 (1.3)
感染性嚢腫	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Mild	0	1 (2.9)	1 (1.5)	0	1 (1.3)

表 2.7.4.7-20. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
感染症および寄生虫症 (Cont.)					
インフルエンザ	0	2 (5.7)	2 (2.9)	0	2 (2.5)
Mild	0	2 (5.7)	2 (2.9)	0	2 (2.5)
喉頭炎	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Mild	0	1 (2.9)	1 (1.5)	0	1 (1.3)
無菌性髄膜炎	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Severe	0	1 (2.9)	1 (1.5)	0	1 (1.3)
上咽頭炎	3 (9.1)	4 (11.4)	7 (10.3)	1 (8.3)	8 (10.0)
Mild	1 (3.0)	4 (11.4)	5 (7.4)	1 (8.3)	6 (7.5)
Moderate	2 (6.1)	0	2 (2.9)	0	2 (2.5)
口腔ヘルペス	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Mild	0	1 (2.9)	1 (1.5)	0	1 (1.3)

表 2.7.4.7-20. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
感染症および寄生虫症 (Cont.)					
中耳炎	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Mild	0	1 (2.9)	1 (1.5)	0	1 (1.3)
咽頭炎	2 (6.1)	2 (5.7)	4 (5.9)	1 (8.3)	5 (6.3)
Mild	2 (6.1)	1 (2.9)	3 (4.4)	1 (8.3)	4 (5.0)
Moderate	0	1 (2.9)	1 (1.5)	0	1 (1.3)
気道感染	1 (3.0)	0	1 (1.5)	0	1 (1.3)
Moderate	1 (3.0)	0	1 (1.5)	0	1 (1.3)
ウイルス性気道感染	0	0	0	1 (8.3)	1 (1.3)
Mild	0	0	0	1 (8.3)	1 (1.3)
鼻炎	1 (3.0)	0	1 (1.5)	0	1 (1.3)
Mild	1 (3.0)	0	1 (1.5)	0	1 (1.3)

表 2.7.4.7-20. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
感染症および寄生虫症 (Cont.)					
癜風	1 (3.0)	0	1 (1.5)	0	1 (1.3)
Mild	1 (3.0)	0	1 (1.5)	0	1 (1.3)
歯膿瘍	0	0	0	1 (8.3)	1 (1.3)
Mild	0	0	0	1 (8.3)	1 (1.3)
気管炎	1 (3.0)	0	1 (1.5)	0	1 (1.3)
Moderate	1 (3.0)	0	1 (1.5)	0	1 (1.3)
上気道感染	2 (6.1)	4 (11.4)	6 (8.8)	2 (16.7)	8 (10.0)
Mild	2 (6.1)	4 (11.4)	6 (8.8)	2 (16.7)	8 (10.0)
尿路感染	1 (3.0)	2 (5.7)	3 (4.4)	0	3 (3.8)
Mild	1 (3.0)	1 (2.9)	2 (2.9)	0	2 (2.5)
Moderate	0	1 (2.9)	1 (1.5)	0	1 (1.3)

表 2.7.4.7-20. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
感染症および寄生虫症 (Cont.)					
水痘	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Mild	0	1 (2.9)	1 (1.5)	0	1 (1.3)
傷害、中毒および処置合併症	0	3 (8.6)	3 (4.4)	1 (8.3)	4 (5.0)
Mild	0	3 (8.6)	3 (4.4)	1 (8.3)	4 (5.0)
眼瞼挫傷	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Mild	0	1 (2.9)	1 (1.5)	0	1 (1.3)
手骨折	0	2 (5.7)	2 (2.9)	0	2 (2.5)
Mild	0	2 (5.7)	2 (2.9)	0	2 (2.5)
関節損傷	0	0	0	1 (8.3)	1 (1.3)
Mild	0	0	0	1 (8.3)	1 (1.3)

表 2.7.4.7-20. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
傷害、中毒および処置合併症 (Cont.)					
靭帯捻挫	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Mild	0	1 (2.9)	1 (1.5)	0	1 (1.3)
臨床検査	5 (15.2)	3 (8.6)	8 (11.8)	0	8 (10.0)
Mild	3 (9.1)	3 (8.6)	6 (8.8)	0	6 (7.5)
Moderate	2 (6.1)	0	2 (2.9)	0	2 (2.5)
血中ビリルビン増加	1 (3.0)	1 (2.9)	2 (2.9)	0	2 (2.5)
Mild	1 (3.0)	1 (2.9)	2 (2.9)	0	2 (2.5)
血中カルシウム減少	1 (3.0)	0	1 (1.5)	0	1 (1.3)
Mild	1 (3.0)	0	1 (1.5)	0	1 (1.3)
血中ナトリウム減少	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Mild	0	1 (2.9)	1 (1.5)	0	1 (1.3)

表 2.7.4.7-20. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
臨床検査 (Cont.)					
骨密度減少	1 (3.0)	0	1 (1.5)	0	1 (1.3)
Mild	1 (3.0)	0	1 (1.5)	0	1 (1.3)
C一反応性蛋白増加	3 (9.1)	0	3 (4.4)	0	3 (3.8)
Mild	2 (6.1)	0	2 (2.9)	0	2 (2.5)
Moderate	1 (3.0)	0	1 (1.5)	0	1 (1.3)
好酸球数増加	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Mild	0	1 (2.9)	1 (1.5)	0	1 (1.3)
リンパ節触知	1 (3.0)	0	1 (1.5)	0	1 (1.3)
Mild	1 (3.0)	0	1 (1.5)	0	1 (1.3)
結核菌群検査陽性	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Mild	0	1 (2.9)	1 (1.5)	0	1 (1.3)

表 2.7.4.7-20. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
臨床検査 (Cont.)					
好中球数減少	1 (3.0)	0	1 (1.5)	0	1 (1.3)
Mild	1 (3.0)	0	1 (1.5)	0	1 (1.3)
白血球数減少	1 (3.0)	0	1 (1.5)	0	1 (1.3)
Moderate	1 (3.0)	0	1 (1.5)	0	1 (1.3)
筋骨格系および結合組織障害	1 (3.0)	2 (5.7)	3 (4.4)	1 (8.3)	4 (5.0)
Mild	1 (3.0)	1 (2.9)	2 (2.9)	1 (8.3)	3 (3.8)
Moderate	0	1 (2.9)	1 (1.5)	0	1 (1.3)
関節痛	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Moderate	0	1 (2.9)	1 (1.5)	0	1 (1.3)
背部痛	1 (3.0)	1 (2.9)	2 (2.9)	0	2 (2.5)
Mild	1 (3.0)	1 (2.9)	2 (2.9)	0	2 (2.5)

表 2.7.4.7-20. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
筋骨格系および結合組織障害 (Cont.)					
筋骨格痛	0	0	0	1 (8.3)	1 (1.3)
Mild	0	0	0	1 (8.3)	1 (1.3)
神経系障害	6 (18.2)	3 (8.6)	9 (13.2)	2 (16.7)	11 (13.8)
Mild	4 (12.1)	2 (5.7)	6 (8.8)	2 (16.7)	8 (10.0)
Moderate	2 (6.1)	1 (2.9)	3 (4.4)	0	3 (3.8)
頭痛	6 (18.2)	2 (5.7)	8 (11.8)	2 (16.7)	10 (12.5)
Mild	4 (12.1)	2 (5.7)	6 (8.8)	2 (16.7)	8 (10.0)
Moderate	2 (6.1)	0	2 (2.9)	0	2 (2.5)
感覚鈍麻	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Moderate	0	1 (2.9)	1 (1.5)	0	1 (1.3)
錯感覚	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Moderate	0	1 (2.9)	1 (1.5)	0	1 (1.3)

表 2.7.4.7-20. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
精神障害	1 (3.0)	1 (2.9)	2 (2.9)	0	2 (2.5)
Mild	1 (3.0)	0	1 (1.5)	0	1 (1.3)
Moderate	0	1 (2.9)	1 (1.5)	0	1 (1.3)
うつ病	1 (3.0)	1 (2.9)	2 (2.9)	0	2 (2.5)
Mild	1 (3.0)	0	1 (1.5)	0	1 (1.3)
Moderate	0	1 (2.9)	1 (1.5)	0	1 (1.3)
生殖系および乳房障害	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Mild	0	1 (2.9)	1 (1.5)	0	1 (1.3)
月経困難症	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Mild	0	1 (2.9)	1 (1.5)	0	1 (1.3)
呼吸器、胸郭および縦隔障害	4 (12.1)	5 (14.3)	9 (13.2)	3 (25.0)	12 (15.0)
Mild	4 (12.1)	5 (14.3)	9 (13.2)	3 (25.0)	12 (15.0)

表 2.7.4.7-20. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)					
喘息	1 (3.0)	0	1 (1.5)	0	1 (1.3)
Mild	1 (3.0)	0	1 (1.5)	0	1 (1.3)
咳嗽	0	2 (5.7)	2 (2.9)	0	2 (2.5)
Mild	0	2 (5.7)	2 (2.9)	0	2 (2.5)
鼻出血	0	0	0	2 (16.7)	2 (2.5)
Mild	0	0	0	2 (16.7)	2 (2.5)
鼻浮腫	1 (3.0)	0	1 (1.5)	0	1 (1.3)
Mild	1 (3.0)	0	1 (1.5)	0	1 (1.3)
口腔咽頭痛	2 (6.1)	1 (2.9)	3 (4.4)	0	3 (3.8)
Mild	2 (6.1)	1 (2.9)	3 (4.4)	0	3 (3.8)

表 2.7.4.7-20. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)					
アレルギー性鼻炎	0	2 (5.7)	2 (2.9)	0	2 (2.5)
Mild	0	2 (5.7)	2 (2.9)	0	2 (2.5)
鼻漏	1 (3.0)	0	1 (1.5)	0	1 (1.3)
Mild	1 (3.0)	0	1 (1.5)	0	1 (1.3)
喘鳴	0	0	0	1 (8.3)	1 (1.3)
Mild	0	0	0	1 (8.3)	1 (1.3)
皮膚および皮下組織障害	1 (3.0)	7 (20.0)	8 (11.8)	3 (25.0)	11 (13.8)
Mild	1 (3.0)	6 (17.1)	7 (10.3)	3 (25.0)	10 (12.5)
Moderate	0	1 (2.9)	1 (1.5)	0	1 (1.3)
脱毛症	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Mild	0	1 (2.9)	1 (1.5)	0	1 (1.3)

表 2.7.4.7-20. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
皮膚および皮下組織障害 (Cont.)					
皮膚炎	0	1 (2.9)	1 (1.5)	1 (8.3)	2 (2.5)
Mild	0	1 (2.9)	1 (1.5)	1 (8.3)	2 (2.5)
紅斑	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Mild	0	1 (2.9)	1 (1.5)	0	1 (1.3)
結節性紅斑	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Moderate	0	1 (2.9)	1 (1.5)	0	1 (1.3)
逆むけ	0	0	0	1 (8.3)	1 (1.3)
Mild	0	0	0	1 (8.3)	1 (1.3)
乾癬	0	0	0	1 (8.3)	1 (1.3)
Mild	0	0	0	1 (8.3)	1 (1.3)

表 2.7.4.7-20. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
皮膚および皮下組織障害 (Cont.)					
紫斑	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Mild	0	1 (2.9)	1 (1.5)	0	1 (1.3)
発疹	1 (3.0)	2 (5.7)	3 (4.4)	0	3 (3.8)
Mild	1 (3.0)	2 (5.7)	3 (4.4)	0	3 (3.8)
痂皮	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Mild	0	1 (2.9)	1 (1.5)	0	1 (1.3)
脂漏	1 (3.0)	0	1 (1.5)	0	1 (1.3)
Mild	1 (3.0)	0	1 (1.5)	0	1 (1.3)
皮膚病変	0	1 (2.9)	1 (1.5)	0	1 (1.3)
Mild	0	1 (2.9)	1 (1.5)	0	1 (1.3)

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
M-PL = maintenance placebo group; M-SD = maintenance standard dose group; M-HD = maintenance high dose group;
Note: Table depicts the most servere adverse event for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
If a subject has an AE with unknown severity, then the subject will be counted in the severity category of "unknown,"even if the subject has another occurrence of the same event with a severity present. The only exception is if the subject has another occurrence of the same AE with the most extreme severity - "Severe." In this case, the subject will be counted under the "Severe" category.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.3__1.3.2.2_A

表 2.7.4.7-21. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた日本人安全性解析対象集団の被験者，M11-290 試験）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=2) n (%)	M-HD (N=3) n (%)	Total-ADA (N=5) n (%)	M-PL (N=0) n (%)	Total (N=5) n (%)
Any adverse event	1 (50.0)	3 (100)	4 (80.0)	0	4 (80.0)
Mild	1 (50.0)	3 (100)	4 (80.0)	0	4 (80.0)
感染症および寄生虫症	1 (50.0)	3 (100)	4 (80.0)	0	4 (80.0)
Mild	1 (50.0)	3 (100)	4 (80.0)	0	4 (80.0)
感染性腸炎	1 (50.0)	0	1 (20.0)	0	1 (20.0)
Mild	1 (50.0)	0	1 (20.0)	0	1 (20.0)
膿痂疹	0	1 (33.3)	1 (20.0)	0	1 (20.0)
Mild	0	1 (33.3)	1 (20.0)	0	1 (20.0)
インフルエンザ	0	1 (33.3)	1 (20.0)	0	1 (20.0)
Mild	0	1 (33.3)	1 (20.0)	0	1 (20.0)
上気道感染	0	1 (33.3)	1 (20.0)	0	1 (20.0)
Mild	0	1 (33.3)	1 (20.0)	0	1 (20.0)
傷害、中毒および処置合併症	0	2 (66.7)	2 (40.0)	0	2 (40.0)
Mild	0	2 (66.7)	2 (40.0)	0	2 (40.0)

表 2.7.4.7-21. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた日本人安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=2) n (%)	M-HD (N=3) n (%)	Total-ADA (N=5) n (%)	M-PL (N=0) n (%)	Total (N=5) n (%)
傷害、中毒および処置合併症 (Cont.)					
眼瞼挫傷	0	1 (33.3)	1 (20.0)	0	1 (20.0)
Mild	0	1 (33.3)	1 (20.0)	0	1 (20.0)
手骨折	0	1 (33.3)	1 (20.0)	0	1 (20.0)
Mild	0	1 (33.3)	1 (20.0)	0	1 (20.0)
靭帯捻挫	0	1 (33.3)	1 (20.0)	0	1 (20.0)
Mild	0	1 (33.3)	1 (20.0)	0	1 (20.0)
皮膚および皮下組織障害	0	1 (33.3)	1 (20.0)	0	1 (20.0)
Mild	0	1 (33.3)	1 (20.0)	0	1 (20.0)
紫斑	0	1 (33.3)	1 (20.0)	0	1 (20.0)
Mild	0	1 (33.3)	1 (20.0)	0	1 (20.0)

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
M-PL = maintenance placebo group; M-SD = maintenance standard dose group; M-HD = maintenance high dose group;
Note: Table depicts the most servere adverse event for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
If a subject has an AE with unknown severity, then the subject will be counted in the severity category of "unknown,"even if the subject has another occurrence of the same event with a severity present. The only exception is if the subject has another occurrence of the same AE with the most extreme severity - "Severe." In this case, the subject will be counted under the "Severe" category.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.3__1.3.2.2_J

表 2.7.4.7-22.　すべての有害事象（MedDRA SOC 及び PT 別，重症度別）（統合 FAS 集団，M10-870 試験）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab (N=59) n (%)
Any adverse event	40 (67.8)
Mild	23 (39.0)
Moderate	14 (23.7)
Severe	3 (5.1)
血液およびリンパ系障害	6 (10.2)
Mild	1 (1.7)
Moderate	4 (6.8)
Severe	1 (1.7)
貧血	4 (6.8)
Moderate	3 (5.1)
Severe	1 (1.7)
失血性貧血	1 (1.7)
Moderate	1 (1.7)
鉄欠乏性貧血	1 (1.7)
Moderate	1 (1.7)
リンパ節炎	1 (1.7)
Mild	1 (1.7)
眼障害	1 (1.7)
Mild	1 (1.7)

表 2.7.4.7-22. すべての有害事象（MedDRA SOC 及び PT 別，重症度別）（統合 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab (N=59) n (%)
眼障害 (Cont.)	
近視	1 (1.7)
Mild	1 (1.7)
胃腸障害	23 (39.0)
Mild	14 (23.7)
Moderate	6 (10.2)
Severe	3 (5.1)
腹部不快感	1 (1.7)
Mild	1 (1.7)
腹痛	1 (1.7)
Mild	1 (1.7)
上腹部痛	2 (3.4)
Mild	1 (1.7)
Moderate	1 (1.7)
口唇症	1 (1.7)
Mild	1 (1.7)
潰瘍性大腸炎	12 (20.3)
Mild	5 (8.5)
Moderate	4 (6.8)
Severe	3 (5.1)

表 2.7.4.7-22. すべての有害事象（MedDRA SOC 及び PT 別，重症度別）（統合 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab (N=59) n (%)
胃腸障害 (Cont.)	
便秘	1 (1.7)
Mild	1 (1.7)
下痢	1 (1.7)
Mild	1 (1.7)
消化不良	2 (3.4)
Mild	2 (3.4)
腸炎	1 (1.7)
Mild	1 (1.7)
胃炎	3 (5.1)
Mild	3 (5.1)
血便排泄	2 (3.4)
Moderate	2 (3.4)
大腸ポリープ	1 (1.7)
Moderate	1 (1.7)

表 2.7.4.7-22. すべての有害事象（MedDRA SOC 及び PT 別，重症度別）（統合 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab (N=59) n (%)
胃腸障害 (Cont.)	
悪心	2 (3.4)
Mild	2 (3.4)
直腸出血	1 (1.7)
Moderate	1 (1.7)
口内炎	1 (1.7)
Mild	1 (1.7)
嘔吐	1 (1.7)
Mild	1 (1.7)
一般・全身障害および投与部位の状態	4 (6.8)
Mild	4 (6.8)
倦怠感	1 (1.7)
Mild	1 (1.7)
末梢性浮腫	1 (1.7)
Mild	1 (1.7)

表 2.7.4.7-22.　すべての有害事象（MedDRA SOC 及び PT 別，重症度別）（統合 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab (N=59) n (%)
一般・全身障害および投与部位の状態 (Cont.)	
発熱	2 (3.4)
Mild	2 (3.4)
肝胆道系障害	1 (1.7)
Moderate	1 (1.7)
胆嚢炎	1 (1.7)
Moderate	1 (1.7)
免疫系障害	1 (1.7)
Mild	1 (1.7)
季節性アレルギー	1 (1.7)
Mild	1 (1.7)
感染症および寄生虫症	24 (40.7)
Mild	20 (33.9)
Moderate	4 (6.8)
肛門膿瘍	1 (1.7)
Mild	1 (1.7)

表 2.7.4.7-22. すべての有害事象（MedDRA SOC 及び PT 別，重症度別）（統合 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab (N=59) n (%)
感染症および寄生虫症 (Cont.)	
気管支炎	3 (5.1)
Mild	2 (3.4)
Moderate	1 (1.7)
ウイルス性胃腸炎	2 (3.4)
Mild	2 (3.4)
帯状疱疹	2 (3.4)
Mild	2 (3.4)
膿痂疹	1 (1.7)
Mild	1 (1.7)
上咽頭炎	5 (8.5)
Mild	4 (6.8)
Moderate	1 (1.7)
口腔ヘルペス	1 (1.7)
Mild	1 (1.7)
中耳炎	1 (1.7)
Mild	1 (1.7)

表 2.7.4.7-22. すべての有害事象（MedDRA SOC 及び PT 別，重症度別）（統合 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab (N=59) n (%)
感染症および寄生虫症 (Cont.)	
咽頭炎	4 (6.8)
Mild	4 (6.8)
敗血症	1 (1.7)
Moderate	1 (1.7)
副鼻腔炎	1 (1.7)
Mild	1 (1.7)
レンサ球菌感染	1 (1.7)
Mild	1 (1.7)
歯膿瘍	1 (1.7)
Moderate	1 (1.7)
上気道感染	7 (11.9)
Mild	7 (11.9)
尿路感染	2 (3.4)
Mild	2 (3.4)

表 2.7.4.7-22.　すべての有害事象（MedDRA SOC 及び PT 別，重症度別）（統合 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab (N=59) n (%)
感染症および寄生虫症 (Cont.)	
ウイルス感染	2 (3.4)
Mild	2 (3.4)
ウイルス性上気道感染	2 (3.4)
Mild	2 (3.4)
外陰膣炎	1 (1.7)
Mild	1 (1.7)
傷害、中毒および処置合併症	5 (8.5)
Mild	2 (3.4)
Moderate	3 (5.1)
足関節部骨折	1 (1.7)
Mild	1 (1.7)
手骨折	1 (1.7)
Moderate	1 (1.7)
四肢損傷	1 (1.7)
Mild	1 (1.7)

表 2.7.4.7-22.　すべての有害事象（MedDRA SOC 及び PT 別，重症度別）（統合 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab (N=59) n (%)
傷害、中毒および処置合併症 (Cont.)	
上肢骨折	1 (1.7)
Moderate	1 (1.7)
手首関節骨折	1 (1.7)
Moderate	1 (1.7)
臨床検査	6 (10.2)
Mild	5 (8.5)
Moderate	1 (1.7)
血中アルカリホスファターゼ増加	1 (1.7)
Moderate	1 (1.7)
体温上昇	1 (1.7)
Mild	1 (1.7)
結核菌群検査陽性	4 (6.8)
Mild	4 (6.8)
代謝および栄養障害	1 (1.7)
Mild	1 (1.7)

表 2.7.4.7-22. すべての有害事象（MedDRA SOC 及び PT 別，重症度別）（統合 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab (N=59) n (%)
代謝および栄養障害 (Cont.)	
食欲減退	1 (1.7)
Mild	1 (1.7)
筋骨格系および結合組織障害	7 (11.9)
Mild	5 (8.5)
Moderate	2 (3.4)
関節痛	4 (6.8)
Mild	4 (6.8)
背部痛	1 (1.7)
Moderate	1 (1.7)
成長不全	1 (1.7)
Moderate	1 (1.7)
若年性特発性関節炎	1 (1.7)
Mild	1 (1.7)
脊椎痛	1 (1.7)
Mild	1 (1.7)

表 2.7.4.7-22.　すべての有害事象（MedDRA SOC 及び PT 別，重症度別）（統合 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab (N=59) n (%)
神経系障害	6 (10.2)
Mild	6 (10.2)
頭痛	5 (8.5)
Mild	5 (8.5)
傾眠	1 (1.7)
Mild	1 (1.7)
精神障害	2 (3.4)
Mild	1 (1.7)
Moderate	1 (1.7)
うつ病	2 (3.4)
Mild	1 (1.7)
Moderate	1 (1.7)
腎および尿路障害	3 (5.1)
Mild	3 (5.1)
血尿	1 (1.7)
Mild	1 (1.7)

表 2.7.4.7-22.　すべての有害事象（MedDRA SOC 及び PT 別，重症度別）（統合 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab (N=59) n (%)
腎および尿路障害 (Cont.)	
腎結石症	1 (1.7)
Mild	1 (1.7)
腎仙痛	1 (1.7)
Mild	1 (1.7)
生殖系および乳房障害	3 (5.1)
Mild	2 (3.4)
Moderate	1 (1.7)
月経困難症	1 (1.7)
Mild	1 (1.7)
卵巣嚢胞	2 (3.4)
Mild	1 (1.7)
Moderate	1 (1.7)
呼吸器、胸郭および縦隔障害	4 (6.8)
Mild	4 (6.8)
喘息	1 (1.7)
Mild	1 (1.7)

表 2.7.4.7-22. すべての有害事象（MedDRA SOC 及び PT 別，重症度別）（統合 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab (N=59) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)	
鼻出血	1 (1.7)
Mild	1 (1.7)
アレルギー性鼻炎	2 (3.4)
Mild	2 (3.4)
鼻漏	1 (1.7)
Mild	1 (1.7)
皮膚および皮下組織障害	5 (8.5)
Mild	5 (8.5)
皮膚炎	1 (1.7)
Mild	1 (1.7)
乾癬様皮膚炎	1 (1.7)
Mild	1 (1.7)
乾癬	1 (1.7)
Mild	1 (1.7)

表 2.7.4.7-22.　すべての有害事象（MedDRA SOC 及び PT 別，重症度別）（統合 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab (N=59) n (%)
皮膚および皮下組織障害 (Cont.)	
発疹	1 (1.7)
Mild	1 (1.7)
皮膚障害	1 (1.7)
Mild	1 (1.7)
蕁麻疹	1 (1.7)
Mild	1 (1.7)
血管障害	1 (1.7)
Mild	1 (1.7)
高血圧	1 (1.7)
Mild	1 (1.7)

Note: Table depicts the most servere adverse event for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.

Cross reference: M10-870 Japan Sub-study CSR_Interim Table 14.3__1.3.2_A

表 2.7.4.7-23.　導入療法期中に発現した重篤な有害事象（MedDRA SOC 及び PT 別）（統合安全性解析対象集団，M11-290 試験）

MedDRA 22.0 System Organ Class Preferred Term	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
Any adverse event	5 (15.6)	4 (7.8)	1 (5.9)	10 (10.0)
血液およびリンパ系障害	2 (6.3)	0	0	2 (2.0)
貧血	2 (6.3)	0	0	2 (2.0)
心臓障害	1 (3.1)	0	0	1 (1.0)
心膜炎	1 (3.1)	0	0	1 (1.0)
胃腸障害	2 (6.3)	3 (5.9)	1 (5.9)	6 (6.0)
潰瘍性大腸炎	2 (6.3)	2 (3.9)	1 (5.9)	5 (5.0)
膵炎	0	1 (2.0)	0	1 (1.0)
傷害、中毒および処置合併症	0	1 (2.0)	0	1 (1.0)
手首関節骨折	0	1 (2.0)	0	1 (1.0)
神経系障害	1 (3.1)	0	0	1 (1.0)
頭痛	1 (3.1)	0	0	1 (1.0)
意識消失	1 (3.1)	0	0	1 (1.0)

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
I-SD = induction standard dose group; I-HD = induction high dose group; I-HD-OL = induction high dose open-label group;
Note: 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__2.1.1.1.1_A

表 2.7.4.7-24. 導入療法期中に発現した重篤な有害事象の 100 人年あたりの発現頻度（MedDRA SOC 及び PT 別）
（統合安全性解析対象集団，M11-290 試験）

MedDRA 22.0 System Organ Class Preferred Term	I-SD (N=32) (PYS=4.6) Events (E/100PY)	I-HD (N=51) (PYS=7.7) Events (E/100PY)	I-HD-OL (N=17) (PYS=2.5) Events (E/100PY)	Total (N=100) (PYS=14.9) Events (E/100PY)
Any adverse event	7 (152.2)	4 (51.9)	1 (40.0)	12 (80.5)
血液およびリンパ系障害	2 (43.5)	0	0	2 (13.4)
貧血	2 (43.5)	0	0	2 (13.4)
心臓障害	1 (21.7)	0	0	1 (6.7)
心膜炎	1 (21.7)	0	0	1 (6.7)
胃腸障害	2 (43.5)	3 (39.0)	1 (40.0)	6 (40.3)
潰瘍性大腸炎	2 (43.5)	2 (26.0)	1 (40.0)	5 (33.6)
膵炎	0	1 (13.0)	0	1 (6.7)
傷害、中毒および処置合併症	0	1 (13.0)	0	1 (6.7)
手首関節骨折	0	1 (13.0)	0	1 (6.7)
神経系障害	2 (43.5)	0	0	2 (13.4)
頭痛	1 (21.7)	0	0	1 (6.7)
意識消失	1 (21.7)	0	0	1 (6.7)

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
I-SD = induction standard dose group; I-HD = induction high dose group; I-HD-OL = induction high dose open-label group;
Note: E/100PY = Events per 100 patient-years.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.3__2.1.1.2.1_A

表 2.7.4.7-25.　導入療法期中に発現した治験薬と関連ありの重篤な有害事象（MedDRA SOC 及び PT 別）（統合安全性解析対象集団，M11-290 試験）

MedDRA 22.0 System Organ Class Preferred Term	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
Any adverse event	2 (6.3)	1 (2.0)	1 (5.9)	4 (4.0)
心臓障害	1 (3.1)	0	0	1 (1.0)
心膜炎	1 (3.1)	0	0	1 (1.0)
胃腸障害	0	1 (2.0)	1 (5.9)	2 (2.0)
潰瘍性大腸炎	0	0	1 (5.9)	1 (1.0)
膵炎	0	1 (2.0)	0	1 (1.0)
神経系障害	1 (3.1)	0	0	1 (1.0)
頭痛	1 (3.1)	0	0	1 (1.0)
意識消失	1 (3.1)	0	0	1 (1.0)

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
I-SD = induction standard dose group; I-HD = induction high dose group; I-HD-OL = induction high dose open-label group;
AEs with unknown relationship were counted as 'reasonable possibility of being related'.
Note: 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__2.1.2.1.1_A

表 2.7.4.7-26. 維持療法期中に発現した重篤な有害事象（MedDRA SOC 及び PT 別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）

MedDRA 22.0 System Organ Class Preferred Term	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
Any adverse event	5 (15.2)	5 (14.3)	10 (14.7)	1 (8.3)	11 (13.8)
血液およびリンパ系障害	1 (3.0)	0	1 (1.5)	0	1 (1.3)
貧血	1 (3.0)	0	1 (1.5)	0	1 (1.3)
胃腸障害	3 (9.1)	1 (2.9)	4 (5.9)	0	4 (5.0)
潰瘍性大腸炎	3 (9.1)	0	3 (4.4)	0	3 (3.8)
消化不良	0	1 (2.9)	1 (1.5)	0	1 (1.3)
小腸炎	1 (3.0)	0	1 (1.5)	0	1 (1.3)
感染症および寄生虫症	3 (9.1)	3 (8.6)	6 (8.8)	0	6 (7.5)
感染性腸炎	1 (3.0)	0	1 (1.5)	0	1 (1.3)
胃腸炎	2 (6.1)	0	2 (2.9)	0	2 (2.5)
無菌性髄膜炎	0	1 (2.9)	1 (1.5)	0	1 (1.3)
咽頭炎	0	1 (2.9)	1 (1.5)	0	1 (1.3)
尿路感染	0	1 (2.9)	1 (1.5)	0	1 (1.3)
傷害、中毒および処置合併症	0	1 (2.9)	1 (1.5)	0	1 (1.3)
手骨折	0	1 (2.9)	1 (1.5)	0	1 (1.3)
皮膚および皮下組織障害	0	1 (2.9)	1 (1.5)	1 (8.3)	2 (2.5)
結節性紅斑	0	1 (2.9)	1 (1.5)	0	1 (1.3)
乾癬	0	0	0	1 (8.3)	1 (1.3)

表 2.7.4.7-26.　維持療法期中に発現した重篤な有害事象（MedDRA SOC 及び PT 別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

One patient ([redacted] who is ongoing study is excluded from interim analysis.
M-PL = maintenance placebo group; M-SD = maintenance standard dose group; M-HD = maintenance high dose group;
Note: 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__2.1.1.1.2_A

表 2.7.4.7-27. 維持療法期中に発現した重篤な有害事象の 100 人年あたりの発現頻度（MedDRA SOC 及び PT 別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）

MedDRA 22.0 System Organ Class Preferred Term	M-SD (N=33) (PYS=20.5) Events (E/100PY)	M-HD (N=35) (PYS=23.2) Events (E/100PY)	Total-ADA (N=68) (PYS=43.7) Events (E/100PY)	M-PL (N=12) (PYS=6.1) Events (E/100PY)	Total (N=80) (PYS=49.8) Events (E/100PY)
Any adverse event	10 (48.8)	6 (25.9)	16 (36.6)	1 (16.4)	17 (34.1)
血液およびリンパ系障害	2 (9.8)	0	2 (4.6)	0	2 (4.0)
貧血	2 (9.8)	0	2 (4.6)	0	2 (4.0)
胃腸障害	5 (24.4)	1 (4.3)	6 (13.7)	0	6 (12.0)
潰瘍性大腸炎	4 (19.5)	0	4 (9.2)	0	4 (8.0)
消化不良	0	1 (4.3)	1 (2.3)	0	1 (2.0)
小腸炎	1 (4.9)	0	1 (2.3)	0	1 (2.0)
感染症および寄生虫症	3 (14.6)	3 (12.9)	6 (13.7)	0	6 (12.0)
感染性腸炎	1 (4.9)	0	1 (2.3)	0	1 (2.0)
胃腸炎	2 (9.8)	0	2 (4.6)	0	2 (4.0)
無菌性髄膜炎	0	1 (4.3)	1 (2.3)	0	1 (2.0)
咽頭炎	0	1 (4.3)	1 (2.3)	0	1 (2.0)
尿路感染	0	1 (4.3)	1 (2.3)	0	1 (2.0)
傷害、中毒および処置合併症	0	1 (4.3)	1 (2.3)	0	1 (2.0)
手骨折	0	1 (4.3)	1 (2.3)	0	1 (2.0)
皮膚および皮下組織障害	0	1 (4.3)	1 (2.3)	1 (16.4)	2 (4.0)
結節性紅斑	0	1 (4.3)	1 (2.3)	0	1 (2.0)
乾癬	0	0	0	1 (16.4)	1 (2.0)

表 2.7.4.7-27.　維持療法期中に発現した重篤な有害事象の 100 人年あたりの発現頻度（MedDRA SOC 及び PT 別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
M-PL = maintenance placebo group; M-SD = maintenance standard dose group; M-HD = maintenance high dose group;
Note: E/100PY = Events per 100 patient-years.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.3__2.1.1.2.2_A

表 2.7.4.7-28.　維持療法期中に発現した治験薬と関連ありの重篤な有害事象（MedDRA SOC 及び PT 別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）

MedDRA 22.0 System Organ Class Preferred Term	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
Any adverse event	0	1 (2.9)	1 (1.5)	1 (8.3)	2 (2.5)
感染症および寄生虫症	0	1 (2.9)	1 (1.5)	0	1 (1.3)
無菌性髄膜炎	0	1 (2.9)	1 (1.5)	0	1 (1.3)
皮膚および皮下組織障害	0	0	0	1 (8.3)	1 (1.3)
乾癬	0	0	0	1 (8.3)	1 (1.3)

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
M-PL = maintenance placebo group; M-SD = maintenance standard dose group; M-HD = maintenance high dose group;
AEs with unknown relationship were counted as 'reasonable possibility of being related'.
Note: 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__2.1.2.1.2_A

表 2.7.4.7-29.　重篤な有害事象の一覧（統合安全性解析対象集団，M11-290 試験）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD-MHD								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:47.2 KG								
[redacted]	MNT	57 TO 358	259	315	R: FRACTURE OF THE PROXIMAL PHALANX OF THE 5TH FINGER OF THE LEFT PALMA WITH THE TRANSLOCATION S: Injury, poisoning and procedural complications P: 手骨折 L: Fractured finger	E: 346 L: 32 DAYS I: YES	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION DISCONTINUED, REMOVING OF THE KIRSCHNER WIRE)	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: TRAUMA WITH FOOTBALL BALL A: NO REASONABLE POSSIBILITY ADJ: All cause hospitalization

表 2.7.4.7-29. 重篤な有害事象の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD-MHD-FREIND								
[redacted]	AGE:[redacted] SEX:MALE RACE:WHITE WEIGHT:22.9 KG							
	FLARE	85 TO 358	1	85	R: FLARE OF ULCERATIVE COLITIS S: Gastrointestinal disorders P: 潰瘍性大腸炎 L: Colitis ulcerative aggravated	E: 110 L: 26 DAYS I: YES	S: MODERATE R: NO REASONABLE POSSIBILITY A: RE- INDUCTION DOSE O: NONE	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ULCERATIVE COLITIS EXACERBATION A: NO REASONABLE POSSIBILITY ADJ: All cause hospitalization, UC related hospitalization

表 2.7.4.7-29. 重篤な有害事象の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MPL							
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:47.5 KG							
[redacted]	MNT	57 TO 365	72	128	R: PSORIASIS S: Skin and subcutaneous tissue disorders P: 乾癬 L: Psoriasis	E: 147 L: 20 DAYS	S: MILD R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: REASONABLE POSSIBILITY ADJ: All cause hospitalization

表 2.7.4.7-29. 重篤な有害事象の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MHD								
[redacted]	AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:91.2 KG							
	FU	359 TO	6	364	R: FUNCTIONAL DYSPEPSIA S: Gastrointestinal disorders P: 消化不良 L: Functional dyspepsia	O: YES I: YES	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: UPPER ENDOSCOPY PERFORMED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FUNCTIONAL DYSPEPSIA PROBABLY AFTER DIETETICAL MISTAKE A: NO REASONABLE POSSIBILITY ADJ: All cause hospitalization

表 2.7.4.7-29. 重篤な有害事象の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD								
[redacted]	AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:56.0 KG							
	FU	16 TO	3	18	R: WORSENING OF ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia aggravated	E: 91 L: 74 DAYS	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION PRESCRIBED, BLOOD TRANSFUSION)	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INTESTINAL BLEEDING A: NO REASONABLE POSSIBILITY ADJ: All cause hospitalization, UC related hospitalization

表 2.7.4.7-29. 重篤な有害事象の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] TRT: ISD								
[redacted]	AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:56.0 KG							
	FU	16 TO	6	21	R: PERICARDITIS S: Cardiac disorders P: 心膜炎 L: Pericarditis	E: 29 L: 9 DAYS	S: SEVERE R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION A: REASONABLE POSSIBILITY ADJ: All cause hospitalization, UC related hospitalization

表 2.7.4.7-29. 重篤な有害事象の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted]([redacted]) TRT: IHD-MHD								
[redacted]	AGE:[redacted] SEX:MALE RACE:WHITE WEIGHT:15.0 KG							
	IND	1 TO 55	10	10	R: WRIST FRACTURE LEFT S: Injury, poisoning and procedural complications P: 手首関節骨折 L: Wrist fracture	E: 29 L: 20 DAYS	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION PRESCRIBED, PLASTER DRESSING)	M: NO S: YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION, PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY O: MECHANICAL INJURY A: NO REASONABLE POSSIBILITY

表 2.7.4.7-29. 重篤な有害事象の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted]([redacted]) TRT: IHDOL-MHD								
[redacted]	AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:31.1 KG							
[redacted]	MNT	57 TO 267	9	65	R: ERYTHREMA NODOSUM S: Skin and subcutaneous tissue disorders P: 結節性紅斑 L: Erythema nodosum	E: 79 L: 15 DAYS	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ERYTHEMA NODOSUM MIGHT HAVE OCCURRED DUE TO URINARY TRACT INFECTION IN PERSON WITH CU A: NO REASONABLE POSSIBILITY ADJ: All cause hospitalization

表 2.7.4.7-29. 重篤な有害事象の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted]([redacted]) TRT: IHDOL-MHD								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:31.1 KG								
	MNT	57 TO 267	9	65	R: URINAL TRACT INFECTION S: Infections and infestations P: 尿路感染 L: Urinary tract infection	E: 72 L: 8 DAYS	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: THAT WAS URINARY TRACT INFECTION, THERE WAS NO CAUSE FOUND. A: REASONABLE POSSIBILITY ADJ: All cause hospitalization

表 2.7.4.7-29. 重篤な有害事象の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted]([redacted]) TRT: IHD								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:52.9 KG								
	IND	1 TO 42	38	38	R: WORSENING ULCERATIVE COLITIS S: Gastrointestinal disorders P: 潰瘍性大腸炎 L: Colitis ulcerative aggravated	E: 274 L: 237 DAYS	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION PRESCRIBED, CONCOMITANT MEDICATION DISCONTINUED, COLOPROTECTOMY TOTAL)	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: STUDY DISEASE RELATED A: NO REASONABLE POSSIBILITY ADJ: All cause hospitalization, Colectomy, UC related hospitalization

表 2.7.4.7-29. 重篤な有害事象の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD-MSD							
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:62.8 KG							
[redacted]	MNT	56 TO 119	68	R: ACUTE GASTROENTERITIS S: Infections and infestations P: 胃腸炎 L: Acute gastroenteritis	E: 72 L: 5 DAYS	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: HOSPITALIZATION	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ACQUIRED VIRAL OR BACTERIAL INFECTION, REACTIVATION OF UC A: REASONABLE POSSIBILITY ADJ: All cause hospitalization

表 2.7.4.7-29. 重篤な有害事象の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MSD								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:43.8 KG								
	MNT	57 TO 128	29	85	R: ACUTE ENTERITIS S: Gastrointestinal disorders P: 小腸炎 L: Acute enteritis	E: 97 L: 13 DAYS I: YES	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: COULD BE RANDOM VIRAL INFECTION CAUSE ACUTE ENTERITIS; COULD BE REACTIVATION OF CMV COLITIS BECAUSE PATIENT IS UNDER IMMUNOSUPPRESSIVE DRUGS; A: NO REASONABLE POSSIBILITY ADJ: All cause hospitalization

表 2.7.4.7-29. 重篤な有害事象の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MSD								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:43.8 KG								
	MNT	57 TO 128	29	85	R: ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia	E: 87 L: 3 DAYS I: YES	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: IS DUE TO ACUTE ENTERITIS, CONCICTENCY OF STOOL WORSENED AND NOW STOOL IS WITH BLOOD ALSO A: NO REASONABLE POSSIBILITY ADJ: All cause hospitalization

表 2.7.4.7-29. 重篤な有害事象の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MSD								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:43.8 KG								
	MNT	57 TO 128	56	112	R: ACUTE GASTROENTERITIS S: Infections and infestations P: 胃腸炎 L: Acute gastroenteritis	E: 120 L: 9 DAYS	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: ACUTE GASTROENTERITIS DUE TO VIRAL OR BACTERIAL INFECTION OR RELAPS OF UC A: NO REASONABLE POSSIBILITY ADJ: All cause hospitalization

表 2.7.4.7-29. 重篤な有害事象の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	------ Epoch ---- Name	Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MSD								
[redacted]	AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:43.8 KG							
	MNT	57 TO 128	72	128	R: SEVERE ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia	E: 147 L: 20 DAYS	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FLARE OF UC A: NO REASONABLE POSSIBILITY ADJ: All cause hospitalization, UC related hospitalization

表 2.7.4.7-29. 重篤な有害事象の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted]([redacted]) TRT: IHD-MSD								
[redacted]	AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:43.8 KG							
	MNT	57 TO 128	72	128	R: UC FLARE S: Gastrointestinal disorders P: 潰瘍性大腸炎 L: Colitis ulcerative aggravated	E: 147 L: 20 DAYS	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CAN BE IN RELATIONSHIP TO ABSENCE OF STUDY DRUG A: NO REASONABLE POSSIBILITY ADJ: All cause hospitalization, UC related hospitalization

表 2.7.4.7-29. 重篤な有害事象の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD							
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:55.0 KG							
	FU	41 TO	17 57	R: ULCERATIVE COLITIS FLARE S: Gastrointestinal disorders P: 潰瘍性大腸炎 L: Colitis ulcerative aggravated	E: 81 L: 25 DAYS	S: SEVERE R: NO REASONABLE POSSIBILITY A: THE PATIENT WAS WITTHDRAWAL FROM STUDY AT WEEK [redacted] - [redacted] [redacted] 20[redacted] O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UC FLARE A: NO REASONABLE POSSIBILITY ADJ: All cause hospitalization, UC related hospitalization

表 2.7.4.7-29. 重篤な有害事象の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD								
[redacted]	AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:58.0 KG							
	IND	1 TO 43	29	29	R: ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia	E: 36 L: 8 DAYS	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION PRESCRIBED, BLOOD TRANSFUSION)	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING DISEASE A: NO REASONABLE POSSIBILITY ADJ: All cause hospitalization
[redacted]	AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:43.0 KG							
	FU	43 TO	10	52	R: HEADACHES, LOSS OF CONSCIOUSNESS S: Nervous system disorders P: 頭痛 L: Headache	E: 68 L: 17 DAYS	S: MILD R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: REASONABLE POSSIBILITY ADJ: All cause hospitalization

表 2.7.4.7-29. 重篤な有害事象の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:43.0 KG								
	FU	43 TO	10	52	R: HEADACHES, LOSS OF CONSCIOUSNESS S: Nervous system disorders P: 意識消失 L: Loss of consciousness	E: 68 L: 17 DAYS	S: MILD R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: REASONABLE POSSIBILITY ADJ: All cause hospitalization

表 2.7.4.7-29. 重篤な有害事象の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD								
[redacted]AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:48.0 KG								
	FU	43 TO	5	47	R: UC FLARE S: Gastrointestinal disorders P: 潰瘍性大腸炎 L: Colitis ulcerative aggravated	E: 56 L: 10 DAYS	S: MODERATE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UC FLARE A: NO REASONABLE POSSIBILITY ADJ: All cause hospitalization, UC related hospitalization

表 2.7.4.7-29. 重篤な有害事象の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHDOL								
[redacted]	AGE:1[redacted]	SEX:FEMALE	RACE:MULTIPLE	WEIGHT:40.8 KG				
	FU	30 TO	7	36	R: WORSENING UC SYMPTOMS S: Gastrointestinal disorders P: 潰瘍性大腸炎 L: Colitis ulcerative aggravated	E: 62 L: 27 DAYS	S: MILD R: REASONABLE POSSIBILITY A: PARTICIPANT WAS WITHDRAWN FROM STUDY ON [redacted]/[redacted]/20[redacted]. O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY ADJ: All cause hospitalization, UC related hospitalization

表 2.7.4.7-29. 重篤な有害事象の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	----- Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] TRT: IHD								
[redacted]	AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:104.2 KG							
	FU	44 TO	22	65	R: PANCREATITIS S: Gastrointestinal disorders P: 膵炎 L: Pancreatitis	E: 79 L: 15 DAYS	S: MODERATE R: REASONABLE POSSIBILITY A: SUBJECT ALREADY DISCONTINUED STUDY DRUG DUE TO BEING A NON RESPONDER AT WEEK 8 O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY ADJ: All cause hospitalization, UC related hospitalization

表 2.7.4.7-29. 重篤な有害事象の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	----- Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted]([redacted]) TRT: IHDOL-MSD-FREIND								
[redacted]	AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:52.8 KG							
	FLARE	127 TO 219	77	203	R: WORSENING ULCERATIVE COLITIS S: Gastrointestinal disorders P: 潰瘍性大腸炎 L: Colitis ulcerative aggravated	O: YES	S: SEVERE R: NO REASONABLE POSSIBILITY A: IV STEROIDS O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CYTOMEGALOVIRUS A: NO REASONABLE POSSIBILITY ADJ: All cause hospitalization, UC related hospitalization

表 2.7.4.7-29. 重篤な有害事象の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MHD								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:43.0 KG								
	MNT	57 TO 365	134	190	R: PHARYNGITIS ACUTA S: Infections and infestations P: 咽頭炎 L: Acute pharyngitis	E: 195 L: 6 DAYS I: YES	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UC A: REASONABLE POSSIBILITY ADJ: All cause hospitalization

表 2.7.4.7-29. 重篤な有害事象の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MSD-FNREIND								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:33.9 KG								
	MNT	60 TO 273	176	235	R: UC FLARE S: Gastrointestinal disorders P: 潰瘍性大腸炎 L: Colitis ulcerative aggravated	E: 243 L: 9 DAYS I: YES	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: COLITIS ULCEROSA FLARE A: NO REASONABLE POSSIBILITY ADJ: All cause hospitalization, UC related hospitalization

表 2.7.4.7-29. 重篤な有害事象の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MSD-FNREIND								
[redacted]	AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:33.9 KG							
	MNT	60 TO 273	210	269	R: UC FLARE S: Gastrointestinal disorders P: 潰瘍性大腸炎 L: Colitis ulcerative aggravated	E: 277 L: 9 DAYS	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UC A: NO REASONABLE POSSIBILITY ADJ: All cause hospitalization, UC related hospitalization

表 2.7.4.7-29. 重篤な有害事象の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD-MHD								
[redacted]	AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:48.1 KG							
	IND	1 TO 59	52	52	R: UC FLARE S: Gastrointestinal disorders P: 潰瘍性大腸炎 L: Colitis ulcerative aggravated	E: 64 L: 13 DAYS I: YES	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION PRESCRIBED, PATIENT UNDERWENT SIGMOIDESCOPY)	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: DISEASE FLARE A: NO REASONABLE POSSIBILITY ADJ: All cause hospitalization, UC related hospitalization

表 2.7.4.7-29. 重篤な有害事象の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD-MSD								
[redacted] AGE:1[redacted] SEX:MALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:56.3 KG								
	FU	121 TO	11	131	R: ULCERATIVE COLITIS FLARE S: Gastrointestinal disorders P: 潰瘍性大腸炎 L: Colitis ulcerative aggravated	E: 138 L: 8 DAYS	S: SEVERE R: NO REASONABLE POSSIBILITY A: STUDY DRUG PREVIOUSLY STOPPED DUE TO WITHDRAWAL OF CONSENT. O: MULTIPLE (CONCOMITANT MEDICATION PRESCRIBED, ON [redacted] SUBJECT'S MOTHER WAS CALLED TO PICK HIM UP AT SCHOOL DUE TO SEVERE ABDOMINAL PAIN. HE WAS BROUGHT INTO CLINIC OF [redacted] WITH SAME COMPLAINT AND WAS ADMITTED TO THE HOSPITAL.)	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: WORSENING ULCERATIVE COLITIS A: NO REASONABLE POSSIBILITY ADJ: All cause hospitalization, UC related hospitalization

表 2.7.4.7-29. 重篤な有害事象の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MSD-FREIND							
[redacted] AGE:1[redacted] SEX:MALE RACE:ASIAN WEIGHT:51.6 KG							
	MNT	57 TO 119	32 88	R: ENTERITIS INFECTIOUS S: Infections and infestations P: 感染性腸炎 L: Enteritis infectious	E: 90 L: 3 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ACCIDENTAL EVENT A: REASONABLE POSSIBILITY ADJ: All cause hospitalization

表 2.7.4.7-29. 重篤な有害事象の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MHD								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:62.0 KG								
[redacted]	MNT	57 TO 364	5	61	R: ASEPTIC MENINGITIS S: Infections and infestations P: 無菌性髄膜炎 L: Aseptic meningitis	E: 67 L: 7 DAYS	S: SEVERE R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: REASONABLE POSSIBILITY ADJ: All cause hospitalization

One patient ([redacted] who is ongoing study is excluded from interim analysis.
IND = Induction Period, MNT = Maintenance Period, FLARE = Flare Period, FU=Follow-up.
# Subject prematurely discontinued.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.3__2.5.1.1_A

表 2.7.4.7-30.　重篤な有害事象（MedDRA SOC 及び PT 別）（統合 FAS 集団，M10-870 試験）

MedDRA 22.0 System Organ Class Preferred Term	Adalimumab (N=59) n (%)
Any adverse event	9 (15.3)
血液およびリンパ系障害	2 (3.4)
貧血	2 (3.4)
失血性貧血	1 (1.7)
胃腸障害	4 (6.8)
潰瘍性大腸炎	3 (5.1)
大腸ポリープ	1 (1.7)
直腸出血	1 (1.7)
肝胆道系障害	1 (1.7)
胆嚢炎	1 (1.7)
感染症および寄生虫症	2 (3.4)
気管支炎	1 (1.7)
敗血症	1 (1.7)
傷害、中毒および処置合併症	1 (1.7)
上肢骨折	1 (1.7)
筋骨格系および結合組織障害	1 (1.7)
成長不全	1 (1.7)
生殖系および乳房障害	1 (1.7)
卵巣嚢胞	1 (1.7)

表 2.7.4.7-30.　重篤な有害事象（MedDRA SOC 及び PT 別）（統合 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	Adalimumab (N=59) n (%)
呼吸器、胸郭および縦隔障害	1 (1.7)
喘息	1 (1.7)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Cross reference: M10-870 Japan Sub-study CSR_Interim Table 14.3__2.1.1.1_A

表 2.7.4.7-31. 重篤な有害事象の 100 人年あたりの発現頻度（MedDRA SOC 及び PT 別）（統合 FAS 集団，M10-870 試験）

MedDRA 22.0 System Organ Class Preferred Term	Adalimumab (N=59) (PYS=84.3) Events (E/100PY)
Any adverse event	17 (20.2)
血液およびリンパ系障害	3 (3.6)
貧血	2 (2.4)
失血性貧血	1 (1.2)
胃腸障害	6 (7.1)
潰瘍性大腸炎	4 (4.7)
大腸ポリープ	1 (1.2)
直腸出血	1 (1.2)
肝胆道系障害	1 (1.2)
胆嚢炎	1 (1.2)
感染症および寄生虫症	2 (2.4)
気管支炎	1 (1.2)
敗血症	1 (1.2)
傷害、中毒および処置合併症	1 (1.2)
上肢骨折	1 (1.2)
筋骨格系および結合組織障害	1 (1.2)
成長不全	1 (1.2)
生殖系および乳房障害	2 (2.4)
卵巣嚢胞	2 (2.4)

表 2.7.4.7-31. 重篤な有害事象の 100 人年あたりの発現頻度（MedDRA SOC 及び PT 別）（統合 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	Adalimumab (N=59) (PYS=84.3) Events (E/100PY)
呼吸器、胸郭および縦隔障害	1 (1.2)
喘息	1 (1.2)

PYS = sum((last dose date of ADA in study M10-870 - first dose date of ADA in study M10-870 + min([redacted]20[redacted] - last dose date of ADA in study M10-870 + 1, 14)) days)/365.25 for ongoing patients; otherwise = sum(last dose date of ADA in study M10-870 - first dose date of ADA in study M10-870 + 14 days)/365.25.
E/100PY = Events per 100 patient-years.

Cross reference: M10-870 Japan Sub-study CSR_Interim Table 14.3__2.1.1.2_A

表 2.7.4.7-32. 治験薬と関連ありの重篤な有害事象（MedDRA SOC 及び PT 別）（統合 FAS 集団，M10-870 試験）

MedDRA 22.0 System Organ Class Preferred Term	Adalimumab (N=59) n (%)
Any adverse event	2 (3.4)
肝胆道系障害	1 (1.7)
胆嚢炎	1 (1.7)
生殖系および乳房障害	1 (1.7)
卵巣嚢胞	1 (1.7)

AEs with unknown relationship were counted as 'reasonable possibility of being related'.
Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Cross reference: M10-870 Japan Sub-study CSR_Interim Table 14.3__2.1.2.1_A

表 2.7.4.7-33.　　重篤な有害事象の一覧（統合 FAS 集団，M10-870 試験）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EOW							
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:55.6 KG							
	TRT	1 TO 342	69 69	R: SEVERE BLOOD ANAEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anaemia	E: 75 L: 7 DAYS I: YES	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: EXACERBATION OF ULCERATIVE COLITIS A: NO REASONABLE POSSIBILITY

表 2.7.4.7-33. 重篤な有害事象の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EOW							
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:55.6 KG							
	TRT	1 TO 342	169 169	R: WORSENING OF THE BLOOD ANAEMIA DUE TO RECTAL BLEEDING S: Blood and lymphatic system disorders P: 失血性貧血 L: Blood loss anemia	E: 174 L: 6 DAYS I: YES	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: HOSPITALIZATION AND BLOOD TRANSFUSION C: NO	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: MODERATE COURSE OF THE ULCERATIVE COLITIS A: NO REASONABLE POSSIBILITY

表 2.7.4.7-33. 重篤な有害事象の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	Name	Epoch	Interval	Rx Day of Onset	Day	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EOW									
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:55.6 KG									
	TRT	1 TO 342	169	169		R: WORSENING OF THE BLOOD ANAEMIA DUE TO RECTAL BLEEDING S: Gastrointestinal disorders P: 直腸出血 L: Rectal bleeding	E: 174 L: 6 DAYS I: YES	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: HOSPITALIZATION AND BLOOD TRANSFUSION C: NO	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: MODERATE COURSE OF THE ULCERATIVE COLITIS A: NO REASONABLE POSSIBILITY

表 2.7.4.7-33.　　重篤な有害事象の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EOW								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:55.6 KG								
	TRT	1 TO 342	334	334	R: EXACERBATION OF THE ULCERATIVE COLITIS S: Gastrointestinal disorders P: 潰瘍性大腸炎 L: Colitis ulcerative aggravated	E: 338 L: 5 DAYS I: YES	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: BLOOD TRANSFUSION C: NO	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: EXACERBATION OF THE MAIN DISEASE A: NO REASONABLE POSSIBILITY

表 2.7.4.7-33. 重篤な有害事象の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EW							
[redacted] AGE:[redacted] SEX:MALE RACE:WHITE WEIGHT:23.8 KG							
	TRT	1 TO 586	152 152	R: BRONCHITIS S: Infections and infestations P: 気管支炎 L: Bronchitis	E: 162 L: 11 DAYS	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION A: REASONABLE POSSIBILITY

表 2.7.4.7-33.　重篤な有害事象の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB 40 MG EW							
[redacted]	AGE:[redacted] SEX:MALE RACE:WHITE WEIGHT:23.8 KG						
	TRT	1 TO 586	179 179	R: BRONCHIAL ASTHMA-OBSERVATION S: Respiratory, thoracic and mediastinal disorders P: 喘息 L: Asthma bronchial	E: 182 L: 4 DAYS I: YES	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE C: NO	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THE CAUSE OF CAUGH WAS PROBABLY ALLERGY. CAUGH WAS IN M11-290 AS AE. AND OCCASIONALLY BLOCKED NOSE. IF IT IS NECESSARY, I'LL ADD IT TO AE PROTOCOL M11-290 A: NO REASONABLE POSSIBILITY

表 2.7.4.7-33.　重篤な有害事象の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB 40 MG EW								
[redacted]	AGE:[redacted]	SEX:MALE	RACE:WHITE	WEIGHT:23.8 KG				
	TRT	1 TO 586	504	504	R: GROWTH FAILURE S: Musculoskeletal and connective tissue disorders P: 成長不全 L: Growth failure	O: YES I: YES	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: HOSPITALIZATION FOR DIAGNOSTICS GROWTH FAILURE AT THE ENDOCRINOLOGY WARD C: NO	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNKNOWN

表 2.7.4.7-33.　　重篤な有害事象の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EOW							
[redacted] AGE:[redacted] SEX:MALE RACE:WHITE WEIGHT:17.4 KG							
	TRT	1 TO 377	80 80	R: FRACTURE OF THE LEFT ELBOW BONE. S: Injury, poisoning and procedural complications P: 上肢骨折 L: Elbow fracture	E: 125 L: 46 DAYS	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION, PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY O: MECHANICAL INJURY A: NO REASONABLE POSSIBILITY

表 2.7.4.7-33. 重篤な有害事象の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	Name	Epoch	Interval	Rx Day of Day	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EOW									
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:80.0 KG									
	TRT	1 TO 664		508	508	R: CHOLECYSTITIS S: Hepatobiliary disorders P: 胆嚢炎 L: Cholecystitis	E: 510 L: 3 DAYS	S: MODERATE R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY

表 2.7.4.7-33.　重篤な有害事象の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB 40 MG EOW								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:62.0 KG								
	TRT	1 TO 651+	102	102	R: COLON POLYPS S: Gastrointestinal disorders P: 大腸ポリープ L: Colonic polyp	E: 104 L: 3 DAYS	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: POLYPECTOMY C: NO	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING DIAGNOSIS A: NO REASONABLE POSSIBILITY

表 2.7.4.7-33.　　重篤な有害事象の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EOW							
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:64.0 KG							
	TRT	1 TO 1199+	56 56	R: RIGHT OVARIAN CYST S: Reproductive system and breast disorders P: 卵巣嚢胞 L: Ovarian cyst	E: 57 L: 2 DAYS	S: MILD R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY

表 2.7.4.7-33.　　重篤な有害事象の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EOW								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:64.0 KG								
	TRT	1 TO 1199+	528	528	R: WORSENING OF THE LEFT OVARIAN CYS S: Reproductive system and breast disorders P: 卵巣嚢胞 L: Ovarian cyst	E: 530 L: 3 DAYS	S: MODERATE R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY

表 2.7.4.7-33.　重篤な有害事象の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EOW							
[redacted]	AGE:1[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:67.0 KG			
	TRT	1 TO 323	164	164 R: ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia	E: 256 L: 93 DAYS	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING DIAGNOSIS A: NO REASONABLE POSSIBILITY

表 2.7.4.7-33. 重篤な有害事象の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB 40 MG EOW							
[redacted]	AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:30.7 KG						
	FU	224 TO	7 230	R: COLITIS ULCEROSA RELAPS S: Gastrointestinal disorders P: 潰瘍性大腸炎 L: Colitis ulcerative aggravated	E: 247 L: 18 DAYS I: YES	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: UNDERLYING UC DISEASE STATE A: NO REASONABLE POSSIBILITY

表 2.7.4.7-33. 重篤な有害事象の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EW							
[redacted] AGE:1[redacted] SEX:MALE RACE:ASIAN WEIGHT:60.2 KG							
	FU	347 TO	12 358	R: AGGRAVATION OF UC S: Gastrointestinal disorders P: 潰瘍性大腸炎 L: Colitis ulcerative aggravated	E: 369 L: 12 DAYS I: YES	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UC A: NO REASONABLE POSSIBILITY

表 2.7.4.7-33. 重篤な有害事象の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB 40 MG EW							
[redacted] AGE:1[redacted] SEX:MALE RACE:ASIAN WEIGHT:60.2 KG							
	FU	347 TO	63 409	R: SEPSIS S: Infections and infestations P: 敗血症 L: Sepsis	E: 425 L: 17 DAYS	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION A: NO REASONABLE POSSIBILITY

表 2.7.4.7-33.　　重篤な有害事象の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	Name	Epoch	Interval	Rx Day of Onset	Day	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EW									
[redacted]	AGE:1[redacted]	SEX:MALE	RACE:ASIAN	WEIGHT:60.2 KG					
	FU	347 TO		68	414	R: AGGRAVATION OF UC S: Gastrointestinal disorders P: 潰瘍性大腸炎 L: Colitis ulcerative aggravated	E: 425 L: 12 DAYS	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: NOT EFFICACY WITH INFLIXIMAB A: NO REASONABLE POSSIBILITY

TRT = OPEN LABEL TREATMENT, FU = FOLLOW-UP.
# Subject prematurely discontinued.
+ Subject is ongoing.

Cross reference: M10-870 Japan Sub-study CSR_Interim Table 14.3__2.5.1.1_A

表 2.7.4.7-34.　治験薬投与の中止に至った有害事象の一覧（統合安全性解析対象集団，M11-290 試験）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD								
[redacted]	AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:56.0 KG							
	FU	16 TO	4	19	R: WORSENING OF ULCERATIVE COLITIS S: Gastrointestinal disorders P: 潰瘍性大腸炎 L: Colitis ulcerative aggravated	E: 31 L: 13 DAYS	S: MODERATE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-34. 治験薬投与の中止に至った有害事象の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] TRT: ISD								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:56.0 KG								
	FU	16 TO	6	21	R: PERICARDITIS S: Cardiac disorders P: 心膜炎 L: Pericarditis	E: 29 L: 9 DAYS	S: SEVERE R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION A: REASONABLE POSSIBILITY ADJ: All cause hospitalization, UC related hospitalization

表 2.7.4.7-34. 治験薬投与の中止に至った有害事象の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted]([redacted]) TRT: ISD								
[redacted]	AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:47.8 KG							
	IND	1 TO 28	28	28	R: WORSENING OF THE SUBJECT'S UC S: Gastrointestinal disorders P: 潰瘍性大腸炎 L: Colitis ulcerative aggravated	O: YES	S: MODERATE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO
INV: [redacted]([redacted]) TRT: ISD-MSD								
[redacted]	AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:62.8 KG							
	MNT	56 TO 119	28	83	R: ENTERITIS S: Gastrointestinal disorders P: 小腸炎 L: Enteritis	O: YES I: YES	S: MODERATE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: NONE	M: NO S: NO

表 2.7.4.7-34. 治験薬投与の中止に至った有害事象の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	----- Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MSD								
[redacted]	AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:43.8 KG							
	MNT	57 TO 128	72	128	R: SEVERE ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia	E: 147 L: 20 DAYS	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FLARE OF UC A: NO REASONABLE POSSIBILITY ADJ: All cause hospitalization, UC related hospitalization

表 2.7.4.7-34. 治験薬投与の中止に至った有害事象の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted]([redacted]) TRT: IHD-MSD								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:43.8 KG								
	MNT	57 TO 128	72	128	R: UC FLARE S: Gastrointestinal disorders P: 潰瘍性大腸炎 L: Colitis ulcerative aggravated	E: 147 L: 20 DAYS	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: CAN BE IN RELATIONSHIP TO ABSENCE OF STUDY DRUG A: NO REASONABLE POSSIBILITY ADJ: All cause hospitalization, UC related hospitalization

表 2.7.4.7-34. 治験薬投与の中止に至った有害事象の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD								
[redacted]	AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:48.0 KG							
	FU	43 TO	5	47	R: UC FLARE S: Gastrointestinal disorders P: 潰瘍性大腸炎 L: Colitis ulcerative aggravated	E: 56 L: 10 DAYS	S: MODERATE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UC FLARE A: NO REASONABLE POSSIBILITY ADJ: All cause hospitalization, UC related hospitalization

表 2.7.4.7-34.　治験薬投与の中止に至った有害事象の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD								
[redacted]	AGE:1[redacted]	SEX:MALE	RACE:ASIAN	WEIGHT:49.5 KG				
[redacted]		IND	1	1	R: INJECTION SITE PAIN S: General disorders and administration site conditions P: 注射部位疼痛 L: Injection site pain	E: 1 L: 1 DAY I: YES	S: MODERATE R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION PRESCRIBED, COOLING)	M: NO S: NO

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
IND = Induction Period, MNT = Maintenance Period, FLARE = Flare Period, FU=Follow-up.
# Subject prematurely discontinued.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.3__2.5.2_A

表 2.7.4.7-35.　　治験薬投与の中止に至った有害事象の一覧（統合 FAS 集団，M10-870 試験）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EOW							
[redacted]	AGE:1[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:30.7 KG			
	FU	224 TO	7 230	R: COLITIS ULCEROSA RELAPS S: Gastrointestinal disorders P: 潰瘍性大腸炎 L: Colitis ulcerative aggravated	E: 247 L: 18 DAYS I: YES	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: UNDERLYING UC DISEASE STATE A: NO REASONABLE POSSIBILITY

表 2.7.4.7-35.　治験薬投与の中止に至った有害事象の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EOW							
[redacted]	AGE:1[redacted]	SEX:MALE	RACE:WHITE	WEIGHT:86.4 KG			
	TRT	1 TO 1057	1056	1056			
				R: UC RELAPSE S: Gastrointestinal disorders P: 潰瘍性大腸炎 L: UC aggravated	O: YES	S: MODERATE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

TRT = OPEN LABEL TREATMENT, FU = FOLLOW-UP.
# Subject prematurely discontinued.

Cross reference: M10-870 Japan Sub-study CSR_Interim Table 14.3__2.5.2_A

表 2.7.4.7-36. 導入療法期中に発現した有害事象の 100 人年あたりの発現頻度の概要（統合安全性解析対象集団，M11-290 試験）

	I-SD (N=32) (PYS=4.6) Events (E/100PY)	I-HD (N=51) (PYS=7.7) Events (E/100PY)	I-HD-OL (N=17) (PYS=2.5) Events (E/100PY)	Total (N=100) (PYS=14.9) Events (E/100PY)
Any treatment-emergent				
Adverse event (AE)	46 (1000.0)	62 (805.2)	34 (1360.0)	142 (953.0)
Serious AE	7 (152.2)	4 (51.9)	1 (40.0)	12 (80.5)
Severe AE	5 (108.7)	1 (13.0)	0	6 (40.3)
AEs leading to discontinuation of study drug	4 (87.0)	1 (13.0)	0	5 (33.6)
AEs rated as possibly related to study drug by the investigator (reasonable possibility)#	8 (173.9)	16 (207.8)	5 (200.0)	29 (194.6)
SAEs rated as possibly related to study drug by the investigator (reasonable possibility)#	3 (65.2)	1 (13.0)	1 (40.0)	5 (33.6)
AEs leading to Death	0	0	0	0
Infections	7 (152.2)	13 (168.8)	7 (280.0)	27 (181.2)
Serious infections	0	0	0	0
Legionella infections	0	0	0	0
Diverticulitis	0	0	0	0
Opportunistic infections excluding oral candidiasis and tuberculosis (TB)	0	0	0	0

表 2.7.4.7-36. 導入療法期中に発現した有害事象の 100 人年あたりの発現頻度の概要（統合安全性解析対象集団，M11-290 試験）（続き）

	I-SD (N=32) (PYS=4.6) Events (E/100PY)	I-HD (N=51) (PYS=7.7) Events (E/100PY)	I-HD-OL (N=17) (PYS=2.5) Events (E/100PY)	Total (N=100) (PYS=14.9) Events (E/100PY)
Oral candidiasis	0	0	0	0
Tuberculosis	0	0	0	0
Active tuberculosis	0	0	0	0
Latent tuberculosis	0	0	0	0
Parasitic infections	0	0	0	0
Reactivation of Hepatitis B	0	0	0	0
Progressive multifocal leukoencephalopathy (PML)	0	0	0	0
Malignancies	0	0	0	0
Lymphoma	0	0	0	0
Hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0
Non-melanoma skin cancer (NMSC)	0	0	0	0
Melanoma	0	0	0	0
Leukemia	0	0	0	0
Malignancy other than lymphoma, HSTCL, leukemia, NMSC or melanoma	0	0	0	0

表 2.7.4.7-36. 導入療法期中に発現した有害事象の 100 人年あたりの発現頻度の概要（統合安全性解析対象集団，M11-290 試験）（続き）

	I-SD (N=32) (PYS=4.6) Events (E/100PY)	I-HD (N=51) (PYS=7.7) Events (E/100PY)	I-HD-OL (N=17) (PYS=2.5) Events (E/100PY)	Total (N=100) (PYS=14.9) Events (E/100PY)
Allergic reactions including angioedema/anaphylaxis	0	1 (13.0)	0	1 (6.7)
Lupus-like reactions and systemic lupus erythematosus	0	0	0	0
Vasculitis	0	0	0	0
Cutaneous vasculitis	0	0	0	0
Non-cutaneous vasculitis	0	0	0	0
Sarcoidosis	0	0	0	0
Autoimmune Hepatitis	0	0	0	0
Myocardial infarction (MI)	0	0	0	0
Cerebrovascular accident (CVA)	0	0	0	0
Congestive heart failure (CHF)	0	0	0	0
Pulmonary embolism	0	0	0	0
Interstitial lung disease	0	0	0	0
Intestinal perforation	0	0	0	0
Pancreatitis	0	1 (13.0)	0	1 (6.7)

表 2.7.4.7-36. 導入療法期中に発現した有害事象の 100 人年あたりの発現頻度の概要（統合安全性解析対象集団，M11-290 試験）（続き）

	I-SD (N=32) (PYS=4.6) Events (E/100PY)	I-HD (N=51) (PYS=7.7) Events (E/100PY)	I-HD-OL (N=17) (PYS=2.5) Events (E/100PY)	Total (N=100) (PYS=14.9) Events (E/100PY)
Stevens-Johnson syndrome	0	0	0	0
Erythema multiforme	0	0	0	0
Worsening or new onset of psoriasis	0	0	0	0
Demyelinating disorder	0	0	0	0
Amyotrophic lateral sclerosis	0	0	0	0
Reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0
Hematologic disorders including pancytopenia	3 (65.2)	3 (39.0)	1 (40.0)	7 (47.0)
Liver failure and other liver events	0	0	0	0
Humira administration related medication error	0	0	0	0
Injection site reaction	1 (21.7)	5 (64.9)	0	6 (40.3)
All deaths	0	0	0	0
Occurring <=70 days after last dose	0	0	0	0
Occurring >70 days after last dose	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.
One patient ([redacted]) who is ongoing study is excluded from interim analysis.
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.
E/100PY = Events per 100 patient-years.
AEs with unknown relationship were counted as 'reasonable possibility of being related'.
AEs with unknown severity were counted as 'severe'.
As assessed by investigator.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.3__1.1.2.1_A

表 2.7.4.7-37.　維持療法期中に発現した有害事象の 100 人年あたりの発現頻度の概要
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）

	M-SD (N=33) (PYS=20.5) Events (E/100PY)	M-HD (N=35) (PYS=23.2) Events (E/100PY)	Total-ADA (N=68) (PYS=43.7) Events (E/100PY)	M-PL (N=12) (PYS=6.1) Events (E/100PY)	Total (N=80) (PYS=49.8) Events (E/100PY)
Any treatment-emergent					
Adverse event (AE)	74 (361.0)	76 (327.6)	150 (343.2)	26 (426.2)	176 (353.4)
Serious AE	10 (48.8)	6 (25.9)	16 (36.6)	1 (16.4)	17 (34.1)
Severe AE	5 (24.4)	1 (4.3)	6 (13.7)	0	6 (12.0)
AEs leading to discontinuation of study drug	3 (14.6)	0	3 (6.9)	0	3 (6.0)
AEs rated as possibly related to study drug by the investigator (reasonable possibility)#	14 (68.3)	20 (86.2)	34 (77.8)	6 (98.4)	40 (80.3)
SAEs rated as possibly related to study drug by the investigator (reasonable possibility)#	0	1 (4.3)	1 (2.3)	1 (16.4)	2 (4.0)
AEs leading to Death	0	0	0	0	0
Infections	18 (87.8)	22 (94.8)	40 (91.5)	9 (147.5)	49 (98.4)
Serious infections	3 (14.6)	3 (12.9)	6 (13.7)	0	6 (12.0)
Legionella infections	0	0	0	0	0
Diverticulitis	0	0	0	0	0
Opportunistic infections excluding oral candidiasis and tuberculosis (TB)	0	0	0	0	0

表 2.7.4.7-37. 維持療法期中に発現した有害事象の 100 人年あたりの発現頻度の概要
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

	M-SD (N=33) (PYS=20.5) Events (E/100PY)	M-HD (N=35) (PYS=23.2) Events (E/100PY)	Total-ADA (N=68) (PYS=43.7) Events (E/100PY)	M-PL (N=12) (PYS=6.1) Events (E/100PY)	Total (N=80) (PYS=49.8) Events (E/100PY)
Oral candidiasis	0	0	0	0	0
Tuberculosis	0	1 (4.3)	1 (2.3)	0	1 (2.0)
Active tuberculosis	0	0	0	0	0
Latent tuberculosis	0	1 (4.3)	1 (2.3)	0	1 (2.0)
Parasitic infections	0	0	0	0	0
Reactivation of Hepatitis B	0	0	0	0	0
Progressive multifocal leukoencephalopathy (PML)	0	0	0	0	0
Malignancies	0	0	0	0	0
Lymphoma	0	0	0	0	0
Hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0	0
Non-melanoma skin cancer (NMSC)	0	0	0	0	0
Melanoma	0	0	0	0	0
Leukemia	0	0	0	0	0
Malignancy other than lymphoma, HSTCL, leukemia, NMSC or melanoma	0	0	0	0	0

表 2.7.4.7-37. 維持療法期中に発現した有害事象の 100 人年あたりの発現頻度の概要
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

	M-SD (N=33) (PYS=20.5) Events (E/100PY)	M-HD (N=35) (PYS=23.2) Events (E/100PY)	Total-ADA (N=68) (PYS=43.7) Events (E/100PY)	M-PL (N=12) (PYS=6.1) Events (E/100PY)	Total (N=80) (PYS=49.8) Events (E/100PY)
Allergic reactions including angioedema/anaphylaxis	2 (9.8)	2 (8.6)	4 (9.2)	0	4 (8.0)
Lupus-like reactions and systemic lupus erythematosus	0	0	0	0	0
Vasculitis	0	0	0	0	0
Cutaneous vasculitis	0	0	0	0	0
Non-cutaneous vasculitis	0	0	0	0	0
Sarcoidosis	0	0	0	0	0
Autoimmune Hepatitis	0	0	0	0	0
Myocardial infarction (MI)	0	0	0	0	0
Cerebrovascular accident (CVA)	0	0	0	0	0
Congestive heart failure (CHF)	0	0	0	0	0
Pulmonary embolism	0	0	0	0	0
Interstitial lung disease	0	0	0	0	0
Intestinal perforation	0	0	0	0	0
Pancreatitis	0	0	0	0	0

表 2.7.4.7-37. 維持療法期中に発現した有害事象の 100 人年あたりの発現頻度の概要
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

	M-SD (N=33) (PYS=20.5) Events (E/100PY)	M-HD (N=35) (PYS=23.2) Events (E/100PY)	Total-ADA (N=68) (PYS=43.7) Events (E/100PY)	M-PL (N=12) (PYS=6.1) Events (E/100PY)	Total (N=80) (PYS=49.8) Events (E/100PY)
Stevens-Johnson syndrome	0	0	0	0	0
Erythema multiforme	0	0	0	0	0
Worsening or new onset of psoriasis	0	0	0	1 (16.4)	1 (2.0)
Demyelinating disorder	0	0	0	0	0
Amyotrophic lateral sclerosis	0	0	0	0	0
Reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0	0
Hematologic disorders including pancytopenia	5 (24.4)	1 (4.3)	6 (13.7)	2 (32.8)	8 (16.1)
Liver failure and other liver events	0	0	0	0	0
Humira administration related medication error	0	0	0	0	0
Injection site reaction	6 (29.3)	3 (12.9)	9 (20.6)	0	9 (18.1)
All deaths	0	0	0	0	0
Occurring <=70 days after last dose	0	0	0	0	0
Occurring >70 days after last dose	0	0	0	0	0

表 2.7.4.7-37.　維持療法期中に発現した有害事象の 100 人年あたりの発現頻度の概要
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

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.
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 M10-870 are excluded.
E/100PY = Events per 100 patient-years.
AEs with unknown relationship were counted as 'reasonable possibility of being related'.
AEs with unknown severity were counted as 'severe'.
As assessed by investigator.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.3__1.1.2.2_A

表 2.7.4.7-38. 導入療法期中に発現した有害事象の 100 人年あたりの発現頻度の概要（日本人安全性解析対象集団，M11-290 試験）

	I-SD (N=2) (PYS=0.2) Events (E/100PY)	I-HD (N=4) (PYS=0.6) Events (E/100PY)	I-HD-OL (N=1) (PYS=0.2) Events (E/100PY)	Total (N=7) (PYS=1.0) Events (E/100PY)
Any treatment-emergent				
Adverse event (AE)	3 (1500.0)	5 (833.3)	3 (1500.0)	11 (1100.0)
Serious AE	0	0	0	0
Severe AE	0	0	0	0
AEs leading to discontinuation of study drug	1 (500.0)	0	0	1 (100.0)
AEs rated as possibly related to study drug by the investigator (reasonable possibility)#	1 (500.0)	1 (166.7)	3 (1500.0)	5 (500.0)
SAEs rated as possibly related to study drug by the investigator (reasonable possibility)#	0	0	0	0
AEs leading to Death	0	0	0	0
Infections	0	3 (500.0)	0	3 (300.0)
Serious infections	0	0	0	0
Legionella infections	0	0	0	0
Diverticulitis	0	0	0	0
Opportunistic infections excluding oral candidiasis and tuberculosis (TB)	0	0	0	0

表 2.7.4.7-38. 導入療法期中に発現した有害事象の 100 人年あたりの発現頻度の概要（日本人安全性解析対象集団，M11-290 試験）（続き）

	I-SD (N=2) (PYS=0.2) Events (E/100PY)	I-HD (N=4) (PYS=0.6) Events (E/100PY)	I-HD-OL (N=1) (PYS=0.2) Events (E/100PY)	Total (N=7) (PYS=1.0) Events (E/100PY)
Oral candidiasis	0	0	0	0
Tuberculosis	0	0	0	0
Active tuberculosis	0	0	0	0
Latent tuberculosis	0	0	0	0
Parasitic infections	0	0	0	0
Reactivation of Hepatitis B	0	0	0	0
Progressive multifocal leukoencephalopathy (PML)	0	0	0	0
Malignancies	0	0	0	0
Lymphoma	0	0	0	0
Hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0
Non-melanoma skin cancer (NMSC)	0	0	0	0
Melanoma	0	0	0	0
Leukemia	0	0	0	0
Malignancy other than lymphoma, HSTCL, leukemia, NMSC or melanoma	0	0	0	0

表 2.7.4.7-38. 導入療法期中に発現した有害事象の 100 人年あたりの発現頻度の概要（日本人安全性解析対象集団，M11-290 試験）（続き）

	I-SD (N=2) (PYS=0.2) Events (E/100PY)	I-HD (N=4) (PYS=0.6) Events (E/100PY)	I-HD-OL (N=1) (PYS=0.2) Events (E/100PY)	Total (N=7) (PYS=1.0) Events (E/100PY)
Allergic reactions including angioedema/anaphylaxis	0	0	0	0
Lupus-like reactions and systemic lupus erythematosus	0	0	0	0
Vasculitis	0	0	0	0
Cutaneous vasculitis	0	0	0	0
Non-cutaneous vasculitis	0	0	0	0
Sarcoidosis	0	0	0	0
Autoimmune Hepatitis	0	0	0	0
Myocardial infarction (MI)	0	0	0	0
Cerebrovascular accident (CVA)	0	0	0	0
Congestive heart failure (CHF)	0	0	0	0
Pulmonary embolism	0	0	0	0
Interstitial lung disease	0	0	0	0
Intestinal perforation	0	0	0	0
Pancreatitis	0	0	0	0

表 2.7.4.7-38. 導入療法期中に発現した有害事象の 100 人年あたりの発現頻度の概要（日本人安全性解析対象集団，M11-290 試験）（続き）

	I-SD (N=2) (PYS=0.2) Events (E/100PY)	I-HD (N=4) (PYS=0.6) Events (E/100PY)	I-HD-OL (N=1) (PYS=0.2) Events (E/100PY)	Total (N=7) (PYS=1.0) Events (E/100PY)
Stevens-Johnson syndrome	0	0	0	0
Erythema multiforme	0	0	0	0
Worsening or new onset of psoriasis	0	0	0	0
Demyelinating disorder	0	0	0	0
Amyotrophic lateral sclerosis	0	0	0	0
Reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0
Hematologic disorders including pancytopenia	0	0	0	0
Liver failure and other liver events	0	0	0	0
Humira administration related medication error	0	0	0	0
Injection site reaction	1 (500.0)	1 (166.7)	0	2 (200.0)
All deaths	0	0	0	0
Occurring <=70 days after last dose	0	0	0	0
Occurring >70 days after last dose	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.
One patient ([redacted]) who is ongoing study is excluded from interim analysis.
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.
E/100PY = Events per 100 patient-years.
AEs with unknown relationship were counted as 'reasonable possibility of being related'.
AEs with unknown severity were counted as 'severe'.
As assessed by investigator.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.3__1.1.2.1_J

表 2.7.4.7-39. 維持療法期中に発現した有害事象の 100 人年あたりの発現頻度の概要
（維持療法期中に治験薬の投与を 1 回以上受けた日本人安全性解析対象集団の被験者，M11-290 試験）

	M-SD (N=2) (PYS=0.3) Events (E/100PY)	M-HD (N=3) (PYS=2.0) Events (E/100PY)	Total-ADA (N=5) (PYS=2.3) Events (E/100PY)	M-PL (N=0) (PYS=0.0) Events (E/100PY)	Total (N=5) (PYS=2.3) Events (E/100PY)
Any treatment-emergent					
Adverse event (AE)	1 (333.3)	7 (350.0)	8 (347.8)	0	8 (347.8)
Serious AE	1 (333.3)	0	1 (43.5)	0	1 (43.5)
Severe AE	0	0	0	0	0
AEs leading to discontinuation of study drug	0	0	0	0	0
AEs rated as possibly related to study drug by the investigator (reasonable possibility)#	0	2 (100.0)	2 (87.0)	0	2 (87.0)
SAEs rated as possibly related to study drug by the investigator (reasonable possibility)#	0	0	0	0	0
AEs leading to Death	0	0	0	0	0
Infections	1 (333.3)	3 (150.0)	4 (173.9)	0	4 (173.9)
Serious infections	1 (333.3)	0	1 (43.5)	0	1 (43.5)
Legionella infections	0	0	0	0	0
Diverticulitis	0	0	0	0	0
Opportunistic infections excluding oral candidiasis and tuberculosis (TB)	0	0	0	0	0

表 2.7.4.7-39. 維持療法期中に発現した有害事象の 100 人年あたりの発現頻度の概要
（維持療法期中に治験薬の投与を 1 回以上受けた日本人安全性解析対象集団の被験者，M11-290 試験）（続き）

	M-SD (N=2) (PYS=0.3) Events (E/100PY)	M-HD (N=3) (PYS=2.0) Events (E/100PY)	Total-ADA (N=5) (PYS=2.3) Events (E/100PY)	M-PL (N=0) (PYS=0.0) Events (E/100PY)	Total (N=5) (PYS=2.3) Events (E/100PY)
Oral candidiasis	0	0	0	0	0
Tuberculosis	0	0	0	0	0
Active tuberculosis	0	0	0	0	0
Latent tuberculosis	0	0	0	0	0
Parasitic infections	0	0	0	0	0
Reactivation of Hepatitis B	0	0	0	0	0
Progressive multifocal leukoencephalopathy (PML)	0	0	0	0	0
Malignancies	0	0	0	0	0
Lymphoma	0	0	0	0	0
Hepatosplenic T-cell lymphoma (HSTCL)	0	0	0	0	0
Non-melanoma skin cancer (NMSC)	0	0	0	0	0
Melanoma	0	0	0	0	0
Leukemia	0	0	0	0	0
Malignancy other than lymphoma, HSTCL, leukemia, NMSC or melanoma	0	0	0	0	0

表 2.7.4.7-39. 維持療法期中に発現した有害事象の 100 人年あたりの発現頻度の概要
（維持療法期中に治験薬の投与を 1 回以上受けた日本人安全性解析対象集団の被験者，M11-290 試験）（続き）

	M-SD (N=2) (PYS=0.3) Events (E/100PY)	M-HD (N=3) (PYS=2.0) Events (E/100PY)	Total-ADA (N=5) (PYS=2.3) Events (E/100PY)	M-PL (N=0) (PYS=0.0) Events (E/100PY)	Total (N=5) (PYS=2.3) Events (E/100PY)
Allergic reactions including angioedema/anaphylaxis	0	0	0	0	0
Lupus-like reactions and systemic lupus erythematosus	0	0	0	0	0
Vasculitis	0	0	0	0	0
Cutaneous vasculitis	0	0	0	0	0
Non-cutaneous vasculitis	0	0	0	0	0
Sarcoidosis	0	0	0	0	0
Autoimmune Hepatitis	0	0	0	0	0
Myocardial infarction (MI)	0	0	0	0	0
Cerebrovascular accident (CVA)	0	0	0	0	0
Congestive heart failure (CHF)	0	0	0	0	0
Pulmonary embolism	0	0	0	0	0
Interstitial lung disease	0	0	0	0	0
Intestinal perforation	0	0	0	0	0
Pancreatitis	0	0	0	0	0

表 2.7.4.7-39. 維持療法期中に発現した有害事象の 100 人年あたりの発現頻度の概要
（維持療法期中に治験薬の投与を 1 回以上受けた日本人安全性解析対象集団の被験者，M11-290 試験）（続き）

	M-SD (N=2) (PYS=0.3) Events (E/100PY)	M-HD (N=3) (PYS=2.0) Events (E/100PY)	Total-ADA (N=5) (PYS=2.3) Events (E/100PY)	M-PL (N=0) (PYS=0.0) Events (E/100PY)	Total (N=5) (PYS=2.3) Events (E/100PY)
Stevens-Johnson syndrome	0	0	0	0	0
Erythema multiforme	0	0	0	0	0
Worsening or new onset of psoriasis	0	0	0	0	0
Demyelinating disorder	0	0	0	0	0
Amyotrophic lateral sclerosis	0	0	0	0	0
Reversible posterior leukoencephalopathy syndrome (RPLS)	0	0	0	0	0
Hematologic disorders including pancytopenia	0	0	0	0	0
Liver failure and other liver events	0	0	0	0	0
Humira administration related medication error	0	0	0	0	0
Injection site reaction	0	0	0	0	0
All deaths	0	0	0	0	0
Occurring <=70 days after last dose	0	0	0	0	0
Occurring >70 days after last dose	0	0	0	0	0

表 2.7.4.7-39.　維持療法期中に発現した有害事象の 100 人年あたりの発現頻度の概要
（維持療法期中に治験薬の投与を 1 回以上受けた日本人安全性解析対象集団の被験者，M11-290 試験）（続き）

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.
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 M10-870 are excluded.
E/100PY = Events per 100 patient-years.
AEs with unknown relationship were counted as 'reasonable possibility of being related'.
AEs with unknown severity were counted as 'severe'.
As assessed by investigator.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.3__1.1.2.2_J

表 2.7.4.7-40.　有害事象の 100 人年あたりの発現頻度の概要（統合 FAS 集団，M10-870 試験）

	Adalimumab (N=59) (PYS=84.3) Events (E/100PY)
Any treatment-emergent	
Adverse event (AE)	160 (189.8)
Serious AE	17 (20.2)
Severe AE	4 (4.7)
AEs leading to discontinuation of study drug	2 (2.4)
AEs rated as possibly related to study drug by the investigator (reasonable possibility)#	18 (21.4)
SAEs rated as possibly related to study drug by the investigator (reasonable possibility)#	3 (3.6)
AEs leading to death	0
Infections	50 (59.3)
Serious infections	2 (2.4)
Legionella infections	0
Diverticulitis	0
Opportunistic infections excluding oral candidiasis and tuberculosis (TB)	0
Oral candidiasis	0

表 2.7.4.7-40. 有害事象の 100 人年あたりの発現頻度の概要（統合 FAS 集団，M10-870 試験）（続き）

	Adalimumab (N=59) (PYS=84.3) Events (E/100PY)
Tuberculosis	4 (4.7)
Active tuberculosis	0
Latent tuberculosis	4 (4.7)
Parasitic infections	0
Reactivation of Hepatitis B	0
Progressive multifocal leukoencephalopathy (PML)	0
Malignancies	0
Lymphoma	0
Hepatosplenic T-cell lymphoma (HSTCL)	0
Non-melanoma skin cancer (NMSC)	0
Melanoma	0
Leukemia	0
Malignancy other than lymphoma, HSTCL, leukemia, NMSC or melanoma	0
Allergic reactions including angioedema/anaphylaxis	4 (4.7)
Lupus-like reactions and systemic lupus erythematosus	0

表 2.7.4.7-40. 有害事象の 100 人年あたりの発現頻度の概要（統合 FAS 集団，M10-870 試験）（続き）

	Adalimumab (N=59) (PYS=84.3) Events (E/100PY)
Vasculitis	0
Cutaneous vasculitis	0
Non-cutaneous vasculitis	0
Sarcoidosis	0
Autoimmune Hepatitis	0
Myocardial infarction (MI)	0
Cerebrovascular accident (CVA)	0
Congestive heart failure (CHF)	0
Pulmonary embolism	0
Interstitial lung disease	0
Intestinal perforation	0
Pancreatitis	0
Stevens-Johnson syndrome	0
Erythema multiforme	0
Worsening or new onset of psoriasis	2 (2.4)

表 2.7.4.7-40.　有害事象の 100 人年あたりの発現頻度の概要（統合 FAS 集団，M10-870 試験）（続き）

	Adalimumab (N=59) (PYS=84.3) Events (E/100PY)
Demyelinating disorder	0
Amyotrophic lateral sclerosis	0
Reversible posterior leukoencephalopathy syndrome (RPLS)	0
Hematologic disorders including pancytopenia	4 (4.7)
Liver failure and other liver events	0
Humira administration related medication error	0
Injection site reaction	0
All deaths	0
Occurring <=70 days after last dose	0
Occurring >70 days after last dose	0

Note: Treatment-emergent adverse events are defined as events with an onset date on or after the first dose date of the study drug and up to 70 days after the last dose date of the study drug.
PYS = sum((last dose date of ADA in study M10-870 - first dose date of ADA in study M10-870 + min([redacted]20[redacted]- last dose date of ADA in study M10-870 + 1, 14)) days)/365.25 for ongoing patients; otherwise = sum(last dose date of ADA in study M10-870 - first dose date of ADA in study M10-870 + 14 days)/365.25.
E/100PY = Events per 100 patient-years.
AEs with unknown relationship were counted as 'reasonable possibility of being related'.
AEs with unknown severity were counted as 'severe'.
As assessed by investigator.

Cross reference: M10-870 Japan Sub-study CSR_Interim Table 14.3__1.1.2_A

表 2.7.4.7-41.　導入療法期中に発現したすべての感染症（MedDRA SOC 及び PT 別）（統合安全性解析対象集団，M11-290 試験）

MedDRA 22.0 System Organ Class Preferred Term	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
Any adverse event	6 (18.8)	11 (21.6)	6 (35.3)	23 (23.0)
感染症および寄生虫症	6 (18.8)	11 (21.6)	6 (35.3)	23 (23.0)
気管支炎	0	0	1 (5.9)	1 (1.0)
せつ	0	1 (2.0)	0	1 (1.0)
サルモネラ菌性胃腸炎	1 (3.1)	0	0	1 (1.0)
上咽頭炎	2 (6.3)	2 (3.9)	1 (5.9)	5 (5.0)
口腔ヘルペス	1 (3.1)	2 (3.9)	0	3 (3.0)
外耳炎	0	1 (2.0)	0	1 (1.0)
咽頭炎	2 (6.3)	1 (2.0)	1 (5.9)	4 (4.0)
レンサ球菌感染	0	0	1 (5.9)	1 (1.0)
上気道感染	0	3 (5.9)	0	3 (3.0)
尿路感染	1 (3.1)	0	0	1 (1.0)
水痘	0	1 (2.0)	0	1 (1.0)
ウイルス感染	0	0	1 (5.9)	1 (1.0)
ウイルス性上気道感染	0	1 (2.0)	0	1 (1.0)
外陰膣真菌感染	0	0	1 (5.9)	1 (1.0)

One patient ([redacted] who is ongoing study is excluded from interim analysis.
I-SD = induction standard dose group; I-HD = induction high dose group; I-HD-OL = induction high dose open-label group;
Note: 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__2.4.1.1_A

表 2.7.4.7-42.　導入療法期中に発現したすべての感染症（MedDRA SOC 及び PT 別）（日本人安全性解析対象集団，M11-290 試験）

MedDRA 22.0 System Organ Class Preferred Term	I-SD (N=2) n (%)	I-HD (N=4) n (%)	I-HD-OL (N=1) n (%)	Total (N=7) n (%)
Any adverse event	0	3 (75.0)	0	3 (42.9)
感染症および寄生虫症	0	3 (75.0)	0	3 (42.9)
外耳炎	0	1 (25.0)	0	1 (14.3)
上気道感染	0	2 (50.0)	0	2 (28.6)

One patient ([redacted] who is ongoing study is excluded from interim analysis.
I-SD = induction standard dose group; I-HD = induction high dose group; I-HD-OL = induction high dose open-label group;
Note: 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__2.4.1.1_J

表 2.7.4.7-43. 維持療法期中に発現したすべての感染症（MedDRA SOC 及び PT 別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）

MedDRA 22.0 System Organ Class Preferred Term	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
Any adverse event	11 (33.3)	16 (45.7)	27 (39.7)	5 (41.7)	32 (40.0)
感染症および寄生虫症	11 (33.3)	16 (45.7)	27 (39.7)	5 (41.7)	32 (40.0)
気管支炎	1 (3.0)	0	1 (1.5)	0	1 (1.3)
感染性腸炎	1 (3.0)	0	1 (1.5)	0	1 (1.3)
胃腸炎	2 (6.1)	0	2 (2.9)	1 (8.3)	3 (3.8)
膿痂疹	0	1 (2.9)	1 (1.5)	0	1 (1.3)
感染性嚢腫	0	1 (2.9)	1 (1.5)	0	1 (1.3)
インフルエンザ	0	2 (5.7)	2 (2.9)	0	2 (2.5)
喉頭炎	0	1 (2.9)	1 (1.5)	0	1 (1.3)
無菌性髄膜炎	0	1 (2.9)	1 (1.5)	0	1 (1.3)
上咽頭炎	3 (9.1)	4 (11.4)	7 (10.3)	1 (8.3)	8 (10.0)
口腔ヘルペス	0	1 (2.9)	1 (1.5)	0	1 (1.3)
中耳炎	0	1 (2.9)	1 (1.5)	0	1 (1.3)
咽頭炎	2 (6.1)	2 (5.7)	4 (5.9)	1 (8.3)	5 (6.3)
気道感染	1 (3.0)	0	1 (1.5)	0	1 (1.3)
ウイルス性気道感染	0	0	0	1 (8.3)	1 (1.3)
鼻炎	1 (3.0)	0	1 (1.5)	0	1 (1.3)
癜風	1 (3.0)	0	1 (1.5)	0	1 (1.3)
歯膿瘍	0	0	0	1 (8.3)	1 (1.3)
気管炎	1 (3.0)	0	1 (1.5)	0	1 (1.3)

表 2.7.4.7-43. 維持療法期中に発現したすべての感染症（MedDRA SOC 及び PT 別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
感染症および寄生虫症 (Cont.)					
上気道感染	2 (6.1)	4 (11.4)	6 (8.8)	2 (16.7)	8 (10.0)
尿路感染	1 (3.0)	2 (5.7)	3 (4.4)	0	3 (3.8)
水痘	0	1 (2.9)	1 (1.5)	0	1 (1.3)

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
M-PL = maintenance placebo group; M-SD = maintenance standard dose group; M-HD = maintenance high dose group;
Note: 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__2.4.1.2_A

表 2.7.4.7-44. 維持療法期中に発現したすべての感染症（MedDRA SOC 及び PT 別）
（維持療法期中に治験薬の投与を 1 回以上受けた日本人安全性解析対象集団の被験者，M11-290 試験）

MedDRA 22.0 System Organ Class Preferred Term	M-SD (N=2) n (%)	M-HD (N=3) n (%)	Total-ADA (N=5) n (%)	M-PL (N=0) n (%)	Total (N=5) n (%)
Any adverse event	1 (50.0)	3 (100)	4 (80.0)	0	4 (80.0)
感染症および寄生虫症	1 (50.0)	3 (100)	4 (80.0)	0	4 (80.0)
感染性腸炎	1 (50.0)	0	1 (20.0)	0	1 (20.0)
膿痂疹	0	1 (33.3)	1 (20.0)	0	1 (20.0)
インフルエンザ	0	1 (33.3)	1 (20.0)	0	1 (20.0)
上気道感染	0	1 (33.3)	1 (20.0)	0	1 (20.0)

One patient ([redacted] who is ongoing study is excluded from interim analysis.
M-PL = maintenance placebo group; M-SD = maintenance standard dose group; M-HD = maintenance high dose group;
Note: 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__2.4.1.2_J

表 2.7.4.7-45.　　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD-MHD								
[redacted]	AGE:1[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:47.2 KG				
	MNT	57 TO 358	208	264	R: OTITIS MEDIA S: Infections and infestations P: 中耳炎 L: Otitis media	E: 273 L: 10 DAYS I: YES	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45.　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD-MHD-FREIND								
[redacted]	AGE:[redacted] SEX:MALE RACE:WHITE WEIGHT:22.9 KG							
	IND	1 TO 56	28	28	R: COLD S: Infections and infestations P: 上咽頭炎 L: Cold	E: 39 L: 12 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO
	FLARE	85 TO 358	66	150	R: RESPIRATORY INFECTION WITH COUGH S: Infections and infestations P: 気道感染 L: Respiratory infection	E: 163 L: 14 DAYS I: YES	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	M: NO S: NO

表 2.7.4.7-45.　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	------ Epoch ---- Name	Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD-MHD-FREIND								
[redacted]	AGE:[redacted] SEX:MALE RACE:WHITE WEIGHT:22.9 KG							
	FLARE	85 TO 358	242	326	R: COLD S: Infections and infestations P: 上咽頭炎 L: Cold	E: 333 L: 8 DAYS I: YES	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO
INV: [redacted] ([redacted]) TRT: ISD								
[redacted]	AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:56.0 KG							
	IND	1 TO 15	1	1	R: URINARY TRACT INFECTION S: Infections and infestations P: 尿路感染 L: Urinary tract infection	E: 21 L: 21 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45. すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD								
[redacted]	AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:47.8 KG							
	FU	29 TO	55	83	R: SALMONELLA ENTERITIS S: Infections and infestations P: サルモネラ菌性胃腸炎 L: Salmonella enteritis	E: 99 L: 17 DAYS	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO
TRT: ISD-MHD								
[redacted]	AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:57.0 KG							
	IND	1 TO 56	46	46	R: COMMON COLD S: Infections and infestations P: 上咽頭炎 L: Common cold	E: 52 L: 7 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	M: NO S: NO

表 2.7.4.7-45. すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD-MHD								
[redacted]	AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:57.0 KG							
	IND	1 TO 56	48	48	R: LABIAL HERPES S: Infections and infestations P: 口腔ヘルペス L: Herpes labialis	E: 52 L: 5 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO
	MNT	57 TO 358	123	179	R: COMMON COLD S: Infections and infestations P: 上咽頭炎 L: Common cold	E: 182 L: 4 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45. すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	------ Epoch ---- Name	Interval	Rx Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted]([redacted]) TRT: ISD-MHD								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:57.0 KG								
	MNT	57 TO 358	123	179	R: LABIAL HERPES S: Infections and infestations P: 口腔ヘルペス L: Herpes labialis	E: 182 L: 4 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO
	MNT	57 TO 358	235	291	R: LABIAL HERPES S: Infections and infestations P: 口腔ヘルペス L: Herpes labialis	E: 294 L: 4 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45.　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MSD								
[redacted] AGE:[redacted] SEX:FEMALE RACE:WHITE WEIGHT:21.5 KG								
	MNT	57 TO 358	64	120	R: UPPER RESPIRATORY TRACT INFECTION S: Infections and infestations P: 上気道感染 L: Upper respiratory tract infection	E: 121 L: 2 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45.　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	----- Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MSD								
[redacted]	AGE:[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:21.5 KG				
	MNT	57 TO 358	208	264	R: UPPER RESPIRATORY TRACT INFECTION S: Infections and infestations P: 上気道感染 L: Upper respiratory tract infection	E: 271 L: 8 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45.　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	----- Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MHD								
[redacted]	AGE:[redacted] SEX:MALE RACE:WHITE WEIGHT:15.0 KG							
	MNT	56 TO 357	125	180	R: UPPER RESPIRATORY TRACT INFECTION S: Infections and infestations P: 上気道感染 L: Upper respiratory tract infection	E: 185 L: 6 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45.　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted]([redacted]) TRT: IHD-MPL-FREIND								
[redacted]	AGE:1[redacted]	SEX:MALE	RACE:WHITE	WEIGHT:43.0 KG				
	IND	1 TO 56	27	27	R: COLD S: Infections and infestations P: 上咽頭炎 L: Cold	E: 36 L: 10 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	M: NO S: NO
	IND	1 TO 56	32	32	R: PHARYNGITIS S: Infections and infestations P: 咽頭炎 L: Pharyngitis	E: 36 L: 5 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45.　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MPL-FREIND								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:43.0 KG								
	MNT	57 TO 98	3	59	R: UPPER RESPIRATORY TRACT INFECTION S: Infections and infestations P: 上気道感染 L: Upper respiratory tract infection	E: 71 L: 13 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO
	MNT	57 TO 98	36	92	R: COLD S: Infections and infestations P: 上咽頭炎 L: Cold	E: 97 L: 6 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45.　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	----- Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MPL-FREIND								
[redacted]	AGE:1[redacted]	SEX:MALE	RACE:WHITE	WEIGHT:43.0 KG				
	FLARE	99 TO 800	18	116	R: URINARY TRACT INFECTION S: Infections and infestations P: 尿路感染 L: Urinary tract infection	E: 120 L: 5 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO
	FLARE	99 TO 800	189	287	R: IMPETIGO ON THE RIGHT CHICK. S: Infections and infestations P: 膿痂疹 L: Impetigo	E: 295 L: 9 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45.　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MPL-FREIND								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:78.8 KG								
	FLARE	148 TO 358	88	235	R: VIRAL UPPER RESPIRATORY TRACT INFECTION S: Infections and infestations P: ウイルス性上気道感染 L: Viral upper respiratory tract infection	E: 239 L: 5 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45.　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MHD-FREIND								
[redacted]	AGE:1[redacted]	SEX:MALE	RACE:WHITE	WEIGHT:110.0 KG				
	IND	1 TO 57	17	17	R: UPPER RESPIRATORY VIRAL INFECTION S: Infections and infestations P: ウイルス性上気道感染 L: Viral upper respiratory tract infection	E: 20 L: 4 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45.　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted]([redacted]) TRT: IHD-MHD-FREIND								
[redacted]	AGE:1[redacted]	SEX:MALE	RACE:WHITE	WEIGHT:110.0 KG				
	MNT	58 TO 281	179	236	R: UPPER RESPIRATORY TRACT INFECTION S: Infections and infestations P: 上気道感染 L: Upper respiratory tract infection	E: 238 L: 3 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45. すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHDOL								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:48.0 KG								
	IND	1 TO 28	13	13	R: VIRAL INFECTION S: Infections and infestations P: ウイルス感染 L: Viral infection	E: 18 L: 6 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45. すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHDOL-MHD								
[redacted]	AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:70.0 KG							
	IND	1 TO 58	26	26	R: PHARYNGITIS S: Infections and infestations P: 咽頭炎 L: Pharyngitis	E: 29 L: 4 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45. すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	------ Epoch ---- Name	Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted] TRT: IHDOL-MHD								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:70.0 KG								
	MNT	59 TO 360	66	124	R: UPPER RESPIRATORY TRACT INFECTION S: Infections and infestations P: 上気道感染 L: Upper respiratory tract infection	E: 126 L: 3 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO
	MNT	59 TO 360	124	182	R: COLD S: Infections and infestations P: 上咽頭炎 L: Cold	E: 187 L: 6 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45.　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day ----- Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHDOL-MHD								
[redacted] AGE:[redacted] SEX:FEMALE RACE:WHITE WEIGHT:20.0 KG								
	MNT	54 TO 358	126	179	R: COLD S: Infections and infestations P: 上咽頭炎 L: Cold	E: 182 L: 4 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO
	MNT	54 TO 358	144	197	R: LARYNGITIS S: Infections and infestations P: 喉頭炎 L: Laryngitis	E: 198 L: 2 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45.　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD								
[redacted]	AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:46.7 KG							
	IND	1 TO 44	15	15	R: COMMON COLD S: Infections and infestations P: 上咽頭炎 L: Common cold	E: 25 L: 11 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45.　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	----- Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted])								
TRT: IHD-MPL								
[redacted]	AGE:[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:48.1 KG				
	MNT	57 TO 357	9	65	R: ACUTE GASTROENTEROCOLITIS S: Infections and infestations P: 胃腸炎 L: Gastroenterocolitis	E: 72 L: 8 DAYS I: YES	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO
	MNT	57 TO 357	9	65	R: PHARYNGITIS S: Infections and infestations P: 咽頭炎 L: Pharyngitis	E: 72 L: 8 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45.　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MPL								
[redacted] AGE:[redacted] SEX:FEMALE RACE:WHITE WEIGHT:48.1 KG								
	MNT	57 TO 357	37	93	R: PHARYNGITIS S: Infections and infestations P: 咽頭炎 L: Pharyngitis	E: 97 L: 5 DAYS I: YES	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO
	MNT	57 TO 357	114	170	R: PHARYNGITIS S: Infections and infestations P: 咽頭炎 L: Pharyngitis	E: 177 L: 8 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45.　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted]([redacted]) TRT: IHDOL-MSD								
[redacted]	AGE:1[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:76.5 KG				
	IND	1 TO 58	35	35	R: COLD S: Infections and infestations P: 上咽頭炎 L: Cold	E: 35 L: 1 DAY	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO
	IND	1 TO 58	37	37	R: COLD S: Infections and infestations P: 上咽頭炎 L: Cold	E: 40 L: 4 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45.　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHDOL-MSD								
[redacted]	AGE:1[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:76.5 KG				
	MNT	59 TO 360	97	155	R: INFECTION OF UPPER RECPIRATORY TRACT INFECTION - COMMON COLD S: Infections and infestations P: 上咽頭炎 L: Common cold	E: 161 L: 7 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45.　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHDOL-MSD								
[redacted]	AGE:1[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:76.5 KG				
[redacted]	MNT	59 TO 360	97	155	R: INFECTION OF UPPER RECPIRATORY TRACT INFECTION - COMMON COLD S: Infections and infestations P: 上気道感染 L: Upper respiratory tract infection	E: 161 L: 7 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45.　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted]) TRT: IHDOL-MHD								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:31.1 KG								
	MNT	57 TO 267	9	65	R: URINAL TRACT INFECTION S: Infections and infestations P: 尿路感染 L: Urinary tract infection	E: 72 L: 8 DAYS	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: THAT WAS URINARY TRACT INFECTION, THERE WAS NO CAUSE FOUND. A: REASONABLE POSSIBILITY ADJ: All cause hospitalization

表 2.7.4.7-45. すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted]) TRT: ISD-MSD								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:62.8 KG								
	MNT	56 TO 119	13	68	R: ACUTE GASTROENTERITIS S: Infections and infestations P: 胃腸炎 L: Acute gastroenteritis	E: 72 L: 5 DAYS	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: HOSPITALIZATION	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ACQUIRED VIRAL OR BACTERIAL INFECTION, REACTIVATION OF UC A: REASONABLE POSSIBILITY ADJ: All cause hospitalization

表 2.7.4.7-45. すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted]([redacted]) TRT: ISD-MSD								
[redacted]	AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:62.8 KG							
	MNT	56 TO 119	45	100	R: RHINITIS S: Infections and infestations P: 鼻炎 L: Rhinitis	E: 103 L: 4 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	M: NO S: NO
TRT: IHD-MSD								
[redacted]	AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:43.8 KG							
	IND	1 TO 56	27	27	R: HERPES SIMPLEX ON UPPER LIP S: Infections and infestations P: 口腔ヘルペス L: Herpes on lip	E: 32 L: 6 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	M: NO S: NO

表 2.7.4.7-45. すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	------ Epoch ---- Name	Interval	Rx Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted]([redacted]) TRT: IHD-MSD								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:43.8 KG								
	MNT	57 TO 128	56	112	R: ACUTE GASTROENTERITIS S: Infections and infestations P: 胃腸炎 L: Acute gastroenteritis	E: 120 L: 9 DAYS	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: ACUTE GASTROENTERITIS DUE TO VIRAL OR BACTERIAL INFECTION OR RELAPS OF UC A: NO REASONABLE POSSIBILITY ADJ: All cause hospitalization

表 2.7.4.7-45. すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD								
[redacted]	AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:55.0 KG							
	IND	1 TO 40	16	16	R: PHARYNGITIS S: Infections and infestations P: 咽頭炎 L: Pharyngitis	E: 24 L: 9 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	M: NO S: NO
[redacted]	AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:58.0 KG							
	FU	44 TO	12	55	R: PHARYNGITIS S: Infections and infestations P: 咽頭炎 L: Pharyngitis	E: 59 L: 5 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45.　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	------ Epoch ---- Name	Interval	Rx Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD-MHD								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:61.0 KG								
	MNT	57 TO 359	67	123	R: PHARYNGITIS S: Infections and infestations P: 咽頭炎 L: Pharyngitis	E: 125 L: 3 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	M: NO S: NO
	MNT	57 TO 359	282	338	R: CHICKENPOX S: Infections and infestations P: 水痘 L: Chickenpox	E: 360 L: 23 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45.　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD-MHD-FNREIND								
[redacted]	AGE:1[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:54.0 KG				
	FLARE	205 TO 358	148	352	R: TONSILLITIS S: Infections and infestations P: 扁桃炎 L: Tonsillitis	E: 358 L: 7 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45.　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted]([redacted]) TRT: ISD-MPL-FREIND								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:58.0 KG								
	MNT	59 TO 84	15	73	R: DENTAL ABSCESS S: Infections and infestations P: 歯膿瘍 L: Dental abscess	E: 79 L: 7 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45.　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MSD								
[redacted]	AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:67.0 KG							
	MNT	59 TO 359	204	262	R: PHARYNGITIS S: Infections and infestations P: 咽頭炎 L: Pharyngitis	E: 265 L: 4 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	M: NO S: NO
[redacted]	AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:60.0 KG							
	MNT	58 TO 359	184	241	R: URINARY TRACT INFECTION S: Infections and infestations P: 尿路感染 L: Urinary tract infection	E: 249 L: 9 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45. すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MHD								
[redacted]	AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:89.0 KG							
	IND	1 TO 55	27	27	R: HERPES LABIALIS S: Infections and infestations P: 口腔ヘルペス L: Herpes labialis	E: 33 L: 7 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	M: NO S: NO
[redacted]	AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:75.0 KG							
	IND	1 TO 56	9	9	R: CHICKENPOX S: Infections and infestations P: 水痘 L: Chickenpox	E: 17 L: 9 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: 16/5000 DOSE ADJOURNED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45. すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted]([redacted]) TRT: IHD-MHD-FNREIND								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:69.0 KG								
	IND	1 TO 57	57	57	R: FURUNCULUS S: Infections and infestations P: せつ L: Furuncle	E: 96 L: 40 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45.　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	----- Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MPL-FREIND								
[redacted]	AGE:1[redacted]	SEX:MALE	RACE:WHITE	WEIGHT:63.0 KG				
	MNT	55 TO 209	22	76	R: UPPER RESPIRATORY TRACT INFECTION S: Infections and infestations P: 上気道感染 L: Upper respiratory tract infection	E: 78 L: 3 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	M: NO S: NO

表 2.7.4.7-45. すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MHD-FREIND								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:55.1 KG								
	MNT	57 TO 84	15	71	R: UTI S: Infections and infestations P: 尿路感染 L: UTI	E: 82 L: 12 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45.　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MHD								
[redacted] AGE:1[redacted] SEX:MALE RACE:ASIAN WEIGHT:46.6 KG								
	MNT	60 TO 361	117	176	R: INFLUENZA A S: Infections and infestations P: インフルエンザ L: Influenza A virus infection	E: 182 L: 7 DAYS	S: MILD R: REASONABLE POSSIBILITY A: ADMINISTRATION D2E7 WAS POSTPONED TO [redacted]/[redacted] THOUGH IT WAS SUPPOSED TO BE GIVEN BY [redacted]/[redacted] O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45. すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHDOL								
[redacted]	AGE:1[redacted] SEX:FEMALE RACE:MULTIPLE WEIGHT:40.8 KG							
	IND	1 TO 29	10	10	R: YEAST VAGINITIS S: Infections and infestations P: 外陰腟真菌感染 L: Yeast vaginitis	E: 26 L: 17 DAYS	S: MILD R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45.　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHDOL-MHD								
[redacted]	AGE:1[redacted]	SEX:MALE	RACE:WHITE	WEIGHT:48.8 KG				
	IND	1 TO 56	26	26	R: BRONCHITIS S: Infections and infestations P: 気管支炎 L: Bronchitis	E: 33 L: 8 DAYS	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE HOLD TILL THE END OF AE O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45.　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD-MPL								
[redacted]	AGE:1[redacted] SEX:MALE RACE:ASIAN WEIGHT:92.9 KG							
	MNT	57 TO 358	35	91	R: VIRAL RESPIRATORY INFECTION WITH WHEEZE S: Infections and infestations P: ウイルス性気道感染 L: Respiratory tract infection viral	E: 91 L: 1 DAY	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	M: NO S: NO

表 2.7.4.7-45. すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted]([redacted]) TRT: IHDOL-MHD-FNREIND								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:97.4 KG								
	MNT	57 TO 107	19	75 &	R: FLU S: Infections and infestations P: インフルエンザ L: Flu	E: 127 L: 53 DAYS I: YES	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45. すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	------ Epoch ---- Name	Interval	Rx Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted] TRT: IHD-MHD								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:67.0 KG								
	MNT	57 TO 411	138	194	R: COLD S: Infections and infestations P: 上咽頭炎 L: Cold	E: 196 L: 3 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO
	MNT	57 TO 411	329	385	R: INFECTED SACRAL CYST S: Infections and infestations P: 感染性嚢腫 L: Infected cyst	E: 412 L: 28 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45.　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MSD								
[redacted]	AGE:1[redacted]	SEX:MALE	RACE:WHITE	WEIGHT:31.5 KG				
	MNT	56 TO 357	175	230	R: COMMON COLD S: Infections and infestations P: 上咽頭炎 L: Common cold	E: 233 L: 4 DAYS	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	M: NO S: NO

表 2.7.4.7-45.　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] TRT: IHD-MHD-FNREIND								
[redacted] AGE:1[redacted] SEX:MALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:68.1 KG								
	IND	1 TO 55	27	27	R: UPPER RESPIRATORY INFECTION S: Infections and infestations P: 上気道感染 L: Upper respiratory infection	E: 37 L: 11 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45.　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] TRT: IHD-MHD-FNREIND								
[redacted]	AGE:1[redacted] SEX:MALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:68.1 KG							
	IND	1 TO 55	54	54	R: UPPER RESPIRATORY INFECTION S: Infections and infestations P: 上気道感染 L: Upper respiratory infection	E: 62 L: 9 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45. すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted]([redacted]) TRT: IHDOL-MSD-FREIND								
[redacted]	AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:52.8 KG							
	IND	1 TO 56	41	41	R: STREP S: Infections and infestations P: レンサ球菌感染 L: Streptococcal infection	E: 51 L: 11 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO
	FLARE	127 TO 219	37	163	R: STREP S: Infections and infestations P: レンサ球菌感染 L: Streptococcal infection	E: 166 L: 4 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45. すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHDOL-MSD-FREIND								
[redacted]	AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:52.8 KG							
	FLARE	127 TO 219	93	219	R: CYTOMEGALOVIRUS (CMV) ILEOCOLITIS S: Infections and infestations P: サイトメガロウイルス性腸炎 L: Cytomegalovirus enterocolitis	E: 243 L: 25 DAYS	S: SEVERE R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO
	FU	220 TO	27	246	R: C. DIFFICILE S: Infections and infestations P: クロストリジウム・ディフィシレ感染 L: Clostridium difficile infection	O: YES	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45. すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	------ Epoch ---- Name	Interval	Rx Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD-MSD								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:91.6 KG								
	MNT	59 TO 360	25	83	R: PHARYNGITIS ACUTA S: Infections and infestations P: 咽頭炎 L: Acute pharyngitis	E: 98 L: 16 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO
	MNT	59 TO 360	295	353	R: ACUTE RESPIRATORY INFECTION S: Infections and infestations P: 気道感染 L: Respiratory infection	E: 386 L: 34 DAYS I: YES	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45. すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted]([redacted]) TRT: IHD-MSD								
[redacted]	AGE:1[redacted]	SEX:MALE	RACE:WHITE	WEIGHT:53.0 KG				
	MNT	58 TO 357	75	132	R: TRACHEITIS ACUTA S: Infections and infestations P: 気管炎 L: Acute tracheitis	E: 136 L: 5 DAYS	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO
	MNT	58 TO 357	219	276	R: PITYRIASIS VERSICOLOR S: Infections and infestations P: 癜風 L: Pityriasis versicolor	O: YES	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45. すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch	Interval	Rx Day of Onset	Day	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] TRT: IHD-MHD									
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:43.0 KG									
	MNT	57 TO 365	134	190		R: PHARYNGITIS ACUTA S: Infections and infestations P: 咽頭炎 L: Acute pharyngitis	E: 195 L: 6 DAYS I: YES	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UC A: REASONABLE POSSIBILITY ADJ: All cause hospitalization

表 2.7.4.7-45.　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] TRT: IHD-MSD-FNREIND								
[redacted]	AGE:1[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:33.9 KG				
	MNT	60 TO 273	28	87	R: RHINOPHARYNGITIS ACUTA S: Infections and infestations P: 上咽頭炎 L: Acute nasopharyngitis	E: 107 L: 21 DAYS I: YES	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO
	MNT	60 TO 273	48	107	R: BRONCHITIS ACUTA S: Infections and infestations P: 気管支炎 L: Acute bronchitis	E: 118 L: 12 DAYS I: YES	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45.　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted]([redacted]) TRT: IHD-MSD-FNREIND								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:33.9 KG								
	MNT	60 TO 273	173	232	R: RHINOPHARYNGITIS ACUTA S: Infections and infestations P: 上咽頭炎 L: Acute nasopharyngitis	E: 243 L: 12 DAYS I: YES	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO
INV: [redacted] [redacted]) TRT: IHDOL-MSD-FREIND								
[redacted] AGE:1[redacted] SEX:MALE RACE:ASIAN WEIGHT:53.5 KG								
	FLARE	105 TO 253	4	108	R: INFECTIOUS ENTERITIS S: Infections and infestations P: 感染性腸炎 L: Enteritis infectious	E: 128 L: 21 DAYS	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45.　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted]([redacted]) TRT: IHD-MHD								
[redacted]	AGE:1[redacted]	SEX:MALE	RACE:ASIAN	WEIGHT:38.7 KG				
	IND	1 TO 56	2	2	R: UPPER RESPIRATORY INFECTION S: Infections and infestations P: 上気道感染 L: Upper respiratory infection	E: 57 L: 56 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45.　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted]([redacted]) TRT: IHD-MHD								
[redacted] AGE:1[redacted] SEX:MALE RACE:ASIAN WEIGHT:38.7 KG								
	MNT	57 TO 358	174	230	R: UPPER RESPIRATORY INFECTION S: Infections and infestations P: 上気道感染 L: Upper respiratory infection	E: 239 L: 10 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45. すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MHD-FNREIND								
[redacted] AGE:1[redacted] SEX:MALE RACE:ASIAN WEIGHT:51.2 KG								
	IND	1 TO 57	8	8	R: OTITIS EXTERNA S: Infections and infestations P: 外耳炎 L: Otitis externa	E: 58 L: 51 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO
	MNT	58 TO 182	7	64	R: IMPETIGO S: Infections and infestations P: 膿痂疹 L: Impetigo	E: 339 L: 276 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45.　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MHD-FNREIND								
[redacted]	AGE:1[redacted]	SEX:MALE	RACE:ASIAN	WEIGHT:51.2 KG				
	FLARE	183 TO 358	112	294	R: COMMON COLD S: Infections and infestations P: 上咽頭炎 L: Common cold	E: 304 L: 11 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45. すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MSD-FREIND								
[redacted] AGE:1[redacted] SEX:MALE RACE:ASIAN WEIGHT:51.6 KG								
	IND	1 TO 56	22	22	R: UPPER RESPIRATORY INFECTION S: Infections and infestations P: 上気道感染 L: Upper respiratory infection	E: 25 L: 4 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-45. すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	----- Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted] TRT: IHD-MSD-FREIND								
[redacted]	AGE:1[redacted]	SEX:MALE	RACE:ASIAN	WEIGHT:51.6 KG				
	MNT	57 TO 119	32	88	R: ENTERITIS INFECTIOUS S: Infections and infestations P: 感染性腸炎 L: Enteritis infectious	E: 90 L: 3 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ACCIDENTAL EVENT A: REASONABLE POSSIBILITY ADJ: All cause hospitalization
	FLARE	120 TO 355	140	259	R: COMMON COLD S: Infections and infestations P: 上咽頭炎 L: Common cold	E: 272 L: 14 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	M: NO S: NO

表 2.7.4.7-45. すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MSD-FREIND								
[redacted]	AGE:1[redacted] SEX:MALE RACE:ASIAN WEIGHT:51.6 KG							
	FU	356 TO	1	356	R: ACUTE PHARYNGITIS S: Infections and infestations P: 咽頭炎 L: Acute pharyngitis	E: 361 L: 6 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO
INV: [redacted] [redacted]) TRT: IHD-MHD								
[redacted]	AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:62.0 KG							
	MNT	57 TO 364	5	61	R: ASEPTIC MENINGITIS S: Infections and infestations P: 無菌性髄膜炎 L: Aseptic meningitis	E: 67 L: 7 DAYS	S: SEVERE R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: REASONABLE POSSIBILITY ADJ: All cause hospitalization

表 2.7.4.7-45.　　すべての感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
IND = Induction Period, MNT = Maintenance Period, FLARE = Flare Period, FU=Follow-up.
# Subject prematurely discontinued.
& Date is estimated.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.3__2.5.6.1_A

表 2.7.4.7-46.　すべての感染症（MedDRA SOC 及び PT 別）（統合 FAS 集団，M10-870 試験）

MedDRA 22.0 System Organ Class Preferred Term	Adalimumab (N=59) n (%)
Any adverse event	24 (40.7)
感染症および寄生虫症	24 (40.7)
肛門膿瘍	1 (1.7)
気管支炎	3 (5.1)
ウイルス性胃腸炎	2 (3.4)
帯状疱疹	2 (3.4)
膿痂疹	1 (1.7)
上咽頭炎	5 (8.5)
口腔ヘルペス	1 (1.7)
中耳炎	1 (1.7)
咽頭炎	4 (6.8)
敗血症	1 (1.7)
副鼻腔炎	1 (1.7)
レンサ球菌感染	1 (1.7)
歯膿瘍	1 (1.7)
上気道感染	7 (11.9)
尿路感染	2 (3.4)
ウイルス感染	2 (3.4)
ウイルス性上気道感染	2 (3.4)
外陰腟炎	1 (1.7)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Cross reference: M10-870 Japan Sub-study CSR_Interim Table 14.3__2.4.1_A

表 2.7.4.7-47.　　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EOW							
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:59.1 KG							
	TRT	1 TO 916	743 743	R: VULVOVAGINITIS S: Infections and infestations P: 外陰腟炎 L: Vulvovaginitis	E: 757 L: 15 DAYS I: YES	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB 40 MG EOW								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:86.6 KG								
	TRT	1 TO 602	63	63	R: UPPER RESPIRATORY TRACT INFECTION S: Infections and infestations P: 上気道感染 L: Upper respiratory tract infection	E: 69 L: 7 DAYS I: YES	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB 40 MG EOW								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:51.1 KG								
	TRT	1 TO 433	131	131	R: OTITIS MEDIA S: Infections and infestations P: 中耳炎 L: Otitis media	E: 139 L: 9 DAYS I: YES	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EOW								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:51.1 KG								
	TRT	1 TO 433	162	162	R: PERIDENTAL ABSCESS S: Infections and infestations P: 歯膿瘍 L: Periodontal abscess	E: 167 L: 6 DAYS	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION PRESCRIBED, EVACUATION OF THE ABSCESS BY THE DENTISTRY ([redacted]20[redacted] AND [redacted]20[redacted])) C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EOW								
[redacted]	AGE:1[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:51.1 KG				
	TRT	1 TO 433	198	198	R: UPPER RESPIRATORY TRACT INFECTION S: Infections and infestations P: 上気道感染 L: Upper respiratory tract infection	E: 203 L: 6 DAYS I: YES	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EOW							
[redacted]	AGE:1[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:51.1 KG			
	TRT	1 TO 433	229 229	R: SINUSITIS S: Infections and infestations P: 副鼻腔炎 L: Sinusitis	E: 236 L: 8 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB 40 MG EW								
[redacted] AGE:[redacted] SEX:MALE RACE:WHITE WEIGHT:23.8 KG								
	TRT	1 TO 586	152	152	R: BRONCHITIS S: Infections and infestations P: 気管支炎 L: Bronchitis	E: 162 L: 11 DAYS	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION A: REASONABLE POSSIBILITY

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EOW								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:67.5 KG								
	TRT	1 TO 995+	16	16	R: HERPES LABIALIS S: Infections and infestations P: 口腔ヘルペス L: Herpes labialis	E: 18 L: 3 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB 40 MG EOW							
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:67.5 KG							
	TRT	1 TO 995+	29	29			
				R: URINARY TRACT INFECTION S: Infections and infestations P: 尿路感染 L: Urinary tract infection	E: 35 L: 7 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB 40 MG EOW							
[redacted]	AGE:1[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:67.5 KG			
	TRT	1 TO 995+	45	45 R: HERPES ON THE LIP S: Infections and infestations P: 口腔ヘルペス L: Herpes on lip	E: 49 L: 5 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO
			79	79 R: COMMON COLD S: Infections and infestations P: 上咽頭炎 L: Common cold	E: 79 L: 1 DAY	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	Name	Epoch	Rx Day of Onset	Day	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB 40 MG EOW								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:67.5 KG								
	TRT	1 TO 995+	154	154	R: HERPES LABIALIS S: Infections and infestations P: 口腔ヘルペス L: Herpes labialis	E: 156 L: 3 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB 40 MG EOW								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:67.5 KG								
	TRT	1 TO 995+	313	313	R: VIRAL GASTROENTERITIS S: Infections and infestations P: ウイルス性胃腸炎 L: Viral gastroenteritis	E: 336 L: 24 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EOW								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:67.5 KG								
	TRT	1 TO 995+	388	388	R: UPPER RESPIRATORY VIRAL INFECTION S: Infections and infestations P: ウイルス性上気道感染 L: Viral upper respiratory tract infection	E: 395 L: 8 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB 40 MG EOW								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:67.5 KG								
	TRT	1 TO 995+	391	391	R: HERPES LABIALIS S: Infections and infestations P: 口腔ヘルペス L: Herpes labialis	E: 397 L: 7 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO
			754	754	R: COLD S: Infections and infestations P: 上咽頭炎 L: Cold	E: 757 L: 4 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of ----- Day	Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB 40 MG EOW								
[redacted]	AGE:1[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:67.5 KG				
	TRT	1 TO 995+	756	756	R: HERPES ON THE LIP S: Infections and infestations P: 口腔ヘルペス L: Herpes on lip	E: 762 L: 7 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO
[redacted]	AGE:1[redacted]	SEX:MALE	RACE:WHITE	WEIGHT:68.0 KG				
	TRT	1 TO 590+	39	39	R: PHARYNGITIS S: Infections and infestations P: 咽頭炎 L: Pharyngitis	E: 44 L: 6 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EOW								
[redacted] AGE: [redacted] SEX:MALE RACE:WHITE WEIGHT:17.4 KG								
	TRT	1 TO 377	163	163	R: BRONCHITIS S: Infections and infestations P: 気管支炎 L: Bronchitis	E: 168 L: 6 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EOW							
[redacted]	AGE:1[redacted]	SEX:MALE	RACE:WHITE	WEIGHT:110.0 KG			
	TRT	1 TO 275+	81	81	E: 83 L: 3 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO
				R: VIRAL UPPER RESPIRATORY TRACT INFECTION S: Infections and infestations P: ウイルス性上気道感染 L: Viral upper respiratory tract infection			

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EOW							
[redacted] AGE:[redacted] SEX:FEMALE RACE:WHITE WEIGHT:24.0 KG							
	TRT	1 TO 182	99 99	R: PHARYNGITIS S: Infections and infestations P: 咽頭炎 L: Pharyngitis	E: 120 L: 22 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB 40 MG EOW								
[redacted]	AGE:1[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:95.0 KG				
	TRT	1 TO 939	22	22	R: URINARY TRACT INFECTION S: Infections and infestations P: 尿路感染 L: Urinary tract infection	E: 27 L: 6 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] TRT: ADALIMUMAB 40 MG EOW								
[redacted]	AGE:1[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:95.0 KG				
	TRT	1 TO 939	170	170	R: URINARY TRACT INFECTION S: Infections and infestations P: 尿路感染 L: Urinary tract infection	E: 350 L: 181 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB 40 MG EOW								
[redacted]	AGE:1[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:95.0 KG				
	TRT	1 TO 939	501	501	R: URINARY TRACT INFECTION S: Infections and infestations P: 尿路感染 L: Urinary tract infection	E: 754 L: 254 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB 40 MG EOW								
[redacted]	AGE:1[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:95.0 KG				
	TRT	1 TO 939	838	838	R: URINARY TRACT INFECTION S: Infections and infestations P: 尿路感染 L: Urinary tract infection	E: 906 L: 69 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EOW								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:64.0 KG								
	TRT	1 TO 826	743	743	R: UPPER RESPIRATORY TRACT INFECTION S: Infections and infestations P: 上気道感染 L: Upper respiratory tract infection	E: 755 L: 13 DAYS	S: MILD R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EOW								
[redacted]	AGE:1[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:67.0 KG				
	TRT	1 TO 323	118	118	R: SHINGLES S: Infections and infestations P: 帯状疱疹 L: Shingles	E: 124 L: 7 DAYS	S: MILD R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EOW								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:76.0 KG								
	TRT	1 TO 573	78	78	R: UPPER RESPIRATORY TRACT INFECTION S: Infections and infestations P: 上気道感染 L: Upper respiratory tract infection	E: 84 L: 7 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB 40 MG EOW								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:76.0 KG								
	TRT	1 TO 573	135	135	R: UPPER RESPIRATORY TRACT INFECTION S: Infections and infestations P: 上気道感染 L: Upper respiratory tract infection	E: 142 L: 8 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	Name	Epoch	Interval	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EOW								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:76.0 KG								
	TRT	1 TO 573	433	433	R: UPPER RESPIRATORY TRACT INFECTION S: Infections and infestations P: 上気道感染 L: Upper respiratory tract infection	E: 440 L: 8 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Day	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EOW								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:70.0 KG								
	TRT	1 TO 280+	166	166	R: UPPER RESPIRATORY TRACT INFECTION S: Infections and infestations P: 上気道感染 L: Upper respiratory tract infection	E: 171 L: 6 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: POSPONED DRUG TODAY O: NONE C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB 40 MG EOW							
[redacted] AGE:1[redacted] SEX:MALE RACE:ASIAN WEIGHT:48.9 KG							
	TRT	1 TO 402	68 68	R: PHARYNGITIS S: Infections and infestations P: 咽頭炎 L: Pharyngitis	E: 79 L: 12 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB 40 MG EOW								
[redacted] AGE:1[redacted] SEX:MALE RACE:ASIAN WEIGHT:48.9 KG								
	TRT	1 TO 402	246	246	R: UPPER RESPIRATORY INFECTION S: Infections and infestations P: 上気道感染 L: Upper respiratory infection	E: 259 L: 14 DAYS	S: MILD R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] TRT: ADALIMUMAB 40 MG EOW								
[redacted]	AGE:1[redacted]	SEX:MALE	RACE:ASIAN	WEIGHT:48.9 KG				
	FU	403 TO	59	461	R: UPPER RESPIRATORY INFECTION S: Infections and infestations P: 上気道感染 L: Upper respiratory infection	O: YES	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EOW								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:79.4 KG								
	TRT	1 TO 1176	468	468	R: PERIANAL ABSCESS S: Infections and infestations P: 肛門膿瘍 L: Perianal abscess	E: 475 L: 8 DAYS I: YES	S: MILD R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION PRESCRIBED, CONCOMITANT MEDICATION DISCONTINUED) C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EW								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:103.0 KG								
	TRT	1 TO 59	27	27	R: UPPER RESPIRATORY TRACT INFECTION S: Infections and infestations P: 上気道感染 L: Upper respiratory tract infection	E: 31 L: 5 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EOW								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:34.5 KG								
	TRT	1 TO 653+	71	71	R: STOMACH FLU S: Infections and infestations P: ウイルス性胃腸炎 L: Stomach flu	E: 72 L: 2 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: STAYED HOME FROM SCHOOL TO REST. C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EOW								
[redacted]	AGE:1[redacted]	SEX:MALE	RACE:WHITE	WEIGHT:34.5 KG				
	TRT	1 TO 653+	329	329	R: VIRAL ILLNESS S: Infections and infestations P: ウイルス感染 L: Viral infection	E: 331 L: 3 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE C: NO	M: NO S: NO
			581	581	R: VIRAL ILLNESS S: Infections and infestations P: ウイルス感染 L: Viral infection	E: 582 L: 2 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE C: NO	M: NO S: NO

表 2.7.4.7-47.　　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	Name	Epoch	Interval	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB 40 MG EW								
[redacted] AGE:1[redacted] SEX:MALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:67.2 KG								
	TRT	1 TO 173	51	51	R: VIRAL SYNDROME S: Infections and infestations P: ウイルス感染 L: Viral syndrome	E: 64 L: 14 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: SUBJECT TOOK OTC MUCINEX C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB 40 MG EOW								
[redacted]	AGE:1[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:30.7 KG				
	TRT	1 TO 223	133	133	R: RHINOPHARYNGITIS S: Infections and infestations P: 上咽頭炎 L: Rhinopharyngitis	E: 154 L: 22 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB 40 MG EOW							
[redacted]	AGE:1[redacted]	SEX:MALE	RACE:WHITE	WEIGHT:86.4 KG			
	TRT	1 TO 1057	21	21	E: 57 L: 37 DAYS I: YES	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO
				R: BRONCHITIS ACUTA S: Infections and infestations P: 気管支炎 L: Acute bronchitis			

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EOW								
[redacted]	AGE:1[redacted]	SEX:MALE	RACE:WHITE	WEIGHT:86.4 KG				
	TRT	1 TO 1057	163	163	R: RHINOPHARYNGITIS S: Infections and infestations P: 上咽頭炎 L: Rhinopharyngitis	E: 190 L: 28 DAYS	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB 40 MG EOW								
[redacted] AGE:1[redacted] SEX:MALE RACE:ASIAN WEIGHT:44.9 KG								
	TRT	1 TO 669	337	337	N: 3 R: COMMON COLD S: Infections and infestations P: 上咽頭炎 L: Common cold	E: 342 L: 6 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EOW								
[redacted] AGE:1[redacted] SEX:MALE RACE:ASIAN WEIGHT:44.9 KG								
	TRT	1 TO 669	587	587	N: 5 R: STREPTOCOCCAL INFECTION S: Infections and infestations P: レンサ球菌感染 L: Streptococcal infection	E: 591 L: 5 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EW								
[redacted]	AGE:1[redacted] SEX:MALE RACE:ASIAN WEIGHT:60.2 KG							
	TRT	1 TO 346	54	54	R: IMPETIGO S: Infections and infestations P: 膿痂疹 L: Impetigo	O: YES	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EW								
[redacted]	AGE:1[redacted]	SEX:MALE	RACE:ASIAN	WEIGHT:60.2 KG				
	TRT	1 TO 346	318	318	R: COMMON COLD S: Infections and infestations P: 上咽頭炎 L: Common cold	E: 321 L: 4 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE C: NO	M: NO S: NO
	FU	347 TO	63	409	R: SEPSIS S: Infections and infestations P: 敗血症 L: Sepsis	E: 425 L: 17 DAYS	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION A: NO REASONABLE POSSIBILITY

表 2.7.4.7-47.　すべての感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted] TRT: ADALIMUMAB 40 MG EW								
[redacted]	AGE:1[redacted]	SEX:MALE	RACE:ASIAN	WEIGHT:58.9 KG				
	TRT	1 TO 195	114	114	R: HERPES ZOSTER S: Infections and infestations P: 帯状疱疹 L: Herpes zoster	E: 125 L: 12 DAYS	S: MILD R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO
			137	137	R: ACUTE PHARYNGITIS S: Infections and infestations P: 咽頭炎 L: Acute pharyngitis	E: 143 L: 7 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

TRT = OPEN LABEL TREATMENT, FU = FOLLOW-UP.
# Subject prematurely discontinued.
+ Subject is ongoing.

Cross reference: M10-870 Japan Sub-study CSR_Interim Table 14.3__2.5.6.1_A

表 2.7.4.7-48.　維持療法期中に発現した重篤な感染症（MedDRA SOC 及び PT 別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）

MedDRA 22.0 System Organ Class Preferred Term	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
Any adverse event	3 (9.1)	3 (8.6)	6 (8.8)	0	6 (7.5)
感染症および寄生虫症	3 (9.1)	3 (8.6)	6 (8.8)	0	6 (7.5)
感染性腸炎	1 (3.0)	0	1 (1.5)	0	1 (1.3)
胃腸炎	2 (6.1)	0	2 (2.9)	0	2 (2.5)
無菌性髄膜炎	0	1 (2.9)	1 (1.5)	0	1 (1.3)
咽頭炎	0	1 (2.9)	1 (1.5)	0	1 (1.3)
尿路感染	0	1 (2.9)	1 (1.5)	0	1 (1.3)

One patient ([redacted] who is ongoing study is excluded from interim analysis.
M-PL = maintenance placebo group; M-SD = maintenance standard dose group; M-HD = maintenance high dose group;
Note: 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__2.4.2.2_A

表 2.7.4.7-49.　　重篤な感染症の一覧（統合安全性解析対象集団，M11-290 試験）

Subject Number	------ Epoch ---- Name	Interval	Rx Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted]([redacted]) TRT: IHDOL-MHD								
[redacted]	AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:31.1 KG							
	MNT	57 TO 267	9	65	R: URINAL TRACT INFECTION S: Infections and infestations P: 尿路感染 L: Urinary tract infection	E: 72 L: 8 DAYS	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: THAT WAS URINARY TRACT INFECTION, THERE WAS NO CAUSE FOUND. A: REASONABLE POSSIBILITY ADJ: All cause hospitalization

表 2.7.4.7-49. 重篤な感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted]([redacted]) TRT: ISD-MSD								
[redacted]	AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:62.8 KG							
	MNT	56 TO 119	13	68	R: ACUTE GASTROENTERITIS S: Infections and infestations P: 胃腸炎 L: Acute gastroenteritis	E: 72 L: 5 DAYS	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: HOSPITALIZATION	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ACQUIRED VIRAL OR BACTERIAL INFECTION, REACTIVATION OF UC A: REASONABLE POSSIBILITY ADJ: All cause hospitalization

表 2.7.4.7-49. 重篤な感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MSD								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:43.8 KG								
	MNT	57 TO 128	56	112	R: ACUTE GASTROENTERITIS S: Infections and infestations P: 胃腸炎 L: Acute gastroenteritis	E: 120 L: 9 DAYS	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: ACUTE GASTROENTERITIS DUE TO VIRAL OR BACTERIAL INFECTION OR RELAPS OF UC A: NO REASONABLE POSSIBILITY ADJ: All cause hospitalization

表 2.7.4.7-49. 重篤な感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted]([redacted]) TRT: IHD-MHD								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:43.0 KG								
	MNT	57 TO 365	134	190	R: PHARYNGITIS ACUTA S: Infections and infestations P: 咽頭炎 L: Acute pharyngitis	E: 195 L: 6 DAYS I: YES	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UC A: REASONABLE POSSIBILITY ADJ: All cause hospitalization

表 2.7.4.7-49. 重篤な感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MSD-FREIND								
[redacted]	AGE:1[redacted] SEX:MALE RACE:ASIAN WEIGHT:51.6 KG							
	MNT	57 TO 119	32	88	R: ENTERITIS INFECTIOUS S: Infections and infestations P: 感染性腸炎 L: Enteritis infectious	E: 90 L: 3 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: ACCIDENTAL EVENT A: REASONABLE POSSIBILITY ADJ: All cause hospitalization

表 2.7.4.7-49.　　重篤な感染症の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MHD								
[redacted]	AGE:1[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:62.0 KG				
[redacted]	MNT	57 TO 364	5	61	R: ASEPTIC MENINGITIS S: Infections and infestations P: 無菌性髄膜炎 L: Aseptic meningitis	E: 67 L: 7 DAYS	S: SEVERE R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: REASONABLE POSSIBILITY ADJ: All cause hospitalization

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
IND = Induction Period, MNT = Maintenance Period, FLARE = Flare Period, FU=Follow-up.
# Subject prematurely discontinued.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.3__2.5.6.2_A

表 2.7.4.7-50.　　重篤な感染症の一覧（統合 FAS 集団，M10-870 試験）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EW								
[redacted]# AGE:[redacted] SEX:MALE RACE:WHITE WEIGHT:23.8 KG								
	TRT	1 TO 586	152	152	R: BRONCHITIS S: Infections and infestations P: 気管支炎 L: Bronchitis	E: 162 L: 11 DAYS	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION A: REASONABLE POSSIBILITY

表 2.7.4.7-50.　　重篤な感染症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of ----- Day	Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EW								
[redacted]# AGE:1[redacted] SEX:MALE RACE:ASIAN WEIGHT:60.2 KG								
[redacted]	FU	347 TO	63	409	R: SEPSIS S: Infections and infestations P: 敗血症 L: Sepsis	E: 425 L: 17 DAYS	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INFECTION A: NO REASONABLE POSSIBILITY

TRT = OPEN LABEL TREATMENT, FU = FOLLOW-UP.
# Subject prematurely discontinued.

Cross reference: M10-870 Japan Sub-study CSR_Interim Table 14.3__2.5.6.2_A

表 2.7.4.7-51.　口腔カンジダ症及び結核を除く日和見感染症の一覧（統合安全性解析対象集団，M11-290 試験）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHDOL-MSD-FREIND								
[redacted]# AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:52.8 KG								
	FLARE	127 TO 219	93	219	R: CYTOMEGALOVIRUS (CMV) ILEOCOLITIS S: Infections and infestations P: サイトメガロウイルス性腸炎 L: Cytomegalovirus enterocolitis	E: 243 L: 25 DAYS	S: SEVERE R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
IND = Induction Period, MNT = Maintenance Period, FLARE = Flare Period, FU=Follow-up.
NOTE: TB = Tuberculosis.
Subject prematurely discontinued.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.3__2.5.6.5_A

表 2.7.4.7-52.　　潜在性結核の一覧（統合安全性解析対象集団，M11-290 試験）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MHD								
[redacted]	AGE:1[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:62.6 KG				
	FU	359 TO	6	364	R: POSITIVE QUANTIFERON TB GOLD TEST WITHOUT CLINICAL SYMPTOMS OF TB INFECTION S: Investigations P: 結核菌群検査陽性 L: Tuberculosis test positive	O: YES I: YES	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
IND = Induction Period, MNT = Maintenance Period, FLARE = Flare Period, FU=Follow-up.
NOTE: TB = Tuberculosis.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.3__2.5.6.7.3_A

表 2.7.4.7-53.　　潜在性結核の一覧（統合 FAS 集団，M10-870 試験）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EO							
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:86.6 KG							
	TRT	1 TO 602	343 343	R: POSITIVE RESULT OF QUANTIFERN TB TEST S: Investigations P: 結核菌群検査陽性 L: Tuberculosis test positive	O: YES I: YES	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

表 2.7.4.7-53.　　潜在性結核の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]) TRT: ADALIMUMAB 40 MG EW							
[redacted]# AGE:[redacted] SEX:MALE RACE:WHITE WEIGHT:23.8 KG							
	TRT	1 TO 586	21 21	R: QTF POSITIVE WITHOUT TB SYMPTOMS S: Investigations P: 結核菌群検査陽性 L: Tuberculosis test positive	E: 22 L: 2 DAYS	S: MILD R: REASONABLE POSSIBILITY A: THE SUBJECT DIDNT RECEIVE THE STUDY DRUG UNTIL CHEMOPROPHYLAXYS.THE CHEMOPROPHYLAXYX IS PLANNED FROM [redacted] O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

表 2.7.4.7-53.　　潜在性結核の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	----- Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted]([redacted]) TRT: ADALIMUMAB 40 MG E								
[redacted]# AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:95.0 KG								
	TRT	1 TO 939	30	30	R: POSITIVE QUANTIFERON TB GOLD TEST RESULT S: Investigations P: 結核菌群検査陽性 L: Tuberculosis test positive	O: YES	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

表 2.7.4.7-53.　　潜在性結核の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG E								
[redacted]# AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:51.0 KG								
	FU	665 TO	8	672	R: POSITIVE QTF S: Investigations P: 結核菌群検査陽性 L: Tuberculosis test positive	O: YES	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE C: NO	M: NO S: NO

TRT = OPEN LABEL TREATMENT, FU = FOLLOW-UP.
NOTE: TB = Tuberculosis.
Subject prematurely discontinued.

Cross reference: M10-870 Japan Sub-study CSR_Interim Table 14.3__2.5.6.7.3_A

表 2.7.4.7-54.　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（統合安全性解析対象集団，M11-290 試験）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD-MHD								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:38.5 KG								
	MNT	57 TO 358	127	183	R: URTICARIA AT INJECTION SITE S: General disorders and administration site conditions P: 注射部位蕁麻疹 L: Urticaria injection site	E: 183 L: 1 DAY	S: MILD R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-54. 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（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	----- Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted]([redacted]) TRT: IHD-MSD								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:53.0 KG								
	MNT	58 TO 357	28	85	R: FACIAL EXANTHEM S: Skin and subcutaneous tissue disorders P: 発疹 L: Exanthema facial	E: 126 L: 42 DAYS I: YES	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	M: NO S: NO
	MNT	58 TO 357	144	201	R: ALLERGIC ASTHMA S: Respiratory, thoracic and mediastinal disorders P: 喘息 L: Allergic asthma	O: YES	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-54. 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（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Epoch Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MSD								
[redacted]# AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:53.5 KG								
	IND	1 TO 59	13	13	R: INJECTION SITE REACTION - RAISED, RED, WELTS X 4 S: General disorders and administration site conditions P: 注射部位蕁麻疹 L: Injection site urticaria	E: 18 L: 6 DAYS	S: MILD R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	M: NO S: NO

表 2.7.4.7-54.　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（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MHD								
[redacted]	AGE:1[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:62.0 KG				
	MNT	57 TO 364	5	61	R: ALLERGIC REACTION TO GABAPENTIN S: Immune system disorders P: 薬物過敏症 L: Specific allergy (drug)	E: 91 L: 31 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION DISCONTINUED	M: NO S: NO

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
IND = Induction Period, MNT = Maintenance Period, FLARE = Flare Period, FU=Follow-up.
# Subject prematurely discontinued.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.3__2.5.8.1_A

表 2.7.4.7-55.　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（統合 FAS 集団，M10-870 試験）

Subject Number	------ Name	Epoch ---- Interval	----- Rx Day of Day	Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EW								
[redacted]# AGE:[redacted] SEX:MALE RACE:WHITE WEIGHT:23.8 KG								
	TRT	1 TO 586	179	179	R: BRONCHIAL ASTHMA-OBSERVATION S: Respiratory, thoracic and mediastinal disorders P: 喘息 L: Asthma bronchial	E: 182 L: 4 DAYS I: YES	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE C: NO	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: THE CAUSE OF CAUGH WAS PROBABLY ALLERGY. CAUGH WAS IN M11-290 AS AE. AND OCCASIONALLY BLOCKED NOSE. IF IT IS NECESSARY, I'LL ADD IT TO AE PROTOCOL M11-290 A: NO REASONABLE POSSIBILITY

表 2.7.4.7-55. 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（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG								
[redacted]# AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:86.4 KG								
	TRT	1 TO 1057	864	864	R: EXANTHEMA ON LEFT SHOULDER S: Skin and subcutaneous tissue disorders P: 発疹 L: Exanthema	E: 1008 L: 145 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE C: NO	M: NO S: NO

表 2.7.4.7-55. 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（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 M							
[redacted] AGE:1[redacted] SEX:MALE RACE:ASIAN WEIGHT:44.9 KG							
	TRT	1 TO 669	31	N: 1 R: URTICARIA S: Skin and subcutaneous tissue disorders P: 蕁麻疹 L: Urticaria	E: 40 L: 10 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

表 2.7.4.7-55.　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（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 M [redacted] AGE:1[redacted] SEX:MALE RACE:ASIAN WEIGHT:44.9 KG								
	TRT	1 TO 669	83	83	N: 2 R: URTICARIA S: Skin and subcutaneous tissue disorders P: 蕁麻疹 L: Urticaria	E: 84 L: 2 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

TRT = OPEN LABEL TREATMENT, FU = FOLLOW-UP.
# Subject prematurely discontinued.

Cross reference: M10-870 Japan Sub-study CSR_Interim Table 14.3__2.5.8.1_A

表 2.7.4.7-56.　膵炎の一覧（統合安全性解析対象集団，M11-290 試験）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD								
[redacted]# AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:104.2 KG								
[redacted]	FU	44 TO	22	65	R: PANCREATITIS S: Gastrointestinal disorders P: 膵炎 L: Pancreatitis	E: 79 L: 15 DAYS	S: MODERATE R: REASONABLE POSSIBILITY A: SUBJECT ALREADY DISCONTINUED STUDY DRUG DUE TO BEING A NON RESPONDER AT WEEK 8 O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: NO REASONABLE POSSIBILITY ADJ: All cause hospitalization, UC related hospitalization

One patient ([redacted] who is ongoing study is excluded from interim analysis.
IND = Induction Period, MNT = Maintenance Period, FLARE = Flare Period, FU=Follow-up.
# Subject prematurely discontinued.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.3__2.5.11.2_A

表 2.7.4.7-57.　　乾癬の悪化又は新規発症の一覧（統合安全性解析対象集団，M11-290 試験）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MPL								
[redacted]	AGE:1[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:47.5 KG				
	MNT	57 TO 365	72	128	R: PSORIASIS S: Skin and subcutaneous tissue disorders P: 乾癬 L: Psoriasis	E: 147 L: 20 DAYS	S: MILD R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION A: REASONABLE POSSIBILITY ADJ: All cause hospitalization

One patient ([redacted] who is ongoing study is excluded from interim analysis.
IND = Induction Period, MNT = Maintenance Period, FLARE = Flare Period, FU=Follow-up.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.3__2.5.12.3_A

表 2.7.4.7-58. 乾癬の悪化又は新規発症の一覧（統合 FAS 集団，M10-870 試験）

Subject Number	Name	Epoch	Interval	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EOW								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:86.6 KG								
	TRT	1 TO 602	420	420	R: PSORIASIS S: Skin and subcutaneous tissue disorders P: 乾癬 L: Psoriasis	O: YES	S: MILD R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE C: NO	M: NO S: NO

表 2.7.4.7-58. 乾癬の悪化又は新規発症の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG E								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:27.0 KG								
	TRT	1 TO 1007	843	843	R: PSORIATIC RASH ON SCALP AND TORSO S: Skin and subcutaneous tissue disorders P: 乾癬様皮膚炎 L: Rash psoriaform		S: MILD R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

TRT = OPEN LABEL TREATMENT, FU = FOLLOW-UP.

Cross reference: M10-870 Japan Sub-study CSR_Interim Table 14.3__2.5.12.3_A

表 2.7.4.7-59. 導入療法期中に発現した汎血球減少症を含む血液障害（MedDRA SOC 及び PT 別）（統合安全性解析対象集団，M11-290 試験）

MedDRA 22.0 System Organ Class Preferred Term	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
Any adverse event	3 (9.4)	3 (5.9)	1 (5.9)	7 (7.0)
血液およびリンパ系障害	3 (9.4)	3 (5.9)	1 (5.9)	7 (7.0)
貧血	3 (9.4)	3 (5.9)	1 (5.9)	7 (7.0)

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
I-SD = induction standard dose group; I-HD = induction high dose group; I-HD-OL = induction high dose open-label group;
Note: 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__2.4.40.1_A

表 2.7.4.7-60.　維持療法期中に発現した汎血球減少症を含む血液障害（MedDRA SOC 及び PT 別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）

MedDRA 22.0 System Organ Class Preferred Term	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
Any adverse event	3 (9.1)	1 (2.9)	4 (5.9)	2 (16.7)	6 (7.5)
血液およびリンパ系障害	3 (9.1)	1 (2.9)	4 (5.9)	2 (16.7)	6 (7.5)
貧血	3 (9.1)	1 (2.9)	4 (5.9)	1 (8.3)	5 (6.3)
好中球減少症	0	0	0	1 (1.3)	1 (1.3)

One patient ([redacted] who is ongoing study is excluded from interim analysis.
M-PL = maintenance placebo group; M-SD = maintenance standard dose group; M-HD = maintenance high dose group;
Note: 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__2.4.40.2_A

表 2.7.4.7-61.　汎血球減少症を含む血液障害の一覧（統合安全性解析対象集団，M11-290 試験）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD-MSD								
[redacted]	AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:59.0 KG							
MNT		57 TO 358	183	239	R: WORSENING OF BLOOD ANAEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia aggravated	O: YES	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-61. 汎血球減少症を含む血液障害の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD								
[redacted]# AGE:17 SEX:MALE RACE:WHITE WEIGHT:56.0 KG								
	FU	16 TO	3	18	R: WORSENING OF ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia aggravated	E: 91 L: 74 DAYS	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION PRESCRIBED, BLOOD TRANSFUSION)	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: INTESTINAL BLEEDING A: NO REASONABLE POSSIBILITY ADJ: All cause hospitalization, UC related hospitalization

表 2.7.4.7-61. 汎血球減少症を含む血液障害の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD-MHD								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:57.0 KG								
[redacted]	MNT	57 TO 358	1	57	R: ANAEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anaemia	E: 127 L: 71 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-61. 汎血球減少症を含む血液障害の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD								
[redacted]# AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:51.0 KG								
	IND	1 TO 29	15	15	R: ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia	O: YES	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	M: NO S: NO

表 2.7.4.7-61. 汎血球減少症を含む血液障害の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHDOL-MHD								
[redacted]	AGE: [redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:20.0 KG				
	IND	1 TO 53	1	1	R: SEVERITY OF ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia aggravated	E: 124 L: 124 DAYS	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-61. 汎血球減少症を含む血液障害の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MSD								
[redacted]# AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:43.8 KG								
	MNT	57 TO 128	29	85	R: ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia	E: 87 L: 3 DAYS I: YES	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O: IS DUE TO ACUTE ENTERITIS, CONCICTENCY OF STOOL WORSENED AND NOW STOOL IS WITH BLOOD ALSO A: NO REASONABLE POSSIBILITY ADJ: All cause hospitalization

表 2.7.4.7-61. 汎血球減少症を含む血液障害の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Epoch Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MSD								
[redacted]# AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:43.8 KG								
[redacted]	MNT	57 TO 128	72	128	R: SEVERE ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia	E: 147 L: 20 DAYS	S: SEVERE R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: YES, LIFE THREATENING, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: FLARE OF UC A: NO REASONABLE POSSIBILITY ADJ: All cause hospitalization, UC related hospitalization

表 2.7.4.7-61. 汎血球減少症を含む血液障害の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MSD								
[redacted]# AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:43.8 KG								
	FU	129 TO	20	148	R: ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia	O: YES I: YES	S: MODERATE R: NO REASONABLE POSSIBILITY A: PATIENT ENDS WITH STUDY DRUG EARLIER.LAST DOSE WAS [redacted]/[redacted]/20[redacted] O: NONE	M: NO S: NO

表 2.7.4.7-61. 汎血球減少症を含む血液障害の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD								
[redacted]# AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:58.0 KG								
	IND	1 TO 43	29	29	R: ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia	E: 36 L: 8 DAYS	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION PRESCRIBED, BLOOD TRANSFUSION)	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING DISEASE A: NO REASONABLE POSSIBILITY ADJ: All cause hospitalization

表 2.7.4.7-61. 汎血球減少症を含む血液障害の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD-MPL-FNREIND							
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:60.0 KG							
[redacted]	MNT	57 TO 294	185	241	R: ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia	O: YES	S: MODERATE R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	M: NO S: NO

表 2.7.4.7-61. 汎血球減少症を含む血液障害の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD-MPL-FREIND								
[redacted]	AGE:1[redacted]	SEX:MALE	RACE:WHITE	WEIGHT:58.0 KG				
	FLARE	85 TO 359	212	296	R: ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia	O: YES	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	M: NO S: NO

表 2.7.4.7-61. 汎血球減少症を含む血液障害の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD								
[redacted]# AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:48.0 KG								
	FU	43 TO	9	51	R: ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia	E: 52 L: 2 DAYS	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-61. 汎血球減少症を含む血液障害の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	------ Epoch ---- Name	Interval	Rx Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHDOL-MSD-FNREIND								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:60.0 KG								
	MNT	57 TO 266	3	59	R: ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia	E: 128 L: 70 DAYS	S: MODERATE R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-61. 汎血球減少症を含む血液障害の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD-MPL								
[redacted] AGE:1[redacted] SEX:MALE RACE:ASIAN WEIGHT:92.9 KG								
	MNT	57 TO 358	71	127	R: NEUTROPENIA S: Blood and lymphatic system disorders P: 好中球減少症 L: Neutropenia	E: 150 L: 24 DAYS	S: MILD R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: AZATHIOPRINE DOSE REDUCED TO 75MG DAILY.	M: NO S: NO

表 2.7.4.7-61. 汎血球減少症を含む血液障害の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD-MHD								
[redacted]	AGE:1[redacted]	SEX:MALE	RACE:WHITE	WEIGHT:72.8 KG				
	IND	1 TO 56	33	33	R: ANEMIA - LOW HB LEVEL IN THE CENTAL LAB RESULT S: Blood and lymphatic system disorders P: 貧血 L: Anemia	O: YES	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-61. 汎血球減少症を含む血液障害の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MHD								
[redacted]	AGE:1[redacted]	SEX:FEMALE	RACE:WHITE	WEIGHT:67.0 KG				
	IND	1 TO 56	1	1	R: ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia	E: 3 L: 3 DAYS	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION PRESCRIBED, TRANSFUSION OF TWO CONCENTRATES OF RED BLOOD CELLS.)	M: NO S: NO

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
IND = Induction Period, MNT = Maintenance Period, FLARE = Flare Period, FU=Follow-up.
# Subject prematurely discontinued.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.3__2.5.14_A

表 2.7.4.7-62.　汎血球減少症を含む血液障害の一覧（統合 FAS 集団，M10-870 試験）

Subject Number	Name	Epoch	Interval	Rx Day of Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EOW								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:55.6 KG								
	TRT	1 TO 342	69	69	R: SEVERE BLOOD ANAEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anaemia	E: 75 L: 7 DAYS I: YES	S: SEVERE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: EXACERBATION OF ULCERATIVE COLITIS A: NO REASONABLE POSSIBILITY

表 2.7.4.7-62. 汎血球減少症を含む血液障害の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Onset	Day	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG EOW								
[redacted]# AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:67.0 KG								
	TRT	1 TO 323	164	164	R: ANEMIA S: Blood and lymphatic system disorders P: 貧血 L: Anemia	E: 256 L: 93 DAYS	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O: UNDERLYING DIAGNOSIS A: NO REASONABLE POSSIBILITY

表 2.7.4.7-62. 汎血球減少症を含む血液障害の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG								
[redacted]# AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:30.7 KG								
	TRT	1 TO 223	133	133	R: ANEMIA WORSENING S: Blood and lymphatic system disorders P: 貧血 L: Anemia aggravated	O: YES	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

表 2.7.4.7-62.　汎血球減少症を含む血液障害の一覧（統合 FAS 集団，M10-870 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	Rx Day of Day	Onset	N: AE Serial Number in M11-290 R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken C: Product Complaint?	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ADALIMUMAB 40 MG								
[redacted]# AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:86.4 KG								
	TRT	1 TO 1057	841	841	R: ANEMIA WORSENING S: Blood and lymphatic system disorders P: 貧血 L: Anemia aggravated	E: 1008 L: 168 DAYS	S: MODERATE R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED C: NO	M: NO S: NO

TRT = OPEN LABEL TREATMENT, FU = FOLLOW-UP.
# Subject prematurely discontinued.

Cross reference: M10-870 Japan Sub-study CSR_Interim Table 14.3__2.5.14_A

表 2.7.4.7-63.　導入療法期中に発現した注射部位反応（MedDRA SOC 及び PT 別）（統合安全性解析対象集団，M11-290 試験）

MedDRA 22.0 System Organ Class Preferred Term	I-SD (N=32) n (%)	I-HD (N=51) n (%)	I-HD-OL (N=17) n (%)	Total (N=100) n (%)
Any adverse event	1 (3.1)	3 (5.9)	0	4 (4.0)
一般・全身障害および投与部位の状態	1 (3.1)	3 (5.9)	0	4 (4.0)
注射部位紅斑	0	1 (2.0)	0	1 (1.0)
注射部位疼痛	1 (3.1)	1 (2.0)	0	2 (2.0)
注射部位蕁麻疹	0	1 (2.0)	0	1 (1.0)

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
I-SD = induction standard dose group; I-HD = induction high dose group; I-HD-OL = induction high dose open-label group;
Note: 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__2.4.43.1_A

表 2.7.4.7-64.　導入療法期中に発現した注射部位反応（MedDRA SOC 及び PT 別）（日本人安全性解析対象集団，M11-290 試験）

MedDRA 22.0 System Organ Class Preferred Term	I-SD (N=2) n (%)	I-HD (N=4) n (%)	I-HD-OL (N=1) n (%)	Total (N=7) n (%)
Any adverse event	1 (50.0)	1 (25.0)	0	2 (28.6)
一般・全身障害および投与部位の状態	1 (50.0)	1 (25.0)	0	2 (28.6)
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)

One patient ([redacted] who is ongoing study is excluded from interim analysis.
I-SD = induction standard dose group; I-HD = induction high dose group; I-HD-OL = induction high dose open-label group;
Note: 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__2.4.43.1_J

表 2.7.4.7-65.　維持療法期中に発現した注射部位反応（MedDRA SOC 及び PT 別）
（維持療法期中に治験薬の投与を 1 回以上受けた統合安全性解析対象集団の被験者，M11-290 試験）

MedDRA 22.0 System Organ Class Preferred Term	M-SD (N=33) n (%)	M-HD (N=35) n (%)	Total-ADA (N=68) n (%)	M-PL (N=12) n (%)	Total (N=80) n (%)
Any adverse event	4 (12.1)	2 (5.7)	6 (8.8)	0	6 (7.5)
一般・全身障害および投与部位の状態	4 (12.1)	2 (5.7)	6 (8.8)	0	6 (7.5)
注射部位紅斑	0	1 (2.9)	1 (1.5)	0	1 (1.3)
注射部位炎症	1 (3.0)	0	1 (1.5)	0	1 (1.3)
注射部位浮腫	1 (3.0)	0	1 (1.5)	0	1 (1.3)
注射部位疼痛	1 (3.0)	0	1 (1.5)	0	1 (1.3)
注射部位そう痒感	0	1 (2.9)	1 (1.5)	0	1 (1.3)
注射部位腫脹	1 (3.0)	0	1 (1.5)	0	1 (1.3)
注射部位蕁麻疹	0	1 (2.9)	1 (1.5)	0	1 (1.3)

One patient ([redacted]) who is ongoing study is excluded from interim analysis.
M-PL = maintenance placebo group; M-SD = maintenance standard dose group; M-HD = maintenance high dose group;
Note: 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__2.4.43.2_A

表 2.7.4.7-66.　　注射部位反応の一覧（統合安全性解析対象集団，M11-290 試験）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD-MSD								
[redacted]# AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:62.8 KG								
	MNT	56 TO 119	1	56	R: OEDEMA IN PLACE OF APPLICATION OF STUDY DRUG S: General disorders and administration site conditions P: 注射部位浮腫 L: Injection site oedema	E: 58 L: 3 DAYS	S: MILD R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	M: NO S: NO

表 2.7.4.7-66. 注射部位反応の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD-MSD								
[redacted]# AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:62.8 KG								
	MNT	56 TO 119	15	70	R: OEDEMA IN PLACE OF APPLICATION OF STUDY DRUG S: General disorders and administration site conditions P: 注射部位浮腫 L: Injection site oedema	E: 71 L: 2 DAYS	S: MILD R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	M: NO S: NO

表 2.7.4.7-66. 注射部位反応の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD-MSD								
[redacted]# AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:62.8 KG								
	MNT	56 TO 119	50	105	R: OEDEMA IN PLACE OF APPLICATION OF STUDY DRUG S: General disorders and administration site conditions P: 注射部位浮腫 L: Injection site oedema	E: 106 L: 2 DAYS	S: MILD R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	M: NO S: NO

表 2.7.4.7-66. 注射部位反応の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT:								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:68.0 KG								
	MNT	58 TO 359	209	266	R: INFLAMMATION OF THE SUBCUTANEOS TISSUE IN THE AREA OF DRUG INJECTION IN THE AREA OF DRUG INJECTION S: General disorders and administration site conditions P: 注射部位炎症 L: Injection site inflammation	E: 297 L: 32 DAYS	S: MODERATE R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-66. 注射部位反応の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD-MHD								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:38.5 KG								
[redacted]	MNT	57 TO 358	120	176	R: REDNESS AT THE INJECTION SITE S: General disorders and administration site conditions P: 注射部位紅斑 L: Injection site redness	E: 177 L: 2 DAYS	S: MILD R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	M: NO S: NO

表 2.7.4.7-66. 注射部位反応の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	------ Name	Epoch ---- Interval	----- Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD-MHD								
[redacted]	AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:38.5 KG							
	MNT	57 TO 358	127	183	R: URTICARIA AT INJECTION SITE S: General disorders and administration site conditions P: 注射部位蕁麻疹 L: Urticaria injection site	E: 183 L: 1 DAY	S: MILD R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION PRESCRIBED	M: NO S: NO

表 2.7.4.7-66. 注射部位反応の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MHD								
[redacted] AGE:1[redacted] SEX:MALE RACE:ASIAN WEIGHT:46.6 KG								
	IND	1 TO 59	11	11	R: REDNESS OF INJECTION SITE WHICH LAST 1DAY S: General disorders and administration site conditions P: 注射部位紅斑 L: Injection site redness	E: 79 L: 69 DAYS I: YES	S: MILD R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	M: NO S: NO

表 2.7.4.7-66.　注射部位反応の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT:								
[redacted] AGE:1[redacted] SEX:MALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:53.7 KG								
	IND	1 TO 55	13	13	R: INJECTION SITE PAIN LEFT ABDOMEN S: General disorders and administration site conditions P: 注射部位疼痛 L: Injection site pain	E: 13 L: 1 DAY	S: MODERATE R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	M: NO S: NO

表 2.7.4.7-66. 注射部位反応の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT:								
[redacted]	AGE:1[redacted] SEX:MALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:53.7 KG							
	IND	1 TO 55	27	27	R: INJECTION SITE PAIN LEFT ABDOMEN S: General disorders and administration site conditions P: 注射部位疼痛 L: Injection site pain	E: 27 L: 1 DAY	S: MILD R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	M: NO S: NO
	IND	1 TO 55	41	41	R: INJECTION SITE PAIN LEFT THIGH S: General disorders and administration site conditions P: 注射部位疼痛 L: Injection site pain	E: 41 L: 1 DAY	S: MILD R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	M: NO S: NO

表 2.7.4.7-66. 注射部位反応の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MSD								
[redacted]	AGE:1[redacted]	SEX:MALE	RACE:WHITE	WEIGHT:31.5 KG				
MNT		56 TO 357	53	108	R: SWELLING OF ARM AFTER GARDASIL SHOT S: General disorders and administration site conditions P: 注射部位腫脹 L: Injection site swelling	E: 108 L: 1 DAY	S: MILD R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	M: NO S: NO

表 2.7.4.7-66.　注射部位反応の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHDOL-MSD								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:50.1 KG								
	MNT	57 TO 358	64	120	R: INJECTION SITE PAIN S: General disorders and administration site conditions P: 注射部位疼痛 L: Injection site pain	E: 120 L: 1 DAY	S: MILD R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	M: NO S: NO

表 2.7.4.7-66. 注射部位反応の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: ISD								
[redacted]# AGE:1[redacted] SEX:MALE RACE:ASIAN WEIGHT:49.5 KG								
	IND	1	1	1	R: INJECTION SITE PAIN S: General disorders and administration site conditions P: 注射部位疼痛 L: Injection site pain	E: 1 L: 1 DAY I: YES	S: MODERATE R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION PRESCRIBED, COOLING)	M: NO S: NO

表 2.7.4.7-66. 注射部位反応の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day of Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MSD								
[redacted]# AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:53.5 KG								
	IND	1 TO 59	13	13	R: INJECTION SITE REACTION - RAISED, RED, WELTS X 4 S: General disorders and administration site conditions P: 注射部位蕁麻疹 L: Injection site urticaria	E: 18 L: 6 DAYS	S: MILD R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	M: NO S: NO

表 2.7.4.7-66.　　注射部位反応の一覧（統合安全性解析対象集団，M11-290 試験）（続き）

Subject Number	Name	Epoch Interval	Rx Day	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.0 Preferred Term L: Lower Level Term	E: Rx Day ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity R: Relationship to Study Drug A: Action Taken with Study Treatment O: Other Actions Taken	M: Malignancy? S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality ADJ: Adjudicated Event
INV: [redacted] ([redacted]) TRT: IHD-MHD								
[redacted]	AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:62.0 KG							
[redacted]	MNT	57 TO 364	107	163	R: ITCHING AT INJECTION SITE POST DOSING S: General disorders and administration site conditions P: 注射部位そう痒感 L: Injection site itching	O: YES I: YES	S: MILD R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION PRESCRIBED, PREMEDICATION WITH OVER THE COUNTER BENADRYL PRIOR TO INJECTIONS)	M: NO S: NO

One patient ([redacted] who is ongoing study is excluded from interim analysis.
IND = Induction Period, MNT = Maintenance Period, FLARE = Flare Period, FU=Follow-up.
# Subject prematurely discontinued.

Cross reference: M11-290 Japan Sub-study CSR_Interim Table 14.3__2.5.17_A

表 2.7.4.7-67.　導入療法期中の治験薬の曝露期間（主試験安全性解析対象集団，M11-290 試験）

	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 2.7.4.7-68.　維持療法期中の治験薬の曝露期間（維持療法期中に治験薬の投与を 1 回以上受けた主試験安全性解析対象集団の被験者，M11-290 試験）

	M-PL (N=12)	M-SD (N=31)	M-HD (N=32)	ADA-Total (N=63)	Total (N=75)
Duration (day)					
n	12	31	32	63	75
Mean (SD)	184.2(123.02)	238.0(104.12)	241.7(106.10)	239.9(104.30)	231.0(108.56)
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	21.2	41.4	47.4

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__7.4

表 2.7.4.7-69.　試験期間全体での治験薬の曝露期間（主試験安全性解析対象集団，M11-290 試験）

	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 2.7.4.7-70.　M10-870 試験での治験薬の曝露期間（主試験 FAS 集団，M10-870 試験）

	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 2.7.4.7-71. M11-290 試験及び M10-870 試験の合計での治験薬の曝露期間（主試験 FAS 集団，M10-870 試験）

	Adalimumab (N=55)
Duration (days)	
n	55
Mean (SD)	864.7(395.08)
Median	811.0
Min, Max	321, 1736
Patient-Years of exposure	130.2

Note: Overall ADA exposure in Study M11-290 and Study M10-870 = ADA exposure in Study M10-870 + Overall ADA exposure in Study M11-290.

Cross reference: M10-870 Main-study CSR_Interim Table 14.1__7.2

表 2.7.4.7-72.　導入療法期中に発現したすべての有害事象（MedDRA SOC 及び PT 別）（主試験安全性解析対象集団，M11-290 試験）

MedDRA 22.0 System Organ Class Preferred Term	I-SD (N=30) n (%)	I-HD (N=47) n (%)	I-HD-OL (N=16) n (%)	Total (N=93) n (%)
Any adverse event	17 (56.7)	23 (48.9)	12 (75.0)	52 (55.9)
血液およびリンパ系障害	3 (10.0)	3 (6.4)	1 (6.3)	7 (7.5)
貧血	3 (10.0)	3 (6.4)	1 (6.3)	7 (7.5)
血小板増加症	0	0	1 (6.3)	1 (1.1)
心臓障害	1 (3.3)	0	0	1 (1.1)
心膜炎	1 (3.3)	0	0	1 (1.1)
内分泌障害	1 (3.3)	0	0	1 (1.1)
甲状腺腫	1 (3.3)	0	0	1 (1.1)
眼障害	1 (3.3)	0	0	1 (1.1)
角膜炎	1 (3.3)	0	0	1 (1.1)
胃腸障害	6 (20.0)	9 (19.1)	5 (31.3)	20 (21.5)
腹痛	0	2 (4.3)	2 (12.5)	4 (4.3)
上腹部痛	1 (3.3)	2 (4.3)	0	3 (3.2)
潰瘍性大腸炎	4 (13.3)	2 (4.3)	1 (6.3)	7 (7.5)
便秘	0	0	1 (6.3)	1 (1.1)
下痢	0	0	1 (6.3)	1 (1.1)
血性下痢	1 (3.3)	0	0	1 (1.1)
小腸炎	1 (3.3)	0	0	1 (1.1)
鼓腸	1 (3.3)	0	0	1 (1.1)
排便回数増加	0	1 (2.1)	0	1 (1.1)

表 2.7.4.7-72. 導入療法期中に発現したすべての有害事象（MedDRA SOC 及び PT 別）（主試験安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	I-SD (N=30) n (%)	I-HD (N=47) n (%)	I-HD-OL (N=16) n (%)	Total (N=93) n (%)
胃腸障害 (Cont.)				
胃食道逆流性疾患	0	1 (2.1)	1 (6.3)	2 (2.2)
血便排泄	0	2 (4.3)	0	2 (2.2)
悪心	0	3 (6.4)	1 (6.3)	4 (4.3)
膵炎	0	1 (2.1)	0	1 (1.1)
嘔吐	0	1 (2.1)	1 (6.3)	2 (2.2)
一般・全身障害および投与部位の状態	3 (10.0)	6 (12.8)	0	9 (9.7)
腋窩痛	0	1 (2.1)	0	1 (1.1)
胸痛	0	1 (2.1)	0	1 (1.1)
疲労	0	1 (2.1)	0	1 (1.1)
注射部位疼痛	0	1 (2.1)	0	1 (1.1)
注射部位蕁麻疹	0	1 (2.1)	0	1 (1.1)
末梢腫脹	1 (3.3)	0	0	1 (1.1)
発熱	2 (6.7)	1 (2.1)	0	3 (3.2)
肝胆道系障害	1 (3.3)	0	0	1 (1.1)
高ビリルビン血症	1 (3.3)	0	0	1 (1.1)
感染症および寄生虫症	6 (20.0)	8 (17.0)	6 (37.5)	20 (21.5)
気管支炎	0	0	1 (6.3)	1 (1.1)
せつ	0	1 (2.1)	0	1 (1.1)
サルモネラ菌性胃腸炎	1 (3.3)	0	0	1 (1.1)
上咽頭炎	2 (6.7)	2 (4.3)	1 (6.3)	5 (5.4)

表 2.7.4.7-72. 導入療法期中に発現したすべての有害事象（MedDRA SOC 及び PT 別）（主試験安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	I-SD (N=30) n (%)	I-HD (N=47) n (%)	I-HD-OL (N=16) n (%)	Total (N=93) n (%)
感染症および寄生虫症 (Cont.)				
口腔ヘルペス	1 (3.3)	2 (4.3)	0	3 (3.2)
咽頭炎	2 (6.7)	1 (2.1)	1 (6.3)	4 (4.3)
レンサ球菌感染	0	0	1 (6.3)	1 (1.1)
上気道感染	0	1 (2.1)	0	1 (1.1)
尿路感染	1 (3.3)	0	0	1 (1.1)
水痘	0	1 (2.1)	0	1 (1.1)
ウイルス感染	0	0	1 (6.3)	1 (1.1)
ウイルス性上気道感染	0	1 (2.1)	0	1 (1.1)
外陰腟真菌感染	0	0	1 (6.3)	1 (1.1)
傷害、中毒および処置合併症	4 (13.3)	2 (4.3)	0	6 (6.5)
節足動物咬傷	1 (3.3)	0	0	1 (1.1)
転倒	1 (3.3)	0	0	1 (1.1)
注入に伴う反応	1 (3.3)	0	0	1 (1.1)
靱帯捻挫	1 (3.3)	0	0	1 (1.1)
処置による疼痛	0	1 (2.1)	0	1 (1.1)
手首関節骨折	0	1 (2.1)	0	1 (1.1)
臨床検査	2 (6.7)	2 (4.3)	1 (6.3)	5 (5.4)
血圧上昇	0	1 (2.1)	0	1 (1.1)
C－反応性蛋白増加	0	1 (2.1)	0	1 (1.1)
ヘモグロビン減少	1 (3.3)	0	0	1 (1.1)
肝酵素上昇	0	0	1 (6.3)	1 (1.1)
体重減少	1 (3.3)	1 (2.1)	0	2 (2.2)

表 2.7.4.7-72. 導入療法期中に発現したすべての有害事象（MedDRA SOC 及び PT 別）（主試験安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	I-SD (N=30) n (%)	I-HD (N=47) n (%)	I-HD-OL (N=16) n (%)	Total (N=93) n (%)
筋骨格系および結合組織障害	2 (6.7)	2 (4.3)	1 (6.3)	5 (5.4)
関節痛	1 (3.3)	0	1 (6.3)	2 (2.2)
背部痛	0	1 (2.1)	0	1 (1.1)
靭帯障害	0	1 (2.1)	0	1 (1.1)
四肢痛	1 (3.3)	0	0	1 (1.1)
神経系障害	5 (16.7)	5 (10.6)	4 (25.0)	14 (15.1)
頭痛	4 (13.3)	5 (10.6)	4 (25.0)	13 (14.0)
意識消失	1 (3.3)	0	0	1 (1.1)
片頭痛	1 (3.3)	0	0	1 (1.1)
錯感覚	1 (3.3)	0	0	1 (1.1)
振戦	0	1 (2.1)	1 (6.3)	2 (2.2)
腎および尿路障害	0	0	1 (6.3)	1 (1.1)
糖尿	0	0	1 (6.3)	1 (1.1)
生殖系および乳房障害	0	1 (2.1)	0	1 (1.1)
乳房痛	0	1 (2.1)	0	1 (1.1)
呼吸器、胸郭および縦隔障害	1 (3.3)	3 (6.4)	3 (18.8)	7 (7.5)
咳嗽	0	1 (2.1)	0	1 (1.1)
鼻閉	0	1 (2.1)	0	1 (1.1)
口腔咽頭痛	1 (3.3)	1 (2.1)	2 (12.5)	4 (4.3)
鼻漏	0	1 (2.1)	1 (6.3)	2 (2.2)

表 2.7.4.7-72. 導入療法期中に発現したすべての有害事象（MedDRA SOC 及び PT 別）（主試験安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	I-SD (N=30) n (%)	I-HD (N=47) n (%)	I-HD-OL (N=16) n (%)	Total (N=93) n (%)
皮膚および皮下組織障害	1 (3.3)	0	1 (6.3)	2 (2.2)
結節性紅斑	1 (3.3)	0	0	1 (1.1)
発疹	0	0	1 (6.3)	1 (1.1)

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
Note: 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__1.2.1.1.1

表 2.7.4.7-73.　維持療法期中に発現したすべての有害事象（MedDRA SOC 及び PT 別）
（維持療法期中に治験薬の投与を 1 回以上受けた主試験安全性解析対象集団の被験者，M11-290 試験）

MedDRA 22.0 System Organ Class Preferred Term	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total-ADA (N=63) n (%)	M-PL (N=12) n (%)	Total (N=75) n (%)
Any adverse event	20 (64.5)	22 (68.8)	42 (66.7)	10 (83.3)	52 (69.3)
血液およびリンパ系障害	4 (12.9)	1 (3.1)	5 (7.9)	2 (16.7)	7 (9.3)
貧血	3 (9.7)	1 (3.1)	4 (6.3)	1 (8.3)	5 (6.7)
リンパ節症	1 (3.2)	0	1 (1.6)	0	1 (1.3)
好中球減少症	0	0	0	1 (8.3)	1 (1.3)
耳および迷路障害	0	1 (3.1)	1 (1.6)	0	1 (1.3)
耳痛	0	1 (3.1)	1 (1.6)	0	1 (1.3)
眼障害	0	0	0	1 (8.3)	1 (1.3)
非感染性結膜炎	0	0	0	1 (8.3)	1 (1.3)
胃腸障害	9 (29.0)	10 (31.3)	19 (30.2)	3 (25.0)	22 (29.3)
腹痛	1 (3.2)	1 (3.1)	2 (3.2)	1 (8.3)	3 (4.0)
上腹部痛	0	2 (6.3)	2 (3.2)	0	2 (2.7)
アフタ性潰瘍	1 (3.2)	0	1 (1.6)	0	1 (1.3)
潰瘍性大腸炎	6 (19.4)	4 (12.5)	10 (15.9)	2 (16.7)	12 (16.0)
便秘	1 (3.2)	0	1 (1.6)	0	1 (1.3)
下痢	0	1 (3.1)	1 (1.6)	0	1 (1.3)
消化不良	0	1 (3.1)	1 (1.6)	0	1 (1.3)
小腸炎	2 (6.5)	1 (3.1)	3 (4.8)	0	3 (4.0)
胃食道逆流性疾患	0	1 (3.1)	1 (1.6)	0	1 (1.3)

表 2.7.4.7-73. 維持療法期中に発現したすべての有害事象（MedDRA SOC 及び PT 別）
（維持療法期中に治験薬の投与を 1 回以上受けた主試験安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total-ADA (N=63) n (%)	M-PL (N=12) n (%)	Total (N=75) n (%)
一般・全身障害および投与部位の状態	5 (16.1)	3 (9.4)	8 (12.7)	1 (8.3)	9 (12.0)
胸痛	0	1 (3.1)	1 (1.6)	0	1 (1.3)
疲労	2 (6.5)	0	2 (3.2)	0	2 (2.7)
炎症	0	0	0	1 (8.3)	1 (1.3)
注射部位紅斑	0	1 (3.1)	1 (1.6)	0	1 (1.3)
注射部位炎症	1 (3.2)	0	1 (1.6)	0	1 (1.3)
注射部位浮腫	1 (3.2)	0	1 (1.6)	0	1 (1.3)
注射部位疼痛	1 (3.2)	0	1 (1.6)	0	1 (1.3)
注射部位そう痒感	0	1 (3.1)	1 (1.6)	0	1 (1.3)
注射部位腫脹	1 (3.2)	0	1 (1.6)	0	1 (1.3)
注射部位蕁麻疹	0	1 (3.1)	1 (1.6)	0	1 (1.3)
倦怠感	0	1 (3.1)	1 (1.6)	0	1 (1.3)
発熱	1 (3.2)	0	1 (1.6)	0	1 (1.3)
免疫系障害	0	1 (3.1)	1 (1.6)	0	1 (1.3)
薬物過敏症	0	1 (3.1)	1 (1.6)	0	1 (1.3)
感染症および寄生虫症	10 (32.3)	13 (40.6)	23 (36.5)	5 (41.7)	28 (37.3)
気管支炎	1 (3.2)	0	1 (1.6)	0	1 (1.3)
胃腸炎	2 (6.5)	0	2 (3.2)	1 (8.3)	3 (4.0)
感染性嚢腫	0	1 (3.1)	1 (1.6)	0	1 (1.3)
インフルエンザ	0	1 (3.1)	1 (1.6)	0	1 (1.3)

表 2.7.4.7-73. 維持療法期中に発現したすべての有害事象（MedDRA SOC 及び PT 別）
（維持療法期中に治験薬の投与を 1 回以上受けた主試験安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total-ADA (N=63) n (%)	M-PL (N=12) n (%)	Total (N=75) n (%)
感染症および寄生虫症 (Cont.)					
喉頭炎	0	1 (3.1)	1 (1.6)	0	1 (1.3)
無菌性髄膜炎	0	1 (3.1)	1 (1.6)	0	1 (1.3)
上咽頭炎	3 (9.7)	4 (12.5)	7 (11.1)	1 (8.3)	8 (10.7)
口腔ヘルペス	0	1 (3.1)	1 (1.6)	0	1 (1.3)
中耳炎	0	1 (3.1)	1 (1.6)	0	1 (1.3)
咽頭炎	2 (6.5)	2 (6.3)	4 (6.3)	1 (8.3)	5 (6.7)
気道感染	1 (3.2)	0	1 (1.6)	0	1 (1.3)
ウイルス性気道感染	0	0	0	1 (8.3)	1 (1.3)
鼻炎	1 (3.2)	0	1 (1.6)	0	1 (1.3)
癜風	1 (3.2)	0	1 (1.6)	0	1 (1.3)
歯膿瘍	0	0	0	1 (8.3)	1 (1.3)
気管炎	1 (3.2)	0	1 (1.6)	0	1 (1.3)
上気道感染	2 (6.5)	3 (9.4)	5 (7.9)	2 (16.7)	7 (9.3)
尿路感染	1 (3.2)	2 (6.3)	3 (4.8)	0	3 (4.0)
水痘	0	1 (3.1)	1 (1.6)	0	1 (1.3)
傷害、中毒および処置合併症	0	1 (3.1)	1 (1.6)	1 (8.3)	2 (2.7)
手骨折	0	1 (3.1)	1 (1.6)	0	1 (1.3)
関節損傷	0	0	0	1 (8.3)	1 (1.3)
臨床検査	5 (16.1)	3 (9.4)	8 (12.7)	0	8 (10.7)
血中ビリルビン増加	1 (3.2)	1 (3.1)	2 (3.2)	0	2 (2.7)
血中カルシウム減少	1 (3.2)	0	1 (1.6)	0	1 (1.3)

表 2.7.4.7-73. 維持療法期中に発現したすべての有害事象（MedDRA SOC 及び PT 別）
（維持療法期中に治験薬の投与を 1 回以上受けた主試験安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total-ADA (N=63) n (%)	M-PL (N=12) n (%)	Total (N=75) n (%)
臨床検査(Cont.)					
血中ナトリウム減少	0	1 (3.1)	1 (1.6)	0	1 (1.3)
骨密度減少	1 (3.2)	0	1 (1.6)	0	1 (1.3)
C一反応性蛋白増加	3 (9.7)	0	3 (4.8)	0	3 (4.0)
好酸球数増加	0	1 (3.1)	1 (1.6)	0	1 (1.3)
リンパ節触知	1 (3.2)	0	1 (1.6)	0	1 (1.3)
結核菌群検査陽性	0	1 (3.1)	1 (1.6)	0	1 (1.3)
好中球数減少	1 (3.2)	0	1 (1.6)	0	1 (1.3)
白血球数減少	1 (3.2)	0	1 (1.6)	0	1 (1.3)
筋骨格系および結合組織障害	1 (3.2)	2 (6.3)	3 (4.8)	1 (8.3)	4 (5.3)
関節痛	0	1 (3.1)	1 (1.6)	0	1 (1.3)
背部痛	1 (3.2)	1 (3.1)	2 (3.2)	0	2 (2.7)
筋骨格痛	0	0	0	1 (8.3)	1 (1.3)
神経系障害	6 (19.4)	3 (9.4)	9 (14.3)	2 (16.7)	11 (14.7)
頭痛	6 (19.4)	2 (6.3)	8 (12.7)	2 (16.7)	10 (13.3)
感覚鈍麻	0	1 (3.1)	1 (1.6)	0	1 (1.3)
錯感覚	0	1 (3.1)	1 (1.6)	0	1 (1.3)
精神障害	1 (3.2)	1 (3.1)	2 (3.2)	0	2 (2.7)
うつ病	1 (3.2)	1 (3.1)	2 (3.2)	0	2 (2.7)

表 2.7.4.7-73. 維持療法期中に発現したすべての有害事象（MedDRA SOC 及び PT 別）
（維持療法期中に治験薬の投与を 1 回以上受けた主試験安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total-ADA (N=63) n (%)	M-PL (N=12) n (%)	Total (N=75) n (%)
生殖系および乳房障害	0	1 (3.1)	1 (1.6)	0	1 (1.3)
月経困難症	0	1 (3.1)	1 (1.6)	0	1 (1.3)
呼吸器、胸郭および縦隔障害	4 (12.9)	5 (15.6)	9 (14.3)	3 (25.0)	12 (16.0)
喘息	1 (3.2)	0	1 (1.6)	0	1 (1.3)
咳嗽	0	2 (6.3)	2 (3.2)	0	2 (2.7)
鼻出血	0	0	0	2 (16.7)	2 (2.7)
鼻浮腫	1 (3.2)	0	1 (1.6)	0	1 (1.3)
口腔咽頭痛	2 (6.5)	1 (3.1)	3 (4.8)	0	3 (4.0)
アレルギー性鼻炎	0	2 (6.3)	2 (3.2)	0	2 (2.7)
鼻漏	1 (3.2)	0	1 (1.6)	0	1 (1.3)
喘鳴	0	0	0	1 (8.3)	1 (1.3)
皮膚および皮下組織障害	1 (3.2)	6 (18.8)	7 (11.1)	3 (25.0)	10 (13.3)
脱毛症	0	1 (3.1)	1 (1.6)	0	1 (1.3)
皮膚炎	0	1 (3.1)	1 (1.6)	1 (8.3)	2 (2.7)
紅斑	0	1 (3.1)	1 (1.6)	0	1 (1.3)
結節性紅斑	0	1 (3.1)	1 (1.6)	0	1 (1.3)
逆むけ	0	0	0	1 (8.3)	1 (1.3)
乾癬	0	0	0	1 (8.3)	1 (1.3)
発疹	1 (3.2)	2 (6.3)	3 (4.8)	0	3 (4.0)
痂皮	0	1 (3.1)	1 (1.6)	0	1 (1.3)
脂漏	1 (3.2)	0	1 (1.6)	0	1 (1.3)

表 2.7.4.7-73. 維持療法期中に発現したすべての有害事象（MedDRA SOC 及び PT 別）
（維持療法期中に治験薬の投与を 1 回以上受けた主試験安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total-ADA (N=63) n (%)	M-PL (N=12) n (%)	Total (N=75) n (%)
皮膚および皮下組織障害 (Cont.)					
皮膚病変	0	1 (3.1)	1 (1.6)	0	1 (1.3)

M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
Note: 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__1.2.1.1.2

表 2.7.4.7-74.　すべての有害事象（MedDRA SOC 及び PT 別）（主試験 FAS 集団，M10-870 試験）

MedDRA 22.0 System Organ Class Preferred Term	Adalimumab (N=55) n (%)
Any adverse event	36 (65.5)
血液およびリンパ系障害	6 (10.9)
貧血	4 (7.3)
失血性貧血	1 (1.8)
鉄欠乏性貧血	1 (1.8)
リンパ節炎	1 (1.8)
胃腸障害	21 (38.2)
腹部不快感	1 (1.8)
腹痛	1 (1.8)
上腹部痛	2 (3.6)
口唇症	1 (1.8)
潰瘍性大腸炎	11 (20.0)
便秘	1 (1.8)
下痢	1 (1.8)
消化不良	2 (3.6)
腸炎	1 (1.8)
胃炎	3 (5.5)
血便排泄	2 (3.6)
大腸ポリープ	1 (1.8)
悪心	1 (1.8)
直腸出血	1 (1.8)
嘔吐	1 (1.8)

表 2.7.4.7-74.　すべての有害事象（MedDRA SOC 及び PT 別）（主試験 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	Adalimumab (N=55) n (%)
一般・全身障害および投与部位の状態	2 (3.6)
末梢性浮腫	1 (1.8)
発熱	1 (1.8)
肝胆道系障害	1 (1.8)
胆嚢炎	1 (1.8)
免疫系障害	1 (1.8)
季節性アレルギー	1 (1.8)
感染症および寄生虫症	20 (36.4)
肛門膿瘍	1 (1.8)
気管支炎	3 (5.5)
ウイルス性胃腸炎	2 (3.6)
帯状疱疹	1 (1.8)
上咽頭炎	3 (5.5)
口腔ヘルペス	1 (1.8)
中耳炎	1 (1.8)
咽頭炎	2 (3.6)
副鼻腔炎	1 (1.8)
歯膿瘍	1 (1.8)
上気道感染	6 (10.9)
尿路感染	2 (3.6)
ウイルス感染	2 (3.6)
ウイルス性上気道感染	2 (3.6)

表 2.7.4.7-74. すべての有害事象（MedDRA SOC 及び PT 別）（主試験 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	Adalimumab (N=55) n (%)
感染症および寄生虫症 (Cont.)	
外陰膣炎	1 (1.8)
傷害、中毒および処置合併症	5 (9.1)
足関節部骨折	1 (1.8)
手骨折	1 (1.8)
四肢損傷	1 (1.8)
上肢骨折	1 (1.8)
手首関節骨折	1 (1.8)
臨床検査	6 (10.9)
血中アルカリホスファターゼ増加	1 (1.8)
体温上昇	1 (1.8)
結核菌群検査陽性	4 (7.3)
筋骨格系および結合組織障害	7 (12.7)
関節痛	4 (7.3)
背部痛	1 (1.8)
成長不全	1 (1.8)
若年性特発性関節炎	1 (1.8)
脊椎痛	1 (1.8)
神経系障害	6 (10.9)
頭痛	5 (9.1)
傾眠	1 (1.8)

表 2.7.4.7-74. すべての有害事象（MedDRA SOC 及び PT 別）（主試験 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term	Adalimumab (N=55) n (%)
精神障害	2 (3.6)
うつ病	2 (3.6)
腎および尿路障害	3 (5.5)
血尿	1 (1.8)
腎結石症	1 (1.8)
腎仙痛	1 (1.8)
生殖系および乳房障害	3 (5.5)
月経困難症	1 (1.8)
卵巣嚢胞	2 (3.6)
呼吸器、胸郭および縦隔障害	4 (7.3)
喘息	1 (1.8)
鼻出血	1 (1.8)
アレルギー性鼻炎	2 (3.6)
鼻漏	1 (1.8)
皮膚および皮下組織障害	4 (7.3)
乾癬様皮膚炎	1 (1.8)
乾癬	1 (1.8)
発疹	1 (1.8)
皮膚障害	1 (1.8)
血管障害	1 (1.8)
高血圧	1 (1.8)

表 2.7.4.7-74.　　すべての有害事象（MedDRA SOC 及び PT 別）（主試験 FAS 集団，M10-870 試験）（続き）

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Cross reference: M10-870 Main-study CSR_Interim Table 14.3__1.2.1.1

表 2.7.4.7-75. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（主試験安全性解析対象集団，M11-290 試験）

MedDRA 22.0 System Organ Class Preferred Term Relationship	I-SD (N=30) n (%)	I-HD (N=47) n (%)	I-HD-OL (N=16) n (%)	Total (N=93) n (%)
Any adverse event	17 (56.7)	23 (48.9)	12 (75.0)	52 (55.9)
No Reasonable Possibility	13 (43.3)	16 (34.0)	11 (68.8)	40 (43.0)
Reasonable Possibility	4 (13.3)	7 (14.9)	1 (6.3)	12 (12.9)
血液およびリンパ系障害	3 (10.0)	3 (6.4)	1 (6.3)	7 (7.5)
No Reasonable Possibility	3 (10.0)	3 (6.4)	1 (6.3)	7 (7.5)
貧血	3 (10.0)	3 (6.4)	1 (6.3)	7 (7.5)
No Reasonable Possibility	3 (10.0)	3 (6.4)	1 (6.3)	7 (7.5)
血小板増加症	0	0	1 (6.3)	1 (1.1)
No Reasonable Possibility	0	0	1 (6.3)	1 (1.1)
心臓障害	1 (3.3)	0	0	1 (1.1)
Reasonable Possibility	1 (3.3)	0	0	1 (1.1)
心膜炎	1 (3.3)	0	0	1 (1.1)
Reasonable Possibility	1 (3.3)	0	0	1 (1.1)
内分泌障害	1 (3.3)	0	0	1 (1.1)
No Reasonable Possibility	1 (3.3)	0	0	1 (1.1)
甲状腺腫	1 (3.3)	0	0	1 (1.1)
No Reasonable Possibility	1 (3.3)	0	0	1 (1.1)

表 2.7.4.7-75. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（主試験安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	I-SD (N=30) n (%)	I-HD (N=47) n (%)	I-HD-OL (N=16) n (%)	Total (N=93) n (%)
眼障害	1 (3.3)	0	0	1 (1.1)
No Reasonable Possibility	1 (3.3)	0	0	1 (1.1)
角膜炎	1 (3.3)	0	0	1 (1.1)
No Reasonable Possibility	1 (3.3)	0	0	1 (1.1)
胃腸障害	6 (20.0)	9 (19.1)	5 (31.3)	20 (21.5)
No Reasonable Possibility	6 (20.0)	6 (12.8)	4 (25.0)	16 (17.2)
Reasonable Possibility	0	3 (6.4)	1 (6.3)	4 (4.3)
腹痛	0	2 (4.3)	2 (12.5)	4 (4.3)
No Reasonable Possibility	0	2 (4.3)	2 (12.5)	4 (4.3)
上腹部痛	1 (3.3)	2 (4.3)	0	3 (3.2)
No Reasonable Possibility	1 (3.3)	2 (4.3)	0	3 (3.2)
潰瘍性大腸炎	4 (13.3)	2 (4.3)	1 (6.3)	7 (7.5)
No Reasonable Possibility	4 (13.3)	2 (4.3)	0	6 (6.5)
Reasonable Possibility	0	0	1 (6.3)	1 (1.1)
便秘	0	0	1 (6.3)	1 (1.1)
No Reasonable Possibility	0	0	1 (6.3)	1 (1.1)
下痢	0	0	1 (6.3)	1 (1.1)
No Reasonable Possibility	0	0	1 (6.3)	1 (1.1)

表 2.7.4.7-75. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（主試験安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	I-SD (N=30) n (%)	I-HD (N=47) n (%)	I-HD-OL (N=16) n (%)	Total (N=93) n (%)
胃腸障害 (Cont.)				
血性下痢	1 (3.3)	0	0	1 (1.1)
No Reasonable Possibility	1 (3.3)	0	0	1 (1.1)
小腸炎	1 (3.3)	0	0	1 (1.1)
No Reasonable Possibility	1 (3.3)	0	0	1 (1.1)
鼓腸	1 (3.3)	0	0	1 (1.1)
No Reasonable Possibility	1 (3.3)	0	0	1 (1.1)
排便回数増加	0	1 (2.1)	0	1 (1.1)
Reasonable Possibility	0	1 (2.1)	0	1 (1.1)
胃食道逆流性疾患	0	1 (2.1)	1 (6.3)	2 (2.2)
No Reasonable Possibility	0	1 (2.1)	1 (6.3)	2 (2.2)
血便排泄	0	2 (4.3)	0	2 (2.2)
No Reasonable Possibility	0	1 (2.1)	0	1 (1.1)
Reasonable Possibility	0	1 (2.1)	0	1 (1.1)
悪心	0	3 (6.4)	1 (6.3)	4 (4.3)
No Reasonable Possibility	0	2 (4.3)	1 (6.3)	3 (3.2)
Reasonable Possibility	0	1 (2.1)	0	1 (1.1)
膵炎	0	1 (2.1)	0	1 (1.1)
Reasonable Possibility	0	1 (2.1)	0	1 (1.1)

表 2.7.4.7-75. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（主試験安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	I-SD (N=30) n (%)	I-HD (N=47) n (%)	I-HD-OL (N=16) n (%)	Total (N=93) n (%)
胃腸障害 (Cont.)				
嘔吐	0	1 (2.1)	1 (6.3)	2 (2.2)
No Reasonable Possibility	0	0	1 (6.3)	1 (1.1)
Reasonable Possibility	0	1 (2.1)	0	1 (1.1)
一般・全身障害および投与部位の状態	3 (10.0)	6 (12.8)	0	9 (9.7)
No Reasonable Possibility	3 (10.0)	3 (6.4)	0	6 (6.5)
Reasonable Possibility	0	3 (6.4)	0	3 (3.2)
腋窩痛	0	1 (2.1)	0	1 (1.1)
No Reasonable Possibility	0	1 (2.1)	0	1 (1.1)
胸痛	0	1 (2.1)	0	1 (1.1)
No Reasonable Possibility	0	1 (2.1)	0	1 (1.1)
疲労	0	1 (2.1)	0	1 (1.1)
No Reasonable Possibility	0	1 (2.1)	0	1 (1.1)
注射部位疼痛	0	1 (2.1)	0	1 (1.1)
Reasonable Possibility	0	1 (2.1)	0	1 (1.1)
注射部位蕁麻疹	0	1 (2.1)	0	1 (1.1)
Reasonable Possibility	0	1 (2.1)	0	1 (1.1)
末梢腫脹	1 (3.3)	0	0	1 (1.1)
No Reasonable Possibility	1 (3.3)	0	0	1 (1.1)

表 2.7.4.7-75. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（主試験安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	I-SD (N=30) n (%)	I-HD (N=47) n (%)	I-HD-OL (N=16) n (%)	Total (N=93) n (%)
一般・全身障害および投与部位の状態 (Cont.)				
発熱	2 (6.7)	1 (2.1)	0	3 (3.2)
No Reasonable Possibility	2 (6.7)	0	0	2 (2.2)
Reasonable Possibility	0	1 (2.1)	0	1 (1.1)
肝胆道系障害	1 (3.3)	0	0	1 (1.1)
Reasonable Possibility	1 (3.3)	0	0	1 (1.1)
高ビリルビン血症	1 (3.3)	0	0	1 (1.1)
Reasonable Possibility	1 (3.3)	0	0	1 (1.1)
感染症および寄生虫症	6 (20.0)	8 (17.0)	6 (37.5)	20 (21.5)
No Reasonable Possibility	6 (20.0)	8 (17.0)	5 (31.3)	19 (20.4)
Reasonable Possibility	0	0	1 (6.3)	1 (1.1)
気管支炎	0	0	1 (6.3)	1 (1.1)
No Reasonable Possibility	0	0	1 (6.3)	1 (1.1)
せつ	0	1 (2.1)	0	1 (1.1)
No Reasonable Possibility	0	1 (2.1)	0	1 (1.1)
サルモネラ菌性胃腸炎	1 (3.3)	0	0	1 (1.1)
No Reasonable Possibility	1 (3.3)	0	0	1 (1.1)
上咽頭炎	2 (6.7)	2 (4.3)	1 (6.3)	5 (5.4)
No Reasonable Possibility	2 (6.7)	2 (4.3)	1 (6.3)	5 (5.4)

表 2.7.4.7-75. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（主試験安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	I-SD (N=30) n (%)	I-HD (N=47) n (%)	I-HD-OL (N=16) n (%)	Total (N=93) n (%)
感染症および寄生虫症 (Cont.)				
口腔ヘルペス	1 (3.3)	2 (4.3)	0	3 (3.2)
No Reasonable Possibility	1 (3.3)	2 (4.3)	0	3 (3.2)
咽頭炎	2 (6.7)	1 (2.1)	1 (6.3)	4 (4.3)
No Reasonable Possibility	2 (6.7)	1 (2.1)	1 (6.3)	4 (4.3)
レンサ球菌感染	0	0	1 (6.3)	1 (1.1)
No Reasonable Possibility	0	0	1 (6.3)	1 (1.1)
上気道感染	0	1 (2.1)	0	1 (1.1)
No Reasonable Possibility	0	1 (2.1)	0	1 (1.1)
尿路感染	1 (3.3)	0	0	1 (1.1)
No Reasonable Possibility	1 (3.3)	0	0	1 (1.1)
水痘	0	1 (2.1)	0	1 (1.1)
No Reasonable Possibility	0	1 (2.1)	0	1 (1.1)
ウイルス感染	0	0	1 (6.3)	1 (1.1)
No Reasonable Possibility	0	0	1 (6.3)	1 (1.1)
ウイルス性上気道感染	0	1 (2.1)	0	1 (1.1)
No Reasonable Possibility	0	1 (2.1)	0	1 (1.1)

表 2.7.4.7-75. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（主試験安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	I-SD (N=30) n (%)	I-HD (N=47) n (%)	I-HD-OL (N=16) n (%)	Total (N=93) n (%)
感染症および寄生虫症 (Cont.)				
外陰膣真菌感染	0	0	1 (6.3)	1 (1.1)
Reasonable Possibility	0	0	1 (6.3)	1 (1.1)
傷害、中毒および処置合併症	4 (13.3)	2 (4.3)	0	6 (6.5)
No Reasonable Possibility	4 (13.3)	2 (4.3)	0	6 (6.5)
節足動物咬傷	1 (3.3)	0	0	1 (1.1)
No Reasonable Possibility	1 (3.3)	0	0	1 (1.1)
転倒	1 (3.3)	0	0	1 (1.1)
No Reasonable Possibility	1 (3.3)	0	0	1 (1.1)
注入に伴う反応	1 (3.3)	0	0	1 (1.1)
No Reasonable Possibility	1 (3.3)	0	0	1 (1.1)
靭帯捻挫	1 (3.3)	0	0	1 (1.1)
No Reasonable Possibility	1 (3.3)	0	0	1 (1.1)
処置による疼痛	0	1 (2.1)	0	1 (1.1)
No Reasonable Possibility	0	1 (2.1)	0	1 (1.1)
手首関節骨折	0	1 (2.1)	0	1 (1.1)
No Reasonable Possibility	0	1 (2.1)	0	1 (1.1)

表 2.7.4.7-75. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（主試験安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	I-SD (N=30) n (%)	I-HD (N=47) n (%)	I-HD-OL (N=16) n (%)	Total (N=93) n (%)
臨床検査	2 (6.7)	2 (4.3)	1 (6.3)	5 (5.4)
No Reasonable Possibility	2 (6.7)	1 (2.1)	1 (6.3)	4 (4.3)
Reasonable Possibility	0	1 (2.1)	0	1 (1.1)
血圧上昇	0	1 (2.1)	0	1 (1.1)
No Reasonable Possibility	0	1 (2.1)	0	1 (1.1)
C－反応性蛋白増加	0	1 (2.1)	0	1 (1.1)
Reasonable Possibility	0	1 (2.1)	0	1 (1.1)
ヘモグロビン減少	1 (3.3)	0	0	1 (1.1)
No Reasonable Possibility	1 (3.3)	0	0	1 (1.1)
肝酵素上昇	0	0	1 (6.3)	1 (1.1)
No Reasonable Possibility	0	0	1 (6.3)	1 (1.1)
体重減少	1 (3.3)	1 (2.1)	0	2 (2.2)
No Reasonable Possibility	1 (3.3)	0	0	1 (1.1)
Reasonable Possibility	0	1 (2.1)	0	1 (1.1)
筋骨格系および結合組織障害	2 (6.7)	2 (4.3)	1 (6.3)	5 (5.4)
No Reasonable Possibility	1 (3.3)	2 (4.3)	1 (6.3)	4 (4.3)
Reasonable Possibility	1 (3.3)	0	0	1 (1.1)
関節痛	1 (3.3)	0	1 (6.3)	2 (2.2)
No Reasonable Possibility	1 (3.3)	0	1 (6.3)	2 (2.2)

表 2.7.4.7-75. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（主試験安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	I-SD (N=30) n (%)	I-HD (N=47) n (%)	I-HD-OL (N=16) n (%)	Total (N=93) n (%)
筋骨格系および結合組織障害 (Cont.)				
背部痛	0	1 (2.1)	0	1 (1.1)
No Reasonable Possibility	0	1 (2.1)	0	1 (1.1)
靭帯障害	0	1 (2.1)	0	1 (1.1)
No Reasonable Possibility	0	1 (2.1)	0	1 (1.1)
四肢痛	1 (3.3)	0	0	1 (1.1)
Reasonable Possibility	1 (3.3)	0	0	1 (1.1)
神経系障害	5 (16.7)	5 (10.6)	4 (25.0)	14 (15.1)
No Reasonable Possibility	3 (10.0)	3 (6.4)	4 (25.0)	10 (10.8)
Reasonable Possibility	2 (6.7)	2 (4.3)	0	4 (4.3)
頭痛	4 (13.3)	5 (10.6)	4 (25.0)	13 (14.0)
No Reasonable Possibility	3 (10.0)	3 (6.4)	4 (25.0)	10 (10.8)
Reasonable Possibility	1 (3.3)	2 (4.3)	0	3 (3.2)
意識消失	1 (3.3)	0	0	1 (1.1)
Reasonable Possibility	1 (3.3)	0	0	1 (1.1)
片頭痛	1 (3.3)	0	0	1 (1.1)
Reasonable Possibility	1 (3.3)	0	0	1 (1.1)
錯感覚	1 (3.3)	0	0	1 (1.1)
Reasonable Possibility	1 (3.3)	0	0	1 (1.1)

表 2.7.4.7-75. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（主試験安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	I-SD (N=30) n (%)	I-HD (N=47) n (%)	I-HD-OL (N=16) n (%)	Total (N=93) n (%)
神経系障害 (Cont.)				
振戦	0	1 (2.1)	1 (6.3)	2 (2.2)
No Reasonable Possibility	0	1 (2.1)	1 (6.3)	2 (2.2)
腎および尿路障害	0	0	1 (6.3)	1 (1.1)
No Reasonable Possibility	0	0	1 (6.3)	1 (1.1)
糖尿	0	0	1 (6.3)	1 (1.1)
No Reasonable Possibility	0	0	1 (6.3)	1 (1.1)
生殖系および乳房障害	0	1 (2.1)	0	1 (1.1)
No Reasonable Possibility	0	1 (2.1)	0	1 (1.1)
乳房痛	0	1 (2.1)	0	1 (1.1)
No Reasonable Possibility	0	1 (2.1)	0	1 (1.1)
呼吸器、胸郭および縦隔障害	1 (3.3)	3 (6.4)	3 (18.8)	7 (7.5)
No Reasonable Possibility	1 (3.3)	3 (6.4)	3 (18.8)	7 (7.5)
咳嗽	0	1 (2.1)	0	1 (1.1)
No Reasonable Possibility	0	1 (2.1)	0	1 (1.1)
鼻閉	0	1 (2.1)	0	1 (1.1)
No Reasonable Possibility	0	1 (2.1)	0	1 (1.1)

表 2.7.4.7-75. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（主試験安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	I-SD (N=30) n (%)	I-HD (N=47) n (%)	I-HD-OL (N=16) n (%)	Total (N=93) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)				
口腔咽頭痛	1 (3.3)	1 (2.1)	2 (12.5)	4 (4.3)
No Reasonable Possibility	1 (3.3)	1 (2.1)	2 (12.5)	4 (4.3)
鼻漏	0	1 (2.1)	1 (6.3)	2 (2.2)
No Reasonable Possibility	0	1 (2.1)	1 (6.3)	2 (2.2)
皮膚および皮下組織障害	1 (3.3)	0	1 (6.3)	2 (2.2)
No Reasonable Possibility	1 (3.3)	0	1 (6.3)	2 (2.2)
結節性紅斑	1 (3.3)	0	0	1 (1.1)
No Reasonable Possibility	1 (3.3)	0	0	1 (1.1)
発疹	0	0	1 (6.3)	1 (1.1)
No Reasonable Possibility	0	0	1 (6.3)	1 (1.1)

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
If a subject has an AE with unknown relationship, then the subject will be counted in the relationship category of "unknown," unless the subject has another occurrence of the same AE with a relationship assessment of "Reasonable Possibility."

Cross reference: M11-290 Main-study CSR_Interim Table 14.3__1.3.1.1

表 2.7.4.7-76. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）
（維持療法期中に治験薬の投与を 1 回以上受けた主試験安全性解析対象集団の被験者，M11-290 試験）

MedDRA 22.0 System Organ Class Preferred Term Relationship	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total-ADA (N=63) n (%)	M-PL (N=12) n (%)	Total (N=75) n (%)
Any adverse event	20 (64.5)	22 (68.8)	42 (66.7)	10 (83.3)	52 (69.3)
No Reasonable Possibility	12 (38.7)	12 (37.5)	24 (38.1)	5 (41.7)	29 (38.7)
Reasonable Possibility	8 (25.8)	10 (31.3)	18 (28.6)	5 (41.7)	23 (30.7)
血液およびリンパ系障害	4 (12.9)	1 (3.1)	5 (7.9)	2 (16.7)	7 (9.3)
No Reasonable Possibility	3 (9.7)	1 (3.1)	4 (6.3)	0	4 (5.3)
Reasonable Possibility	1 (3.2)	0	1 (1.6)	2 (16.7)	3 (4.0)
貧血	3 (9.7)	1 (3.1)	4 (6.3)	1 (8.3)	5 (6.7)
No Reasonable Possibility	2 (6.5)	1 (3.1)	3 (4.8)	0	3 (4.0)
Reasonable Possibility	1 (3.2)	0	1 (1.6)	1 (8.3)	2 (2.7)
リンパ節症	1 (3.2)	0	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	1 (3.2)	0	1 (1.6)	0	1 (1.3)
好中球減少症	0	0	0	1 (8.3)	1 (1.3)
Reasonable Possibility	0	0	0	1 (8.3)	1 (1.3)
耳および迷路障害	0	1 (3.1)	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)
耳痛	0	1 (3.1)	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)
眼障害	0	0	0	1 (8.3)	1 (1.3)
No Reasonable Possibility	0	0	0	1 (8.3)	1 (1.3)

表 2.7.4.7-76. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）
（維持療法期中に治験薬の投与を 1 回以上受けた主試験安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total-ADA (N=63) n (%)	M-PL (N=12) n (%)	Total (N=75) n (%)
眼障害 (Cont.)					
非感染性結膜炎	0	0	0	1 (8.3)	1 (1.3)
No Reasonable Possibility	0	0	0	1 (8.3)	1 (1.3)
胃腸障害	9 (29.0)	10 (31.3)	19 (30.2)	3 (25.0)	22 (29.3)
No Reasonable Possibility	7 (22.6)	7 (21.9)	14 (22.2)	3 (25.0)	17 (22.7)
Reasonable Possibility	2 (6.5)	3 (9.4)	5 (7.9)	0	5 (6.7)
腹痛	1 (3.2)	1 (3.1)	2 (3.2)	1 (8.3)	3 (4.0)
No Reasonable Possibility	1 (3.2)	1 (3.1)	2 (3.2)	1 (8.3)	3 (4.0)
上腹部痛	0	2 (6.3)	2 (3.2)	0	2 (2.7)
No Reasonable Possibility	0	2 (6.3)	2 (3.2)	0	2 (2.7)
アフタ性潰瘍	1 (3.2)	0	1 (1.6)	0	1 (1.3)
Reasonable Possibility	1 (3.2)	0	1 (1.6)	0	1 (1.3)
潰瘍性大腸炎	6 (19.4)	4 (12.5)	10 (15.9)	2 (16.7)	12 (16.0)
No Reasonable Possibility	5 (16.1)	2 (6.3)	7 (11.1)	2 (16.7)	9 (12.0)
Reasonable Possibility	1 (3.2)	2 (6.3)	3 (4.8)	0	3 (4.0)
便秘	1 (3.2)	0	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	1 (3.2)	0	1 (1.6)	0	1 (1.3)
下痢	0	1 (3.1)	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)

表 2.7.4.7-76. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）
（維持療法期中に治験薬の投与を 1 回以上受けた主試験安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total-ADA (N=63) n (%)	M-PL (N=12) n (%)	Total (N=75) n (%)
胃腸障害 (Cont.)					
消化不良	0	1 (3.1)	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)
小腸炎	2 (6.5)	1 (3.1)	3 (4.8)	0	3 (4.0)
No Reasonable Possibility	2 (6.5)	0	2 (3.2)	0	2 (2.7)
Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)
胃食道逆流性疾患	0	1 (3.1)	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)
一般・全身障害および投与部位の状態	5 (16.1)	3 (9.4)	8 (12.7)	1 (8.3)	9 (12.0)
No Reasonable Possibility	1 (3.2)	1 (3.1)	2 (3.2)	0	2 (2.7)
Reasonable Possibility	4 (12.9)	2 (6.3)	6 (9.5)	1 (8.3)	7 (9.3)
胸痛	0	1 (3.1)	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)
疲労	2 (6.5)	0	2 (3.2)	0	2 (2.7)
Reasonable Possibility	2 (6.5)	0	2 (3.2)	0	2 (2.7)
炎症	0	0	0	1 (8.3)	1 (1.3)
Reasonable Possibility	0	0	0	1 (8.3)	1 (1.3)
注射部位紅斑	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)

表 2.7.4.7-76. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）
（維持療法期中に治験薬の投与を 1 回以上受けた主試験安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total-ADA (N=63) n (%)	M-PL (N=12) n (%)	Total (N=75) n (%)
一般・全身障害および投与部位の状態 (Cont.)					
注射部位炎症	1 (3.2)	0	1 (1.6)	0	1 (1.3)
Reasonable Possibility	1 (3.2)	0	1 (1.6)	0	1 (1.3)
注射部位浮腫	1 (3.2)	0	1 (1.6)	0	1 (1.3)
Reasonable Possibility	1 (3.2)	0	1 (1.6)	0	1 (1.3)
注射部位疼痛	1 (3.2)	0	1 (1.6)	0	1 (1.3)
Reasonable Possibility	1 (3.2)	0	1 (1.6)	0	1 (1.3)
注射部位そう痒感	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)
注射部位腫脹	1 (3.2)	0	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	1 (3.2)	0	1 (1.6)	0	1 (1.3)
注射部位蕁麻疹	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)
倦怠感	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)
発熱	1 (3.2)	0	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	1 (3.2)	0	1 (1.6)	0	1 (1.3)

表 2.7.4.7-76. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）
（維持療法期中に治験薬の投与を 1 回以上受けた主試験安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total-ADA (N=63) n (%)	M-PL (N=12) n (%)	Total (N=75) n (%)
免疫系障害	0	1 (3.1)	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)
薬物過敏症	0	1 (3.1)	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)
感染症および寄生虫症	10 (32.3)	13 (40.6)	23 (36.5)	5 (41.7)	28 (37.3)
No Reasonable Possibility	10 (32.3)	12 (37.5)	22 (34.9)	5 (41.7)	27 (36.0)
Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)
気管支炎	1 (3.2)	0	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	1 (3.2)	0	1 (1.6)	0	1 (1.3)
胃腸炎	2 (6.5)	0	2 (3.2)	1 (8.3)	3 (4.0)
No Reasonable Possibility	2 (6.5)	0	2 (3.2)	1 (8.3)	3 (4.0)
感染性嚢腫	0	1 (3.1)	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)
インフルエンザ	0	1 (3.1)	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)
喉頭炎	0	1 (3.1)	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)

表 2.7.4.7-76. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）
（維持療法期中に治験薬の投与を 1 回以上受けた主試験安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total-ADA (N=63) n (%)	M-PL (N=12) n (%)	Total (N=75) n (%)
感染症および寄生虫症 (Cont.)					
無菌性髄膜炎	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)
上咽頭炎	3 (9.7)	4 (12.5)	7 (11.1)	1 (8.3)	8 (10.7)
No Reasonable Possibility	3 (9.7)	4 (12.5)	7 (11.1)	1 (8.3)	8 (10.7)
口腔ヘルペス	0	1 (3.1)	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)
中耳炎	0	1 (3.1)	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)
咽頭炎	2 (6.5)	2 (6.3)	4 (6.3)	1 (8.3)	5 (6.7)
No Reasonable Possibility	2 (6.5)	2 (6.3)	4 (6.3)	1 (8.3)	5 (6.7)
気道感染	1 (3.2)	0	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	1 (3.2)	0	1 (1.6)	0	1 (1.3)
ウイルス性気道感染	0	0	0	1 (8.3)	1 (1.3)
No Reasonable Possibility	0	0	0	1 (8.3)	1 (1.3)
鼻炎	1 (3.2)	0	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	1 (3.2)	0	1 (1.6)	0	1 (1.3)

表 2.7.4.7-76. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）
（維持療法期中に治験薬の投与を 1 回以上受けた主試験安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total-ADA (N=63) n (%)	M-PL (N=12) n (%)	Total (N=75) n (%)
感染症および寄生虫症 (Cont.)					
癜風	1 (3.2)	0	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	1 (3.2)	0	1 (1.6)	0	1 (1.3)
歯膿瘍	0	0	0	1 (8.3)	1 (1.3)
No Reasonable Possibility	0	0	0	1 (8.3)	1 (1.3)
気管炎	1 (3.2)	0	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	1 (3.2)	0	1 (1.6)	0	1 (1.3)
上気道感染	2 (6.5)	3 (9.4)	5 (7.9)	2 (16.7)	7 (9.3)
No Reasonable Possibility	2 (6.5)	3 (9.4)	5 (7.9)	2 (16.7)	7 (9.3)
尿路感染	1 (3.2)	2 (6.3)	3 (4.8)	0	3 (4.0)
No Reasonable Possibility	1 (3.2)	2 (6.3)	3 (4.8)	0	3 (4.0)
水痘	0	1 (3.1)	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)
傷害、中毒および処置合併症	0	1 (3.1)	1 (1.6)	1 (8.3)	2 (2.7)
No Reasonable Possibility	0	1 (3.1)	1 (1.6)	1 (8.3)	2 (2.7)
手骨折	0	1 (3.1)	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)

表 2.7.4.7-76. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）
（維持療法期中に治験薬の投与を 1 回以上受けた主試験安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total-ADA (N=63) n (%)	M-PL (N=12) n (%)	Total (N=75) n (%)
傷害、中毒および処置合併症 (Cont.)					
関節損傷	0	0	0	1 (8.3)	1 (1.3)
No Reasonable Possibility	0	0	0	1 (8.3)	1 (1.3)
臨床検査	5 (16.1)	3 (9.4)	8 (12.7)	0	8 (10.7)
No Reasonable Possibility	4 (12.9)	1 (3.1)	5 (7.9)	0	5 (6.7)
Reasonable Possibility	1 (3.2)	2 (6.3)	3 (4.8)	0	3 (4.0)
血中ビリルビン増加	1 (3.2)	1 (3.1)	2 (3.2)	0	2 (2.7)
No Reasonable Possibility	1 (3.2)	0	1 (1.6)	0	1 (1.3)
Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)
血中カルシウム減少	1 (3.2)	0	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	1 (3.2)	0	1 (1.6)	0	1 (1.3)
血中ナトリウム減少	0	1 (3.1)	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)
骨密度減少	1 (3.2)	0	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	1 (3.2)	0	1 (1.6)	0	1 (1.3)
C一反応性蛋白増加	3 (9.7)	0	3 (4.8)	0	3 (4.0)
No Reasonable Possibility	2 (6.5)	0	2 (3.2)	0	2 (2.7)
Reasonable Possibility	1 (3.2)	0	1 (1.6)	0	1 (1.3)
好酸球数増加	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)

表 2.7.4.7-76. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）
（維持療法期中に治験薬の投与を 1 回以上受けた主試験安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total-ADA (N=63) n (%)	M-PL (N=12) n (%)	Total (N=75) n (%)
臨床検査 (Cont.)					
リンパ節触知	1 (3.2)	0	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	1 (3.2)	0	1 (1.6)	0	1 (1.3)
結核菌群検査陽性	0	1 (3.1)	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)
好中球数減少	1 (3.2)	0	1 (1.6)	0	1 (1.3)
Reasonable Possibility	1 (3.2)	0	1 (1.6)	0	1 (1.3)
白血球数減少	1 (3.2)	0	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	1 (3.2)	0	1 (1.6)	0	1 (1.3)
筋骨格系および結合組織障害	1 (3.2)	2 (6.3)	3 (4.8)	1 (8.3)	4 (5.3)
No Reasonable Possibility	1 (3.2)	1 (3.1)	2 (3.2)	1 (8.3)	3 (4.0)
Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)
関節痛	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)
背部痛	1 (3.2)	1 (3.1)	2 (3.2)	0	2 (2.7)
No Reasonable Possibility	1 (3.2)	1 (3.1)	2 (3.2)	0	2 (2.7)
筋骨格痛	0	0	0	1 (8.3)	1 (1.3)
No Reasonable Possibility	0	0	0	1 (8.3)	1 (1.3)

表 2.7.4.7-76. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）
（維持療法期中に治験薬の投与を 1 回以上受けた主試験安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total-ADA (N=63) n (%)	M-PL (N=12) n (%)	Total (N=75) n (%)
神経系障害	6 (19.4)	3 (9.4)	9 (14.3)	2 (16.7)	11 (14.7)
No Reasonable Possibility	4 (12.9)	2 (6.3)	6 (9.5)	1 (8.3)	7 (9.3)
Reasonable Possibility	2 (6.5)	1 (3.1)	3 (4.8)	1 (8.3)	4 (5.3)
頭痛	6 (19.4)	2 (6.3)	8 (12.7)	2 (16.7)	10 (13.3)
No Reasonable Possibility	4 (12.9)	2 (6.3)	6 (9.5)	1 (8.3)	7 (9.3)
Reasonable Possibility	2 (6.5)	0	2 (3.2)	1 (8.3)	3 (4.0)
感覚鈍麻	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)
錯感覚	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)
精神障害	1 (3.2)	1 (3.1)	2 (3.2)	0	2 (2.7)
No Reasonable Possibility	1 (3.2)	1 (3.1)	2 (3.2)	0	2 (2.7)
うつ病	1 (3.2)	1 (3.1)	2 (3.2)	0	2 (2.7)
No Reasonable Possibility	1 (3.2)	1 (3.1)	2 (3.2)	0	2 (2.7)
生殖系および乳房障害	0	1 (3.1)	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)
月経困難症	0	1 (3.1)	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)

表 2.7.4.7-76. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）
（維持療法期中に治験薬の投与を 1 回以上受けた主試験安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total-ADA (N=63) n (%)	M-PL (N=12) n (%)	Total (N=75) n (%)
呼吸器、胸郭および縦隔障害	4 (12.9)	5 (15.6)	9 (14.3)	3 (25.0)	12 (16.0)
No Reasonable Possibility	4 (12.9)	5 (15.6)	9 (14.3)	3 (25.0)	12 (16.0)
喘息	1 (3.2)	0	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	1 (3.2)	0	1 (1.6)	0	1 (1.3)
咳嗽	0	2 (6.3)	2 (3.2)	0	2 (2.7)
No Reasonable Possibility	0	2 (6.3)	2 (3.2)	0	2 (2.7)
鼻出血	0	0	0	2 (16.7)	2 (2.7)
No Reasonable Possibility	0	0	0	2 (16.7)	2 (2.7)
鼻浮腫	1 (3.2)	0	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	1 (3.2)	0	1 (1.6)	0	1 (1.3)
口腔咽頭痛	2 (6.5)	1 (3.1)	3 (4.8)	0	3 (4.0)
No Reasonable Possibility	2 (6.5)	1 (3.1)	3 (4.8)	0	3 (4.0)
アレルギー性鼻炎	0	2 (6.3)	2 (3.2)	0	2 (2.7)
No Reasonable Possibility	0	2 (6.3)	2 (3.2)	0	2 (2.7)
鼻漏	1 (3.2)	0	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	1 (3.2)	0	1 (1.6)	0	1 (1.3)

表 2.7.4.7-76. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）
（維持療法期中に治験薬の投与を 1 回以上受けた主試験安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total-ADA (N=63) n (%)	M-PL (N=12) n (%)	Total (N=75) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)					
喘鳴	0	0	0	1 (8.3)	1 (1.3)
No Reasonable Possibility	0	0	0	1 (8.3)	1 (1.3)
皮膚および皮下組織障害	1 (3.2)	6 (18.8)	7 (11.1)	3 (25.0)	10 (13.3)
No Reasonable Possibility	1 (3.2)	2 (6.3)	3 (4.8)	1 (8.3)	4 (5.3)
Reasonable Possibility	0	4 (12.5)	4 (6.3)	2 (16.7)	6 (8.0)
脱毛症	0	1 (3.1)	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)
皮膚炎	0	1 (3.1)	1 (1.6)	1 (8.3)	2 (2.7)
No Reasonable Possibility	0	0	0	1 (8.3)	1 (1.3)
Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)
紅斑	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)
結節性紅斑	0	1 (3.1)	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)
逆むけ	0	0	0	1 (8.3)	1 (1.3)
Reasonable Possibility	0	0	0	1 (8.3)	1 (1.3)
乾癬	0	0	0	1 (8.3)	1 (1.3)
Reasonable Possibility	0	0	0	1 (8.3)	1 (1.3)

表 2.7.4.7-76. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）
（維持療法期中に治験薬の投与を 1 回以上受けた主試験安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total-ADA (N=63) n (%)	M-PL (N=12) n (%)	Total (N=75) n (%)
皮膚および皮下組織障害 (Cont.)					
発疹	1 (3.2)	2 (6.3)	3 (4.8)	0	3 (4.0)
No Reasonable Possibility	1 (3.2)	0	1 (1.6)	0	1 (1.3)
Reasonable Possibility	0	2 (6.3)	2 (3.2)	0	2 (2.7)
痂皮	0	1 (3.1)	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)
脂漏	1 (3.2)	0	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	1 (3.2)	0	1 (1.6)	0	1 (1.3)
皮膚病変	0	1 (3.1)	1 (1.6)	0	1 (1.3)
No Reasonable Possibility	0	1 (3.1)	1 (1.6)	0	1 (1.3)

M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
If a subject has an AE with unknown relationship, then the subject will be counted in the relationship category of "unknown," unless the subject has another occurrence of the same AE with a relationship assessment of "Reasonable Possibility."

Cross reference: M11-290 Main-study CSR_Interim Table 14.3__1.3.1.2

表 2.7.4.7-77.　すべての有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（主試験 FAS 集団，M10-870 試験）

MedDRA 22.0 System Organ Class Preferred Term Relationship	Adalimumab (N=55) n (%)
Any adverse event	36 (65.5)
No Reasonable Possibility	25 (45.5)
Reasonable Possibility	11 (20.0)
血液およびリンパ系障害	6 (10.9)
No Reasonable Possibility	6 (10.9)
貧血	4 (7.3)
No Reasonable Possibility	4 (7.3)
失血性貧血	1 (1.8)
No Reasonable Possibility	1 (1.8)
鉄欠乏性貧血	1 (1.8)
No Reasonable Possibility	1 (1.8)
リンパ節炎	1 (1.8)
No Reasonable Possibility	1 (1.8)
胃腸障害	21 (38.2)
No Reasonable Possibility	19 (34.5)
Reasonable Possibility	2 (3.6)
腹部不快感	1 (1.8)
No Reasonable Possibility	1 (1.8)

表 2.7.4.7-77.　すべての有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（主試験 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	Adalimumab (N=55) n (%)
胃腸障害 (Cont.)	
腹痛	1 (1.8)
No Reasonable Possibility	1 (1.8)
上腹部痛	2 (3.6)
No Reasonable Possibility	2 (3.6)
口唇症	1 (1.8)
No Reasonable Possibility	1 (1.8)
潰瘍性大腸炎	11 (20.0)
No Reasonable Possibility	10 (18.2)
Reasonable Possibility	1 (1.8)
便秘	1 (1.8)
No Reasonable Possibility	1 (1.8)
下痢	1 (1.8)
No Reasonable Possibility	1 (1.8)
消化不良	2 (3.6)
No Reasonable Possibility	2 (3.6)
腸炎	1 (1.8)
No Reasonable Possibility	1 (1.8)

表 2.7.4.7-77.　すべての有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（主試験 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	Adalimumab (N=55) n (%)
胃腸障害 (Cont.)	
胃炎	3 (5.5)
No Reasonable Possibility	2 (3.6)
Reasonable Possibility	1 (1.8)
血便排泄	2 (3.6)
No Reasonable Possibility	2 (3.6)
大腸ポリープ	1 (1.8)
No Reasonable Possibility	1 (1.8)
悪心	1 (1.8)
No Reasonable Possibility	1 (1.8)
直腸出血	1 (1.8)
No Reasonable Possibility	1 (1.8)
嘔吐	1 (1.8)
No Reasonable Possibility	1 (1.8)
一般・全身障害および投与部位の状態	2 (3.6)
No Reasonable Possibility	1 (1.8)
Reasonable Possibility	1 (1.8)
末梢性浮腫	1 (1.8)
No Reasonable Possibility	1 (1.8)

表 2.7.4.7-77.　すべての有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（主試験 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	Adalimumab (N=55) n (%)
一般・全身障害および投与部位の状態 (Cont.)	
発熱	1 (1.8)
Reasonable Possibility	1 (1.8)
肝胆道系障害	1 (1.8)
Reasonable Possibility	1 (1.8)
胆嚢炎	1 (1.8)
Reasonable Possibility	1 (1.8)
免疫系障害	1 (1.8)
No Reasonable Possibility	1 (1.8)
季節性アレルギー	1 (1.8)
No Reasonable Possibility	1 (1.8)
感染症および寄生虫症	20 (36.4)
No Reasonable Possibility	17 (30.9)
Reasonable Possibility	3 (5.5)
肛門膿瘍	1 (1.8)
Reasonable Possibility	1 (1.8)
気管支炎	3 (5.5)
No Reasonable Possibility	3 (5.5)

表 2.7.4.7-77.　すべての有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（主試験 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	Adalimumab (N=55) n (%)
感染症および寄生虫症 (Cont.)	
ウイルス性胃腸炎	2 (3.6)
No Reasonable Possibility	2 (3.6)
帯状疱疹	1 (1.8)
Reasonable Possibility	1 (1.8)
上咽頭炎	3 (5.5)
No Reasonable Possibility	3 (5.5)
口腔ヘルペス	1 (1.8)
No Reasonable Possibility	1 (1.8)
中耳炎	1 (1.8)
No Reasonable Possibility	1 (1.8)
咽頭炎	2 (3.6)
No Reasonable Possibility	2 (3.6)
副鼻腔炎	1 (1.8)
No Reasonable Possibility	1 (1.8)
歯膿瘍	1 (1.8)
No Reasonable Possibility	1 (1.8)

表 2.7.4.7-77.　すべての有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（主試験 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	Adalimumab (N=55) n (%)
感染症および寄生虫症 (Cont.)	
上気道感染	6 (10.9)
No Reasonable Possibility	5 (9.1)
Reasonable Possibility	1 (1.8)
尿路感染	2 (3.6)
No Reasonable Possibility	2 (3.6)
ウイルス感染	2 (3.6)
No Reasonable Possibility	2 (3.6)
ウイルス性上気道感染	2 (3.6)
No Reasonable Possibility	2 (3.6)
外陰膣炎	1 (1.8)
No Reasonable Possibility	1 (1.8)
傷害、中毒および処置合併症	5 (9.1)
No Reasonable Possibility	5 (9.1)
足関節部骨折	1 (1.8)
No Reasonable Possibility	1 (1.8)
手骨折	1 (1.8)
No Reasonable Possibility	1 (1.8)

表 2.7.4.7-77.　すべての有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（主試験 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	Adalimumab (N=55) n (%)
傷害、中毒および処置合併症 (Cont.)	
四肢損傷	1 (1.8)
No Reasonable Possibility	1 (1.8)
上肢骨折	1 (1.8)
No Reasonable Possibility	1 (1.8)
手首関節骨折	1 (1.8)
No Reasonable Possibility	1 (1.8)
臨床検査	6 (10.9)
No Reasonable Possibility	5 (9.1)
Reasonable Possibility	1 (1.8)
血中アルカリホスファターゼ増加	1 (1.8)
No Reasonable Possibility	1 (1.8)
体温上昇	1 (1.8)
No Reasonable Possibility	1 (1.8)
結核菌群検査陽性	4 (7.3)
No Reasonable Possibility	3 (5.5)
Reasonable Possibility	1 (1.8)
筋骨格系および結合組織障害	7 (12.7)
No Reasonable Possibility	5 (9.1)
Reasonable Possibility	2 (3.6)

表 2.7.4.7-77.　すべての有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（主試験 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	Adalimumab (N=55) n (%)
筋骨格系および結合組織障害 (Cont.)	
関節痛	4 (7.3)
No Reasonable Possibility	2 (3.6)
Reasonable Possibility	2 (3.6)
背部痛	1 (1.8)
No Reasonable Possibility	1 (1.8)
成長不全	1 (1.8)
No Reasonable Possibility	1 (1.8)
若年性特発性関節炎	1 (1.8)
No Reasonable Possibility	1 (1.8)
脊椎痛	1 (1.8)
No Reasonable Possibility	1 (1.8)
神経系障害	6 (10.9)
No Reasonable Possibility	6 (10.9)
頭痛	5 (9.1)
No Reasonable Possibility	5 (9.1)
傾眠	1 (1.8)
No Reasonable Possibility	1 (1.8)

表 2.7.4.7-77.　すべての有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（主試験 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	Adalimumab (N=55) n (%)
精神障害	2 (3.6)
No Reasonable Possibility	2 (3.6)
うつ病	2 (3.6)
No Reasonable Possibility	2 (3.6)
腎および尿路障害	3 (5.5)
No Reasonable Possibility	2 (3.6)
Reasonable Possibility	1 (1.8)
血尿	1 (1.8)
No Reasonable Possibility	1 (1.8)
腎結石症	1 (1.8)
Reasonable Possibility	1 (1.8)
腎仙痛	1 (1.8)
No Reasonable Possibility	1 (1.8)
生殖系および乳房障害	3 (5.5)
No Reasonable Possibility	2 (3.6)
Reasonable Possibility	1 (1.8)
月経困難症	1 (1.8)
No Reasonable Possibility	1 (1.8)

表 2.7.4.7-77.　すべての有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（主試験 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	Adalimumab (N=55) n (%)
生殖系および乳房障害 (Cont.)	
卵巣嚢胞	2 (3.6)
No Reasonable Possibility	1 (1.8)
Reasonable Possibility	1 (1.8)
呼吸器、胸郭および縦隔障害	4 (7.3)
No Reasonable Possibility	4 (7.3)
喘息	1 (1.8)
No Reasonable Possibility	1 (1.8)
鼻出血	1 (1.8)
No Reasonable Possibility	1 (1.8)
アレルギー性鼻炎	2 (3.6)
No Reasonable Possibility	2 (3.6)
鼻漏	1 (1.8)
No Reasonable Possibility	1 (1.8)
皮膚および皮下組織障害	4 (7.3)
No Reasonable Possibility	1 (1.8)
Reasonable Possibility	3 (5.5)
乾癬様皮膚炎	1 (1.8)
Reasonable Possibility	1 (1.8)

表 2.7.4.7-77.　すべての有害事象（MedDRA SOC 及び PT 別，治験薬との因果関係別）（主試験 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Relationship	Adalimumab (N=55) n (%)
皮膚および皮下組織障害 (Cont.)	
乾癬	1 (1.8)
Reasonable Possibility	1 (1.8)
発疹	1 (1.8)
No Reasonable Possibility	1 (1.8)
皮膚障害	1 (1.8)
Reasonable Possibility	1 (1.8)
血管障害	1 (1.8)
No Reasonable Possibility	1 (1.8)
高血圧	1 (1.8)
No Reasonable Possibility	1 (1.8)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.
If a subject has an AE with unknown relationship, then the subject will be counted in the relationship category of "unknown", unless the subject has another occurrence of the same AE with a relationship assessment of "Reasonable Possibility."

Cross reference: M10-870 Main-study CSR_Interim Table 14.3__1.3.1

表 2.7.4.7-78. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M11-290 試験）

MedDRA 22.0 System Organ Class Preferred Term Severity	I-SD (N=30) n (%)	I-HD (N=47) n (%)	I-HD-OL (N=16) n (%)	Total (N=93) n (%)
Any adverse event	17 (56.7)	23 (48.9)	12 (75.0)	52 (55.9)
Mild	11 (36.7)	15 (31.9)	10 (62.5)	36 (38.7)
Moderate	2 (6.7)	7 (14.9)	2 (12.5)	11 (11.8)
Severe	4 (13.3)	1 (2.1)	0	5 (5.4)
血液およびリンパ系障害	3 (10.0)	3 (6.4)	1 (6.3)	7 (7.5)
Mild	1 (3.3)	1 (2.1)	1 (6.3)	3 (3.2)
Moderate	1 (3.3)	2 (4.3)	0	3 (3.2)
Severe	1 (3.3)	0	0	1 (1.1)
貧血	3 (10.0)	3 (6.4)	1 (6.3)	7 (7.5)
Mild	1 (3.3)	1 (2.1)	1 (6.3)	3 (3.2)
Moderate	1 (3.3)	2 (4.3)	0	3 (3.2)
Severe	1 (3.3)	0	0	1 (1.1)
血小板増加症	0	0	1 (6.3)	1 (1.1)
Mild	0	0	1 (6.3)	1 (1.1)
心臓障害	1 (3.3)	0	0	1 (1.1)
Severe	1 (3.3)	0	0	1 (1.1)
心膜炎	1 (3.3)	0	0	1 (1.1)
Severe	1 (3.3)	0	0	1 (1.1)
内分泌障害	1 (3.3)	0	0	1 (1.1)
Mild	1 (3.3)	0	0	1 (1.1)

表 2.7.4.7-78. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	I-SD (N=30) n (%)	I-HD (N=47) n (%)	I-HD-OL (N=16) n (%)	Total (N=93) n (%)
内分泌障害 (Cont.)				
甲状腺腫	1 (3.3)	0	0	1 (1.1)
Mild	1 (3.3)	0	0	1 (1.1)
眼障害	1 (3.3)	0	0	1 (1.1)
Mild	1 (3.3)	0	0	1 (1.1)
角膜炎	1 (3.3)	0	0	1 (1.1)
Mild	1 (3.3)	0	0	1 (1.1)
胃腸障害	6 (20.0)	9 (19.1)	5 (31.3)	20 (21.5)
Mild	2 (6.7)	4 (8.5)	4 (25.0)	10 (10.8)
Moderate	2 (6.7)	4 (8.5)	1 (6.3)	7 (7.5)
Severe	2 (6.7)	1 (2.1)	0	3 (3.2)
腹痛	0	2 (4.3)	2 (12.5)	4 (4.3)
Mild	0	2 (4.3)	2 (12.5)	4 (4.3)
上腹部痛	1 (3.3)	2 (4.3)	0	3 (3.2)
Mild	1 (3.3)	1 (2.1)	0	2 (2.2)
Moderate	0	1 (2.1)	0	1 (1.1)
潰瘍性大腸炎	4 (13.3)	2 (4.3)	1 (6.3)	7 (7.5)
Mild	0	0	1 (6.3)	1 (1.1)
Moderate	2 (6.7)	1 (2.1)	0	3 (3.2)
Severe	2 (6.7)	1 (2.1)	0	3 (3.2)

表 2.7.4.7-78. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	I-SD (N=30) n (%)	I-HD (N=47) n (%)	I-HD-OL (N=16) n (%)	Total (N=93) n (%)
胃腸障害 (Cont.)				
便秘	0	0	1 (6.3)	1 (1.1)
Mild	0	0	1 (6.3)	1 (1.1)
下痢	0	0	1 (6.3)	1 (1.1)
Mild	0	0	1 (6.3)	1 (1.1)
血性下痢	1 (3.3)	0	0	1 (1.1)
Mild	1 (3.3)	0	0	1 (1.1)
小腸炎	1 (3.3)	0	0	1 (1.1)
Mild	1 (3.3)	0	0	1 (1.1)
鼓腸	1 (3.3)	0	0	1 (1.1)
Mild	1 (3.3)	0	0	1 (1.1)
排便回数増加	0	1 (2.1)	0	1 (1.1)
Moderate	0	1 (2.1)	0	1 (1.1)
胃食道逆流性疾患	0	1 (2.1)	1 (6.3)	2 (2.2)
Mild	0	1 (2.1)	1 (6.3)	2 (2.2)

表 2.7.4.7-78. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	I-SD (N=30) n (%)	I-HD (N=47) n (%)	I-HD-OL (N=16) n (%)	Total (N=93) n (%)
胃腸障害 (Cont.)				
血便排泄	0	2 (4.3)	0	2 (2.2)
Mild	0	1 (2.1)	0	1 (1.1)
Moderate	0	1 (2.1)	0	1 (1.1)
悪心	0	3 (6.4)	1 (6.3)	4 (4.3)
Mild	0	3 (6.4)	1 (6.3)	4 (4.3)
膵炎	0	1 (2.1)	0	1 (1.1)
Moderate	0	1 (2.1)	0	1 (1.1)
嘔吐	0	1 (2.1)	1 (6.3)	2 (2.2)
Mild	0	1 (2.1)	0	1 (1.1)
Moderate	0	0	1 (6.3)	1 (1.1)
一般・全身障害および投与部位の状態	3 (10.0)	6 (12.8)	0	9 (9.7)
Mild	2 (6.7)	5 (10.6)	0	7 (7.5)
Moderate	1 (3.3)	1 (2.1)	0	2 (2.2)
腋窩痛	0	1 (2.1)	0	1 (1.1)
Mild	0	1 (2.1)	0	1 (1.1)
胸痛	0	1 (2.1)	0	1 (1.1)
Mild	0	1 (2.1)	0	1 (1.1)

表 2.7.4.7-78. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	I-SD (N=30) n (%)	I-HD (N=47) n (%)	I-HD-OL (N=16) n (%)	Total (N=93) n (%)
一般・全身障害および投与部位の状態 (Cont.)				
疲労	0	1 (2.1)	0	1 (1.1)
Mild	0	1 (2.1)	0	1 (1.1)
注射部位疼痛	0	1 (2.1)	0	1 (1.1)
Moderate	0	1 (2.1)	0	1 (1.1)
注射部位蕁麻疹	0	1 (2.1)	0	1 (1.1)
Mild	0	1 (2.1)	0	1 (1.1)
末梢腫脹	1 (3.3)	0	0	1 (1.1)
Mild	1 (3.3)	0	0	1 (1.1)
発熱	2 (6.7)	1 (2.1)	0	3 (3.2)
Mild	1 (3.3)	1 (2.1)	0	2 (2.2)
Moderate	1 (3.3)	0	0	1 (1.1)
肝胆道系障害	1 (3.3)	0	0	1 (1.1)
Mild	1 (3.3)	0	0	1 (1.1)
高ビリルビン血症	1 (3.3)	0	0	1 (1.1)
Mild	1 (3.3)	0	0	1 (1.1)

表 2.7.4.7-78. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	I-SD (N=30) n (%)	I-HD (N=47) n (%)	I-HD-OL (N=16) n (%)	Total (N=93) n (%)
感染症および寄生虫症	6 (20.0)	8 (17.0)	6 (37.5)	20 (21.5)
Mild	5 (16.7)	8 (17.0)	5 (31.3)	18 (19.4)
Moderate	0	0	1 (6.3)	1 (1.1)
Severe	1 (3.3)	0	0	1 (1.1)
気管支炎	0	0	1 (6.3)	1 (1.1)
Moderate	0	0	1 (6.3)	1 (1.1)
せつ	0	1 (2.1)	0	1 (1.1)
Mild	0	1 (2.1)	0	1 (1.1)
サルモネラ菌性胃腸炎	1 (3.3)	0	0	1 (1.1)
Severe	1 (3.3)	0	0	1 (1.1)
上咽頭炎	2 (6.7)	2 (4.3)	1 (6.3)	5 (5.4)
Mild	2 (6.7)	2 (4.3)	1 (6.3)	5 (5.4)
口腔ヘルペス	1 (3.3)	2 (4.3)	0	3 (3.2)
Mild	1 (3.3)	2 (4.3)	0	3 (3.2)
咽頭炎	2 (6.7)	1 (2.1)	1 (6.3)	4 (4.3)
Mild	2 (6.7)	1 (2.1)	1 (6.3)	4 (4.3)

表 2.7.4.7-78. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	I-SD (N=30) n (%)	I-HD (N=47) n (%)	I-HD-OL (N=16) n (%)	Total (N=93) n (%)
感染症および寄生虫症 (Cont.)				
レンサ球菌感染	0	0	1 (6.3)	1 (1.1)
Mild	0	0	1 (6.3)	1 (1.1)
上気道感染	0	1 (2.1)	0	1 (1.1)
Mild	0	1 (2.1)	0	1 (1.1)
尿路感染	1 (3.3)	0	0	1 (1.1)
Mild	1 (3.3)	0	0	1 (1.1)
水痘	0	1 (2.1)	0	1 (1.1)
Mild	0	1 (2.1)	0	1 (1.1)
ウイルス感染	0	0	1 (6.3)	1 (1.1)
Mild	0	0	1 (6.3)	1 (1.1)
ウイルス性上気道感染	0	1 (2.1)	0	1 (1.1)
Mild	0	1 (2.1)	0	1 (1.1)
外陰膣真菌感染	0	0	1 (6.3)	1 (1.1)
Mild	0	0	1 (6.3)	1 (1.1)

表 2.7.4.7-78. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	I-SD (N=30) n (%)	I-HD (N=47) n (%)	I-HD-OL (N=16) n (%)	Total (N=93) n (%)
傷害、中毒および処置合併症	4 (13.3)	2 (4.3)	0	6 (6.5)
Mild	4 (13.3)	1 (2.1)	0	5 (5.4)
Moderate	0	1 (2.1)	0	1 (1.1)
節足動物咬傷	1 (3.3)	0	0	1 (1.1)
Mild	1 (3.3)	0	0	1 (1.1)
転倒	1 (3.3)	0	0	1 (1.1)
Mild	1 (3.3)	0	0	1 (1.1)
注入に伴う反応	1 (3.3)	0	0	1 (1.1)
Mild	1 (3.3)	0	0	1 (1.1)
靭帯捻挫	1 (3.3)	0	0	1 (1.1)
Mild	1 (3.3)	0	0	1 (1.1)
処置による疼痛	0	1 (2.1)	0	1 (1.1)
Mild	0	1 (2.1)	0	1 (1.1)
手首関節骨折	0	1 (2.1)	0	1 (1.1)
Moderate	0	1 (2.1)	0	1 (1.1)

表 2.7.4.7-78. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	I-SD (N=30) n (%)	I-HD (N=47) n (%)	I-HD-OL (N=16) n (%)	Total (N=93) n (%)
臨床検査	2 (6.7)	2 (4.3)	1 (6.3)	5 (5.4)
Mild	2 (6.7)	1 (2.1)	1 (6.3)	4 (4.3)
Moderate	0	1 (2.1)	0	1 (1.1)
血圧上昇	0	1 (2.1)	0	1 (1.1)
Mild	0	1 (2.1)	0	1 (1.1)
C－反応性蛋白増加	0	1 (2.1)	0	1 (1.1)
Moderate	0	1 (2.1)	0	1 (1.1)
ヘモグロビン減少	1 (3.3)	0	0	1 (1.1)
Mild	1 (3.3)	0	0	1 (1.1)
肝酵素上昇	0	0	1 (6.3)	1 (1.1)
Mild	0	0	1 (6.3)	1 (1.1)
体重減少	1 (3.3)	1 (2.1)	0	2 (2.2)
Mild	1 (3.3)	0	0	1 (1.1)
Moderate	0	1 (2.1)	0	1 (1.1)
筋骨格系および結合組織障害	2 (6.7)	2 (4.3)	1 (6.3)	5 (5.4)
Mild	2 (6.7)	2 (4.3)	1 (6.3)	5 (5.4)

表 2.7.4.7-78. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	I-SD (N=30) n (%)	I-HD (N=47) n (%)	I-HD-OL (N=16) n (%)	Total (N=93) n (%)
筋骨格系および結合組織障害 (Cont.)				
関節痛	1 (3.3)	0	1 (6.3)	2 (2.2)
Mild	1 (3.3)	0	1 (6.3)	2 (2.2)
背部痛	0	1 (2.1)	0	1 (1.1)
Mild	0	1 (2.1)	0	1 (1.1)
靭帯障害	0	1 (2.1)	0	1 (1.1)
Mild	0	1 (2.1)	0	1 (1.1)
四肢痛	1 (3.3)	0	0	1 (1.1)
Mild	1 (3.3)	0	0	1 (1.1)
神経系障害	5 (16.7)	5 (10.6)	4 (25.0)	14 (15.1)
Mild	4 (13.3)	5 (10.6)	4 (25.0)	13 (14.0)
Moderate	1 (3.3)	0	0	1 (1.1)
頭痛	4 (13.3)	5 (10.6)	4 (25.0)	13 (14.0)
Mild	4 (13.3)	5 (10.6)	4 (25.0)	13 (14.0)
意識消失	1 (3.3)	0	0	1 (1.1)
Mild	1 (3.3)	0	0	1 (1.1)

表 2.7.4.7-78. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	I-SD (N=30) n (%)	I-HD (N=47) n (%)	I-HD-OL (N=16) n (%)	Total (N=93) n (%)
神経系障害 (Cont.)				
片頭痛	1 (3.3)	0	0	1 (1.1)
Moderate	1 (3.3)	0	0	1 (1.1)
錯感覚	1 (3.3)	0	0	1 (1.1)
Moderate	1 (3.3)	0	0	1 (1.1)
振戦	0	1 (2.1)	1 (6.3)	2 (2.2)
Mild	0	1 (2.1)	1 (6.3)	2 (2.2)
腎および尿路障害	0	0	1 (6.3)	1 (1.1)
Mild	0	0	1 (6.3)	1 (1.1)
糖尿	0	0	1 (6.3)	1 (1.1)
Mild	0	0	1 (6.3)	1 (1.1)
生殖系および乳房障害	0	1 (2.1)	0	1 (1.1)
Mild	0	1 (2.1)	0	1 (1.1)
乳房痛	0	1 (2.1)	0	1 (1.1)
Mild	0	1 (2.1)	0	1 (1.1)

表 2.7.4.7-78. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	I-SD (N=30) n (%)	I-HD (N=47) n (%)	I-HD-OL (N=16) n (%)	Total (N=93) n (%)
呼吸器、胸郭および縦隔障害	1 (3.3)	3 (6.4)	3 (18.8)	7 (7.5)
Mild	1 (3.3)	3 (6.4)	3 (18.8)	7 (7.5)
咳嗽	0	1 (2.1)	0	1 (1.1)
Mild	0	1 (2.1)	0	1 (1.1)
鼻閉	0	1 (2.1)	0	1 (1.1)
Mild	0	1 (2.1)	0	1 (1.1)
口腔咽頭痛	1 (3.3)	1 (2.1)	2 (12.5)	4 (4.3)
Mild	1 (3.3)	1 (2.1)	2 (12.5)	4 (4.3)
鼻漏	0	1 (2.1)	1 (6.3)	2 (2.2)
Mild	0	1 (2.1)	1 (6.3)	2 (2.2)
皮膚および皮下組織障害	1 (3.3)	0	1 (6.3)	2 (2.2)
Mild	0	0	1 (6.3)	1 (1.1)
Moderate	1 (3.3)	0	0	1 (1.1)
結節性紅斑	1 (3.3)	0	0	1 (1.1)
Moderate	1 (3.3)	0	0	1 (1.1)

表 2.7.4.7-78. 導入療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験安全性解析対象集団，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	I-SD (N=30) n (%)	I-HD (N=47) n (%)	I-HD-OL (N=16) n (%)	Total (N=93) n (%)
皮膚および皮下組織障害 (Cont.)				
発疹	0	0	1 (6.3)	1 (1.1)
Mild	0	0	1 (6.3)	1 (1.1)

I-SD = induction standard dose group, I-HD = induction high dose group, I-HD-OL = induction high dose open-label group.
Note: Table depicts the most servere adverse event for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
If a subject has an AE with unknown severity, then the subject will be counted in the severity category of "unknown,"even if the subject has another occurrence of the same event with a severity present. The only exception is if the subject has another occurrence of the same AE with the most extreme severity - "Severe." In this case, the subject will be counted under the "Severe" category.

Cross reference: M11-290 Main-study CSR_Interim Table 14.3__1.3.2.1

表 2.7.4.7-79. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた主試験安全性解析対象集団の被験者，M11-290 試験）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total-ADA (N=63) n (%)	M-PL (N=12) n (%)	Total (N=75) n (%)
Any adverse event	20 (64.5)	22 (68.8)	42 (66.7)	10 (83.3)	52 (69.3)
Mild	6 (19.4)	14 (43.8)	20 (31.7)	8 (66.7)	28 (37.3)
Moderate	11 (35.5)	7 (21.9)	18 (28.6)	2 (16.7)	20 (26.7)
Severe	3 (9.7)	1 (3.1)	4 (6.3)	0	4 (5.3)
血液およびリンパ系障害	4 (12.9)	1 (3.1)	5 (7.9)	2 (16.7)	7 (9.3)
Mild	1 (3.2)	1 (3.1)	2 (3.2)	1 (8.3)	3 (4.0)
Moderate	2 (6.5)	0	2 (3.2)	1 (8.3)	3 (4.0)
Severe	1 (3.2)	0	1 (1.6)	0	1 (1.3)
貧血	3 (9.7)	1 (3.1)	4 (6.3)	1 (8.3)	5 (6.7)
Mild	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Moderate	2 (6.5)	0	2 (3.2)	1 (8.3)	3 (4.0)
Severe	1 (3.2)	0	1 (1.6)	0	1 (1.3)
リンパ節症	1 (3.2)	0	1 (1.6)	0	1 (1.3)
Mild	1 (3.2)	0	1 (1.6)	0	1 (1.3)
好中球減少症	0	0	0	1 (8.3)	1 (1.3)
Mild	0	0	0	1 (8.3)	1 (1.3)
耳および迷路障害	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Mild	0	1 (3.1)	1 (1.6)	0	1 (1.3)
耳痛	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Mild	0	1 (3.1)	1 (1.6)	0	1 (1.3)

表 2.7.4.7-79. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた主試験安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total-ADA (N=63) n (%)	M-PL (N=12) n (%)	Total (N=75) n (%)
眼障害	0	0	0	1 (8.3)	1 (1.3)
Mild	0	0	0	1 (8.3)	1 (1.3)
非感染性結膜炎	0	0	0	1 (8.3)	1 (1.3)
Mild	0	0	0	1 (8.3)	1 (1.3)
胃腸障害	9 (29.0)	10 (31.3)	19 (30.2)	3 (25.0)	22 (29.3)
Mild	3 (9.7)	6 (18.8)	9 (14.3)	2 (16.7)	11 (14.7)
Moderate	3 (9.7)	4 (12.5)	7 (11.1)	1 (8.3)	8 (10.7)
Severe	3 (9.7)	0	3 (4.8)	0	3 (4.0)
腹痛	1 (3.2)	1 (3.1)	2 (3.2)	1 (8.3)	3 (4.0)
Mild	1 (3.2)	1 (3.1)	2 (3.2)	1 (8.3)	3 (4.0)
上腹部痛	0	2 (6.3)	2 (3.2)	0	2 (2.7)
Mild	0	2 (6.3)	2 (3.2)	0	2 (2.7)
アフタ性潰瘍	1 (3.2)	0	1 (1.6)	0	1 (1.3)
Mild	1 (3.2)	0	1 (1.6)	0	1 (1.3)
潰瘍性大腸炎	6 (19.4)	4 (12.5)	10 (15.9)	2 (16.7)	12 (16.0)
Mild	1 (3.2)	0	1 (1.6)	1 (8.3)	2 (2.7)
Moderate	2 (6.5)	4 (12.5)	6 (9.5)	1 (8.3)	7 (9.3)
Severe	3 (9.7)	0	3 (4.8)	0	3 (4.0)

表 2.7.4.7-79. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた主試験安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total-ADA (N=63) n (%)	M-PL (N=12) n (%)	Total (N=75) n (%)
胃腸障害 (Cont.)					
便秘	1 (3.2)	0	1 (1.6)	0	1 (1.3)
Mild	1 (3.2)	0	1 (1.6)	0	1 (1.3)
下痢	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Mild	0	1 (3.1)	1 (1.6)	0	1 (1.3)
消化不良	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Mild	0	1 (3.1)	1 (1.6)	0	1 (1.3)
小腸炎	2 (6.5)	1 (3.1)	3 (4.8)	0	3 (4.0)
Mild	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Moderate	2 (6.5)	0	2 (3.2)	0	2 (2.7)
胃食道逆流性疾患	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Mild	0	1 (3.1)	1 (1.6)	0	1 (1.3)
一般・全身障害および投与部位の状態	5 (16.1)	3 (9.4)	8 (12.7)	1 (8.3)	9 (12.0)
Mild	3 (9.7)	2 (6.3)	5 (7.9)	1 (8.3)	6 (8.0)
Moderate	2 (6.5)	1 (3.1)	3 (4.8)	0	3 (4.0)
胸痛	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Mild	0	1 (3.1)	1 (1.6)	0	1 (1.3)

表 2.7.4.7-79.　維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた主試験安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total-ADA (N=63) n (%)	M-PL (N=12) n (%)	Total (N=75) n (%)
一般・全身障害および投与部位の状態 (Cont.)					
疲労	2 (6.5)	0	2 (3.2)	0	2 (2.7)
Mild	2 (6.5)	0	2 (3.2)	0	2 (2.7)
炎症	0	0	0	1 (8.3)	1 (1.3)
Mild	0	0	0	1 (8.3)	1 (1.3)
注射部位紅斑	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Mild	0	1 (3.1)	1 (1.6)	0	1 (1.3)
注射部位炎症	1 (3.2)	0	1 (1.6)	0	1 (1.3)
Moderate	1 (3.2)	0	1 (1.6)	0	1 (1.3)
注射部位浮腫	1 (3.2)	0	1 (1.6)	0	1 (1.3)
Mild	1 (3.2)	0	1 (1.6)	0	1 (1.3)
注射部位疼痛	1 (3.2)	0	1 (1.6)	0	1 (1.3)
Mild	1 (3.2)	0	1 (1.6)	0	1 (1.3)
注射部位そう痒感	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Mild	0	1 (3.1)	1 (1.6)	0	1 (1.3)

表 2.7.4.7-79. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた主試験安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total-ADA (N=63) n (%)	M-PL (N=12) n (%)	Total (N=75) n (%)
一般・全身障害および投与部位の状態 (Cont.)					
注射部位腫脹	1 (3.2)	0	1 (1.6)	0	1 (1.3)
Mild	1 (3.2)	0	1 (1.6)	0	1 (1.3)
注射部位蕁麻疹	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Mild	0	1 (3.1)	1 (1.6)	0	1 (1.3)
倦怠感	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Moderate	0	1 (3.1)	1 (1.6)	0	1 (1.3)
発熱	1 (3.2)	0	1 (1.6)	0	1 (1.3)
Moderate	1 (3.2)	0	1 (1.6)	0	1 (1.3)
免疫系障害	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Mild	0	1 (3.1)	1 (1.6)	0	1 (1.3)
薬物過敏症	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Mild	0	1 (3.1)	1 (1.6)	0	1 (1.3)
感染症および寄生虫症	10 (32.3)	13 (40.6)	23 (36.5)	5 (41.7)	28 (37.3)
Mild	4 (12.9)	10 (31.3)	14 (22.2)	5 (41.7)	19 (25.3)
Moderate	6 (19.4)	2 (6.3)	8 (12.7)	0	8 (10.7)
Severe	0	1 (3.1)	1 (1.6)	0	1 (1.3)

表 2.7.4.7-79. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた主試験安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total-ADA (N=63) n (%)	M-PL (N=12) n (%)	Total (N=75) n (%)
感染症および寄生虫症 (Cont.)					
気管支炎	1 (3.2)	0	1 (1.6)	0	1 (1.3)
Moderate	1 (3.2)	0	1 (1.6)	0	1 (1.3)
胃腸炎	2 (6.5)	0	2 (3.2)	1 (8.3)	3 (4.0)
Mild	0	0	0	1 (8.3)	1 (1.3)
Moderate	2 (6.5)	0	2 (3.2)	0	2 (2.7)
感染性嚢腫	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Mild	0	1 (3.1)	1 (1.6)	0	1 (1.3)
インフルエンザ	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Mild	0	1 (3.1)	1 (1.6)	0	1 (1.3)
喉頭炎	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Mild	0	1 (3.1)	1 (1.6)	0	1 (1.3)
無菌性髄膜炎	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Severe	0	1 (3.1)	1 (1.6)	0	1 (1.3)
上咽頭炎	3 (9.7)	4 (12.5)	7 (11.1)	1 (8.3)	8 (10.7)
Mild	1 (3.2)	4 (12.5)	5 (7.9)	1 (8.3)	6 (8.0)
Moderate	2 (6.5)	0	2 (3.2)	0	2 (2.7)

表 2.7.4.7-79. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた主試験安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total-ADA (N=63) n (%)	M-PL (N=12) n (%)	Total (N=75) n (%)
感染症および寄生虫症 (Cont.)					
口腔ヘルペス	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Mild	0	1 (3.1)	1 (1.6)	0	1 (1.3)
中耳炎	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Mild	0	1 (3.1)	1 (1.6)	0	1 (1.3)
咽頭炎	2 (6.5)	2 (6.3)	4 (6.3)	1 (8.3)	5 (6.7)
Mild	2 (6.5)	1 (3.1)	3 (4.8)	1 (8.3)	4 (5.3)
Moderate	0	1 (3.1)	1 (1.6)	0	1 (1.3)
気道感染	1 (3.2)	0	1 (1.6)	0	1 (1.3)
Moderate	1 (3.2)	0	1 (1.6)	0	1 (1.3)
ウイルス性気道感染	0	0	0	1 (8.3)	1 (1.3)
Mild	0	0	0	1 (8.3)	1 (1.3)
鼻炎	1 (3.2)	0	1 (1.6)	0	1 (1.3)
Mild	1 (3.2)	0	1 (1.6)	0	1 (1.3)
癜風	1 (3.2)	0	1 (1.6)	0	1 (1.3)
Mild	1 (3.2)	0	1 (1.6)	0	1 (1.3)

表 2.7.4.7-79. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた主試験安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total-ADA (N=63) n (%)	M-PL (N=12) n (%)	Total (N=75) n (%)
感染症および寄生虫症 (Cont.)					
歯膿瘍	0	0	0	1 (8.3)	1 (1.3)
Mild	0	0	0	1 (8.3)	1 (1.3)
気管炎	1 (3.2)	0	1 (1.6)	0	1 (1.3)
Moderate	1 (3.2)	0	1 (1.6)	0	1 (1.3)
上気道感染	2 (6.5)	3 (9.4)	5 (7.9)	2 (16.7)	7 (9.3)
Mild	2 (6.5)	3 (9.4)	5 (7.9)	2 (16.7)	7 (9.3)
尿路感染	1 (3.2)	2 (6.3)	3 (4.8)	0	3 (4.0)
Mild	1 (3.2)	1 (3.1)	2 (3.2)	0	2 (2.7)
Moderate	0	1 (3.1)	1 (1.6)	0	1 (1.3)
水痘	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Mild	0	1 (3.1)	1 (1.6)	0	1 (1.3)
傷害、中毒および処置合併症	0	1 (3.1)	1 (1.6)	1 (8.3)	2 (2.7)
Mild	0	1 (3.1)	1 (1.6)	1 (8.3)	2 (2.7)
手骨折	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Mild	0	1 (3.1)	1 (1.6)	0	1 (1.3)

表 2.7.4.7-79. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた主試験安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total-ADA (N=63) n (%)	M-PL (N=12) n (%)	Total (N=75) n (%)
傷害、中毒および処置合併症 (Cont.)					
関節損傷	0	0	0	1 (8.3)	1 (1.3)
Mild	0	0	0	1 (8.3)	1 (1.3)
臨床検査	5 (16.1)	3 (9.4)	8 (12.7)	0	8 (10.7)
Mild	3 (9.7)	3 (9.4)	6 (9.5)	0	6 (8.0)
Moderate	2 (6.5)	0	2 (3.2)	0	2 (2.7)
血中ビリルビン増加	1 (3.2)	1 (3.1)	2 (3.2)	0	2 (2.7)
Mild	1 (3.2)	1 (3.1)	2 (3.2)	0	2 (2.7)
血中カルシウム減少	1 (3.2)	0	1 (1.6)	0	1 (1.3)
Mild	1 (3.2)	0	1 (1.6)	0	1 (1.3)
血中ナトリウム減少	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Mild	0	1 (3.1)	1 (1.6)	0	1 (1.3)
骨密度減少	1 (3.2)	0	1 (1.6)	0	1 (1.3)
Mild	1 (3.2)	0	1 (1.6)	0	1 (1.3)
C－反応性蛋白増加	3 (9.7)	0	3 (4.8)	0	3 (4.0)
Mild	2 (6.5)	0	2 (3.2)	0	2 (2.7)
Moderate	1 (3.2)	0	1 (1.6)	0	1 (1.3)

表 2.7.4.7-79. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた主試験安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total-ADA (N=63) n (%)	M-PL (N=12) n (%)	Total (N=75) n (%)
臨床検査 (Cont.)					
好酸球数増加	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Mild	0	1 (3.1)	1 (1.6)	0	1 (1.3)
リンパ節触知	1 (3.2)	0	1 (1.6)	0	1 (1.3)
Mild	1 (3.2)	0	1 (1.6)	0	1 (1.3)
結核菌群検査陽性	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Mild	0	1 (3.1)	1 (1.6)	0	1 (1.3)
好中球数減少	1 (3.2)	0	1 (1.6)	0	1 (1.3)
Mild	1 (3.2)	0	1 (1.6)	0	1 (1.3)
白血球数減少	1 (3.2)	0	1 (1.6)	0	1 (1.3)
Moderate	1 (3.2)	0	1 (1.6)	0	1 (1.3)
筋骨格系および結合組織障害	1 (3.2)	2 (6.3)	3 (4.8)	1 (8.3)	4 (5.3)
Mild	1 (3.2)	1 (3.1)	2 (3.2)	1 (8.3)	3 (4.0)
Moderate	0	1 (3.1)	1 (1.6)	0	1 (1.3)
関節痛	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Moderate	0	1 (3.1)	1 (1.6)	0	1 (1.3)

表 2.7.4.7-79. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた主試験安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total-ADA (N=63) n (%)	M-PL (N=12) n (%)	Total (N=75) n (%)
筋骨格系および結合組織障害 (Cont.)					
背部痛	1 (3.2)	1 (3.1)	2 (3.2)	0	2 (2.7)
Mild	1 (3.2)	1 (3.1)	2 (3.2)	0	2 (2.7)
筋骨格痛	0	0	0	1 (8.3)	1 (1.3)
Mild	0	0	0	1 (8.3)	1 (1.3)
神経系障害	6 (19.4)	3 (9.4)	9 (14.3)	2 (16.7)	11 (14.7)
Mild	4 (12.9)	2 (6.3)	6 (9.5)	2 (16.7)	8 (10.7)
Moderate	2 (6.5)	1 (3.1)	3 (4.8)	0	3 (4.0)
頭痛	6 (19.4)	2 (6.3)	8 (12.7)	2 (16.7)	10 (13.3)
Mild	4 (12.9)	2 (6.3)	6 (9.5)	2 (16.7)	8 (10.7)
Moderate	2 (6.5)	0	2 (3.2)	0	2 (2.7)
感覚鈍麻	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Moderate	0	1 (3.1)	1 (1.6)	0	1 (1.3)
錯感覚	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Moderate	0	1 (3.1)	1 (1.6)	0	1 (1.3)
精神障害	1 (3.2)	1 (3.1)	2 (3.2)	0	2 (2.7)
Mild	1 (3.2)	0	1 (1.6)	0	1 (1.3)
Moderate	0	1 (3.1)	1 (1.6)	0	1 (1.3)

表 2.7.4.7-79. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた主試験安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total-ADA (N=63) n (%)	M-PL (N=12) n (%)	Total (N=75) n (%)
精神障害 (Cont.)					
うつ病	1 (3.2)	1 (3.1)	2 (3.2)	0	2 (2.7)
Mild	1 (3.2)	0	1 (1.6)	0	1 (1.3)
Moderate	0	1 (3.1)	1 (1.6)	0	1 (1.3)
生殖系および乳房障害	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Mild	0	1 (3.1)	1 (1.6)	0	1 (1.3)
月経困難症	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Mild	0	1 (3.1)	1 (1.6)	0	1 (1.3)
呼吸器、胸郭および縦隔障害	4 (12.9)	5 (15.6)	9 (14.3)	3 (25.0)	12 (16.0)
Mild	4 (12.9)	5 (15.6)	9 (14.3)	3 (25.0)	12 (16.0)
喘息	1 (3.2)	0	1 (1.6)	0	1 (1.3)
Mild	1 (3.2)	0	1 (1.6)	0	1 (1.3)
咳嗽	0	2 (6.3)	2 (3.2)	0	2 (2.7)
Mild	0	2 (6.3)	2 (3.2)	0	2 (2.7)
鼻出血	0	0	0	2 (16.7)	2 (2.7)
Mild	0	0	0	2 (16.7)	2 (2.7)

表 2.7.4.7-79. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた主試験安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total-ADA (N=63) n (%)	M-PL (N=12) n (%)	Total (N=75) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)					
鼻浮腫	1 (3.2)	0	1 (1.6)	0	1 (1.3)
Mild	1 (3.2)	0	1 (1.6)	0	1 (1.3)
口腔咽頭痛	2 (6.5)	1 (3.1)	3 (4.8)	0	3 (4.0)
Mild	2 (6.5)	1 (3.1)	3 (4.8)	0	3 (4.0)
アレルギー性鼻炎	0	2 (6.3)	2 (3.2)	0	2 (2.7)
Mild	0	2 (6.3)	2 (3.2)	0	2 (2.7)
鼻漏	1 (3.2)	0	1 (1.6)	0	1 (1.3)
Mild	1 (3.2)	0	1 (1.6)	0	1 (1.3)
喘鳴	0	0	0	1 (8.3)	1 (1.3)
Mild	0	0	0	1 (8.3)	1 (1.3)
皮膚および皮下組織障害	1 (3.2)	6 (18.8)	7 (11.1)	3 (25.0)	10 (13.3)
Mild	1 (3.2)	5 (15.6)	6 (9.5)	3 (25.0)	9 (12.0)
Moderate	0	1 (3.1)	1 (1.6)	0	1 (1.3)
脱毛症	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Mild	0	1 (3.1)	1 (1.6)	0	1 (1.3)

表 2.7.4.7-79. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた主試験安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total-ADA (N=63) n (%)	M-PL (N=12) n (%)	Total (N=75) n (%)
皮膚および皮下組織障害 (Cont.)					
皮膚炎	0	1 (3.1)	1 (1.6)	1 (8.3)	2 (2.7)
Mild	0	1 (3.1)	1 (1.6)	1 (8.3)	2 (2.7)
紅斑	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Mild	0	1 (3.1)	1 (1.6)	0	1 (1.3)
結節性紅斑	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Moderate	0	1 (3.1)	1 (1.6)	0	1 (1.3)
逆むけ	0	0	0	1 (8.3)	1 (1.3)
Mild	0	0	0	1 (8.3)	1 (1.3)
乾癬	0	0	0	1 (8.3)	1 (1.3)
Mild	0	0	0	1 (8.3)	1 (1.3)
発疹	1 (3.2)	2 (6.3)	3 (4.8)	0	3 (4.0)
Mild	1 (3.2)	2 (6.3)	3 (4.8)	0	3 (4.0)
痂皮	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Mild	0	1 (3.1)	1 (1.6)	0	1 (1.3)

表 2.7.4.7-79. 維持療法期中に発現した有害事象（MedDRA SOC 及び PT 別，重症度別）
（維持療法期中に治験薬の投与を 1 回以上受けた主試験安全性解析対象集団の被験者，M11-290 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	M-SD (N=31) n (%)	M-HD (N=32) n (%)	Total-ADA (N=63) n (%)	M-PL (N=12) n (%)	Total (N=75) n (%)
皮膚および皮下組織障害 (Cont.)					
脂漏	1 (3.2)	0	1 (1.6)	0	1 (1.3)
Mild	1 (3.2)	0	1 (1.6)	0	1 (1.3)
皮膚病変	0	1 (3.1)	1 (1.6)	0	1 (1.3)
Mild	0	1 (3.1)	1 (1.6)	0	1 (1.3)

M-PL = maintenance placebo group, M-SD = maintenance standard dose group, M-HD = maintenance high dose group.
Note: Table depicts the most servere adverse event for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
If a subject has an AE with unknown severity, then the subject will be counted in the severity category of "unknown,"even if the subject has another occurrence of the same event with a severity present. The only exception is if the subject has another occurrence of the same AE with the most extreme severity - "Severe." In this case, the subject will be counted under the "Severe" category.

Cross reference: M11-290 Main-study CSR_Interim Table 14.3__1.3.2.2

表 2.7.4.7-80.　すべての有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験 FAS 集団，M10-870 試験）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab (N=55) n (%)
Any adverse event	36 (65.5)
Mild	20 (36.4)
Moderate	14 (25.5)
Severe	2 (3.6)
血液およびリンパ系障害	6 (10.9)
Mild	1 (1.8)
Moderate	4 (7.3)
Severe	1 (1.8)
貧血	4 (7.3)
Moderate	3 (5.5)
Severe	1 (1.8)
失血性貧血	1 (1.8)
Moderate	1 (1.8)
鉄欠乏性貧血	1 (1.8)
Moderate	1 (1.8)
リンパ節炎	1 (1.8)
Mild	1 (1.8)
胃腸障害	21 (38.2)
Mild	13 (23.6)
Moderate	6 (10.9)
Severe	2 (3.6)

表 2.7.4.7-80. すべての有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab (N=55) n (%)
胃腸障害 (Cont.)	
腹部不快感	1 (1.8)
Mild	1 (1.8)
腹痛	1 (1.8)
Mild	1 (1.8)
上腹部痛	2 (3.6)
Mild	1 (1.8)
Moderate	1 (1.8)
口唇症	1 (1.8)
Mild	1 (1.8)
潰瘍性大腸炎	11 (20.0)
Mild	5 (9.1)
Moderate	4 (7.3)
Severe	2 (3.6)
便秘	1 (1.8)
Mild	1 (1.8)
下痢	1 (1.8)
Mild	1 (1.8)

表 2.7.4.7-80. すべての有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab (N=55) n (%)
胃腸障害 (Cont.)	
消化不良	2 (3.6)
Mild	2 (3.6)
腸炎	1 (1.8)
Mild	1 (1.8)
胃炎	3 (5.5)
Mild	3 (5.5)
血便排泄	2 (3.6)
Moderate	2 (3.6)
大腸ポリープ	1 (1.8)
Moderate	1 (1.8)
悪心	1 (1.8)
Mild	1 (1.8)
直腸出血	1 (1.8)
Moderate	1 (1.8)

表 2.7.4.7-80.　すべての有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab (N=55) n (%)
胃腸障害 (Cont.)	
嘔吐	1 (1.8)
Mild	1 (1.8)
一般・全身障害および投与部位の状態	2 (3.6)
Mild	2 (3.6)
末梢性浮腫	1 (1.8)
Mild	1 (1.8)
発熱	1 (1.8)
Mild	1 (1.8)
肝胆道系障害	1 (1.8)
Moderate	1 (1.8)
胆嚢炎	1 (1.8)
Moderate	1 (1.8)
免疫系障害	1 (1.8)
Mild	1 (1.8)

表 2.7.4.7-80.　すべての有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab (N=55) n (%)
免疫系障害 (Cont.)	
季節性アレルギー	1 (1.8)
Mild	1 (1.8)
感染症および寄生虫症	20 (36.4)
Mild	17 (30.9)
Moderate	3 (5.5)
肛門膿瘍	1 (1.8)
Mild	1 (1.8)
気管支炎	3 (5.5)
Mild	2 (3.6)
Moderate	1 (1.8)
ウイルス性胃腸炎	2 (3.6)
Mild	2 (3.6)
帯状疱疹	1 (1.8)
Mild	1 (1.8)
上咽頭炎	3 (5.5)
Mild	2 (3.6)
Moderate	1 (1.8)

表 2.7.4.7-80.　すべての有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab (N=55) n (%)
感染症および寄生虫症 (Cont.)	
口腔ヘルペス	1 (1.8)
Mild	1 (1.8)
中耳炎	1 (1.8)
Mild	1 (1.8)
咽頭炎	2 (3.6)
Mild	2 (3.6)
副鼻腔炎	1 (1.8)
Mild	1 (1.8)
歯膿瘍	1 (1.8)
Moderate	1 (1.8)
上気道感染	6 (10.9)
Mild	6 (10.9)
尿路感染	2 (3.6)
Mild	2 (3.6)

表 2.7.4.7-80. すべての有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab (N=55) n (%)
感染症および寄生虫症 (Cont.)	
ウイルス感染	2 (3.6)
Mild	2 (3.6)
ウイルス性上気道感染	2 (3.6)
Mild	2 (3.6)
外陰膣炎	1 (1.8)
Mild	1 (1.8)
傷害、中毒および処置合併症	5 (9.1)
Mild	2 (3.6)
Moderate	3 (5.5)
足関節部骨折	1 (1.8)
Mild	1 (1.8)
手骨折	1 (1.8)
Moderate	1 (1.8)
四肢損傷	1 (1.8)
Mild	1 (1.8)

表 2.7.4.7-80. すべての有害事象（MedDRA SOC 及び PT 別，重症度別）（主試験 FAS 集団，M10-870 試験）（続き）

MedDRA 22.0 System Organ Class Preferred Term Severity	Adalimumab (N=55) n (%)
傷害、中毒および処置合併症 (Cont.)	
上肢骨折	1 (1.8)
Moderate	1 (1.8)
手首関節骨折	1 (1.8)
Moderate	1 (1.8)
臨床検査	6 (10.9)
Mild	5 (9.1)
Moderate	1 (1.8)
血中アルカリホスファターゼ増加	1 (1.8)
Moderate	1 (1.8)
体温上昇	1 (1.8)
Mild	1 (1.8)
結核菌群検査陽性	4 (7.3)
Mild	4 (7.3)
筋骨格系および結合組織障害	7 (12.7)
Mild	5 (9.1)
Moderate	2 (3.6)