TABLE 14.2 4.J

Change from Baseline to Each Planned Visit in Health-Related Quality of Life as Assessed by EQ-5D-5L
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
EQ-5D-5L Usual Activities									
BASELINE	7		2.4 (1.40)	2.0	1.0, 5.0				
Low dose	4		2.3 (0.96)	2.5	1.0, 3.0				
High dose	3		2.7 (2.08)	2.0	1.0, 5.0				
WEEK 24	5	2.2	2.4 (1.34)	3.0	1.0, 4.0	0.2 (0.84)	0.0	-1.0, 1.0	0.6213
Low dose	2	1.5	2.0 (1.41)	2.0	1.0, 3.0	0.5 (0.71)	0.5	0.0, 1.0	0.5000
High dose	3	2.7	2.7 (1.53)	3.0	1.0, 4.0	0.0 (1.00)	0.0	-1.0, 1.0	>0.999
WEEK 48	4	2.3	2.8 (1.50)	3.0	1.0, 4.0	0.5 (1.29)	0.5	-1.0, 2.0	0.4950
Low dose	1	1.0	1.0 (N/A)	1.0	1.0, 1.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	3	2.7	3.3 (1.15)	4.0	2.0, 4.0	0.7 (1.53)	1.0	-1.0, 2.0	0.5286
EQ-5D-5L Pain/Discomfort									
BASELINE	7		2.1 (1.07)	2.0	1.0, 4.0				
Low dose	4		2.0 (0.82)	2.0	1.0, 3.0				
High dose	3		2.3 (1.53)	2.0	1.0, 4.0				
WEEK 24	5	2.0	2.0 (1.22)	2.0	1.0, 4.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	2	1.5	1.5 (0.71)	1.5	1.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	2.3	2.3 (1.53)	2.0	1.0, 4.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 48	4	2.0	2.3 (1.50)	2.0	1.0, 4.0	0.3 (0.50)	0.0	0.0, 1.0	0.3910
Low dose	1	1.0	1.0 (N/A)	1.0	1.0, 1.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	3	2.3	2.7 (1.53)	3.0	1.0, 4.0	0.3 (0.58)	0.0	0.0, 1.0	0.4226

&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 4.J

Change from Baseline to Each Planned Visit in Health-Related Quality of Life as Assessed by EQ-5D-5L
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
EQ-5D-5L Anxiety/Depression									
BASELINE	7		1.6 (0.79)	1.0	1.0, 3.0				
Low dose	4		1.3 (0.50)	1.0	1.0, 2.0				
High dose	3		2.0 (1.00)	2.0	1.0, 3.0				
WEEK 24	5	1.8	2.2 (1.30)	2.0	1.0, 4.0	0.4 (0.55)	0.0	0.0, 1.0	0.1778
Low dose	2	1.5	2.0 (1.41)	2.0	1.0, 3.0	0.5 (0.71)	0.5	0.0, 1.0	0.5000
High dose	3	2.0	2.3 (1.53)	2.0	1.0, 4.0	0.3 (0.58)	0.0	0.0, 1.0	0.4226
WEEK 48	4	1.8	1.3 (0.50)	1.0	1.0, 2.0	-0.5 (1.00)	0.0	-2.0, 0.0	0.3910
Low dose	1	1.0	1.0 (N/A)	1.0	1.0, 1.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	3	2.0	1.3 (0.58)	1.0	1.0, 2.0	-0.7 (1.15)	0.0	-2.0, 0.0	0.4226
EQ-5D-5L VAS									
BASELINE	7		70.4 (22.20)	79.0	40.0, 94.0				
Low dose	4		80.8 (9.91)	79.5	70.0, 94.0				
High dose	3		56.7 (28.87)	40.0	40.0, 90.0				
WEEK 24	5	68.8	69.2 (22.49)	60.0	45.0, 96.0	0.4 (13.24)	5.0	-20.0, 15.0	0.9494
Low dose	2	87.0	75.0 (21.21)	75.0	60.0, 90.0	-12.0 (11.31)	-12.0	-20.0, -4.0	0.3743
High dose	3	56.7	65.3 (27.02)	55.0	45.0, 96.0	8.7 (5.51)	6.0	5.0, 15.0	0.1124
WEEK 48	4	66.0	73.0 (9.02)	76.0	60.0, 80.0	7.0 (27.78)	2.0	-16.0, 40.0	0.6490
Low dose	1	94.0	78.0 (N/A)	78.0	78.0, 78.0	-16.0 (N/A)	-16.0	-16.0, -16.0	
High dose	3	56.7	71.3 (10.26)	74.0	60.0, 80.0	14.7 (28.38)	20.0	-16.0, 40.0	0.4652

&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 4.J

Change from Baseline to Each Planned Visit in Health-Related Quality of Life as Assessed by EQ-5D-5L
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
EQ-5D-5L Summary Index - Based on USA									
BASELINE	7		0.711 (0.2936)	0.729	0.126, 1.000				
Low dose	4		0.793 (0.1453)	0.754	0.666, 1.000				
High dose	3		0.601 (0.4420)	0.678	0.126, 1.000				
WEEK 24	5	0.694	0.727 (0.2773)	0.710	0.367, 1.000	0.033 (0.1313)	0.000	-0.120, 0.241	0.6042
Low dose	2	0.833	0.855 (0.2051)	0.855	0.710, 1.000	0.022 (0.0311)	0.022	0.000, 0.044	0.5000
High dose	3	0.601	0.642 (0.3247)	0.558	0.367, 1.000	0.040 (0.1838)	0.000	-0.120, 0.241	0.7405
WEEK 48	4	0.701	0.588 (0.3542)	0.676	0.111, 0.888	-0.114 (0.0709)	-0.131	-0.177, -0.015	0.0492*
Low dose	1	1.000	0.823 (N/A)	0.823	0.823, 0.823	-0.177 (N/A)	-0.177	-0.177, -0.177	
High dose	3	0.601	0.509 (0.3888)	0.528	0.111, 0.888	-0.092 (0.0696)	-0.112	-0.150, -0.015	0.1484

&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

表31　MMSEスコア（FAS）：M15-737試験

[redacted]20[redacted] 07:19 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.2__5

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Attention/Calculation									
BASELINE	79		4.2 (1.22)	5.0	0.0, 5.0				
Low dose	33		4.4 (0.96)	5.0	2.0, 5.0				
High dose	46		4.0 (1.37)	5.0	0.0, 5.0				
WEEK 24	64	4.3	4.4 (1.14)	5.0	1.0, 5.0	0.1 (1.27)	0.0	-4.0, 3.0	0.4326
Low dose	26	4.4	4.5 (0.95)	5.0	1.0, 5.0	0.1 (1.23)	0.0	-2.0, 3.0	0.7525
High dose	38	4.2	4.3 (1.26)	5.0	1.0, 5.0	0.2 (1.31)	0.0	-4.0, 3.0	0.4606
WEEK 48	24	4.0	4.1 (1.35)	5.0	0.0, 5.0	0.0 (1.00)	0.0	-2.0, 3.0	0.8399
Low dose	9	4.8	4.3 (0.87)	5.0	3.0, 5.0	-0.4 (0.53)	0.0	-1.0, 0.0	0.0353*
High dose	15	3.6	3.9 (1.58)	5.0	0.0, 5.0	0.3 (1.11)	0.0	-2.0, 3.0	0.2654
WEEK 72	3	4.7	5.0 (0.00)	5.0	5.0, 5.0	0.3 (0.58)	0.0	0.0, 1.0	0.4226
Low dose	1	5.0	5.0 (N/A)	5.0	5.0, 5.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	2	4.5	5.0 (0.00)	5.0	5.0, 5.0	0.5 (0.71)	0.5	0.0, 1.0	0.5000
POST-BASELINE MINIMUM	66	4.2	4.3 (1.25)	5.0	0.0, 5.0	0.1 (1.25)	0.0	-4.0, 3.0	0.4945
Low dose	26	4.4	4.4 (0.99)	5.0	1.0, 5.0	0.0 (1.23)	0.0	-2.0, 3.0	>0.999
High dose	40	4.1	4.3 (1.41)	5.0	0.0, 5.0	0.2 (1.28)	0.0	-4.0, 3.0	0.3920
POST-BASELINE MAXIMUM	67	4.2	4.4 (1.16)	5.0	0.0, 5.0	0.3 (1.16)	0.0	-4.0, 3.0	0.0629
Low dose	26	4.4	4.7 (0.89)	5.0	1.0, 5.0	0.2 (1.11)	0.0	-2.0, 3.0	0.2978
High dose	41	4.0	4.3 (1.29)	5.0	0.0, 5.0	0.3 (1.21)	0.0	-4.0, 3.0	0.1291

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 5

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS)

Parameter Time Point Dose Category	N	Baseline Mean	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	Change from Baseline P-Value &
MMSE - Comprehension									
BASELINE	79		3.0 (0.11)	3.0	2.0, 3.0				
Low dose	33		3.0 (0.00)	3.0	3.0, 3.0				
High dose	46		3.0 (0.15)	3.0	2.0, 3.0				
WEEK 24	65	3.0	2.9 (0.39)	3.0	0.0, 3.0	-0.0 (0.41)	0.0	-3.0, 1.0	0.3698
Low dose	26	3.0	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	39	3.0	2.9 (0.50)	3.0	0.0, 3.0	-0.1 (0.53)	0.0	-3.0, 1.0	0.3725
WEEK 48	24	3.0	3.0 (0.20)	3.0	2.0, 3.0	0.0 (0.29)	0.0	-1.0, 1.0	>0.999
Low dose	9	3.0	2.9 (0.33)	3.0	2.0, 3.0	-0.1 (0.33)	0.0	-1.0, 0.0	0.3466
High dose	15	2.9	3.0 (0.00)	3.0	3.0, 3.0	0.1 (0.26)	0.0	0.0, 1.0	0.3343
WEEK 72	3	3.0	2.3 (0.58)	2.0	2.0, 3.0	-0.7 (0.58)	-1.0	-1.0, 0.0	0.1835
Low dose	1	3.0	3.0 (N/A)	3.0	3.0, 3.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	2	3.0	2.0 (0.00)	2.0	2.0, 2.0	-1.0 (0.00)	-1.0	-1.0, -1.0	<=0.001***
POST-BASELINE MINIMUM	67	3.0	2.9 (0.42)	3.0	0.0, 3.0	-0.1 (0.44)	0.0	-3.0, 1.0	0.1672
Low dose	26	3.0	3.0 (0.20)	3.0	2.0, 3.0	-0.0 (0.20)	0.0	-1.0, 0.0	0.3269
High dose	41	3.0	2.9 (0.51)	3.0	0.0, 3.0	-0.1 (0.54)	0.0	-3.0, 1.0	0.2531
POST-BASELINE MAXIMUM	67	3.0	3.0 (0.37)	3.0	0.0, 3.0	-0.0 (0.39)	0.0	-3.0, 1.0	0.5311
Low dose	26	3.0	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	41	3.0	2.9 (0.47)	3.0	0.0, 3.0	-0.0 (0.50)	0.0	-3.0, 1.0	0.5337

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 5

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Drawing									
BASELINE	79		0.9 (0.30)	1.0	0.0, 1.0				
Low dose	33		1.0 (0.17)	1.0	0.0, 1.0				
High dose	46		0.8 (0.36)	1.0	0.0, 1.0				
WEEK 24	65	0.9	0.9 (0.35)	1.0	0.0, 1.0	-0.1 (0.39)	0.0	-1.0, 1.0	0.2084
Low dose	26	1.0	0.8 (0.37)	1.0	0.0, 1.0	-0.2 (0.37)	0.0	-1.0, 0.0	0.0430*
High dose	39	0.9	0.9 (0.34)	1.0	0.0, 1.0	0.0 (0.40)	0.0	-1.0, 1.0	>0.999
WEEK 48	24	0.8	0.9 (0.34)	1.0	0.0, 1.0	0.1 (0.45)	0.0	-1.0, 1.0	0.1853
Low dose	9	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	15	0.6	0.8 (0.41)	1.0	0.0, 1.0	0.2 (0.56)	0.0	-1.0, 1.0	0.1887
WEEK 72	3	0.7	0.7 (0.58)	1.0	0.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	1	1.0	1.0 (N/A)	1.0	1.0, 1.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	2	0.5	0.5 (0.71)	0.5	0.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MINIMUM	67	0.9	0.8 (0.40)	1.0	0.0, 1.0	-0.1 (0.38)	0.0	-1.0, 1.0	0.0572
Low dose	26	1.0	0.8 (0.37)	1.0	0.0, 1.0	-0.2 (0.37)	0.0	-1.0, 0.0	0.0430*
High dose	41	0.8	0.8 (0.42)	1.0	0.0, 1.0	-0.0 (0.38)	0.0	-1.0, 1.0	0.4210
POST-BASELINE MAXIMUM	67	0.9	0.9 (0.33)	1.0	0.0, 1.0	-0.0 (0.41)	0.0	-1.0, 1.0	0.7655
Low dose	26	1.0	0.9 (0.33)	1.0	0.0, 1.0	-0.1 (0.33)	0.0	-1.0, 0.0	0.0830
High dose	41	0.8	0.9 (0.33)	1.0	0.0, 1.0	0.0 (0.44)	0.0	-1.0, 1.0	0.4863

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 5

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Naming									
BASELINE	79		2.0 (0.00)	2.0	2.0, 2.0				
Low dose	33		2.0 (0.00)	2.0	2.0, 2.0				
High dose	46		2.0 (0.00)	2.0	2.0, 2.0				
WEEK 24	65	2.0	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	26	2.0	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	39	2.0	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 48	24	2.0	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	9	2.0	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	15	2.0	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 72	3	2.0	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	1	2.0	2.0 (N/A)	2.0	2.0, 2.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	2	2.0	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MINIMUM	67	2.0	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	26	2.0	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	41	2.0	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MAXIMUM	67	2.0	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	26	2.0	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	41	2.0	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 5

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Orientation to Place									
BASELINE	79		4.9 (0.50)	5.0	2.0, 5.0				
Low dose	33		4.9 (0.55)	5.0	2.0, 5.0				
High dose	46		4.8 (0.47)	5.0	3.0, 5.0				
WEEK 24	65	4.9	4.8 (0.70)	5.0	1.0, 5.0	-0.1 (0.55)	0.0	-3.0, 1.0	0.0734
Low dose	26	4.8	4.7 (0.83)	5.0	1.0, 5.0	-0.1 (0.33)	0.0	-1.0, 0.0	0.0830
High dose	39	4.9	4.8 (0.60)	5.0	2.0, 5.0	-0.1 (0.66)	0.0	-3.0, 1.0	0.2299
WEEK 48	24	4.9	4.9 (0.61)	5.0	2.0, 5.0	0.0 (0.29)	0.0	-1.0, 1.0	>0.999
Low dose	9	5.0	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	15	4.8	4.8 (0.77)	5.0	2.0, 5.0	0.0 (0.38)	0.0	-1.0, 1.0	>0.999
WEEK 72	3	5.0	4.7 (0.58)	5.0	4.0, 5.0	-0.3 (0.58)	0.0	-1.0, 0.0	0.4226
Low dose	1	5.0	5.0 (N/A)	5.0	5.0, 5.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	2	5.0	4.5 (0.71)	4.5	4.0, 5.0	-0.5 (0.71)	-0.5	-1.0, 0.0	0.5000
POST-BASELINE MINIMUM	67	4.9	4.7 (0.77)	5.0	1.0, 5.0	-0.1 (0.56)	0.0	-3.0, 1.0	0.0319*
Low dose	26	4.8	4.7 (0.83)	5.0	1.0, 5.0	-0.1 (0.33)	0.0	-1.0, 0.0	0.0830
High dose	41	4.9	4.7 (0.74)	5.0	2.0, 5.0	-0.2 (0.67)	0.0	-3.0, 1.0	0.1091
POST-BASELINE MAXIMUM	67	4.9	4.8 (0.76)	5.0	1.0, 5.0	-0.1 (0.54)	0.0	-3.0, 1.0	0.0734
Low dose	26	4.8	4.8 (0.82)	5.0	1.0, 5.0	-0.1 (0.27)	0.0	-1.0, 0.0	0.1613
High dose	41	4.9	4.8 (0.73)	5.0	2.0, 5.0	-0.1 (0.65)	0.0	-3.0, 1.0	0.1598

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 5

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Orientation to Time									
BASELINE	79		4.8 (0.62)	5.0	2.0, 5.0				
Low dose	33		4.7 (0.76)	5.0	2.0, 5.0				
High dose	46		4.8 (0.51)	5.0	3.0, 5.0				
WEEK 24	65	4.8	4.7 (0.89)	5.0	0.0, 5.0	-0.1 (0.71)	0.0	-4.0, 1.0	0.2257
Low dose	26	4.7	4.7 (0.87)	5.0	1.0, 5.0	0.0 (0.45)	0.0	-1.0, 1.0	0.6636
High dose	39	4.8	4.6 (0.90)	5.0	0.0, 5.0	-0.2 (0.83)	0.0	-4.0, 1.0	0.1323
WEEK 48	24	4.8	4.5 (1.06)	5.0	1.0, 5.0	-0.3 (0.69)	0.0	-2.0, 1.0	0.0499*
Low dose	9	4.6	4.4 (1.33)	5.0	1.0, 5.0	-0.1 (0.60)	0.0	-1.0, 1.0	0.5943
High dose	15	4.9	4.5 (0.92)	5.0	2.0, 5.0	-0.4 (0.74)	0.0	-2.0, 0.0	0.0541
WEEK 72	3	5.0	4.7 (0.58)	5.0	4.0, 5.0	-0.3 (0.58)	0.0	-1.0, 0.0	0.4226
Low dose	1	5.0	5.0 (N/A)	5.0	5.0, 5.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	2	5.0	4.5 (0.71)	4.5	4.0, 5.0	-0.5 (0.71)	-0.5	-1.0, 0.0	0.5000
POST-BASELINE MINIMUM	67	4.8	4.5 (1.03)	5.0	0.0, 5.0	-0.2 (0.78)	0.0	-4.0, 1.0	0.0147*
Low dose	26	4.7	4.6 (1.10)	5.0	1.0, 5.0	-0.1 (0.48)	0.0	-1.0, 1.0	0.4250
High dose	41	4.8	4.5 (1.00)	5.0	0.0, 5.0	-0.3 (0.91)	0.0	-4.0, 1.0	0.0212*
POST-BASELINE MAXIMUM	67	4.8	4.6 (0.93)	5.0	0.0, 5.0	-0.1 (0.74)	0.0	-4.0, 1.0	0.1402
Low dose	26	4.7	4.8 (0.86)	5.0	1.0, 5.0	0.1 (0.39)	0.0	-1.0, 1.0	0.3269
High dose	41	4.8	4.6 (0.98)	5.0	0.0, 5.0	-0.3 (0.87)	0.0	-4.0, 1.0	0.0544

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 5

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Reading									
BASELINE	79		1.0 (0.16)	1.0	0.0, 1.0				
Low dose	33		1.0 (0.00)	1.0	1.0, 1.0				
High dose	46		1.0 (0.21)	1.0	0.0, 1.0				
WEEK 24	65	1.0	1.0 (0.12)	1.0	0.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	26	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	39	1.0	1.0 (0.16)	1.0	0.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 48	24	0.9	1.0 (0.00)	1.0	1.0, 1.0	0.1 (0.28)	0.0	0.0, 1.0	0.1617
Low dose	9	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	15	0.9	1.0 (0.00)	1.0	1.0, 1.0	0.1 (0.35)	0.0	0.0, 1.0	0.1643
WEEK 72	3	0.3	1.0 (0.00)	1.0	1.0, 1.0	0.7 (0.58)	1.0	0.0, 1.0	0.1835
Low dose	1	1.0	1.0 (N/A)	1.0	1.0, 1.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	2	0.0	1.0 (0.00)	1.0	1.0, 1.0	1.0 (0.00)	1.0	1.0, 1.0	<=0.001***
POST-BASELINE MINIMUM	67	1.0	1.0 (0.12)	1.0	0.0, 1.0	0.0 (0.12)	0.0	0.0, 1.0	0.3210
Low dose	26	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	41	1.0	1.0 (0.16)	1.0	0.0, 1.0	0.0 (0.16)	0.0	0.0, 1.0	0.3233
POST-BASELINE MAXIMUM	67	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.17)	0.0	0.0, 1.0	0.1589
Low dose	26	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	41	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.22)	0.0	0.0, 1.0	0.1598

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 5

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Recall									
BASELINE	79		2.7 (0.61)	3.0	0.0, 3.0				
Low dose	33		2.6 (0.56)	3.0	1.0, 3.0				
High dose	46		2.7 (0.65)	3.0	0.0, 3.0				
WEEK 24	65	2.7	2.8 (0.43)	3.0	1.0, 3.0	0.1 (0.57)	0.0	-1.0, 2.0	0.0882
Low dose	26	2.6	2.8 (0.51)	3.0	1.0, 3.0	0.2 (0.54)	0.0	-1.0, 2.0	0.1613
High dose	39	2.7	2.8 (0.37)	3.0	2.0, 3.0	0.1 (0.60)	0.0	-1.0, 2.0	0.2909
WEEK 48	24	2.8	2.8 (0.53)	3.0	1.0, 3.0	-0.0 (0.55)	0.0	-1.0, 1.0	0.7140
Low dose	9	2.9	2.9 (0.33)	3.0	2.0, 3.0	0.0 (0.50)	0.0	-1.0, 1.0	>0.999
High dose	15	2.7	2.7 (0.62)	3.0	1.0, 3.0	-0.1 (0.59)	0.0	-1.0, 1.0	0.6702
WEEK 72	3	3.0	2.3 (0.58)	2.0	2.0, 3.0	-0.7 (0.58)	-1.0	-1.0, 0.0	0.1835
Low dose	1	3.0	3.0 (N/A)	3.0	3.0, 3.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	2	3.0	2.0 (0.00)	2.0	2.0, 2.0	-1.0 (0.00)	-1.0	-1.0, -1.0	<=0.001***
POST-BASELINE MINIMUM	67	2.7	2.7 (0.51)	3.0	1.0, 3.0	0.0 (0.59)	0.0	-1.0, 2.0	0.5356
Low dose	26	2.6	2.7 (0.53)	3.0	1.0, 3.0	0.1 (0.59)	0.0	-1.0, 2.0	0.3269
High dose	41	2.7	2.7 (0.50)	3.0	1.0, 3.0	0.0 (0.59)	0.0	-1.0, 2.0	>0.999
POST-BASELINE MAXIMUM	67	2.7	2.8 (0.48)	3.0	1.0, 3.0	0.1 (0.61)	0.0	-1.0, 2.0	0.1631
Low dose	26	2.6	2.8 (0.49)	3.0	1.0, 3.0	0.2 (0.57)	0.0	-1.0, 2.0	0.0961
High dose	41	2.7	2.8 (0.47)	3.0	1.0, 3.0	0.0 (0.63)	0.0	-1.0, 2.0	0.6230

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 5

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Registration									
BASELINE	79		3.0 (0.11)	3.0	2.0, 3.0				
Low dose	33		3.0 (0.00)	3.0	3.0, 3.0				
High dose	46		3.0 (0.15)	3.0	2.0, 3.0				
WEEK 24	65	3.0	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	26	3.0	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	39	3.0	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 48	24	3.0	3.0 (0.20)	3.0	2.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	9	3.0	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	15	2.9	2.9 (0.26)	3.0	2.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 72	3	3.0	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	1	3.0	3.0 (N/A)	3.0	3.0, 3.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	2	3.0	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MINIMUM	67	3.0	3.0 (0.12)	3.0	2.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	26	3.0	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	41	3.0	3.0 (0.16)	3.0	2.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MAXIMUM	67	3.0	3.0 (0.12)	3.0	2.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	26	3.0	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	41	3.0	3.0 (0.16)	3.0	2.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 5

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Repetition									
BASELINE	79		0.9 (0.25)	1.0	0.0, 1.0				
Low dose	33		1.0 (0.17)	1.0	0.0, 1.0				
High dose	46		0.9 (0.28)	1.0	0.0, 1.0				
WEEK 24	65	0.9	0.9 (0.24)	1.0	0.0, 1.0	0.0 (0.25)	0.0	-1.0, 1.0	>0.999
Low dose	26	1.0	1.0 (0.20)	1.0	0.0, 1.0	0.0 (0.28)	0.0	-1.0, 1.0	>0.999
High dose	39	0.9	0.9 (0.27)	1.0	0.0, 1.0	0.0 (0.23)	0.0	-1.0, 1.0	>0.999
WEEK 48	24	1.0	1.0 (0.20)	1.0	0.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	9	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	15	0.9	0.9 (0.26)	1.0	0.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 72	3	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	1	1.0	1.0 (N/A)	1.0	1.0, 1.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	2	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MINIMUM	67	0.9	0.9 (0.26)	1.0	0.0, 1.0	-0.0 (0.21)	0.0	-1.0, 1.0	0.5676
Low dose	26	1.0	1.0 (0.20)	1.0	0.0, 1.0	0.0 (0.28)	0.0	-1.0, 1.0	>0.999
High dose	41	0.9	0.9 (0.30)	1.0	0.0, 1.0	-0.0 (0.16)	0.0	-1.0, 0.0	0.3233
POST-BASELINE MAXIMUM	67	0.9	1.0 (0.21)	1.0	0.0, 1.0	0.0 (0.21)	0.0	-1.0, 1.0	0.5676
Low dose	26	1.0	1.0 (0.20)	1.0	0.0, 1.0	0.0 (0.28)	0.0	-1.0, 1.0	>0.999
High dose	41	0.9	1.0 (0.22)	1.0	0.0, 1.0	0.0 (0.16)	0.0	0.0, 1.0	0.3233

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 5

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Total									
BASELINE	79		28.2 (2.22)	29.0	18.0, 30.0				
Low dose	33		28.5 (1.95)	29.0	21.0, 30.0				
High dose	46		28.0 (2.39)	29.0	18.0, 30.0				
WEEK 24	65	28.4	28.4 (3.15)	30.0	12.0, 30.0	-0.1 (2.32)	0.0	-13.0, 4.0	0.7901
Low dose	26	28.5	28.5 (2.93)	29.0	15.0, 30.0	-0.0 (1.95)	0.0	-6.0, 4.0	0.9207
High dose	39	28.4	28.3 (3.32)	30.0	12.0, 30.0	-0.1 (2.56)	0.0	-13.0, 3.0	0.8040
WEEK 48	24	28.0	27.8 (3.47)	29.0	14.0, 30.0	-0.1 (1.51)	0.0	-4.0, 3.0	0.6893
Low dose	9	29.2	28.6 (2.24)	29.0	23.0, 30.0	-0.7 (1.00)	0.0	-3.0, 0.0	0.0805
High dose	15	27.2	27.4 (4.05)	29.0	14.0, 30.0	0.2 (1.70)	0.0	-4.0, 3.0	0.6554
WEEK 72	3	28.7	27.3 (3.06)	28.0	24.0, 30.0	-1.3 (1.53)	-1.0	-3.0, 0.0	0.2697
Low dose	1	30.0	30.0 (N/A)	30.0	30.0, 30.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	2	28.0	26.0 (2.83)	26.0	24.0, 28.0	-2.0 (1.41)	-2.0	-3.0, -1.0	0.2952
POST-BASELINE MINIMUM	67	28.3	27.9 (3.62)	29.0	12.0, 30.0	-0.3 (2.31)	0.0	-13.0, 4.0	0.2275
Low dose	26	28.5	28.3 (3.12)	29.0	15.0, 30.0	-0.2 (1.99)	0.0	-6.0, 4.0	0.5589
High dose	41	28.1	27.7 (3.93)	29.0	12.0, 30.0	-0.4 (2.51)	0.0	-13.0, 3.0	0.2965
POST-BASELINE MAXIMUM	67	28.3	28.3 (3.56)	30.0	12.0, 30.0	0.0 (2.29)	0.0	-13.0, 4.0	0.9577
Low dose	26	28.5	28.7 (2.93)	30.0	15.0, 30.0	0.2 (1.83)	0.0	-6.0, 4.0	0.5975
High dose	41	28.1	28.0 (3.91)	30.0	12.0, 30.0	-0.1 (2.56)	0.0	-13.0, 3.0	0.8083

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 5

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Writing									
BASELINE	79		1.0 (0.16)	1.0	0.0, 1.0				
Low dose	33		1.0 (0.00)	1.0	1.0, 1.0				
High dose	46		1.0 (0.21)	1.0	0.0, 1.0				
WEEK 24	65	1.0	1.0 (0.21)	1.0	0.0, 1.0	-0.0 (0.17)	0.0	-1.0, 0.0	0.1589
Low dose	26	1.0	1.0 (0.20)	1.0	0.0, 1.0	-0.0 (0.20)	0.0	-1.0, 0.0	0.3269
High dose	39	1.0	0.9 (0.22)	1.0	0.0, 1.0	-0.0 (0.16)	0.0	-1.0, 0.0	0.3236
WEEK 48	24	0.9	0.9 (0.34)	1.0	0.0, 1.0	-0.0 (0.20)	0.0	-1.0, 0.0	0.3277
Low dose	9	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	15	0.9	0.8 (0.41)	1.0	0.0, 1.0	-0.1 (0.26)	0.0	-1.0, 0.0	0.3343
WEEK 72	3	1.0	0.7 (0.58)	1.0	0.0, 1.0	-0.3 (0.58)	0.0	-1.0, 0.0	0.4226
Low dose	1	1.0	1.0 (N/A)	1.0	1.0, 1.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	2	1.0	0.5 (0.71)	0.5	0.0, 1.0	-0.5 (0.71)	-0.5	-1.0, 0.0	0.5000
POST-BASELINE MINIMUM	67	1.0	0.9 (0.26)	1.0	0.0, 1.0	-0.0 (0.21)	0.0	-1.0, 0.0	0.0832
Low dose	26	1.0	1.0 (0.20)	1.0	0.0, 1.0	-0.0 (0.20)	0.0	-1.0, 0.0	0.3269
High dose	41	1.0	0.9 (0.30)	1.0	0.0, 1.0	-0.0 (0.22)	0.0	-1.0, 0.0	0.1598
POST-BASELINE MAXIMUM	67	1.0	0.9 (0.26)	1.0	0.0, 1.0	-0.0 (0.21)	0.0	-1.0, 0.0	0.0832
Low dose	26	1.0	1.0 (0.20)	1.0	0.0, 1.0	-0.0 (0.20)	0.0	-1.0, 0.0	0.3269
High dose	41	1.0	0.9 (0.30)	1.0	0.0, 1.0	-0.0 (0.22)	0.0	-1.0, 0.0	0.1598

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

表32　MMSEスコア（FAS，日本人部分集団）：M15-737試験

[redacted]20[redacted] 04:20 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.2__5.J

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Attention/Calculation									
BASELINE	7		4.6 (0.79)	5.0	3.0, 5.0				
Low dose	4		4.3 (0.96)	4.5	3.0, 5.0				
High dose	3		5.0 (0.00)	5.0	5.0, 5.0				
WEEK 24	5	4.6	4.2 (1.79)	5.0	1.0, 5.0	-0.4 (0.89)	0.0	-2.0, 0.0	0.3739
Low dose	2	4.0	3.0 (2.83)	3.0	1.0, 5.0	-1.0 (1.41)	-1.0	-2.0, 0.0	0.5000
High dose	3	5.0	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 48	4	5.0	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	1	5.0	5.0 (N/A)	5.0	5.0, 5.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	3	5.0	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MINIMUM	5	4.6	4.2 (1.79)	5.0	1.0, 5.0	-0.4 (0.89)	0.0	-2.0, 0.0	0.3739
Low dose	2	4.0	3.0 (2.83)	3.0	1.0, 5.0	-1.0 (1.41)	-1.0	-2.0, 0.0	0.5000
High dose	3	5.0	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MAXIMUM	5	4.6	4.2 (1.79)	5.0	1.0, 5.0	-0.4 (0.89)	0.0	-2.0, 0.0	0.3739
Low dose	2	4.0	3.0 (2.83)	3.0	1.0, 5.0	-1.0 (1.41)	-1.0	-2.0, 0.0	0.5000
High dose	3	5.0	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	
MMSE - Comprehension									
BASELINE	7		3.0 (0.00)	3.0	3.0, 3.0				
Low dose	4		3.0 (0.00)	3.0	3.0, 3.0				
High dose	3		3.0 (0.00)	3.0	3.0, 3.0				

&: P-value is obtained from two-sided paired-sample t-test.

Program Source Code: [redacted]

TABLE 14.2 5.J

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Comprehension									
WEEK 24	5	3.0	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	2	3.0	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	3.0	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 48	4	3.0	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	1	3.0	3.0 (N/A)	3.0	3.0, 3.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	3	3.0	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MINIMUM	5	3.0	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	2	3.0	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	3.0	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MAXIMUM	5	3.0	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	2	3.0	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	3.0	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
MMSE - Drawing									
BASELINE	7		1.0 (0.00)	1.0	1.0, 1.0				
Low dose	4		1.0 (0.00)	1.0	1.0, 1.0				
High dose	3		1.0 (0.00)	1.0	1.0, 1.0				
WEEK 24	5	1.0	0.8 (0.45)	1.0	0.0, 1.0	-0.2 (0.45)	0.0	-1.0, 0.0	0.3739
Low dose	2	1.0	0.5 (0.71)	0.5	0.0, 1.0	-0.5 (0.71)	-0.5	-1.0, 0.0	0.5000
High dose	3	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	

&: P-value is obtained from two-sided paired-sample t-test.

Program Source Code: [redacted]

TABLE 14.2 5.J

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Drawing									
WEEK 48	4	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	1	1.0	1.0 (N/A)	1.0	1.0, 1.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	3	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MINIMUM	5	1.0	0.8 (0.45)	1.0	0.0, 1.0	-0.2 (0.45)	0.0	-1.0, 0.0	0.3739
Low dose	2	1.0	0.5 (0.71)	0.5	0.0, 1.0	-0.5 (0.71)	-0.5	-1.0, 0.0	0.5000
High dose	3	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MAXIMUM	5	1.0	0.8 (0.45)	1.0	0.0, 1.0	-0.2 (0.45)	0.0	-1.0, 0.0	0.3739
Low dose	2	1.0	0.5 (0.71)	0.5	0.0, 1.0	-0.5 (0.71)	-0.5	-1.0, 0.0	0.5000
High dose	3	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
MMSE - Naming									
BASELINE	7		2.0 (0.00)	2.0	2.0, 2.0				
Low dose	4		2.0 (0.00)	2.0	2.0, 2.0				
High dose	3		2.0 (0.00)	2.0	2.0, 2.0				
WEEK 24	5	2.0	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	2	2.0	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	2.0	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 48	4	2.0	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	1	2.0	2.0 (N/A)	2.0	2.0, 2.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	3	2.0	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	

&: P-value is obtained from two-sided paired-sample t-test.

Program Source Code: [redacted]

TABLE 14.2 5.J

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Naming									
POST-BASELINE MINIMUM	5	2.0	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	2	2.0	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	2.0	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MAXIMUM	5	2.0	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	2	2.0	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	2.0	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
MMSE - Orientation to Place									
BASELINE	7		4.6 (1.13)	5.0	2.0, 5.0				
Low dose	4		4.3 (1.50)	5.0	2.0, 5.0				
High dose	3		5.0 (0.00)	5.0	5.0, 5.0				
WEEK 24	5	4.4	4.2 (1.79)	5.0	1.0, 5.0	-0.2 (0.45)	0.0	-1.0, 0.0	0.3739
Low dose	2	3.5	3.0 (2.83)	3.0	1.0, 5.0	-0.5 (0.71)	-0.5	-1.0, 0.0	0.5000
High dose	3	5.0	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 48	4	5.0	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	1	5.0	5.0 (N/A)	5.0	5.0, 5.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	3	5.0	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MINIMUM	5	4.4	4.2 (1.79)	5.0	1.0, 5.0	-0.2 (0.45)	0.0	-1.0, 0.0	0.3739
Low dose	2	3.5	3.0 (2.83)	3.0	1.0, 5.0	-0.5 (0.71)	-0.5	-1.0, 0.0	0.5000
High dose	3	5.0	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	

&: P-value is obtained from two-sided paired-sample t-test.

Program Source Code: [redacted]

TABLE 14.2 5.J

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Orientation to Place									
POST-BASELINE MAXIMUM	5	4.4	4.2 (1.79)	5.0	1.0, 5.0	-0.2 (0.45)	0.0	-1.0, 0.0	0.3739
Low dose	2	3.5	3.0 (2.83)	3.0	1.0, 5.0	-0.5 (0.71)	-0.5	-1.0, 0.0	0.5000
High dose	3	5.0	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	
MMSE - Orientation to Time									
BASELINE	7		4.6 (1.13)	5.0	2.0, 5.0				
Low dose	4		4.3 (1.50)	5.0	2.0, 5.0				
High dose	3		5.0 (0.00)	5.0	5.0, 5.0				
WEEK 24	5	4.4	4.2 (1.79)	5.0	1.0, 5.0	-0.2 (0.45)	0.0	-1.0, 0.0	0.3739
Low dose	2	3.5	3.0 (2.83)	3.0	1.0, 5.0	-0.5 (0.71)	-0.5	-1.0, 0.0	0.5000
High dose	3	5.0	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 48	4	5.0	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	1	5.0	5.0 (N/A)	5.0	5.0, 5.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	3	5.0	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MINIMUM	5	4.4	4.2 (1.79)	5.0	1.0, 5.0	-0.2 (0.45)	0.0	-1.0, 0.0	0.3739
Low dose	2	3.5	3.0 (2.83)	3.0	1.0, 5.0	-0.5 (0.71)	-0.5	-1.0, 0.0	0.5000
High dose	3	5.0	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MAXIMUM	5	4.4	4.2 (1.79)	5.0	1.0, 5.0	-0.2 (0.45)	0.0	-1.0, 0.0	0.3739
Low dose	2	3.5	3.0 (2.83)	3.0	1.0, 5.0	-0.5 (0.71)	-0.5	-1.0, 0.0	0.5000
High dose	3	5.0	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	

&: P-value is obtained from two-sided paired-sample t-test.

Program Source Code: [redacted]

TABLE 14.2 5.J

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Reading									
BASELINE	7		1.0 (0.00)	1.0	1.0, 1.0				
Low dose	4		1.0 (0.00)	1.0	1.0, 1.0				
High dose	3		1.0 (0.00)	1.0	1.0, 1.0				
WEEK 24	5	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	2	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 48	4	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	1	1.0	1.0 (N/A)	1.0	1.0, 1.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	3	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MINIMUM	5	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	2	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MAXIMUM	5	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	2	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
MMSE - Recall									
BASELINE	7		2.4 (0.79)	3.0	1.0, 3.0				
Low dose	4		2.5 (0.58)	2.5	2.0, 3.0				
High dose	3		2.3 (1.15)	3.0	1.0, 3.0				

&: P-value is obtained from two-sided paired-sample t-test.

Program Source Code: [redacted]

TABLE 14.2 5.J

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Recall									
WEEK 24	5	2.4	2.6 (0.89)	3.0	1.0, 3.0	0.2 (1.10)	0.0	-1.0, 2.0	0.7040
Low dose	2	2.5	2.0 (1.41)	2.0	1.0, 3.0	-0.5 (0.71)	-0.5	-1.0, 0.0	0.5000
High dose	3	2.3	3.0 (0.00)	3.0	3.0, 3.0	0.7 (1.15)	0.0	0.0, 2.0	0.4226
WEEK 48	4	2.5	2.8 (0.50)	3.0	2.0, 3.0	0.3 (0.50)	0.0	0.0, 1.0	0.3910
Low dose	1	3.0	3.0 (N/A)	3.0	3.0, 3.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	3	2.3	2.7 (0.58)	3.0	2.0, 3.0	0.3 (0.58)	0.0	0.0, 1.0	0.4226
POST-BASELINE MINIMUM	5	2.4	2.4 (0.89)	3.0	1.0, 3.0	0.0 (0.71)	0.0	-1.0, 1.0	>0.999
Low dose	2	2.5	2.0 (1.41)	2.0	1.0, 3.0	-0.5 (0.71)	-0.5	-1.0, 0.0	0.5000
High dose	3	2.3	2.7 (0.58)	3.0	2.0, 3.0	0.3 (0.58)	0.0	0.0, 1.0	0.4226
POST-BASELINE MAXIMUM	5	2.4	2.6 (0.89)	3.0	1.0, 3.0	0.2 (1.10)	0.0	-1.0, 2.0	0.7040
Low dose	2	2.5	2.0 (1.41)	2.0	1.0, 3.0	-0.5 (0.71)	-0.5	-1.0, 0.0	0.5000
High dose	3	2.3	3.0 (0.00)	3.0	3.0, 3.0	0.7 (1.15)	0.0	0.0, 2.0	0.4226
MMSE - Registration									
BASELINE	7		3.0 (0.00)	3.0	3.0, 3.0				
Low dose	4		3.0 (0.00)	3.0	3.0, 3.0				
High dose	3		3.0 (0.00)	3.0	3.0, 3.0				
WEEK 24	5	3.0	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	2	3.0	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	3.0	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	

&: P-value is obtained from two-sided paired-sample t-test.

Program Source Code: [redacted]

TABLE 14.2 5.J

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS - Japan Subjects)

Parameter Time Point Dose Category	N	Baseline Mean	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
MMSE - Registration									
WEEK 48	4	3.0	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	1	3.0	3.0 (N/A)	3.0	3.0, 3.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	3	3.0	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MINIMUM	5	3.0	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	2	3.0	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	3.0	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MAXIMUM	5	3.0	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	2	3.0	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	3.0	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
MMSE - Repetition									
BASELINE	7		1.0 (0.00)	1.0	1.0, 1.0				
Low dose	4		1.0 (0.00)	1.0	1.0, 1.0				
High dose	3		1.0 (0.00)	1.0	1.0, 1.0				
WEEK 24	5	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	2	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 48	4	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	1	1.0	1.0 (N/A)	1.0	1.0, 1.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	3	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	

&: P-value is obtained from two-sided paired-sample t-test.

Program Source Code: [redacted]

TABLE 14.2 5.J

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Repetition									
POST-BASELINE MINIMUM	5	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	2	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MAXIMUM	5	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	2	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
MMSE - Total									
BASELINE	7		28.1 (3.29)	30.0	21.0, 30.0				
Low dose	4		27.3 (4.27)	29.0	21.0, 30.0				
High dose	3		29.3 (1.15)	30.0	28.0, 30.0				
WEEK 24	5	27.8	27.0 (6.71)	30.0	15.0, 30.0	-0.8 (3.03)	0.0	-6.0, 2.0	0.5870
Low dose	2	25.5	22.5 (10.61)	22.5	15.0, 30.0	-3.0 (4.24)	-3.0	-6.0, 0.0	0.5000
High dose	3	29.3	30.0 (0.00)	30.0	30.0, 30.0	0.7 (1.15)	0.0	0.0, 2.0	0.4226
WEEK 48	4	29.5	29.8 (0.50)	30.0	29.0, 30.0	0.3 (0.50)	0.0	0.0, 1.0	0.3910
Low dose	1	30.0	30.0 (N/A)	30.0	30.0, 30.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	3	29.3	29.7 (0.58)	30.0	29.0, 30.0	0.3 (0.58)	0.0	0.0, 1.0	0.4226
POST-BASELINE MINIMUM	5	27.8	26.8 (6.61)	30.0	15.0, 30.0	-1.0 (2.83)	0.0	-6.0, 1.0	0.4734
Low dose	2	25.5	22.5 (10.61)	22.5	15.0, 30.0	-3.0 (4.24)	-3.0	-6.0, 0.0	0.5000
High dose	3	29.3	29.7 (0.58)	30.0	29.0, 30.0	0.3 (0.58)	0.0	0.0, 1.0	0.4226

&: P-value is obtained from two-sided paired-sample t-test.

Program Source Code: [redacted]

TABLE 14.2 5.J

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Total									
POST-BASELINE MAXIMUM	5	27.8	27.0 (6.71)	30.0	15.0, 30.0	-0.8 (3.03)	0.0	-6.0, 2.0	0.5870
Low dose	2	25.5	22.5 (10.61)	22.5	15.0, 30.0	-3.0 (4.24)	-3.0	-6.0, 0.0	0.5000
High dose	3	29.3	30.0 (0.00)	30.0	30.0, 30.0	0.7 (1.15)	0.0	0.0, 2.0	0.4226
MMSE - Writing									
BASELINE	7		1.0 (0.00)	1.0	1.0, 1.0				
Low dose	4		1.0 (0.00)	1.0	1.0, 1.0				
High dose	3		1.0 (0.00)	1.0	1.0, 1.0				
WEEK 24	5	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	2	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 48	4	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	1	1.0	1.0 (N/A)	1.0	1.0, 1.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	3	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MINIMUM	5	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	2	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MAXIMUM	5	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	2	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	1.0	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	

&: P-value is obtained from two-sided paired-sample t-test.

Program Source Code: [redacted]

表33　有害事象の概要（安全性解析対象集団）：M15-737試験

[redacted]20[redacted] 07:21 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.3__1.1

Overview of Treatment-Emergent Adverse Events and All Deaths
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=45) n (%)	High Dose (N=60) n (%)	All Subjects (N=105) n (%)
Subjects with:			
Any TEAE	25 (55.6)	41 (68.3)	66 (62.9)
Any severe TEAE	4 (8.9)	8 (13.3)	12 (11.4)
Any TEAE that is considered associated with study drug$	16 (35.6)	28 (46.7)	44 (41.9)
Any TEAE that is considered associated with product complaint$	11 (24.4)	15 (25.0)	26 (24.8)
ABBV-951	3 (6.7)	9 (15.0)	12 (11.4)
Infusion pump	0	1 (1.7)	1 (1.0)
Vial adapter	0	0	0
Syringes	0	1 (1.7)	1 (1.0)
[redacted] infusion set (total)	4 (8.9)	2 (3.3)	6 (5.7)
[redacted] infusion set 6 mm	1 (2.2)	1 (1.7)	2 (1.9)
[redacted] infusion set 9 mm	3 (6.7)	1 (1.7)	4 (3.8)
Neria guard infusion set (total)	5 (11.1)	8 (13.3)	13 (12.4)
Neria guard infusion set 6 mm	3 (6.7)	2 (3.3)	5 (4.8)
Neria guard infusion set 9 mm	2 (4.4)	7 (11.7)	9 (8.6)
Any TEAE that is considered associated with loading dose$	0	0	0
Any TEAE that is considered associated with rescue dose$	0	2 (3.3)	2 (1.9)
Any TEAE that is considered associated with COVID-19 infection	0	1 (1.7)	1 (1.0)
Any TEAE leading to prematurely discontinuation of study drug	1 (2.2)	4 (6.7)	5 (4.8)
Any TEAE leading to death (fatal TEAE)	1 (2.2)	2 (3.3)	3 (2.9)
Any serious TEAE	7 (15.6)	10 (16.7)	17 (16.2)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
$ As assessed by investigator.

Program Source Code: [redacted]

TABLE 14.3 1.1

Overview of Treatment-Emergent Adverse Events and All Deaths
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=45) n (%)	High Dose (N=60) n (%)	All Subjects (N=105) n (%)
Any SAE that is considered associated with infusion pump$	1 (2.2)	1 (1.7)	2 (1.9)
Possible	0	0	0
Probable	0	1 (1.7)	1 (1.0)
Causal relationship	1 (2.2)	0	1 (1.0)
Any SAE that is considered associated with neria guards infusion set$	1 (2.2)	1 (1.7)	2 (1.9)
Possible	0	1 (1.7)	1 (1.0)
Probable	1 (2.2)	0	1 (1.0)
Causal relationship	0	0	0
Any SAE that is considered associated with product complaint$	2 (4.4)	1 (1.7)	3 (2.9)
ABBV-951	1 (2.2)	0	1 (1.0)
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	0	0	0
[redacted] infusion set 6 mm	0	0	0
[redacted] infusion set 9 mm	0	0	0
Neria guard infusion set (total)	1 (2.2)	1 (1.7)	2 (1.9)
Neria guard infusion set 6 mm	1 (2.2)	0	1 (1.0)
Neria guard infusion set 9 mm	0	1 (1.7)	1 (1.0)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
$ As assessed by investigator.

Program Source Code: [redacted]

TABLE 14.3 1.1

Overview of Treatment-Emergent Adverse Events and All Deaths
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=45) n (%)	High Dose (N=60) n (%)	All Subjects (N=105) n (%)
All deaths#	1 (2.2)	2 (3.3)	3 (2.9)
All TE-deaths	1 (2.2)	2 (3.3)	3 (2.9)
Deaths related to COVID-19 infection	0	0	0
AESI: polyneuropathy (narrow)	0	0	0
AESI: weight loss	1 (2.2)	3 (5.0)	4 (3.8)
AESI: hallucinations/psychosis	4 (8.9)	6 (10.0)	10 (9.5)
AESI: somnolence	0	0	0
AESI: infusion site related infections	8 (17.8)	9 (15.0)	17 (16.2)
AESI: infusion site related non infection reactions	11 (24.4)	17 (28.3)	28 (26.7)
AESI: falls and associated injuries	4 (8.9)	11 (18.3)	15 (14.3)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Includes non treatment-emergent deaths.

Program Source Code: [redacted]

表34　すべての有害事象（安全性解析対象集団）：M15-737試験

[redacted]20[redacted] 04:21 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Any adverse event	25 (55.6)	41 (68.3)	66 (62.9)
心臓障害	0	1 (1.7)	1 (1.0)
左脚ブロック	0	1 (1.7)	1 (1.0)
耳および迷路障害	0	1 (1.7)	1 (1.0)
回転性めまい	0	1 (1.7)	1 (1.0)
眼障害	1 (2.2)	2 (3.3)	3 (2.9)
眼瞼痙攣	0	1 (1.7)	1 (1.0)
眼充血	0	1 (1.7)	1 (1.0)
硝子体浮遊物	1 (2.2)	0	1 (1.0)
胃腸障害	5 (11.1)	4 (6.7)	9 (8.6)
腹部不快感	0	1 (1.7)	1 (1.0)
腹部膨満	0	1 (1.7)	1 (1.0)
腹痛	0	1 (1.7)	1 (1.0)
便秘	3 (6.7)	2 (3.3)	5 (4.8)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
胃腸障害 (Cont.)			
出血性腸憩室	0	1 (1.7)	1 (1.0)
嚥下障害	1 (2.2)	0	1 (1.0)
胃潰瘍	1 (2.2)	0	1 (1.0)
胃食道逆流性疾患	1 (2.2)	0	1 (1.0)
流涎過多	0	1 (1.7)	1 (1.0)
一般・全身障害および投与部位の状態	11 (24.4)	18 (30.0)	29 (27.6)
投与部位漏出	1 (2.2)	0	1 (1.0)
薬効欠如	1 (2.2)	0	1 (1.0)
注入部位内出血	2 (4.4)	2 (3.3)	4 (3.8)
注入部位皮膚炎	1 (2.2)	0	1 (1.0)
注入部位紅斑	6 (13.3)	7 (11.7)	13 (12.4)
注入部位血管外漏出	0	2 (3.3)	2 (1.9)
注入部位血腫	1 (2.2)	1 (1.7)	2 (1.9)
注入部位出血	0	1 (1.7)	1 (1.0)
注入部位硬結	0	2 (3.3)	2 (1.9)
注入部位炎症	0	1 (1.7)	1 (1.0)
注入部位刺激感	1 (2.2)	0	1 (1.0)
注入部位腫瘤	1 (2.2)	0	1 (1.0)
注入部位結節	0	2 (3.3)	2 (1.9)
注入部位浮腫	1 (2.2)	1 (1.7)	2 (1.9)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
一般・全身障害および投与部位の状態 (Cont.)			
注入部位疼痛	1 (2.2)	1 (1.7)	2 (1.9)
注入部位丘疹	1 (2.2)	3 (5.0)	4 (3.8)
注入部位異常感覚	0	1 (1.7)	1 (1.0)
注入部位発疹	0	1 (1.7)	1 (1.0)
注入部位反応	0	1 (1.7)	1 (1.0)
注入部位腫脹	0	1 (1.7)	1 (1.0)
注射部位内出血	1 (2.2)	0	1 (1.0)
注射部位紅斑	1 (2.2)	1 (1.7)	2 (1.9)
注射部位硬結	0	1 (1.7)	1 (1.0)
注射部位炎症	0	1 (1.7)	1 (1.0)
注射部位浮腫	0	1 (1.7)	1 (1.0)
末梢性浮腫	0	1 (1.7)	1 (1.0)
穿刺部位紅斑	1 (2.2)	0	1 (1.0)
感染症および寄生虫症	11 (24.4)	12 (20.0)	23 (21.9)
COVID-19	0	1 (1.7)	1 (1.0)
膀胱炎	1 (2.2)	0	1 (1.0)
大腸菌性尿路感染	0	1 (1.7)	1 (1.0)
胃腸炎	1 (2.2)	1 (1.7)	2 (1.9)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
感染症および寄生虫症 (Cont.)			
ヘリコバクター性胃炎	1 (2.2)	0	1 (1.0)
ヘリコバクター感染	1 (2.2)	0	1 (1.0)
帯状疱疹	0	1 (1.7)	1 (1.0)
注入部位膿瘍	1 (2.2)	0	1 (1.0)
注入部位蜂巣炎	4 (8.9)	8 (13.3)	12 (11.4)
注入部位感染	3 (6.7)	1 (1.7)	4 (3.8)
注射部位感染	0	1 (1.7)	1 (1.0)
上咽頭炎	1 (2.2)	0	1 (1.0)
上気道感染	1 (2.2)	0	1 (1.0)
尿路感染	0	2 (3.3)	2 (1.9)
傷害、中毒および処置合併症	5 (11.1)	11 (18.3)	16 (15.2)
節足動物刺傷	1 (2.2)	0	1 (1.0)
顔面骨骨折	0	1 (1.7)	1 (1.0)
転倒	3 (6.7)	9 (15.0)	12 (11.4)
転位骨折	0	1 (1.7)	1 (1.0)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	Dose Category High Dose (N=60) n (%)	All Subjects (N=105) n (%)
傷害、中毒および処置合併症 (Cont.)			
手骨折	0	2 (3.3)	2 (1.9)
股関節部骨折	1 (2.2)	1 (1.7)	2 (1.9)
上腕骨骨折	0	1 (1.7)	1 (1.0)
四肢損傷	0	1 (1.7)	1 (1.0)
肉離れ	1 (2.2)	0	1 (1.0)
処置による疼痛	0	1 (1.7)	1 (1.0)
肩甲骨骨折	0	1 (1.7)	1 (1.0)
臨床検査	4 (8.9)	4 (6.7)	8 (7.6)
血中葉酸減少	0	1 (1.7)	1 (1.0)
血中ホモシステイン増加	2 (4.4)	0	2 (1.9)
リンパ球数減少	1 (2.2)	0	1 (1.0)
プロトロンビン時間延長	0	1 (1.7)	1 (1.0)
ビタミンB12減少	1 (2.2)	0	1 (1.0)
ビタミンB6減少	2 (4.4)	0	2 (1.9)
体重減少	0	3 (5.0)	3 (2.9)
代謝および栄養障害	2 (4.4)	4 (6.7)	6 (5.7)
鉄欠乏	1 (2.2)	1 (1.7)	2 (1.9)
ビタミンB12欠乏	1 (2.2)	3 (5.0)	4 (3.8)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
筋骨格系および結合組織障害	2 (4.4)	6 (10.0)	8 (7.6)
背部痛	0	2 (3.3)	2 (1.9)
滑液包炎	0	1 (1.7)	1 (1.0)
出血性関節症	0	1 (1.7)	1 (1.0)
椎間板変性症	0	1 (1.7)	1 (1.0)
筋力低下	0	1 (1.7)	1 (1.0)
筋骨格硬直	0	1 (1.7)	1 (1.0)
変形性関節症	1 (2.2)	0	1 (1.0)
骨粗鬆症	1 (2.2)	1 (1.7)	2 (1.9)
四肢痛	1 (2.2)	0	1 (1.0)
腱鞘炎	1 (2.2)	0	1 (1.0)
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 (1.7)	1 (1.0)
ケラトアカントーマ	0	1 (1.7)	1 (1.0)
神経系障害	4 (8.9)	15 (25.0)	19 (18.1)
健忘	1 (2.2)	0	1 (1.0)
平衡障害	0	1 (1.7)	1 (1.0)
認知障害	1 (2.2)	1 (1.7)	2 (1.9)
注意力障害	0	1 (1.7)	1 (1.0)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
神経系障害 (Cont.)			
ジストニア	0	1 (1.7)	1 (1.0)
すくみ現象	1 (2.2)	1 (1.7)	2 (1.9)
頭蓋内出血	1 (2.2)	0	1 (1.0)
頭部不快感	0	1 (1.7)	1 (1.0)
感覚鈍麻	0	1 (1.7)	1 (1.0)
反射減弱	1 (2.2)	1 (1.7)	2 (1.9)
記憶障害	0	2 (3.3)	2 (1.9)
オンオフ現象	1 (2.2)	4 (6.7)	5 (4.8)
パーキンソン病	1 (2.2)	3 (5.0)	4 (3.8)
精神運動亢進	0	1 (1.7)	1 (1.0)
失神	0	2 (3.3)	2 (1.9)
一過性脳虚血発作	0	1 (1.7)	1 (1.0)
振戦	1 (2.2)	0	1 (1.0)
精神障害	8 (17.8)	11 (18.3)	19 (18.1)
攻撃性	0	1 (1.7)	1 (1.0)
激越	0	1 (1.7)	1 (1.0)
不安	1 (2.2)	2 (3.3)	3 (2.9)
歯ぎしり	1 (2.2)	0	1 (1.0)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
精神障害 (Cont.)			
錯乱状態	0	1 (1.7)	1 (1.0)
妄想	0	1 (1.7)	1 (1.0)
抑うつ気分	1 (2.2)	0	1 (1.0)
うつ病	2 (4.4)	1 (1.7)	3 (2.9)
自傷性皮膚症	0	1 (1.7)	1 (1.0)
幻覚	2 (4.4)	5 (8.3)	7 (6.7)
幻視	1 (2.2)	0	1 (1.0)
錯覚	1 (2.2)	0	1 (1.0)
衝動制御障害	0	1 (1.7)	1 (1.0)
衝動行為	1 (2.2)	0	1 (1.0)
パニック発作	0	1 (1.7)	1 (1.0)
妄想症	1 (2.2)	0	1 (1.0)
精神病性障害	1 (2.2)	1 (1.7)	2 (1.9)
レム睡眠行動障害	1 (2.2)	0	1 (1.0)
腎および尿路障害	1 (2.2)	1 (1.7)	2 (1.9)
膀胱痙縮	1 (2.2)	0	1 (1.0)
血尿	0	1 (1.7)	1 (1.0)
生殖系および乳房障害	2 (4.4)	1 (1.7)	3 (2.9)
良性前立腺肥大症	1 (2.2)	0	1 (1.0)
勃起不全	0	1 (1.7)	1 (1.0)
外陰腟乾燥	1 (2.2)	0	1 (1.0)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	Dose Category High Dose (N=60) n (%)	All Subjects (N=105) n (%)
呼吸器、胸郭および縦隔障害	2 (4.4)	1 (1.7)	3 (2.9)
窒息	1 (2.2)	0	1 (1.0)
誤嚥	1 (2.2)	0	1 (1.0)
呼吸困難	1 (2.2)	0	1 (1.0)
痰貯留	0	1 (1.7)	1 (1.0)
皮膚および皮下組織障害	4 (8.9)	1 (1.7)	5 (4.8)
光線角化症	1 (2.2)	0	1 (1.0)
脱毛症	1 (2.2)	0	1 (1.0)
湿疹	1 (2.2)	1 (1.7)	2 (1.9)
発疹	1 (2.2)	0	1 (1.0)
蕁麻疹	1 (2.2)	0	1 (1.0)
血管障害	1 (2.2)	6 (10.0)	7 (6.7)
血腫	1 (2.2)	0	1 (1.0)
高血圧	0	1 (1.7)	1 (1.0)
低血圧	0	1 (1.7)	1 (1.0)
起立性高血圧	0	1 (1.7)	1 (1.0)
起立性低血圧	0	2 (3.3)	2 (1.9)
表在性血栓性静脈炎	0	1 (1.7)	1 (1.0)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

表35　治験薬との因果関係別の有害事象（安全性解析対象集団）：M15-737試験

[redacted]20[redacted] 04:21 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.3__1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=45) n (%)	Dose Category High Dose (N=60) n (%)	All Subjects (N=105) n (%)
Any adverse event	25 (55.6)	41 (68.3)	66 (62.9)
No reasonable possibility	9 (20.0)	13 (21.7)	22 (21.0)
Reasonable possibility	16 (35.6)	28 (46.7)	44 (41.9)
心臓障害	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)
左脚ブロック	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)
耳および迷路障害	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)
回転性めまい	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
眼障害	1 (2.2)	2 (3.3)	3 (2.9)
No reasonable possibility	1 (2.2)	2 (3.3)	3 (2.9)
眼瞼痙攣	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)
眼充血	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)
硝子体浮遊物	1 (2.2)	0	1 (1.0)
No reasonable possibility	1 (2.2)	0	1 (1.0)
胃腸障害	5 (11.1)	4 (6.7)	9 (8.6)
No reasonable possibility	5 (11.1)	2 (3.3)	7 (6.7)
Reasonable possibility	0	2 (3.3)	2 (1.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
胃腸障害 (Cont.)			
腹部不快感	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)
腹部膨満	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)
腹痛	0	1 (1.7)	1 (1.0)
Reasonable possibility	0	1 (1.7)	1 (1.0)
便秘	3 (6.7)	2 (3.3)	5 (4.8)
No reasonable possibility	3 (6.7)	1 (1.7)	4 (3.8)
Reasonable possibility	0	1 (1.7)	1 (1.0)
出血性腸憩室	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
胃腸障害 (Cont.)			
嚥下障害	1 (2.2)	0	1 (1.0)
No reasonable possibility	1 (2.2)	0	1 (1.0)
胃潰瘍	1 (2.2)	0	1 (1.0)
No reasonable possibility	1 (2.2)	0	1 (1.0)
胃食道逆流性疾患	1 (2.2)	0	1 (1.0)
No reasonable possibility	1 (2.2)	0	1 (1.0)
流涎過多	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)
一般・全身障害および投与部位の状態	11 (24.4)	18 (30.0)	29 (27.6)
No reasonable possibility	1 (2.2)	2 (3.3)	3 (2.9)
Reasonable possibility	10 (22.2)	16 (26.7)	26 (24.8)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
一般・全身障害および投与部位の状態 (Cont.)			
投与部位漏出	1 (2.2)	0	1 (1.0)
Reasonable possibility	1 (2.2)	0	1 (1.0)
薬効欠如	1 (2.2)	0	1 (1.0)
Reasonable possibility	1 (2.2)	0	1 (1.0)
注入部位内出血	2 (4.4)	2 (3.3)	4 (3.8)
Reasonable possibility	2 (4.4)	2 (3.3)	4 (3.8)
注入部位皮膚炎	1 (2.2)	0	1 (1.0)
Reasonable possibility	1 (2.2)	0	1 (1.0)
注入部位紅斑	6 (13.3)	7 (11.7)	13 (12.4)
No reasonable possibility	2 (4.4)	1 (1.7)	3 (2.9)
Reasonable possibility	4 (8.9)	6 (10.0)	10 (9.5)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
一般・全身障害および投与部位の状態 (Cont.)			
注入部位血管外漏出	0	2 (3.3)	2 (1.9)
Reasonable possibility	0	2 (3.3)	2 (1.9)
注入部位血腫	1 (2.2)	1 (1.7)	2 (1.9)
Reasonable possibility	1 (2.2)	1 (1.7)	2 (1.9)
注入部位出血	0	1 (1.7)	1 (1.0)
Reasonable possibility	0	1 (1.7)	1 (1.0)
注入部位硬結	0	2 (3.3)	2 (1.9)
Reasonable possibility	0	2 (3.3)	2 (1.9)
注入部位炎症	0	1 (1.7)	1 (1.0)
Reasonable possibility	0	1 (1.7)	1 (1.0)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
一般・全身障害および投与部位の状態 (Cont.)			
注入部位刺激感	1 (2.2)	0	1 (1.0)
Reasonable possibility	1 (2.2)	0	1 (1.0)
注入部位腫瘤	1 (2.2)	0	1 (1.0)
Reasonable possibility	1 (2.2)	0	1 (1.0)
注入部位結節	0	2 (3.3)	2 (1.9)
Reasonable possibility	0	2 (3.3)	2 (1.9)
注入部位浮腫	1 (2.2)	1 (1.7)	2 (1.9)
Reasonable possibility	1 (2.2)	1 (1.7)	2 (1.9)
注入部位疼痛	1 (2.2)	1 (1.7)	2 (1.9)
Reasonable possibility	1 (2.2)	1 (1.7)	2 (1.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
一般・全身障害および投与部位の状態 (Cont.)			
注入部位丘疹	1 (2.2)	3 (5.0)	4 (3.8)
Reasonable possibility	1 (2.2)	3 (5.0)	4 (3.8)
注入部位異常感覚	0	1 (1.7)	1 (1.0)
Reasonable possibility	0	1 (1.7)	1 (1.0)
注入部位発疹	0	1 (1.7)	1 (1.0)
Reasonable possibility	0	1 (1.7)	1 (1.0)
注入部位反応	0	1 (1.7)	1 (1.0)
Reasonable possibility	0	1 (1.7)	1 (1.0)
注入部位腫脹	0	1 (1.7)	1 (1.0)
Reasonable possibility	0	1 (1.7)	1 (1.0)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
一般・全身障害および投与部位の状態 (Cont.)			
注射部位内出血	1 (2.2)	0	1 (1.0)
Reasonable possibility	1 (2.2)	0	1 (1.0)
注射部位紅斑	1 (2.2)	1 (1.7)	2 (1.9)
Reasonable possibility	1 (2.2)	1 (1.7)	2 (1.9)
注射部位硬結	0	1 (1.7)	1 (1.0)
Reasonable possibility	0	1 (1.7)	1 (1.0)
注射部位炎症	0	1 (1.7)	1 (1.0)
Reasonable possibility	0	1 (1.7)	1 (1.0)
注射部位浮腫	0	1 (1.7)	1 (1.0)
Reasonable possibility	0	1 (1.7)	1 (1.0)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
一般・全身障害および投与部位の状態 (Cont.)			
末梢性浮腫	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)
穿刺部位紅斑	1 (2.2)	0	1 (1.0)
Reasonable possibility	1 (2.2)	0	1 (1.0)
感染症および寄生虫症	11 (24.4)	12 (20.0)	23 (21.9)
No reasonable possibility	5 (11.1)	3 (5.0)	8 (7.6)
Reasonable possibility	6 (13.3)	9 (15.0)	15 (14.3)
COVID-19	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)
膀胱炎	1 (2.2)	0	1 (1.0)
No reasonable possibility	1 (2.2)	0	1 (1.0)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
感染症および寄生虫症 (Cont.)			
大腸菌性尿路感染	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)
胃腸炎	1 (2.2)	1 (1.7)	2 (1.9)
No reasonable possibility	1 (2.2)	1 (1.7)	2 (1.9)
ヘリコバクター性胃炎	1 (2.2)	0	1 (1.0)
No reasonable possibility	1 (2.2)	0	1 (1.0)
ヘリコバクター感染	1 (2.2)	0	1 (1.0)
No reasonable possibility	1 (2.2)	0	1 (1.0)
帯状疱疹	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
感染症および寄生虫症 (Cont.)			
注入部位膿瘍	1 (2.2)	0	1 (1.0)
Reasonable possibility	1 (2.2)	0	1 (1.0)
注入部位蜂巣炎	4 (8.9)	8 (13.3)	12 (11.4)
No reasonable possibility	1 (2.2)	0	1 (1.0)
Reasonable possibility	3 (6.7)	8 (13.3)	11 (10.5)
注入部位感染	3 (6.7)	1 (1.7)	4 (3.8)
No reasonable possibility	1 (2.2)	0	1 (1.0)
Reasonable possibility	2 (4.4)	1 (1.7)	3 (2.9)
注射部位感染	0	1 (1.7)	1 (1.0)
Reasonable possibility	0	1 (1.7)	1 (1.0)
上咽頭炎	1 (2.2)	0	1 (1.0)
No reasonable possibility	1 (2.2)	0	1 (1.0)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
感染症および寄生虫症 (Cont.)			
上気道感染	1 (2.2)	0	1 (1.0)
No reasonable possibility	1 (2.2)	0	1 (1.0)
尿路感染	0	2 (3.3)	2 (1.9)
No reasonable possibility	0	2 (3.3)	2 (1.9)
傷害、中毒および処置合併症	5 (11.1)	11 (18.3)	16 (15.2)
No reasonable possibility	5 (11.1)	10 (16.7)	15 (14.3)
Reasonable possibility	0	1 (1.7)	1 (1.0)
節足動物刺傷	1 (2.2)	0	1 (1.0)
No reasonable possibility	1 (2.2)	0	1 (1.0)
顔面骨骨折	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
傷害、中毒および処置合併症 (Cont.)			
転倒	3 (6.7)	9 (15.0)	12 (11.4)
No reasonable possibility	3 (6.7)	9 (15.0)	12 (11.4)
転位骨折	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)
手骨折	0	2 (3.3)	2 (1.9)
No reasonable possibility	0	2 (3.3)	2 (1.9)
股関節部骨折	1 (2.2)	1 (1.7)	2 (1.9)
No reasonable possibility	1 (2.2)	1 (1.7)	2 (1.9)
上腕骨骨折	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
傷害、中毒および処置合併症 (Cont.)			
四肢損傷	0	1 (1.7)	1 (1.0)
Reasonable possibility	0	1 (1.7)	1 (1.0)
肉離れ	1 (2.2)	0	1 (1.0)
No reasonable possibility	1 (2.2)	0	1 (1.0)
処置による疼痛	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)
肩甲骨骨折	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)
臨床検査	4 (8.9)	4 (6.7)	8 (7.6)
No reasonable possibility	2 (4.4)	2 (3.3)	4 (3.8)
Reasonable possibility	2 (4.4)	2 (3.3)	4 (3.8)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
臨床検査 (Cont.)			
血中葉酸減少	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)
血中ホモシステイン増加	2 (4.4)	0	2 (1.9)
Reasonable possibility	2 (4.4)	0	2 (1.9)
リンパ球数減少	1 (2.2)	0	1 (1.0)
No reasonable possibility	1 (2.2)	0	1 (1.0)
プロトロンビン時間延長	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)
ビタミンB12減少	1 (2.2)	0	1 (1.0)
Reasonable possibility	1 (2.2)	0	1 (1.0)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
臨床検査 (Cont.)			
ビタミンB6減少	2 (4.4)	0	2 (1.9)
No reasonable possibility	1 (2.2)	0	1 (1.0)
Reasonable possibility	1 (2.2)	0	1 (1.0)
体重減少	0	3 (5.0)	3 (2.9)
No reasonable possibility	0	1 (1.7)	1 (1.0)
Reasonable possibility	0	2 (3.3)	2 (1.9)
代謝および栄養障害	2 (4.4)	4 (6.7)	6 (5.7)
No reasonable possibility	2 (4.4)	1 (1.7)	3 (2.9)
Reasonable possibility	0	3 (5.0)	3 (2.9)
鉄欠乏	1 (2.2)	1 (1.7)	2 (1.9)
No reasonable possibility	1 (2.2)	1 (1.7)	2 (1.9)
ビタミンB12欠乏	1 (2.2)	3 (5.0)	4 (3.8)
No reasonable possibility	1 (2.2)	0	1 (1.0)
Reasonable possibility	0	3 (5.0)	3 (2.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
筋骨格系および結合組織障害	2 (4.4)	6 (10.0)	8 (7.6)
No reasonable possibility	2 (4.4)	5 (8.3)	7 (6.7)
Reasonable possibility	0	1 (1.7)	1 (1.0)
背部痛	0	2 (3.3)	2 (1.9)
No reasonable possibility	0	2 (3.3)	2 (1.9)
滑液包炎	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)
出血性関節症	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)
椎間板変性症	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
筋骨格系および結合組織障害 (Cont.)			
筋力低下	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)
筋骨格硬直	0	1 (1.7)	1 (1.0)
Reasonable possibility	0	1 (1.7)	1 (1.0)
変形性関節症	1 (2.2)	0	1 (1.0)
No reasonable possibility	1 (2.2)	0	1 (1.0)
骨粗鬆症	1 (2.2)	1 (1.7)	2 (1.9)
No reasonable possibility	1 (2.2)	1 (1.7)	2 (1.9)
四肢痛	1 (2.2)	0	1 (1.0)
No reasonable possibility	1 (2.2)	0	1 (1.0)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
筋骨格系および結合組織障害 (Cont.)			
腱鞘炎	1 (2.2)	0	1 (1.0)
No reasonable possibility	1 (2.2)	0	1 (1.0)
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 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)
ケラトアカントーマ	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)
神経系障害	4 (8.9)	15 (25.0)	19 (18.1)
No reasonable possibility	3 (6.7)	8 (13.3)	11 (10.5)
Reasonable possibility	1 (2.2)	7 (11.7)	8 (7.6)
健忘	1 (2.2)	0	1 (1.0)
No reasonable possibility	1 (2.2)	0	1 (1.0)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
神経系障害 (Cont.)			
平衡障害	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)
認知障害	1 (2.2)	1 (1.7)	2 (1.9)
No reasonable possibility	1 (2.2)	0	1 (1.0)
Reasonable possibility	0	1 (1.7)	1 (1.0)
注意力障害	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)
ジストニア	0	1 (1.7)	1 (1.0)
Reasonable possibility	0	1 (1.7)	1 (1.0)
すくみ現象	1 (2.2)	1 (1.7)	2 (1.9)
No reasonable possibility	1 (2.2)	1 (1.7)	2 (1.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=45) n (%)	Dose Category High Dose (N=60) n (%)	All Subjects (N=105) n (%)
神経系障害 (Cont.)			
頭蓋内出血	1 (2.2)	0	1 (1.0)
No reasonable possibility	1 (2.2)	0	1 (1.0)
頭部不快感	0	1 (1.7)	1 (1.0)
Reasonable possibility	0	1 (1.7)	1 (1.0)
感覚鈍麻	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)
反射減弱	1 (2.2)	1 (1.7)	2 (1.9)
No reasonable possibility	1 (2.2)	1 (1.7)	2 (1.9)
記憶障害	0	2 (3.3)	2 (1.9)
No reasonable possibility	0	2 (3.3)	2 (1.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
神経系障害 (Cont.)			
オンオフ現象	1 (2.2)	4 (6.7)	5 (4.8)
Reasonable possibility	1 (2.2)	4 (6.7)	5 (4.8)
パーキンソン病	1 (2.2)	3 (5.0)	4 (3.8)
No reasonable possibility	0	2 (3.3)	2 (1.9)
Reasonable possibility	1 (2.2)	1 (1.7)	2 (1.9)
精神運動亢進	0	1 (1.7)	1 (1.0)
Reasonable possibility	0	1 (1.7)	1 (1.0)
失神	0	2 (3.3)	2 (1.9)
No reasonable possibility	0	1 (1.7)	1 (1.0)
Reasonable possibility	0	1 (1.7)	1 (1.0)
一過性脳虚血発作	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=45) n (%)	Dose Category High Dose (N=60) n (%)	All Subjects (N=105) n (%)
神経系障害 (Cont.)			
振戦	1 (2.2)	0	1 (1.0)
No reasonable possibility	1 (2.2)	0	1 (1.0)
精神障害	8 (17.8)	11 (18.3)	19 (18.1)
No reasonable possibility	2 (4.4)	6 (10.0)	8 (7.6)
Reasonable possibility	6 (13.3)	5 (8.3)	11 (10.5)
攻撃性	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)
激越	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)
不安	1 (2.2)	2 (3.3)	3 (2.9)
No reasonable possibility	1 (2.2)	2 (3.3)	3 (2.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
精神障害 (Cont.)			
歯ぎしり	1 (2.2)	0	1 (1.0)
No reasonable possibility	1 (2.2)	0	1 (1.0)
錯乱状態	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)
妄想	0	1 (1.7)	1 (1.0)
Reasonable possibility	0	1 (1.7)	1 (1.0)
抑うつ気分	1 (2.2)	0	1 (1.0)
Reasonable possibility	1 (2.2)	0	1 (1.0)
うつ病	2 (4.4)	1 (1.7)	3 (2.9)
No reasonable possibility	2 (4.4)	1 (1.7)	3 (2.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
精神障害 (Cont.)			
自傷性皮膚症	0	1 (1.7)	1 (1.0)
Reasonable possibility	0	1 (1.7)	1 (1.0)
幻覚	2 (4.4)	5 (8.3)	7 (6.7)
No reasonable possibility	0	3 (5.0)	3 (2.9)
Reasonable possibility	2 (4.4)	2 (3.3)	4 (3.8)
幻視	1 (2.2)	0	1 (1.0)
Reasonable possibility	1 (2.2)	0	1 (1.0)
錯覚	1 (2.2)	0	1 (1.0)
Reasonable possibility	1 (2.2)	0	1 (1.0)
衝動制御障害	0	1 (1.7)	1 (1.0)
Reasonable possibility	0	1 (1.7)	1 (1.0)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
精神障害 (Cont.)			
衝動行為	1 (2.2)	0	1 (1.0)
Reasonable possibility	1 (2.2)	0	1 (1.0)
パニック発作	0	1 (1.7)	1 (1.0)
Reasonable possibility	0	1 (1.7)	1 (1.0)
妄想症	1 (2.2)	0	1 (1.0)
Reasonable possibility	1 (2.2)	0	1 (1.0)
精神病性障害	1 (2.2)	1 (1.7)	2 (1.9)
Reasonable possibility	1 (2.2)	1 (1.7)	2 (1.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
精神障害 (Cont.)			
レム睡眠行動障害	1 (2.2)	0	1 (1.0)
No reasonable possibility	1 (2.2)	0	1 (1.0)
腎および尿路障害	1 (2.2)	1 (1.7)	2 (1.9)
No reasonable possibility	1 (2.2)	1 (1.7)	2 (1.9)
膀胱痙縮	1 (2.2)	0	1 (1.0)
No reasonable possibility	1 (2.2)	0	1 (1.0)
血尿	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)
生殖系および乳房障害	2 (4.4)	1 (1.7)	3 (2.9)
No reasonable possibility	2 (4.4)	1 (1.7)	3 (2.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
生殖系および乳房障害 (Cont.)			
良性前立腺肥大症	1 (2.2)	0	1 (1.0)
No reasonable possibility	1 (2.2)	0	1 (1.0)
勃起不全	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)
外陰腟乾燥	1 (2.2)	0	1 (1.0)
No reasonable possibility	1 (2.2)	0	1 (1.0)
呼吸器、胸郭および縦隔障害	2 (4.4)	1 (1.7)	3 (2.9)
No reasonable possibility	2 (4.4)	1 (1.7)	3 (2.9)
窒息	1 (2.2)	0	1 (1.0)
No reasonable possibility	1 (2.2)	0	1 (1.0)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)			
誤嚥	1 (2.2)	0	1 (1.0)
No reasonable possibility	1 (2.2)	0	1 (1.0)
呼吸困難	1 (2.2)	0	1 (1.0)
No reasonable possibility	1 (2.2)	0	1 (1.0)
痰貯留	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)
皮膚および皮下組織障害	4 (8.9)	1 (1.7)	5 (4.8)
No reasonable possibility	3 (6.7)	1 (1.7)	4 (3.8)
Reasonable possibility	1 (2.2)	0	1 (1.0)
光線角化症	1 (2.2)	0	1 (1.0)
No reasonable possibility	1 (2.2)	0	1 (1.0)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
皮膚および皮下組織障害 (Cont.)			
脱毛症	1 (2.2)	0	1 (1.0)
No reasonable possibility	1 (2.2)	0	1 (1.0)
湿疹	1 (2.2)	1 (1.7)	2 (1.9)
No reasonable possibility	0	1 (1.7)	1 (1.0)
Reasonable possibility	1 (2.2)	0	1 (1.0)
発疹	1 (2.2)	0	1 (1.0)
No reasonable possibility	1 (2.2)	0	1 (1.0)
蕁麻疹	1 (2.2)	0	1 (1.0)
No reasonable possibility	1 (2.2)	0	1 (1.0)
血管障害	1 (2.2)	6 (10.0)	7 (6.7)
No reasonable possibility	1 (2.2)	5 (8.3)	6 (5.7)
Reasonable possibility	0	1 (1.7)	1 (1.0)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
血管障害 (Cont.)			
血腫	1 (2.2)	0	1 (1.0)
No reasonable possibility	1 (2.2)	0	1 (1.0)
高血圧	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)
低血圧	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)
起立性高血圧	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)
起立性低血圧	0	2 (3.3)	2 (1.9)
No reasonable possibility	0	1 (1.7)	1 (1.0)
Reasonable possibility	0	1 (1.7)	1 (1.0)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=45) n (%)	Dose Category High Dose (N=60) n (%)	All Subjects (N=105) n (%)
血管障害 (Cont.)			
表在性血栓性静脈炎	0	1 (1.7)	1 (1.0)
No reasonable possibility	0	1 (1.7)	1 (1.0)

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.

Program Source Code: [redacted]

表36　死亡した被験者一覧：M15-737試験

[redacted]20[redacted] 04:22 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.3__2.1

Listing of All Deaths
(All Screened Subjects)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 HIGH DOSE								
[redacted]# Age: 8[redacted] Sex: Male Race: WHITE Weight: 5[redacted].[redacted] kg								
	TRT	1 TO 174	174	174	R: END STAGE PARKINSON DISEASE S: 神経系障害 P: パーキンソン病 L: End stage Parkinson's disease	E: 174 L: 1 Day	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DRUG WITHDRAWN O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED	S: Yes, Death of subject R: NOT RELATED O: CARDIO RESPIRATORY FAILURE A: NO REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.1

Listing of All Deaths
(All Screened Subjects)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE [redacted]# Age: 7[redacted] Sex: Female Race: ASIAN Weight: 4[redacted].[redacted] kg								
	TRT	1 TO 243	243	243	R: DUE TO ASPIRATION S: 呼吸器、胸郭および縦隔障害 P: 誤嚥 L: Aspiration	E: 243 L: 1 Day	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DRUG WITHDRAWN O: NONE	S: Yes, Death of subject R: NOT RELATED O: ASPIRATION ACCIDENTALLY A: NO REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.1

Listing of All Deaths
(All Screened Subjects)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted]# Age: 7[redacted] Sex: Female Race: ASIAN Weight: 4[redacted].[redacted] kg								
[redacted]	TRT	1 TO 243	243	243	R: SUFFOCATION S: 呼吸器、胸郭および縦隔障害 P: 窒息 L: Suffocation	E: 243 L: 1 Day	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DRUG WITHDRAWN O: NONE	S: Yes, Death of subject R: NOT RELATED O: ASPIRATION ACCIDENTALLY A: NO REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.1

Listing of All Deaths
(All Screened Subjects)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 HIGH DOSE								
[redacted]# Age: 7[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg								
	TRT	1 TO 233	232	232	R: END STAGE PARKINSON'S DISEASE S: 神経系障害 P: パーキンソン病 L: End stage Parkinson's disease	E: 234 L: 3 Days	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DRUG WITHDRAWN O: MULTIPLE: (CONCOMITANT MEDICATION OR THERAPY DISCONTINUED; Other: SUBJECT WAS PLACED ON HOSPICE AND DIED AT HOME ON [redacted] 20[redacted]; CONCOMITANT MEDICATION OR THERAPY STARTED)	S: Yes, Death of subject R: NOT RELATED O: PROGRESSION OF HER PARKINSON'S TO DEATH

Subject prematurely discontinued.

Program Source Code: [redacted]

表37　重篤な有害事象（安全性解析対象集団）：M15-737試験

[redacted]20[redacted] 04:21 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.3__1.11.1

Subjects with Treatment-Emergent Serious Adverse Events
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Any adverse event	7 (15.6)	10 (16.7)	17 (16.2)
胃腸障害	0	1 (1.7)	1 (1.0)
出血性腸憩室	0	1 (1.7)	1 (1.0)
感染症および寄生虫症	2 (4.4)	2 (3.3)	4 (3.8)
胃腸炎	0	1 (1.7)	1 (1.0)
注入部位膿瘍	1 (2.2)	0	1 (1.0)
注入部位蜂巣炎	1 (2.2)	1 (1.7)	2 (1.9)
傷害、中毒および処置合併症	2 (4.4)	4 (6.7)	6 (5.7)
転倒	1 (2.2)	1 (1.7)	2 (1.9)
転位骨折	0	1 (1.7)	1 (1.0)
股関節部骨折	1 (2.2)	1 (1.7)	2 (1.9)
処置による疼痛	0	1 (1.7)	1 (1.0)
肩甲骨骨折	0	1 (1.7)	1 (1.0)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.11.1

Subjects with Treatment-Emergent Serious Adverse Events
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
筋骨格系および結合組織障害	1 (2.2)	1 (1.7)	2 (1.9)
滑液包炎	0	1 (1.7)	1 (1.0)
四肢痛	1 (2.2)	0	1 (1.0)
神経系障害	1 (2.2)	3 (5.0)	4 (3.8)
頭蓋内出血	1 (2.2)	0	1 (1.0)
パーキンソン病	0	2 (3.3)	2 (1.9)
一過性脳虚血発作	0	1 (1.7)	1 (1.0)
精神障害	1 (2.2)	1 (1.7)	2 (1.9)
幻覚	0	1 (1.7)	1 (1.0)
精神病性障害	1 (2.2)	1 (1.7)	2 (1.9)
呼吸器、胸郭および縦隔障害	1 (2.2)	0	1 (1.0)
窒息	1 (2.2)	0	1 (1.0)
誤嚥	1 (2.2)	0	1 (1.0)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

表38　中止に至った有害事象（安全性解析対象集団）：M15-737試験

[redacted]20[redacted] 04:21 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.3__1.8.1

Subjects with Treatment-Emergent Adverse Events
Leading to Study Drug Premature Discontinuation (Withdrawn) by Primary System
Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Any adverse event	1 (2.2)	4 (6.7)	5 (4.8)
一般・全身障害および投与部位の状態	0	1 (1.7)	1 (1.0)
注入部位発疹	0	1 (1.7)	1 (1.0)
感染症および寄生虫症	0	1 (1.7)	1 (1.0)
注入部位蜂巣炎	0	1 (1.7)	1 (1.0)
神経系障害	0	2 (3.3)	2 (1.9)
パーキンソン病	0	2 (3.3)	2 (1.9)
呼吸器、胸郭および縦隔障害	1 (2.2)	0	1 (1.0)
窒息	1 (2.2)	0	1 (1.0)
誤嚥	1 (2.2)	0	1 (1.0)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

表39　有害事象の90日間ごとの初回発現割合の推移（安全性解析対象集団）：M15-737試験

[redacted]20[redacted] 04:22 <[redacted]>
ABBV-951
STUDY M15-737 - FIRST INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.3 1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N_eval (%)	 Days 91 to 180 (N=75) n/N_eval (%)	 Days 181 to 270 (N=73) n/N_eval (%)	 Days 271 to 360 (N=62) n/N_eval (%)
Total (Any Dose)				
Any adverse event	43/105 (41.0)	12/38 (31.6)	9/26 (34.6)	0/14
心臓障害	0/105	0/75	1/73 (1.4)	0/61
左脚ブロック	0/105	0/75	1/73 (1.4)	0/61
耳および迷路障害	0/105	1/75 (1.3)	0/72	0/61
回転性めまい	0/105	1/75 (1.3)	0/72	0/61
眼障害	0/105	2/75 (2.7)	0/71	1/60 (1.7)
眼瞼痙攣	0/105	1/75 (1.3)	0/72	0/61
眼充血	0/105	1/75 (1.3)	0/72	0/61
硝子体浮遊物	0/105	0/75	0/73	1/62 (1.6)
胃腸障害	7/105 (6.7)	0/69	1/67 (1.5)	1/57 (1.8)
腹部不快感	0/105	0/75	1/73 (1.4)	0/61
腹部膨満	1/105 (1.0)	0/74	0/72	0/62
腹痛	0/105	1/75 (1.3)	0/72	0/62
便秘	4/105 (3.8)	0/72	1/70 (1.4)	0/59
出血性腸憩室	1/105 (1.0)	0/74	0/72	0/62
嚥下障害	1/105 (1.0)	0/74	0/72	0/61
胃潰瘍	0/105	0/75	0/73	1/62 (1.6)
胃食道逆流性疾患	1/105 (1.0)	0/74	0/72	0/61

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
Total (Any Dose)				
Any adverse event	1/7 (14.3)	1/2 (50.0)	0/0	66/105 (62.9)
心臓障害	0/26	0/4	0/0	1/105 (1.0)
左脚ブロック	0/26	0/4	0/0	1/105 (1.0)
耳および迷路障害	0/26	0/4	0/0	1/105 (1.0)
回転性めまい	0/26	0/4	0/0	1/105 (1.0)
眼障害	0/24	0/4	0/0	3/105 (2.9)
眼瞼痙攣	0/25	0/4	0/0	1/105 (1.0)
眼充血	0/25	0/4	0/0	1/105 (1.0)
硝子体浮遊物	0/26	0/4	0/0	1/105 (1.0)
胃腸障害	0/25	0/4	0/0	9/105 (8.6)
腹部不快感	0/26	0/4	0/0	1/105 (1.0)
腹部膨満	0/26	0/4	0/0	1/105 (1.0)
腹痛	0/26	0/4	0/0	1/105 (1.0)
便秘	0/26	0/4	0/0	5/105 (4.8)
出血性腸憩室	0/26	0/4	0/0	1/105 (1.0)
嚥下障害	0/26	0/4	0/0	1/105 (1.0)
胃潰瘍	0/25	0/4	0/0	1/105 (1.0)
胃食道逆流性疾患	0/26	0/4	0/0	1/105 (1.0)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
Total (Any Dose)				
胃腸障害 (Cont.)				
流涎過多	0/105	0/75	1/73 (1.4)	0/61
一般・全身障害および投与部位の状態	18/105 (17.1)	8/58 (13.8)	1/50 (2.0)	1/41 (2.4)
投与部位漏出	0/105	1/75 (1.3)	0/72	0/61
薬効欠如	1/105 (1.0)	0/74	0/72	0/61
注入部位内出血	2/105 (1.9)	1/73 (1.4)	1/70 (1.4)	0/59
注入部位皮膚炎	0/105	1/75 (1.3)	0/72	0/61
注入部位紅斑	6/105 (5.7)	4/69 (5.8)	2/64 (3.1)	1/53 (1.9)
注入部位血管外漏出	0/105	1/75 (1.3)	0/72	0/61
注入部位血腫	1/105 (1.0)	1/75 (1.3)	0/72	0/61
注入部位出血	0/105	1/75 (1.3)	0/72	0/62
注入部位硬結	0/105	1/75 (1.3)	0/72	1/61 (1.6)
注入部位炎症	0/105	1/75 (1.3)	0/72	0/61
注入部位刺激感	0/105	1/75 (1.3)	0/72	0/61
注入部位腫瘤	0/105	0/75	1/73 (1.4)	0/61
注入部位結節	2/105 (1.9)	0/73	0/71	0/61
注入部位浮腫	2/105 (1.9)	0/73	0/72	0/61
注入部位疼痛	1/105 (1.0)	0/74	0/72	0/61
注入部位丘疹	4/105 (3.8)	0/71	0/70	0/60
注入部位異常感覚	1/105 (1.0)	0/74	0/72	0/62
注入部位発疹	1/105 (1.0)	0/74	0/73	0/62
注入部位反応	0/105	1/75 (1.3)	0/72	0/61

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
Total (Any Dose)				
胃腸障害 (Cont.)				
流涎過多	0/26	0/4	0/0	1/105 (1.0)
一般・全身障害および投与部位の状態	1/21 (4.8)	0/4	0/0	29/105 (27.6)
投与部位漏出	0/25	0/4	0/0	1/105 (1.0)
薬効欠如	0/26	0/4	0/0	1/105 (1.0)
注入部位内出血	0/25	0/4	0/0	4/105 (3.8)
注入部位皮膚炎	0/26	0/4	0/0	1/105 (1.0)
注入部位紅斑	0/24	0/4	0/0	13/105 (12.4)
注入部位血管外漏出	1/26 (3.8)	0/4	0/0	2/105 (1.9)
注入部位血腫	0/26	0/4	0/0	2/105 (1.9)
注入部位出血	0/26	0/4	0/0	1/105 (1.0)
注入部位硬結	0/25	0/4	0/0	2/105 (1.9)
注入部位炎症	0/26	0/4	0/0	1/105 (1.0)
注入部位刺激感	0/26	0/4	0/0	1/105 (1.0)
注入部位腫瘤	0/26	0/4	0/0	1/105 (1.0)
注入部位結節	0/26	0/4	0/0	2/105 (1.9)
注入部位浮腫	0/26	0/4	0/0	2/105 (1.9)
注入部位疼痛	1/26 (3.8)	0/4	0/0	2/105 (1.9)
注入部位丘疹	0/26	0/4	0/0	4/105 (3.8)
注入部位異常感覚	0/26	0/4	0/0	1/105 (1.0)
注入部位発疹	0/26	0/4	0/0	1/105 (1.0)
注入部位反応	0/26	0/4	0/0	1/105 (1.0)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態(Cont.)				
注入部位腫脹	1/105 (1.0)	0/74	0/72	0/62
注射部位内出血	0/105	1/75 (1.3)	0/72	0/61
注射部位紅斑	2/105 (1.9)	0/73	0/71	0/60
注射部位硬結	1/105 (1.0)	0/74	0/72	0/61
注射部位炎症	1/105 (1.0)	0/74	0/72	0/61
注射部位浮腫	1/105 (1.0)	0/74	0/73	0/62
末梢性浮腫	1/105 (1.0)	0/74	0/72	0/61
穿刺部位紅斑	0/105	1/75 (1.3)	0/72	0/61
感染症および寄生虫症	9/105 (8.6)	5/67 (7.5)	5/60 (8.3)	2/48 (4.2)
COVID-19	0/105	0/75	0/73	0/62
膀胱炎	1/105 (1.0)	0/74	0/72	0/61
大腸菌性尿路感染	0/105	1/75 (1.3)	0/72	0/61
胃腸炎	1/105 (1.0)	0/74	1/72 (1.4)	0/60
ヘリコバクター性胃炎	1/105 (1.0)	0/74	0/72	0/61
ヘリコバクター感染	0/105	0/75	0/73	1/62 (1.6)
帯状疱疹	0/105	1/75 (1.3)	0/72	0/61
注入部位膿瘍	0/105	0/75	1/73 (1.4)	0/61
注入部位蜂巣炎	6/105 (5.7)	0/70	3/68 (4.4)	2/58 (3.4)
注入部位感染	0/105	3/75 (4.0)	1/70 (1.4)	0/59

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態(Cont.)				
注入部位腫脹	0/26	0/4	0/0	1/105 (1.0)
注射部位内出血	0/26	0/4	0/0	1/105 (1.0)
注射部位紅斑	0/25	0/4	0/0	2/105 (1.9)
注射部位硬結	0/25	0/4	0/0	1/105 (1.0)
注射部位炎症	0/26	0/4	0/0	1/105 (1.0)
注射部位浮腫	0/26	0/4	0/0	1/105 (1.0)
末梢性浮腫	0/26	0/4	0/0	1/105 (1.0)
穿刺部位紅斑	0/26	0/4	0/0	1/105 (1.0)
感染症および寄生虫症	2/20 (10.0)	0/3	0/0	23/105 (21.9)
COVID-19	1/26 (3.8)	0/3	0/0	1/105 (1.0)
膀胱炎	0/26	0/4	0/0	1/105 (1.0)
大腸菌性尿路感染	0/26	0/4	0/0	1/105 (1.0)
胃腸炎	0/25	0/4	0/0	2/105 (1.9)
ヘリコバクター性胃炎	0/26	0/4	0/0	1/105 (1.0)
ヘリコバクター感染	0/25	0/4	0/0	1/105 (1.0)
帯状疱疹	0/26	0/4	0/0	1/105 (1.0)
注入部位膿瘍	0/25	0/4	0/0	1/105 (1.0)
注入部位蜂巣炎	1/24 (4.2)	0/4	0/0	12/105 (11.4)
注入部位感染	0/25	0/4	0/0	4/105 (3.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
Total (Any Dose)				
感染症および寄生虫症 (Cont.)				
注射部位感染	0/105	0/75	1/73 (1.4)	0/61
上咽頭炎	0/105	0/75	1/73 (1.4)	0/61
上気道感染	0/105	1/75 (1.3)	0/72	0/61
尿路感染	1/105 (1.0)	1/74 (1.4)	0/71	0/60
傷害、中毒および処置合併症	6/105 (5.7)	7/69 (10.1)	3/60 (5.0)	0/47
節足動物刺傷	0/105	1/75 (1.3)	0/72	0/61
顔面骨骨折	1/105 (1.0)	0/74	0/72	0/62
転倒	5/105 (4.8)	4/70 (5.7)	3/64 (4.7)	0/51
転位骨折	0/105	1/75 (1.3)	0/72	0/61
手骨折	0/105	1/75 (1.3)	1/72 (1.4)	0/60
股関節部骨折	1/105 (1.0)	1/74 (1.4)	0/71	0/61
上腕骨骨折	1/105 (1.0)	0/74	0/72	0/62
四肢損傷	0/105	1/75 (1.3)	0/72	0/61
肉離れ	1/105 (1.0)	0/74	0/72	0/61
処置による疼痛	0/105	1/75 (1.3)	0/72	0/61
肩甲骨骨折	1/105 (1.0)	0/74	0/72	0/61
臨床検査	4/105 (3.8)	1/72 (1.4)	3/69 (4.3)	0/57
血中葉酸減少	1/105 (1.0)	0/74	0/72	0/61
血中ホモシステイン増加	2/105 (1.9)	0/74	0/72	0/61
リンパ球数減少	0/105	0/75	1/73 (1.4)	0/62

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
Total (Any Dose)				
感染症および寄生虫症 (Cont.)				
注射部位感染	0/26	0/4	0/0	1/105 (1.0)
上咽頭炎	0/25	0/4	0/0	1/105 (1.0)
上気道感染	0/26	0/4	0/0	1/105 (1.0)
尿路感染	0/25	0/4	0/0	2/105 (1.9)
傷害、中毒および処置合併症	0/20	0/4	0/0	16/105 (15.2)
節足動物刺傷	0/25	0/4	0/0	1/105 (1.0)
顔面骨骨折	0/26	0/4	0/0	1/105 (1.0)
転倒	0/22	0/4	0/0	12/105 (11.4)
転位骨折	0/26	0/4	0/0	1/105 (1.0)
手骨折	0/24	0/4	0/0	2/105 (1.9)
股関節部骨折	0/26	0/4	0/0	2/105 (1.9)
上腕骨骨折	0/26	0/4	0/0	1/105 (1.0)
四肢損傷	0/26	0/4	0/0	1/105 (1.0)
肉離れ	0/26	0/4	0/0	1/105 (1.0)
処置による疼痛	0/25	0/4	0/0	1/105 (1.0)
肩甲骨骨折	0/25	0/4	0/0	1/105 (1.0)
臨床検査	0/25	0/4	0/0	8/105 (7.6)
血中葉酸減少	0/26	0/4	0/0	1/105 (1.0)
血中ホモシステイン増加	0/26	0/4	0/0	2/105 (1.9)
リンパ球数減少	0/26	0/4	0/0	1/105 (1.0)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
Total (Any Dose)				
臨床検査 (Cont.)				
プロトロンビン時間延長	1/105 (1.0)	0/74	0/72	0/61
ビタミンB12減少	0/105	1/75 (1.3)	0/72	0/61
ビタミンB6減少	0/105	0/75	2/73 (2.7)	0/60
体重減少	1/105 (1.0)	1/74 (1.4)	1/71 (1.4)	0/60
代謝および栄養障害	1/105 (1.0)	2/74 (2.7)	3/70 (4.3)	0/57
鉄欠乏	0/105	2/75 (2.7)	0/71	0/61
ビタミンB12欠乏	1/105 (1.0)	0/74	3/72 (4.2)	0/58
筋骨格系および結合組織障害	2/105 (1.9)	3/74 (4.1)	2/69 (2.9)	1/56 (1.8)
背部痛	0/105	1/75 (1.3)	1/72 (1.4)	0/60
滑液包炎	1/105 (1.0)	0/74	0/72	0/61
出血性関節症	0/105	1/75 (1.3)	0/72	0/61
椎間板変性症	0/105	0/75	1/73 (1.4)	0/61
筋力低下	0/105	1/75 (1.3)	0/72	0/61
筋骨格硬直	0/105	1/75 (1.3)	0/72	0/61
変形性関節症	0/105	0/75	0/73	1/62 (1.6)
骨粗鬆症	1/105 (1.0)	0/74	0/72	1/61 (1.6)
四肢痛	0/105	0/75	0/73	1/62 (1.6)
腱鞘炎	1/105 (1.0)	0/75	0/73	0/62

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
Total (Any Dose)				
臨床検査 (Cont.)				
プロトロンビン時間延長	0/26	0/4	0/0	1/105 (1.0)
ビタミンB12減少	0/26	0/4	0/0	1/105 (1.0)
ビタミンB6減少	0/26	0/4	0/0	2/105 (1.9)
体重減少	0/25	0/4	0/0	3/105 (2.9)
代謝および栄養障害	0/21	0/4	0/0	6/105 (5.7)
鉄欠乏	0/25	0/4	0/0	2/105 (1.9)
ビタミンB12欠乏	0/22	0/4	0/0	4/105 (3.8)
筋骨格系および結合組織障害	0/24	0/4	0/0	8/105 (7.6)
背部痛	0/25	0/4	0/0	2/105 (1.9)
滑液包炎	0/26	0/4	0/0	1/105 (1.0)
出血性関節症	0/26	0/4	0/0	1/105 (1.0)
椎間板変性症	0/25	0/4	0/0	1/105 (1.0)
筋力低下	0/26	0/4	0/0	1/105 (1.0)
筋骨格硬直	0/26	0/4	0/0	1/105 (1.0)
変形性関節症	0/26	0/4	0/0	1/105 (1.0)
骨粗鬆症	0/26	0/4	0/0	2/105 (1.9)
四肢痛	0/26	0/4	0/0	1/105 (1.0)
腱鞘炎	0/26	0/4	0/0	1/105 (1.0)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
Total (Any Dose)				
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）	0/105	0/75	1/73 (1.4)	0/61
ケラトアカントーマ	0/105	0/75	1/73 (1.4)	0/61
神経系障害	10/105 (9.5)	4/68 (5.9)	4/62 (6.5)	0/50
健忘	1/105 (1.0)	0/75	0/73	0/62
平衡障害	1/105 (1.0)	0/74	0/72	0/61
認知障害	2/105 (1.9)	0/73	0/71	0/60
注意力障害	1/105 (1.0)	0/74	0/72	0/62
ジストニア	1/105 (1.0)	0/74	0/72	0/61
すくみ現象	0/105	2/75 (2.7)	0/71	0/60
頭蓋内出血	0/105	0/75	1/73 (1.4)	0/61
頭部不快感	1/105 (1.0)	0/75	0/73	0/62
感覚鈍麻	0/105	0/75	1/73 (1.4)	0/61
反射減弱	1/105 (1.0)	1/75 (1.3)	0/72	0/61
記憶障害	1/105 (1.0)	0/74	0/72	0/62
オンオフ現象	2/105 (1.9)	2/74 (2.7)	1/70 (1.4)	0/58
パーキンソン病	0/105	3/75 (4.0)	1/70 (1.4)	0/60
精神運動亢進	0/105	0/75	1/73 (1.4)	0/61
失神	1/105 (1.0)	1/74 (1.4)	0/71	0/60
一過性脳虚血発作	1/105 (1.0)	0/74	0/72	0/61
振戦	0/105	1/75 (1.3)	0/72	0/61

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
Total (Any Dose)				
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）	0/26	0/4	0/0	1/105 (1.0)
ケラトアカントーマ	0/26	0/4	0/0	1/105 (1.0)
神経系障害	0/23	1/4 (25.0)	0/0	19/105 (18.1)
健忘	0/26	0/4	0/0	1/105 (1.0)
平衡障害	0/26	0/4	0/0	1/105 (1.0)
認知障害	0/26	0/4	0/0	2/105 (1.9)
注意力障害	0/26	0/4	0/0	1/105 (1.0)
ジストニア	0/26	0/4	0/0	1/105 (1.0)
すくみ現象	0/26	0/4	0/0	2/105 (1.9)
頭蓋内出血	0/26	0/4	0/0	1/105 (1.0)
頭部不快感	0/26	0/4	0/0	1/105 (1.0)
感覚鈍麻	0/25	0/4	0/0	1/105 (1.0)
反射減弱	0/26	0/4	0/0	2/105 (1.9)
記憶障害	0/26	1/4 (25.0)	0/0	2/105 (1.9)
オンオフ現象	0/26	0/4	0/0	5/105 (4.8)
パーキンソン病	0/26	0/4	0/0	4/105 (3.8)
精神運動亢進	0/25	0/4	0/0	1/105 (1.0)
失神	0/25	0/4	0/0	2/105 (1.9)
一過性脳虚血発作	0/26	0/4	0/0	1/105 (1.0)
振戦	0/26	0/4	0/0	1/105 (1.0)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
Total (Any Dose)				
精神障害	9/105 (8.6)	5/66 (7.6)	5/59 (8.5)	0/45
攻撃性	1/105 (1.0)	0/74	0/72	0/62
激越	1/105 (1.0)	0/74	0/72	0/61
不安	1/105 (1.0)	1/74 (1.4)	1/71 (1.4)	0/59
歯ぎしり	1/105 (1.0)	0/74	0/72	0/61
錯乱状態	0/105	0/75	1/73 (1.4)	0/61
妄想	0/105	0/75	1/73 (1.4)	0/61
抑うつ気分	0/105	0/75	1/73 (1.4)	0/61
うつ病	2/105 (1.9)	1/73 (1.4)	0/70	0/60
自傷性皮膚症	0/105	1/75 (1.3)	0/72	0/61
幻覚	3/105 (2.9)	2/72 (2.8)	2/68 (2.9)	0/55
幻視	0/105	1/75 (1.3)	0/72	0/61
錯覚	0/105	0/75	1/73 (1.4)	0/61
衝動制御障害	0/105	1/75 (1.3)	0/72	0/62
衝動行為	0/105	1/75 (1.3)	0/72	0/61
パニック発作	0/105	1/75 (1.3)	0/72	0/61
妄想症	0/105	0/75	1/73 (1.4)	0/61
精神病性障害	0/105	2/75 (2.7)	0/71	0/60
レム睡眠行動障害	1/105 (1.0)	0/74	0/72	0/61
腎および尿路障害	1/105 (1.0)	1/74 (1.4)	0/71	0/60
膀胱痙縮	1/105 (1.0)	0/74	0/72	0/61

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
Total (Any Dose)				
精神障害	0/21	0/3	0/0	19/105 (18.1)
攻撃性	0/26	0/4	0/0	1/105 (1.0)
激越	0/26	0/4	0/0	1/105 (1.0)
不安	0/24	0/3	0/0	3/105 (2.9)
歯ぎしり	0/25	0/4	0/0	1/105 (1.0)
錯乱状態	0/26	0/4	0/0	1/105 (1.0)
妄想	0/25	0/4	0/0	1/105 (1.0)
抑うつ気分	0/26	0/4	0/0	1/105 (1.0)
うつ病	0/26	0/4	0/0	3/105 (2.9)
自傷性皮膚症	0/26	0/4	0/0	1/105 (1.0)
幻覚	0/23	0/3	0/0	7/105 (6.7)
幻視	0/26	0/4	0/0	1/105 (1.0)
錯覚	0/26	0/4	0/0	1/105 (1.0)
衝動制御障害	0/26	0/4	0/0	1/105 (1.0)
衝動行為	0/26	0/4	0/0	1/105 (1.0)
パニック発作	0/26	0/4	0/0	1/105 (1.0)
妄想症	0/26	0/4	0/0	1/105 (1.0)
精神病性障害	0/26	0/4	0/0	2/105 (1.9)
レム睡眠行動障害	0/26	0/4	0/0	1/105 (1.0)
腎および尿路障害	0/26	0/4	0/0	2/105 (1.9)
膀胱痙縮	0/26	0/4	0/0	1/105 (1.0)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
Total (Any Dose)				
腎および尿路障害 (Cont.)				
血尿	0/105	1/75 (1.3)	0/72	0/61
生殖系および乳房障害	3/105 (2.9)	0/72	0/70	0/59
良性前立腺肥大症	1/105 (1.0)	0/74	0/72	0/61
勃起不全	1/105 (1.0)	0/74	0/72	0/61
外陰腟乾燥	1/105 (1.0)	0/74	0/72	0/61
呼吸器、胸郭および縦隔障害	0/105	0/75	1/73 (1.4)	1/61 (1.6)
窒息	0/105	0/75	1/73 (1.4)	0/61
誤嚥	0/105	0/75	1/73 (1.4)	0/61
呼吸困難	0/105	0/75	0/73	1/62 (1.6)
痰貯留	0/105	0/75	0/73	0/62
皮膚および皮下組織障害	0/105	2/75 (2.7)	1/71 (1.4)	2/59 (3.4)
光線角化症	0/105	0/75	1/73 (1.4)	0/61
脱毛症	0/105	1/75 (1.3)	0/72	0/61
湿疹	0/105	1/75 (1.3)	0/72	1/61 (1.6)
発疹	0/105	1/75 (1.3)	0/72	0/61
蕁麻疹	0/105	0/75	0/73	1/62 (1.6)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
Total (Any Dose)				
腎および尿路障害 (Cont.)				
血尿	0/26	0/4	0/0	1/105 (1.0)
生殖系および乳房障害	0/26	0/4	0/0	3/105 (2.9)
良性前立腺肥大症	0/26	0/4	0/0	1/105 (1.0)
勃起不全	0/26	0/4	0/0	1/105 (1.0)
外陰腟乾燥	0/26	0/4	0/0	1/105 (1.0)
呼吸器、胸郭および縦隔障害	1/25 (4.0)	0/4	0/0	3/105 (2.9)
窒息	0/26	0/4	0/0	1/105 (1.0)
誤嚥	0/26	0/4	0/0	1/105 (1.0)
呼吸困難	0/25	0/4	0/0	1/105 (1.0)
痰貯留	1/26 (3.8)	0/4	0/0	1/105 (1.0)
皮膚および皮下組織障害	0/23	0/4	0/0	5/105 (4.8)
光線角化症	0/25	0/4	0/0	1/105 (1.0)
脱毛症	0/26	0/4	0/0	1/105 (1.0)
湿疹	0/25	0/4	0/0	2/105 (1.9)
発疹	0/26	0/4	0/0	1/105 (1.0)
蕁麻疹	0/25	0/4	0/0	1/105 (1.0)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
Total (Any Dose)				
血管障害	2/105 (1.9)	4/73 (5.5)	1/67 (1.5)	0/55
血腫	0/105	1/75 (1.3)	0/72	0/61
高血圧	0/105	1/75 (1.3)	0/72	0/61
低血圧	1/105 (1.0)	0/74	0/72	0/61
起立性高血圧	1/105 (1.0)	0/74	0/72	0/61
起立性低血圧	0/105	2/75 (2.7)	0/71	0/60
表在性血栓性静脈炎	0/105	0/75	1/73 (1.4)	0/61

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
Total (Any Dose)				
血管障害	0/24	0/3	0/0	7/105 (6.7)
血腫	0/26	0/4	0/0	1/105 (1.0)
高血圧	0/26	0/4	0/0	1/105 (1.0)
低血圧	0/26	0/4	0/0	1/105 (1.0)
起立性高血圧	0/26	0/4	0/0	1/105 (1.0)
起立性低血圧	0/25	0/4	0/0	2/105 (1.9)
表在性血栓性静脈炎	0/25	0/3	0/0	1/105 (1.0)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
Low Dose				
Any adverse event	16/45 (35.6)	5/17 (29.4)	4/12 (33.3)	0/5
眼障害	0/45	0/29	0/29	1/24 (4.2)
硝子体浮遊物	0/45	0/29	0/29	1/24 (4.2)
胃腸障害	4/45 (8.9)	0/26	0/26	1/21 (4.8)
便秘	2/45 (4.4)	0/28	1/28 (3.6)	0/22
嚥下障害	1/45 (2.2)	0/28	0/28	0/23
胃潰瘍	0/45	0/29	0/29	1/24 (4.2)
胃食道逆流性疾患	1/45 (2.2)	0/28	0/28	0/23
一般・全身障害および投与部位の状態	6/45 (13.3)	4/23 (17.4)	1/19 (5.3)	0/14
投与部位漏出	0/45	1/29 (3.4)	0/28	0/23
薬効欠如	1/45 (2.2)	0/28	0/28	0/23
注入部位内出血	1/45 (2.2)	0/28	1/28 (3.6)	0/22
注入部位皮膚炎	0/45	1/29 (3.4)	0/28	0/23
注入部位紅斑	1/45 (2.2)	2/28 (7.1)	2/26 (7.7)	1/20 (5.0)
注入部位血腫	0/45	1/29 (3.4)	0/28	0/23
注入部位刺激感	0/45	1/29 (3.4)	0/28	0/23
注入部位腫瘤	0/45	0/29	1/29 (3.4)	0/23
注入部位浮腫	1/45 (2.2)	0/28	0/28	0/23
注入部位疼痛	1/45 (2.2)	0/28	0/28	0/23
注入部位丘疹	1/45 (2.2)	0/28	0/28	0/23

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
Low Dose				
Any adverse event	0/3	0/1	0/0	25/45 (55.6)
眼障害	0/10	0/1	0/0	1/45 (2.2)
硝子体浮遊物	0/10	0/1	0/0	1/45 (2.2)
胃腸障害	0/9	0/1	0/0	5/45 (11.1)
便秘	0/10	0/1	0/0	3/45 (6.7)
嚥下障害	0/10	0/1	0/0	1/45 (2.2)
胃潰瘍	0/9	0/1	0/0	1/45 (2.2)
胃食道逆流性疾患	0/10	0/1	0/0	1/45 (2.2)
一般・全身障害および投与部位の状態	0/7	0/1	0/0	11/45 (24.4)
投与部位漏出	0/9	0/1	0/0	1/45 (2.2)
薬効欠如	0/10	0/1	0/0	1/45 (2.2)
注入部位内出血	0/9	0/1	0/0	2/45 (4.4)
注入部位皮膚炎	0/10	0/1	0/0	1/45 (2.2)
注入部位紅斑	0/8	0/1	0/0	6/45 (13.3)
注入部位血腫	0/10	0/1	0/0	1/45 (2.2)
注入部位刺激感	0/10	0/1	0/0	1/45 (2.2)
注入部位腫瘤	0/10	0/1	0/0	1/45 (2.2)
注入部位浮腫	0/10	0/1	0/0	1/45 (2.2)
注入部位疼痛	0/10	0/1	0/0	1/45 (2.2)
注入部位丘疹	0/10	0/1	0/0	1/45 (2.2)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
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n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
Low Dose				
一般・全身障害および投与部位の状態(Cont.)				
注射部位内出血	0/45	1/29 (3.4)	0/28	0/23
注射部位紅斑	1/45 (2.2)	0/28	0/28	0/23
穿刺部位紅斑	0/45	1/29 (3.4)	0/28	0/23
感染症および寄生虫症	4/45 (8.9)	2/26 (7.7)	3/24 (12.5)	2/16 (12.5)
膀胱炎	1/45 (2.2)	0/28	0/28	0/23
胃腸炎	1/45 (2.2)	0/28	0/28	0/23
ヘリコバクター性胃炎	1/45 (2.2)	0/28	0/28	0/23
ヘリコバクター感染	0/45	0/29	0/29	1/24 (4.2)
注入部位膿瘍	0/45	0/29	1/29 (3.4)	0/23
注入部位蜂巣炎	2/45 (4.4)	0/28	0/28	2/23 (8.7)
注入部位感染	0/45	2/29 (6.9)	1/27 (3.7)	0/21
上咽頭炎	0/45	0/29	1/29 (3.4)	0/23
上気道感染	0/45	1/29 (3.4)	0/28	0/23
傷害、中毒および処置合併症	1/45 (2.2)	3/28 (10.7)	1/25 (4.0)	0/19
節足動物刺傷	0/45	1/29 (3.4)	0/28	0/23
転倒	0/45	2/29 (6.9)	1/27 (3.7)	0/21
股関節部骨折	0/45	1/29 (3.4)	0/28	0/23

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
Low Dose				
一般・全身障害および投与部位の状態(Cont.)				
注射部位内出血	0/10	0/1	0/0	1/45 (2.2)
注射部位紅斑	0/10	0/1	0/0	1/45 (2.2)
穿刺部位紅斑	0/10	0/1	0/0	1/45 (2.2)
感染症および寄生虫症	0/7	0/1	0/0	11/45 (24.4)
膀胱炎	0/10	0/1	0/0	1/45 (2.2)
胃腸炎	0/10	0/1	0/0	1/45 (2.2)
ヘリコバクター性胃炎	0/10	0/1	0/0	1/45 (2.2)
ヘリコバクター感染	0/9	0/1	0/0	1/45 (2.2)
注入部位膿瘍	0/9	0/1	0/0	1/45 (2.2)
注入部位蜂巣炎	0/10	0/1	0/0	4/45 (8.9)
注入部位感染	0/9	0/1	0/0	3/45 (6.7)
上咽頭炎	0/9	0/1	0/0	1/45 (2.2)
上気道感染	0/10	0/1	0/0	1/45 (2.2)
傷害、中毒および処置合併症	0/8	0/1	0/0	5/45 (11.1)
節足動物刺傷	0/9	0/1	0/0	1/45 (2.2)
転倒	0/9	0/1	0/0	3/45 (6.7)
股関節部骨折	0/10	0/1	0/0	1/45 (2.2)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
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N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
Low Dose				
傷害、中毒および処置合併症(Cont.)				
肉離れ	1/45 (2.2)	0/28	0/28	0/23
臨床検査	2/45 (4.4)	0/28	2/28 (7.1)	0/22
血中ホモシステイン増加	2/45 (4.4)	0/28	0/28	0/23
リンパ球数減少	0/45	0/29	1/29 (3.4)	0/24
ビタミンB12減少	0/45	1/29 (3.4)	0/28	0/23
ビタミンB6減少	0/45	0/29	2/29 (6.9)	0/22
代謝および栄養障害	0/45	1/29 (3.4)	1/28 (3.6)	0/22
鉄欠乏	0/45	1/29 (3.4)	0/28	0/23
ビタミンB12欠乏	0/45	0/29	1/29 (3.4)	0/23
筋骨格系および結合組織障害	1/45 (2.2)	0/29	0/29	1/24 (4.2)
変形性関節症	0/45	0/29	0/29	1/24 (4.2)
骨粗鬆症	0/45	0/29	0/29	1/24 (4.2)
四肢痛	0/45	0/29	0/29	1/24 (4.2)
腱鞘炎	1/45 (2.2)	0/29	0/29	0/24
神経系障害	2/45 (4.4)	1/28 (3.6)	1/27 (3.7)	0/21
健忘	1/45 (2.2)	0/29	0/29	0/24
認知障害	1/45 (2.2)	0/28	0/28	0/23

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
Low Dose				
傷害、中毒および処置合併症(Cont.)				
肉離れ	0/10	0/1	0/0	1/45 (2.2)
臨床検査	0/10	0/1	0/0	4/45 (8.9)
血中ホモシステイン増加	0/10	0/1	0/0	2/45 (4.4)
リンパ球数減少	0/10	0/1	0/0	1/45 (2.2)
ビタミンB12減少	0/10	0/1	0/0	1/45 (2.2)
ビタミンB6減少	0/10	0/1	0/0	2/45 (4.4)
代謝および栄養障害	0/8	0/1	0/0	2/45 (4.4)
鉄欠乏	0/9	0/1	0/0	1/45 (2.2)
ビタミンB12欠乏	0/9	0/1	0/0	1/45 (2.2)
筋骨格系および結合組織障害	0/10	0/1	0/0	2/45 (4.4)
変形性関節症	0/10	0/1	0/0	1/45 (2.2)
骨粗鬆症	0/10	0/1	0/0	1/45 (2.2)
四肢痛	0/10	0/1	0/0	1/45 (2.2)
腱鞘炎	0/10	0/1	0/0	1/45 (2.2)
神経系障害	0/10	0/1	0/0	4/45 (8.9)
健忘	0/10	0/1	0/0	1/45 (2.2)
認知障害	0/10	0/1	0/0	1/45 (2.2)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
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Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
Low Dose				
神経系障害 (Cont.)				
すくみ現象	0/45	1/29 (3.4)	0/28	0/23
頭蓋内出血	0/45	0/29	1/29 (3.4)	0/23
反射減弱	1/45 (2.2)	0/29	0/29	0/24
オンオフ現象	0/45	0/29	1/29 (3.4)	0/23
パーキンソン病	0/45	1/29 (3.4)	0/28	0/23
振戦	0/45	1/29 (3.4)	0/28	0/23
精神障害	4/45 (8.9)	3/25 (12.0)	1/22 (4.5)	0/16
不安	0/45	1/29 (3.4)	0/28	0/23
歯ぎしり	1/45 (2.2)	0/28	0/28	0/23
抑うつ気分	0/45	0/29	1/29 (3.4)	0/23
うつ病	1/45 (2.2)	1/28 (3.6)	0/27	0/22
幻覚	1/45 (2.2)	1/28 (3.6)	0/27	0/22
幻視	0/45	1/29 (3.4)	0/28	0/23
錯覚	0/45	0/29	1/29 (3.4)	0/23
衝動行為	0/45	1/29 (3.4)	0/28	0/23
妄想症	0/45	0/29	1/29 (3.4)	0/23
精神病性障害	0/45	1/29 (3.4)	0/28	0/23
レム睡眠行動障害	1/45 (2.2)	0/28	0/28	0/23

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
Low Dose				
神経系障害 (Cont.)				
すくみ現象	0/10	0/1	0/0	1/45 (2.2)
頭蓋内出血	0/10	0/1	0/0	1/45 (2.2)
反射減弱	0/10	0/1	0/0	1/45 (2.2)
オンオフ現象	0/10	0/1	0/0	1/45 (2.2)
パーキンソン病	0/10	0/1	0/0	1/45 (2.2)
振戦	0/10	0/1	0/0	1/45 (2.2)
精神障害	0/8	0/1	0/0	8/45 (17.8)
不安	0/9	0/1	0/0	1/45 (2.2)
歯ぎしり	0/9	0/1	0/0	1/45 (2.2)
抑うつ気分	0/10	0/1	0/0	1/45 (2.2)
うつ病	0/10	0/1	0/0	2/45 (4.4)
幻覚	0/9	0/1	0/0	2/45 (4.4)
幻視	0/10	0/1	0/0	1/45 (2.2)
錯覚	0/10	0/1	0/0	1/45 (2.2)
衝動行為	0/10	0/1	0/0	1/45 (2.2)
妄想症	0/10	0/1	0/0	1/45 (2.2)
精神病性障害	0/10	0/1	0/0	1/45 (2.2)
レム睡眠行動障害	0/10	0/1	0/0	1/45 (2.2)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
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Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
Low Dose				
腎および尿路障害	1/45 (2.2)	0/28	0/28	0/23
膀胱痙縮	1/45 (2.2)	0/28	0/28	0/23
生殖系および乳房障害	2/45 (4.4)	0/27	0/27	0/22
良性前立腺肥大症	1/45 (2.2)	0/28	0/28	0/23
外陰膣乾燥	1/45 (2.2)	0/28	0/28	0/23
呼吸器、胸郭および縦隔障害	0/45	0/29	1/29 (3.4)	1/23 (4.3)
窒息	0/45	0/29	1/29 (3.4)	0/23
誤嚥	0/45	0/29	1/29 (3.4)	0/23
呼吸困難	0/45	0/29	0/29	1/24 (4.2)
皮膚および皮下組織障害	0/45	2/29 (6.9)	1/27 (3.7)	1/21 (4.8)
光線角化症	0/45	0/29	1/29 (3.4)	0/23
脱毛症	0/45	1/29 (3.4)	0/28	0/23
湿疹	0/45	1/29 (3.4)	0/28	0/23
発疹	0/45	1/29 (3.4)	0/28	0/23
蕁麻疹	0/45	0/29	0/29	1/24 (4.2)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
Low Dose				
腎および尿路障害	0/10	0/1	0/0	1/45 (2.2)
膀胱痙縮	0/10	0/1	0/0	1/45 (2.2)
生殖系および乳房障害	0/10	0/1	0/0	2/45 (4.4)
良性前立腺肥大症	0/10	0/1	0/0	1/45 (2.2)
外陰腟乾燥	0/10	0/1	0/0	1/45 (2.2)
呼吸器、胸郭および縦隔障害	0/9	0/1	0/0	2/45 (4.4)
窒息	0/10	0/1	0/0	1/45 (2.2)
誤嚥	0/10	0/1	0/0	1/45 (2.2)
呼吸困難	0/9	0/1	0/0	1/45 (2.2)
皮膚および皮下組織障害	0/8	0/1	0/0	4/45 (8.9)
光線角化症	0/9	0/1	0/0	1/45 (2.2)
脱毛症	0/10	0/1	0/0	1/45 (2.2)
湿疹	0/10	0/1	0/0	1/45 (2.2)
発疹	0/10	0/1	0/0	1/45 (2.2)
蕁麻疹	0/9	0/1	0/0	1/45 (2.2)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
Low Dose				
血管障害	0/45	1/29 (3.4)	0/28	0/23
血腫	0/45	1/29 (3.4)	0/28	0/23

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
Low Dose				
血管障害	0/10	0/1	0/0	1/45 (2.2)
血腫	0/10	0/1	0/0	1/45 (2.2)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
High Dose				
Any adverse event	27/60 (45.0)	7/21 (33.3)	5/14 (35.7)	0/9
心臓障害	0/60	0/46	1/44 (2.3)	0/37
左脚ブロック	0/60	0/46	1/44 (2.3)	0/37
耳および迷路障害	0/60	1/46 (2.2)	0/43	0/37
回転性めまい	0/60	1/46 (2.2)	0/43	0/37
眼障害	0/60	2/46 (4.3)	0/42	0/36
眼瞼痙攣	0/60	1/46 (2.2)	0/43	0/37
眼充血	0/60	1/46 (2.2)	0/43	0/37
胃腸障害	3/60 (5.0)	0/43	1/41 (2.4)	0/36
腹部不快感	0/60	0/46	1/44 (2.3)	0/37
腹部膨満	1/60 (1.7)	0/45	0/43	0/38
腹痛	0/60	1/46 (2.2)	0/43	0/38
便秘	2/60 (3.3)	0/44	0/42	0/37
出血性腸憩室	1/60 (1.7)	0/45	0/43	0/38
流涎過多	0/60	0/46	1/44 (2.3)	0/37

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
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n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
High Dose				
Any adverse event	1/4 (25.0)	1/1 (100)	0/0	41/60 (68.3)
心臓障害	0/16	0/3	0/0	1/60 (1.7)
左脚ブロック	0/16	0/3	0/0	1/60 (1.7)
耳および迷路障害	0/16	0/3	0/0	1/60 (1.7)
回転性めまい	0/16	0/3	0/0	1/60 (1.7)
眼障害	0/14	0/3	0/0	2/60 (3.3)
眼瞼痙攣	0/15	0/3	0/0	1/60 (1.7)
眼充血	0/15	0/3	0/0	1/60 (1.7)
胃腸障害	0/16	0/3	0/0	4/60 (6.7)
腹部不快感	0/16	0/3	0/0	1/60 (1.7)
腹部膨満	0/16	0/3	0/0	1/60 (1.7)
腹痛	0/16	0/3	0/0	1/60 (1.7)
便秘	0/16	0/3	0/0	2/60 (3.3)
出血性腸憩室	0/16	0/3	0/0	1/60 (1.7)
流涎過多	0/16	0/3	0/0	1/60 (1.7)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
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Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
High Dose				
一般・全身障害および投与部位の状態	12/60 (20.0)	4/35 (11.4)	0/31	1/27 (3.7)
注入部位内出血	1/60 (1.7)	1/45 (2.2)	0/42	0/37
注入部位紅斑	5/60 (8.3)	2/41 (4.9)	0/38	0/33
注入部位血管外漏出	0/60	1/46 (2.2)	0/43	0/37
注入部位血腫	1/60 (1.7)	0/46	0/44	0/38
注入部位出血	0/60	1/46 (2.2)	0/43	0/38
注入部位硬結	0/60	1/46 (2.2)	0/43	1/37 (2.7)
注入部位炎症	0/60	1/46 (2.2)	0/43	0/37
注入部位結節	2/60 (3.3)	0/44	0/42	0/37
注入部位浮腫	1/60 (1.7)	0/45	0/44	0/38
注入部位疼痛	0/60	0/46	0/44	0/38
注入部位丘疹	3/60 (5.0)	0/43	0/42	0/37
注入部位異常感覚	1/60 (1.7)	0/45	0/43	0/38
注入部位発疹	1/60 (1.7)	0/45	0/44	0/38
注入部位反応	0/60	1/46 (2.2)	0/43	0/37
注入部位腫脹	1/60 (1.7)	0/45	0/43	0/38
注射部位紅斑	1/60 (1.7)	0/45	0/43	0/37
注射部位硬結	1/60 (1.7)	0/45	0/43	0/37
注射部位炎症	1/60 (1.7)	0/45	0/43	0/37
注射部位浮腫	1/60 (1.7)	0/45	0/44	0/38
末梢性浮腫	1/60 (1.7)	0/45	0/43	0/37

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n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
High Dose				
一般・全身障害および投与部位の状態	1/14 (7.1)	0/3	0/0	18/60 (30.0)
注入部位内出血	0/16	0/3	0/0	2/60 (3.3)
注入部位紅斑	0/16	0/3	0/0	7/60 (11.7)
注入部位血管外漏出	1/16 (6.3)	0/3	0/0	2/60 (3.3)
注入部位血腫	0/16	0/3	0/0	1/60 (1.7)
注入部位出血	0/16	0/3	0/0	1/60 (1.7)
注入部位硬結	0/15	0/3	0/0	2/60 (3.3)
注入部位炎症	0/16	0/3	0/0	1/60 (1.7)
注入部位結節	0/16	0/3	0/0	2/60 (3.3)
注入部位浮腫	0/16	0/3	0/0	1/60 (1.7)
注入部位疼痛	1/16 (6.3)	0/3	0/0	1/60 (1.7)
注入部位丘疹	0/16	0/3	0/0	3/60 (5.0)
注入部位異常感覚	0/16	0/3	0/0	1/60 (1.7)
注入部位発疹	0/16	0/3	0/0	1/60 (1.7)
注入部位反応	0/16	0/3	0/0	1/60 (1.7)
注入部位腫脹	0/16	0/3	0/0	1/60 (1.7)
注射部位紅斑	0/15	0/3	0/0	1/60 (1.7)
注射部位硬結	0/15	0/3	0/0	1/60 (1.7)
注射部位炎症	0/16	0/3	0/0	1/60 (1.7)
注射部位浮腫	0/16	0/3	0/0	1/60 (1.7)
末梢性浮腫	0/16	0/3	0/0	1/60 (1.7)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
High Dose				
感染症および寄生虫症	5/60 (8.3)	3/41 (7.3)	2/36 (5.6)	0/32
COVID-19	0/60	0/46	0/44	0/38
大腸菌性尿路感染	0/60	1/46 (2.2)	0/43	0/37
胃腸炎	0/60	0/46	1/44 (2.3)	0/37
帯状疱疹	0/60	1/46 (2.2)	0/43	0/37
注入部位蜂巣炎	4/60 (6.7)	0/42	3/40 (7.5)	0/35
注入部位感染	0/60	1/46 (2.2)	0/43	0/38
注射部位感染	0/60	0/46	1/44 (2.3)	0/37
尿路感染	1/60 (1.7)	1/45 (2.2)	0/42	0/36
傷害、中毒および処置合併症	5/60 (8.3)	4/41 (9.8)	2/35 (5.7)	0/28
顔面骨骨折	1/60 (1.7)	0/45	0/43	0/38
転倒	5/60 (8.3)	2/41 (4.9)	2/37 (5.4)	0/30
転位骨折	0/60	1/46 (2.2)	0/43	0/37
手骨折	0/60	1/46 (2.2)	1/43 (2.3)	0/36
股関節部骨折	1/60 (1.7)	0/45	0/43	0/38
上腕骨骨折	1/60 (1.7)	0/45	0/43	0/38
四肢損傷	0/60	1/46 (2.2)	0/43	0/37
処置による疼痛	0/60	1/46 (2.2)	0/43	0/37
肩甲骨骨折	1/60 (1.7)	0/45	0/43	0/37

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
High Dose				
感染症および寄生虫症	2/13 (15.4)	0/2	0/0	12/60 (20.0)
COVID-19	1/16 (6.3)	0/2	0/0	1/60 (1.7)
大腸菌性尿路感染	0/16	0/3	0/0	1/60 (1.7)
胃腸炎	0/15	0/3	0/0	1/60 (1.7)
帯状疱疹	0/16	0/3	0/0	1/60 (1.7)
注入部位蜂巣炎	1/14 (7.1)	0/3	0/0	8/60 (13.3)
注入部位感染	0/16	0/3	0/0	1/60 (1.7)
注射部位感染	0/16	0/3	0/0	1/60 (1.7)
尿路感染	0/15	0/3	0/0	2/60 (3.3)
傷害、中毒および処置合併症	0/12	0/3	0/0	11/60 (18.3)
顔面骨骨折	0/16	0/3	0/0	1/60 (1.7)
転倒	0/13	0/3	0/0	9/60 (15.0)
転位骨折	0/16	0/3	0/0	1/60 (1.7)
手骨折	0/14	0/3	0/0	2/60 (3.3)
股関節部骨折	0/16	0/3	0/0	1/60 (1.7)
上腕骨骨折	0/16	0/3	0/0	1/60 (1.7)
四肢損傷	0/16	0/3	0/0	1/60 (1.7)
処置による疼痛	0/15	0/3	0/0	1/60 (1.7)
肩甲骨骨折	0/15	0/3	0/0	1/60 (1.7)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
High Dose				
臨床検査	2/60 (3.3)	1/44 (2.3)	1/41 (2.4)	0/35
血中葉酸減少	1/60 (1.7)	0/45	0/43	0/37
プロトロンビン時間延長	1/60 (1.7)	0/45	0/43	0/37
体重減少	1/60 (1.7)	1/45 (2.2)	1/42 (2.4)	0/36
代謝および栄養障害	1/60 (1.7)	1/45 (2.2)	2/42 (4.8)	0/35
鉄欠乏	0/60	1/46 (2.2)	0/43	0/38
ビタミンB12欠乏	1/60 (1.7)	0/45	2/43 (4.7)	0/35
筋骨格系および結合組織障害	1/60 (1.7)	3/45 (6.7)	2/40 (5.0)	0/32
背部痛	0/60	1/46 (2.2)	1/43 (2.3)	0/36
滑液包炎	1/60 (1.7)	0/45	0/43	0/37
出血性関節症	0/60	1/46 (2.2)	0/43	0/37
椎間板変性症	0/60	0/46	1/44 (2.3)	0/37
筋力低下	0/60	1/46 (2.2)	0/43	0/37
筋骨格硬直	0/60	1/46 (2.2)	0/43	0/37
骨粗鬆症	1/60 (1.7)	0/45	0/43	0/37
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）	0/60	0/46	1/44 (2.3)	0/37
ケラトアカントーマ	0/60	0/46	1/44 (2.3)	0/37

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
High Dose				
臨床検査	0/15	0/3	0/0	4/60 (6.7)
血中葉酸減少	0/16	0/3	0/0	1/60 (1.7)
プロトロンビン時間延長	0/16	0/3	0/0	1/60 (1.7)
体重減少	0/15	0/3	0/0	3/60 (5.0)
代謝および栄養障害	0/13	0/3	0/0	4/60 (6.7)
鉄欠乏	0/16	0/3	0/0	1/60 (1.7)
ビタミンB12欠乏	0/13	0/3	0/0	3/60 (5.0)
筋骨格系および結合組織障害	0/14	0/3	0/0	6/60 (10.0)
背部痛	0/15	0/3	0/0	2/60 (3.3)
滑液包炎	0/16	0/3	0/0	1/60 (1.7)
出血性関節症	0/16	0/3	0/0	1/60 (1.7)
椎間板変性症	0/15	0/3	0/0	1/60 (1.7)
筋力低下	0/16	0/3	0/0	1/60 (1.7)
筋骨格硬直	0/16	0/3	0/0	1/60 (1.7)
骨粗鬆症	0/16	0/3	0/0	1/60 (1.7)
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）	0/16	0/3	0/0	1/60 (1.7)
ケラトアカントーマ	0/16	0/3	0/0	1/60 (1.7)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
High Dose				
神経系障害	8/60 (13.3)	3/40 (7.5)	3/35 (8.6)	0/29
平衡障害	1/60 (1.7)	0/45	0/43	0/37
認知障害	1/60 (1.7)	0/45	0/43	0/37
注意力障害	1/60 (1.7)	0/45	0/43	0/38
ジストニア	1/60 (1.7)	0/45	0/43	0/37
すくみ現象	0/60	1/46 (2.2)	0/43	0/37
頭部不快感	1/60 (1.7)	0/46	0/44	0/38
感覚鈍麻	0/60	0/46	1/44 (2.3)	0/37
反射減弱	0/60	1/46 (2.2)	0/43	0/37
記憶障害	1/60 (1.7)	0/45	0/43	0/38
オンオフ現象	2/60 (3.3)	2/45 (4.4)	0/41	0/35
パーキンソン病	0/60	2/46 (4.3)	1/42 (2.4)	0/37
精神運動亢進	0/60	0/46	1/44 (2.3)	0/37
失神	1/60 (1.7)	1/45 (2.2)	0/42	0/36
一過性脳虚血発作	1/60 (1.7)	0/45	0/43	0/37
精神障害	5/60 (8.3)	2/41 (4.9)	4/37 (10.8)	0/29
攻撃性	1/60 (1.7)	0/45	0/43	0/38
激越	1/60 (1.7)	0/45	0/43	0/37
不安	1/60 (1.7)	0/45	1/43 (2.3)	0/36
錯乱状態	0/60	0/46	1/44 (2.3)	0/37
妄想	0/60	0/46	1/44 (2.3)	0/37
うつ病	1/60 (1.7)	0/45	0/43	0/38
自傷性皮膚症	0/60	1/46 (2.2)	0/43	0/37

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
High Dose				
神経系障害	0/13	1/3 (33.3)	0/0	15/60 (25.0)
平衡障害	0/16	0/3	0/0	1/60 (1.7)
認知障害	0/16	0/3	0/0	1/60 (1.7)
注意力障害	0/16	0/3	0/0	1/60 (1.7)
ジストニア	0/16	0/3	0/0	1/60 (1.7)
すくみ現象	0/16	0/3	0/0	1/60 (1.7)
頭部不快感	0/16	0/3	0/0	1/60 (1.7)
感覚鈍麻	0/15	0/3	0/0	1/60 (1.7)
反射減弱	0/16	0/3	0/0	1/60 (1.7)
記憶障害	0/16	1/3 (33.3)	0/0	2/60 (3.3)
オンオフ現象	0/16	0/3	0/0	4/60 (6.7)
パーキンソン病	0/16	0/3	0/0	3/60 (5.0)
精神運動亢進	0/15	0/3	0/0	1/60 (1.7)
失神	0/15	0/3	0/0	2/60 (3.3)
一過性脳虚血発作	0/16	0/3	0/0	1/60 (1.7)
精神障害	0/13	0/2	0/0	11/60 (18.3)
攻撃性	0/16	0/3	0/0	1/60 (1.7)
激越	0/16	0/3	0/0	1/60 (1.7)
不安	0/15	0/2	0/0	2/60 (3.3)
錯乱状態	0/16	0/3	0/0	1/60 (1.7)
妄想	0/15	0/3	0/0	1/60 (1.7)
うつ病	0/16	0/3	0/0	1/60 (1.7)
自傷性皮膚症	0/16	0/3	0/0	1/60 (1.7)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
High Dose				
精神障害 (Cont.)				
幻覚	2/60 (3.3)	1/44 (2.3)	2/41 (4.9)	0/33
衝動制御障害	0/60	1/46 (2.2)	0/43	0/38
パニック発作	0/60	1/46 (2.2)	0/43	0/37
精神病性障害	0/60	1/46 (2.2)	0/43	0/37
腎および尿路障害	0/60	1/46 (2.2)	0/43	0/37
血尿	0/60	1/46 (2.2)	0/43	0/37
生殖系および乳房障害	1/60 (1.7)	0/45	0/43	0/37
勃起不全	1/60 (1.7)	0/45	0/43	0/37
呼吸器、胸郭および縦隔障害	0/60	0/46	0/44	0/38
痰貯留	0/60	0/46	0/44	0/38
皮膚および皮下組織障害	0/60	0/46	0/44	1/38 (2.6)
湿疹	0/60	0/46	0/44	1/38 (2.6)
血管障害	2/60 (3.3)	3/44 (6.8)	1/39 (2.6)	0/32
高血圧	0/60	1/46 (2.2)	0/43	0/37
低血圧	1/60 (1.7)	0/45	0/43	0/37

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
High Dose				
精神障害 (Cont.)				
幻覚	0/14	0/2	0/0	5/60 (8.3)
衝動制御障害	0/16	0/3	0/0	1/60 (1.7)
パニック発作	0/16	0/3	0/0	1/60 (1.7)
精神病性障害	0/16	0/3	0/0	1/60 (1.7)
腎および尿路障害	0/16	0/3	0/0	1/60 (1.7)
血尿	0/16	0/3	0/0	1/60 (1.7)
生殖系および乳房障害	0/16	0/3	0/0	1/60 (1.7)
勃起不全	0/16	0/3	0/0	1/60 (1.7)
呼吸器、胸郭および縦隔障害	1/16 (6.3)	0/3	0/0	1/60 (1.7)
痰貯留	1/16 (6.3)	0/3	0/0	1/60 (1.7)
皮膚および皮下組織障害	0/15	0/3	0/0	1/60 (1.7)
湿疹	0/15	0/3	0/0	1/60 (1.7)
血管障害	0/14	0/2	0/0	6/60 (10.0)
高血圧	0/16	0/3	0/0	1/60 (1.7)
低血圧	0/16	0/3	0/0	1/60 (1.7)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
High Dose				
血管障害 (Cont.)				
起立性高血圧	1/60 (1.7)	0/45	0/43	0/37
起立性低血圧	0/60	2/46 (4.3)	0/42	0/36
表在性血栓性静脈炎	0/60	0/46	1/44 (2.3)	0/37

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
High Dose				
血管障害 (Cont.)				
起立性高血圧	0/16	0/3	0/0	1/60 (1.7)
起立性低血圧	0/15	0/3	0/0	2/60 (3.3)
表在性血栓性静脈炎	0/15	0/2	0/0	1/60 (1.7)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

表40　有害事象の90日間ごとの有病割合の推移（安全性解析対象集団）：M15-737試験

[redacted]20[redacted] 04:22 <[redacted]>
ABBV-951
STUDY M15-737 - FIRST INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.3 1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N_eval (%)	 Days 91 to 180 (N=75) n/N_eval (%)	 Days 181 to 270 (N=73) n/N_eval (%)	 Days 271 to 360 (N=62) n/N_eval (%)
Total (Any Dose)				
Any adverse event	43/105 (41.0)	44/75 (58.7)	48/73 (65.8)	37/62 (59.7)
心臓障害	0/105	0/75	1/73 (1.4)	1/62 (1.6)
左脚ブロック	0/105	0/75	1/73 (1.4)	1/62 (1.6)
耳および迷路障害	0/105	1/75 (1.3)	0/73	0/62
回転性めまい	0/105	1/75 (1.3)	0/73	0/62
眼障害	0/105	2/75 (2.7)	1/73 (1.4)	2/62 (3.2)
眼瞼痙攣	0/105	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
眼充血	0/105	1/75 (1.3)	0/73	0/62
硝子体浮遊物	0/105	0/75	0/73	1/62 (1.6)
胃腸障害	7/105 (6.7)	6/75 (8.0)	6/73 (8.2)	5/62 (8.1)
腹部不快感	0/105	0/75	1/73 (1.4)	0/62
腹部膨満	1/105 (1.0)	1/75 (1.3)	1/73 (1.4)	0/62
腹痛	0/105	1/75 (1.3)	1/73 (1.4)	0/62
便秘	4/105 (3.8)	3/75 (4.0)	3/73 (4.1)	3/62 (4.8)
出血性腸憩室	1/105 (1.0)	1/75 (1.3)	0/73	0/62
嚥下障害	1/105 (1.0)	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
胃潰瘍	0/105	0/75	0/73	1/62 (1.6)
胃食道逆流性疾患	1/105 (1.0)	1/75 (1.3)	1/73 (1.4)	0/62

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
Total (Any Dose)				
Any adverse event	17/26 (65.4)	3/4 (75.0)	0/0	66/105 (62.9)
心臓障害	0/26	0/4	0/0	1/105 (1.0)
左脚ブロック	0/26	0/4	0/0	1/105 (1.0)
耳および迷路障害	0/26	0/4	0/0	1/105 (1.0)
回転性めまい	0/26	0/4	0/0	1/105 (1.0)
眼障害	1/26 (3.8)	0/4	0/0	3/105 (2.9)
眼瞼痙攣	1/26 (3.8)	0/4	0/0	1/105 (1.0)
眼充血	0/26	0/4	0/0	1/105 (1.0)
硝子体浮遊物	0/26	0/4	0/0	1/105 (1.0)
胃腸障害	1/26 (3.8)	0/4	0/0	9/105 (8.6)
腹部不快感	0/26	0/4	0/0	1/105 (1.0)
腹部膨満	0/26	0/4	0/0	1/105 (1.0)
腹痛	0/26	0/4	0/0	1/105 (1.0)
便秘	0/26	0/4	0/0	5/105 (4.8)
出血性腸憩室	0/26	0/4	0/0	1/105 (1.0)
嚥下障害	0/26	0/4	0/0	1/105 (1.0)
胃潰瘍	1/26 (3.8)	0/4	0/0	1/105 (1.0)
胃食道逆流性疾患	0/26	0/4	0/0	1/105 (1.0)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
Total (Any Dose)				
胃腸障害 (Cont.)				
流涎過多	0/105	0/75	1/73 (1.4)	1/62 (1.6)
一般・全身障害および投与部位の状態	18/105 (17.1)	22/75 (29.3)	19/73 (26.0)	14/62 (22.6)
投与部位漏出	0/105	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
薬効欠如	1/105 (1.0)	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
注入部位内出血	2/105 (1.9)	2/75 (2.7)	3/73 (4.1)	2/62 (3.2)
注入部位皮膚炎	0/105	1/75 (1.3)	1/73 (1.4)	0/62
注入部位紅斑	6/105 (5.7)	8/75 (10.7)	9/73 (12.3)	6/62 (9.7)
注入部位血管外漏出	0/105	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
注入部位血腫	1/105 (1.0)	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
注入部位出血	0/105	1/75 (1.3)	1/73 (1.4)	0/62
注入部位硬結	0/105	1/75 (1.3)	1/73 (1.4)	2/62 (3.2)
注入部位炎症	0/105	1/75 (1.3)	0/73	0/62
注入部位刺激感	0/105	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
注入部位腫瘤	0/105	0/75	1/73 (1.4)	0/62
注入部位結節	2/105 (1.9)	2/75 (2.7)	2/73 (2.7)	1/62 (1.6)
注入部位浮腫	2/105 (1.9)	0/75	1/73 (1.4)	1/62 (1.6)
注入部位疼痛	1/105 (1.0)	0/75	0/73	0/62
注入部位丘疹	4/105 (3.8)	2/75 (2.7)	1/73 (1.4)	1/62 (1.6)
注入部位異常感覚	1/105 (1.0)	0/75	0/73	0/62
注入部位発疹	1/105 (1.0)	1/75 (1.3)	0/73	0/62
注入部位反応	0/105	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
Total (Any Dose)				
胃腸障害 (Cont.)				
流涎過多	0/26	0/4	0/0	1/105 (1.0)
一般・全身障害および投与部位の状態	4/26 (15.4)	0/4	0/0	29/105 (27.6)
投与部位漏出	1/26 (3.8)	0/4	0/0	1/105 (1.0)
薬効欠如	0/26	0/4	0/0	1/105 (1.0)
注入部位内出血	1/26 (3.8)	0/4	0/0	4/105 (3.8)
注入部位皮膚炎	0/26	0/4	0/0	1/105 (1.0)
注入部位紅斑	2/26 (7.7)	0/4	0/0	13/105 (12.4)
注入部位血管外漏出	1/26 (3.8)	0/4	0/0	2/105 (1.9)
注入部位血腫	0/26	0/4	0/0	2/105 (1.9)
注入部位出血	0/26	0/4	0/0	1/105 (1.0)
注入部位硬結	0/26	0/4	0/0	2/105 (1.9)
注入部位炎症	0/26	0/4	0/0	1/105 (1.0)
注入部位刺激感	0/26	0/4	0/0	1/105 (1.0)
注入部位腫瘤	0/26	0/4	0/0	1/105 (1.0)
注入部位結節	0/26	0/4	0/0	2/105 (1.9)
注入部位浮腫	0/26	0/4	0/0	2/105 (1.9)
注入部位疼痛	1/26 (3.8)	0/4	0/0	2/105 (1.9)
注入部位丘疹	0/26	0/4	0/0	4/105 (3.8)
注入部位異常感覚	0/26	0/4	0/0	1/105 (1.0)
注入部位発疹	0/26	0/4	0/0	1/105 (1.0)
注入部位反応	0/26	0/4	0/0	1/105 (1.0)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態(Cont.)				
注入部位腫脹	1/105 (1.0)	0/75	0/73	0/62
注射部位内出血	0/105	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
注射部位紅斑	2/105 (1.9)	2/75 (2.7)	1/73 (1.4)	0/62
注射部位硬結	1/105 (1.0)	1/75 (1.3)	1/73 (1.4)	0/62
注射部位炎症	1/105 (1.0)	0/75	0/73	0/62
注射部位浮腫	1/105 (1.0)	0/75	0/73	0/62
末梢性浮腫	1/105 (1.0)	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
穿刺部位紅斑	0/105	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
感染症および寄生虫症	9/105 (8.6)	10/75 (13.3)	13/73 (17.8)	9/62 (14.5)
COVID-19	0/105	0/75	0/73	0/62
膀胱炎	1/105 (1.0)	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
大腸菌性尿路感染	0/105	1/75 (1.3)	1/73 (1.4)	0/62
胃腸炎	1/105 (1.0)	0/75	2/73 (2.7)	0/62
ヘリコバクター性胃炎	1/105 (1.0)	1/75 (1.3)	1/73 (1.4)	0/62
ヘリコバクター感染	0/105	0/75	0/73	1/62 (1.6)
帯状疱疹	0/105	1/75 (1.3)	1/73 (1.4)	0/62
注入部位膿瘍	0/105	0/75	1/73 (1.4)	1/62 (1.6)
注入部位蜂巣炎	6/105 (5.7)	1/75 (1.3)	4/73 (5.5)	4/62 (6.5)
注入部位感染	0/105	3/75 (4.0)	2/73 (2.7)	2/62 (3.2)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態(Cont.)				
注入部位腫脹	0/26	0/4	0/0	1/105 (1.0)
注射部位内出血	0/26	0/4	0/0	1/105 (1.0)
注射部位紅斑	0/26	0/4	0/0	2/105 (1.9)
注射部位硬結	0/26	0/4	0/0	1/105 (1.0)
注射部位炎症	0/26	0/4	0/0	1/105 (1.0)
注射部位浮腫	0/26	0/4	0/0	1/105 (1.0)
末梢性浮腫	0/26	0/4	0/0	1/105 (1.0)
穿刺部位紅斑	0/26	0/4	0/0	1/105 (1.0)
感染症および寄生虫症	4/26 (15.4)	1/4 (25.0)	0/0	23/105 (21.9)
COVID-19	1/26 (3.8)	1/4 (25.0)	0/0	1/105 (1.0)
膀胱炎	0/26	0/4	0/0	1/105 (1.0)
大腸菌性尿路感染	0/26	0/4	0/0	1/105 (1.0)
胃腸炎	0/26	0/4	0/0	2/105 (1.9)
ヘリコバクター性胃炎	0/26	0/4	0/0	1/105 (1.0)
ヘリコバクター感染	1/26 (3.8)	0/4	0/0	1/105 (1.0)
帯状疱疹	0/26	0/4	0/0	1/105 (1.0)
注入部位膿瘍	0/26	0/4	0/0	1/105 (1.0)
注入部位蜂巣炎	2/26 (7.7)	0/4	0/0	12/105 (11.4)
注入部位感染	0/26	0/4	0/0	4/105 (3.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
Total (Any Dose)				
感染症および寄生虫症 (Cont.)				
注射部位感染	0/105	0/75	1/73 (1.4)	0/62
上咽頭炎	0/105	0/75	1/73 (1.4)	0/62
上気道感染	0/105	1/75 (1.3)	0/73	0/62
尿路感染	1/105 (1.0)	2/75 (2.7)	2/73 (2.7)	2/62 (3.2)
傷害、中毒および処置合併症	6/105 (5.7)	10/75 (13.3)	8/73 (11.0)	5/62 (8.1)
節足動物刺傷	0/105	1/75 (1.3)	0/73	0/62
顔面骨骨折	1/105 (1.0)	1/75 (1.3)	0/73	0/62
転倒	5/105 (4.8)	4/75 (5.3)	3/73 (4.1)	0/62
転位骨折	0/105	1/75 (1.3)	0/73	0/62
手骨折	0/105	1/75 (1.3)	2/73 (2.7)	1/62 (1.6)
股関節部骨折	1/105 (1.0)	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
上腕骨骨折	1/105 (1.0)	1/75 (1.3)	0/73	0/62
四肢損傷	0/105	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
肉離れ	1/105 (1.0)	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
処置による疼痛	0/105	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
肩甲骨骨折	1/105 (1.0)	1/75 (1.3)	0/73	0/62
臨床検査	4/105 (3.8)	4/75 (5.3)	6/73 (8.2)	5/62 (8.1)
血中葉酸減少	1/105 (1.0)	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
血中ホモシステイン増加	2/105 (1.9)	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
リンパ球数減少	0/105	0/75	1/73 (1.4)	0/62

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
Total (Any Dose)				
感染症および寄生虫症 (Cont.)				
注射部位感染	0/26	0/4	0/0	1/105 (1.0)
上咽頭炎	0/26	0/4	0/0	1/105 (1.0)
上気道感染	0/26	0/4	0/0	1/105 (1.0)
尿路感染	1/26 (3.8)	0/4	0/0	2/105 (1.9)
傷害、中毒および処置合併症	1/26 (3.8)	0/4	0/0	16/105 (15.2)
節足動物刺傷	0/26	0/4	0/0	1/105 (1.0)
顔面骨骨折	0/26	0/4	0/0	1/105 (1.0)
転倒	0/26	0/4	0/0	12/105 (11.4)
転位骨折	0/26	0/4	0/0	1/105 (1.0)
手骨折	1/26 (3.8)	0/4	0/0	2/105 (1.9)
股関節部骨折	0/26	0/4	0/0	2/105 (1.9)
上腕骨骨折	0/26	0/4	0/0	1/105 (1.0)
四肢損傷	0/26	0/4	0/0	1/105 (1.0)
肉離れ	0/26	0/4	0/0	1/105 (1.0)
処置による疼痛	0/26	0/4	0/0	1/105 (1.0)
肩甲骨骨折	0/26	0/4	0/0	1/105 (1.0)
臨床検査	1/26 (3.8)	0/4	0/0	8/105 (7.6)
血中葉酸減少	0/26	0/4	0/0	1/105 (1.0)
血中ホモシステイン増加	0/26	0/4	0/0	2/105 (1.9)
リンパ球数減少	0/26	0/4	0/0	1/105 (1.0)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
Total (Any Dose)				
臨床検査 (Cont.)				
プロトロンビン時間延長	1/105 (1.0)	0/75	0/73	0/62
ビタミンB12減少	0/105	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
ビタミンB6減少	0/105	0/75	2/73 (2.7)	2/62 (3.2)
体重減少	1/105 (1.0)	2/75 (2.7)	2/73 (2.7)	2/62 (3.2)
代謝および栄養障害	1/105 (1.0)	3/75 (4.0)	6/73 (8.2)	5/62 (8.1)
鉄欠乏	0/105	2/75 (2.7)	2/73 (2.7)	1/62 (1.6)
ビタミンB12欠乏	1/105 (1.0)	1/75 (1.3)	4/73 (5.5)	4/62 (6.5)
筋骨格系および結合組織障害	2/105 (1.9)	4/75 (5.3)	5/73 (6.8)	6/62 (9.7)
背部痛	0/105	1/75 (1.3)	2/73 (2.7)	2/62 (3.2)
滑液包炎	1/105 (1.0)	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
出血性関節症	0/105	1/75 (1.3)	0/73	0/62
椎間板変性症	0/105	0/75	1/73 (1.4)	1/62 (1.6)
筋力低下	0/105	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
筋骨格硬直	0/105	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
変形性関節症	0/105	0/75	0/73	1/62 (1.6)
骨粗鬆症	1/105 (1.0)	1/75 (1.3)	1/73 (1.4)	2/62 (3.2)
四肢痛	0/105	0/75	0/73	1/62 (1.6)
腱鞘炎	1/105 (1.0)	0/75	0/73	0/62

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
Total (Any Dose)				
臨床検査 (Cont.)				
プロトロンビン時間延長	0/26	0/4	0/0	1/105 (1.0)
ビタミンB12減少	0/26	0/4	0/0	1/105 (1.0)
ビタミンB6減少	0/26	0/4	0/0	2/105 (1.9)
体重減少	1/26 (3.8)	0/4	0/0	3/105 (2.9)
代謝および栄養障害	5/26 (19.2)	0/4	0/0	6/105 (5.7)
鉄欠乏	1/26 (3.8)	0/4	0/0	2/105 (1.9)
ビタミンB12欠乏	4/26 (15.4)	0/4	0/0	4/105 (3.8)
筋骨格系および結合組織障害	2/26 (7.7)	0/4	0/0	8/105 (7.6)
背部痛	1/26 (3.8)	0/4	0/0	2/105 (1.9)
滑液包炎	0/26	0/4	0/0	1/105 (1.0)
出血性関節症	0/26	0/4	0/0	1/105 (1.0)
椎間板変性症	1/26 (3.8)	0/4	0/0	1/105 (1.0)
筋力低下	0/26	0/4	0/0	1/105 (1.0)
筋骨格硬直	0/26	0/4	0/0	1/105 (1.0)
変形性関節症	0/26	0/4	0/0	1/105 (1.0)
骨粗鬆症	0/26	0/4	0/0	2/105 (1.9)
四肢痛	0/26	0/4	0/0	1/105 (1.0)
腱鞘炎	0/26	0/4	0/0	1/105 (1.0)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
Total (Any Dose)				
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）	0/105	0/75	1/73 (1.4)	0/62
ケラトアカントーマ	0/105	0/75	1/73 (1.4)	0/62
神経系障害	10/105 (9.5)	10/75 (13.3)	12/73 (16.4)	9/62 (14.5)
健忘	1/105 (1.0)	0/75	0/73	0/62
平衡障害	1/105 (1.0)	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
認知障害	2/105 (1.9)	2/75 (2.7)	2/73 (2.7)	2/62 (3.2)
注意力障害	1/105 (1.0)	1/75 (1.3)	1/73 (1.4)	0/62
ジストニア	1/105 (1.0)	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
すくみ現象	0/105	2/75 (2.7)	1/73 (1.4)	1/62 (1.6)
頭蓋内出血	0/105	0/75	1/73 (1.4)	1/62 (1.6)
頭部不快感	1/105 (1.0)	0/75	0/73	0/62
感覚鈍麻	0/105	0/75	1/73 (1.4)	1/62 (1.6)
反射減弱	1/105 (1.0)	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
記憶障害	1/105 (1.0)	1/75 (1.3)	1/73 (1.4)	0/62
オンオフ現象	2/105 (1.9)	2/75 (2.7)	3/73 (4.1)	2/62 (3.2)
パーキンソン病	0/105	3/75 (4.0)	3/73 (4.1)	2/62 (3.2)
精神運動亢進	0/105	0/75	1/73 (1.4)	0/62
失神	1/105 (1.0)	2/75 (2.7)	1/73 (1.4)	1/62 (1.6)
一過性脳虚血発作	1/105 (1.0)	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
振戦	0/105	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
Total (Any Dose)				
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）	0/26	0/4	0/0	1/105 (1.0)
ケラトアカントーマ	0/26	0/4	0/0	1/105 (1.0)
神経系障害	1/26 (3.8)	1/4 (25.0)	0/0	19/105 (18.1)
健忘	0/26	0/4	0/0	1/105 (1.0)
平衡障害	0/26	0/4	0/0	1/105 (1.0)
認知障害	0/26	0/4	0/0	2/105 (1.9)
注意力障害	0/26	0/4	0/0	1/105 (1.0)
ジストニア	0/26	0/4	0/0	1/105 (1.0)
すくみ現象	0/26	0/4	0/0	2/105 (1.9)
頭蓋内出血	0/26	0/4	0/0	1/105 (1.0)
頭部不快感	0/26	0/4	0/0	1/105 (1.0)
感覚鈍麻	1/26 (3.8)	0/4	0/0	1/105 (1.0)
反射減弱	0/26	0/4	0/0	2/105 (1.9)
記憶障害	0/26	1/4 (25.0)	0/0	2/105 (1.9)
オンオフ現象	0/26	0/4	0/0	5/105 (4.8)
パーキンソン病	0/26	0/4	0/0	4/105 (3.8)
精神運動亢進	0/26	0/4	0/0	1/105 (1.0)
失神	0/26	0/4	0/0	2/105 (1.9)
一過性脳虚血発作	0/26	0/4	0/0	1/105 (1.0)
振戦	0/26	0/4	0/0	1/105 (1.0)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
Total (Any Dose)				
精神障害	9/105 (8.6)	12/75 (16.0)	15/73 (20.5)	13/62 (21.0)
攻撃性	1/105 (1.0)	1/75 (1.3)	0/73	0/62
激越	1/105 (1.0)	0/75	0/73	0/62
不安	1/105 (1.0)	1/75 (1.3)	2/73 (2.7)	2/62 (3.2)
歯ぎしり	1/105 (1.0)	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
錯乱状態	0/105	0/75	1/73 (1.4)	1/62 (1.6)
妄想	0/105	0/75	1/73 (1.4)	1/62 (1.6)
抑うつ気分	0/105	0/75	1/73 (1.4)	1/62 (1.6)
うつ病	2/105 (1.9)	3/75 (4.0)	3/73 (4.1)	2/62 (3.2)
自傷性皮膚症	0/105	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
幻覚	3/105 (2.9)	4/75 (5.3)	4/73 (5.5)	3/62 (4.8)
幻視	0/105	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
錯覚	0/105	0/75	1/73 (1.4)	1/62 (1.6)
衝動制御障害	0/105	1/75 (1.3)	1/73 (1.4)	0/62
衝動行為	0/105	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
パニック発作	0/105	1/75 (1.3)	1/73 (1.4)	0/62
妄想症	0/105	0/75	1/73 (1.4)	1/62 (1.6)
精神病性障害	0/105	2/75 (2.7)	2/73 (2.7)	1/62 (1.6)
レム睡眠行動障害	1/105 (1.0)	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
腎および尿路障害	1/105 (1.0)	2/75 (2.7)	2/73 (2.7)	2/62 (3.2)
膀胱痙縮	1/105 (1.0)	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
Total (Any Dose)				
精神障害	4/26 (15.4)	1/4 (25.0)	0/0	19/105 (18.1)
攻撃性	0/26	0/4	0/0	1/105 (1.0)
激越	0/26	0/4	0/0	1/105 (1.0)
不安	2/26 (7.7)	1/4 (25.0)	0/0	3/105 (2.9)
歯ぎしり	1/26 (3.8)	0/4	0/0	1/105 (1.0)
錯乱状態	0/26	0/4	0/0	1/105 (1.0)
妄想	1/26 (3.8)	0/4	0/0	1/105 (1.0)
抑うつ気分	0/26	0/4	0/0	1/105 (1.0)
うつ病	0/26	0/4	0/0	3/105 (2.9)
自傷性皮膚症	0/26	0/4	0/0	1/105 (1.0)
幻覚	1/26 (3.8)	0/4	0/0	7/105 (6.7)
幻視	0/26	0/4	0/0	1/105 (1.0)
錯覚	0/26	0/4	0/0	1/105 (1.0)
衝動制御障害	0/26	0/4	0/0	1/105 (1.0)
衝動行為	0/26	0/4	0/0	1/105 (1.0)
パニック発作	0/26	0/4	0/0	1/105 (1.0)
妄想症	0/26	0/4	0/0	1/105 (1.0)
精神病性障害	0/26	0/4	0/0	2/105 (1.9)
レム睡眠行動障害	0/26	0/4	0/0	1/105 (1.0)
腎および尿路障害	0/26	0/4	0/0	2/105 (1.9)
膀胱痙縮	0/26	0/4	0/0	1/105 (1.0)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
Total (Any Dose)				
腎および尿路障害 (Cont.)				
血尿	0/105	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
生殖系および乳房障害	3/105 (2.9)	3/75 (4.0)	3/73 (4.1)	3/62 (4.8)
良性前立腺肥大症	1/105 (1.0)	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
勃起不全	1/105 (1.0)	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
外陰腟乾燥	1/105 (1.0)	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
呼吸器、胸郭および縦隔障害	0/105	0/75	1/73 (1.4)	1/62 (1.6)
窒息	0/105	0/75	1/73 (1.4)	0/62
誤嚥	0/105	0/75	1/73 (1.4)	0/62
呼吸困難	0/105	0/75	0/73	1/62 (1.6)
痰貯留	0/105	0/75	0/73	0/62
皮膚および皮下組織障害	0/105	2/75 (2.7)	3/73 (4.1)	4/62 (6.5)
光線角化症	0/105	0/75	1/73 (1.4)	0/62
脱毛症	0/105	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
湿疹	0/105	1/75 (1.3)	1/73 (1.4)	2/62 (3.2)
発疹	0/105	1/75 (1.3)	0/73	0/62
蕁麻疹	0/105	0/75	0/73	1/62 (1.6)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
Total (Any Dose)				
腎および尿路障害 (Cont.)				
血尿	0/26	0/4	0/0	1/105 (1.0)
生殖系および乳房障害	0/26	0/4	0/0	3/105 (2.9)
良性前立腺肥大症	0/26	0/4	0/0	1/105 (1.0)
勃起不全	0/26	0/4	0/0	1/105 (1.0)
外陰腟乾燥	0/26	0/4	0/0	1/105 (1.0)
呼吸器、胸郭および縦隔障害	1/26 (3.8)	0/4	0/0	3/105 (2.9)
窒息	0/26	0/4	0/0	1/105 (1.0)
誤嚥	0/26	0/4	0/0	1/105 (1.0)
呼吸困難	0/26	0/4	0/0	1/105 (1.0)
痰貯留	1/26 (3.8)	0/4	0/0	1/105 (1.0)
皮膚および皮下組織障害	1/26 (3.8)	0/4	0/0	5/105 (4.8)
光線角化症	0/26	0/4	0/0	1/105 (1.0)
脱毛症	0/26	0/4	0/0	1/105 (1.0)
湿疹	1/26 (3.8)	0/4	0/0	2/105 (1.9)
発疹	0/26	0/4	0/0	1/105 (1.0)
蕁麻疹	0/26	0/4	0/0	1/105 (1.0)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
Total (Any Dose)				
血管障害	2/105 (1.9)	6/75 (8.0)	6/73 (8.2)	6/62 (9.7)
血腫	0/105	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
高血圧	0/105	1/75 (1.3)	0/73	0/62
低血圧	1/105 (1.0)	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
起立性高血圧	1/105 (1.0)	1/75 (1.3)	1/73 (1.4)	1/62 (1.6)
起立性低血圧	0/105	2/75 (2.7)	2/73 (2.7)	2/62 (3.2)
表在性血栓性静脈炎	0/105	0/75	1/73 (1.4)	1/62 (1.6)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
Total (Any Dose)				
血管障害	2/26 (7.7)	1/4 (25.0)	0/0	7/105 (6.7)
血腫	0/26	0/4	0/0	1/105 (1.0)
高血圧	0/26	0/4	0/0	1/105 (1.0)
低血圧	0/26	0/4	0/0	1/105 (1.0)
起立性高血圧	0/26	0/4	0/0	1/105 (1.0)
起立性低血圧	1/26 (3.8)	0/4	0/0	2/105 (1.9)
表在性血栓性静脈炎	1/26 (3.8)	1/4 (25.0)	0/0	1/105 (1.0)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
Low Dose				
Any adverse event	16/45 (35.6)	16/29 (55.2)	20/29 (69.0)	15/24 (62.5)
眼障害	0/45	0/29	0/29	1/24 (4.2)
硝子体浮遊物	0/45	0/29	0/29	1/24 (4.2)
胃腸障害	4/45 (8.9)	3/29 (10.3)	3/29 (10.3)	3/24 (12.5)
便秘	2/45 (4.4)	1/29 (3.4)	2/29 (6.9)	2/24 (8.3)
嚥下障害	1/45 (2.2)	1/29 (3.4)	1/29 (3.4)	1/24 (4.2)
胃潰瘍	0/45	0/29	0/29	1/24 (4.2)
胃食道逆流性疾患	1/45 (2.2)	1/29 (3.4)	1/29 (3.4)	0/24
一般・全身障害および投与部位の状態	6/45 (13.3)	10/29 (34.5)	10/29 (34.5)	8/24 (33.3)
投与部位漏出	0/45	1/29 (3.4)	1/29 (3.4)	1/24 (4.2)
薬効欠如	1/45 (2.2)	1/29 (3.4)	1/29 (3.4)	1/24 (4.2)
注入部位内出血	1/45 (2.2)	1/29 (3.4)	2/29 (6.9)	1/24 (4.2)
注入部位皮膚炎	0/45	1/29 (3.4)	1/29 (3.4)	0/24
注入部位紅斑	1/45 (2.2)	3/29 (10.3)	4/29 (13.8)	4/24 (16.7)
注入部位血腫	0/45	1/29 (3.4)	1/29 (3.4)	1/24 (4.2)
注入部位刺激感	0/45	1/29 (3.4)	1/29 (3.4)	1/24 (4.2)
注入部位腫瘤	0/45	0/29	1/29 (3.4)	0/24
注入部位浮腫	1/45 (2.2)	0/29	1/29 (3.4)	1/24 (4.2)
注入部位疼痛	1/45 (2.2)	0/29	0/29	0/24
注入部位丘疹	1/45 (2.2)	1/29 (3.4)	1/29 (3.4)	1/24 (4.2)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
Low Dose				
Any adverse event	6/10 (60.0)	0/1	0/0	25/45 (55.6)
眼障害	0/10	0/1	0/0	1/45 (2.2)
硝子体浮遊物	0/10	0/1	0/0	1/45 (2.2)
胃腸障害	1/10 (10.0)	0/1	0/0	5/45 (11.1)
便秘	0/10	0/1	0/0	3/45 (6.7)
嚥下障害	0/10	0/1	0/0	1/45 (2.2)
胃潰瘍	1/10 (10.0)	0/1	0/0	1/45 (2.2)
胃食道逆流性疾患	0/10	0/1	0/0	1/45 (2.2)
一般・全身障害および投与部位の状態	3/10 (30.0)	0/1	0/0	11/45 (24.4)
投与部位漏出	1/10 (10.0)	0/1	0/0	1/45 (2.2)
薬効欠如	0/10	0/1	0/0	1/45 (2.2)
注入部位内出血	1/10 (10.0)	0/1	0/0	2/45 (4.4)
注入部位皮膚炎	0/10	0/1	0/0	1/45 (2.2)
注入部位紅斑	2/10 (20.0)	0/1	0/0	6/45 (13.3)
注入部位血腫	0/10	0/1	0/0	1/45 (2.2)
注入部位刺激感	0/10	0/1	0/0	1/45 (2.2)
注入部位腫瘤	0/10	0/1	0/0	1/45 (2.2)
注入部位浮腫	0/10	0/1	0/0	1/45 (2.2)
注入部位疼痛	0/10	0/1	0/0	1/45 (2.2)
注入部位丘疹	0/10	0/1	0/0	1/45 (2.2)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
Low Dose				
一般・全身障害および投与部位の状態(Cont.)				
注射部位内出血	0/45	1/29 (3.4)	1/29 (3.4)	1/24 (4.2)
注射部位紅斑	1/45 (2.2)	1/29 (3.4)	0/29	0/24
穿刺部位紅斑	0/45	1/29 (3.4)	1/29 (3.4)	1/24 (4.2)
感染症および寄生虫症	4/45 (8.9)	4/29 (13.8)	6/29 (20.7)	7/24 (29.2)
膀胱炎	1/45 (2.2)	1/29 (3.4)	1/29 (3.4)	1/24 (4.2)
胃腸炎	1/45 (2.2)	0/29	1/29 (3.4)	0/24
ヘリコバクター性胃炎	1/45 (2.2)	1/29 (3.4)	1/29 (3.4)	0/24
ヘリコバクター感染	0/45	0/29	0/29	1/24 (4.2)
注入部位膿瘍	0/45	0/29	1/29 (3.4)	1/24 (4.2)
注入部位蜂巣炎	2/45 (4.4)	0/29	0/29	3/24 (12.5)
注入部位感染	0/45	2/29 (6.9)	1/29 (3.4)	2/24 (8.3)
上咽頭炎	0/45	0/29	1/29 (3.4)	0/24
上気道感染	0/45	1/29 (3.4)	0/29	0/24
傷害、中毒および処置合併症	1/45 (2.2)	4/29 (13.8)	3/29 (10.3)	2/24 (8.3)
節足動物刺傷	0/45	1/29 (3.4)	0/29	0/24
転倒	0/45	2/29 (6.9)	1/29 (3.4)	0/24
股関節部骨折	0/45	1/29 (3.4)	1/29 (3.4)	1/24 (4.2)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
Low Dose				
一般・全身障害および投与部位の状態(Cont.)				
注射部位内出血	0/10	0/1	0/0	1/45 (2.2)
注射部位紅斑	0/10	0/1	0/0	1/45 (2.2)
穿刺部位紅斑	0/10	0/1	0/0	1/45 (2.2)
感染症および寄生虫症	1/10 (10.0)	0/1	0/0	11/45 (24.4)
膀胱炎	0/10	0/1	0/0	1/45 (2.2)
胃腸炎	0/10	0/1	0/0	1/45 (2.2)
ヘリコバクター性胃炎	0/10	0/1	0/0	1/45 (2.2)
ヘリコバクター感染	1/10 (10.0)	0/1	0/0	1/45 (2.2)
注入部位膿瘍	0/10	0/1	0/0	1/45 (2.2)
注入部位蜂巣炎	0/10	0/1	0/0	4/45 (8.9)
注入部位感染	0/10	0/1	0/0	3/45 (6.7)
上咽頭炎	0/10	0/1	0/0	1/45 (2.2)
上気道感染	0/10	0/1	0/0	1/45 (2.2)
傷害、中毒および処置合併症	0/10	0/1	0/0	5/45 (11.1)
節足動物刺傷	0/10	0/1	0/0	1/45 (2.2)
転倒	0/10	0/1	0/0	3/45 (6.7)
股関節部骨折	0/10	0/1	0/0	1/45 (2.2)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
Low Dose				
傷害、中毒および処置合併症(Cont.)				
肉離れ	1/45 (2.2)	1/29 (3.4)	1/29 (3.4)	1/24 (4.2)
臨床検査	2/45 (4.4)	1/29 (3.4)	3/29 (10.3)	2/24 (8.3)
血中ホモシステイン増加	2/45 (4.4)	1/29 (3.4)	1/29 (3.4)	1/24 (4.2)
リンパ球数減少	0/45	0/29	1/29 (3.4)	0/24
ビタミンB12減少	0/45	1/29 (3.4)	1/29 (3.4)	1/24 (4.2)
ビタミンB6減少	0/45	0/29	2/29 (6.9)	2/24 (8.3)
代謝および栄養障害	0/45	1/29 (3.4)	2/29 (6.9)	2/24 (8.3)
鉄欠乏	0/45	1/29 (3.4)	1/29 (3.4)	1/24 (4.2)
ビタミンB12欠乏	0/45	0/29	1/29 (3.4)	1/24 (4.2)
筋骨格系および結合組織障害	1/45 (2.2)	0/29	0/29	1/24 (4.2)
変形性関節症	0/45	0/29	0/29	1/24 (4.2)
骨粗鬆症	0/45	0/29	0/29	1/24 (4.2)
四肢痛	0/45	0/29	0/29	1/24 (4.2)
腱鞘炎	1/45 (2.2)	0/29	0/29	0/24
神経系障害	2/45 (4.4)	2/29 (6.9)	3/29 (10.3)	3/24 (12.5)
健忘	1/45 (2.2)	0/29	0/29	0/24
認知障害	1/45 (2.2)	1/29 (3.4)	1/29 (3.4)	1/24 (4.2)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
Low Dose				
傷害、中毒および処置合併症(Cont.)				
肉離れ	0/10	0/1	0/0	1/45 (2.2)
臨床検査	0/10	0/1	0/0	4/45 (8.9)
血中ホモシステイン増加	0/10	0/1	0/0	2/45 (4.4)
リンパ球数減少	0/10	0/1	0/0	1/45 (2.2)
ビタミンB12減少	0/10	0/1	0/0	1/45 (2.2)
ビタミンB6減少	0/10	0/1	0/0	2/45 (4.4)
代謝および栄養障害	2/10 (20.0)	0/1	0/0	2/45 (4.4)
鉄欠乏	1/10 (10.0)	0/1	0/0	1/45 (2.2)
ビタミンB12欠乏	1/10 (10.0)	0/1	0/0	1/45 (2.2)
筋骨格系および結合組織障害	0/10	0/1	0/0	2/45 (4.4)
変形性関節症	0/10	0/1	0/0	1/45 (2.2)
骨粗鬆症	0/10	0/1	0/0	1/45 (2.2)
四肢痛	0/10	0/1	0/0	1/45 (2.2)
腱鞘炎	0/10	0/1	0/0	1/45 (2.2)
神経系障害	0/10	0/1	0/0	4/45 (8.9)
健忘	0/10	0/1	0/0	1/45 (2.2)
認知障害	0/10	0/1	0/0	1/45 (2.2)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
Low Dose				
神経系障害 (Cont.)				
すくみ現象	0/45	1/29 (3.4)	0/29	0/24
頭蓋内出血	0/45	0/29	1/29 (3.4)	1/24 (4.2)
反射減弱	1/45 (2.2)	0/29	0/29	0/24
オンオフ現象	0/45	0/29	1/29 (3.4)	1/24 (4.2)
パーキンソン病	0/45	1/29 (3.4)	1/29 (3.4)	1/24 (4.2)
振戦	0/45	1/29 (3.4)	1/29 (3.4)	1/24 (4.2)
精神障害	4/45 (8.9)	7/29 (24.1)	8/29 (27.6)	8/24 (33.3)
不安	0/45	1/29 (3.4)	1/29 (3.4)	1/24 (4.2)
歯ぎしり	1/45 (2.2)	1/29 (3.4)	1/29 (3.4)	1/24 (4.2)
抑うつ気分	0/45	0/29	1/29 (3.4)	1/24 (4.2)
うつ病	1/45 (2.2)	2/29 (6.9)	2/29 (6.9)	2/24 (8.3)
幻覚	1/45 (2.2)	2/29 (6.9)	1/29 (3.4)	1/24 (4.2)
幻視	0/45	1/29 (3.4)	1/29 (3.4)	1/24 (4.2)
錯覚	0/45	0/29	1/29 (3.4)	1/24 (4.2)
衝動行為	0/45	1/29 (3.4)	1/29 (3.4)	1/24 (4.2)
妄想症	0/45	0/29	1/29 (3.4)	1/24 (4.2)
精神病性障害	0/45	1/29 (3.4)	1/29 (3.4)	1/24 (4.2)
レム睡眠行動障害	1/45 (2.2)	1/29 (3.4)	1/29 (3.4)	1/24 (4.2)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
Low Dose				
神経系障害 (Cont.)				
すくみ現象	0/10	0/1	0/0	1/45 (2.2)
頭蓋内出血	0/10	0/1	0/0	1/45 (2.2)
反射減弱	0/10	0/1	0/0	1/45 (2.2)
オンオフ現象	0/10	0/1	0/0	1/45 (2.2)
パーキンソン病	0/10	0/1	0/0	1/45 (2.2)
振戦	0/10	0/1	0/0	1/45 (2.2)
精神障害	2/10 (20.0)	0/1	0/0	8/45 (17.8)
不安	1/10 (10.0)	0/1	0/0	1/45 (2.2)
歯ぎしり	1/10 (10.0)	0/1	0/0	1/45 (2.2)
抑うつ気分	0/10	0/1	0/0	1/45 (2.2)
うつ病	0/10	0/1	0/0	2/45 (4.4)
幻覚	1/10 (10.0)	0/1	0/0	2/45 (4.4)
幻視	0/10	0/1	0/0	1/45 (2.2)
錯覚	0/10	0/1	0/0	1/45 (2.2)
衝動行為	0/10	0/1	0/0	1/45 (2.2)
妄想症	0/10	0/1	0/0	1/45 (2.2)
精神病性障害	0/10	0/1	0/0	1/45 (2.2)
レム睡眠行動障害	0/10	0/1	0/0	1/45 (2.2)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
Low Dose				
腎および尿路障害	1/45 (2.2)	1/29 (3.4)	1/29 (3.4)	1/24 (4.2)
膀胱痙縮	1/45 (2.2)	1/29 (3.4)	1/29 (3.4)	1/24 (4.2)
生殖系および乳房障害	2/45 (4.4)	2/29 (6.9)	2/29 (6.9)	2/24 (8.3)
良性前立腺肥大症	1/45 (2.2)	1/29 (3.4)	1/29 (3.4)	1/24 (4.2)
外陰腟乾燥	1/45 (2.2)	1/29 (3.4)	1/29 (3.4)	1/24 (4.2)
呼吸器、胸郭および縦隔障害	0/45	0/29	1/29 (3.4)	1/24 (4.2)
窒息	0/45	0/29	1/29 (3.4)	0/24
誤嚥	0/45	0/29	1/29 (3.4)	0/24
呼吸困難	0/45	0/29	0/29	1/24 (4.2)
皮膚および皮下組織障害	0/45	2/29 (6.9)	3/29 (10.3)	3/24 (12.5)
光線角化症	0/45	0/29	1/29 (3.4)	0/24
脱毛症	0/45	1/29 (3.4)	1/29 (3.4)	1/24 (4.2)
湿疹	0/45	1/29 (3.4)	1/29 (3.4)	1/24 (4.2)
発疹	0/45	1/29 (3.4)	0/29	0/24
蕁麻疹	0/45	0/29	0/29	1/24 (4.2)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
Low Dose				
腎および尿路障害	0/10	0/1	0/0	1/45 (2.2)
膀胱痙縮	0/10	0/1	0/0	1/45 (2.2)
生殖系および乳房障害	0/10	0/1	0/0	2/45 (4.4)
良性前立腺肥大症	0/10	0/1	0/0	1/45 (2.2)
外陰腟乾燥	0/10	0/1	0/0	1/45 (2.2)
呼吸器、胸郭および縦隔障害	0/10	0/1	0/0	2/45 (4.4)
窒息	0/10	0/1	0/0	1/45 (2.2)
誤嚥	0/10	0/1	0/0	1/45 (2.2)
呼吸困難	0/10	0/1	0/0	1/45 (2.2)
皮膚および皮下組織障害	0/10	0/1	0/0	4/45 (8.9)
光線角化症	0/10	0/1	0/0	1/45 (2.2)
脱毛症	0/10	0/1	0/0	1/45 (2.2)
湿疹	0/10	0/1	0/0	1/45 (2.2)
発疹	0/10	0/1	0/0	1/45 (2.2)
蕁麻疹	0/10	0/1	0/0	1/45 (2.2)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
Low Dose				
血管障害	0/45	1/29 (3.4)	1/29 (3.4)	1/24 (4.2)
血腫	0/45	1/29 (3.4)	1/29 (3.4)	1/24 (4.2)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
Low Dose				
血管障害	0/10	0/1	0/0	1/45 (2.2)
血腫	0/10	0/1	0/0	1/45 (2.2)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
High Dose				
Any adverse event	27/60 (45.0)	28/46 (60.9)	28/44 (63.6)	22/38 (57.9)
心臓障害	0/60	0/46	1/44 (2.3)	1/38 (2.6)
左脚ブロック	0/60	0/46	1/44 (2.3)	1/38 (2.6)
耳および迷路障害	0/60	1/46 (2.2)	0/44	0/38
回転性めまい	0/60	1/46 (2.2)	0/44	0/38
眼障害	0/60	2/46 (4.3)	1/44 (2.3)	1/38 (2.6)
眼瞼痙攣	0/60	1/46 (2.2)	1/44 (2.3)	1/38 (2.6)
眼充血	0/60	1/46 (2.2)	0/44	0/38
胃腸障害	3/60 (5.0)	3/46 (6.5)	3/44 (6.8)	2/38 (5.3)
腹部不快感	0/60	0/46	1/44 (2.3)	0/38
腹部膨満	1/60 (1.7)	1/46 (2.2)	1/44 (2.3)	0/38
腹痛	0/60	1/46 (2.2)	1/44 (2.3)	0/38
便秘	2/60 (3.3)	2/46 (4.3)	1/44 (2.3)	1/38 (2.6)
出血性腸憩室	1/60 (1.7)	1/46 (2.2)	0/44	0/38
流涎過多	0/60	0/46	1/44 (2.3)	1/38 (2.6)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
High Dose				
Any adverse event	11/16 (68.8)	3/3 (100)	0/0	41/60 (68.3)
心臓障害	0/16	0/3	0/0	1/60 (1.7)
左脚ブロック	0/16	0/3	0/0	1/60 (1.7)
耳および迷路障害	0/16	0/3	0/0	1/60 (1.7)
回転性めまい	0/16	0/3	0/0	1/60 (1.7)
眼障害	1/16 (6.3)	0/3	0/0	2/60 (3.3)
眼瞼痙攣	1/16 (6.3)	0/3	0/0	1/60 (1.7)
眼充血	0/16	0/3	0/0	1/60 (1.7)
胃腸障害	0/16	0/3	0/0	4/60 (6.7)
腹部不快感	0/16	0/3	0/0	1/60 (1.7)
腹部膨満	0/16	0/3	0/0	1/60 (1.7)
腹痛	0/16	0/3	0/0	1/60 (1.7)
便秘	0/16	0/3	0/0	2/60 (3.3)
出血性腸憩室	0/16	0/3	0/0	1/60 (1.7)
流涎過多	0/16	0/3	0/0	1/60 (1.7)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
High Dose				
一般・全身障害および投与部位の状態	12/60 (20.0)	12/46 (26.1)	9/44 (20.5)	6/38 (15.8)
注入部位内出血	1/60 (1.7)	1/46 (2.2)	1/44 (2.3)	1/38 (2.6)
注入部位紅斑	5/60 (8.3)	5/46 (10.9)	5/44 (11.4)	2/38 (5.3)
注入部位血管外漏出	0/60	1/46 (2.2)	1/44 (2.3)	1/38 (2.6)
注入部位血腫	1/60 (1.7)	0/46	0/44	0/38
注入部位出血	0/60	1/46 (2.2)	1/44 (2.3)	0/38
注入部位硬結	0/60	1/46 (2.2)	1/44 (2.3)	2/38 (5.3)
注入部位炎症	0/60	1/46 (2.2)	0/44	0/38
注入部位結節	2/60 (3.3)	2/46 (4.3)	2/44 (4.5)	1/38 (2.6)
注入部位浮腫	1/60 (1.7)	0/46	0/44	0/38
注入部位疼痛	0/60	0/46	0/44	0/38
注入部位丘疹	3/60 (5.0)	1/46 (2.2)	0/44	0/38
注入部位異常感覚	1/60 (1.7)	0/46	0/44	0/38
注入部位発疹	1/60 (1.7)	1/46 (2.2)	0/44	0/38
注入部位反応	0/60	1/46 (2.2)	1/44 (2.3)	1/38 (2.6)
注入部位腫脹	1/60 (1.7)	0/46	0/44	0/38
注射部位紅斑	1/60 (1.7)	1/46 (2.2)	1/44 (2.3)	0/38
注射部位硬結	1/60 (1.7)	1/46 (2.2)	1/44 (2.3)	0/38
注射部位炎症	1/60 (1.7)	0/46	0/44	0/38
注射部位浮腫	1/60 (1.7)	0/46	0/44	0/38
末梢性浮腫	1/60 (1.7)	1/46 (2.2)	1/44 (2.3)	1/38 (2.6)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
High Dose				
一般・全身障害および投与部位の状態	1/16 (6.3)	0/3	0/0	18/60 (30.0)
注入部位内出血	0/16	0/3	0/0	2/60 (3.3)
注入部位紅斑	0/16	0/3	0/0	7/60 (11.7)
注入部位血管外漏出	1/16 (6.3)	0/3	0/0	2/60 (3.3)
注入部位血腫	0/16	0/3	0/0	1/60 (1.7)
注入部位出血	0/16	0/3	0/0	1/60 (1.7)
注入部位硬結	0/16	0/3	0/0	2/60 (3.3)
注入部位炎症	0/16	0/3	0/0	1/60 (1.7)
注入部位結節	0/16	0/3	0/0	2/60 (3.3)
注入部位浮腫	0/16	0/3	0/0	1/60 (1.7)
注入部位疼痛	1/16 (6.3)	0/3	0/0	1/60 (1.7)
注入部位丘疹	0/16	0/3	0/0	3/60 (5.0)
注入部位異常感覚	0/16	0/3	0/0	1/60 (1.7)
注入部位発疹	0/16	0/3	0/0	1/60 (1.7)
注入部位反応	0/16	0/3	0/0	1/60 (1.7)
注入部位腫脹	0/16	0/3	0/0	1/60 (1.7)
注射部位紅斑	0/16	0/3	0/0	1/60 (1.7)
注射部位硬結	0/16	0/3	0/0	1/60 (1.7)
注射部位炎症	0/16	0/3	0/0	1/60 (1.7)
注射部位浮腫	0/16	0/3	0/0	1/60 (1.7)
末梢性浮腫	0/16	0/3	0/0	1/60 (1.7)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
High Dose				
感染症および寄生虫症	5/60 (8.3)	6/46 (13.0)	7/44 (15.9)	2/38 (5.3)
COVID-19	0/60	0/46	0/44	0/38
大腸菌性尿路感染	0/60	1/46 (2.2)	1/44 (2.3)	0/38
胃腸炎	0/60	0/46	1/44 (2.3)	0/38
帯状疱疹	0/60	1/46 (2.2)	1/44 (2.3)	0/38
注入部位蜂巣炎	4/60 (6.7)	1/46 (2.2)	4/44 (9.1)	1/38 (2.6)
注入部位感染	0/60	1/46 (2.2)	1/44 (2.3)	0/38
注射部位感染	0/60	0/46	1/44 (2.3)	0/38
尿路感染	1/60 (1.7)	2/46 (4.3)	2/44 (4.5)	2/38 (5.3)
傷害、中毒および処置合併症	5/60 (8.3)	6/46 (13.0)	5/44 (11.4)	3/38 (7.9)
顔面骨骨折	1/60 (1.7)	1/46 (2.2)	0/44	0/38
転倒	5/60 (8.3)	2/46 (4.3)	2/44 (4.5)	0/38
転位骨折	0/60	1/46 (2.2)	0/44	0/38
手骨折	0/60	1/46 (2.2)	2/44 (4.5)	1/38 (2.6)
股関節部骨折	1/60 (1.7)	0/46	0/44	0/38
上腕骨骨折	1/60 (1.7)	1/46 (2.2)	0/44	0/38
四肢損傷	0/60	1/46 (2.2)	1/44 (2.3)	1/38 (2.6)
処置による疼痛	0/60	1/46 (2.2)	1/44 (2.3)	1/38 (2.6)
肩甲骨骨折	1/60 (1.7)	1/46 (2.2)	0/44	0/38

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
High Dose				
感染症および寄生虫症	3/16 (18.8)	1/3 (33.3)	0/0	12/60 (20.0)
COVID-19	1/16 (6.3)	1/3 (33.3)	0/0	1/60 (1.7)
大腸菌性尿路感染	0/16	0/3	0/0	1/60 (1.7)
胃腸炎	0/16	0/3	0/0	1/60 (1.7)
帯状疱疹	0/16	0/3	0/0	1/60 (1.7)
注入部位蜂巣炎	2/16 (12.5)	0/3	0/0	8/60 (13.3)
注入部位感染	0/16	0/3	0/0	1/60 (1.7)
注射部位感染	0/16	0/3	0/0	1/60 (1.7)
尿路感染	1/16 (6.3)	0/3	0/0	2/60 (3.3)
傷害、中毒および処置合併症	1/16 (6.3)	0/3	0/0	11/60 (18.3)
顔面骨骨折	0/16	0/3	0/0	1/60 (1.7)
転倒	0/16	0/3	0/0	9/60 (15.0)
転位骨折	0/16	0/3	0/0	1/60 (1.7)
手骨折	1/16 (6.3)	0/3	0/0	2/60 (3.3)
股関節部骨折	0/16	0/3	0/0	1/60 (1.7)
上腕骨骨折	0/16	0/3	0/0	1/60 (1.7)
四肢損傷	0/16	0/3	0/0	1/60 (1.7)
処置による疼痛	0/16	0/3	0/0	1/60 (1.7)
肩甲骨骨折	0/16	0/3	0/0	1/60 (1.7)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
High Dose				
臨床検査	2/60 (3.3)	3/46 (6.5)	3/44 (6.8)	3/38 (7.9)
血中葉酸減少	1/60 (1.7)	1/46 (2.2)	1/44 (2.3)	1/38 (2.6)
プロトロンビン時間延長	1/60 (1.7)	0/46	0/44	0/38
体重減少	1/60 (1.7)	2/46 (4.3)	2/44 (4.5)	2/38 (5.3)
代謝および栄養障害	1/60 (1.7)	2/46 (4.3)	4/44 (9.1)	3/38 (7.9)
鉄欠乏	0/60	1/46 (2.2)	1/44 (2.3)	0/38
ビタミンB12欠乏	1/60 (1.7)	1/46 (2.2)	3/44 (6.8)	3/38 (7.9)
筋骨格系および結合組織障害	1/60 (1.7)	4/46 (8.7)	5/44 (11.4)	5/38 (13.2)
背部痛	0/60	1/46 (2.2)	2/44 (4.5)	2/38 (5.3)
滑液包炎	1/60 (1.7)	1/46 (2.2)	1/44 (2.3)	1/38 (2.6)
出血性関節症	0/60	1/46 (2.2)	0/44	0/38
椎間板変性症	0/60	0/46	1/44 (2.3)	1/38 (2.6)
筋力低下	0/60	1/46 (2.2)	1/44 (2.3)	1/38 (2.6)
筋骨格硬直	0/60	1/46 (2.2)	1/44 (2.3)	1/38 (2.6)
骨粗鬆症	1/60 (1.7)	1/46 (2.2)	1/44 (2.3)	1/38 (2.6)
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）	0/60	0/46	1/44 (2.3)	0/38
ケラトアカントーマ	0/60	0/46	1/44 (2.3)	0/38

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
High Dose				
臨床検査	1/16 (6.3)	0/3	0/0	4/60 (6.7)
血中葉酸減少	0/16	0/3	0/0	1/60 (1.7)
プロトロンビン時間延長	0/16	0/3	0/0	1/60 (1.7)
体重減少	1/16 (6.3)	0/3	0/0	3/60 (5.0)
代謝および栄養障害	3/16 (18.8)	0/3	0/0	4/60 (6.7)
鉄欠乏	0/16	0/3	0/0	1/60 (1.7)
ビタミンB12欠乏	3/16 (18.8)	0/3	0/0	3/60 (5.0)
筋骨格系および結合組織障害	2/16 (12.5)	0/3	0/0	6/60 (10.0)
背部痛	1/16 (6.3)	0/3	0/0	2/60 (3.3)
滑液包炎	0/16	0/3	0/0	1/60 (1.7)
出血性関節症	0/16	0/3	0/0	1/60 (1.7)
椎間板変性症	1/16 (6.3)	0/3	0/0	1/60 (1.7)
筋力低下	0/16	0/3	0/0	1/60 (1.7)
筋骨格硬直	0/16	0/3	0/0	1/60 (1.7)
骨粗鬆症	0/16	0/3	0/0	1/60 (1.7)
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）	0/16	0/3	0/0	1/60 (1.7)
ケラトアカントーマ	0/16	0/3	0/0	1/60 (1.7)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
High Dose				
神経系障害	8/60 (13.3)	8/46 (17.4)	9/44 (20.5)	6/38 (15.8)
平衡障害	1/60 (1.7)	1/46 (2.2)	1/44 (2.3)	1/38 (2.6)
認知障害	1/60 (1.7)	1/46 (2.2)	1/44 (2.3)	1/38 (2.6)
注意力障害	1/60 (1.7)	1/46 (2.2)	1/44 (2.3)	0/38
ジストニア	1/60 (1.7)	1/46 (2.2)	1/44 (2.3)	1/38 (2.6)
すくみ現象	0/60	1/46 (2.2)	1/44 (2.3)	1/38 (2.6)
頭部不快感	1/60 (1.7)	0/46	0/44	0/38
感覚鈍麻	0/60	0/46	1/44 (2.3)	1/38 (2.6)
反射減弱	0/60	1/46 (2.2)	1/44 (2.3)	1/38 (2.6)
記憶障害	1/60 (1.7)	1/46 (2.2)	1/44 (2.3)	0/38
オンオフ現象	2/60 (3.3)	2/46 (4.3)	2/44 (4.5)	1/38 (2.6)
パーキンソン病	0/60	2/46 (4.3)	2/44 (4.5)	1/38 (2.6)
精神運動亢進	0/60	0/46	1/44 (2.3)	0/38
失神	1/60 (1.7)	2/46 (4.3)	1/44 (2.3)	1/38 (2.6)
一過性脳虚血発作	1/60 (1.7)	1/46 (2.2)	1/44 (2.3)	1/38 (2.6)
精神障害	5/60 (8.3)	5/46 (10.9)	7/44 (15.9)	5/38 (13.2)
攻撃性	1/60 (1.7)	1/46 (2.2)	0/44	0/38
激越	1/60 (1.7)	0/46	0/44	0/38
不安	1/60 (1.7)	0/46	1/44 (2.3)	1/38 (2.6)
錯乱状態	0/60	0/46	1/44 (2.3)	1/38 (2.6)
妄想	0/60	0/46	1/44 (2.3)	1/38 (2.6)
うつ病	1/60 (1.7)	1/46 (2.2)	1/44 (2.3)	0/38
自傷性皮膚症	0/60	1/46 (2.2)	1/44 (2.3)	1/38 (2.6)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
High Dose				
神経系障害	1/16 (6.3)	1/3 (33.3)	0/0	15/60 (25.0)
平衡障害	0/16	0/3	0/0	1/60 (1.7)
認知障害	0/16	0/3	0/0	1/60 (1.7)
注意力障害	0/16	0/3	0/0	1/60 (1.7)
ジストニア	0/16	0/3	0/0	1/60 (1.7)
すくみ現象	0/16	0/3	0/0	1/60 (1.7)
頭部不快感	0/16	0/3	0/0	1/60 (1.7)
感覚鈍麻	1/16 (6.3)	0/3	0/0	1/60 (1.7)
反射減弱	0/16	0/3	0/0	1/60 (1.7)
記憶障害	0/16	1/3 (33.3)	0/0	2/60 (3.3)
オンオフ現象	0/16	0/3	0/0	4/60 (6.7)
パーキンソン病	0/16	0/3	0/0	3/60 (5.0)
精神運動亢進	0/16	0/3	0/0	1/60 (1.7)
失神	0/16	0/3	0/0	2/60 (3.3)
一過性脳虚血発作	0/16	0/3	0/0	1/60 (1.7)
精神障害	2/16 (12.5)	1/3 (33.3)	0/0	11/60 (18.3)
攻撃性	0/16	0/3	0/0	1/60 (1.7)
激越	0/16	0/3	0/0	1/60 (1.7)
不安	1/16 (6.3)	1/3 (33.3)	0/0	2/60 (3.3)
錯乱状態	0/16	0/3	0/0	1/60 (1.7)
妄想	1/16 (6.3)	0/3	0/0	1/60 (1.7)
うつ病	0/16	0/3	0/0	1/60 (1.7)
自傷性皮膚症	0/16	0/3	0/0	1/60 (1.7)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
High Dose				
精神障害 (Cont.)				
幻覚	2/60 (3.3)	2/46 (4.3)	3/44 (6.8)	2/38 (5.3)
衝動制御障害	0/60	1/46 (2.2)	1/44 (2.3)	0/38
パニック発作	0/60	1/46 (2.2)	1/44 (2.3)	0/38
精神病性障害	0/60	1/46 (2.2)	1/44 (2.3)	0/38
腎および尿路障害	0/60	1/46 (2.2)	1/44 (2.3)	1/38 (2.6)
血尿	0/60	1/46 (2.2)	1/44 (2.3)	1/38 (2.6)
生殖系および乳房障害	1/60 (1.7)	1/46 (2.2)	1/44 (2.3)	1/38 (2.6)
勃起不全	1/60 (1.7)	1/46 (2.2)	1/44 (2.3)	1/38 (2.6)
呼吸器、胸郭および縦隔障害	0/60	0/46	0/44	0/38
痰貯留	0/60	0/46	0/44	0/38
皮膚および皮下組織障害	0/60	0/46	0/44	1/38 (2.6)
湿疹	0/60	0/46	0/44	1/38 (2.6)
血管障害	2/60 (3.3)	5/46 (10.9)	5/44 (11.4)	5/38 (13.2)
高血圧	0/60	1/46 (2.2)	0/44	0/38
低血圧	1/60 (1.7)	1/46 (2.2)	1/44 (2.3)	1/38 (2.6)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
High Dose				
精神障害 (Cont.)				
幻覚	0/16	0/3	0/0	5/60 (8.3)
衝動制御障害	0/16	0/3	0/0	1/60 (1.7)
パニック発作	0/16	0/3	0/0	1/60 (1.7)
精神病性障害	0/16	0/3	0/0	1/60 (1.7)
腎および尿路障害	0/16	0/3	0/0	1/60 (1.7)
血尿	0/16	0/3	0/0	1/60 (1.7)
生殖系および乳房障害	0/16	0/3	0/0	1/60 (1.7)
勃起不全	0/16	0/3	0/0	1/60 (1.7)
呼吸器、胸郭および縦隔障害	1/16 (6.3)	0/3	0/0	1/60 (1.7)
痰貯留	1/16 (6.3)	0/3	0/0	1/60 (1.7)
皮膚および皮下組織障害	1/16 (6.3)	0/3	0/0	1/60 (1.7)
湿疹	1/16 (6.3)	0/3	0/0	1/60 (1.7)
血管障害	2/16 (12.5)	1/3 (33.3)	0/0	6/60 (10.0)
高血圧	0/16	0/3	0/0	1/60 (1.7)
低血圧	0/16	0/3	0/0	1/60 (1.7)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=105) n/N eval (%)	 Days 91 to 180 (N=75) n/N eval (%)	 Days 181 to 270 (N=73) n/N eval (%)	 Days 271 to 360 (N=62) n/N eval (%)
High Dose				
血管障害 (Cont.)				
起立性高血圧	1/60 (1.7)	1/46 (2.2)	1/44 (2.3)	1/38 (2.6)
起立性低血圧	0/60	2/46 (4.3)	2/44 (4.5)	2/38 (5.3)
表在性血栓性静脈炎	0/60	0/46	1/44 (2.3)	1/38 (2.6)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=26) n/N eval (%)	 Days 451 to 540 (N=4) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=105) n/N eval (%)
High Dose				
血管障害 (Cont.)				
起立性高血圧	0/16	0/3	0/0	1/60 (1.7)
起立性低血圧	1/16 (6.3)	0/3	0/0	2/60 (3.3)
表在性血栓性静脈炎	1/16 (6.3)	1/3 (33.3)	0/0	1/60 (1.7)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

表41　有害事象の概要（安全性解析対象集団，日本人部分集団）：M15-737試験

[redacted]20[redacted] 04:22 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.3__1.1.J

Overview of Treatment-Emergent Adverse Events and All Deaths for Japan and Non-Japan subjects
(Safety Analysis Set)

	Japan		
	Dose Category		
	Low Dose (N=7) n (%)	High Dose (N=4) n (%)	All Subjects (N=11) n (%)
Subjects with:			
Any TEAE	5 (71.4)	3 (75.0)	8 (72.7)
Any severe TEAE	1 (14.3)	0	1 (9.1)
Any TEAE that is considered associated with study drug$	3 (42.9)	2 (50.0)	5 (45.5)
Any TEAE that is considered associated with product complaint$	1 (14.3)	2 (50.0)	3 (27.3)
ABBV-951	1 (14.3)	1 (25.0)	2 (18.2)
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	0	0	0
[redacted] infusion set 6 mm	0	0	0
[redacted] infusion set 9 mm	0	0	0
Neria guard infusion set (total)	0	2 (50.0)	2 (18.2)
Neria guard infusion set 6 mm	0	0	0
Neria guard infusion set 9 mm	0	2 (50.0)	2 (18.2)
Any TEAE that is considered associated with loading dose$	0	0	0
Any TEAE that is considered associated with rescue dose$	0	0	0
Any TEAE that is considered associated with COVID-19 infection	0	0	0
Any TEAE leading to prematurely discontinuation of study drug	1 (14.3)	0	1 (9.1)
Any TEAE leading to death (fatal TEAE)	1 (14.3)	0	1 (9.1)
Any serious TEAE	1 (14.3)	1 (25.0)	2 (18.2)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
$ As assessed by investigator.

Program Source Code: [redacted]

TABLE 14.3 1.1.J

Overview of Treatment-Emergent Adverse Events and All Deaths for Japan and Non-Japan subjects
(Safety Analysis Set)

	Non-Japan		
	Dose Category		
	Low Dose (N=38) n (%)	High Dose (N=56) n (%)	All Subjects (N=94) n (%)
Subjects with:			
Any TEAE	20 (52.6)	38 (67.9)	58 (61.7)
Any severe TEAE	3 (7.9)	8 (14.3)	11 (11.7)
Any TEAE that is considered associated with study drug$	13 (34.2)	26 (46.4)	39 (41.5)
Any TEAE that is considered associated with product complaint$	10 (26.3)	13 (23.2)	23 (24.5)
ABBV-951	2 (5.3)	8 (14.3)	10 (10.6)
Infusion pump	0	1 (1.8)	1 (1.1)
Vial adapter	0	0	0
Syringes	0	1 (1.8)	1 (1.1)
[redacted] infusion set (total)	4 (10.5)	2 (3.6)	6 (6.4)
[redacted] infusion set 6 mm	1 (2.6)	1 (1.8)	2 (2.1)
[redacted] infusion set 9 mm	3 (7.9)	1 (1.8)	4 (4.3)
Neria guard infusion set (total)	5 (13.2)	6 (10.7)	11 (11.7)
Neria guard infusion set 6 mm	3 (7.9)	2 (3.6)	5 (5.3)
Neria guard infusion set 9 mm	2 (5.3)	5 (8.9)	7 (7.4)
Any TEAE that is considered associated with loading dose$	0	0	0
Any TEAE that is considered associated with rescue dose$	0	2 (3.6)	2 (2.1)
Any TEAE that is considered associated with COVID-19 infection	0	1 (1.8)	1 (1.1)
Any TEAE leading to prematurely discontinuation of study drug	0	4 (7.1)	4 (4.3)
Any TEAE leading to death (fatal TEAE)	0	2 (3.6)	2 (2.1)
Any serious TEAE	6 (15.8)	9 (16.1)	15 (16.0)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
$ As assessed by investigator.

Program Source Code: [redacted]

TABLE 14.3 1.1.J

Overview of Treatment-Emergent Adverse Events and All Deaths for Japan and Non-Japan subjects
(Safety Analysis Set)

	Japan		
	Dose Category		
	Low Dose (N=7) n (%)	High Dose (N=4) n (%)	All Subjects (N=11) n (%)
Any SAE that is considered associated with infusion pump$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with neria guards infusion set$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with product complaint$	0	0	0
ABBV-951	0	0	0
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	0	0	0
[redacted] infusion set 6 mm	0	0	0
[redacted] infusion set 9 mm	0	0	0
Neria guard infusion set (total)	0	0	0
Neria guard infusion set 6 mm	0	0	0
Neria guard infusion set 9 mm	0	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
$ As assessed by investigator.

Program Source Code: [redacted]

TABLE 14.3 1.1.J

Overview of Treatment-Emergent Adverse Events and All Deaths for Japan and Non-Japan subjects
(Safety Analysis Set)

	Non-Japan		
	Dose Category		
	Low Dose (N=38) n (%)	High Dose (N=56) n (%)	All Subjects (N=94) n (%)
Any SAE that is considered associated with infusion pump$	1 (2.6)	1 (1.8)	2 (2.1)
Possible	0	0	0
Probable	0	1 (1.8)	1 (1.1)
Causal relationship	1 (2.6)	0	1 (1.1)
Any SAE that is considered associated with neria guards infusion set$	1 (2.6)	1 (1.8)	2 (2.1)
Possible	0	1 (1.8)	1 (1.1)
Probable	1 (2.6)	0	1 (1.1)
Causal relationship	0	0	0
Any SAE that is considered associated with product complaint$	2 (5.3)	1 (1.8)	3 (3.2)
ABBV-951	1 (2.6)	0	1 (1.1)
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	0	0	0
[redacted] infusion set 6 mm	0	0	0
[redacted] infusion set 9 mm	0	0	0
Neria guard infusion set (total)	1 (2.6)	1 (1.8)	2 (2.1)
Neria guard infusion set 6 mm	1 (2.6)	0	1 (1.1)
Neria guard infusion set 9 mm	0	1 (1.8)	1 (1.1)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
$ As assessed by investigator.

Program Source Code: [redacted]

TABLE 14.3 1.1.J

Overview of Treatment-Emergent Adverse Events and All Deaths for Japan and Non-Japan subjects
(Safety Analysis Set)

	Japan		
	Dose Category		
	Low Dose (N=7) n (%)	High Dose (N=4) n (%)	All Subjects (N=11) n (%)
All deaths#	1 (14.3)	0	1 (9.1)
All TE-deaths	1 (14.3)	0	1 (9.1)
Deaths related to COVID-19 infection	0	0	0
AESI: polyneuropathy (narrow)	0	0	0
AESI: weight loss	0	0	0
AESI: hallucinations/psychosis	1 (14.3)	0	1 (9.1)
AESI: somnolence	0	0	0
AESI: infusion site related infections	0	1 (25.0)	1 (9.1)
AESI: infusion site related non infection reactions	1 (14.3)	2 (50.0)	3 (27.3)
AESI: falls and associated injuries	0	1 (25.0)	1 (9.1)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Includes non treatment-emergent deaths.

Program Source Code: [redacted]

TABLE 14.3 1.1.J

Overview of Treatment-Emergent Adverse Events and All Deaths for Japan and Non-Japan subjects
(Safety Analysis Set)

	Non-Japan		
	Dose Category		
	Low Dose (N=38) n (%)	High Dose (N=56) n (%)	All Subjects (N=94) n (%)
All deaths#	0	2 (3.6)	2 (2.1)
All TE-deaths	0	2 (3.6)	2 (2.1)
Deaths related to COVID-19 infection	0	0	0
AESI: polyneuropathy (narrow)	0	0	0
AESI: weight loss	1 (2.6)	3 (5.4)	4 (4.3)
AESI: hallucinations/psychosis	3 (7.9)	6 (10.7)	9 (9.6)
AESI: somnolence	0	0	0
AESI: infusion site related infections	8 (21.1)	8 (14.3)	16 (17.0)
AESI: infusion site related non infection reactions	10 (26.3)	15 (26.8)	25 (26.6)
AESI: falls and associated injuries	4 (10.5)	10 (17.9)	14 (14.9)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Includes non treatment-emergent deaths.

Program Source Code: [redacted]

表42　すべての有害事象（安全性解析対象集団，部分集団別）：M15-737試験

[redacted]20[redacted] 04:22 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.3__1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Sex: Male	N=23	N=45	N=68
Any adverse event	11 (47.8)	31 (68.9)	42 (61.8)
眼障害	0	2 (4.4)	2 (2.9)
眼瞼痙攣	0	1 (2.2)	1 (1.5)
眼充血	0	1 (2.2)	1 (1.5)
胃腸障害	2 (8.7)	3 (6.7)	5 (7.4)
腹部膨満	0	1 (2.2)	1 (1.5)
腹痛	0	1 (2.2)	1 (1.5)
便秘	2 (8.7)	1 (2.2)	3 (4.4)
出血性腸憩室	0	1 (2.2)	1 (1.5)
嚥下障害	1 (4.3)	0	1 (1.5)
流涎過多	0	1 (2.2)	1 (1.5)
一般・全身障害および投与部位の状態	5 (21.7)	15 (33.3)	20 (29.4)
投与部位漏出	1 (4.3)	0	1 (1.5)
薬効欠如	1 (4.3)	0	1 (1.5)
注入部位内出血	1 (4.3)	2 (4.4)	3 (4.4)
注入部位紅斑	4 (17.4)	6 (13.3)	10 (14.7)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Sex: Male (Cont.)	N=23	N=45	N=68
一般・全身障害および投与部位の状態 (Cont.)			
注入部位血管外漏出	0	1 (2.2)	1 (1.5)
注入部位血腫	0	1 (2.2)	1 (1.5)
注入部位出血	0	1 (2.2)	1 (1.5)
注入部位硬結	0	2 (4.4)	2 (2.9)
注入部位炎症	0	1 (2.2)	1 (1.5)
注入部位刺激感	1 (4.3)	0	1 (1.5)
注入部位結節	0	2 (4.4)	2 (2.9)
注入部位浮腫	0	1 (2.2)	1 (1.5)
注入部位丘疹	0	2 (4.4)	2 (2.9)
注入部位異常感覚	0	1 (2.2)	1 (1.5)
注入部位発疹	0	1 (2.2)	1 (1.5)
注入部位反応	0	1 (2.2)	1 (1.5)
注入部位腫脹	0	1 (2.2)	1 (1.5)
注射部位紅斑	0	1 (2.2)	1 (1.5)
注射部位硬結	0	1 (2.2)	1 (1.5)
注射部位炎症	0	1 (2.2)	1 (1.5)
注射部位浮腫	0	1 (2.2)	1 (1.5)
末梢性浮腫	0	1 (2.2)	1 (1.5)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Sex: Male (Cont.)	N=23	N=45	N=68
感染症および寄生虫症	6 (26.1)	8 (17.8)	14 (20.6)
COVID-19	0	1 (2.2)	1 (1.5)
胃腸炎	1 (4.3)	1 (2.2)	2 (2.9)
帯状疱疹	0	1 (2.2)	1 (1.5)
注入部位蜂巣炎	1 (4.3)	5 (11.1)	6 (8.8)
注入部位感染	3 (13.0)	1 (2.2)	4 (5.9)
注射部位感染	0	1 (2.2)	1 (1.5)
上咽頭炎	1 (4.3)	0	1 (1.5)
上気道感染	1 (4.3)	0	1 (1.5)
傷害、中毒および処置合併症	3 (13.0)	8 (17.8)	11 (16.2)
節足動物刺傷	1 (4.3)	0	1 (1.5)
顔面骨骨折	0	1 (2.2)	1 (1.5)
転倒	1 (4.3)	6 (13.3)	7 (10.3)
手骨折	0	2 (4.4)	2 (2.9)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Sex: Male (Cont.)	N=23	N=45	N=68
傷害、中毒および処置合併症 (Cont.)			
股関節部骨折	1 (4.3)	1 (2.2)	2 (2.9)
上腕骨骨折	0	1 (2.2)	1 (1.5)
四肢損傷	0	1 (2.2)	1 (1.5)
肉離れ	1 (4.3)	0	1 (1.5)
処置による疼痛	0	1 (2.2)	1 (1.5)
肩甲骨骨折	0	1 (2.2)	1 (1.5)
臨床検査	2 (8.7)	4 (8.9)	6 (8.8)
血中葉酸減少	0	1 (2.2)	1 (1.5)
血中ホモシステイン増加	2 (8.7)	0	2 (2.9)
プロトロンビン時間延長	0	1 (2.2)	1 (1.5)
ビタミンB12減少	1 (4.3)	0	1 (1.5)
ビタミンB6減少	1 (4.3)	0	1 (1.5)
体重減少	0	3 (6.7)	3 (4.4)
代謝および栄養障害	0	3 (6.7)	3 (4.4)
鉄欠乏	0	1 (2.2)	1 (1.5)
ビタミンB12欠乏	0	2 (4.4)	2 (2.9)
筋骨格系および結合組織障害	0	5 (11.1)	5 (7.4)
背部痛	0	1 (2.2)	1 (1.5)
滑液包炎	0	1 (2.2)	1 (1.5)
出血性関節症	0	1 (2.2)	1 (1.5)
椎間板変性症	0	1 (2.2)	1 (1.5)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	Dose Category High Dose (N=60) n (%)	All Subjects (N=105) n (%)
Sex: Male (Cont.)	N=23	N=45	N=68
筋骨格系および結合組織障害 (Cont.)			
筋力低下	0	1 (2.2)	1 (1.5)
筋骨格硬直	0	1 (2.2)	1 (1.5)
骨粗鬆症	0	1 (2.2)	1 (1.5)
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 (1.5)
ケラトアカントーマ	0	1 (2.2)	1 (1.5)
神経系障害	1 (4.3)	10 (22.2)	11 (16.2)
認知障害	1 (4.3)	0	1 (1.5)
注意力障害	0	1 (2.2)	1 (1.5)
ジストニア	0	1 (2.2)	1 (1.5)
すくみ現象	0	1 (2.2)	1 (1.5)
頭部不快感	0	1 (2.2)	1 (1.5)
感覚鈍麻	0	1 (2.2)	1 (1.5)
反射減弱	0	1 (2.2)	1 (1.5)
記憶障害	0	2 (4.4)	2 (2.9)
オンオフ現象	1 (4.3)	1 (2.2)	2 (2.9)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Sex: Male (Cont.)	N=23	N=45	N=68
神経系障害 (Cont.)			
パーキンソン病	1 (4.3)	2 (4.4)	3 (4.4)
精神運動亢進	0	1 (2.2)	1 (1.5)
失神	0	1 (2.2)	1 (1.5)
一過性脳虚血発作	0	1 (2.2)	1 (1.5)
精神障害	3 (13.0)	8 (17.8)	11 (16.2)
攻撃性	0	1 (2.2)	1 (1.5)
錯乱状態	0	1 (2.2)	1 (1.5)
妄想	0	1 (2.2)	1 (1.5)
抑うつ気分	1 (4.3)	0	1 (1.5)
うつ病	0	1 (2.2)	1 (1.5)
自傷性皮膚症	0	1 (2.2)	1 (1.5)
幻覚	1 (4.3)	3 (6.7)	4 (5.9)
錯覚	1 (4.3)	0	1 (1.5)
衝動制御障害	0	1 (2.2)	1 (1.5)
妄想症	1 (4.3)	0	1 (1.5)
レム睡眠行動障害	1 (4.3)	0	1 (1.5)
生殖系および乳房障害	1 (4.3)	1 (2.2)	2 (2.9)
良性前立腺肥大症	1 (4.3)	0	1 (1.5)
勃起不全	0	1 (2.2)	1 (1.5)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Sex: Male (Cont.)	N=23	N=45	N=68
呼吸器、胸郭および縦隔障害	0	1 (2.2)	1 (1.5)
痰貯留	0	1 (2.2)	1 (1.5)
皮膚および皮下組織障害	2 (8.7)	1 (2.2)	3 (4.4)
光線角化症	1 (4.3)	0	1 (1.5)
湿疹	1 (4.3)	1 (2.2)	2 (2.9)
血管障害	0	3 (6.7)	3 (4.4)
起立性高血圧	0	1 (2.2)	1 (1.5)
起立性低血圧	0	2 (4.4)	2 (2.9)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Sex: Female	N=22	N=15	N=37
Any adverse event	14 (63.6)	10 (66.7)	24 (64.9)
心臓障害	0	1 (6.7)	1 (2.7)
左脚ブロック	0	1 (6.7)	1 (2.7)
耳および迷路障害	0	1 (6.7)	1 (2.7)
回転性めまい	0	1 (6.7)	1 (2.7)
眼障害	1 (4.5)	0	1 (2.7)
硝子体浮遊物	1 (4.5)	0	1 (2.7)
胃腸障害	3 (13.6)	1 (6.7)	4 (10.8)
腹部不快感	0	1 (6.7)	1 (2.7)
便秘	1 (4.5)	1 (6.7)	2 (5.4)
胃潰瘍	1 (4.5)	0	1 (2.7)
胃食道逆流性疾患	1 (4.5)	0	1 (2.7)
一般・全身障害および投与部位の状態	6 (27.3)	3 (20.0)	9 (24.3)
注入部位内出血	1 (4.5)	0	1 (2.7)
注入部位皮膚炎	1 (4.5)	0	1 (2.7)
注入部位紅斑	2 (9.1)	1 (6.7)	3 (8.1)
注入部位血管外漏出	0	1 (6.7)	1 (2.7)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	Dose Category High Dose (N=60) n (%)	All Subjects (N=105) n (%)
Sex: Female (Cont.)	N=22	N=15	N=37
一般・全身障害および投与部位の状態 (Cont.)			
注入部位血腫	1 (4.5)	0	1 (2.7)
注入部位腫瘤	1 (4.5)	0	1 (2.7)
注入部位浮腫	1 (4.5)	0	1 (2.7)
注入部位疼痛	1 (4.5)	1 (6.7)	2 (5.4)
注入部位丘疹	1 (4.5)	1 (6.7)	2 (5.4)
注射部位内出血	1 (4.5)	0	1 (2.7)
注射部位紅斑	1 (4.5)	0	1 (2.7)
穿刺部位紅斑	1 (4.5)	0	1 (2.7)
感染症および寄生虫症	5 (22.7)	4 (26.7)	9 (24.3)
膀胱炎	1 (4.5)	0	1 (2.7)
大腸菌性尿路感染	0	1 (6.7)	1 (2.7)
ヘリコバクター性胃炎	1 (4.5)	0	1 (2.7)
ヘリコバクター感染	1 (4.5)	0	1 (2.7)
注入部位膿瘍	1 (4.5)	0	1 (2.7)
注入部位蜂巣炎	3 (13.6)	3 (20.0)	6 (16.2)
尿路感染	0	2 (13.3)	2 (5.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	Dose Category High Dose (N=60) n (%)	All Subjects (N=105) n (%)
Sex: Female (Cont.)	N=22	N=15	N=37
傷害、中毒および処置合併症	2 (9.1)	3 (20.0)	5 (13.5)
転倒	2 (9.1)	3 (20.0)	5 (13.5)
転位骨折	0	1 (6.7)	1 (2.7)
臨床検査	2 (9.1)	0	2 (5.4)
リンパ球数減少	1 (4.5)	0	1 (2.7)
ビタミンB6減少	1 (4.5)	0	1 (2.7)
代謝および栄養障害	2 (9.1)	1 (6.7)	3 (8.1)
鉄欠乏	1 (4.5)	0	1 (2.7)
ビタミンB12欠乏	1 (4.5)	1 (6.7)	2 (5.4)
筋骨格系および結合組織障害	2 (9.1)	1 (6.7)	3 (8.1)
背部痛	0	1 (6.7)	1 (2.7)
変形性関節症	1 (4.5)	0	1 (2.7)
骨粗鬆症	1 (4.5)	0	1 (2.7)
四肢痛	1 (4.5)	0	1 (2.7)
腱鞘炎	1 (4.5)	0	1 (2.7)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	Dose Category High Dose (N=60) n (%)	All Subjects (N=105) n (%)
Sex: Female (Cont.)	N=22	N=15	N=37
神経系障害	3 (13.6)	5 (33.3)	8 (21.6)
健忘	1 (4.5)	0	1 (2.7)
平衡障害	0	1 (6.7)	1 (2.7)
認知障害	0	1 (6.7)	1 (2.7)
すくみ現象	1 (4.5)	0	1 (2.7)
頭蓋内出血	1 (4.5)	0	1 (2.7)
反射減弱	1 (4.5)	0	1 (2.7)
オンオフ現象	0	3 (20.0)	3 (8.1)
パーキンソン病	0	1 (6.7)	1 (2.7)
失神	0	1 (6.7)	1 (2.7)
振戦	1 (4.5)	0	1 (2.7)
精神障害	5 (22.7)	3 (20.0)	8 (21.6)
激越	0	1 (6.7)	1 (2.7)
不安	1 (4.5)	2 (13.3)	3 (8.1)
歯ぎしり	1 (4.5)	0	1 (2.7)
うつ病	2 (9.1)	0	2 (5.4)
幻覚	1 (4.5)	2 (13.3)	3 (8.1)
幻視	1 (4.5)	0	1 (2.7)
衝動行為	1 (4.5)	0	1 (2.7)
パニック発作	0	1 (6.7)	1 (2.7)
精神病性障害	1 (4.5)	1 (6.7)	2 (5.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Sex: Female (Cont.)	N=22	N=15	N=37
腎および尿路障害	1 (4.5)	1 (6.7)	2 (5.4)
膀胱痙縮	1 (4.5)	0	1 (2.7)
血尿	0	1 (6.7)	1 (2.7)
生殖系および乳房障害	1 (4.5)	0	1 (2.7)
外陰腟乾燥	1 (4.5)	0	1 (2.7)
呼吸器、胸郭および縦隔障害	2 (9.1)	0	2 (5.4)
窒息	1 (4.5)	0	1 (2.7)
誤嚥	1 (4.5)	0	1 (2.7)
呼吸困難	1 (4.5)	0	1 (2.7)
皮膚および皮下組織障害	2 (9.1)	0	2 (5.4)
脱毛症	1 (4.5)	0	1 (2.7)
発疹	1 (4.5)	0	1 (2.7)
蕁麻疹	1 (4.5)	0	1 (2.7)
血管障害	1 (4.5)	3 (20.0)	4 (10.8)
血腫	1 (4.5)	0	1 (2.7)
高血圧	0	1 (6.7)	1 (2.7)
低血圧	0	1 (6.7)	1 (2.7)
表在性血栓性静脈炎	0	1 (6.7)	1 (2.7)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Race: White	N=35	N=55	N=90
Any adverse event	20 (57.1)	38 (69.1)	58 (64.4)
心臓障害	0	1 (1.8)	1 (1.1)
左脚ブロック	0	1 (1.8)	1 (1.1)
耳および迷路障害	0	1 (1.8)	1 (1.1)
回転性めまい	0	1 (1.8)	1 (1.1)
眼障害	1 (2.9)	1 (1.8)	2 (2.2)
眼瞼痙攣	0	1 (1.8)	1 (1.1)
硝子体浮遊物	1 (2.9)	0	1 (1.1)
胃腸障害	4 (11.4)	4 (7.3)	8 (8.9)
腹部不快感	0	1 (1.8)	1 (1.1)
腹部膨満	0	1 (1.8)	1 (1.1)
腹痛	0	1 (1.8)	1 (1.1)
便秘	2 (5.7)	2 (3.6)	4 (4.4)
出血性腸憩室	0	1 (1.8)	1 (1.1)
嚥下障害	1 (2.9)	0	1 (1.1)
胃潰瘍	1 (2.9)	0	1 (1.1)
胃食道逆流性疾患	1 (2.9)	0	1 (1.1)
流涎過多	0	1 (1.8)	1 (1.1)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	Dose Category High Dose (N=60) n (%)	All Subjects (N=105) n (%)
Race: White (Cont.)	N=35	N=55	N=90
一般・全身障害および投与部位の状態	10 (28.6)	16 (29.1)	26 (28.9)
投与部位漏出	1 (2.9)	0	1 (1.1)
薬効欠如	1 (2.9)	0	1 (1.1)
注入部位内出血	2 (5.7)	2 (3.6)	4 (4.4)
注入部位紅斑	6 (17.1)	7 (12.7)	13 (14.4)
注入部位血管外漏出	0	2 (3.6)	2 (2.2)
注入部位血腫	1 (2.9)	1 (1.8)	2 (2.2)
注入部位出血	0	1 (1.8)	1 (1.1)
注入部位硬結	0	1 (1.8)	1 (1.1)
注入部位炎症	0	1 (1.8)	1 (1.1)
注入部位刺激感	1 (2.9)	0	1 (1.1)
注入部位腫瘤	1 (2.9)	0	1 (1.1)
注入部位結節	0	2 (3.6)	2 (2.2)
注入部位浮腫	1 (2.9)	1 (1.8)	2 (2.2)
注入部位疼痛	1 (2.9)	1 (1.8)	2 (2.2)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Race: White (Cont.)	N=35	N=55	N=90
一般・全身障害および投与部位の状態 (Cont.)			
注入部位丘疹	1 (2.9)	3 (5.5)	4 (4.4)
注入部位異常感覚	0	1 (1.8)	1 (1.1)
注入部位発疹	0	1 (1.8)	1 (1.1)
注入部位反応	0	1 (1.8)	1 (1.1)
注入部位腫脹	0	1 (1.8)	1 (1.1)
注射部位内出血	1 (2.9)	0	1 (1.1)
注射部位紅斑	1 (2.9)	0	1 (1.1)
注射部位炎症	0	1 (1.8)	1 (1.1)
注射部位浮腫	0	1 (1.8)	1 (1.1)
末梢性浮腫	0	1 (1.8)	1 (1.1)
穿刺部位紅斑	1 (2.9)	0	1 (1.1)
感染症および寄生虫症	11 (31.4)	11 (20.0)	22 (24.4)
COVID-19	0	1 (1.8)	1 (1.1)
膀胱炎	1 (2.9)	0	1 (1.1)
大腸菌性尿路感染	0	1 (1.8)	1 (1.1)
胃腸炎	1 (2.9)	1 (1.8)	2 (2.2)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Race: White (Cont.)	N=35	N=55	N=90
感染症および寄生虫症 (Cont.)			
ヘリコバクター性胃炎	1 (2.9)	0	1 (1.1)
ヘリコバクター感染	1 (2.9)	0	1 (1.1)
帯状疱疹	0	1 (1.8)	1 (1.1)
注入部位膿瘍	1 (2.9)	0	1 (1.1)
注入部位蜂巣炎	4 (11.4)	7 (12.7)	11 (12.2)
注入部位感染	3 (8.6)	1 (1.8)	4 (4.4)
注射部位感染	0	1 (1.8)	1 (1.1)
上咽頭炎	1 (2.9)	0	1 (1.1)
上気道感染	1 (2.9)	0	1 (1.1)
尿路感染	0	2 (3.6)	2 (2.2)
傷害、中毒および処置合併症	5 (14.3)	10 (18.2)	15 (16.7)
節足動物刺傷	1 (2.9)	0	1 (1.1)
顔面骨骨折	0	1 (1.8)	1 (1.1)
転倒	3 (8.6)	8 (14.5)	11 (12.2)
転位骨折	0	1 (1.8)	1 (1.1)
手骨折	0	2 (3.6)	2 (2.2)
股関節部骨折	1 (2.9)	1 (1.8)	2 (2.2)
上腕骨骨折	0	1 (1.8)	1 (1.1)
四肢損傷	0	1 (1.8)	1 (1.1)
肉離れ	1 (2.9)	0	1 (1.1)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Race: White (Cont.)	N=35	N=55	N=90
傷害、中毒および処置合併症 (Cont.)			
処置による疼痛	0	1 (1.8)	1 (1.1)
臨床検査	3 (8.6)	4 (7.3)	7 (7.8)
血中葉酸減少	0	1 (1.8)	1 (1.1)
血中ホモシステイン増加	1 (2.9)	0	1 (1.1)
リンパ球数減少	1 (2.9)	0	1 (1.1)
プロトロンビン時間延長	0	1 (1.8)	1 (1.1)
ビタミンB12減少	1 (2.9)	0	1 (1.1)
ビタミンB6減少	2 (5.7)	0	2 (2.2)
体重減少	0	3 (5.5)	3 (3.3)
代謝および栄養障害	2 (5.7)	3 (5.5)	5 (5.6)
鉄欠乏	1 (2.9)	1 (1.8)	2 (2.2)
ビタミンB12欠乏	1 (2.9)	2 (3.6)	3 (3.3)
筋骨格系および結合組織障害	1 (2.9)	6 (10.9)	7 (7.8)
背部痛	0	2 (3.6)	2 (2.2)
滑液包炎	0	1 (1.8)	1 (1.1)
出血性関節症	0	1 (1.8)	1 (1.1)
椎間板変性症	0	1 (1.8)	1 (1.1)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Race: White (Cont.)	N=35	N=55	N=90
筋骨格系および結合組織障害 (Cont.)			
筋力低下	0	1 (1.8)	1 (1.1)
筋骨格硬直	0	1 (1.8)	1 (1.1)
変形性関節症	1 (2.9)	0	1 (1.1)
骨粗鬆症	1 (2.9)	1 (1.8)	2 (2.2)
四肢痛	1 (2.9)	0	1 (1.1)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0	1 (1.8)	1 (1.1)
ケラトアカントーマ	0	1 (1.8)	1 (1.1)
神経系障害	4 (11.4)	14 (25.5)	18 (20.0)
健忘	1 (2.9)	0	1 (1.1)
平衡障害	0	1 (1.8)	1 (1.1)
認知障害	1 (2.9)	1 (1.8)	2 (2.2)
注意力障害	0	1 (1.8)	1 (1.1)
ジストニア	0	1 (1.8)	1 (1.1)
すくみ現象	1 (2.9)	1 (1.8)	2 (2.2)
頭蓋内出血	1 (2.9)	0	1 (1.1)
頭部不快感	0	1 (1.8)	1 (1.1)
反射減弱	1 (2.9)	1 (1.8)	2 (2.2)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Race: White (Cont.)	N=35	N=55	N=90
神経系障害 (Cont.)			
記憶障害	0	2 (3.6)	2 (2.2)
オンオフ現象	1 (2.9)	4 (7.3)	5 (5.6)
パーキンソン病	1 (2.9)	3 (5.5)	4 (4.4)
精神運動亢進	0	1 (1.8)	1 (1.1)
失神	0	2 (3.6)	2 (2.2)
一過性脳虚血発作	0	1 (1.8)	1 (1.1)
振戦	1 (2.9)	0	1 (1.1)
精神障害	7 (20.0)	11 (20.0)	18 (20.0)
攻撃性	0	1 (1.8)	1 (1.1)
激越	0	1 (1.8)	1 (1.1)
不安	1 (2.9)	2 (3.6)	3 (3.3)
歯ぎしり	1 (2.9)	0	1 (1.1)
錯乱状態	0	1 (1.8)	1 (1.1)
妄想	0	1 (1.8)	1 (1.1)
抑うつ気分	1 (2.9)	0	1 (1.1)
うつ病	2 (5.7)	1 (1.8)	3 (3.3)
自傷性皮膚症	0	1 (1.8)	1 (1.1)
幻覚	1 (2.9)	5 (9.1)	6 (6.7)
幻視	1 (2.9)	0	1 (1.1)
錯覚	1 (2.9)	0	1 (1.1)
衝動制御障害	0	1 (1.8)	1 (1.1)
衝動行為	1 (2.9)	0	1 (1.1)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Race: White (Cont.)	N=35	N=55	N=90
精神障害 (Cont.)			
パニック発作	0	1 (1.8)	1 (1.1)
妄想症	1 (2.9)	0	1 (1.1)
精神病性障害	1 (2.9)	1 (1.8)	2 (2.2)
レム睡眠行動障害	1 (2.9)	0	1 (1.1)
腎および尿路障害	1 (2.9)	1 (1.8)	2 (2.2)
膀胱痙縮	1 (2.9)	0	1 (1.1)
血尿	0	1 (1.8)	1 (1.1)
生殖系および乳房障害	2 (5.7)	1 (1.8)	3 (3.3)
良性前立腺肥大症	1 (2.9)	0	1 (1.1)
勃起不全	0	1 (1.8)	1 (1.1)
外陰腟乾燥	1 (2.9)	0	1 (1.1)
呼吸器、胸郭および縦隔障害	1 (2.9)	0	1 (1.1)
呼吸困難	1 (2.9)	0	1 (1.1)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Race: White (Cont.)	N=35	N=55	N=90
皮膚および皮下組織障害	4 (11.4)	0	4 (4.4)
光線角化症	1 (2.9)	0	1 (1.1)
脱毛症	1 (2.9)	0	1 (1.1)
湿疹	1 (2.9)	0	1 (1.1)
発疹	1 (2.9)	0	1 (1.1)
蕁麻疹	1 (2.9)	0	1 (1.1)
血管障害	1 (2.9)	6 (10.9)	7 (7.8)
血腫	1 (2.9)	0	1 (1.1)
高血圧	0	1 (1.8)	1 (1.1)
低血圧	0	1 (1.8)	1 (1.1)
起立性高血圧	0	1 (1.8)	1 (1.1)
起立性低血圧	0	2 (3.6)	2 (2.2)
表在性血栓性静脈炎	0	1 (1.8)	1 (1.1)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Race: Asian	N=9	N=5	N=14
Any adverse event	5 (55.6)	3 (60.0)	8 (57.1)
眼障害	0	1 (20.0)	1 (7.1)
眼充血	0	1 (20.0)	1 (7.1)
胃腸障害	1 (11.1)	0	1 (7.1)
便秘	1 (11.1)	0	1 (7.1)
一般・全身障害および投与部位の状態	1 (11.1)	2 (40.0)	3 (21.4)
注入部位皮膚炎	1 (11.1)	0	1 (7.1)
注入部位硬結	0	1 (20.0)	1 (7.1)
注射部位紅斑	0	1 (20.0)	1 (7.1)
注射部位硬結	0	1 (20.0)	1 (7.1)
感染症および寄生虫症	0	1 (20.0)	1 (7.1)
注入部位蜂巣炎	0	1 (20.0)	1 (7.1)
傷害、中毒および処置合併症	0	1 (20.0)	1 (7.1)
転倒	0	1 (20.0)	1 (7.1)
肩甲骨骨折	0	1 (20.0)	1 (7.1)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Race: Asian (Cont.)	N=9	N=5	N=14
臨床検査	1 (11.1)	0	1 (7.1)
血中ホモシステイン増加	1 (11.1)	0	1 (7.1)
代謝および栄養障害	0	1 (20.0)	1 (7.1)
ビタミンB12欠乏	0	1 (20.0)	1 (7.1)
筋骨格系および結合組織障害	1 (11.1)	0	1 (7.1)
腱鞘炎	1 (11.1)	0	1 (7.1)
神経系障害	0	1 (20.0)	1 (7.1)
感覚鈍麻	0	1 (20.0)	1 (7.1)
精神障害	1 (11.1)	0	1 (7.1)
幻覚	1 (11.1)	0	1 (7.1)
呼吸器、胸郭および縦隔障害	1 (11.1)	1 (20.0)	2 (14.3)
窒息	1 (11.1)	0	1 (7.1)
誤嚥	1 (11.1)	0	1 (7.1)
痰貯留	0	1 (20.0)	1 (7.1)
皮膚および皮下組織障害	0	1 (20.0)	1 (7.1)
湿疹	0	1 (20.0)	1 (7.1)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Race: Other	N=1	N=0	N=1
Any adverse event	0	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Age category: <65	N=26	N=34	N=60
Any adverse event	15 (57.7)	19 (55.9)	34 (56.7)
眼障害	0	1 (2.9)	1 (1.7)
眼瞼痙攣	0	1 (2.9)	1 (1.7)
胃腸障害	2 (7.7)	1 (2.9)	3 (5.0)
腹部膨満	0	1 (2.9)	1 (1.7)
腹痛	0	1 (2.9)	1 (1.7)
便秘	1 (3.8)	0	1 (1.7)
胃潰瘍	1 (3.8)	0	1 (1.7)
一般・全身障害および投与部位の状態	5 (19.2)	7 (20.6)	12 (20.0)
注入部位内出血	1 (3.8)	1 (2.9)	2 (3.3)
注入部位紅斑	2 (7.7)	2 (5.9)	4 (6.7)
注入部位血管外漏出	0	2 (5.9)	2 (3.3)
注入部位血腫	1 (3.8)	1 (2.9)	2 (3.3)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Age category: <65 (Cont.)	N=26	N=34	N=60
一般・全身障害および投与部位の状態 (Cont.)			
注入部位硬結	0	1 (2.9)	1 (1.7)
注入部位浮腫	0	1 (2.9)	1 (1.7)
注入部位疼痛	0	1 (2.9)	1 (1.7)
注入部位丘疹	0	1 (2.9)	1 (1.7)
注入部位発疹	0	1 (2.9)	1 (1.7)
注射部位内出血	1 (3.8)	0	1 (1.7)
注射部位紅斑	1 (3.8)	0	1 (1.7)
注射部位炎症	0	1 (2.9)	1 (1.7)
感染症および寄生虫症	5 (19.2)	8 (23.5)	13 (21.7)
COVID-19	0	1 (2.9)	1 (1.7)
胃腸炎	1 (3.8)	1 (2.9)	2 (3.3)
ヘリコバクター感染	1 (3.8)	0	1 (1.7)
注入部位膿瘍	1 (3.8)	0	1 (1.7)
注入部位蜂巣炎	1 (3.8)	5 (14.7)	6 (10.0)
注入部位感染	1 (3.8)	0	1 (1.7)
上咽頭炎	1 (3.8)	0	1 (1.7)
上気道感染	1 (3.8)	0	1 (1.7)
尿路感染	0	2 (5.9)	2 (3.3)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Age category: <65 (Cont.)	N=26	N=34	N=60
傷害、中毒および処置合併症	3 (11.5)	3 (8.8)	6 (10.0)
節足動物刺傷	1 (3.8)	0	1 (1.7)
転倒	1 (3.8)	2 (5.9)	3 (5.0)
手骨折	0	1 (2.9)	1 (1.7)
肉離れ	1 (3.8)	0	1 (1.7)
処置による疼痛	0	1 (2.9)	1 (1.7)
臨床検査	2 (7.7)	2 (5.9)	4 (6.7)
血中ホモシステイン増加	1 (3.8)	0	1 (1.7)
リンパ球数減少	1 (3.8)	0	1 (1.7)
プロトロンビン時間延長	0	1 (2.9)	1 (1.7)
体重減少	0	2 (5.9)	2 (3.3)
代謝および栄養障害	2 (7.7)	4 (11.8)	6 (10.0)
鉄欠乏	1 (3.8)	1 (2.9)	2 (3.3)
ビタミンB12欠乏	1 (3.8)	3 (8.8)	4 (6.7)
筋骨格系および結合組織障害	1 (3.8)	3 (8.8)	4 (6.7)
背部痛	0	1 (2.9)	1 (1.7)
椎間板変性症	0	1 (2.9)	1 (1.7)
筋力低下	0	1 (2.9)	1 (1.7)
筋骨格硬直	0	1 (2.9)	1 (1.7)
腱鞘炎	1 (3.8)	0	1 (1.7)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Age category: <65 (Cont.)	N=26	N=34	N=60
神経系障害	0	8 (23.5)	8 (13.3)
平衡障害	0	1 (2.9)	1 (1.7)
注意力障害	0	1 (2.9)	1 (1.7)
ジストニア	0	1 (2.9)	1 (1.7)
頭部不快感	0	1 (2.9)	1 (1.7)
感覚鈍麻	0	1 (2.9)	1 (1.7)
反射減弱	0	1 (2.9)	1 (1.7)
記憶障害	0	1 (2.9)	1 (1.7)
オンオフ現象	0	2 (5.9)	2 (3.3)
パーキンソン病	0	1 (2.9)	1 (1.7)
精神運動亢進	0	1 (2.9)	1 (1.7)
失神	0	2 (5.9)	2 (3.3)
精神障害	4 (15.4)	3 (8.8)	7 (11.7)
不安	1 (3.8)	0	1 (1.7)
歯ぎしり	1 (3.8)	0	1 (1.7)
妄想	0	1 (2.9)	1 (1.7)
うつ病	0	1 (2.9)	1 (1.7)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Age category: <65 (Cont.)	N=26	N=34	N=60
精神障害 (Cont.)			
幻覚	1 (3.8)	1 (2.9)	2 (3.3)
幻視	1 (3.8)	0	1 (1.7)
錯覚	1 (3.8)	0	1 (1.7)
衝動制御障害	0	1 (2.9)	1 (1.7)
妄想症	1 (3.8)	0	1 (1.7)
腎および尿路障害	1 (3.8)	0	1 (1.7)
膀胱痙縮	1 (3.8)	0	1 (1.7)
生殖系および乳房障害	1 (3.8)	0	1 (1.7)
良性前立腺肥大症	1 (3.8)	0	1 (1.7)
呼吸器、胸郭および縦隔障害	1 (3.8)	0	1 (1.7)
呼吸困難	1 (3.8)	0	1 (1.7)
皮膚および皮下組織障害	2 (7.7)	0	2 (3.3)
光線角化症	1 (3.8)	0	1 (1.7)
蕁麻疹	1 (3.8)	0	1 (1.7)
血管障害	0	3 (8.8)	3 (5.0)
低血圧	0	1 (2.9)	1 (1.7)
起立性高血圧	0	1 (2.9)	1 (1.7)
起立性低血圧	0	1 (2.9)	1 (1.7)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Age category: >=65	N=19	N=26	N=45
Any adverse event	10 (52.6)	22 (84.6)	32 (71.1)
心臓障害	0	1 (3.8)	1 (2.2)
左脚ブロック	0	1 (3.8)	1 (2.2)
耳および迷路障害	0	1 (3.8)	1 (2.2)
回転性めまい	0	1 (3.8)	1 (2.2)
眼障害	1 (5.3)	1 (3.8)	2 (4.4)
眼充血	0	1 (3.8)	1 (2.2)
硝子体浮遊物	1 (5.3)	0	1 (2.2)
胃腸障害	3 (15.8)	3 (11.5)	6 (13.3)
腹部不快感	0	1 (3.8)	1 (2.2)
便秘	2 (10.5)	2 (7.7)	4 (8.9)
出血性腸憩室	0	1 (3.8)	1 (2.2)
嚥下障害	1 (5.3)	0	1 (2.2)
胃食道逆流性疾患	1 (5.3)	0	1 (2.2)
流涎過多	0	1 (3.8)	1 (2.2)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Age category: >=65 (Cont.)	N=19	N=26	N=45
一般・全身障害および投与部位の状態	6 (31.6)	11 (42.3)	17 (37.8)
投与部位漏出	1 (5.3)	0	1 (2.2)
薬効欠如	1 (5.3)	0	1 (2.2)
注入部位内出血	1 (5.3)	1 (3.8)	2 (4.4)
注入部位皮膚炎	1 (5.3)	0	1 (2.2)
注入部位紅斑	4 (21.1)	5 (19.2)	9 (20.0)
注入部位出血	0	1 (3.8)	1 (2.2)
注入部位硬結	0	1 (3.8)	1 (2.2)
注入部位炎症	0	1 (3.8)	1 (2.2)
注入部位刺激感	1 (5.3)	0	1 (2.2)
注入部位腫瘤	1 (5.3)	0	1 (2.2)
注入部位結節	0	2 (7.7)	2 (4.4)
注入部位浮腫	1 (5.3)	0	1 (2.2)
注入部位疼痛	1 (5.3)	0	1 (2.2)
注入部位丘疹	1 (5.3)	2 (7.7)	3 (6.7)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Age category: >=65 (Cont.)	N=19	N=26	N=45
一般・全身障害および投与部位の状態 (Cont.)			
注入部位異常感覚	0	1 (3.8)	1 (2.2)
注入部位反応	0	1 (3.8)	1 (2.2)
注入部位腫脹	0	1 (3.8)	1 (2.2)
注射部位紅斑	0	1 (3.8)	1 (2.2)
注射部位硬結	0	1 (3.8)	1 (2.2)
注射部位浮腫	0	1 (3.8)	1 (2.2)
末梢性浮腫	0	1 (3.8)	1 (2.2)
穿刺部位紅斑	1 (5.3)	0	1 (2.2)
感染症および寄生虫症	6 (31.6)	4 (15.4)	10 (22.2)
膀胱炎	1 (5.3)	0	1 (2.2)
大腸菌性尿路感染	0	1 (3.8)	1 (2.2)
ヘリコバクター性胃炎	1 (5.3)	0	1 (2.2)
帯状疱疹	0	1 (3.8)	1 (2.2)
注入部位蜂巣炎	3 (15.8)	3 (11.5)	6 (13.3)
注入部位感染	2 (10.5)	1 (3.8)	3 (6.7)
注射部位感染	0	1 (3.8)	1 (2.2)
傷害、中毒および処置合併症	2 (10.5)	8 (30.8)	10 (22.2)
顔面骨骨折	0	1 (3.8)	1 (2.2)
転倒	2 (10.5)	7 (26.9)	9 (20.0)
転位骨折	0	1 (3.8)	1 (2.2)
手骨折	0	1 (3.8)	1 (2.2)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Age category: >=65 (Cont.)	N=19	N=26	N=45
傷害、中毒および処置合併症 (Cont.)			
股関節部骨折	1 (5.3)	1 (3.8)	2 (4.4)
上腕骨骨折	0	1 (3.8)	1 (2.2)
四肢損傷	0	1 (3.8)	1 (2.2)
肩甲骨骨折	0	1 (3.8)	1 (2.2)
臨床検査	2 (10.5)	2 (7.7)	4 (8.9)
血中葉酸減少	0	1 (3.8)	1 (2.2)
血中ホモシステイン増加	1 (5.3)	0	1 (2.2)
ビタミンB12減少	1 (5.3)	0	1 (2.2)
ビタミンB6減少	2 (10.5)	0	2 (4.4)
体重減少	0	1 (3.8)	1 (2.2)
筋骨格系および結合組織障害	1 (5.3)	3 (11.5)	4 (8.9)
背部痛	0	1 (3.8)	1 (2.2)
滑液包炎	0	1 (3.8)	1 (2.2)
出血性関節症	0	1 (3.8)	1 (2.2)
変形性関節症	1 (5.3)	0	1 (2.2)
骨粗鬆症	1 (5.3)	1 (3.8)	2 (4.4)
四肢痛	1 (5.3)	0	1 (2.2)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Age category: >=65 (Cont.)	N=19	N=26	N=45
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 (3.8)	1 (2.2)
ケラトアカントーマ	0	1 (3.8)	1 (2.2)
神経系障害	4 (21.1)	7 (26.9)	11 (24.4)
健忘	1 (5.3)	0	1 (2.2)
認知障害	1 (5.3)	1 (3.8)	2 (4.4)
すくみ現象	1 (5.3)	1 (3.8)	2 (4.4)
頭蓋内出血	1 (5.3)	0	1 (2.2)
反射減弱	1 (5.3)	0	1 (2.2)
記憶障害	0	1 (3.8)	1 (2.2)
オンオフ現象	1 (5.3)	2 (7.7)	3 (6.7)
パーキンソン病	1 (5.3)	2 (7.7)	3 (6.7)
一過性脳虚血発作	0	1 (3.8)	1 (2.2)
振戦	1 (5.3)	0	1 (2.2)
精神障害	4 (21.1)	8 (30.8)	12 (26.7)
攻撃性	0	1 (3.8)	1 (2.2)
激越	0	1 (3.8)	1 (2.2)
不安	0	2 (7.7)	2 (4.4)
錯乱状態	0	1 (3.8)	1 (2.2)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Age category: >=65 (Cont.)	N=19	N=26	N=45
精神障害 (Cont.)			
抑うつ気分	1 (5.3)	0	1 (2.2)
うつ病	2 (10.5)	0	2 (4.4)
自傷性皮膚症	0	1 (3.8)	1 (2.2)
幻覚	1 (5.3)	4 (15.4)	5 (11.1)
衝動行為	1 (5.3)	0	1 (2.2)
パニック発作	0	1 (3.8)	1 (2.2)
精神病性障害	1 (5.3)	1 (3.8)	2 (4.4)
レム睡眠行動障害	1 (5.3)	0	1 (2.2)
腎および尿路障害	0	1 (3.8)	1 (2.2)
血尿	0	1 (3.8)	1 (2.2)
生殖系および乳房障害	1 (5.3)	1 (3.8)	2 (4.4)
勃起不全	0	1 (3.8)	1 (2.2)
外陰腟乾燥	1 (5.3)	0	1 (2.2)
呼吸器、胸郭および縦隔障害	1 (5.3)	1 (3.8)	2 (4.4)
窒息	1 (5.3)	0	1 (2.2)
誤嚥	1 (5.3)	0	1 (2.2)
痰貯留	0	1 (3.8)	1 (2.2)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Age category: >=65 (Cont.)	N=19	N=26	N=45
皮膚および皮下組織障害	2 (10.5)	1 (3.8)	3 (6.7)
脱毛症	1 (5.3)	0	1 (2.2)
湿疹	1 (5.3)	1 (3.8)	2 (4.4)
発疹	1 (5.3)	0	1 (2.2)
血管障害	1 (5.3)	3 (11.5)	4 (8.9)
血腫	1 (5.3)	0	1 (2.2)
高血圧	0	1 (3.8)	1 (2.2)
起立性低血圧	0	1 (3.8)	1 (2.2)
表在性血栓性静脈炎	0	1 (3.8)	1 (2.2)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Geographic region: North America	N=17	N=30	N=47
Any adverse event	8 (47.1)	22 (73.3)	30 (63.8)
心臓障害	0	1 (3.3)	1 (2.1)
左脚ブロック	0	1 (3.3)	1 (2.1)
胃腸障害	0	1 (3.3)	1 (2.1)
腹部不快感	0	1 (3.3)	1 (2.1)
便秘	0	1 (3.3)	1 (2.1)
一般・全身障害および投与部位の状態	6 (35.3)	11 (36.7)	17 (36.2)
投与部位漏出	1 (5.9)	0	1 (2.1)
注入部位内出血	1 (5.9)	2 (6.7)	3 (6.4)
注入部位紅斑	4 (23.5)	7 (23.3)	11 (23.4)
注入部位血管外漏出	0	2 (6.7)	2 (4.3)
注入部位出血	0	1 (3.3)	1 (2.1)
注入部位硬結	0	1 (3.3)	1 (2.1)
注入部位結節	0	1 (3.3)	1 (2.1)
注入部位浮腫	0	1 (3.3)	1 (2.1)
注入部位疼痛	1 (5.9)	1 (3.3)	2 (4.3)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Geographic region: North America (Cont.)	N=17	N=30	N=47
一般・全身障害および投与部位の状態 (Cont.)			
注入部位丘疹	0	3 (10.0)	3 (6.4)
注入部位異常感覚	0	1 (3.3)	1 (2.1)
注入部位発疹	0	1 (3.3)	1 (2.1)
注入部位反応	0	1 (3.3)	1 (2.1)
注入部位腫脹	0	1 (3.3)	1 (2.1)
注射部位内出血	1 (5.9)	0	1 (2.1)
注射部位紅斑	1 (5.9)	0	1 (2.1)
注射部位浮腫	0	1 (3.3)	1 (2.1)
穿刺部位紅斑	1 (5.9)	0	1 (2.1)
感染症および寄生虫症	3 (17.6)	9 (30.0)	12 (25.5)
COVID-19	0	1 (3.3)	1 (2.1)
大腸菌性尿路感染	0	1 (3.3)	1 (2.1)
胃腸炎	0	1 (3.3)	1 (2.1)
注入部位蜂巣炎	2 (11.8)	6 (20.0)	8 (17.0)
注入部位感染	1 (5.9)	1 (3.3)	2 (4.3)
尿路感染	0	2 (6.7)	2 (4.3)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Geographic region: North America (Cont.)	N=17	N=30	N=47
傷害、中毒および処置合併症	3 (17.6)	6 (20.0)	9 (19.1)
転倒	3 (17.6)	5 (16.7)	8 (17.0)
転位骨折	0	1 (3.3)	1 (2.1)
手骨折	0	1 (3.3)	1 (2.1)
股関節部骨折	1 (5.9)	0	1 (2.1)
四肢損傷	0	1 (3.3)	1 (2.1)
臨床検査	0	2 (6.7)	2 (4.3)
血中葉酸減少	0	1 (3.3)	1 (2.1)
体重減少	0	1 (3.3)	1 (2.1)
筋骨格系および結合組織障害	0	2 (6.7)	2 (4.3)
背部痛	0	1 (3.3)	1 (2.1)
椎間板変性症	0	1 (3.3)	1 (2.1)
神経系障害	2 (11.8)	6 (20.0)	8 (17.0)
健忘	1 (5.9)	0	1 (2.1)
平衡障害	0	1 (3.3)	1 (2.1)
認知障害	0	1 (3.3)	1 (2.1)
頭蓋内出血	1 (5.9)	0	1 (2.1)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Geographic region: North America (Cont.)	N=17	N=30	N=47
神経系障害 (Cont.)			
反射減弱	1 (5.9)	0	1 (2.1)
記憶障害	0	1 (3.3)	1 (2.1)
オンオフ現象	0	2 (6.7)	2 (4.3)
パーキンソン病	0	1 (3.3)	1 (2.1)
精神運動亢進	0	1 (3.3)	1 (2.1)
失神	0	1 (3.3)	1 (2.1)
精神障害	1 (5.9)	6 (20.0)	7 (14.9)
不安	0	1 (3.3)	1 (2.1)
錯乱状態	0	1 (3.3)	1 (2.1)
妄想	0	1 (3.3)	1 (2.1)
うつ病	1 (5.9)	0	1 (2.1)
自傷性皮膚症	0	1 (3.3)	1 (2.1)
幻覚	0	3 (10.0)	3 (6.4)
パニック発作	0	1 (3.3)	1 (2.1)
精神病性障害	0	1 (3.3)	1 (2.1)
腎および尿路障害	0	1 (3.3)	1 (2.1)
血尿	0	1 (3.3)	1 (2.1)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Geographic region: North America (Cont.)	N=17	N=30	N=47
血管障害	1 (5.9)	3 (10.0)	4 (8.5)
血腫	1 (5.9)	0	1 (2.1)
高血圧	0	1 (3.3)	1 (2.1)
低血圧	0	1 (3.3)	1 (2.1)
表在性血栓性静脈炎	0	1 (3.3)	1 (2.1)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Geographic region: Europe and Australia	N=21	N=26	N=47
Any adverse event	12 (57.1)	16 (61.5)	28 (59.6)
耳および迷路障害	0	1 (3.8)	1 (2.1)
回転性めまい	0	1 (3.8)	1 (2.1)
眼障害	1 (4.8)	1 (3.8)	2 (4.3)
眼瞼痙攣	0	1 (3.8)	1 (2.1)
硝子体浮遊物	1 (4.8)	0	1 (2.1)
胃腸障害	4 (19.0)	3 (11.5)	7 (14.9)
腹部膨満	0	1 (3.8)	1 (2.1)
腹痛	0	1 (3.8)	1 (2.1)
便秘	2 (9.5)	1 (3.8)	3 (6.4)
出血性腸憩室	0	1 (3.8)	1 (2.1)
嚥下障害	1 (4.8)	0	1 (2.1)
胃潰瘍	1 (4.8)	0	1 (2.1)
胃食道逆流性疾患	1 (4.8)	0	1 (2.1)
流涎過多	0	1 (3.8)	1 (2.1)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Geographic region: Europe and Australia (Cont.)	N=21	N=26	N=47
一般・全身障害および投与部位の状態	4 (19.0)	5 (19.2)	9 (19.1)
薬効欠如	1 (4.8)	0	1 (2.1)
注入部位内出血	1 (4.8)	0	1 (2.1)
注入部位紅斑	2 (9.5)	0	2 (4.3)
注入部位血腫	1 (4.8)	1 (3.8)	2 (4.3)
注入部位炎症	0	1 (3.8)	1 (2.1)
注入部位刺激感	1 (4.8)	0	1 (2.1)
注入部位腫瘤	1 (4.8)	0	1 (2.1)
注入部位結節	0	1 (3.8)	1 (2.1)
注入部位浮腫	1 (4.8)	0	1 (2.1)
注入部位丘疹	1 (4.8)	0	1 (2.1)
注射部位炎症	0	1 (3.8)	1 (2.1)
末梢性浮腫	0	1 (3.8)	1 (2.1)
感染症および寄生虫症	8 (38.1)	2 (7.7)	10 (21.3)
膀胱炎	1 (4.8)	0	1 (2.1)
胃腸炎	1 (4.8)	0	1 (2.1)
ヘリコバクター性胃炎	1 (4.8)	0	1 (2.1)
ヘリコバクター感染	1 (4.8)	0	1 (2.1)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Geographic region: Europe and Australia (Cont.)	N=21	N=26	N=47
感染症および寄生虫症 (Cont.)			
帯状疱疹	0	1 (3.8)	1 (2.1)
注入部位膿瘍	1 (4.8)	0	1 (2.1)
注入部位蜂巣炎	2 (9.5)	1 (3.8)	3 (6.4)
注入部位感染	2 (9.5)	0	2 (4.3)
注射部位感染	0	1 (3.8)	1 (2.1)
上咽頭炎	1 (4.8)	0	1 (2.1)
上気道感染	1 (4.8)	0	1 (2.1)
傷害、中毒および処置合併症	2 (9.5)	4 (15.4)	6 (12.8)
節足動物刺傷	1 (4.8)	0	1 (2.1)
顔面骨骨折	0	1 (3.8)	1 (2.1)
転倒	0	3 (11.5)	3 (6.4)
手骨折	0	1 (3.8)	1 (2.1)
股関節部骨折	0	1 (3.8)	1 (2.1)
上腕骨骨折	0	1 (3.8)	1 (2.1)
肉離れ	1 (4.8)	0	1 (2.1)
処置による疼痛	0	1 (3.8)	1 (2.1)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Geographic region: Europe and Australia (Cont.)	N=21	N=26	N=47
臨床検査	3 (14.3)	2 (7.7)	5 (10.6)
血中ホモシステイン増加	1 (4.8)	0	1 (2.1)
リンパ球数減少	1 (4.8)	0	1 (2.1)
プロトロンビン時間延長	0	1 (3.8)	1 (2.1)
ビタミンB12減少	1 (4.8)	0	1 (2.1)
ビタミンB6減少	2 (9.5)	0	2 (4.3)
体重減少	0	2 (7.7)	2 (4.3)
代謝および栄養障害	2 (9.5)	3 (11.5)	5 (10.6)
鉄欠乏	1 (4.8)	1 (3.8)	2 (4.3)
ビタミンB12欠乏	1 (4.8)	2 (7.7)	3 (6.4)
筋骨格系および結合組織障害	1 (4.8)	4 (15.4)	5 (10.6)
背部痛	0	1 (3.8)	1 (2.1)
滑液包炎	0	1 (3.8)	1 (2.1)
出血性関節症	0	1 (3.8)	1 (2.1)
筋力低下	0	1 (3.8)	1 (2.1)
筋骨格硬直	0	1 (3.8)	1 (2.1)
変形性関節症	1 (4.8)	0	1 (2.1)
骨粗鬆症	1 (4.8)	1 (3.8)	2 (4.3)
四肢痛	1 (4.8)	0	1 (2.1)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Geographic region: Europe and Australia (Cont.)	N=21	N=26	N=47
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 (3.8)	1 (2.1)
ケラトアカントーマ	0	1 (3.8)	1 (2.1)
神経系障害	2 (9.5)	8 (30.8)	10 (21.3)
認知障害	1 (4.8)	0	1 (2.1)
注意力障害	0	1 (3.8)	1 (2.1)
ジストニア	0	1 (3.8)	1 (2.1)
すくみ現象	1 (4.8)	1 (3.8)	2 (4.3)
頭部不快感	0	1 (3.8)	1 (2.1)
反射減弱	0	1 (3.8)	1 (2.1)
記憶障害	0	1 (3.8)	1 (2.1)
オンオフ現象	1 (4.8)	2 (7.7)	3 (6.4)
パーキンソン病	1 (4.8)	2 (7.7)	3 (6.4)
失神	0	1 (3.8)	1 (2.1)
一過性脳虚血発作	0	1 (3.8)	1 (2.1)
振戦	1 (4.8)	0	1 (2.1)
精神障害	6 (28.6)	5 (19.2)	11 (23.4)
攻撃性	0	1 (3.8)	1 (2.1)
激越	0	1 (3.8)	1 (2.1)
不安	1 (4.8)	1 (3.8)	2 (4.3)
歯ぎしり	1 (4.8)	0	1 (2.1)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Geographic region: Europe and Australia (Cont.)	N=21	N=26	N=47
精神障害 (Cont.)			
抑うつ気分	1 (4.8)	0	1 (2.1)
うつ病	1 (4.8)	1 (3.8)	2 (4.3)
幻覚	1 (4.8)	2 (7.7)	3 (6.4)
幻視	1 (4.8)	0	1 (2.1)
錯覚	1 (4.8)	0	1 (2.1)
衝動制御障害	0	1 (3.8)	1 (2.1)
衝動行為	1 (4.8)	0	1 (2.1)
妄想症	1 (4.8)	0	1 (2.1)
精神病性障害	1 (4.8)	0	1 (2.1)
レム睡眠行動障害	1 (4.8)	0	1 (2.1)
腎および尿路障害	1 (4.8)	0	1 (2.1)
膀胱痙縮	1 (4.8)	0	1 (2.1)
生殖系および乳房障害	2 (9.5)	1 (3.8)	3 (6.4)
良性前立腺肥大症	1 (4.8)	0	1 (2.1)
勃起不全	0	1 (3.8)	1 (2.1)
外陰腟乾燥	1 (4.8)	0	1 (2.1)
呼吸器、胸郭および縦隔障害	1 (4.8)	0	1 (2.1)
呼吸困難	1 (4.8)	0	1 (2.1)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Geographic region: Europe and Australia (Cont.)	N=21	N=26	N=47
皮膚および皮下組織障害	4 (19.0)	0	4 (8.5)
光線角化症	1 (4.8)	0	1 (2.1)
脱毛症	1 (4.8)	0	1 (2.1)
湿疹	1 (4.8)	0	1 (2.1)
発疹	1 (4.8)	0	1 (2.1)
蕁麻疹	1 (4.8)	0	1 (2.1)
血管障害	0	3 (11.5)	3 (6.4)
起立性高血圧	0	1 (3.8)	1 (2.1)
起立性低血圧	0	2 (7.7)	2 (4.3)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Geographic region: Japan	N=7	N=4	N=11
Any adverse event	5 (71.4)	3 (75.0)	8 (72.7)
眼障害	0	1 (25.0)	1 (9.1)
眼充血	0	1 (25.0)	1 (9.1)
胃腸障害	1 (14.3)	0	1 (9.1)
便秘	1 (14.3)	0	1 (9.1)
一般・全身障害および投与部位の状態	1 (14.3)	2 (50.0)	3 (27.3)
注入部位皮膚炎	1 (14.3)	0	1 (9.1)
注入部位硬結	0	1 (25.0)	1 (9.1)
注射部位紅斑	0	1 (25.0)	1 (9.1)
注射部位硬結	0	1 (25.0)	1 (9.1)
感染症および寄生虫症	0	1 (25.0)	1 (9.1)
注入部位蜂巣炎	0	1 (25.0)	1 (9.1)
傷害、中毒および処置合併症	0	1 (25.0)	1 (9.1)
転倒	0	1 (25.0)	1 (9.1)
肩甲骨骨折	0	1 (25.0)	1 (9.1)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
Geographic region: Japan (Cont.)	N=7	N=4	N=11
臨床検査	1 (14.3)	0	1 (9.1)
血中ホモシステイン増加	1 (14.3)	0	1 (9.1)
代謝および栄養障害	0	1 (25.0)	1 (9.1)
ビタミンB12欠乏	0	1 (25.0)	1 (9.1)
筋骨格系および結合組織障害	1 (14.3)	0	1 (9.1)
腱鞘炎	1 (14.3)	0	1 (9.1)
神経系障害	0	1 (25.0)	1 (9.1)
感覚鈍麻	0	1 (25.0)	1 (9.1)
精神障害	1 (14.3)	0	1 (9.1)
幻覚	1 (14.3)	0	1 (9.1)
呼吸器、胸郭および縦隔障害	1 (14.3)	1 (25.0)	2 (18.2)
窒息	1 (14.3)	0	1 (9.1)
誤嚥	1 (14.3)	0	1 (9.1)
痰貯留	0	1 (25.0)	1 (9.1)
皮膚および皮下組織障害	0	1 (25.0)	1 (9.1)
湿疹	0	1 (25.0)	1 (9.1)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
PD duration: < 10 years	N=27	N=35	N=62
Any adverse event	16 (59.3)	21 (60.0)	37 (59.7)
耳および迷路障害	0	1 (2.9)	1 (1.6)
回転性めまい	0	1 (2.9)	1 (1.6)
眼障害	1 (3.7)	2 (5.7)	3 (4.8)
眼瞼痙攣	0	1 (2.9)	1 (1.6)
眼充血	0	1 (2.9)	1 (1.6)
硝子体浮遊物	1 (3.7)	0	1 (1.6)
胃腸障害	4 (14.8)	1 (2.9)	5 (8.1)
腹部膨満	0	1 (2.9)	1 (1.6)
腹痛	0	1 (2.9)	1 (1.6)
便秘	2 (7.4)	0	2 (3.2)
胃潰瘍	1 (3.7)	0	1 (1.6)
胃食道逆流性疾患	1 (3.7)	0	1 (1.6)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
PD duration: < 10 years (Cont.)	N=27	N=35	N=62
一般・全身障害および投与部位の状態	5 (18.5)	8 (22.9)	13 (21.0)
投与部位漏出	1 (3.7)	0	1 (1.6)
注入部位内出血	1 (3.7)	2 (5.7)	3 (4.8)
注入部位紅斑	4 (14.8)	3 (8.6)	7 (11.3)
注入部位血管外漏出	0	1 (2.9)	1 (1.6)
注入部位血腫	0	1 (2.9)	1 (1.6)
注入部位出血	0	1 (2.9)	1 (1.6)
注入部位結節	0	2 (5.7)	2 (3.2)
注入部位疼痛	1 (3.7)	0	1 (1.6)
注入部位異常感覚	0	1 (2.9)	1 (1.6)
注入部位腫脹	0	1 (2.9)	1 (1.6)
注射部位炎症	0	1 (2.9)	1 (1.6)
注射部位浮腫	0	1 (2.9)	1 (1.6)
穿刺部位紅斑	1 (3.7)	0	1 (1.6)
感染症および寄生虫症	7 (25.9)	8 (22.9)	15 (24.2)
COVID-19	0	1 (2.9)	1 (1.6)
大腸菌性尿路感染	0	1 (2.9)	1 (1.6)
胃腸炎	1 (3.7)	1 (2.9)	2 (3.2)
ヘリコバクター性胃炎	1 (3.7)	0	1 (1.6)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
PD duration: < 10 years (Cont.)	N=27	N=35	N=62
感染症および寄生虫症 (Cont.)			
ヘリコバクター感染	1 (3.7)	0	1 (1.6)
帯状疱疹	0	1 (2.9)	1 (1.6)
注入部位膿瘍	1 (3.7)	0	1 (1.6)
注入部位蜂巣炎	2 (7.4)	4 (11.4)	6 (9.7)
注入部位感染	2 (7.4)	1 (2.9)	3 (4.8)
注射部位感染	0	1 (2.9)	1 (1.6)
上咽頭炎	1 (3.7)	0	1 (1.6)
上気道感染	1 (3.7)	0	1 (1.6)
尿路感染	0	1 (2.9)	1 (1.6)
傷害、中毒および処置合併症	4 (14.8)	5 (14.3)	9 (14.5)
節足動物刺傷	1 (3.7)	0	1 (1.6)
転倒	2 (7.4)	4 (11.4)	6 (9.7)
転位骨折	0	1 (2.9)	1 (1.6)
股関節部骨折	1 (3.7)	0	1 (1.6)
肉離れ	1 (3.7)	0	1 (1.6)
処置による疼痛	0	1 (2.9)	1 (1.6)
肩甲骨骨折	0	1 (2.9)	1 (1.6)
臨床検査	1 (3.7)	1 (2.9)	2 (3.2)
血中ホモシステイン増加	1 (3.7)	0	1 (1.6)
体重減少	0	1 (2.9)	1 (1.6)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
PD duration: < 10 years (Cont.)	N=27	N=35	N=62
代謝および栄養障害	2 (7.4)	3 (8.6)	5 (8.1)
鉄欠乏	1 (3.7)	1 (2.9)	2 (3.2)
ビタミンB12欠乏	1 (3.7)	2 (5.7)	3 (4.8)
筋骨格系および結合組織障害	1 (3.7)	1 (2.9)	2 (3.2)
背部痛	0	1 (2.9)	1 (1.6)
腱鞘炎	1 (3.7)	0	1 (1.6)
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 (2.9)	1 (1.6)
ケラトアカントーマ	0	1 (2.9)	1 (1.6)
神経系障害	0	6 (17.1)	6 (9.7)
平衡障害	0	1 (2.9)	1 (1.6)
認知障害	0	1 (2.9)	1 (1.6)
注意力障害	0	1 (2.9)	1 (1.6)
頭部不快感	0	1 (2.9)	1 (1.6)
記憶障害	0	1 (2.9)	1 (1.6)
オンオフ現象	0	2 (5.7)	2 (3.2)
精神運動亢進	0	1 (2.9)	1 (1.6)
失神	0	1 (2.9)	1 (1.6)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
PD duration: < 10 years (Cont.)	N=27	N=35	N=62
精神障害	5 (18.5)	5 (14.3)	10 (16.1)
激越	0	1 (2.9)	1 (1.6)
不安	1 (3.7)	2 (5.7)	3 (4.8)
歯ぎしり	1 (3.7)	0	1 (1.6)
妄想	0	1 (2.9)	1 (1.6)
うつ病	1 (3.7)	1 (2.9)	2 (3.2)
幻覚	2 (7.4)	2 (5.7)	4 (6.5)
錯覚	1 (3.7)	0	1 (1.6)
衝動制御障害	0	1 (2.9)	1 (1.6)
パニック発作	0	1 (2.9)	1 (1.6)
妄想症	1 (3.7)	0	1 (1.6)
精神病性障害	1 (3.7)	1 (2.9)	2 (3.2)
生殖系および乳房障害	1 (3.7)	0	1 (1.6)
良性前立腺肥大症	1 (3.7)	0	1 (1.6)
呼吸器、胸郭および縦隔障害	1 (3.7)	1 (2.9)	2 (3.2)
呼吸困難	1 (3.7)	0	1 (1.6)
痰貯留	0	1 (2.9)	1 (1.6)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
PD duration: < 10 years (Cont.)	N=27	N=35	N=62
皮膚および皮下組織障害	3 (11.1)	1 (2.9)	4 (6.5)
光線角化症	1 (3.7)	0	1 (1.6)
脱毛症	1 (3.7)	0	1 (1.6)
湿疹	0	1 (2.9)	1 (1.6)
発疹	1 (3.7)	0	1 (1.6)
蕁麻疹	1 (3.7)	0	1 (1.6)
血管障害	1 (3.7)	3 (8.6)	4 (6.5)
血腫	1 (3.7)	0	1 (1.6)
高血圧	0	1 (2.9)	1 (1.6)
低血圧	0	1 (2.9)	1 (1.6)
表在性血栓性静脈炎	0	1 (2.9)	1 (1.6)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
PD duration: >= 10 years	N=18	N=25	N=43
Any adverse event	9 (50.0)	20 (80.0)	29 (67.4)
心臓障害	0	1 (4.0)	1 (2.3)
左脚ブロック	0	1 (4.0)	1 (2.3)
胃腸障害	1 (5.6)	3 (12.0)	4 (9.3)
腹部不快感	0	1 (4.0)	1 (2.3)
便秘	1 (5.6)	2 (8.0)	3 (7.0)
出血性腸憩室	0	1 (4.0)	1 (2.3)
嚥下障害	1 (5.6)	0	1 (2.3)
流涎過多	0	1 (4.0)	1 (2.3)
一般・全身障害および投与部位の状態	6 (33.3)	10 (40.0)	16 (37.2)
薬効欠如	1 (5.6)	0	1 (2.3)
注入部位内出血	1 (5.6)	0	1 (2.3)
注入部位皮膚炎	1 (5.6)	0	1 (2.3)
注入部位紅斑	2 (11.1)	4 (16.0)	6 (14.0)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
PD duration: >= 10 years (Cont.)	N=18	N=25	N=43
一般・全身障害および投与部位の状態 (Cont.)			
注入部位血管外漏出	0	1 (4.0)	1 (2.3)
注入部位血腫	1 (5.6)	0	1 (2.3)
注入部位硬結	0	2 (8.0)	2 (4.7)
注入部位炎症	0	1 (4.0)	1 (2.3)
注入部位刺激感	1 (5.6)	0	1 (2.3)
注入部位腫瘤	1 (5.6)	0	1 (2.3)
注入部位浮腫	1 (5.6)	1 (4.0)	2 (4.7)
注入部位疼痛	0	1 (4.0)	1 (2.3)
注入部位丘疹	1 (5.6)	3 (12.0)	4 (9.3)
注入部位発疹	0	1 (4.0)	1 (2.3)
注入部位反応	0	1 (4.0)	1 (2.3)
注射部位内出血	1 (5.6)	0	1 (2.3)
注射部位紅斑	1 (5.6)	1 (4.0)	2 (4.7)
注射部位硬結	0	1 (4.0)	1 (2.3)
末梢性浮腫	0	1 (4.0)	1 (2.3)
感染症および寄生虫症	4 (22.2)	4 (16.0)	8 (18.6)
膀胱炎	1 (5.6)	0	1 (2.3)
注入部位蜂巣炎	2 (11.1)	4 (16.0)	6 (14.0)
注入部位感染	1 (5.6)	0	1 (2.3)
尿路感染	0	1 (4.0)	1 (2.3)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
PD duration: >= 10 years (Cont.)	N=18	N=25	N=43
傷害、中毒および処置合併症	1 (5.6)	6 (24.0)	7 (16.3)
顔面骨骨折	0	1 (4.0)	1 (2.3)
転倒	1 (5.6)	5 (20.0)	6 (14.0)
手骨折	0	2 (8.0)	2 (4.7)
股関節部骨折	0	1 (4.0)	1 (2.3)
上腕骨骨折	0	1 (4.0)	1 (2.3)
四肢損傷	0	1 (4.0)	1 (2.3)
臨床検査	3 (16.7)	3 (12.0)	6 (14.0)
血中葉酸減少	0	1 (4.0)	1 (2.3)
血中ホモシステイン増加	1 (5.6)	0	1 (2.3)
リンパ球数減少	1 (5.6)	0	1 (2.3)
プロトロンビン時間延長	0	1 (4.0)	1 (2.3)
ビタミンB12減少	1 (5.6)	0	1 (2.3)
ビタミンB6減少	2 (11.1)	0	2 (4.7)
体重減少	0	2 (8.0)	2 (4.7)
代謝および栄養障害	0	1 (4.0)	1 (2.3)
ビタミンB12欠乏	0	1 (4.0)	1 (2.3)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
PD duration: >= 10 years (Cont.)	N=18	N=25	N=43
筋骨格系および結合組織障害	1 (5.6)	5 (20.0)	6 (14.0)
背部痛	0	1 (4.0)	1 (2.3)
滑液包炎	0	1 (4.0)	1 (2.3)
出血性関節症	0	1 (4.0)	1 (2.3)
椎間板変性症	0	1 (4.0)	1 (2.3)
筋力低下	0	1 (4.0)	1 (2.3)
筋骨格硬直	0	1 (4.0)	1 (2.3)
変形性関節症	1 (5.6)	0	1 (2.3)
骨粗鬆症	1 (5.6)	1 (4.0)	2 (4.7)
四肢痛	1 (5.6)	0	1 (2.3)
神経系障害	4 (22.2)	9 (36.0)	13 (30.2)
健忘	1 (5.6)	0	1 (2.3)
認知障害	1 (5.6)	0	1 (2.3)
ジストニア	0	1 (4.0)	1 (2.3)
すくみ現象	1 (5.6)	1 (4.0)	2 (4.7)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
PD duration: >= 10 years (Cont.)	N=18	N=25	N=43
神経系障害 (Cont.)			
頭蓋内出血	1 (5.6)	0	1 (2.3)
感覚鈍麻	0	1 (4.0)	1 (2.3)
反射減弱	1 (5.6)	1 (4.0)	2 (4.7)
記憶障害	0	1 (4.0)	1 (2.3)
オンオフ現象	1 (5.6)	2 (8.0)	3 (7.0)
パーキンソン病	1 (5.6)	3 (12.0)	4 (9.3)
失神	0	1 (4.0)	1 (2.3)
一過性脳虚血発作	0	1 (4.0)	1 (2.3)
振戦	1 (5.6)	0	1 (2.3)
精神障害	3 (16.7)	6 (24.0)	9 (20.9)
攻撃性	0	1 (4.0)	1 (2.3)
錯乱状態	0	1 (4.0)	1 (2.3)
抑うつ気分	1 (5.6)	0	1 (2.3)
うつ病	1 (5.6)	0	1 (2.3)
自傷性皮膚症	0	1 (4.0)	1 (2.3)
幻覚	0	3 (12.0)	3 (7.0)
幻視	1 (5.6)	0	1 (2.3)
衝動行為	1 (5.6)	0	1 (2.3)
レム睡眠行動障害	1 (5.6)	0	1 (2.3)
腎および尿路障害	1 (5.6)	1 (4.0)	2 (4.7)
膀胱痙縮	1 (5.6)	0	1 (2.3)
血尿	0	1 (4.0)	1 (2.3)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.3

Subjects with Treatment-Emergent Adverse Events by Subgroups
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=45) n (%)	 High Dose (N=60) n (%)	 All Subjects (N=105) n (%)
PD duration: >= 10 years (Cont.)	N=18	N=25	N=43
生殖系および乳房障害	1 (5.6)	1 (4.0)	2 (4.7)
勃起不全	0	1 (4.0)	1 (2.3)
外陰腟乾燥	1 (5.6)	0	1 (2.3)
呼吸器、胸郭および縦隔障害	1 (5.6)	0	1 (2.3)
窒息	1 (5.6)	0	1 (2.3)
誤嚥	1 (5.6)	0	1 (2.3)
皮膚および皮下組織障害	1 (5.6)	0	1 (2.3)
湿疹	1 (5.6)	0	1 (2.3)
血管障害	0	3 (12.0)	3 (7.0)
起立性高血圧	0	1 (4.0)	1 (2.3)
起立性低血圧	0	2 (8.0)	2 (4.7)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

表43　治験薬との因果関係別の有害事象（安全性解析対象集団，日本人部分集団）：M15-737試験

[redacted]20[redacted] 04:22 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.3__1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=7) n (%)	Dose Category High Dose (N=4) n (%)	All Subjects (N=11) n (%)
Any adverse event	5 (71.4)	3 (75.0)	8 (72.7)
No reasonable possibility	2 (28.6)	1 (25.0)	3 (27.3)
Reasonable possibility	3 (42.9)	2 (50.0)	5 (45.5)
眼障害	0	1 (25.0)	1 (9.1)
No reasonable possibility	0	1 (25.0)	1 (9.1)
眼充血	0	1 (25.0)	1 (9.1)
No reasonable possibility	0	1 (25.0)	1 (9.1)
胃腸障害	1 (14.3)	0	1 (9.1)
No reasonable possibility	1 (14.3)	0	1 (9.1)
便秘	1 (14.3)	0	1 (9.1)
No reasonable possibility	1 (14.3)	0	1 (9.1)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=7) n (%)	 High Dose (N=4) n (%)	 All Subjects (N=11) n (%)
一般・全身障害および投与部位の状態	1 (14.3)	2 (50.0)	3 (27.3)
Reasonable possibility	1 (14.3)	2 (50.0)	3 (27.3)
注入部位皮膚炎	1 (14.3)	0	1 (9.1)
Reasonable possibility	1 (14.3)	0	1 (9.1)
注入部位硬結	0	1 (25.0)	1 (9.1)
Reasonable possibility	0	1 (25.0)	1 (9.1)
注射部位紅斑	0	1 (25.0)	1 (9.1)
Reasonable possibility	0	1 (25.0)	1 (9.1)
注射部位硬結	0	1 (25.0)	1 (9.1)
Reasonable possibility	0	1 (25.0)	1 (9.1)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=7) n (%)	 High Dose (N=4) n (%)	 All Subjects (N=11) n (%)
感染症および寄生虫症	0	1 (25.0)	1 (9.1)
Reasonable possibility	0	1 (25.0)	1 (9.1)
注入部位蜂巣炎	0	1 (25.0)	1 (9.1)
Reasonable possibility	0	1 (25.0)	1 (9.1)
傷害、中毒および処置合併症	0	1 (25.0)	1 (9.1)
No reasonable possibility	0	1 (25.0)	1 (9.1)
転倒	0	1 (25.0)	1 (9.1)
No reasonable possibility	0	1 (25.0)	1 (9.1)
肩甲骨骨折	0	1 (25.0)	1 (9.1)
No reasonable possibility	0	1 (25.0)	1 (9.1)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=7) n (%)	 High Dose (N=4) n (%)	 All Subjects (N=11) n (%)
臨床検査	1 (14.3)	0	1 (9.1)
Reasonable possibility	1 (14.3)	0	1 (9.1)
血中ホモシステイン増加	1 (14.3)	0	1 (9.1)
Reasonable possibility	1 (14.3)	0	1 (9.1)
代謝および栄養障害	0	1 (25.0)	1 (9.1)
Reasonable possibility	0	1 (25.0)	1 (9.1)
ビタミンB12欠乏	0	1 (25.0)	1 (9.1)
Reasonable possibility	0	1 (25.0)	1 (9.1)
筋骨格系および結合組織障害	1 (14.3)	0	1 (9.1)
No reasonable possibility	1 (14.3)	0	1 (9.1)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=7) n (%)	 High Dose (N=4) n (%)	 All Subjects (N=11) n (%)
筋骨格系および結合組織障害 (Cont.)			
腱鞘炎	1 (14.3)	0	1 (9.1)
No reasonable possibility	1 (14.3)	0	1 (9.1)
神経系障害	0	1 (25.0)	1 (9.1)
No reasonable possibility	0	1 (25.0)	1 (9.1)
感覚鈍麻	0	1 (25.0)	1 (9.1)
No reasonable possibility	0	1 (25.0)	1 (9.1)
精神障害	1 (14.3)	0	1 (9.1)
Reasonable possibility	1 (14.3)	0	1 (9.1)
幻覚	1 (14.3)	0	1 (9.1)
Reasonable possibility	1 (14.3)	0	1 (9.1)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=7) n (%)	 High Dose (N=4) n (%)	 All Subjects (N=11) n (%)
呼吸器、胸郭および縦隔障害	1 (14.3)	1 (25.0)	2 (18.2)
No reasonable possibility	1 (14.3)	1 (25.0)	2 (18.2)
窒息	1 (14.3)	0	1 (9.1)
No reasonable possibility	1 (14.3)	0	1 (9.1)
誤嚥	1 (14.3)	0	1 (9.1)
No reasonable possibility	1 (14.3)	0	1 (9.1)
痰貯留	0	1 (25.0)	1 (9.1)
No reasonable possibility	0	1 (25.0)	1 (9.1)
皮膚および皮下組織障害	0	1 (25.0)	1 (9.1)
No reasonable possibility	0	1 (25.0)	1 (9.1)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=7) n (%)	Dose Category High Dose (N=4) n (%)	All Subjects (N=11) n (%)
皮膚および皮下組織障害 (Cont.)			
湿疹	0	1 (25.0)	1 (9.1)
No reasonable possibility	0	1 (25.0)	1 (9.1)

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.

Program Source Code: [redacted]

表44　重篤な有害事象（安全性解析対象集団，日本人部分集団）：M15-737試験

[redacted]20[redacted] 04:22 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.3__1.11.1.J

Subjects with Treatment-Emergent Serious Adverse Events
by Primary System Organ Class and Preferred Term
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=7) n (%)	 High Dose (N=4) n (%)	 All Subjects (N=11) n (%)
Any adverse event	1 (14.3)	1 (25.0)	2 (18.2)
傷害、中毒および処置合併症	0	1 (25.0)	1 (9.1)
肩甲骨骨折	0	1 (25.0)	1 (9.1)
呼吸器、胸郭および縦隔障害	1 (14.3)	0	1 (9.1)
窒息	1 (14.3)	0	1 (9.1)
誤嚥	1 (14.3)	0	1 (9.1)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

表45　中止に至った有害事象（安全性解析対象集団，日本人部分集団）：M15-737試験

[redacted]20[redacted] 04:22 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.3__1.8.1.J

Subjects with Treatment-Emergent Adverse Events
Leading to Study Drug Premature Discontinuation (Withdrawn) by Primary System
Organ Class and Preferred Term
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=7) n (%)	 High Dose (N=4) n (%)	 All Subjects (N=11) n (%)
Any adverse event	1 (14.3)	0	1 (9.1)
呼吸器、胸郭および縦隔障害	1 (14.3)	0	1 (9.1)
窒息	1 (14.3)	0	1 (9.1)
誤嚥	1 (14.3)	0	1 (9.1)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
転倒	X			X
転位骨折	X			X

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	6[redacted]	FEMALE	WHITE

Medical History	Onset Year
OSTEPENIA	20[redacted]
POST-MENOPAUSAL	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
ONSET OF MOTOR FLUCTUATION	20[redacted]
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]

Prior Procedures	Procedure Year
NOT REPORTED	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	LESS THAN 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.47	0.50	0.43	60	0.19	[redacted] / 364
ABBV-951	0.50	0.54	0.47	60	0.19	[redacted] / 532

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	908.39		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
M15-741 /ABBV-951	1639.2		SC / CONTINUOUS	[redacted] / 2	[redacted] / 5
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 4	
M15-741 /ABBV-951	1454.79		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
M15-741 /ABBV-951	204.9		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
M15-741 /ABBV-951	1639.2		SC / CONTINUOUS	[redacted] / 8	[redacted] / 10
M15-741 /ABBV-951	1654.56		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
M15-741 /ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 12	[redacted] / 22
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 13	
M15-741 /ABBV-951	1541.87		SC / CONTINUOUS	[redacted] / 23	[redacted] / 23
M15-741 /ABBV-951	240.75		SC / CONTINUOUS	[redacted] / 24	[redacted] / 24

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
NOT REPORTED			

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
PARACETAMOL	1000 mg	TID	Y-M: 20[redacted] / 523	NOT REPORTED
MACROGOL 3350	17 g	QD	Y-M: 20[redacted] / 523	Y-M: 20[redacted] / 527
OXYCODONE	5 mg	OTHER: EVERY 4 HOURS	Y-M: 20[redacted] / 523	Y-M: 20[redacted] / 528
CELECOXIB	100 mg	BID	Y-M: 20[redacted] / 523	Y-M: 20[redacted] / 539

Event #1: Serious Adverse Event, Event of Interest - Falls and Associated Injuries

Event Description	MECHANICAL FALL
Preferred Term	転倒
AE Onset Date / Rx Day	[redacted] / 523
Age at AE Onset	6[redacted]

Laboratory Testing

NOT REPORTED

Microbiology

NOT REPORTED

SAE Supplemental Procedure

NOT REPORTED

AE Stopped Rx Day	523
Duration of AE	1 DAY
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
Other Cause of Event	POOR BALANCE DUE TO PD
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #2: Serious Adverse Event, Event of Interest - Falls and Associated Injuries

Event Description	CLOSED DISPLACED FRACTURE OF LEFT FEMORAL NECK
Preferred Term	転位骨折
AE Onset Date / Rx Day	[redacted]20[redacted] / 523
Age at AE Onset	6[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 523): Albumin: 44 [33 - 48] G/L; Alkaline Phosphatase: 99 [35 - 115] U/L; Basophils: 0.03 [0 - 0.1] 10^9/L; Bilirubin: 15 [2 - 26] UMOL/L; Blood: TRACE [NOT REPORTED - NOT REPORTED] NEG; Blood Urea Nitrogen: 7.1 [2.9 - 8.9] MMOL/L; Calcium: 2.47 [2.12 - 2.62] MMOL/L; Chloride: 106 [99 - 109] MMOL/L; Creatinine: 57 [44 - 88] UMOL/L; Eosinophils/Leukocytes: 0 [1 - 4] %; Ery. Mean Corpuscular HGB Concentration: 323 [320 - 355] G/L; Ery. Mean Corpuscular Hemoglobin: 29.8 [27 - 34] PG; Erythrocytes: 3.93 [3.7 - 5.1] mU/L; Glucose: 6.4 [3.6 - 5.5] MMOL/L; Glucose: NEG [82.8724 - 115.3008] mg/dL; Hematocrit: 0.36 [0.34 - 0.46] FRACTION OF 1; Hemoglobin: 117 [113 - 155] G/L; Ketones: TRACE [NOT REPORTED - NOT REPORTED] NEG; Leukocytes: 15.2 [3.8 - 11] 10^9/L; Lymphocytes: 0.86 [1 - 3.9] 10^9/L; Lymphocytes/Leukocytes: 5.6 [20 - 44] %; Monocytes: 0.89 [0 - 0.8] 10^9/L; Monocytes/Leukocytes: 5.8 [2 - 9] %; Neutrophils: 13.37 [1.9 - 7.4] 10^9/L; Platelets: 174 [150 - 400] 10^9/L; Potassium: 4.1 [3.5 - 4.9] MMOL/L; Protein: 72 [63 - 82] G/L; Prothrombin Time: 13 [12 - 14] SEC; Sodium: 138 [135 - 145] MMOL/L

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 525): TOTAL HIP ARTHROPLASTY:TOTAL HIP ARTHROPLASTY COMPLETED ON

[redacted]20[redacted]

AE Stopped Rx Day	525
Duration of AE	3 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
Other Cause of Event	MECHANICAL FALL
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Generated: [redacted]20[redacted]:09:38
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者は米国の 6[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に左大腿頚部の閉鎖転位骨折及び機械的転倒を発現した。

Event 1 及び 2 の臨床経過：

関連する病歴は，骨減少症，パーキンソン病，閉経，非喫煙者，及び飲酒者（1 日 2 杯未満）であった。

投与 523 日目，被験者は左大腿頚部の閉鎖転位骨折及び機械的転倒を発現した。投与 523 日目，機械的転倒は消失した。投与 525 日目，左大腿頚部の閉鎖転位骨折は消失した。

投与 523 日目，被験者は自宅の玄関の階段から誤って機械的転倒し，左臀部を痛めたため救急診療部に来院した。救急診療部で行われた X 線検査により左大腿頚部の閉鎖転位骨折が認められ，被験者は入院した。投与 525 日目，整形外科医にかかり，完全股関節形成術が予定され，同日完了した。被験者は必要に応じて経口鎮痛剤が投与された。投与 527 日目，被験者は退院した。

被験者に MIRALAX，CELEBREX，オキシコドン，及びアセトアミノフェンが投与された。

Causality for ABBV-951 (Open Label)

---

1) Fracture displacement (10053206) (Fracture displacement (10053206)) [v.24.1] [10053206]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

2) Fall (10016173) (Fall (10016173)) [v.24.1] [10016173]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of CLOSED DISPLACED FRATURE OF LEFT FEMORAL NECK

- Investigator: Mechanical fall

- AbbVie: More likely a related to current mechanical fall in an elderly female with history of osteopenia.

Event of MECHANICAL FALL

- Investigator: Poor balance due to PD (Parkinson's disease)

- AbbVie: More likely related to missing the front step on the home stairs, age, and Parkinson disease.

Relevant Laboratory & Other Diagnostic Tests

[redacted] 20[redacted] **ALBUMIN:** 4.4 G/DL (normal 3.3 to 4.8)

[redacted] 20[redacted] **ALKALINE PHOSPHATASE:** 99 U/L (normal 35 to 115)

[redacted] 20[redacted] **BASOPHILS ABS:** 0.03 K/UL (normal 0.00 to 0.10)

[redacted] 20[redacted] **BLOOD UREA NITROGEN:** 20 mg/dL (normal 8 to 25)

[redacted] 20[redacted] **BLOOD URINE:** Trace, no reference range

[redacted] 20[redacted] **CALCIUM:** 9.9 mg/dL (normal 8.5 to 10.5)

[redacted] 20[redacted] **CHLORIDE:** 106 MMOL/L (normal 99 to 109)

[redacted] 20[redacted] **CREATININE:** 0.64 mg/dL (normal 0.50 to 1.00)

[redacted] 20[redacted] **EOSINOPHILS:** 0.00%

[redacted] 20[redacted] **GLUCOSE:** 116 mg/dL (normal 65 to 99)

[redacted] 20[redacted] **HEMATOCRIT:** 36.2% (normal 34.0 to 46.0)

[redacted] 20[redacted] **HEMOGLOBIN:** 11.7 G/DL (normal 11.3 to 15.5)

[redacted] 20[redacted] **LYMPHOCYTES:** 5.60%

[redacted] 20[redacted] **LYMPHOCYTES ABS:** 0.86 K/UL (normal 1.00 to 3.90)

[redacted] 20[redacted] **MCH:** 29.8 PG (normal 27.0 to 34.0)

[redacted] 20[redacted] **MCHC:** 32.3 G/DL (normal 32.0 to 35.5)

[redacted] 20[redacted] **MONOCYTES:** 5.80%

[redacted] 20[redacted] **MONOCYTES ABS:** 0.89 K/UL (normal 0.00 to 0.80)

[redacted] 20[redacted] **NEUTROPHILS ABS:** 13.37 K/UL (normal 1.90 to 7.40)

[redacted] 20[redacted] **PLATELET COUNT:** 174 K/UL (normal 150 to 400)

[redacted] 20[redacted] **POTASSIUM:** 4.1 MMOL/L (normal 3.5 to 4.9)

[redacted] 20[redacted] **PROTHROMBIN TIME:** 13.2 SEC (normal 11.7 to 14.4)

[redacted] 20[redacted] **RBC:** 3.93 mU/L (normal 3.70 to 5.10)

[redacted] 20[redacted] **SODIUM:** 138 MMOL/L (normal 135 to 145)

[redacted] 20[redacted] **TOTAL BILIRUBIN:** 0.9 mg/dL (normal 0.1 to 1.5)

[redacted] 20[redacted] **TOTAL PROTEIN:** 7.2 G/DL (normal 6.3 to 8.2)

[redacted] 20[redacted] **URINE GLUCOSE:** Negative, no reference range

[redacted] 20[redacted] **URINE KETONES:** Trace, no reference range

[redacted] 20[redacted] **WHITE BLOOD CELLS:** 5.23 K/UL (normal 3.8 to 11)

[redacted] 20[redacted] **X-RAY:** CLOSED DISPLACED FRACTURE OF LEFT FEMORAL NECK.

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
血中ナトリウム減少	X			

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	7[redacted]	MALE	AMERICAN INDIAN OR ALASKA NATIVE

Medical History	Onset Year
PARKINSON'S DISEASE	20[redacted]
DECREASED SODIUM LEVELS	20[redacted]
NAUSEA	20[redacted]
CONSTIPATION	20[redacted]
GERD	20[redacted]
HYPERTENSION	20[redacted]
BILATERAL MILD ANKLE EDEMA	20[redacted]
OVERACTIVE BLADDER	20[redacted]
DRY EYES	20[redacted]
DEPRESSION	20[redacted]
SLEEP PROBLEMS	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
NOT REPORTED	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			

CIGARS	NEVER
E-CIGARETTES	NEVER
PIPES	NEVER

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	LESS THAN 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.26	0.27	0.24	60	0.11	[redacted] / 381
ABBV-951	0.26	0.27	0.24	60	0.11	[redacted] / 581
ABBV-951	0.27	0.28	0.26	60	0.11	[redacted] / 644

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	635.19		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
M15-741 /ABBV-951	983.52		SC / CONTINUOUS	[redacted] / 9	[redacted] / 18
M15-741 /ABBV-951	986.93		SC / CONTINUOUS	[redacted] / 19	[redacted] / 19
M15-741 /ABBV-951	963.03		SC / CONTINUOUS	[redacted] / 20	[redacted] / 20
M15-741 /ABBV-951	942.54		SC / CONTINUOUS	[redacted] / 21	[redacted] / 27
M15-741 /ABBV-951	950.73		SC / CONTINUOUS	[redacted] / 28	[redacted] / 28
M15-741 /ABBV-951	983.52		SC / CONTINUOUS	[redacted] / 29	[redacted] / 39
M15-741 /ABBV-951	980.10		SC / CONTINUOUS	[redacted] / 40	[redacted] / 40
M15-741 /ABBV-951	942.54		SC / CONTINUOUS	[redacted] / 41	[redacted] / 91
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 92	
M15-741 /ABBV-951	1002.47		SC / CONTINUOUS	[redacted] / 92	[redacted] / 92
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 93	
M15-741 /ABBV-951	1052.16		SC / CONTINUOUS	[redacted] / 93	[redacted] / 93
M15-741 /ABBV-951	1065.48		SC / CONTINUOUS	[redacted] / 94	[redacted] / 180
M15-741 /ABBV-951	1043.45		SC / CONTINUOUS	[redacted] / 181	[redacted] / 181
M15-741 /ABBV-951	1032.86		SC / CONTINUOUS	[redacted] / 182	[redacted] / 182
M15-741 /ABBV-951	1024.5		SC / CONTINUOUS	[redacted] / 183	[redacted] / 271
M15-741 /ABBV-951	1059.16		SC / CONTINUOUS	[redacted] / 272	[redacted] / 272
M15-741 /ABBV-951	1088.01		SC / CONTINUOUS	[redacted] / 273	[redacted] / 273
ABBV-951	532.74		SC / CONTINUOUS	[redacted] / 381	[redacted] / 381
ABBV-951	1065.48		SC / CONTINUOUS	[redacted] / 382	[redacted] / 632

ABBV-951	1072.99	SC / CONTINUOUS	[redacted]20[redacted] / 633	[redacted]20[redacted] / 633
ABBV-951	1092.62	SC / CONTINUOUS	[redacted]20[redacted] / 634	[redacted]20[redacted] / 635

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
VITAMIN B12 NOS	100 OTHER: MCG	QD	Y-M: 20[redacted]
ONDANSETRON	4 mg	OTHER: Q8HOURS	Y-M: 20[redacted]-[redacted]
MACROGOL 3350	17 OTHER: GRAM	QD	Y-M: 20[redacted]-[redacted]
OMEPRAZOLE	40 mg	QD	Y-M: 20[redacted]-[redacted]
PROPRANOLOL	20 mg	QD	Y-M: 20[redacted]-[redacted]
MIRABEGRON	50 mg	QD	Y-M: 20[redacted]-[redacted]
RASAGILINE	1.000 mg	QD	Y-M: 20[redacted]-[redacted] / -363
CICLOSPORIN	1 gtt	PRN	Y-M: 20[redacted]-[redacted] / -309
CARBIDOPA MONOHYDRATE;LEVODOPA	200.000 mg	QID	Y-M: 20[redacted]-[redacted] / -275
MELATONIN	5 mg	QD	Y-M: 20[redacted]-[redacted] / -133
AMANTADINE	100.000 mg	TID	Y-M: 20[redacted]-[redacted] / -121
SERTRALINE HYDROCHLORIDE	50 mg	QD	Y-M: 20[redacted]-[redacted] / -121

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
VITAMIN B12 NOS	100 OTHER: MCG	QD	Y-M: 20[redacted]	NOT REPORTED
ONDANSETRON	4 mg	OTHER: Q8HOURS	Y-M: 20[redacted]-[redacted]	NOT REPORTED
MACROGOL 3350	17 OTHER: GRAM	QD	Y-M: 20[redacted]-[redacted]	NOT REPORTED
OMEPRAZOLE	40 mg	QD	Y-M: 20[redacted]-[redacted]	NOT REPORTED
PROPRANOLOL	20 mg	QD	Y-M: 20[redacted]-[redacted]	NOT REPORTED
MIRABEGRON	50 mg	QD	Y-M: 20[redacted]-[redacted]	NOT REPORTED
CICLOSPORIN	1 gtt	PRN	Y-M: 20[redacted]-[redacted] / -309	NOT REPORTED
MELATONIN	5 mg	QD	Y-M: 20[redacted]-[redacted] / -133	NOT REPORTED
SERTRALINE HYDROCHLORIDE	50 mg	QD	Y-M: 20[redacted]-[redacted] / -121	NOT REPORTED

Event #1: Serious Adverse Event

Event Description	LOW SODIUM
Preferred Term	血中ナトリウム減少
AE Onset Date / Rx Day	[redacted]20[redacted] / 38
Age at AE Onset	7[redacted]

Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
SAE Supplemental Procedure	
NOT REPORTED	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	PATIENT HAS A HISTORY OF LOW SODIUM
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Generated: [redacted]20[redacted]:09:38
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者は米国の 7[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に血中ナトリウム減少を発現した。

Event 1 の臨床経過：

関連する病歴は，パーキンソン病，悪心，便秘，胃食道逆流症，高血圧，両側性の軽度のくるぶし浮腫，過活動膀胱，非喫煙者，及び飲酒者（1 日 2 杯未満）であった。

投与 1 日目から 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するための治験薬の調整を必要とした。投与 5 週時に，被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 38 日目，被験者は血中ナトリウム減少を発現した。
本重篤な有害事象発現前の投与 37 日目，被験者に臨床検査を実施した。
投与 39 日目，被験者は臨床検査で確認された血中ナトリウム減少，疲労，及び錯乱のため入院した。治験責任医師によると，被験者には血中ナトリウム減少の病歴があった。被験者に静脈内輸液が実施され，塩分の摂取を増やすよう指導された。投与 40 日目，被験者は退院した。
被験者に塩化ナトリウム 0.9%が投与された。

The patient's past medications include:

CARBIDOPA/ LEVODOPA IMMEDIATE RELEASE 25/100 for PARKINSONS DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Sodium low (10041274) (Blood sodium decreased (10005802)) [v.23.0] [10041274]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of LOW SODIUM

- Investigator: Not applicable.

- AbbVie: More likely related to advanced age and concomitant use of Zoloft

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20**[redacted] **SODIUM:** 124 MMOL/L (normal 136 to 145)

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
転倒				X
股関節部骨折	X			X
注入部位蜂巣炎				X
注入部位紅斑				X

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	7[redacted]	MALE	WHITE

Medical History	Onset Year
INGUINAL HERNIA	19[redacted]
ALLERGIES TO MOLD	19[redacted]
HAYFEVER	19[redacted]
SEASONAL ALLERGIES	19[redacted]
NEPHROLITHIASIS	20[redacted]
PARKINSON DISEASE	20[redacted]
ATRIAL FIBRILLATION	20[redacted]
ANXIETY	20[redacted]
DAYTIME SOMNOLENCE	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
INGUINAL HERNIA REPAIR	19[redacted]
INGUINAL HERNIA REPAIR	19[redacted]
CARDIAC ABLATION WITH LOOP DEVICE	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.33	0.35	0.32	60	0.15	[redacted] / 366
ABBV-951	0.33	0.35	0.32	60	0.15	[redacted] / 536
ABBV-951	0.30	0.32	0.34		0.00	[redacted] / 703

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	480.83		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
M15-741 /ABBV-951	781.35		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
M15-741 /ABBV-951	448.04		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
M15-741 /ABBV-951	1305.89		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
M15-741 /ABBV-951	901.56		SC / CONTINUOUS	[redacted] / 15	[redacted] / 15
M15-741 /ABBV-951	109.28		SC / CONTINUOUS	[redacted] / 16	[redacted] / 16
M15-741 /ABBV-951	5.46		SC / CONTINUOUS	[redacted] / 20	[redacted] / 20
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 21	
M15-741 /ABBV-951	404.33		SC / CONTINUOUS	[redacted] / 21	[redacted] / 21
M15-741 /ABBV-951	1213.00		SC / CONTINUOUS	[redacted] / 22	[redacted] / 22
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 23	
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted] / 23	[redacted] / 26
M15-741 /ABBV-951	1256.72		SC / CONTINUOUS	[redacted] / 27	[redacted] / 27
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 28	
M15-741 /ABBV-951	945.27		SC / CONTINUOUS	[redacted] / 28	[redacted] / 28
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 31	

M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 36	
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 37	
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 38	
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 39	
M15-741 /ABBV-951	300.52		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 40	
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 41	
M15-741 /ABBV-951	1289.50		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 42	
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 43
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 43	
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 44	
M15-741 /ABBV-951	1256.72		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 45	
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 46	
M15-741 /ABBV-951	1262.18		SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 55
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 48	
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 49	
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 50	
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 51	
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 52	
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 53	
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 54	
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 55	
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 56	
M15-741 /ABBV-951	1245.79		SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
M15-741 /ABBV-951	1131.04		SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
M15-741 /ABBV-951	300.52		SC / CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 59	
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
M15-741 /ABBV-951	1218.47		SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 61	
M15-741 /ABBV-951	152.99		SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 85

M15-741 /ABBV-951	1273.11		SC / CONTINUOUS	[redacted]20[redacted] / 86	[redacted]20[redacted] / 86
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 87	[redacted]20[redacted] / 92
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 91	
M15-741 /ABBV-951	907.02		SC / CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 93
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 94	
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 94	[redacted]20[redacted] / 94
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 95	
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 95	[redacted]20[redacted] / 97
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 98	
M15-741 /ABBV-951	1374.87		SC / CONTINUOUS	[redacted]20[redacted] / 98	[redacted]20[redacted] / 98
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 99	
M15-741 /ABBV-951	1408.51		SC / CONTINUOUS	[redacted]20[redacted] / 99	[redacted]20[redacted] / 99
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 100	
M15-741 /ABBV-951	5.46		SC / CONTINUOUS	[redacted]20[redacted] / 100	[redacted]20[redacted] / 100
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 101	
M15-741 /ABBV-951	645.26		SC / CONTINUOUS	[redacted]20[redacted] / 101	[redacted]20[redacted] / 101
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 102	[redacted]20[redacted] / 102
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 103	
M15-741 /ABBV-951	1278.57		SC / CONTINUOUS	[redacted]20[redacted] / 103	[redacted]20[redacted] / 103
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 104	[redacted]20[redacted] / 104
M15-741 /ABBV-951	1207.54		SC / CONTINUOUS	[redacted]20[redacted] / 105	[redacted]20[redacted] / 105
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 106	
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 106	[redacted]20[redacted] / 107
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 108	
M15-741 /ABBV-951	1256.72		SC / CONTINUOUS	[redacted]20[redacted] / 108	[redacted]20[redacted] / 108
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 109	
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 109	[redacted]20[redacted] / 111
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 111	
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 112	
M15-741 /ABBV-951	628.36		SC / CONTINUOUS	[redacted]20[redacted] / 112	[redacted]20[redacted] / 112
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 113	
M15-741 /ABBV-951	655.68		SC / CONTINUOUS	[redacted]20[redacted] / 113	[redacted]20[redacted] / 113
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 114	[redacted]20[redacted] / 117
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 115	
M15-741 /ABBV-951	1289.50		SC / CONTINUOUS	[redacted]20[redacted] / 118	[redacted]20[redacted] / 118
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 119	
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 119	[redacted]20[redacted] / 121

M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 120	
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 121	
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 122	
M15-741 /ABBV-951	1245.79		SC / CONTINUOUS	[redacted]20[redacted] / 122	[redacted]20[redacted] / 122
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 123	
M15-741 /ABBV-951	1234.86		SC / CONTINUOUS	[redacted]20[redacted] / 123	[redacted]20[redacted] / 123
M15-741 /ABBV-951	1294.96		SC / CONTINUOUS	[redacted]20[redacted] / 124	[redacted]20[redacted] / 124
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 125	
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 125	[redacted]20[redacted] / 126
M15-741 /ABBV-951	1294.96		SC / CONTINUOUS	[redacted]20[redacted] / 127	[redacted]20[redacted] / 127
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 128	
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 128	[redacted]20[redacted] / 128
M15-741 /ABBV-951	1223.93		SC / CONTINUOUS	[redacted]20[redacted] / 129	[redacted]20[redacted] / 129
M15-741 /ABBV-951	1294.96		SC / CONTINUOUS	[redacted]20[redacted] / 130	[redacted]20[redacted] / 130
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 131	[redacted]20[redacted] / 131
M15-741 /ABBV-951	1251.25		SC / CONTINUOUS	[redacted]20[redacted] / 132	[redacted]20[redacted] / 132
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 133	[redacted]20[redacted] / 134
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 135	
M15-741 /ABBV-951	1202.08		SC / CONTINUOUS	[redacted]20[redacted] / 135	[redacted]20[redacted] / 135
M15-741 /ABBV-951	81.96		SC / CONTINUOUS	[redacted]20[redacted] / 136	[redacted]20[redacted] / 136
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 137	[redacted]20[redacted] / 138
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 138	
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 139	
M15-741 /ABBV-951	1256.72		SC / CONTINUOUS	[redacted]20[redacted] / 139	[redacted]20[redacted] / 139
M15-741 /ABBV-951	71.03		SC / CONTINUOUS	[redacted]20[redacted] / 140	[redacted]20[redacted] / 140
M15-741 /ABBV-951	1256.72		SC / CONTINUOUS	[redacted]20[redacted] / 141	[redacted]20[redacted] / 141
M15-741 /ABBV-951	1278.57		SC / CONTINUOUS	[redacted]20[redacted] / 142	[redacted]20[redacted] / 142
M15-741 /ABBV-951	1316.82		SC / CONTINUOUS	[redacted]20[redacted] / 143	[redacted]20[redacted] / 143
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 144	
M15-741 /ABBV-951	1300.43		SC / CONTINUOUS	[redacted]20[redacted] / 144	[redacted]20[redacted] / 144
M15-741 /ABBV-951	1262.18		SC / CONTINUOUS	[redacted]20[redacted] / 145	[redacted]20[redacted] / 145
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 146	
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 146	[redacted]20[redacted] / 146
M15-741 /ABBV-951	1294.96		SC / CONTINUOUS	[redacted]20[redacted] / 147	[redacted]20[redacted] / 147
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 148	
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 148	[redacted]20[redacted] / 148
M15-741 /ABBV-951	1152.90		SC / CONTINUOUS	[redacted]20[redacted] / 149	[redacted]20[redacted] / 149

M15-741 /ABBV-951	76.49		SC / CONTINUOUS	[redacted]20[redacted] / 152	[redacted]20[redacted] / 152
M15-741 /ABBV-951	371.55		SC / CONTINUOUS	[redacted]20[redacted] / 154	[redacted]20[redacted] / 154
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 155	[redacted]20[redacted] / 155
M15-741 /ABBV-951	710.32		SC / CONTINUOUS	[redacted]20[redacted] / 156	[redacted]20[redacted] / 156
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 157	
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 157	[redacted]20[redacted] / 158
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 159	
M15-741 /ABBV-951	1256.72		SC / CONTINUOUS	[redacted]20[redacted] / 159	[redacted]20[redacted] / 159
M15-741 /ABBV-951	1191.15		SC / CONTINUOUS	[redacted]20[redacted] / 160	[redacted]20[redacted] / 160
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 161	
M15-741 /ABBV-951	300.52		SC / CONTINUOUS	[redacted]20[redacted] / 161	[redacted]20[redacted] / 161
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 162	
M15-741 /ABBV-951	1213.00		SC / CONTINUOUS	[redacted]20[redacted] / 162	[redacted]20[redacted] / 162
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 163	
M15-741 /ABBV-951	1240.32		SC / CONTINUOUS	[redacted]20[redacted] / 163	[redacted]20[redacted] / 163
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 164	[redacted]20[redacted] / 166
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 166	
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 167	
M15-741 /ABBV-951	1196.61		SC / CONTINUOUS	[redacted]20[redacted] / 167	[redacted]20[redacted] / 167
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 168	[redacted]20[redacted] / 168
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 169	
M15-741 /ABBV-951	622.89		SC / CONTINUOUS	[redacted]20[redacted] / 169	[redacted]20[redacted] / 169
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 170	
M15-741 /ABBV-951	1251.25		SC / CONTINUOUS	[redacted]20[redacted] / 170	[redacted]20[redacted] / 170
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 171	
M15-741 /ABBV-951	1256.72		SC / CONTINUOUS	[redacted]20[redacted] / 171	[redacted]20[redacted] / 171
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 172	
M15-741 /ABBV-951	1251.25		SC / CONTINUOUS	[redacted]20[redacted] / 172	[redacted]20[redacted] / 172
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 173	[redacted]20[redacted] / 173
M15-741 /ABBV-951	1251.25		SC / CONTINUOUS	[redacted]20[redacted] / 174	[redacted]20[redacted] / 174
M15-741 /ABBV-951	1202.08		SC / CONTINUOUS	[redacted]20[redacted] / 175	[redacted]20[redacted] / 175
M15-741 /ABBV-951	1256.72		SC / CONTINUOUS	[redacted]20[redacted] / 176	[redacted]20[redacted] / 176
M15-741 /ABBV-951	1262.18		SC / CONTINUOUS	[redacted]20[redacted] / 177	[redacted]20[redacted] / 177
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 178	
M15-741 /ABBV-951	1256.72		SC / CONTINUOUS	[redacted]20[redacted] / 178	[redacted]20[redacted] / 178
M15-741 /ABBV-951	1305.89		SC / CONTINUOUS	[redacted]20[redacted] / 179	[redacted]20[redacted] / 179
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 180	[redacted]20[redacted] / 180

M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 181	
M15-741 /ABBV-951	1256.72		SC / CONTINUOUS	[redacted]20[redacted] / 181	[redacted]20[redacted] / 181
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 182	
M15-741 /ABBV-951	1049.08		SC / CONTINUOUS	[redacted]20[redacted] / 182	[redacted]20[redacted] / 182
M15-741 /ABBV-951	256.80		SC / CONTINUOUS	[redacted]20[redacted] / 183	[redacted]20[redacted] / 183
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 184	
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 184	[redacted]20[redacted] / 184
M15-741 /ABBV-951	1191.15		SC / CONTINUOUS	[redacted]20[redacted] / 185	[redacted]20[redacted] / 185
M15-741 /ABBV-951	1267.64		SC / CONTINUOUS	[redacted]20[redacted] / 186	[redacted]20[redacted] / 186
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 187	
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 187	[redacted]20[redacted] / 188
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 188	
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 189	
M15-741 /ABBV-951	1289.50		SC / CONTINUOUS	[redacted]20[redacted] / 189	[redacted]20[redacted] / 189
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 190	
M15-741 /ABBV-951	1305.89		SC / CONTINUOUS	[redacted]20[redacted] / 190	[redacted]20[redacted] / 190
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 191	[redacted]20[redacted] / 191
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 192	
M15-741 /ABBV-951	1256.72		SC / CONTINUOUS	[redacted]20[redacted] / 192	[redacted]20[redacted] / 192
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 193	[redacted]20[redacted] / 193
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 194	[redacted]20[redacted] / 195
M15-741 /ABBV-951	1016.30		SC / CONTINUOUS	[redacted]20[redacted] / 196	[redacted]20[redacted] / 196
M15-741 /ABBV-951	1256.72		SC / CONTINUOUS	[redacted]20[redacted] / 197	[redacted]20[redacted] / 197
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 198	[redacted]20[redacted] / 199
M15-741 /ABBV-951	1294.96		SC / CONTINUOUS	[redacted]20[redacted] / 200	[redacted]20[redacted] / 200
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 201	[redacted]20[redacted] / 202
M15-741 /ABBV-951	1300.09		SC / CONTINUOUS	[redacted]20[redacted] / 203	[redacted]20[redacted] / 203
M15-741 /ABBV-951	1313.92		SC / CONTINUOUS	[redacted]20[redacted] / 204	[redacted]20[redacted] / 204
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 205	[redacted]20[redacted] / 207
M15-741 /ABBV-951	1223.93		SC / CONTINUOUS	[redacted]20[redacted] / 208	[redacted]20[redacted] / 208
M15-741 /ABBV-951	240.41		SC / CONTINUOUS	[redacted]20[redacted] / 209	[redacted]20[redacted] / 209
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 210	
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 210	[redacted]20[redacted] / 210
M15-741 /ABBV-951	1174.76		SC / CONTINUOUS	[redacted]20[redacted] / 211	[redacted]20[redacted] / 211
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 213	
M15-741 /ABBV-951	125.50		SC / CONTINUOUS	[redacted]20[redacted] / 213	[redacted]20[redacted] / 213
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 214	

M15-741 /ABBV-951	1416.37		SC / CONTINUOUS	[redacted]20[redacted] / 214	[redacted]20[redacted] / 214
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 215	
M15-741 /ABBV-951	1302.82		SC / CONTINUOUS	[redacted]20[redacted] / 215	[redacted]20[redacted] / 215
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 216	
M15-741 /ABBV-951	902.41		SC / CONTINUOUS	[redacted]20[redacted] / 216	[redacted]20[redacted] / 216
M15-741 /ABBV-951	1434.3		SC / CONTINUOUS	[redacted]20[redacted] / 217	[redacted]20[redacted] / 219
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 219	
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 220	
M15-741 /ABBV-951	1374.53		SC / CONTINUOUS	[redacted]20[redacted] / 220	[redacted]20[redacted] / 220
M15-741 /ABBV-951	1410.39		SC / CONTINUOUS	[redacted]20[redacted] / 221	[redacted]20[redacted] / 221
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 222	
M15-741 /ABBV-951	1404.41		SC / CONTINUOUS	[redacted]20[redacted] / 222	[redacted]20[redacted] / 222
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 223	
M15-741 /ABBV-951	1368.56		SC / CONTINUOUS	[redacted]20[redacted] / 223	[redacted]20[redacted] / 223
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 224	
M15-741 /ABBV-951	1434.3		SC / CONTINUOUS	[redacted]20[redacted] / 224	[redacted]20[redacted] / 224
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 225	
M15-741 /ABBV-951	1374.53		SC / CONTINUOUS	[redacted]20[redacted] / 225	[redacted]20[redacted] / 226
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 226	
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 227	
M15-741 /ABBV-951	1434.3		SC / CONTINUOUS	[redacted]20[redacted] / 227	[redacted]20[redacted] / 227
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 228	
M15-741 /ABBV-951	1374.53		SC / CONTINUOUS	[redacted]20[redacted] / 228	[redacted]20[redacted] / 229
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 229	
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 230	
M15-741 /ABBV-951	1308.79		SC / CONTINUOUS	[redacted]20[redacted] / 230	[redacted]20[redacted] / 230
M15-741 /ABBV-951	1434.3		SC / CONTINUOUS	[redacted]20[redacted] / 231	[redacted]20[redacted] / 231
M15-741 /ABBV-951	1344.65		SC / CONTINUOUS	[redacted]20[redacted] / 232	[redacted]20[redacted] / 232
ABBV-951	619.82		SC / CONTINUOUS	[redacted]20[redacted] / 366	[redacted]20[redacted] / 366
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 367	[redacted]20[redacted] / 448
ABBV-951	1056.43		SC / CONTINUOUS	[redacted]20[redacted] / 449	[redacted]20[redacted] / 449
ABBV-951	675.31		SC / CONTINUOUS	[redacted]20[redacted] / 450	[redacted]20[redacted] / 450
ABBV-951	0		SC / CONTINUOUS	[redacted]20[redacted] / 535	[redacted]20[redacted] / 535
ABBV-951	957.90		SC / CONTINUOUS	[redacted]20[redacted] / 701	[redacted]20[redacted] / 701

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
VITAMINS NOS	1 OTHER: TAB	QD	Y-M: 19[redacted]
ASCORBIC ACID	1000 mg	QD	Y-M: 19[redacted]
FEXOFENADINE	180 mg	PRN	Y-M: 20[redacted]
FLUNISOLIDE	1 OTHER: SPRAY	PRN	Y-M: 20[redacted]
ACETYLSALICYLIC ACID	81 mg	QD	Y-M: 20[redacted]
ARMODAFINIL	75 mg	QD	Y-M: 20[redacted]-[redacted] / -272
BACITRACIN;NEOMYCIN SULFATE;POLYMYXIN B SULFATE	1 OTHER: APPLICATION	PRN	Y-M: 20[redacted]-[redacted] / 42
AZELASTINE	1 OTHER: SPRAY	PRN	Y-M: 20[redacted]-[redacted] / 154

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
VITAMINS NOS	1 OTHER: TAB	QD	Y-M: 19[redacted]	NOT REPORTED
ASCORBIC ACID	1000 mg	QD	Y-M: 19[redacted]	NOT REPORTED
FEXOFENADINE	180 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
FLUNISOLIDE	1 OTHER: SPRAY	PRN	Y-M: 20[redacted]	NOT REPORTED
ACETYLSALICYLIC ACID	81 mg	QD	Y-M: 20[redacted]	NOT REPORTED
ARMODAFINIL	75 mg	QD	Y-M: 20[redacted]-[redacted] / -272	NOT REPORTED
AZELASTINE	1 OTHER: SPRAY	PRN	Y-M: 20[redacted]-[redacted] / 154	NOT REPORTED
HYDROCODONE BITARTRATE;PARACETAMOL	5/325 mg	TID	Y-M: 20[redacted]-[redacted] / 505	Y-M: 20[redacted]-[redacted] / 511
CEFALEXIN	500 mg	TID	Y-M: 20[redacted]-[redacted] / 723	NOT REPORTED
SULFAMETHOXAZOLE;TRIMETHOPRIM	800-160 mg	BID	Y-M: 20[redacted]-[redacted] / 723	NOT REPORTED

Event #1: Event of Interest - Falls and Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred Term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 505
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped Rx Day	505
Duration of AE	1 DAY
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Serious Adverse Event, Event of Interest - Falls and Associated Injuries

Event Description	FRACTURED HIP
Preferred Term	股関節部骨折
AE Onset Date / Rx Day	[redacted]20[redacted] / 505
Age at AE Onset	7[redacted]

Laboratory Testing

NOT REPORTED

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 507): SURGERY TO INSERT SCREWS IN HIP. WE ARE AWAITING MORE INFORMATION.:SURGERY WAS SUCESSFUL. PINS WERE PLACED INTO THE HEAD OF THE FEMUR. STUDY DRUG WAS INTERRUPTED DURING SURGERY AND FOR 24 HOURS AFTER. STUDY DRUG WAS REINTRODUCED WITH NO PROBLEMS.

AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to	NOT REPORTED

[redacted] **Infusion Set**	
Other Cause of Event	SUBJECT TRIPPED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #3: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	ABDOMEN INFUSION SITE ERYTHEMA GRADE 5
Preferred Term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 534
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped Rx Day	538
Duration of AE	5 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS AT INFUSION SITE
Preferred Term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 713
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Generated: [redacted] 20[redacted]:09:38

Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者は米国の 7[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に股関節部骨折を発現した。

Event 2 の臨床経過：

関連する病歴は，パーキンソン病，非喫煙者，及び非飲酒者であった。

投与 505 日目，被験者は股関節部骨折を発現した。

投与 505 日目，被験者は仕事場で滑り股関節を骨折し，入院した。投与 507 日目，被験者に骨折整復手術を実施した。手術は成功した。大腿骨頭にピンを留置した。

Causality for ABBV-951 (Open Label)

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1) Fractured hip (10017287) (Hip fracture (020100)) [v.23.1] [10017287]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: No

Alternative Etiology for ABBV-951 (Open Label)

Event of FRACTURED HIP

- Investigator: Subject tripped

- AbbVie: More likely related to traumatic injury from tripping in an advanced aged patient with a history of Parkinson's disease and daytime somnolence.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BODY WEIGHT:** 6[redacted] KG

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
妄想				X
胃腸炎	X			
体重減少				X

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	5[redacted]	MALE	WHITE

Medical History	Onset Year
CHRONIC STREP THROAT	NOT REPORTED
DAYTIME SLEEPINESS	NOT REPORTED
FOCAL WEAKNESS	NOT REPORTED
HALLUCINATIONS	NOT REPORTED
MOUTH SORES	NOT REPORTED
NEUROPATHY	NOT REPORTED
SLOWING COGNITIVE IMPAIRMENT	NOT REPORTED
WEAKNESS	NOT REPORTED
CHRONIC STREP THROAT	19[redacted]
CHRONIC LEFT SHOULDER DISLOCATION	19[redacted]
DROOLING	19[redacted]
ANXIETY	19[redacted]
DEPRESSION	19[redacted]
MILD APATHY	19[redacted]
EARLY SATIETY	20[redacted]
URINARY URGENCY	20[redacted]
MIGRAINES	20[redacted]
LEFT HAND TREMOR	20[redacted]
LOSS OF SMELL	20[redacted]
CONSTIPATION	20[redacted]
BRAIN FOG	20[redacted]
RAPID EYE MOVEMENT SLEEP BEHAVIOR DISORDER (RBD OR REM)	20[redacted]
SHORT-TERM MEMORY LOSS	20[redacted]

CHOKING (OCCASIONAL)	20[redacted]
COUGHING WHEN EATING (OCCASIONAL)	20[redacted]
DIZZINESS	20[redacted]
LIGHTHEADEDNESS	20[redacted]
FATIGUE	20[redacted]
MASKING OF FACE	20[redacted]
MILD HYPOPHOMIA	20[redacted]
LUMP ON LEFT NECK	20[redacted]
NON-HODGKIN'S (B-CELL) LYMPHOMA	20[redacted]
NUMBNESS IN FINGERS	20[redacted]
SOLID TUMOR IN NASOPHARYNX	20[redacted]
LACK OF IMPULSE CONTROL WITH INTERNET USE FOR SEXUAL DESIRES	20[redacted]
DYSPHAGIA	20[redacted]
LEFT CARPAL TUNNEL SYNDROME	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
ONSET OF MOTOR FLUCTUATION	20[redacted]
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]

Prior Procedures	Procedure Year
TONSILS REMOVED	19[redacted]
SHOULDER SURGERY	19[redacted]
SOLID TUMOR IN NASOPHARYNX	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	LESS THAN 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.29	0.32	0.26	120	0.24	[redacted]20[redacted] / 366
ABBV-951	0.38	0.41	0.35	120	0.30	[redacted]20[redacted] / 436
ABBV-951	0.50	0.56	0.44	120	0.30	[redacted]20[redacted] / 485
ABBV-951	0.56	0.58	0.54	120	0.30	[redacted]20[redacted] / 534
ABBV-951	0.50	0.52	0.48	120	0.30	[redacted]20[redacted] / 618
ABBV-951	0.50	0.52	0.48	120	0.11	[redacted]20[redacted] / 703

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	245.88		SC / CONTINUOUS	[redacted]20[redacted] / 1	[redacted]20[redacted] / 1
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 2	
M15-741 /ABBV-951	792.28		SC / CONTINUOUS	[redacted]20[redacted] / 2	[redacted]20[redacted] / 2
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 3	
M15-741 /ABBV-951	798.42		SC / CONTINUOUS	[redacted]20[redacted] / 3	[redacted]20[redacted] / 3
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 4	
M15-741 /ABBV-951	922.90		SC / CONTINUOUS	[redacted]20[redacted] / 4	[redacted]20[redacted] / 4
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 5	
M15-741 /ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 5	[redacted]20[redacted] / 5
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 6	
M15-741 /ABBV-951	915.04		SC / CONTINUOUS	[redacted]20[redacted] / 6	[redacted]20[redacted] / 6
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 7	
M15-741 /ABBV-951	899.34		SC / CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 7
M15-741 /ABBV-951	988.13		SC / CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 8
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 9	
M15-741 /ABBV-951	1012.20		SC / CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 9
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 10	
M15-741 /ABBV-951	1065.48		SC / CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 11
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 11	
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 12	
M15-741 /ABBV-951	1029.96		SC / CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 13	
M15-741 /ABBV-951	1065.48		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 19
M15-741 /ABBV-951	1034.40		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
M15-741 /ABBV-951	1021.08		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21

M15-741 /ABBV-951	1043.28		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 23	
M15-741 /ABBV-951	1065.48		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 27
M15-741 /ABBV-951	986.76		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 29	
M15-741 /ABBV-951	1188.42		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
M15-741 /ABBV-951	1114.14		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
M15-741 /ABBV-951	1188.42		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 32
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 33	
M15-741 /ABBV-951	1124.04		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 34	
M15-741 /ABBV-951	559.54		SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
M15-741 /ABBV-951	1188.42		SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 36
M15-741 /ABBV-951	990.35		SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
M15-741 /ABBV-951	1188.42		SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
M15-741 /ABBV-951	747.71		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 40	
M15-741 /ABBV-951	807.13		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
M15-741 /ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 41	
M15-741 /ABBV-951	1158.70		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 42	
M15-741 /ABBV-951	1109.19		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 43	
M15-741 /ABBV-951	1114.14		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
M15-741 /ABBV-951	1158.70		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
M15-741 /ABBV-951	1188.42		SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 46
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 47	
M15-741 /ABBV-951	1148.80		SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
M15-741 /ABBV-951	1188.42		SC / CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 50
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 51	
M15-741 /ABBV-951	1163.66		SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 52	
M15-741 /ABBV-951	1188.42		SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 53	
M15-741 /ABBV-951	1148.80		SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
M15-741 /ABBV-951	1178.51		SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
M15-741 /ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 55	

M15-741 /ABBV-951	1138.90		SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 56	
M15-741 /ABBV-951	1163.66		SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 57	
M15-741 /ABBV-951	1188.42		SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 58
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 58	
M15-741 /ABBV-951	1005.20		SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
M15-741 /ABBV-951		122.94	SC / ONCE	[redacted]20[redacted] / 60	
M15-741 /ABBV-951	1188.42		SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 61	
M15-741 /ABBV-951	1163.66		SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
M15-741 /ABBV-951	1188.42		SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
M15-741 /ABBV-951		122.94	SC / ONCE	[redacted]20[redacted] / 63	
M15-741 /ABBV-951	1138.90		SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
M15-741 /ABBV-951	1221.71		SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
M15-741 /ABBV-951	928.88		SC / CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 66	
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 67	
M15-741 /ABBV-951	655.68		SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 69	
M15-741 /ABBV-951	1120.12		SC / CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 70	
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 71	
M15-741 /ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 72	
M15-741 /ABBV-951	1218.47		SC / CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
M15-741 /ABBV-951	1147.44		SC / CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 74	
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 74	[redacted]20[redacted] / 74
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 76	
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 76
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 78
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 79	
M15-741 /ABBV-951	1256.72		SC / CONTINUOUS	[redacted]20[redacted] / 79	[redacted]20[redacted] / 79

M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 80
M15-741 /ABBV-951	1294.96		SC / CONTINUOUS	[redacted]20[redacted] / 81	[redacted]20[redacted] / 81
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 82	
M15-741 /ABBV-951	1234.86		SC / CONTINUOUS	[redacted]20[redacted] / 82	[redacted]20[redacted] / 82
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 84	
M15-741 /ABBV-951	1256.72		SC / CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 85	[redacted]20[redacted] / 85
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 86	[redacted]20[redacted] / 86
M15-741 /ABBV-951	934.34		SC / CONTINUOUS	[redacted]20[redacted] / 87	[redacted]20[redacted] / 87
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 88	[redacted]20[redacted] / 88
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 89	
M15-741 /ABBV-951	1273.11		SC / CONTINUOUS	[redacted]20[redacted] / 89	[redacted]20[redacted] / 89
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 90
M15-741 /ABBV-951	1092.8		SC / CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 92	
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 98
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 95	
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 99	
M15-741 /ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 99	[redacted]20[redacted] / 99
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 100	[redacted]20[redacted] / 101
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 102	[redacted]20[redacted] / 102
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 103	[redacted]20[redacted] / 103
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 104	
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 104	[redacted]20[redacted] / 104
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 105	
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 105	[redacted]20[redacted] / 107
M15-741 /ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 108	
M15-741 /ABBV-951	1267.64		SC / CONTINUOUS	[redacted]20[redacted] / 108	[redacted]20[redacted] / 108
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 109	[redacted]20[redacted] / 109
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 110	
M15-741 /ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 110	[redacted]20[redacted] / 110
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 111	[redacted]20[redacted] / 111
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 112	[redacted]20[redacted] / 112
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 113	[redacted]20[redacted] / 113
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 114	[redacted]20[redacted] / 114
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 115	[redacted]20[redacted] / 115

M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 116	
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 116	[redacted]20[redacted] / 117
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 117	
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 118	[redacted]20[redacted] / 118
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 119	
M15-741 /ABBV-951	1240.32		SC / CONTINUOUS	[redacted]20[redacted] / 119	[redacted]20[redacted] / 119
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 120	[redacted]20[redacted] / 120
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 121	
M15-741 /ABBV-951	1273.11		SC / CONTINUOUS	[redacted]20[redacted] / 121	[redacted]20[redacted] / 121
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 122	[redacted]20[redacted] / 124
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 125	
M15-741 /ABBV-951	1202.08		SC / CONTINUOUS	[redacted]20[redacted] / 125	[redacted]20[redacted] / 125
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 126	
M15-741 /ABBV-951	628.36		SC / CONTINUOUS	[redacted]20[redacted] / 126	[redacted]20[redacted] / 126
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 127	[redacted]20[redacted] / 127
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 128	
M15-741 /ABBV-951	1141.97		SC / CONTINUOUS	[redacted]20[redacted] / 128	[redacted]20[redacted] / 128
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 129	[redacted]20[redacted] / 129
M15-741 /ABBV-951	1202.08		SC / CONTINUOUS	[redacted]20[redacted] / 130	[redacted]20[redacted] / 130
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 131	[redacted]20[redacted] / 134
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 135	[redacted]20[redacted] / 135
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 136	[redacted]20[redacted] / 136
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 137	[redacted]20[redacted] / 137
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 138	[redacted]20[redacted] / 138
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 139	[redacted]20[redacted] / 139
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 140	[redacted]20[redacted] / 140
M15-741 /ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 141	
M15-741 /ABBV-951	1202.08		SC / CONTINUOUS	[redacted]20[redacted] / 141	[redacted]20[redacted] / 141
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 142	[redacted]20[redacted] / 150
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 151	[redacted]20[redacted] / 151
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 152	[redacted]20[redacted] / 152
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 153	
M15-741 /ABBV-951	1256.72		SC / CONTINUOUS	[redacted]20[redacted] / 153	[redacted]20[redacted] / 153
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 154	[redacted]20[redacted] / 154
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 155	[redacted]20[redacted] / 155
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 156	[redacted]20[redacted] / 160
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 159	

M15-741 /ABBV-951	1174.76		SC / CONTINUOUS	[redacted] / 161	[redacted] / 161
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted] / 162	[redacted] / 165
M15-741 /ABBV-951	1038.16		SC / CONTINUOUS	[redacted] / 166	[redacted] / 166
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted] / 167	[redacted] / 167
M15-741 /ABBV-951	546.4		SC / CONTINUOUS	[redacted] / 168	[redacted] / 168
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted] / 169	[redacted] / 170
M15-741 /ABBV-951	683		SC / CONTINUOUS	[redacted] / 171	[redacted] / 171
M15-741 /ABBV-951	819.6		SC / CONTINUOUS	[redacted] / 172	[redacted] / 172
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted] / 173	[redacted] / 173
M15-741 /ABBV-951	409.8		SC / CONTINUOUS	[redacted] / 174	[redacted] / 174
M15-741 /ABBV-951	109.28		SC / CONTINUOUS	[redacted] / 180	[redacted] / 180
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted] / 181	[redacted] / 181
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted] / 182	[redacted] / 182
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted] / 183	[redacted] / 183
M15-741 /ABBV-951	1289.50		SC / CONTINUOUS	[redacted] / 184	[redacted] / 184
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted] / 185	[redacted] / 272
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted] / 273	
M15-741 /ABBV-951	1294.96		SC / CONTINUOUS	[redacted] / 273	[redacted] / 273
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted] / 274	[redacted] / 274
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted] / 275	
M15-741 /ABBV-951	1229.4		SC / CONTINUOUS	[redacted] / 275	[redacted] / 275
ABBV-951	611.96		SC / CONTINUOUS	[redacted] / 366	[redacted] / 366
ABBV-951	1311.36		SC / CONTINUOUS	[redacted] / 367	[redacted] / 367
ABBV-951		40.98	SC / ONCE	[redacted] / 368	
ABBV-951	1294.96		SC / CONTINUOUS	[redacted] / 368	[redacted] / 368
ABBV-951	1311.36		SC / CONTINUOUS	[redacted] / 369	[redacted] / 430
ABBV-951		40.98	SC / ONCE	[redacted] / 431	
ABBV-951	1284.04		SC / CONTINUOUS	[redacted] / 431	[redacted] / 431
ABBV-951		40.98	SC / ONCE	[redacted] / 432	
ABBV-951	1311.36		SC / CONTINUOUS	[redacted] / 432	[redacted] / 432
ABBV-951		40.98	SC / ONCE	[redacted] / 433	
ABBV-951	1207.54		SC / CONTINUOUS	[redacted] / 433	[redacted] / 433
ABBV-951		81.96	SC / ONCE	[redacted] / 434	
ABBV-951	1284.04		SC / CONTINUOUS	[redacted] / 434	[redacted] / 434
ABBV-951	1311.36		SC / CONTINUOUS	[redacted] / 435	[redacted] / 531
ABBV-951		51.22	SC / ONCE	[redacted] / 530	
ABBV-951		51.22	SC / ONCE	[redacted] / 532	

ABBV-951	1747.11		SC / CONTINUOUS	[redacted]20[redacted] / 532	[redacted]20[redacted] / 532
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 533	
ABBV-951	2247.07		SC / CONTINUOUS	[redacted]20[redacted] / 533	[redacted]20[redacted] / 533
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 534	[redacted]20[redacted] / 700
ABBV-951	2124.13		SC / CONTINUOUS	[redacted]20[redacted] / 701	[redacted]20[redacted] / 701
ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 702	[redacted]20[redacted] / 702

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
PAROXETINE HYDROCHLORIDE	20 mg	QD	Y-M: 19[redacted]
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	250, 250, 65 mg	PRN	Y-M: 20[redacted]
AMANTADINE	100.000 mg	TID	Y-M: 20[redacted]
HYDROCORTISONE	1 OTHER: DOSE	PRN	Y-M: 20[redacted]-[redacted] / 23
RASAGILINE	1.000 mg	QD	Y-M: 20[redacted]-[redacted] / 66
BACITRACIN;NEOMYCIN;POLYMYXIN B	SMALL AMOUNT mg	PRN	Y-M: 20[redacted]-[redacted] / 117

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
PAROXETINE HYDROCHLORIDE	20 mg	QD	Y-M: 19[redacted]	NOT REPORTED
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	250, 250, 65 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
HYDROCORTISONE	1 OTHER: DOSE	PRN	Y-M: 20[redacted]-[redacted] / 23	NOT REPORTED
BACITRACIN;NEOMYCIN;POLYMYXIN B	SMALL AMOUNT mg	PRN	Y-M: 20[redacted]-[redacted] / 117	NOT REPORTED
HYDROMORPHONE HYDROCHLORIDE	240 OTHER: MG/ML	PRN	Y-M: 20[redacted]-[redacted] / 547	Y-M: 20[redacted]-[redacted] / 548

Event #1: Serious Adverse Event

Event Description	GASTROENTERITIS
Preferred Term	胃腸炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 547
Age at AE Onset	5[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 547): Basophils: 0.06 [0 - 0.2] 10^9/L; Eosinophils: 0.19 [0 - 0.8] 10^9/L; Ery. Mean Corpuscular HGB Concentration: 346 [300 - 370] G/L; Ery. Mean Corpuscular Hemoglobin: 29.9 [26 - 36] PG/L; Erythrocytes: 5.7

[4.3 - 6.1] 10^12/L; Hematocrit: 0.49 [0.4 - 0.54] FRACTION OF 1; Hemoglobin: 171 [140 - 180] G/L; Leukocytes: 11.8 [3.5 - 11.5] 10^9/L; Lymphocytes: 1.35 [0.6 - 5.2] 10^9/L; Monocytes: 0.88 [0 - 1] 10^9/L; NPTST013-MCV: 87 [80 - 120] FL; Neutrophils: 9.24 [2 - 8] 10^9/L; Platelets: 233 [150 - 400] 10^9/L

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 547): CT RENAL STONE WITHOUT CONTRAST:LIVER MORPHOLOGY: UNREMARKABLE. PANCREAS: APPEARS NORMAL. SPLEEN: APPEARS NORMAL. ADRENAL GLANDS APPEAR TO BE NORMAL. BOWEL: THERE IS MODERATE FLUID FILLED DISTENTION OF THE STOMACH AND ALSO MULTIPLE MID AND PROXIMAL SMALL BOWEL LOOPS. THE DISTAL SMALL BOWEL IS COLLAPSED. THE DILATED LOOPS ARE NOT THICKENED.; [redacted]20[redacted] (RX DAY 548): SMALL BOWEL SERIES:CONTRAST EMPRIES PROMPTLY FROM THE STOMACH INTO THE SMALL BOWEL. THERE IS NO ABNORMAL SMAL BOWEL DILATION, FOLD THICKENING OR IRREGULATOR. NO STRICTURE OR TRANSITION SEEN

AE Stopped Rx Day	548
Duration of AE	2 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
Other Cause of Event	PI DETERMINED THAT THE PATIENT WAS ADMITTED FOR GASTROENTERITIS BASED ON LAB, IMAGING AND ADMISSIONS
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #2: Event of Interest - Hallucinations/Psychosis

Event Description	DELUSIONS
Preferred Term	妄想
AE Onset Date / Rx Day	[redacted]20[redacted] / 617
Age at AE Onset	5[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Event of Interest - Weight Loss

Event Description	WEIGHT LOSS
Preferred Term	体重減少
AE Onset Date / Rx Day	[redacted]20[redacted] / 618
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Generated: [redacted]20[redacted]:09:38
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者は米国の 5[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に胃腸炎を発現した。

Event 1 の臨床経過：

関連する病歴は，パーキンソン病，非喫煙者，及び現飲酒者（1 日 2 杯未満）であった。

投与 547 日目，被験者は胃腸炎を発現した。投与 548 日目，胃腸炎は消失した。

被験者は背部及び脇腹全体に鋭い痛みを発現した（日時不明）。被験者は緊急治療室に来院した。投与 547 日目，被験者は入院した。嘔吐及び悪心の症状が認められた。投与 548 日目，被験者は退院した。

治験責任医師によると，被験者のリスク因子は胃腸炎を引き起こしやすい体質であった。

被験者にヒドロモルフォンが投与された。

Causality for ABBV-951 (Open Label)

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1) Gastroenteritis (10017888) (Gastroenteritis (10017888)) [v.24.1] [10017888]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of GASTROENTERITIS

- Investigator: PI determined that the patient was admitted for gastroenteritis based on lab, imaging and admissions.

- AbbVie: More likely related to commonly occurring incidental event in the general population. Event recovered within one day and study drug was ongoing at the time of event recovery.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] PHYSICAL EXAMINATION:** CONSTITUTIONAL: WELL DEVELOPED, NON-TOXIC APPEARENCE, NO ACUTE DISTRESS HENT: NORMOCEPHALIC, ATRAUMATIC, BILATERAL EXTERNAL EARS NORMAL, NO PHARYNGEAL ERYTHMEA, SWELLING OF EXUDE, NOSE NORMAL. EYES: PERRL, EOMI, CONJUCTIVA NORMAL, NO DISCHARGE. NECK: NORMAL RANGE OF MOTION, NO TENDERNESS, NO STRIDOR, NO MENINGISMUS. CARDIOVASCULAR: NORMAL HEART RATE, NORMAL RHYTHM. THORAX AND LUNGS: NO RESPIRATORY DISTRESS. NO CHEST WALL TENDERNESS. CTABL, NO WHEEZES RALES OR RHONCHI. ABDOMEN: BOWEL SOUNDS NORMAL. SOFT, NON-DISTENDED. MILD DIFFUSE TENDERNESS WITHOUT RIGIDITY, ROEBOUND OR GUARDING. NO MASSES. NO PULSATILE MASSES. NO PERITONEAL SIGNS. SKIN: WARM, DRY, NO LESIONS OR RASHES. BACK: NO FOCAL BONY TENDERNESS, NO CVA TENDERNESS. ETREMITIES: INTACT DIATAL PULSES. NO CYANOSIS OR ERYTHEMA. NO DEMA. MUSCULOSKELETAL: NO TENDERNESS TO PALPATION OR MAJOR DEFORMITIES NOTED. NEUROLOGIC: ALERT AND ORIENTED X3, NORMAL MOTOR FUNCTION, NORMAL SENSATION., NO FOCAL DEFICITS NOTED. PSYCHIATRIC: ALERT, NORMAL, MOOD NORMAL

ADVERSE EVENTS OF SPECIAL INTEREST AND **OTHER AREAS OF SPECIAL INTEREST

Weight Decreased: Day 1 weight 18[redacted].[redacted] lbs. Weight at time of event 17[redacted] lbs. Weight loss occurred over a period of 3 months. Change in diet or mobility level with pump/infusion therapy reported as the patient noted experiencing more physical activity during this time via boxing and walking. The patient made some lifestyle changes. Onset of weight loss did not coincide with worsening PD symptoms or eating difficulties. Subject experienced previous episode of cognitive decline and temporal episodes of activity increase/more active since treatment began, and dyskinesia and depression worsening since treatment began. No additional conditions or circumstances reported.

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
反射減弱				X
注入部位蜂巣炎	X			X

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	6[redacted]	FEMALE	WHITE

Medical History	Onset Year
ANXIETY	19[redacted]
INSOMNIA	19[redacted]
DEPRESSION	19[redacted]
GASTROESOPHAGEAL REFLUX	19[redacted]
HYPERTENSION	20[redacted]
POST-MENOPAUSAL	20[redacted]
OSTEOARTHRITIS	20[redacted]
MENINGIOMA, RIGHT FRONTAL	20[redacted]
PARKINSON'S DISEASE	20[redacted]
CERVICALGIA	20[redacted]
HYPERCHOLESTEROLEMIA	20[redacted]
ALLERGY - MOLD	20[redacted]
ALLERGY - POLLEN	20[redacted]
CONSTIPATION	20[redacted]
PSORIASIS (ON RIGHT ELBOW)	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
DEEP BRAIN STIMULATOR, GLOBUS PALLIDUS INTERNA (DBS GPI) IMPLANT	20[redacted]

DEEP BRAIN STIMULATOR, GLOBUS PALLIDUS INTERNA (DBS GPI), EXPLANT	20[redacted]
DEEP BRAIN STIMULATOR, SUBTHALAMIC NUCLEUS (DBS STN), IMPLANT	20[redacted]
IMPULSE GENERATOR (IPG) PLACEMENT	20[redacted]
RIGHT KNEE ARTHROPLASTY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	10 CIGARETTE	5	19[redacted]
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	LESS THAN 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.38	0.40	0.36	60	0.11	[redacted]20[redacted] / 365

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 1	
M15-741 /ABBV-951	832.06		SC / CONTINUOUS	[redacted]20[redacted] / 1	[redacted]20[redacted] / 1
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 2	
M15-741 /ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 2	[redacted]20[redacted] / 2
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 3	
M15-741 /ABBV-951	1815.41		SC / CONTINUOUS	[redacted]20[redacted] / 3	[redacted]20[redacted] / 3
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 4	
M15-741 /ABBV-951	1790.82		SC / CONTINUOUS	[redacted]20[redacted] / 4	[redacted]20[redacted] / 4
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 5	
M15-741 /ABBV-951	1657.98		SC / CONTINUOUS	[redacted]20[redacted] / 5	[redacted]20[redacted] / 5
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 6	
M15-741 /ABBV-951	1595.48		SC / CONTINUOUS	[redacted]20[redacted] / 6	[redacted]20[redacted] / 6
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 7	
M15-741 /ABBV-951	1554.16		SC / CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 7

M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 8	
M15-741 /ABBV-951	1519.50		SC / CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 8
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 9	
M15-741 /ABBV-951	1423.54		SC / CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 9
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 10	
M15-741 /ABBV-951	1425.25		SC / CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 10
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 11	
M15-741 /ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 11	[redacted]20[redacted] / 11
M15-741 /ABBV-951	1309.14		SC / CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
M15-741 /ABBV-951	1270.38		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 19
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 20	
M15-741 /ABBV-951	1394.17		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 21	
M15-741 /ABBV-951	1469.81		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 22	
M15-741 /ABBV-951	1475.28		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 27
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 27	
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 28	
M15-741 /ABBV-951	1485.35		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 29	
M15-741 /ABBV-951	1462.98		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
M15-741 /ABBV-951	1475.28		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 40
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 41	
M15-741 /ABBV-951	1500.72		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 42	
M15-741 /ABBV-951	1532.99		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
M15-741 /ABBV-951	1492.18		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
M15-741 /ABBV-951	1475.28		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 89
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 90	
M15-741 /ABBV-951	1544.43		SC / CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 90
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 91	
M15-741 /ABBV-951	1568.85		SC / CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
M15-741 /ABBV-951	1566.46		SC / CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 92
M15-741 /ABBV-951	1598.22		SC / CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 180
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 181	
M15-741 /ABBV-951	1570.21		SC / CONTINUOUS	[redacted]20[redacted] / 181	[redacted]20[redacted] / 181
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 182	

M15-741 /ABBV-951	1560.31		SC / CONTINUOUS	[redacted]20[redacted] / 182	[redacted]20[redacted] / 182
M15-741 /ABBV-951	1570.55		SC / CONTINUOUS	[redacted]20[redacted] / 183	[redacted]20[redacted] / 183
M15-741 /ABBV-951	1598.22		SC / CONTINUOUS	[redacted]20[redacted] / 184	[redacted]20[redacted] / 271
M15-741 /ABBV-951	1587.97		SC / CONTINUOUS	[redacted]20[redacted] / 272	[redacted]20[redacted] / 272
M15-741 /ABBV-951	1553.31		SC / CONTINUOUS	[redacted]20[redacted] / 273	[redacted]20[redacted] / 273
M15-741 /ABBV-951	1573.97		SC / CONTINUOUS	[redacted]20[redacted] / 274	[redacted]20[redacted] / 274
M15-741 /ABBV-951	1598.22		SC / CONTINUOUS	[redacted]20[redacted] / 275	[redacted]20[redacted] / 362
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 363	
M15-741 /ABBV-951	1593.26		SC / CONTINUOUS	[redacted]20[redacted] / 363	[redacted]20[redacted] / 363
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 364	
M15-741 /ABBV-951	1530.60		SC / CONTINUOUS	[redacted]20[redacted] / 364	[redacted]20[redacted] / 364
ABBV-951	486.63		SC / CONTINUOUS	[redacted]20[redacted] / 365	[redacted]20[redacted] / 365
ABBV-951	1557.24		SC / CONTINUOUS	[redacted]20[redacted] / 366	[redacted]20[redacted] / 450
ABBV-951	1588.65		SC / CONTINUOUS	[redacted]20[redacted] / 451	[redacted]20[redacted] / 451
ABBV-951	1523.09		SC / CONTINUOUS	[redacted]20[redacted] / 452	[redacted]20[redacted] / 452

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
TRAZODONE HYDROCHLORIDE	50 mg	PRN	Y-M: 20[redacted]-[redacted]
PARACETAMOL	500 mg	PRN	Y-M: 20[redacted]
CLONAZEPAM	1 mg	PRN	Y-M: 20[redacted]-[redacted]
OMEPRAZOLE	20 mg	QD	Y-M: 20[redacted]-[redacted]
DOCUSATE SODIUM	100 mg	PRN	Y-M: 20[redacted]
LACTOBACILLUS ACIDOPHILUS	50000 OTHER: UNITS	QD	Y-M: 20[redacted]-[redacted]
COLECALCIFEROL	1000 OTHER: UNITS	QD	Y-M: 20[redacted]-[redacted]
CALCIUM ASCORBATE	1000 mg	PRN	Y-M: 20[redacted]-[redacted]
ISTRADEFYLLINE	42.000 mg	PRN	Y-M: 20[redacted]-[redacted] / -75
ESCITALOPRAM OXALATE	20 mg	QD	Y-M: 20[redacted]-[redacted] / -41
OXYCODONE	5 mg	PRN	Y-M: 20[redacted]-[redacted] / -36
CYANOCOBALAMIN	1000 OTHER: MCG	QD	Y-M: 20[redacted]-[redacted] / -32
FOLIC ACID	400 OTHER: MCG	QD	Y-M: 20[redacted]-[redacted] / -30
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	PRN	Y-M: 20[redacted]-[redacted] / 1
CANNABIS SATIVA	10 mg	QD	Y-M: 20[redacted]-[redacted] / 53
IBUPROFEN	600 mg	PRN	Y-M: 20[redacted]-[redacted] / 64
CALCIUM	200 mg	BID	Y-M: 20[redacted]-[redacted] / 171
COLECALCIFEROL	600 IU	BID	Y-M: 20[redacted]-[redacted] / 171

PYRIDOXINE HYDROCHLORIDE	25 ug	OTHER: QOD	Y-M: 20[redacted] / 197

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
TRAZODONE HYDROCHLORIDE	50 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
PARACETAMOL	500 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
CLONAZEPAM	1 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
OMEPRAZOLE	20 mg	QD	Y-M: 20[redacted]	NOT REPORTED
DOCUSATE SODIUM	100 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
LACTOBACILLUS ACIDOPHILUS	50000 OTHER: UNITS	QD	Y-M: 20[redacted]	NOT REPORTED
COLECALCIFEROL	1000 OTHER: UNITS	QD	Y-M: 20[redacted]	NOT REPORTED
CALCIUM ASCORBATE	1000 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
ESCITALOPRAM OXALATE	20 mg	QD	Y-M: 20[redacted] / -41	NOT REPORTED
OXYCODONE	5 mg	PRN	Y-M: 20[redacted] / -36	NOT REPORTED
CYANOCOBALAMIN	1000 OTHER: MCG	QD	Y-M: 20[redacted] / -32	NOT REPORTED
FOLIC ACID	400 OTHER: MCG	QD	Y-M: 20[redacted] / -30	NOT REPORTED
CANNABIS SATIVA	10 mg	QD	Y-M: 20[redacted] / 53	NOT REPORTED
IBUPROFEN	600 mg	PRN	Y-M: 20[redacted] / 64	NOT REPORTED
CALCIUM	200 mg	BID	Y-M: 20[redacted] / 171	NOT REPORTED
COLECALCIFEROL	600 IU	BID	Y-M: 20[redacted] / 171	NOT REPORTED
PYRIDOXINE HYDROCHLORIDE	25 ug	OTHER: QOD	Y-M: 20[redacted] / 197	NOT REPORTED
GABAPENTIN	100 mg	TID	Y-M: 20[redacted] / 397	NOT REPORTED
DOXYCYCLINE	100 mg	BID	Y-M: 20[redacted] / 397	Y-M: 20[redacted] / 411
DOXYCYCLINE	100 mg	BID	Y-M: 20[redacted] / 430	Y-M: 20[redacted] / 433
MACROGOL 3350	17 g	PRN	Y-M: 20[redacted] / 433	Y-M: 20[redacted] / 435
SENNOSIDE A+B	17.2 mg	BID	Y-M: 20[redacted] / 433	Y-M: 20[redacted] / 435
VANCOMYCIN HYDROCHLORIDE	1.25 g	OTHER: EVERY 12 HOURS	Y-M: 20[redacted] / 433	Y-M: 20[redacted] / 435
ENOXAPARIN SODIUM	40 mg	OTHER: ONCE	Y-M: 20[redacted] / 434	Y-M: 20[redacted] / 434
PANTOPRAZOLE SODIUM SESQUIHYDRATE	40 mg	QD	Y-M: 20[redacted] / 434	Y-M: 20[redacted] / 435
SULFAMETHOXAZOLE;TRIMETHOPRIM	800-160 mg	BID	Y-M: 20[redacted] / 436	NOT REPORTED

Event #1: Event of Interest - Polyneuropathy

Event Description	HYPOREFLEXIVITY OF KNEES AND ANKLES
Preferred Term	反射減弱
AE Onset Date / Rx Day	[redacted]20[redacted] / 365
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS AT INFUSION SITE, RIGHT UPPER THIGH
Preferred Term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 393
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped Rx Day	429

Duration of AE	37 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS AT INFUSION SITE, RIGHT FLANK
Preferred Term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 430
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped Rx Day	433
Duration of AE	4 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Serious Adverse Event, Event of Interest - Infusion Site Related Infections

Event Description	ABDOMINAL WALL CELLULITIS, RIGHT FLANK, AT INFUSION SITE
Preferred Term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 433
Age at AE Onset	6[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 433): Leukocytes: 12.4 [4 - 9.5] 10^9/L

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 433): INCISION AND DRAIN OF ABDOMEN:SMALL AMOUNT OF FLUID OUT, PACKING PLACED; ULTRASOUND OF ABDOMEN:FLUID POCKET REVEALED

AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	PROBABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	PROBABLY RELATED TO THE CANNULA
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Generated: [redacted]20[redacted]:09:38

Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者は米国の 6[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に右脇腹の腹壁部に注入部位蜂巣炎を発現した。

Event 4 の臨床経過：

関連する病歴は，パーキンソン病，元喫煙者（1 日 10 本を 5 年間），及び現飲酒者（1 日 2 杯未満）であった。

投与 433 日目，被験者は右脇腹の腹壁部に注入部位蜂巣炎を発現した。

被験者は本事象発現前の投与から約 13 ヵ月後に右大腿部上部，投与から約 14 ヵ月後に右脇腹にそれぞれ非重篤の注入部位蜂巣炎を発現した。

投与 433 日目，被験者は右側腹部の注入部位に発赤，熱感，浮腫，及び疼痛の増強が 3 日間発現したため救急診療部にかかった。また，わずかに出血を伴った化膿部の排膿が認められた。被験者によると，発熱，悪寒，胸痛，息切れ，悪心，又は嘔吐は認められなかった。検査の結果，中心に硬化した部位が認められ，ベッドにて行った超音波検査で液状ポケットが確認された。切開及びドレナージが実施され，膿の顕著な排出はなかったが，小胞形成を認めたためパッキングを行った。臨床検査を実施し，抗生物質の静脈内投与を開始した。同日，抗生物質の静脈内投与を継続し精密な管理を行うために，被験者は入院した。蜂巣炎のモニタリングを行い，入院中に改善が認められた。投与 435 日目，被験者は退院し，経口の抗生物質の投与及びパッキングの交換が行われた。

被験者に VANCOCIN 及び BACTRIM が投与された。

Causality for ABBV-951 (Open Label)

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1) Infusion site cellulitis (10065455) (Infusion site cellulitis (10065455)) [v.24.1] [10065455]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of ABDOMINAL WALL CELLULITIS, RIGHT FLANK, AT INFUSION SITE

- Investigator: Probably related to the cannula

- AbbVie: Not applicable

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ULTRASOUND OF ABDOMEN:** Fluid pocket revealed

[redacted] **20[redacted] WHITE BLOOD CELLS:** 12.4 X10**3/MCL (normal 4.0 to 9.5)

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
注入部位蜂巣炎				X
注入部位丘疹				X
パーキンソン病	X	X	X	
** Disc. due to adverse event				X

Disc = Discontinued.

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	7[redacted]	FEMALE	WHITE

Medical History	Onset Year
HEADACHES	NOT REPORTED
APPENDICITIS	19[redacted]
MIXED INCONTINENCE	19[redacted]
PREMENOPAUSAL MENORRHAGIA	19[redacted]
CHOLECYSTITIS	19[redacted]
ADDISON DISEASE	19[redacted]
HASHIMOTOS THYROIDITIS	19[redacted]
BILATERAL CATARACTS	20[redacted]
CELIAC -NON TROPICAL SPRUE	20[redacted]
WALKING PNEUMONIA	20[redacted]
RESTLESS LEG SYNDROME	20[redacted]
LEFT BUNDLE BRANCH BLOCK	20[redacted]
EPIRETINAL MEMBRANE	20[redacted]
MACULAR DEGENERATION BOTH EYES	20[redacted]
POLYMYALGIA RHEUMATICA	20[redacted]
OSTEOARTHRITIS	20[redacted]
CARPAL TUNNEL SYNDROME LEFT HAND	20[redacted]
URINARY TRACT INFECTION	20[redacted]
ADRENAL INSUFICIENCY	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
APPENDECTOMY	19[redacted]
CESAREAN SECTION	19[redacted]
HYSTERECTOMY	19[redacted]
CHOLECYSTECTOMY	19[redacted]
BLADDER REPAIR	19[redacted]
BILATERAL CATARACT EXTRACTION	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	3 CIGARETTE	3	19[redacted]
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	LESS THAN 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.57	0.68	0.48	60	0.15	[redacted]20[redacted] / 367
ABBV-951	0.55	0.66	0.46		0.15	[redacted]20[redacted] / 535
ABBV-951	0.55	0.64	0.46	60	0.15	[redacted]20[redacted] / 563

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	669.34		SC / CONTINUOUS	[redacted]20[redacted] / 3	[redacted]20[redacted] / 3
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 4	
M15-741 /ABBV-951	1147.44		SC / CONTINUOUS	[redacted]20[redacted] / 4	[redacted]20[redacted] / 5

M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 5	
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 6	
M15-741 /ABBV-951	1105.77		SC / CONTINUOUS	[redacted]20[redacted] / 6	[redacted]20[redacted] / 6
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 7	
M15-741 /ABBV-951	1056.77		SC / CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 7
M15-741 /ABBV-951	1393.32		SC / CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 12
M15-741 /ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 13	
M15-741 /ABBV-951	1234.52		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 14	
M15-741 /ABBV-951	1066.33		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 15	
M15-741 /ABBV-951	1055.57		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
M15-741 /ABBV-951	1147.44		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 19
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 20	
M15-741 /ABBV-951	1128.31		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
M15-741 /ABBV-951	1147.44		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 22	
M15-741 /ABBV-951	1111.75		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 23	
M15-741 /ABBV-951	1220.17		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
M15-741 /ABBV-951	1393.32		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 29
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 30	
M15-741 /ABBV-951	1166.05		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 31	
M15-741 /ABBV-951	1171.00		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
M15-741 /ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 40
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 41	
M15-741 /ABBV-951	1036.79		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 42	
M15-741 /ABBV-951	1070.77		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
M15-741 /ABBV-951	1147.44		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 89
M15-741 /ABBV-951	1058.99		SC / CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 90
M15-741 /ABBV-951	928.53		SC / CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
M15-741 /ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 184
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 185	
M15-741 /ABBV-951	1193.54		SC / CONTINUOUS	[redacted]20[redacted] / 185	[redacted]20[redacted] / 185
M15-741 /ABBV-951	1225.98		SC / CONTINUOUS	[redacted]20[redacted] / 186	[redacted]20[redacted] / 186

M15-741 /ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 187	[redacted]20[redacted] / 266
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 267	
M15-741 /ABBV-951	507.12		SC / CONTINUOUS	[redacted]20[redacted] / 267	[redacted]20[redacted] / 267
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 268	
M15-741 /ABBV-951	680.26		SC / CONTINUOUS	[redacted]20[redacted] / 268	[redacted]20[redacted] / 268
ABBV-951	1850.07		SC / CONTINUOUS	[redacted]20[redacted] / 533	[redacted]20[redacted] / 533
ABBV-951	2335.86		SC / CONTINUOUS	[redacted]20[redacted] / 534	[redacted]20[redacted] / 539
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 540	
ABBV-951	2337.56		SC / CONTINUOUS	[redacted]20[redacted] / 540	[redacted]20[redacted] / 540
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 541	[redacted]20[redacted] / 542
ABBV-951	1795.60		SC / CONTINUOUS	[redacted]20[redacted] / 543	[redacted]20[redacted] / 543
ABBV-951	291.12		SC / CONTINUOUS	[redacted]20[redacted] / 544	[redacted]20[redacted] / 544

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
GABAPENTIN	100 mg	OTHER: EVERY MORNING	Y-M: 20[redacted]-[redacted]
LEVOTHYROXINE	100 OTHER: MCG	QD	Y-M: 20[redacted]-[redacted]
COLECALCIFEROL	2000 IU	QD	Y-M: 20[redacted]-[redacted]
ASCORBIC ACID;TOCOPHERYL ACETATE	1 OTHER: TABLET	QD	Y-M: 20[redacted]-[redacted]
PREDNISOLONE	5 mg	QD	Y-M: 20[redacted]-[redacted]
GABAPENTIN	400 mg	OTHER: EVERY NIGHT	Y-M: 20[redacted]-[redacted] / 66
FLUDROCORTISONE	0.3 mg	QD	Y-M: 20[redacted]-[redacted] / 289
FOLIC ACID	1 mg	QD	Y-M: 20[redacted]-[redacted] / 289
PYRIDOXINE HYDROCHLORIDE	100 mg	QD	Y-M: 20[redacted]-[redacted] / 289
SOLIFENACIN	10 mg	QD	Y-M: 20[redacted]-[redacted] / 289

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
GABAPENTIN	100 mg	OTHER: EVERY MORNING	Y-M: 20[redacted]-[redacted]	Y-M: 20[redacted]-[redacted] / 597
LEVOTHYROXINE	100 OTHER: MCG	QD	Y-M: 20[redacted]-[redacted]	Y-M: 20[redacted]-[redacted] / 597
COLECALCIFEROL	2000 IU	QD	Y-M: 20[redacted]-[redacted]	Y-M: 20[redacted]-[redacted] / 597
ASCORBIC ACID;TOCOPHERYL ACETATE	1 OTHER: TABLET	QD	Y-M: 20[redacted]-[redacted]	Y-M: 20[redacted]-[redacted] / 597
PREDNISOLONE	5 mg	QD	Y-M: 20[redacted]-[redacted]	Y-M: 20[redacted]-[redacted] / 597

GABAPENTIN	400 mg	OTHER: EVERY NIGHT	Y-M: 20[redacted] / 66	Y-M: 20[redacted] / 597
FLUDROCORTISONE	0.3 mg	QD	Y-M: 20[redacted] / 289	Y-M: 20[redacted] / 597
FOLIC ACID	1 mg	QD	Y-M: 20[redacted] / 289	Y-M: 20[redacted] / 597
PYRIDOXINE HYDROCHLORIDE	100 mg	QD	Y-M: 20[redacted] / 289	Y-M: 20[redacted] / 597
SOLIFENACIN	10 mg	QD	Y-M: 20[redacted] / 289	Y-M: 20[redacted] / 597
CEFALEXIN	500 mg	QID	Y-M: 20[redacted] / 372	Y-M: 20[redacted] / 597
CEFALEXIN	500 mg	QID	Y-M: 20[redacted] / 519	Y-M: 20[redacted] / 526
HYDROMORPHONE	1 mg	OTHER: 1 DOSE PER HOUR FOR PAIN	Y-M: 20[redacted] / 598	ONGOING
PHENOBARBITAL	100 OTHER: MG/ML	OTHER: EVERY 3 HOURS AS NEEDED	Y-M: 20[redacted] / 598	ONGOING

Event #1: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	PAPULE RIGHT UPPER ABDOMEN AT INFUSION SITE
Preferred Term	注入部位丘疹
AE Onset Date / Rx Day	[redacted]20[redacted] / 367
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped Rx Day	535
Duration of AE	169 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	PAPULE LEFT LOWER ABDOMEN AT INFUSION SITE
Preferred Term	注入部位丘疹
AE Onset Date / Rx Day	[redacted]20[redacted] / 367
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped Rx Day	535
Duration of AE	169 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Event of Interest - Infusion Site Related Infections

Event Description	LEFT ABDOMINAL WALL CELLULITIS AT INFUSION SITE
Preferred Term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 372
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped Rx Day	535
Duration of AE	164 DAYS

Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS OF THE LEFT LOWER ABDOMINAL WALL AT INFUSION SITE
Preferred Term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 519
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped Rx Day	535
Duration of AE	17 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #5: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, Death

Event Description	END STAGE PARKINSON'S DISEASE
Preferred Term	パーキンソン病
AE Onset Date / Rx Day	[redacted]20[redacted] / 598
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
SAE Supplemental Procedure	
NOT REPORTED	
AE Stopped Rx Day	600 (1 DAY AFTER LAST TREATMENT)
Duration of AE	3 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	PROGRESSION OF HER PARKINSON'S TO DEATH
Discontinued Study Drug Due to the Event	YES
SAE Criteria	DEATH OF SUBJECT

Generated: [redacted]20[redacted]:09:38

Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者は米国の 7[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に死亡に至った終末期のパーキンソン病を発現した。

Event 5 の臨床経過：

関連する病歴は，アジソン病，橋本甲状腺炎，非熱帯性セリアックスプルー，左脚ブロック，リウマチ性多発筋痛，変形性関節症，副腎不全，元喫煙者（1 日 3 本を 3 年間），及び現飲酒者（1 日 2 杯未満）であった。

- 投与 598 日目，被験者は終末期のパーキンソン病を発現した。投与 600 日目，被験者は死亡した。死因は終末期のパーキンソン病と報告された。剖検は実施されなかった。

投与 597 日目，被験者は長椅子に座ったまま反応がなくなり始めた。また，被験者は水，食事及び薬を拒否するようになった。治験責任医師によると，これは非常に時間をかけて進行したものと，被験者の家族が報告したとのことであった。投与 598 日目，被験者は家族により緊急治療室に連れてこられ，譫妄，食欲不振，新たに認められた寝たきりの状態，及び新たに認められた失禁を伴っていた。被験者の家族は臨床検査及び診断検査を拒否し，被験者をホスピスへ移すことを決めた。投与 600 日目，被験者は死亡した。被験者は，治験の医学専門家の承認を得て，死亡時に治験薬投与中であった。

治験責任医師によると，本事象と関連するリスク因子はパーキンソン病であった。

被験者にヒドロモルフォン及びフェノバルビタールが投与された。

Causality for ABBV-951 (Open Label)

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1) End stage Parkinson's disease (10076917) (Parkinson's disease (10061536)) [v.24.0] [10076917]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of END STAGE PARKINSON'S DISEASE

- Investigator: PROGRESSION OF HER PARKINSON'S TO DEATH

- AbbVie: More likely related to the progression of pre existing Parkinson disease in an elderly subject with multiple comorbidities.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BMI:** 17.98 kg/m2

[redacted] **20[redacted] BODY WEIGHT:** 4[redacted].[redacted] KG

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
冠動脈疾患	X			
注入部位紅斑				X

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	6[redacted]	MALE	WHITE

Medical History	Onset Year
HERNIA	19[redacted]
TONSILLITIS	19[redacted]
TYPE 1 DIABETES	19[redacted]
CHRONIC BACK PAIN	19[redacted]
HERPES SIMPLEX VIRUS	19[redacted]
MIXED HYPERLIPIDEMIA	20[redacted]
INTERMITTENT VERTIGO	20[redacted]
SLEEP APNEA	20[redacted]
SCOLIOSIS	20[redacted]
SPONDYLOLISTHESIS	20[redacted]
CAROTID STENOSIS	20[redacted]
CEREBROVASCULAR ACCIDENT	20[redacted]
HYPERTENSION	20[redacted]
ERECTILE DYSFUNCTION	20[redacted]
GENERALIZED ANXIETY DISORDER	20[redacted]
DEPRESSION	20[redacted]
ALLERGIES	20[redacted]
LEFT HIP OSTEOARTHRITIS	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]

Prior Procedures	Procedure Year
HERNIA REPAIR	19[redacted]
TONSILLECTOMY	19[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	4 CIGARETTE	4	19[redacted]
CIGARS	FORMER			
E-CIGARETTES	NEVER			
PIPES	FORMER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	LESS THAN 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.21	0.23	0.19		0.11	[redacted]20[redacted] / 363
ABBV-951	0.22	0.25	0.19	60	0.15	[redacted]20[redacted] / 371
ABBV-951	0.22	0.25	0.19	60	0.15	[redacted]20[redacted] / 532
ABBV-951	0.22	0.25	0.19	60	0.15	[redacted]20[redacted] / 691

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	375.65		SC / CONTINUOUS	[redacted]20[redacted] / 1	[redacted]20[redacted] / 1
M15-741 /ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 2	[redacted]20[redacted] / 5
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 6	
M15-741 /ABBV-951	815.16		SC / CONTINUOUS	[redacted]20[redacted] / 6	[redacted]20[redacted] / 6
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 7	
M15-741 /ABBV-951	912.82		SC / CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 7
M15-741 /ABBV-951	983.52		SC / CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 12
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 13	
M15-741 /ABBV-951	946.63		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
M15-741 /ABBV-951		75.13	SC / ONCE	[redacted]20[redacted] / 14	
M15-741 /ABBV-951	889.26		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
M15-741 /ABBV-951	849.65		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15

M15-741 /ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 18
M15-741 /ABBV-951	848.96		SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 20	
M15-741 /ABBV-951	950.05		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
M15-741 /ABBV-951	846.23		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
M15-741 /ABBV-951	935.36		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
M15-741 /ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 25
M15-741 /ABBV-951	934.85		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 27	
M15-741 /ABBV-951	749.59		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 28	
M15-741 /ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
M15-741 /ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 41
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 42	
M15-741 /ABBV-951	914.19		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 43	
M15-741 /ABBV-951	877.65		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
M15-741 /ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 82
M15-741 /ABBV-951	894.73		SC / CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
M15-741 /ABBV-951		75.13	SC / ONCE	[redacted]20[redacted] / 84	
M15-741 /ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
M15-741 /ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 85	[redacted]20[redacted] / 180
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 181	
M15-741 /ABBV-951	868.09		SC / CONTINUOUS	[redacted]20[redacted] / 181	[redacted]20[redacted] / 181
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 182	
M15-741 /ABBV-951	834.62		SC / CONTINUOUS	[redacted]20[redacted] / 182	[redacted]20[redacted] / 182
M15-741 /ABBV-951	778.62		SC / CONTINUOUS	[redacted]20[redacted] / 183	[redacted]20[redacted] / 270
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 271	
M15-741 /ABBV-951	825.57		SC / CONTINUOUS	[redacted]20[redacted] / 271	[redacted]20[redacted] / 271
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 272	
M15-741 /ABBV-951	895.07		SC / CONTINUOUS	[redacted]20[redacted] / 272	[redacted]20[redacted] / 272
M15-741 /ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 273	[redacted]20[redacted] / 362
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 361	
M15-741 /ABBV-951		112.69	SC / ONCE	[redacted]20[redacted] / 362	
ABBV-951	394.43		SC / CONTINUOUS	[redacted]20[redacted] / 363	[redacted]20[redacted] / 363
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 364	[redacted]20[redacted] / 529
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 530	

ABBV-951	918.46		SC / CONTINUOUS	[redacted]20[redacted] / 530	[redacted]20[redacted] / 530
ABBV-951	929.05		SC / CONTINUOUS	[redacted]20[redacted] / 531	[redacted]20[redacted] / 531
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 532	
ABBV-951	862.11		SC / CONTINUOUS	[redacted]20[redacted] / 532	[redacted]20[redacted] / 532
ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 533	[redacted]20[redacted] / 613
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 614	
ABBV-951	911.63		SC / CONTINUOUS	[redacted]20[redacted] / 614	[redacted]20[redacted] / 614
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 615	
ABBV-951	920.00		SC / CONTINUOUS	[redacted]20[redacted] / 615	[redacted]20[redacted] / 615
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 689	
ABBV-951	924.09		SC / CONTINUOUS	[redacted]20[redacted] / 689	[redacted]20[redacted] / 689
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 690	
ABBV-951	901.73		SC / CONTINUOUS	[redacted]20[redacted] / 690	[redacted]20[redacted] / 690

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
INSULIN ASPART	33-55 OTHER: UNITS, VIA INSULIN PUMP	OTHER: INSULIN PUMP	Y-M: 19[redacted]
SILDENAFIL	20 mg	PRN	Y-M: 20[redacted]-[redacted]
INSULIN DEGLUDEC	12 OTHER: UNITS	QD	Y-M: 20[redacted]-[redacted]
LOSARTAN	25 mg	QD	Y-M: 20[redacted]-[redacted] / -150
PARACETAMOL	500-1000 mg	PRN	Y-M: 20[redacted]-[redacted] / -150
CLOPIDOGREL	75 mg	QD	Y-M: 20[redacted]-[redacted] / -113
ASTAXANTHIN	4 mg	QD	Y-M: 20[redacted]-[redacted] / -35
COLECALCIFEROL	5000 IU	QD	Y-M: 20[redacted]-[redacted] / -35
CURCUMA LONGA	400 mg	BID	Y-M: 20[redacted]-[redacted] / -35
IBUPROFEN	200 mg	PRN	Y-M: 20[redacted]-[redacted] / -35
MAGNESIUM OXIDE	400 mg	QD	Y-M: 20[redacted]-[redacted] / -35
MELATONIN	300 OTHER: MCG	OTHER: QHS	Y-M: 20[redacted]-[redacted] / -35
TRAMADOL	50 mg	PRN	Y-M: 20[redacted]-[redacted] / -35
METOPROLOL TARTRATE	50 mg	QD	Y-M: 20[redacted]-[redacted] / 327
DOCUSATE SODIUM;SENNOSIDE A+B	100 mg	BID	Y-M: 20[redacted]-[redacted] / 331
LISINOPRIL	15 mg	BID	Y-M: 20[redacted]-[redacted] / 331
LORAZEPAM	0.5 mg	PRN	Y-M: 20[redacted]-[redacted] / 331
MACROGOL 3350	17 g	PRN	Y-M: 20[redacted]-[redacted] / 331
LIDOCAINE	1-2 OTHER: PATCHES	QD	Y-M: 20[redacted]-[redacted] / 338
CLOPIDOGREL BISULFATE	75 mg	QD	Y-M: 20[redacted]-[redacted] / 339

FLUTICASONE PROPIONATE	2 OTHER: SPRAYS	QD	Y-M: 20[redacted] / 345
POTASSIUM CHLORIDE	10 mEq	QD	Y-M: 20[redacted] / 352

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
INSULIN ASPART	33-55 OTHER: UNITS, VIA INSULIN PUMP	OTHER: INSULIN PUMP	Y-M: 19[redacted]	NOT REPORTED
SILDENAFIL	20 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
INSULIN DEGLUDEC	12 OTHER: UNITS	QD	Y-M: 20[redacted]	NOT REPORTED
LOSARTAN	25 mg	QD	Y-M: 20[redacted] / -150	NOT REPORTED
PARACETAMOL	500-1000 mg	PRN	Y-M: 20[redacted] / -150	NOT REPORTED
CLOPIDOGREL	75 mg	QD	Y-M: 20[redacted] / -113	NOT REPORTED
ASTAXANTHIN	4 mg	QD	Y-M: 20[redacted] / -35	NOT REPORTED
COLECALCIFEROL	5000 IU	QD	Y-M: 20[redacted] / -35	NOT REPORTED
CURCUMA LONGA	400 mg	BID	Y-M: 20[redacted] / -35	NOT REPORTED
IBUPROFEN	200 mg	PRN	Y-M: 20[redacted] / -35	NOT REPORTED
MAGNESIUM OXIDE	400 mg	QD	Y-M: 20[redacted] / -35	NOT REPORTED
MELATONIN	300 OTHER: MCG	OTHER: QHS	Y-M: 20[redacted] / -35	NOT REPORTED
TRAMADOL	50 mg	PRN	Y-M: 20[redacted] / -35	NOT REPORTED
METOPROLOL TARTRATE	50 mg	QD	Y-M: 20[redacted] / 327	NOT REPORTED
DOCUSATE SODIUM;SENNOSIDE A+B	100 mg	BID	Y-M: 20[redacted] / 331	NOT REPORTED
LISINOPRIL	15 mg	BID	Y-M: 20[redacted] / 331	NOT REPORTED
LORAZEPAM	0.5 mg	PRN	Y-M: 20[redacted] / 331	NOT REPORTED
MACROGOL 3350	17 g	PRN	Y-M: 20[redacted] / 331	NOT REPORTED
LIDOCAINE	1-2 OTHER: PATCHES	QD	Y-M: 20[redacted] / 338	NOT REPORTED
CLOPIDOGREL BISULFATE	75 mg	QD	Y-M: 20[redacted] / 339	NOT REPORTED
FLUTICASONE PROPIONATE	2 OTHER: SPRAYS	QD	Y-M: 20[redacted] / 345	NOT REPORTED
POTASSIUM CHLORIDE	10 mEq	QD	Y-M: 20[redacted] / 352	NOT REPORTED
BETAMETHASONE	6 mg	OTHER: ONCE	Y-M: 20[redacted] / 377	Y-M: 20[redacted] / 377
LIDOCAINE	1 mL	OTHER: ONCE	Y-M: 20[redacted] / 377	Y-M: 20[redacted] / 377
SULFAMETHOXAZOLE;TRIMETHOPRIM	800-160 mg	BID	Y-M: 20[redacted] / 580	Y-M: 20[redacted] / 586

Event #1: Serious Adverse Event

Event Description	CORONARY ARTERY DISEASE
Preferred Term	冠動脈疾患
AE Onset Date / Rx Day	[redacted]20[redacted] / 328
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
SAE Supplemental Procedure	
NOT REPORTED	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	PATIENT HAD AN NSTEMI RECENTLY (SEE SEPARATE SAE REPORT PREVIOUSLY ENTERED) AND WAS FOUND TO HAVE DIFFUSE DISEASE FROM HIS DM1. RECOMMENDED TO HAVE CABG WHICH WAS COMPLETED [redacted]20[redacted]
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION, LIFE THREATENING

Event #2: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE ERYTHEMA
Preferred Term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 579
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	

NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Generated: [redacted] 20[redacted]:09:38

Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者は米国の 6[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に心内膜下心筋梗塞，冠動脈疾患，心停止，及び低ナトリウム血症を発現した。

Event 1 の臨床経過：

関連する病歴は，1 型糖尿病，混合型脂質異常症，頸動脈狭窄症，脳血管発作，高血圧，パーキンソン病，全般性不安障害，元喫煙者（1 日 4 本を 4 年間），及び現飲酒者（1 日 2 杯未満）であった。また，被験者の父親に糖尿病，高血圧，及び冠動脈疾患の病歴が，母親に脳卒中の病歴があった。

投与 1 日目から 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するための治験薬の調整を必要とした。投与 5 週時に，被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 326 日目，被験者は心内膜下心筋梗塞及び低ナトリウム血症を発現した。投与 328 日目被験者は，冠動脈疾患を発現した。投与 335 日目，低ナトリウム血症は消失した。投与 336 日目被験者は，心停止を発現した。投与 336 日目，心停止は消失した。

投与 326 日目，被験者は浮動性めまい，悪心，及び嘔吐を訴え，救急診療部に来院した。被験者によると，症状は 1 週間ほど継続しており，2 種類の薬剤（ロスバスタチン及びヒドロクロロチアジド）を新たに服用し始めた辺りから症状が出たことに気が付いたとのことであった。被験者はこれまでヒドロクロロチアジドを不定期に使用していたと述べた。被験者は嘔吐をしたと述べ，「古い血液」のようだと言われたと報告した。被験者は最近旅行に行ったことはなく，病気の人と接触したこともなかった。被験者は妻と 2 階建ての自宅に住み，大きな問題もなく階段を使っていた。被験者によると，経口摂取も少なかったとのことであった。被験者はインスリン注入ポンプでグルコース値を管理していた。また，Sinemet（CD/LD）でも注入ポンプを使用した経験があり，現在治験に参加している。被験者は低ナトリウム血症及び脱水のため入院した。被験者は横紋筋融解症（非重篤）とも診断された。また，被験者は頚部痛及び嘔吐のエピソードを発現した。初回採血時のトロポニンは陰性であったが，その後の採血では上昇した（心内膜下心筋梗塞）。

被験者は他院へ移送され，低ナトリウム血症，心内膜下心筋梗塞，及び上部消化管出血の疑いのため集中治療室に入院した。被験者に衰弱，便秘，悪心，嘔吐，及び不安が認められた。発熱，悪寒，咳嗽，息切れ，及び下痢は認められなかった。トロポニンは投与 327 日目の遅くまで上昇した。投与 328 日目，被験者は心臓カテーテル処置を受け，びまん性の糖尿病性心疾患が発見された。投与 335 日目，横紋筋融解症（非重篤）は消失した。投与 336 日目，被験者は 3 ヵ所の冠動脈バイパス移植を受けた。夕方，被験者に迷走神経反射が認められ，心停止を引き起こした。心肺機能蘇生を受けた結果，被験者は自発循環が回復し，その後再挿管され，最終的には抜管された。当初はラシックスが必要であった。両側性の胸腔チューブが挿管され，その後抜管された。集中治療室に滞在している期間を通して血圧は不安定であった。数日間利尿剤を休薬した後，フロセミドの静脈内投与に移行し，その後経口投与に切り替えた。酸素の補給は徐々に中止した。手術前の体重は約 12[redacted] ポンドであり，退院時は 14[redacted] ポンドであった。経口ラシックス 20 mg 1 日 2 回を 7 日間，及び塩化カリウム 10 mEq を毎日投与し，カリウム値を 4.3 の高値に維持した状態で，室内での酸素飽和濃度が 97%となり被験者は退院した。クレアチニンは術後の最高値が 1.19 であり，安定して推移した。

被験者にフロセミド，リシノプリル，メトプロロール酒石酸塩，5%デキストロースを含む乳酸リンゲル液，生理食塩水，及び塩化カリウムが投与された。

The patient's past medications include:

ROPINIROLE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Non ST segment elevation myocardial infarction (10064347) (Acute myocardial infarction (10000891)) [v.23.1] [10064347]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

2) Coronary artery disease (10011078) (Coronary artery disease (10011078)) [v.23.1] [10011078]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: No

3) Cardiac arrest (10007515) (Cardiac arrest (10007515)) [v.23.1] [10007515]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

4) Hyponatremia (10021038) (Hyponatraemia (10021036)) [v.23.1] [10021038]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of NSTEMI

- Investigator: Likely underlying coronary artery disease (for NSTEMI). Hypernatremia due to dehydration and poor oral intake (which could be due to NSTEMI). Rhabdomyolysis (non-serious) is due to statin therapy (discontinued).

- AbbVie: More likely related to a history of hypertension, mixed hyperlipidemia, cerebrovascular accident, diabetes and Parkinson's disease in a 6[redacted] year old patient with family history of coronary arterial disease.

Event of CORONARY ARTERY DISEASE

- Investigator: Patient had an NSTEMI recently and was found to have diffuse disease from his DM1. Recommended to have CABG which was completed [redacted] 20[redacted].

- AbbVie: More likely related to a history of hypertension, mixed hyperlipidemia, cerebrovascular accident, diabetes and Parkinson's disease in a 6[redacted] year old patient with family history of coronary arterial disease.

Event of CARDIAC ARREST

- Investigator: Post-surgical vasovagal reaction

- AbbVie: More likely related to a complication of concurrent bypass surgery in a 6[redacted] year old patient with a history of hypertension, mixed hyperlipidemia, cerebrovascular accident, sleep apnea diabetes and Parkinson's disease

Event of HYPONATREMIA

- Investigator: Hyponatremia due to dehydration and poor oral intake (which could be due to NSTEMI).

- AbbVie: More likely related to reported nausea, vomiting, poor oral intake, rhabdomyolysis and dehydration in an advanced aged patient with a history of type 1 diabetes.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BLOOD PH:** 7.28 no unit (normal 7.35 to 7.45)

[redacted] **20[redacted] BLOOD PH:** 7.48 no unit (normal 7.35 to 7.45)
[redacted] **20[redacted] BODY WEIGHT:** 14[redacted] Pounds

[redacted] **20[redacted] CARDIAC CATHETERIZATION:** 1. Diffusely diseased diabetic appearing left anterior descending artery with high-grade stenosis in the midportion as well as diffuse disease. This appears to be affecting multiple small diagonal vessels. 2. High-grade stenosis in the proximal circumflex and 1st obtuse marginal vessel. 3. High-grade stenosis in the posterior descending artery and posterolateral vessel. 4. Diabetic appearance to the coronary artery disease. 5. Normal resting end-diastolic pressure of the left ventricle without aortic valve gradient on pullback

[redacted] **20[redacted] CREATININE:** 1.19 no units

[redacted] **20[redacted] CREATININE KINASE:** 445 IU/L (normal 25 to 300)

[redacted] **20[redacted] HEMOGLOBIN:** 6.9 G/DL (normal 13.6 to 18.0)

[redacted] **20[redacted] HEMOGLOBIN:** 13.6 G/DL (normal 13.6 to 18.0)

[redacted] **20[redacted] LACTATE:** 6.4 MMOL/L (normal 0.5 to 2.0)

[redacted] **20[redacted] OCCULT BLOOD, GASTRIC:** specimen: emesis - positive

[redacted] **20[redacted] POTASSIUM:** 3.3 MMOL/L (normal 3.8 to 5.0)

[redacted] **20[redacted] POTASSIUM:** 4.3 MMOL/L (normal 3.8 to 5.0)

[redacted] **20[redacted] SODIUM:** 117 MMOL/L (normal 135 to 144)

[redacted] **20[redacted] SODIUM:** 127 MMOL/L (normal 135 to 144)

[redacted] **20[redacted] TRANSESOPHAGEAL ECHOCARDIOGRAM:** Successful

[redacted] **20[redacted] TROPONIN:** 3.79 NG/ML (normal 0 to 0.03)

[redacted] **20[redacted] WBC:** 20.27 X10**3/MCL (normal 4 to 10)

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
心房細動	X			
冠動脈疾患	X			
転倒				X
注入部位紅斑				X
肺塞栓症	X			

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	7[redacted]	MALE	WHITE

Medical History	Onset Year
ANXIETY	NOT REPORTED
GASTRIC REFLUX	19[redacted]
HYPERCHOLESTEROLEMIA	19[redacted]
NISSEN FUNDOPLICATION	19[redacted]
ERECTILE DYSFUNCTION	20[redacted]
RESTLESS LEG SYNDROME	20[redacted]
HEADACHE	20[redacted]
DEPRESSION	20[redacted]
BILATERAL KNEE PAIN	20[redacted]
OSTEOARTHRITIS	20[redacted]
CONSTIPATION	20[redacted]
INSOMNIA	20[redacted]
PERIPHERAL NEUROPATHY	20[redacted]
RIGHT SHOULDER PAIN	20[redacted]
HEARTBURN	20[redacted]
LEFT SHOULDER PAIN	20[redacted]
OVERACTIVE BLADDER	20[redacted]
ORTHOSTATIC HYPOTENSION	20[redacted]
VITAMIN B 12 DEFICIENCY	20[redacted]
VITAMIN B 6 DEFICIENCY	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
NISSEN FUNDOPLICATION	19[redacted]
DEEP BRAIN STIMULATOR	20[redacted]
RIGHT TOTAL KNEE ARTHROPLASTY	20[redacted]
RIGHT SHOULDER ARTHROPLASTY	20[redacted]
LEFT TOTAL KNEE ARTHROPLASTY	20[redacted]
LEFT SHOULDER ARTHROPLASTY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	10 CIGARETTE	10	19[redacted]
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	FORMER	LESS THAN 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.70	0.71	0.68	0	0.00	[redacted]20[redacted] / 365
ABBV-951	0.70	0.71	0.68	0	0.00	[redacted]20[redacted] / 382
ABBV-951	0.70	0.71	0.68	60	0.19	[redacted]20[redacted] / 395
ABBV-951	0.70	0.71	0.68	0	0.00	[redacted]20[redacted] / 421
ABBV-951	0.70	0.71	0.68	0	0.00	[redacted]20[redacted] / 435
ABBV-951	0.7	0.71	0.68	0	0.00	[redacted]20[redacted] / 449
ABBV-951	0.69	0.71	0.67	0	0.00	[redacted]20[redacted] / 463
ABBV-951	0.69	0.71	0.67	0	0.00	[redacted]20[redacted] / 477
ABBV-951	0.69	0.71	0.67	0	0.00	[redacted]20[redacted] / 491
ABBV-951	0.69	0.71	0.67	0	0.00	[redacted]20[redacted] / 505

ABBV-951	0.69	0.71	0.67	0	0.00	[redacted] / 523
ABBV-951	0.69	0.71	0.67	0	0.00	[redacted] / 535
ABBV-951	0.69	0.71	0.67	0	0.00	[redacted] / 571
ABBV-951	0.69	0.71	0.67	0	0.00	[redacted] / 589
ABBV-951	0.69	0.71	0.67	0	0.00	[redacted] / 596
ABBV-951	0.69	0.71	0.67	0	0.00	[redacted] / 624
ABBV-951	0.69	0.71	0.67	0	0.00	[redacted] / 640
ABBV-951	0.69	0.71	0.67	0	0.00	[redacted] / 653
ABBV-951	0.69	0.71	0.67	0	0.00	[redacted] / 667
ABBV-951	0.69	0.71	0.67	0	0.00	[redacted] / 680
ABBV-951	0.69	0.71	0.67	0	0.00	[redacted] / 695

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	1506.01		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
M15-741 /ABBV-951	2581.74		SC / CONTINUOUS	[redacted] / 2	[redacted] / 5
M15-741 /ABBV-951	2560.22		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
M15-741 /ABBV-951		0	SC / ONCE	[redacted] / 7	
M15-741 /ABBV-951	2506.43		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
M15-741 /ABBV-951	2581.74		SC / CONTINUOUS	[redacted] / 8	[redacted] / 12
M15-741 /ABBV-951	2559.03		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
M15-741 /ABBV-951	2597.10		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
M15-741 /ABBV-951	2663.7		SC / CONTINUOUS	[redacted] / 15	[redacted] / 20
M15-741 /ABBV-951		0	SC / ONCE	[redacted] / 21	
M15-741 /ABBV-951	2591.98		SC / CONTINUOUS	[redacted] / 21	[redacted] / 21
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted] / 22	
M15-741 /ABBV-951	2627.15		SC / CONTINUOUS	[redacted] / 22	[redacted] / 22
M15-741 /ABBV-951	2745.66		SC / CONTINUOUS	[redacted] / 23	[redacted] / 26
M15-741 /ABBV-951	2688.45		SC / CONTINUOUS	[redacted] / 27	[redacted] / 27
M15-741 /ABBV-951	2699.89		SC / CONTINUOUS	[redacted] / 28	[redacted] / 28
M15-741 /ABBV-951	2745.66		SC / CONTINUOUS	[redacted] / 29	[redacted] / 33
M15-741 /ABBV-951		0	SC / ONCE	[redacted] / 34	
M15-741 /ABBV-951	2693.23		SC / CONTINUOUS	[redacted] / 34	[redacted] / 34
M15-741 /ABBV-951	2685.89		SC / CONTINUOUS	[redacted] / 35	[redacted] / 35
M15-741 /ABBV-951	2704.68		SC / CONTINUOUS	[redacted] / 36	[redacted] / 40
M15-741 /ABBV-951	2705.02		SC / CONTINUOUS	[redacted] / 41	[redacted] / 41

M15-741 /ABBV-951	2688.28		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
M15-741 /ABBV-951	2704.68		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 61
M15-741 /ABBV-951	2733.02		SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
M15-741 /ABBV-951	2659.60		SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
M15-741 /ABBV-951	2704.68		SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 89
M15-741 /ABBV-951		0	SC / ONCE	[redacted]20[redacted] / 90	
M15-741 /ABBV-951	2608.71		SC / CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 90
M15-741 /ABBV-951		0	SC / ONCE	[redacted]20[redacted] / 91	
M15-741 /ABBV-951	2796.88		SC / CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
M15-741 /ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 180
M15-741 /ABBV-951	2754.19		SC / CONTINUOUS	[redacted]20[redacted] / 181	[redacted]20[redacted] / 181
M15-741 /ABBV-951	2721.75		SC / CONTINUOUS	[redacted]20[redacted] / 182	[redacted]20[redacted] / 182
M15-741 /ABBV-951	2786.64		SC / CONTINUOUS	[redacted]20[redacted] / 183	[redacted]20[redacted] / 267
M15-741 /ABBV-951	2772.29		SC / CONTINUOUS	[redacted]20[redacted] / 268	[redacted]20[redacted] / 268
M15-741 /ABBV-951	2783.22		SC / CONTINUOUS	[redacted]20[redacted] / 269	[redacted]20[redacted] / 269
M15-741 /ABBV-951	2786.64		SC / CONTINUOUS	[redacted]20[redacted] / 270	[redacted]20[redacted] / 362
M15-741 /ABBV-951	2780.15		SC / CONTINUOUS	[redacted]20[redacted] / 363	[redacted]20[redacted] / 363
M15-741 /ABBV-951	2716.97		SC / CONTINUOUS	[redacted]20[redacted] / 364	[redacted]20[redacted] / 364
ABBV-951	1553.82		SC / CONTINUOUS	[redacted]20[redacted] / 365	[redacted]20[redacted] / 365
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 366	[redacted]20[redacted] / 532
ABBV-951	2779.46		SC / CONTINUOUS	[redacted]20[redacted] / 533	[redacted]20[redacted] / 533
ABBV-951	2771.27		SC / CONTINUOUS	[redacted]20[redacted] / 534	[redacted]20[redacted] / 534
ABBV-951	2745.66		SC / CONTINUOUS	[redacted]20[redacted] / 535	[redacted]20[redacted] / 621
ABBV-951	2782.71		SC / CONTINUOUS	[redacted]20[redacted] / 622	[redacted]20[redacted] / 622
ABBV-951	2740.19		SC / CONTINUOUS	[redacted]20[redacted] / 623	[redacted]20[redacted] / 623
ABBV-951	2745.66		SC / CONTINUOUS	[redacted]20[redacted] / 624	[redacted]20[redacted] / 705

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
SILDENAFIL	20 mg	TID	Y-M: 20[redacted]-[redacted]
ROPINIROLE	1 mg	TID	Y-M: 20[redacted]
ROSUVASTATIN	10 mg	OTHER: QHS	Y-M: 20[redacted]
IBUPROFEN	200 mg	PRN	Y-M: 20[redacted]
CITALOPRAM	40 mg	OTHER: QAM	Y-M: 20[redacted]
MAGNESIUM CARBONATE	1 OTHER: TBSP	OTHER: QHS	Y-M: 20[redacted]
CALCIUM CARBONATE	1 OTHER: TAB	PRN	Y-M: 20[redacted]
MIRABEGRON	25 mg	QD	Y-M: 20[redacted]-[redacted]

CURCUMA LONGA	500 mg	BID	Y-M: 20[redacted]
PYRIDOSTIGMINE	60 mg	TID	Y-M: 20[redacted]-[redacted]
MELATONIN	3 mg	OTHER: QHS	Y-M: 20[redacted]-[redacted]
ACETYLSALICYLIC ACID	81 mg	QD	Y-M: 20[redacted]-[redacted] / 191
AMIODARONE	200 mg	QD	Y-M: 20[redacted]-[redacted] / 263
VITAMIN B12 NOS	1000 MCG OTHER: MCG	OTHER: MONTHLY	Y-M: 20[redacted]-[redacted] / 327

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
SILDENAFIL	20 mg	TID	Y-M: 20[redacted]-[redacted]	NOT REPORTED
ROPINIROLE	1 mg	TID	Y-M: 20[redacted]	NOT REPORTED
ROSUVASTATIN	10 mg	OTHER: QHS	Y-M: 20[redacted]	NOT REPORTED
IBUPROFEN	200 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
CITALOPRAM	40 mg	OTHER: QAM	Y-M: 20[redacted]	NOT REPORTED
MAGNESIUM CARBONATE	1 OTHER: TBSP	OTHER: QHS	Y-M: 20[redacted]	NOT REPORTED
CALCIUM CARBONATE	1 OTHER: TAB	PRN	Y-M: 20[redacted]	NOT REPORTED
MIRABEGRON	25 mg	QD	Y-M: 20[redacted]-[redacted]	NOT REPORTED
CURCUMA LONGA	500 mg	BID	Y-M: 20[redacted]	NOT REPORTED
PYRIDOSTIGMINE	60 mg	TID	Y-M: 20[redacted]-[redacted]	NOT REPORTED
MELATONIN	3 mg	OTHER: QHS	Y-M: 20[redacted]-[redacted]	NOT REPORTED
ACETYLSALICYLIC ACID	81 mg	QD	Y-M: 20[redacted]-[redacted] / 191	NOT REPORTED
AMIODARONE	200 mg	QD	Y-M: 20[redacted]-[redacted] / 263	NOT REPORTED
VITAMIN B12 NOS	1000 MCG OTHER: MCG	OTHER: MONTHLY	Y-M: 20[redacted]-[redacted] / 327	NOT REPORTED
CLINDAMYCIN	300 mg	BID	Y-M: 20[redacted]-[redacted] / 441	NOT REPORTED
TOZINAMERAN	1 SHOT PFIZER mL	OTHER: ONCE	Y-M: 20[redacted]-[redacted] / 441	Y-M: 20[redacted]-[redacted] / 441
TOZINAMERAN	1 mg	OTHER: ONCE	Y-M: 20[redacted]-[redacted] / 463	Y-M: 20[redacted]-[redacted] / 463

Event #1: Serious Adverse Event

Event Description	CORONARY ARTERY DISEASE
Preferred Term	冠動脈疾患
AE Onset Date / Rx Day	[redacted]20[redacted] / 191
Age at AE Onset	7[redacted]
Laboratory Testing	

NOT REPORTED

Microbiology

NOT REPORTED

SAE Supplemental Procedure

NOT REPORTED

AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	RISK FACTORS, FAMILY HISTORY
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #2: Serious Adverse Event

Event Description	ATRIAL FIBRILLATION
Preferred Term	心房細動
AE Onset Date / Rx Day	[redacted]20[redacted] / 195
Age at AE Onset	7[redacted]

Laboratory Testing

NOT REPORTED

Microbiology

NOT REPORTED

SAE Supplemental Procedure

NOT REPORTED

AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	RISK FACTOR, NEW DIAGNOSIS OF CORONARY ARTERY DISEASE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #3: Serious Adverse Event

Event Description	PULMONARY EMBOLI
Preferred Term	肺塞栓症
AE Onset Date / Rx Day	[redacted]20[redacted] / 333
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
SAE Supplemental Procedure	
NOT REPORTED	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	SUBJECT HAS A HISTORY OF ATRIAL FIBRILLATION, PER LAST AE, NEW SINCE SIGNING CONSENT
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #4: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	ERYTHEMA TO INFUSION SITE LEFT LOWER ABDOMEN
Preferred Term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 441
Age at AE Onset	7[redacted]
Laboratory Testing	

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #5: Event of Interest - Falls and Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred Term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 577
Age at AE Onset	7[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped Rx Day	577
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Generated: [redacted]20[redacted]:09:38
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者は米国の 7[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に冠動脈疾患，尿路感染，及び心房細動を発現した。

Event 1 及び 2 の臨床経過：

関連する病歴は，高コレステロール血症，パーキンソン病，うつ病，過活動膀胱，起立性低血圧，不安，元喫煙者（1 日 10 本を 10 年間），及び元飲酒者（1 日 2 杯未満）であった。

投与 1 日目から 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するための治験薬の調整を必要とした。投与 5 週時に，被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 191 日目，被験者は冠動脈疾患を発現した。投与 195 日目，被験者は尿路感染及び心房細動を発現した。投与 199 日目，尿路感染は消失した。

投与 191 日目，被験者は胸部圧迫感及び心窩部痛のため緊急治療室に来院した。投与 192 日目，被験者に心臓カテーテル手術を実施し，ステントを 2 本留置した。投与 195 日目，被験者は尿路感染を発現し，入院が延長となった。被験者に精神錯乱及び尿閉の症状が認められた。入院中，被験者に心房細動も認められた。心房細動は無症候性であり，入院中の心臓モニタリングで当該リズムを記録した。投与 199 日目，被験者は退院した。

治験責任医師は，被験者に心疾患の家族歴があることを指摘した。

被験者にアミオダロン，メトプロロール，クロピドグレル硫酸塩，アスピリン，及び BACTRIM が投与された。

The patient's past medications include:

CARBIDOPA/LEVODOPA for PARKINSON'S DISEASE (20[redacted] - [redacted] 20[redacted], 20[redacted] - [redacted] 20[redacted])

AMANTADINE for PARKINSON'S DISEASE (20[redacted] - 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Coronary artery disease (10011078) (Coronary artery disease (10011078)) [v.23.1] [10011078]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

2) Urinary tract infection (10046571) (Urinary tract infection (10046571)) [v.23.1] [10046571]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

3) Atrial fibrillation (10003658) (Atrial fibrillation (10003658)) [v.23.1] [10003658]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of CORONARY ARTERY DISEASE

- Investigator: Risk factor: Family history

- AbbVie: More likely related to a history of hypercholesterolemia and Parkinson's disease in an advanced aged patient

Event of URINARY TRACT INFECTION

- **Investigator:** Risk factor, urinary retention due to Parkinson's disease

- **AbbVie:** More likely related to a history of overactive bladder and Parkinson's disease in an advanced aged patient

Event of ATRIAL FIBRILLATION

- **Investigator:** Risk factor, new diagnosis of coronary artery disease

- **AbbVie:** More likely related to a history of hypercholesterolemia and Parkinson's disease in an advanced aged patient with concurrent event of coronary artery disease with a report of recent stent placement.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] EKG:** Not clinically significant

[redacted] **20[redacted] EKG:** Not clinically significant

[redacted] **20[redacted] EKG:** Not clinically significant

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者は米国の 7[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に肺塞栓症を発現した。

Event 3 の臨床経過：

関連する病歴は，高コレステロール血症，パーキンソン病，うつ病，不安，元喫煙者（1 日 10 本を 10 年間），及び元飲酒者（1 日 2 杯未満）であった。

投与 333 日目，被験者は肺塞栓症を発現した。

本事象発現前の投与から約 6 ヵ月後に，被験者は尿路感染のために入院期間を延長した。投与から約 6 ヵ月後の入院中に，被験者に心房細動（間欠性）と評価された心リズム異常が記録された。

投与から約 10 ヵ月後，被験者は胸痛及び最近の病歴である心房細動のため入院した。被験者は胸部 CT スキャンにより肺塞栓症と診断された。大静脈フィルターが留置され，心臓専門医は抗凝血剤の投与に反対する決断をした。投与 334 日目，被験者は退院した。

治験責任医師によると，関連するリスク因子は心房細動であった。

The patient's past medications include:

SINEMET CR for PARKINSON'S DISEASE (20[redacted] - [redacted] 20[redacted])

RYTARY for PARKINSON'S DISEASE (20[redacted] - [redacted] 20[redacted])

AMANTADINE for PARKINSON'S DISEASE (20[redacted] - 20[redacted])

VITAMIN B12 for VITAMIN B 12 DEFICIENCY ([redacted] 20[redacted] - [redacted] 20[redacted])

VITAMIN B 6 for VITAMIN B DEFICIENCY ([redacted] 20[redacted] - [redacted] 20[redacted])

CEFDINAR for GRADE 1 MILD ERYTHEMA TO INSERTION/INFUSION SITE ([redacted] 20[redacted] - [redacted] 20[redacted])

METOPROLOL for CORONARY ARTERY DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

PLAVIX for PREVENTATIVE BLOOD THINNER, CORONARY ARTERY DISEASE and PREVENTATIVE BLOOD THINNER, CORONARY ARTERY DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

ELIQUIS for ATRIAL FIBRILLATION ([redacted] 20[redacted] - [redacted] 20[redacted])

OMNICEF for ERYTHEMA TO INFUSION SITE GRADE 2 ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Pulmonary embolism (10037377) (Pulmonary embolism (10037377)) [v.23.1] [10037377]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of PULMONARY EMBOLI

- **Investigator:** Subject has a history of atrial fibrillation, per last AE, new since signing consent.

- **AbbVie:** More likely related to reported atrial fibrillation, elevated hsCRP, and recent hospitalization in a 7[redacted] year old subject with Parkinson's disorder

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BLOOD PRESSURE:** 101/57 mmHg

[redacted] **20[redacted] BLOOD PRESSURE - SCREENING:** 128/88 mmHg

[redacted] **20[redacted] CT CHEST:** PULMONARY EMBOLI

[redacted] **20[redacted] PULSE:** 67 bpm

[redacted] **20[redacted] PULSE - SCREENING:** 69 bpm

[redacted] **20[redacted] WEIGHT:** 16[redacted] Pounds

[redacted] **20[redacted] WEIGHT - SCREENING:** 8[redacted] KG

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
注入部位内出血				X
注入部位蜂巣炎	X	X		X
注入部位紅斑				X
注入部位出血				X
注入部位感染				X
注入部位結節				X
注入部位異常感覚				X
注入部位腫脹				X
** Disc. due to adverse event				X

Disc = Discontinued.

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	7[redacted]	MALE	WHITE

Medical History	Onset Year
ARRYTHMIA-AFIB	19[redacted]
HYPERTENSION	19[redacted]
GLASSES- READING	20[redacted]
LBP (LOWER BACK PAIN)	20[redacted]
CONSTIPATION- OCCASIONALLY	20[redacted]
DEPRESSION	20[redacted]
BPH (BENIGN PROSTATIC HYPERPLASIA	20[redacted]
KERATOSIS	20[redacted]
MILD CATARACTS	20[redacted]
BLADDER INCONTINENCE	20[redacted]
GYRAL PETECHIAL HEMORRHAGE	20[redacted]
CONCUSSION	20[redacted]
NOSE BLEEDS FREQUENT	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
LASIX	20[redacted]
KERATOSIS REMOVED	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.48	0.46	0.50	60	0.19	[redacted]20[redacted] / 367
ABBV-951	0.48	0.46	0.50	60	0.19	[redacted]20[redacted] / 537

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	625.45		SC / CONTINUOUS	[redacted]20[redacted] / 1	[redacted]20[redacted] / 1
M15-741 /ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 2	[redacted]20[redacted] / 5
M15-741 /ABBV-951	1335.43		SC / CONTINUOUS	[redacted]20[redacted] / 6	[redacted]20[redacted] / 6
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 7	
M15-741 /ABBV-951	1318.53		SC / CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 7
M15-741 /ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 9
M15-741 /ABBV-951	1377.95		SC / CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 10
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 11	

M15-741 /ABBV-951	1598.22		SC / CONTINUOUS	[redacted] / 11	[redacted] / 12
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted] / 13	
M15-741 /ABBV-951	1584.90		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted] / 14	
M15-741 /ABBV-951	1551.60		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted] / 15	
M15-741 /ABBV-951	1598.22		SC / CONTINUOUS	[redacted] / 15	[redacted] / 19
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted] / 16	
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 17	
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted] / 18	
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted] / 19	
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 20	
M15-741 /ABBV-951	1666.00		SC / CONTINUOUS	[redacted] / 20	[redacted] / 20
M15-741 /ABBV-951	1670.95		SC / CONTINUOUS	[redacted] / 21	[redacted] / 21
M15-741 /ABBV-951	1721.16		SC / CONTINUOUS	[redacted] / 22	[redacted] / 28
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted] / 23	
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted] / 24	
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted] / 25	
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted] / 26	
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted] / 27	
M15-741 /ABBV-951		162.21	SC / ONCE	[redacted] / 28	
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted] / 29	
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ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 535	
ABBV-951	1917.86		SC / CONTINUOUS	[redacted]20[redacted] / 535	[redacted]20[redacted] / 535
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 536	
ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 536	[redacted]20[redacted] / 536
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 537	
ABBV-951	1958.84		SC / CONTINUOUS	[redacted]20[redacted] / 537	[redacted]20[redacted] / 537
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 538	
ABBV-951	1967.04		SC / CONTINUOUS	[redacted]20[redacted] / 538	[redacted]20[redacted] / 562
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 539	
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 540	
ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 541	
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 542	
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 543	
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 544	
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 545	
ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 546	
ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 547	
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 548	
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 550	
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 551	
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 552	
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 555	
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 557	
ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 558	
ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 559	
ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 560	
ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 561	
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 562	

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
LOSARTAN	100 mg	QD	Y-M: 20[redacted]
SERTRALINE	100 mg	QD	Y-M: 20[redacted]
SELEGILINE	5.000 mg	BID	Y-M: 20[redacted] / -150
AMLODIPINE	10 mg	QD	Y-M: 20[redacted] / -7
MACROGOL 3350	17 g	PRN	Y-M: 20[redacted] / 109
APIXABAN	5 mg	BID	Y-M: 20[redacted] / 110
PRAMIPEXOLE	0.500 mg	TID	Y-M: 20[redacted] / 278
HYDROCHLOROTHIAZIDE	25 mg	BID	Y-M: 20[redacted] / 299
SULFAMETHOXAZOLE;TRIMETHOPRIM	1 OTHER: TAB	BID	Y-M: 20[redacted] / 360

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
LOSARTAN	100 mg	QD	Y-M: 20[redacted]	ONGOING
SERTRALINE	100 mg	QD	Y-M: 20[redacted]	ONGOING
AMLODIPINE	10 mg	QD	Y-M: 20[redacted] / -7	ONGOING
MACROGOL 3350	17 g	PRN	Y-M: 20[redacted] / 109	ONGOING
APIXABAN	5 mg	BID	Y-M: 20[redacted] / 110	ONGOING
HYDROCHLOROTHIAZIDE	25 mg	BID	Y-M: 20[redacted] / 299	Y-M: 20[redacted] / 557
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 368	NOT REPORTED
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 390	NOT REPORTED
DIPHTHERIA VACCINE TOXOID;TETANUS VACCINE TOXOID	1 OTHER: DOSE	OTHER: ONCE	Y-M: 20[redacted] / 408	Y-M: 20[redacted] / 408
HYDROCHLOROTHIAZIDE	25 mg	QD	Y-M: 20[redacted] / 529	Y-M: 20[redacted] / 557
SULFAMETHOXAZOLE;TRIMETHOPRIM	1 OTHER: TABLET	BID	Y-M: 20[redacted] / 550	Y-M: 20[redacted] / 552
HYDROCODONE;PARACETAMOL	650 mg	OTHER: Q4H	Y-M: 20[redacted] / 552	Y-M: 20[redacted] / 553
MACROGOL 3350	17 g	QD	Y-M: 20[redacted] / 552	Y-M: 20[redacted] / 553
ONDANSETRON	4 mg	OTHER: Q6H	Y-M: 20[redacted] / 552	Y-M: 20[redacted] / 553
SODIUM CHLORIDE	1000 mL	OTHER: ONCE	Y-M: 20[redacted] / 552	Y-M: 20[redacted] / 555
CEFAZOLIN	2 g	OTHER: Q8H	Y-M: 20[redacted] / 552	Y-M: 20[redacted] / 557
VANCOMYCIN	1750 mg	OTHER: Q24H	Y-M: 20[redacted] / 552	Y-M: 20[redacted] / 557

GLUCOSE	500 mL	OTHER: Q8H	Y-M: 20[redacted] / 556	Y-M: 20[redacted] / 557
SODIUM CHLORIDE	250 mL	OTHER: Q8H	Y-M: 20[redacted] / 556	Y-M: 20[redacted] / 557
SODIUM CHLORIDE	500 mL	OTHER: Q8H	Y-M: 20[redacted] / 556	Y-M: 20[redacted] / 557
CYANOCOBALAMIN	1000 OTHER: MCG	QD	Y-M: 20[redacted] / 557	ONGOING
CEFALEXIN	500 mg	QID	Y-M: 20[redacted] / 557	Y-M: 20[redacted] / 567
METOPROLOL	25 mg	QD	Y-M: 20[redacted] / 558	Y-M: 20[redacted] / 559
HYDROCHLOROTHIAZIDE	25 mg	QD	Y-M: 20[redacted] / 559	ONGOING

Event #1: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	REDNESS AT INFUSION SITE
Preferred Term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 406
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped Rx Day	408
Duration of AE	3 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	RAISED NODULE AT INFUSION SITE
Preferred Term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 406

Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped Rx Day	408
Duration of AE	3 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	TINGLING AT INFUSION SITE
Preferred Term	注入部位異常感覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 406
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped Rx Day	408
Duration of AE	3 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	REDNESS AT THE INFUSION SITE
Preferred Term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 418
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped Rx Day	431
Duration of AE	14 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #5: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	SMALL NODULE AT INFUSION SITE
Preferred Term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 418
Age at AE Onset	7[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped Rx Day	431
Duration of AE	14 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #6: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	TINGLING DURING INFUSION AT THE INFUSION SITE AFTER GIVING EXTRA DOSE
Preferred Term	注入部位異常感覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 418
Age at AE Onset	7[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped Rx Day	431
Duration of AE	14 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #7: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	BRUISE AT INFUSION SITE
Preferred Term	注入部位内出血
AE Onset Date / Rx Day	[redacted]20[redacted] / 438
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped Rx Day	440
Duration of AE	3 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #8: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	RED AT THE INFUSION SITE
Preferred Term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 438
Age at AE Onset	7[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped Rx Day	440
Duration of AE	3 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #9: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	SLIGHTLY SWOLLEN AT INFUSION SITE
Preferred Term	注入部位腫脹
AE Onset Date / Rx Day	[redacted]20[redacted] / 438
Age at AE Onset	7[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped Rx Day	440
Duration of AE	3 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #10: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE RED IN COLOR
Preferred Term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 527
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped Rx Day	563
Duration of AE	37 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #11: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	DRAINING BLOOD AT INFUSION SITE
Preferred Term	注入部位出血
AE Onset Date / Rx Day	[redacted]20[redacted] / 527
Age at AE Onset	7[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped Rx Day	563
Duration of AE	37 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #12: Event of Interest - Infusion Site Related Infections

Event Description	DRAINING PUS AT INFUSION SITE
Preferred Term	注入部位感染
AE Onset Date / Rx Day	[redacted]20[redacted] / 527
Age at AE Onset	7[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped Rx Day	563
Duration of AE	37 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to	NOT APPLICABLE

[redacted] **Infusion Set**	
SAE: Investigator Opinion of Relationship to [redacted] **Infusion Set**	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #13: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE NODULE
Preferred Term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 527
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped Rx Day	563
Duration of AE	37 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] **Infusion Set**	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] **Infusion Set**	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #14: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS AT THE INFUSION SITE
Preferred Term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 549
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 551): Alanine Aminotransferase: 4 [7 - 52] U/L; Aspartate Aminotransferase: 18 [13 - 39] U/L; Calcium: 2.32 [2.12 - 2.62] MMOL/L; Chloride: 92 [98 - 108] MMOL/L; Creatinine: 85 [53 - 106] UMOL/L; Erythrocytes: 3.9 [4.2 - 5.5] 10^12/L; Glucose: 7.5 [3.9 - 5.5] MMOL/L; Hematocrit: 0.37 [0.4 - 0.54] FRACTION OF 1; Hemoglobin: 128 [134 - 170] G/L; Leukocytes: 9.6 [3.6 - 10.6] 10^9/L; NPTST004-BUN: 26 [5 - 20] MG/DL; Potassium: 3.6 [3.5 - 5.5] MMOL/L; Sodium: 127 [135 - 145] MMOL/L

Microbiology

[redacted]20[redacted] (RX DAY 551): BLOOD BLOOD CULTURE: NEGATIVE-SHOWED NO GROWTH; [redacted]20[redacted] (RX DAY 554): WOUND WOUND CULTURE: POSITIVE-STAPH AUREAS

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 555): PACKING AND UNPACKING WOUND:-PACKING REMOVED TODAY - SOME RESIDUAL PURULENT MATERIAL EXPRESSED, IRRIGATED WITH NORMAL SALINE UNTIL CLEAR, DRESSING APPLIED WITH SMALL WICK PLACED IN WOUND. -WOUND CULTURE WITH GPC - ID FOLLOWING,DEFER ABX TO ID -DAILY DRESSING CHANGES + PRN SOILING (DRY GAUZE DRESSING, WICK AS NEEDED) -SURGERY WILL SIGN OFF; RECOMMEND HAVING WOUND TEAM FOLLOW THE WOUND WHILE INPATIENT. DOES NOT REQUIRE PAC KING

AE Stopped Rx Day	563
Duration of AE	15 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	PROBABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	POSSIBLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	NOT REPORTED
Discontinued Study Drug Due to the Event	YES
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Generated: [redacted]20[redacted]:09:38

Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者は米国の 7[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に注入部位蜂巣炎を発現した。

Event 14 の臨床経過：

関連する病歴は，高血圧，パーキンソン病，非喫煙者，及び非飲酒者であった。

投与 549 日目，被験者は注入部位蜂巣炎を発現した。投与 563 日目，注入部位蜂巣炎は消失した。

治験責任医師によると，被験者は過去に膿及び血液の排出とともに，注入部位に非重篤な感染症，発赤，及び結節の出現を発現したことがあった。

投与 547 日目，被験者は注入ポンプの位置を変更した。投与 549 日目，被験者は体調がすぐれなかった。被験者は昼寝をし，2 時間後に気分が悪くなったため注入ポンプを確認した。被験者は変更前の注入部位が赤くなっていることに気が付いた。夕方までに，被験者は 100.4°Fの低グレードの発熱を発現した。被験者は疼きと嗜眠を認め，やや混乱していた。投与 550 日目，変更前の注入部位は悪化しているようだった。腹部は赤く，圧痛があった。発熱及び悪寒が 48 時間続き，医師により Bactrim の投与が開始された。その後，被験者の変更前の注入部位から黄色がかかった膿が出現し，発疹が広がり始めた。被験者は緊急治療室に行くよう指示された。変更後の部位での注入は順調であった。

投与 551 日目，被験者は腹壁の蜂巣炎，悪寒の症状，及び腹部の発赤のため入院した。悪心，嘔吐，下痢，又は便秘は認められなかった。被験者に抗生物質が投与された。投与 555 日目，創傷パッキングが除去され，化膿物の残留物を培養物とともに検査に送った。創傷部位を生理食塩水で清潔になるまで洗浄した。創傷部位に小さなドレーン（wick）を入れ，再度包帯を巻いた。投与 557 日目，被験者は退院した。

本事象により被験者は治験を中止した。

被験者にジフテリア・破傷風混合ワクチン，セファレキシン，デキストロース 5%，ポリエチレングリコール，オンダンセトロン，アセトアミノフェン / ヒドロコドン配合剤，塩化ナトリウム，バンコマイシン，セファゾリン，及び BACTRIM DS が投与された。

The patient's past medications include:

BACTRIM DS for INFECTION ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Infusion site cellulitis (10065455) (Infusion site cellulitis (10065455)) [v.24.0] [10065455]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Yes

Rechallenge: No rechallenge was done, recurrence is not applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of CELLULITIS AT THE INFUSION SITE

- Investigator: Not applicable

- AbbVie: Not applicable

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BLOOD CULTURE:** Negative - no growth

[redacted] **20[redacted] BUN:** 26 mg/dL (normal 5 to 20)

[redacted] **20[redacted] CALCIUM:** 9.3 mg/dL (normal 8.5 to 10.5)

[redacted] **20[redacted] CREATININE:** 0.96 mg/dL (normal 0.6 to 1.2)

[redacted] **20[redacted] GLUCOSE:** 136 mg/dL (normal 70 to 99)

[redacted] **20[redacted] HEMATOCRIT:** 37.2% (normal 40 to 54)

[redacted] **20[redacted] HEMOGLOBIN:** 12.8 G/DL (normal 13.4 to 17)

[redacted] **20[redacted] POTASSIUM:** 3.6 MMOL/L (norm 3.5 to 5.5)

[redacted] **20[redacted] RED BLOOD CELLS:** 3.93 X10**3/MM**3 (normal 4.18 to 5.51)

[redacted] **20[redacted] SODIUM:** 127 MMOL/L (normal 135 to 145)

[redacted] **20[redacted] WHITE BLOOD CELLS:** 9.6 X10**9/L (normal 3.6 to 10.6)

[redacted] **20[redacted] WOUND CULTURE:** Positive staph Aureas

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
転倒	X			X
頭蓋内出血	X			X

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	7[redacted]	FEMALE	WHITE

Medical History	Onset Year
MENOPAUSE	19[redacted]
OSTEOPOROSIS	20[redacted]
PARKINSON'S DISEASE	20[redacted]
HYPOGLYCEMIA	20[redacted]
AMNESIA	20[redacted]
ANXIETY	20[redacted]
DEPRESSION	20[redacted]
REM SLEEP BEHAVIOR DISORDER	20[redacted]
VITAMIN B-12 DEFICIENCY	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
DBS	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	1 CIGARETTE	10	19[redacted]
CIGARS	NEVER			

E-CIGARETTES	NEVER
PIPES	NEVER

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	LESS THAN 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.27	0.28	0.24	60	0.11	[redacted] / 364
ABBV-951	0.27	0.28	0.24	60	0.11	[redacted] / 517
ABBV-951	0.27	0.28	0.24	60	0.19	[redacted] / 552
ABBV-951	0.27	0.28	0.24	60	0.19	[redacted] / 620
ABBV-951	0.27	0.28	0.24	60	0.24	[redacted] / 651

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	594.72		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
M15-741 /ABBV-951	1106.46		SC / CONTINUOUS	[redacted] / 9	[redacted] / 17
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 14	
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 17	
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 18	
M15-741 /ABBV-951	1080.84		SC / CONTINUOUS	[redacted] / 18	[redacted] / 18
M15-741 /ABBV-951	1149.14		SC / CONTINUOUS	[redacted] / 19	[redacted] / 19
M15-741 /ABBV-951	1179.88		SC / CONTINUOUS	[redacted] / 20	[redacted] / 20
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 21	
M15-741 /ABBV-951	1275.50		SC / CONTINUOUS	[redacted] / 21	[redacted] / 21
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 22	
M15-741 /ABBV-951	940.83		SC / CONTINUOUS	[redacted] / 22	[redacted] / 22
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 23	
M15-741 /ABBV-951	901.56		SC / CONTINUOUS	[redacted] / 23	[redacted] / 23
M15-741 /ABBV-951	1128.65		SC / CONTINUOUS	[redacted] / 24	[redacted] / 24
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 25	
M15-741 /ABBV-951	1073.16		SC / CONTINUOUS	[redacted] / 25	[redacted] / 25
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 26	
M15-741 /ABBV-951	1216.59		SC / CONTINUOUS	[redacted] / 26	[redacted] / 26
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 27	

M15-741 /ABBV-951	1255.01		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 28	
M15-741 /ABBV-951	1140.61		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
M15-741 /ABBV-951	961.32		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 30	
M15-741 /ABBV-951	1014.25		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 31	
M15-741 /ABBV-951	1120.12		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 32	
M15-741 /ABBV-951	1158.19		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 33	
M15-741 /ABBV-951	1231.96		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 34	
M15-741 /ABBV-951	1196.95		SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 35	
M15-741 /ABBV-951	1181.59		SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 36	
M15-741 /ABBV-951	1225.98		SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 37	
M15-741 /ABBV-951	1218.64		SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 38	
M15-741 /ABBV-951	1186.71		SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 39	
M15-741 /ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 40	
M15-741 /ABBV-951	1008.27		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 41	
M15-741 /ABBV-951	1077.43		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
M15-741 /ABBV-951	1046.69		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 43	
M15-741 /ABBV-951	1079.82		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
M15-741 /ABBV-951	1111.92		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 45	
M15-741 /ABBV-951	1003.15		SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 46	
M15-741 /ABBV-951	1101.33		SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 47	

M15-741 /ABBV-951	1063.77		SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 48	
M15-741 /ABBV-951	1084.26		SC / CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
M15-741 /ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 50	
M15-741 /ABBV-951	1072.31		SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 51	
M15-741 /ABBV-951	1068.89		SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
M15-741 /ABBV-951	1193.54		SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
M15-741 /ABBV-951	1255.01		SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 54	
M15-741 /ABBV-951	1029.62		SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
M15-741 /ABBV-951	1109.87		SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 56	
M15-741 /ABBV-951	1064.96		SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
M15-741 /ABBV-951	903.26		SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
M15-741 /ABBV-951	1142.31		SC / CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
M15-741 /ABBV-951	1038.16		SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
M15-741 /ABBV-951	1024.5		SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
M15-741 /ABBV-951	1012.54		SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 62	
M15-741 /ABBV-951	912.65		SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 63	
M15-741 /ABBV-951	1042.42		SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 64	
M15-741 /ABBV-951	1076.57		SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 65	
M15-741 /ABBV-951	1014.59		SC / CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 66	
M15-741 /ABBV-951	1138.56		SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 67	
M15-741 /ABBV-951	1030.81		SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 68	
M15-741 /ABBV-951	1003.15		SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 69	
M15-741 /ABBV-951	995.47		SC / CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 70	

M15-741 /ABBV-951	1008.27		SC / CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 71	
M15-741 /ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 72	
M15-741 /ABBV-951	1005.71		SC / CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 73	
M15-741 /ABBV-951	1031.67		SC / CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 74	
M15-741 /ABBV-951	1032.18		SC / CONTINUOUS	[redacted]20[redacted] / 74	[redacted]20[redacted] / 74
M15-741 /ABBV-951	1004.86		SC / CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 76	
M15-741 /ABBV-951	1033.37		SC / CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 76
M15-741 /ABBV-951	999.74		SC / CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 77
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 78	
M15-741 /ABBV-951	1087.33		SC / CONTINUOUS	[redacted]20[redacted] / 78	[redacted]20[redacted] / 78
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 79	
M15-741 /ABBV-951	1099.97		SC / CONTINUOUS	[redacted]20[redacted] / 79	[redacted]20[redacted] / 79
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 80	
M15-741 /ABBV-951	1078.28		SC / CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 80
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 81	
M15-741 /ABBV-951	1014.25		SC / CONTINUOUS	[redacted]20[redacted] / 81	[redacted]20[redacted] / 81
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 82	
M15-741 /ABBV-951	1122.16		SC / CONTINUOUS	[redacted]20[redacted] / 82	[redacted]20[redacted] / 82
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 83	
M15-741 /ABBV-951	1019.37		SC / CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
M15-741 /ABBV-951	1028.76		SC / CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
M15-741 /ABBV-951	910.09		SC / CONTINUOUS	[redacted]20[redacted] / 85	[redacted]20[redacted] / 85
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 86	
M15-741 /ABBV-951	953.29		SC / CONTINUOUS	[redacted]20[redacted] / 86	[redacted]20[redacted] / 86
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 87	
M15-741 /ABBV-951	1044.99		SC / CONTINUOUS	[redacted]20[redacted] / 87	[redacted]20[redacted] / 87
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 88	
M15-741 /ABBV-951	1018.01		SC / CONTINUOUS	[redacted]20[redacted] / 88	[redacted]20[redacted] / 88
M15-741 /ABBV-951	1112.43		SC / CONTINUOUS	[redacted]20[redacted] / 89	[redacted]20[redacted] / 89
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 178
M15-741 /ABBV-951	1234.86		SC / CONTINUOUS	[redacted]20[redacted] / 179	[redacted]20[redacted] / 179
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 180	

M15-741 /ABBV-951	848.62		SC / CONTINUOUS	[redacted]20[redacted] / 180	[redacted]20[redacted] / 180
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 181	
M15-741 /ABBV-951	844.35		SC / CONTINUOUS	[redacted]20[redacted] / 181	[redacted]20[redacted] / 181
M15-741 /ABBV-951	812.42		SC / CONTINUOUS	[redacted]20[redacted] / 182	[redacted]20[redacted] / 182
M15-741 /ABBV-951	910.09		SC / CONTINUOUS	[redacted]20[redacted] / 183	[redacted]20[redacted] / 183
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 184	
M15-741 /ABBV-951	812.42		SC / CONTINUOUS	[redacted]20[redacted] / 184	[redacted]20[redacted] / 184
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 185	
M15-741 /ABBV-951	857.16		SC / CONTINUOUS	[redacted]20[redacted] / 185	[redacted]20[redacted] / 185
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 186	
M15-741 /ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 186	[redacted]20[redacted] / 186
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 187	
M15-741 /ABBV-951	835.99		SC / CONTINUOUS	[redacted]20[redacted] / 187	[redacted]20[redacted] / 187
M15-741 /ABBV-951	912.65		SC / CONTINUOUS	[redacted]20[redacted] / 188	[redacted]20[redacted] / 188
M15-741 /ABBV-951	744.98		SC / CONTINUOUS	[redacted]20[redacted] / 189	[redacted]20[redacted] / 189
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 190	
M15-741 /ABBV-951	858.01		SC / CONTINUOUS	[redacted]20[redacted] / 190	[redacted]20[redacted] / 190
M15-741 /ABBV-951	864.50		SC / CONTINUOUS	[redacted]20[redacted] / 191	[redacted]20[redacted] / 191
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 192	
M15-741 /ABBV-951	865.70		SC / CONTINUOUS	[redacted]20[redacted] / 192	[redacted]20[redacted] / 192
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 193	
M15-741 /ABBV-951	871.33		SC / CONTINUOUS	[redacted]20[redacted] / 193	[redacted]20[redacted] / 193
M15-741 /ABBV-951	758.13		SC / CONTINUOUS	[redacted]20[redacted] / 194	[redacted]20[redacted] / 194
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 195	
M15-741 /ABBV-951	766.66		SC / CONTINUOUS	[redacted]20[redacted] / 195	[redacted]20[redacted] / 195
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 196	
M15-741 /ABBV-951	823.01		SC / CONTINUOUS	[redacted]20[redacted] / 196	[redacted]20[redacted] / 196
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 197	
M15-741 /ABBV-951	867.92		SC / CONTINUOUS	[redacted]20[redacted] / 197	[redacted]20[redacted] / 197
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 198	
M15-741 /ABBV-951	858.01		SC / CONTINUOUS	[redacted]20[redacted] / 198	[redacted]20[redacted] / 198
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 199	
M15-741 /ABBV-951	851.18		SC / CONTINUOUS	[redacted]20[redacted] / 199	[redacted]20[redacted] / 199
M15-741 /ABBV-951	840.60		SC / CONTINUOUS	[redacted]20[redacted] / 200	[redacted]20[redacted] / 200
M15-741 /ABBV-951	766.32		SC / CONTINUOUS	[redacted]20[redacted] / 201	[redacted]20[redacted] / 201
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 202	
M15-741 /ABBV-951	939.97		SC / CONTINUOUS	[redacted]20[redacted] / 202	[redacted]20[redacted] / 202

M15-741 /ABBV-951	888.75		SC / CONTINUOUS	[redacted]20[redacted] / 203	[redacted]20[redacted] / 203
M15-741 /ABBV-951	957.05		SC / CONTINUOUS	[redacted]20[redacted] / 204	[redacted]20[redacted] / 204
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 205	
M15-741 /ABBV-951	925.46		SC / CONTINUOUS	[redacted]20[redacted] / 205	[redacted]20[redacted] / 205
M15-741 /ABBV-951	405.18		SC / CONTINUOUS	[redacted]20[redacted] / 206	[redacted]20[redacted] / 206
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 207	
M15-741 /ABBV-951	846.92		SC / CONTINUOUS	[redacted]20[redacted] / 207	[redacted]20[redacted] / 207
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 208	
M15-741 /ABBV-951	882.77		SC / CONTINUOUS	[redacted]20[redacted] / 208	[redacted]20[redacted] / 208
M15-741 /ABBV-951	854.09		SC / CONTINUOUS	[redacted]20[redacted] / 209	[redacted]20[redacted] / 209
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 210	
M15-741 /ABBV-951	910.09		SC / CONTINUOUS	[redacted]20[redacted] / 210	[redacted]20[redacted] / 210
M15-741 /ABBV-951	857.16		SC / CONTINUOUS	[redacted]20[redacted] / 211	[redacted]20[redacted] / 211
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 212	
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M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 213	
M15-741 /ABBV-951	858.36		SC / CONTINUOUS	[redacted]20[redacted] / 213	[redacted]20[redacted] / 213
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 214	
M15-741 /ABBV-951	898.99		SC / CONTINUOUS	[redacted]20[redacted] / 214	[redacted]20[redacted] / 214
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 215	
M15-741 /ABBV-951	851.18		SC / CONTINUOUS	[redacted]20[redacted] / 215	[redacted]20[redacted] / 215
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 216	
M15-741 /ABBV-951	886.19		SC / CONTINUOUS	[redacted]20[redacted] / 216	[redacted]20[redacted] / 216
M15-741 /ABBV-951	846.06		SC / CONTINUOUS	[redacted]20[redacted] / 217	[redacted]20[redacted] / 217
M15-741 /ABBV-951	854.60		SC / CONTINUOUS	[redacted]20[redacted] / 218	[redacted]20[redacted] / 218
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 219	
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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 220	
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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 227	
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M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 228	
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M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 229	
M15-741 /ABBV-951	999.74		SC / CONTINUOUS	[redacted]20[redacted] / 229	[redacted]20[redacted] / 229
M15-741 /ABBV-951	911.29		SC / CONTINUOUS	[redacted]20[redacted] / 230	[redacted]20[redacted] / 230
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 231	
M15-741 /ABBV-951	912.65		SC / CONTINUOUS	[redacted]20[redacted] / 231	[redacted]20[redacted] / 231
M15-741 /ABBV-951	852.89		SC / CONTINUOUS	[redacted]20[redacted] / 232	[redacted]20[redacted] / 232
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 233	
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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 235	
M15-741 /ABBV-951	849.82		SC / CONTINUOUS	[redacted]20[redacted] / 235	[redacted]20[redacted] / 235
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 236	
M15-741 /ABBV-951	908.04		SC / CONTINUOUS	[redacted]20[redacted] / 236	[redacted]20[redacted] / 236
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 237	
M15-741 /ABBV-951	895.24		SC / CONTINUOUS	[redacted]20[redacted] / 237	[redacted]20[redacted] / 237
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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 243	
M15-741 /ABBV-951	959.10		SC / CONTINUOUS	[redacted]20[redacted] / 243	[redacted]20[redacted] / 243
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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 245	
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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 247	
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M15-741 /ABBV-951	863.14		SC / CONTINUOUS	[redacted]20[redacted] / 248	[redacted]20[redacted] / 248
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M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 256	
M15-741 /ABBV-951	886.53		SC / CONTINUOUS	[redacted]20[redacted] / 256	[redacted]20[redacted] / 256
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M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 278	
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M15-741 /ABBV-951	874.92		SC / CONTINUOUS	[redacted]20[redacted] / 306	[redacted]20[redacted] / 306
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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 313	
M15-741 /ABBV-951	885.16		SC / CONTINUOUS	[redacted]20[redacted] / 313	[redacted]20[redacted] / 313
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 314	
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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 316	
M15-741 /ABBV-951	883.11		SC / CONTINUOUS	[redacted]20[redacted] / 316	[redacted]20[redacted] / 316
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M15-741 /ABBV-951	884.14		SC / CONTINUOUS	[redacted]20[redacted] / 317	[redacted]20[redacted] / 317
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M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 319	
M15-741 /ABBV-951	871.84		SC / CONTINUOUS	[redacted]20[redacted] / 319	[redacted]20[redacted] / 319
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 320	
M15-741 /ABBV-951	764.27		SC / CONTINUOUS	[redacted]20[redacted] / 320	[redacted]20[redacted] / 320
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 321	
M15-741 /ABBV-951	888.24		SC / CONTINUOUS	[redacted]20[redacted] / 321	[redacted]20[redacted] / 321

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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 328	
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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 329	
M15-741 /ABBV-951	880.04		SC / CONTINUOUS	[redacted]20[redacted] / 329	[redacted]20[redacted] / 329
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 330	
M15-741 /ABBV-951	881.07		SC / CONTINUOUS	[redacted]20[redacted] / 330	[redacted]20[redacted] / 330
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 331	
M15-741 /ABBV-951	859.55		SC / CONTINUOUS	[redacted]20[redacted] / 331	[redacted]20[redacted] / 331
M15-741 /ABBV-951	852.38		SC / CONTINUOUS	[redacted]20[redacted] / 332	[redacted]20[redacted] / 332
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 333	
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M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 334	
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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 335	
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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 336	
M15-741 /ABBV-951	893.36		SC / CONTINUOUS	[redacted]20[redacted] / 336	[redacted]20[redacted] / 336
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 337	
M15-741 /ABBV-951	882.09		SC / CONTINUOUS	[redacted]20[redacted] / 337	[redacted]20[redacted] / 337
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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 339	
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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 340	
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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 341	

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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 342	
M15-741 /ABBV-951	880.04		SC / CONTINUOUS	[redacted]20[redacted] / 342	[redacted]20[redacted] / 342
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 343	
M15-741 /ABBV-951	884.14		SC / CONTINUOUS	[redacted]20[redacted] / 343	[redacted]20[redacted] / 344
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 344	
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 345	
M15-741 /ABBV-951	915.90		SC / CONTINUOUS	[redacted]20[redacted] / 345	[redacted]20[redacted] / 345
M15-741 /ABBV-951	943.56		SC / CONTINUOUS	[redacted]20[redacted] / 346	[redacted]20[redacted] / 346
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 347	
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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 348	
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M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 350	
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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 351	
M15-741 /ABBV-951	897.46		SC / CONTINUOUS	[redacted]20[redacted] / 351	[redacted]20[redacted] / 351
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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 353	
M15-741 /ABBV-951	872.87		SC / CONTINUOUS	[redacted]20[redacted] / 353	[redacted]20[redacted] / 353
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 354	
M15-741 /ABBV-951	893.36		SC / CONTINUOUS	[redacted]20[redacted] / 354	[redacted]20[redacted] / 354
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 355	
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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 359	
M15-741 /ABBV-951	894.38		SC / CONTINUOUS	[redacted]20[redacted] / 359	[redacted]20[redacted] / 359
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M15-741 /ABBV-951	872.87		SC / CONTINUOUS	[redacted]20[redacted] / 360	[redacted]20[redacted] / 360

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ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 369	
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ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 370	
ABBV-951	1063.94		SC / CONTINUOUS	[redacted]20[redacted] / 370	[redacted]20[redacted] / 370
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 371	
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ABBV-951	1052.67		SC / CONTINUOUS	[redacted]20[redacted] / 380	[redacted]20[redacted] / 380
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ABBV-951	1077.94		SC / CONTINUOUS	[redacted] / 386	[redacted] / 386
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ABBV-951	1067.87		SC / CONTINUOUS	[redacted]20[redacted] / 407	[redacted]20[redacted] / 407
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ABBV-951	1060.35		SC / CONTINUOUS	[redacted]20[redacted] / 425	[redacted]20[redacted] / 425
ABBV-951	1048.57		SC / CONTINUOUS	[redacted]20[redacted] / 426	[redacted]20[redacted] / 426
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ABBV-951	1116.19		SC / CONTINUOUS	[redacted] / 603	[redacted] / 603
ABBV-951		32.44	SC / ONCE	[redacted] / 604	
ABBV-951	1095.01		SC / CONTINUOUS	[redacted] / 604	[redacted] / 604
ABBV-951		32.44	SC / ONCE	[redacted] / 605	
ABBV-951	1128.65		SC / CONTINUOUS	[redacted] / 605	[redacted] / 605
ABBV-951	1130.53		SC / CONTINUOUS	[redacted] / 606	[redacted] / 606
ABBV-951		32.44	SC / ONCE	[redacted] / 607	
ABBV-951	1083.23		SC / CONTINUOUS	[redacted] / 607	[redacted] / 607
ABBV-951	1131.56		SC / CONTINUOUS	[redacted] / 608	[redacted] / 608
ABBV-951	1130.53		SC / CONTINUOUS	[redacted] / 609	[redacted] / 609
ABBV-951		32.44	SC / ONCE	[redacted] / 610	
ABBV-951	1038.50		SC / CONTINUOUS	[redacted] / 610	[redacted] / 610
ABBV-951		32.44	SC / ONCE	[redacted] / 611	

ABBV-951	1123.53		SC / CONTINUOUS	[redacted]20[redacted] / 611	[redacted]20[redacted] / 611
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 612	
ABBV-951	1129.16		SC / CONTINUOUS	[redacted]20[redacted] / 612	[redacted]20[redacted] / 612
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 613	
ABBV-951	1123.53		SC / CONTINUOUS	[redacted]20[redacted] / 613	[redacted]20[redacted] / 613
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 614	
ABBV-951	1098.26		SC / CONTINUOUS	[redacted]20[redacted] / 614	[redacted]20[redacted] / 614
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 615	
ABBV-951	1082.21		SC / CONTINUOUS	[redacted]20[redacted] / 615	[redacted]20[redacted] / 615
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 616	
ABBV-951	1131.56		SC / CONTINUOUS	[redacted]20[redacted] / 616	[redacted]20[redacted] / 616
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 617	
ABBV-951	1125.41		SC / CONTINUOUS	[redacted]20[redacted] / 617	[redacted]20[redacted] / 617
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 618	
ABBV-951	1142.48		SC / CONTINUOUS	[redacted]20[redacted] / 618	[redacted]20[redacted] / 618
ABBV-951	1130.87		SC / CONTINUOUS	[redacted]20[redacted] / 619	[redacted]20[redacted] / 619
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 620	
ABBV-951	1104.92		SC / CONTINUOUS	[redacted]20[redacted] / 620	[redacted]20[redacted] / 620
ABBV-951	1127.80		SC / CONTINUOUS	[redacted]20[redacted] / 621	[redacted]20[redacted] / 621
ABBV-951	1138.56		SC / CONTINUOUS	[redacted]20[redacted] / 622	[redacted]20[redacted] / 622
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 623	
ABBV-951	1135.99		SC / CONTINUOUS	[redacted]20[redacted] / 623	[redacted]20[redacted] / 623
ABBV-951	1115.16		SC / CONTINUOUS	[redacted]20[redacted] / 624	[redacted]20[redacted] / 624
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 625	
ABBV-951	1126.95		SC / CONTINUOUS	[redacted]20[redacted] / 625	[redacted]20[redacted] / 625
ABBV-951	1127.29		SC / CONTINUOUS	[redacted]20[redacted] / 626	[redacted]20[redacted] / 626
ABBV-951	1118.41		SC / CONTINUOUS	[redacted]20[redacted] / 627	[redacted]20[redacted] / 627
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 628	
ABBV-951	1094.16		SC / CONTINUOUS	[redacted]20[redacted] / 628	[redacted]20[redacted] / 628
ABBV-951	1125.41		SC / CONTINUOUS	[redacted]20[redacted] / 629	[redacted]20[redacted] / 629
ABBV-951	1141.29		SC / CONTINUOUS	[redacted]20[redacted] / 630	[redacted]20[redacted] / 630
ABBV-951	1135.31		SC / CONTINUOUS	[redacted]20[redacted] / 631	[redacted]20[redacted] / 631
ABBV-951	1136.85		SC / CONTINUOUS	[redacted]20[redacted] / 632	[redacted]20[redacted] / 632
ABBV-951	1106.80		SC / CONTINUOUS	[redacted]20[redacted] / 633	[redacted]20[redacted] / 633
ABBV-951	1137.19		SC / CONTINUOUS	[redacted]20[redacted] / 634	[redacted]20[redacted] / 634
ABBV-951	1130.36		SC / CONTINUOUS	[redacted]20[redacted] / 635	[redacted]20[redacted] / 635
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 636	

ABBV-951	1128.65		SC / CONTINUOUS	[redacted]20[redacted] / 636	[redacted]20[redacted] / 636
ABBV-951	1138.21		SC / CONTINUOUS	[redacted]20[redacted] / 637	[redacted]20[redacted] / 637
ABBV-951	1124.38		SC / CONTINUOUS	[redacted]20[redacted] / 638	[redacted]20[redacted] / 638
ABBV-951	1093.65		SC / CONTINUOUS	[redacted]20[redacted] / 639	[redacted]20[redacted] / 639
ABBV-951	1127.29		SC / CONTINUOUS	[redacted]20[redacted] / 640	[redacted]20[redacted] / 640
ABBV-951	1097.06		SC / CONTINUOUS	[redacted]20[redacted] / 641	[redacted]20[redacted] / 641
ABBV-951	1123.02		SC / CONTINUOUS	[redacted]20[redacted] / 642	[redacted]20[redacted] / 642
ABBV-951	1120.80		SC / CONTINUOUS	[redacted]20[redacted] / 643	[redacted]20[redacted] / 643
ABBV-951	1121.99		SC / CONTINUOUS	[redacted]20[redacted] / 644	[redacted]20[redacted] / 644
ABBV-951	1118.24		SC / CONTINUOUS	[redacted]20[redacted] / 645	[redacted]20[redacted] / 645
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 646	
ABBV-951	1123.36		SC / CONTINUOUS	[redacted]20[redacted] / 646	[redacted]20[redacted] / 646
ABBV-951	1119.60		SC / CONTINUOUS	[redacted]20[redacted] / 647	[redacted]20[redacted] / 647
ABBV-951	1124.21		SC / CONTINUOUS	[redacted]20[redacted] / 648	[redacted]20[redacted] / 648
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 649	
ABBV-951	1127.46		SC / CONTINUOUS	[redacted]20[redacted] / 649	[redacted]20[redacted] / 649
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 650	
ABBV-951	1088.36		SC / CONTINUOUS	[redacted]20[redacted] / 650	[redacted]20[redacted] / 650
ABBV-951	1129.85		SC / CONTINUOUS	[redacted]20[redacted] / 651	[redacted]20[redacted] / 651
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 652	
ABBV-951	1131.56		SC / CONTINUOUS	[redacted]20[redacted] / 652	[redacted]20[redacted] / 652

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
CLONAZEPAM	0.5 mg	QD	Y-M: 20[redacted]-[redacted] / -154
ESCITALOPRAM OXALATE	10 mg	QD	Y-M: 20[redacted]-[redacted] / -51
ALPRAZOLAM	0.25 mg	PRN	Y-M: 20[redacted]-[redacted] / -15

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
CLONAZEPAM	0.5 mg	QD	Y-M: 20[redacted]-[redacted] / -154	NOT REPORTED
ESCITALOPRAM OXALATE	10 mg	QD	Y-M: 20[redacted]-[redacted] / -51	NOT REPORTED
ALPRAZOLAM	0.25 mg	PRN	Y-M: 20[redacted]-[redacted] / -15	NOT REPORTED

Event #1: Serious Adverse Event, Event of Interest - Falls and Associated Injuries

Event Description	FALL W/ SEQUALAE

Preferred Term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 618
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
SAE Supplemental Procedure	
NOT REPORTED	
AE Stopped Rx Day	618
Duration of AE	1 DAY
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	FALL RELATED TO IMBALANCE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #2: Serious Adverse Event, Event of Interest - Concurrent Events of Falls and Associated Injuries

Event Description	INTRACRANIAL HEMORRHAGE
Preferred Term	頭蓋内出血
AE Onset Date / Rx Day	[redacted]20[redacted] / 618
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
SAE Supplemental Procedure	
NOT REPORTED	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY

SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	IMBALANCE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Generated: [redacted]20[redacted]:09:38

Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者は米国の 7[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に後遺症を伴う転倒及び頭蓋内出血を発現した。

Event 1 及び 2 の臨床経過：

関連する病歴は，骨粗鬆症，パーキンソン病，低血糖，レム睡眠行動障害，ビタミン B12 欠乏症，及び飲酒者（1 日 2 杯未満）であった。

投与 618 日目，被験者は後遺症を伴う転倒及び頭蓋内出血を発現した。投与 618 日目日目遺症を伴う転倒及び頭蓋内出血は消失した。

投与 618 日目，被験者は救急診療部に来院し，自宅で転倒し頭を打ち付けたと報告した。同日，被験者は脳 CT スキャンにより頭蓋内出血が確認され，精密検査のため入院した。

治験責任医師によると，被験者のリスク因子は平衡失調であった。

Causality for ABBV-951 (Open Label)

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1) Fall (10016173) (Fall (10016173)) [v.24.0] [10016173]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

2) Intracranial hemorrhage (10022763) (Haemorrhage intracranial (10018985)) [v.24.0] [10022763]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of FALL W/ SEQUALAE

- Investigator: Fall related to imbalance

- AbbVie: More likely related to age, reported imbalance with underlying Parkinson disease, confounded by history of vitamin B12 deficiency and hypoglycemia.

Event of INTRACRANIAL HEMORRHAGE

- Investigator: Imbalance

- AbbVie: More likely related to trauma from current fall and hitting head in an elderly subject with Parkinson disease.

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
胸痛	X			

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	6[redacted]	FEMALE	WHITE

Medical History	Onset Year
FRONTAL POLYPS (SINUSES)	19[redacted]
ABNORMAL UTERINE BLEEDING	19[redacted]
ORTHOSTATIC HYPOTENSION	20[redacted]
APPENDICITIS	20[redacted]
GALLSTONES	20[redacted]
ANXIETY	20[redacted]
INSOMNIA	20[redacted]
CONSTIPATION	20[redacted]
CATARACT OD	20[redacted]
NEUROPATHIC PAIN	20[redacted]
ATRIAL FIBRILLATION	20[redacted]
GASTROESOPHAGEAL REFLUX	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
POLYPECTOMY SINUS	19[redacted]
CAESAREAN	19[redacted]
CAESAREAN	19[redacted]
HYSTERECTOMY	19[redacted]
APPENDECTOMY	20[redacted]

CHOLECYSTECTOMY	20[redacted]
CATARACT RESECTION, RIGHT EYE	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	FORMER	LESS THAN 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.52	0.59	0.46		0.19	[redacted]20[redacted] / 365
ABBV-951	0.52	0.6	0.46	60	0.19	[redacted]20[redacted] / 534
ABBV-951	0.5	0.61	0.46	60	0.19	[redacted]20[redacted] / 555
ABBV-951	0.52	0.61	0.46		0.19	[redacted]20[redacted] / 697

Daily Dose (mg LD) by Molecular Weight

Feeder Study /Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 5	[redacted]20[redacted] / 5
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 6	
M15-741 /ABBV-951	518.39		SC / CONTINUOUS	[redacted]20[redacted] / 6	[redacted]20[redacted] / 6
M15-741 /ABBV-951		93.91	SC / ONCE	[redacted]20[redacted] / 7	
M15-741 /ABBV-951	882.77		SC / CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 7
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 8	
M15-741 /ABBV-951	1128.14		SC / CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 8
M15-741 /ABBV-951	1270.38		SC / CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 13
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 14	
M15-741 /ABBV-951	1231.61		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 15	
M15-741 /ABBV-951	1249.20		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
M15-741 /ABBV-951	1270.38		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16

M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 17	
M15-741 /ABBV-951	1238.62		SC / CONTINUOUS	[redacted] / 17	[redacted] / 17
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 18	
M15-741 /ABBV-951	1366.17		SC / CONTINUOUS	[redacted] / 18	[redacted] / 18
M15-741 /ABBV-951	1475.28		SC / CONTINUOUS	[redacted] / 19	[redacted] / 26
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 27	
M15-741 /ABBV-951	1308.45		SC / CONTINUOUS	[redacted] / 27	[redacted] / 27
M15-741 /ABBV-951	476.39		SC / CONTINUOUS	[redacted] / 28	[redacted] / 28
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 38	
M15-741 /ABBV-951	1291.04		SC / CONTINUOUS	[redacted] / 38	[redacted] / 38
M15-741 /ABBV-951		75.13	SC / ONCE	[redacted] / 39	
M15-741 /ABBV-951	1335.94		SC / CONTINUOUS	[redacted] / 39	[redacted] / 39
M15-741 /ABBV-951	1065.48		SC / CONTINUOUS	[redacted] / 40	[redacted] / 93
M15-741 /ABBV-951		153.67	SC / ONCE	[redacted] / 94	
M15-741 /ABBV-951	1307.94		SC / CONTINUOUS	[redacted] / 94	[redacted] / 94
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted] / 95	
M15-741 /ABBV-951	1475.28		SC / CONTINUOUS	[redacted] / 95	[redacted] / 180
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted] / 181	
M15-741 /ABBV-951	1626.56		SC / CONTINUOUS	[redacted] / 181	[redacted] / 181
M15-741 /ABBV-951		153.67	SC / ONCE	[redacted] / 182	
M15-741 /ABBV-951	1553.31		SC / CONTINUOUS	[redacted] / 182	[redacted] / 182
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted] / 183	[redacted] / 270
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted] / 271	
M15-741 /ABBV-951	1674.54		SC / CONTINUOUS	[redacted] / 271	[redacted] / 271
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted] / 272	
M15-741 /ABBV-951	1739.60		SC / CONTINUOUS	[redacted] / 272	[redacted] / 272
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted] / 273	
M15-741 /ABBV-951	1711.42		SC / CONTINUOUS	[redacted] / 273	[redacted] / 273
M15-741 /ABBV-951	1516.26		SC / CONTINUOUS	[redacted] / 274	[redacted] / 362
M15-741 /ABBV-951		194.65	SC / ONCE	[redacted] / 363	
M15-741 /ABBV-951	2062.66		SC / CONTINUOUS	[redacted] / 363	[redacted] / 363
M15-741 /ABBV-951		162.21	SC / ONCE	[redacted] / 364	
M15-741 /ABBV-951	2243.99		SC / CONTINUOUS	[redacted] / 364	[redacted] / 364
ABBV-951	861.26		SC / CONTINUOUS	[redacted] / 365	[redacted] / 365
ABBV-951	2130.96		SC / CONTINUOUS	[redacted] / 366	[redacted] / 446
ABBV-951	2346.10		SC / CONTINUOUS	[redacted] / 447	[redacted] / 447
ABBV-951		194.65	SC / ONCE	[redacted] / 448	

ABBV-951	2405.86		SC / CONTINUOUS	20[redacted] / 448 20[redacted] / 448
ABBV-951		227.09	SC / ONCE	20[redacted] / 449
ABBV-951	2317.07		SC / CONTINUOUS	20[redacted] / 449 20[redacted] / 449
ABBV-951	2417.82		SC / CONTINUOUS	20[redacted] / 450 20[redacted] / 531
ABBV-951		162.21	SC / ONCE	20[redacted] / 532
ABBV-951	2343.54		SC / CONTINUOUS	20[redacted] / 532 20[redacted] / 532
ABBV-951		129.77	SC / ONCE	20[redacted] / 533
ABBV-951	2346.10		SC / CONTINUOUS	20[redacted] / 533 20[redacted] / 533
ABBV-951	2448.55		SC / CONTINUOUS	20[redacted] / 534 20[redacted] / 534
ABBV-951	2458.8		SC / CONTINUOUS	20[redacted] / 535 20[redacted] / 617
ABBV-951		129.77	SC / ONCE	20[redacted] / 618
ABBV-951	2452.82		SC / CONTINUOUS	20[redacted] / 618 20[redacted] / 618
ABBV-951		194.65	SC / ONCE	20[redacted] / 619
ABBV-951	2292.31		SC / CONTINUOUS	20[redacted] / 619 20[redacted] / 619
ABBV-951	2499.78		SC / CONTINUOUS	20[redacted] / 620 20[redacted] / 695
ABBV-951		129.77	SC / ONCE	20[redacted] / 695
ABBV-951		227.09	SC / ONCE	20[redacted] / 696
ABBV-951	2441.38		SC / CONTINUOUS	20[redacted] / 696 20[redacted] / 696

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
CLONAZEPAM	0.5 mg	PRN	Y-M: 20[redacted]
FOLIC ACID	5 mg	QD	Y-M: 20[redacted]
MACROGOL 3350	17 g	PRN	Y-M: 20[redacted]
SENNOSIDE A+B	17 mg	PRN	Y-M: 20[redacted]
NICOTINAMIDE	1 OTHER: CAPS	QD	Y-M: 20[redacted]
VITAMIN D NOS	10000 IU	OTHER: ONCE A WEEK	Y-M: 20[redacted] / -244
DABIGATRAN ETEXILATE MESILATE	110 mg	BID	Y-M: 20[redacted] / -123
AMIODARONE	100 mg	QD	Y-M: 20[redacted] / -83
DIGOXIN	0.125 mg	QD	Y-M: 20[redacted] / -83
DEXLANSOPRAZOLE	60 mg	QD	Y-M: 20[redacted] / -41
PRAMIPEXOLE	0.500 mg	BID	Y-M: 20[redacted] / 12
QUETIAPINE	12.5 mg	QD	Y-M: 20[redacted] / 40
TRAZODONE	25 mg	QD	Y-M: 20[redacted] / 40
DOMPERIDONE	10 mg	TID	Y-M: 20[redacted] / 183
PREGABALIN	25 mg	QD	Y-M: 20[redacted] / 275

PREGABALIN	50 mg	BID	Y-M: 20[redacted] / 275
GLYCERYL TRINITRATE	0.2 mg	OTHER: PER 24 HRS, CONTINUOUS	Y-M: 20[redacted] / 321
ISOSORBIDE DINITRATE	0.4 mg	PRN	Y-M: 20[redacted] / 321
MIDODRINE	2.5 mg	BID	Y-M: 20[redacted] / 321

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
CLONAZEPAM	0.5 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
FOLIC ACID	5 mg	QD	Y-M: 20[redacted]	NOT REPORTED
MACROGOL 3350	17 g	PRN	Y-M: 20[redacted]	NOT REPORTED
SENNOSIDE A+B	17 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
NICOTINAMIDE	1 OTHER: CAPS	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 393
VITAMIN D NOS	10000 IU	OTHER: ONCE A WEEK	Y-M: 20[redacted] / -244	NOT REPORTED
DABIGATRAN ETEXILATE MESILATE	110 mg	BID	Y-M: 20[redacted] / -123	Y-M: 20[redacted] / 589
AMIODARONE	100 mg	QD	Y-M: 20[redacted] / -83	NOT REPORTED
DIGOXIN	0.125 mg	QD	Y-M: 20[redacted] / -83	NOT REPORTED
DEXLANSOPRAZOLE	60 mg	QD	Y-M: 20[redacted] / -41	NOT REPORTED
TRAZODONE	25 mg	QD	Y-M: 20[redacted] / 40	NOT REPORTED
QUETIAPINE	12.5 mg	QD	Y-M: 20[redacted] / 40	Y-M: 20[redacted] / 697
DOMPERIDONE	10 mg	TID	Y-M: 20[redacted] / 183	NOT REPORTED
PREGABALIN	50 mg	BID	Y-M: 20[redacted] / 275	NOT REPORTED
PREGABALIN	25 mg	QD	Y-M: 20[redacted] / 275	Y-M: 20[redacted] / 697
GLYCERYL TRINITRATE	0.2 mg	OTHER: PER 24 HRS, CONTINUOUS	Y-M: 20[redacted] / 321	NOT REPORTED
ISOSORBIDE DINITRATE	0.4 mg	PRN	Y-M: 20[redacted] / 321	NOT REPORTED
MIDODRINE	2.5 mg	BID	Y-M: 20[redacted] / 321	NOT REPORTED
CYCLOBENZAPRINE HYDROCHLORIDE	10 mg	QD	Y-M: 20[redacted] / 365	NOT REPORTED
NICOTINAMIDE	1 OTHER: CAPS	OTHER: EVERY 2 DAYS	Y-M: 20[redacted] / 393	NOT REPORTED
DOCUSATE SODIUM	2 OTHER: CAPS	PRN	Y-M: 20[redacted] / 450	NOT REPORTED
APIXABAN	5 mg	BID	Y-M: 20[redacted] / 590	NOT REPORTED
PARACETAMOL	1 g	TID	Y-M: 20[redacted] / 697	NOT REPORTED

Event #1: Serious Adverse Event

Event Description	CHEST PAIN OF UNDETERMINED ETIOLOGY
Preferred Term	胸痛
AE Onset Date / Rx Day	[redacted]20[redacted] / 304
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
SAE Supplemental Procedure	
NOT REPORTED	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	HOSPITAL PHYSICIAN ORDERED A CONSULTATION IN GASTROENTEROLOGY, SO GASTRIC ORIGIN SUSPECTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Generated: [redacted]20[redacted]:09:38

Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者はカナダの 7[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に原因不明の胸痛を発現した。

Event 1 の臨床経過：

関連する病歴は，起立性低血圧，パーキンソン病，心房細動，胃食道逆流症，及び元飲酒者（1 日 2 杯未満）であった。

投与 1 日目から 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するための治験薬の調整を必要とした。投与 5 週時に，被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 304 日目，被験者は原因不明の胸痛を発現した。

被験者は過去に胸部痛を 15 日間発現していた。被験者は緊急治療室に来院するよう指導された。投与 318 日目，被験者は緊急治療室に来院し，不安定狭心症の診断に基づいて入院した。投与 320 日目，緊急冠動脈造影が実施され，結果は正常であった。投与 321 日目，被験者は退院した。

被験者に NITRO-DUR が投与された。

The patient's past medications include:

CARBIDOPA/LEVODOPA SUSTAINED RELEASE (SINEMET CR) for PARKINSON'S DISEASE ([redacted])

RASAGILINE for PARKINSON'S DISEASE ([redacted])

AMANTADINE for PARKINSON'S DISEASE ([redacted])

Causality for ABBV-951 (Open Label)

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1) Chest pain (10008479) (Chest pain (10008479)) [v.23.1] [10008479]

Causality asper reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: No

Alternative Etiology for ABBV-951 (Open Label)

Event of CHEST PAIN OF UNDETERMINED ETIOLOGY

- Investigator:

- AbbVie: More likely related to a history of gastro-esophageal reflux disease, Parkinson's disease and atrial fibrillation in an advanced aged patient.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] CORONAROGRAPHY:** Results not yet reported

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
転倒				X
幻覚	X			X
注入部位蜂巣炎				X
精神病性障害	X			X

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	7[redacted]	FEMALE	WHITE

Medical History	Onset Year
ORTHOSTATIC HYPOTENSION	19[redacted]
DEPRESSION	19[redacted]
SURGICALLY STERILE	19[redacted]
UTERINE DESCENT	19[redacted]
HALLUCINATIONS	19[redacted]
ANXIETY	20[redacted]
CONSTIPATION	20[redacted]
GASTROINTESTINAL REFLUX	20[redacted]
DEPRESSION	20[redacted]
INSOMNIA	20[redacted]
CARPAL TUNNEL SYNDROME	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
TUBAL LIGATION	19[redacted]
HYSTERECTOMY	19[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	3 CIGARETTE	0	19[redacted]
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	FORMER	LESS THAN 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.53	0.57	0.46	60	0.30	[redacted] / 368
ABBV-951	0.52	0.57	0.46	60	0.24	[redacted] / 528
ABBV-951	0.5	0.56	0.46	60	0.24	[redacted] / 547
ABBV-951	0.5	0.5	0.46	240	0.11	[redacted] / 561

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951		206.60	SC / ONCE	[redacted] / 5	
M15-741 /ABBV-951	767.00		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
M15-741 /ABBV-951		262.95	SC / ONCE	[redacted] / 6	
M15-741 /ABBV-951	1077.09		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
M15-741 /ABBV-951		75.13	SC / ONCE	[redacted] / 7	
M15-741 /ABBV-951	1508.06		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
M15-741 /ABBV-951	1639.2		SC / CONTINUOUS	[redacted] / 8	[redacted] / 12
M15-741 /ABBV-951		131.47	SC / ONCE	[redacted] / 13	
M15-741 /ABBV-951	1534.87		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
M15-741 /ABBV-951		93.91	SC / ONCE	[redacted] / 14	
M15-741 /ABBV-951	1399.80		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
M15-741 /ABBV-951	1434.3		SC / CONTINUOUS	[redacted] / 15	[redacted] / 19
M15-741 /ABBV-951		131.47	SC / ONCE	[redacted] / 20	
M15-741 /ABBV-951	1481.25		SC / CONTINUOUS	[redacted] / 20	[redacted] / 20
M15-741 /ABBV-951		93.91	SC / ONCE	[redacted] / 21	
M15-741 /ABBV-951	1455.30		SC / CONTINUOUS	[redacted] / 21	[redacted] / 21

M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 22	
M15-741 /ABBV-951	1611.53		SC / CONTINUOUS	[redacted] / 22	[redacted] / 22
M15-741 /ABBV-951	1721.16		SC / CONTINUOUS	[redacted] / 23	[redacted] / 26
M15-741 /ABBV-951		162.21	SC / ONCE	[redacted] / 27	
M15-741 /ABBV-951	1563.21		SC / CONTINUOUS	[redacted] / 27	[redacted] / 27
M15-741 /ABBV-951		129.77	SC / ONCE	[redacted] / 28	
M15-741 /ABBV-951	1453.76		SC / CONTINUOUS	[redacted] / 28	[redacted] / 28
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted] / 29	
M15-741 /ABBV-951	1472.03		SC / CONTINUOUS	[redacted] / 29	[redacted] / 29
M15-741 /ABBV-951	1516.26		SC / CONTINUOUS	[redacted] / 30	[redacted] / 40
M15-741 /ABBV-951		81.96	SC / ONCE	[redacted] / 41	
M15-741 /ABBV-951	1368.04		SC / CONTINUOUS	[redacted] / 41	[redacted] / 41
M15-741 /ABBV-951		122.94	SC / ONCE	[redacted] / 42	
M15-741 /ABBV-951	1297.52		SC / CONTINUOUS	[redacted] / 42	[redacted] / 42
M15-741 /ABBV-951	1229.4		SC / CONTINUOUS	[redacted] / 43	[redacted] / 89
M15-741 /ABBV-951		245.88	SC / ONCE	[redacted] / 90	
M15-741 /ABBV-951	1495.77		SC / CONTINUOUS	[redacted] / 90	[redacted] / 90
M15-741 /ABBV-951		286.86	SC / ONCE	[redacted] / 91	
M15-741 /ABBV-951	1572.26		SC / CONTINUOUS	[redacted] / 91	[redacted] / 91
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted] / 92	
M15-741 /ABBV-951	1639.2		SC / CONTINUOUS	[redacted] / 92	[redacted] / 178
M15-741 /ABBV-951	1723.20		SC / CONTINUOUS	[redacted] / 179	[redacted] / 179
M15-741 /ABBV-951		163.92	SC / ONCE	[redacted] / 180	
M15-741 /ABBV-951	1857.76		SC / CONTINUOUS	[redacted] / 180	[redacted] / 180
M15-741 /ABBV-951		81.96	SC / ONCE	[redacted] / 181	
M15-741 /ABBV-951	1885.08		SC / CONTINUOUS	[redacted] / 181	[redacted] / 270
M15-741 /ABBV-951		286.86	SC / ONCE	[redacted] / 271	
M15-741 /ABBV-951	1961.91		SC / CONTINUOUS	[redacted] / 271	[redacted] / 271
M15-741 /ABBV-951		327.84	SC / ONCE	[redacted] / 272	
M15-741 /ABBV-951	2012.45		SC / CONTINUOUS	[redacted] / 272	[redacted] / 272
M15-741 /ABBV-951	2114.73		SC / CONTINUOUS	[redacted] / 273	[redacted] / 273
M15-741 /ABBV-951	2171.94		SC / CONTINUOUS	[redacted] / 274	[redacted] / 364
M15-741 /ABBV-951		245.88	SC / ONCE	[redacted] / 365	
M15-741 /ABBV-951	2099.20		SC / CONTINUOUS	[redacted] / 365	[redacted] / 365
M15-741 /ABBV-951		286.86	SC / ONCE	[redacted] / 366	
M15-741 /ABBV-951	2057.70		SC / CONTINUOUS	[redacted] / 366	[redacted] / 366
M15-741 /ABBV-951		81.96	SC / ONCE	[redacted] / 367	

M15-741 /ABBV-951	2124.13		SC / CONTINUOUS	[redacted]20[redacted] / 367	[redacted]20[redacted] / 367
ABBV-951	1176.46		SC / CONTINUOUS	[redacted]20[redacted] / 368	[redacted]20[redacted] / 368
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 369	[redacted]20[redacted] / 447
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 448	
ABBV-951	2189.35		SC / CONTINUOUS	[redacted]20[redacted] / 448	[redacted]20[redacted] / 448
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 449	
ABBV-951	2144.96		SC / CONTINUOUS	[redacted]20[redacted] / 449	[redacted]20[redacted] / 449
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 450	[redacted]20[redacted] / 525
ABBV-951	2162.89		SC / CONTINUOUS	[redacted]20[redacted] / 526	[redacted]20[redacted] / 526
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 527	
ABBV-951	1719.45		SC / CONTINUOUS	[redacted]20[redacted] / 527	[redacted]20[redacted] / 527
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 528	
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 528	[redacted]20[redacted] / 615
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 616	
ABBV-951	1988.72		SC / CONTINUOUS	[redacted]20[redacted] / 616	[redacted]20[redacted] / 616
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 617	
ABBV-951	1990.94		SC / CONTINUOUS	[redacted]20[redacted] / 617	[redacted]20[redacted] / 617

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
PANTOPRAZOLE	40 mg	BID	Y-M: 20[redacted]-[redacted]
OXAZEPAM	15 mg	PRN	Y-M: 20[redacted]-[redacted]
TRAZODONE	100 mg	QD	Y-M: 20[redacted]-[redacted]
DOMPERIDONE	10 mg	TID	Y-M: 20[redacted]-[redacted]
NICOTINAMIDE	1 OTHER: 1 CO	QD	Y-M: 20[redacted]-[redacted] / -11
PRAMIPEXOLE	0.250 mg	QD	Y-M: 20[redacted]-[redacted] / 7
LORAZEPAM	0.5 mg	PRN	Y-M: 20[redacted]-[redacted] / 43
SERTRALINE	100 mg	QD	Y-M: 20[redacted]-[redacted] / 121
DONEPEZIL HYDROCHLORIDE	10 mg	QD	Y-M: 20[redacted]-[redacted] / 256
MELATONIN	10 mg	QD	Y-M: 20[redacted]-[redacted] / 298
OXAZEPAM	15 mg	QD	Y-M: 20[redacted]-[redacted] / 320
MIDODRINE HYDROCHLORIDE	10 mg	QD	Y-M: 20[redacted]-[redacted] / 340
MIDODRINE HYDROCHLORIDE	7,5 mg	QD	Y-M: 20[redacted]-[redacted] / 340

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
PANTOPRAZOLE	40 mg	BID	Y-M: 20[redacted]	NOT REPORTED
OXAZEPAM	15 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
TRAZODONE	100 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 567
DOMPERIDONE	10 mg	TID	Y-M: 20[redacted]	Y-M: 20[redacted] / 520
NICOTINAMIDE	1 OTHER: 1 CO	QD	Y-M: 20[redacted] / -11	NOT REPORTED
LORAZEPAM	0.5 mg	PRN	Y-M: 20[redacted] / 43	NOT REPORTED
SERTRALINE	100 mg	QD	Y-M: 20[redacted] / 121	NOT REPORTED
DONEPEZIL HYDROCHLORIDE	10 mg	QD	Y-M: 20[redacted] / 256	NOT REPORTED
MELATONIN	10 mg	QD	Y-M: 20[redacted] / 298	NOT REPORTED
OXAZEPAM	15 mg	QD	Y-M: 20[redacted] / 320	Y-M: 20[redacted] / 476
MIDODRINE HYDROCHLORIDE	10 mg	QD	Y-M: 20[redacted] / 340	Y-M: 20[redacted] / 566
MIDODRINE HYDROCHLORIDE	7,5 mg	QD	Y-M: 20[redacted] / 340	Y-M: 20[redacted] / 566
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 398	NOT REPORTED
OXAZEPAM	7,5 mg	QD	Y-M: 20[redacted] / 476	Y-M: 20[redacted] / 478
QUETIAPINE FUMARATE	6,25 mg	QD	Y-M: 20[redacted] / 476	Y-M: 20[redacted] / 478
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 479	NOT REPORTED
QUETIAPINE FUMARATE	12.5 mg	QD	Y-M: 20[redacted] / 479	Y-M: 20[redacted] / 529
OXAZEPAM	22.5 mg	QD	Y-M: 20[redacted] / 479	Y-M: 20[redacted] / 566
CALCIUM CARBONATE;COLECALCIFEROL	500MG/800UI OTHER: SEE DOSE	QD	Y-M: 20[redacted] / 491	NOT REPORTED
DOCUSATE SODIUM	100 mg	PRN	Y-M: 20[redacted] / 493	NOT REPORTED
SENNOSIDE A+B	8,6 mg	PRN	Y-M: 20[redacted] / 493	NOT REPORTED
MACROGOL 3350	17 g	PRN	Y-M: 20[redacted] / 499	NOT REPORTED
DALTEPARIN	5000 IU	QD	Y-M: 20[redacted] / 521	Y-M: 20[redacted] / 582
QUETIAPINE FUMARATE	25 mg	QD	Y-M: 20[redacted] / 529	NOT REPORTED
DOMPERIDONE	10 mg	TID	Y-M: 20[redacted] / 546	NOT REPORTED
BISACODYL	10 mg	QD	Y-M: 20[redacted] / 553	Y-M: 20[redacted] / 554
SODIUM CHLORIDE	1 g	BID	Y-M: 20[redacted] / 554	NOT REPORTED
FOSFOMYCIN	3 g	QD	Y-M: 20[redacted] / 556	Y-M: 20[redacted] / 556

CEFADROXIL	1 g	BID	Y-M: 20[redacted] / 564	Y-M: 20[redacted] / 570
MIDODRINE	10 mg	TID	Y-M: 20[redacted] / 567	NOT REPORTED
OXAZEPAM	15 mg	QD	Y-M: 20[redacted] / 567	NOT REPORTED
QUETIAPINE FUMARATE	75 mg	QD	Y-M: 20[redacted] / 567	NOT REPORTED

Event #1: Event of Interest - Hallucinations/Psychosis

Event Description	INCREASED HALLUCINATIONS
Preferred Term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 381
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped Rx Day	567
Duration of AE	187 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest - Falls and Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred Term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 398
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped Rx Day	398
Duration of AE	1 DAY
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Event of Interest - Falls and Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred Term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 399
Age at AE Onset	7[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped Rx Day	399
Duration of AE	1 DAY
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE

Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Serious Adverse Event, Event of Interest - Hallucinations/Psychosis

Event Description	INCREASED HALLUCINATIONS
Preferred Term	幻覚
AE Onset Date / Rx Day	[redacted] / 545
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted] (RX DAY 546): Creatinine: 74 [NOT REPORTED - NOT REPORTED] UNK; Leukocytes: OVER 20 [NOT REPORTED - NOT REPORTED] UNKNOWN; NPTST002-BACTERIA: 3 + [NOT REPORTED - NOT REPORTED] UNKNOWN; [redacted] (RX DAY 547): Hemoglobin: 112 [117 - 161] G/L; Leukocytes: 5.4 [4.5 - 11] 10^9/L

Microbiology

[redacted] (RX DAY 546): URINE CULTURE: POSITIVE-E. COLI NO SYMPTOMS

SAE Supplemental Procedure

[redacted] (RX DAY 558): X-RAY OF LUNGS:NORMAL; [redacted] (RX DAY 564): ABDOMINAL SURFACE ECHOGRAPHY:CUTANEOUS THICKENING OF 4MM WITH MODERATE EDEMA. NO LIQUID COLLECTION. AUGMENTATION OF TISSUE VASCULARIZATION. NO FOREIGN BODY. PROBABLE INFECTIOUS PROCESS

AE Stopped Rx Day	567
Duration of AE	23 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
Other Cause of Event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #5: Serious Adverse Event, Event of Interest - Hallucinations/Psychosis

Event Description	PSYCHOTIC STATE
Preferred Term	精神病性障害
AE Onset Date / Rx Day	[redacted] / 545
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 546): Creatinine: 74 [NOT REPORTED - NOT REPORTED] UNK; Leukocytes: OVER 20 [NOT REPORTED - NOT REPORTED] UNKNOWN; NPTST002-BACTERIA: 3 + [NOT REPORTED - NOT REPORTED] UNKNOWN; [redacted]20[redacted] (RX DAY 547): Hemoglobin: 112 [117 - 161] G/L; Leukocytes: 5.4 [4.5 - 11] 10^9/L

Microbiology

[redacted]20[redacted] (RX DAY 546): URINE CULTURE: POSITIVE-E. COLI NO SYMPTOMS

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 558): X-RAY OF LUNGS:NORMAL; [redacted]20[redacted] (RX DAY 564): ABDOMINAL SURFACE ECHOGRAPHY:CUTANEOUS THICKENING OF 4MM WITH MODERATE EDEMA. NO LIQUID COLLECTION. AUGMENTATION OF TISSUE VASCULARIZATION. NO FOREIGN BODY. PROBABLE INFECTIOUS PROCESS

AE Stopped Rx Day	567
Duration of AE	23 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
Other Cause of Event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #6: Event of Interest - Infusion Site Related Infections

Event Description	OLD INFUSION SITE CELLULITIS (RIGHT SIDE OF ABDOMEN)
Preferred Term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 563
Age at AE Onset	7[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped Rx Day	570
Duration of AE	8 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to	NOT APPLICABLE

Infusion Pump	
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #7: Event of Interest - Hallucinations/Psychosis

Event Description	INCREASED HALLUCINATIONS
Preferred Term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 635
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Generated: [redacted]20[redacted]:09:38

Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者はカナダの 7[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に幻覚の増強及び精神病性障害を発現した。

Event 4 及び 5 の臨床経過：

関連する病歴は，うつ病，幻覚，不安，パーキンソン病，不眠症，元喫煙者（1 日 3 本），及び元飲酒者（1 日 2 杯未満）であった。

投与 545 日目，被験者は幻覚の増強及び精神病性障害を発現した。投与 567 日目，幻覚の増強及び精神病状態は消失した。

投与 545 日目，被験者は精神病要素を伴う幻覚の増強のため緊急治療室に来院した。投与 546 日目，担当の神経科医が精密検査のため被験者を入院させることを決めた。クエチアピンフマル酸塩の用量が調整された（詳細は不明）。入院中，注入ポンプの注入速度を変更した。幻覚の増強及び精神病性障害は退院時に消失したと考えられた。投与 567 日目，被験者は退院した。

治験責任医師によると，うつ病，不安，幻覚の病歴以外のリスク因子は，過去に発現した不安の増強（非重篤），軽度の認知機能障害（非重篤），軽度のパニック発作（非重篤），及び幻覚の増強（非重篤）であった。

The patient's past medications include:

PRAMIPEXOLE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Hallucinations aggravated (10019078) (Hallucination (10019063)) [v.24.0] [10019078]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Not Applicable

2) Psychotic state (10037259) (Psychotic disorder (10061920)) [v.24.0] [10037259]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of INCREASED HALLUCINATIONS

- Investigator: Not applicable.

- AbbVie: Not applicable

Event of PSYCHOTIC STATE

- Investigator: Not applicable.

- AbbVie: Not applicable

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ABDOMINAL ULTRASOUND:** CUTANEOUS THICKENING OF 4MM WITH MODERATE EDEMA. NO LIQUID COLLECTION. AUGMENTATION OF TISSUE VASCULARIZATION. NO FOREIGN BODY. PROBABLE INFECTIOUS PROCESS

[redacted] **20[redacted] CREATININE:** 74 UM/L

[redacted] **20[redacted] HEMOGLOBIN:** 112 G/L

[redacted] **20[redacted] URINE BACTERIA:** 3+

[redacted] **20[redacted] URINE CULTURE:** positive E.coli, no symptoms

[redacted] **20[redacted] URINE WBC:** over 20

[redacted] **20[redacted] WBC:** 5.4 X10**3/MM**3

[redacted] **20**[redacted] **WEIGHT:** 10[redacted] Pounds

[redacted] **20**[redacted] **X-RAY CHEST:** normal

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
転倒				X
肩甲骨骨折	X			X

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	7[redacted]	MALE	ASIAN

Medical History	Onset Year
CEREBRAL INFARCTION	19[redacted]
CERVICAL SPINE SURGERY	20[redacted]
CATARACT SURGERY(BOTH EYES)	20[redacted]
ATRIAL FIBRILLATION	20[redacted]
DYSLIPIDEMIA	20[redacted]
HYPERTENSION	20[redacted]
HYPERURICEMIA	20[redacted]
LOW BACK PAIN	20[redacted]
LOSS OF APPETITE	20[redacted]
INSOMNIA	20[redacted]
CONSTIPATION DUE TO PD	20[redacted]
BENIGN PROSTATIC HYPERPLASIA	20[redacted]
ABDOMINAL DISTENSION	20[redacted]
IMPULSE CONTROL DUE TO PD	20[redacted]
FREQUENT URINATION DUE TO PD	20[redacted]
ALLERGIC RHINITIS	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
CERVICAL SPINE SURGERY	20[redacted]

CATARACT SURGERY(BOTH EYES)	20[redacted]
ATRIAL FIBRILLATION ABLATION SURGERY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	1 CIGARETTE	37	20[redacted]
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	LESS THAN 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.45	0.49	0.36	120	0.24	[redacted]20[redacted] / 364
ABBV-951	0.52	0.56	0.45	120	0.24	[redacted]20[redacted] / 478
ABBV-951	0.52	0.56	0.45	120	0.24	[redacted]20[redacted] / 534
ABBV-951	0.49	0.52	0.46	120	0.24	[redacted]20[redacted] / 572
ABBV-951	0.47	0.49	0.44	120	0.19	[redacted]20[redacted] / 583
ABBV-951	0.46	0.48	0.44	90	0.15	[redacted]20[redacted] / 622
ABBV-951	0.46	0.48	0.44	90	0.15	[redacted]20[redacted] / 686
ABBV-951	0.47	0.49	0.45	90	0.15	[redacted]20[redacted] / 713
ABBV-951	0.48	0.50	0.46	90	0.15	[redacted]20[redacted] / 749

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 1	
M15-741 /ABBV-951	796.03		SC / CONTINUOUS	[redacted]20[redacted] / 1	[redacted]20[redacted] / 1
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 2	
M15-741 /ABBV-951	2219.06		SC / CONTINUOUS	[redacted]20[redacted] / 2	[redacted]20[redacted] / 2
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 3	
M15-741 /ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 3	[redacted]20[redacted] / 4
M15-741 /ABBV-951	2254.75		SC / CONTINUOUS	[redacted]20[redacted] / 5	[redacted]20[redacted] / 5
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 6	

M15-741 /ABBV-951	2078.02		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
M15-741 /ABBV-951	2171.94		SC / CONTINUOUS	[redacted] / 7	[redacted] / 11
M15-741 /ABBV-951	2155.71		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 13	
M15-741 /ABBV-951	1557.75		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 14	
M15-741 /ABBV-951	1597.02		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 15	
M15-741 /ABBV-951	1781.77		SC / CONTINUOUS	[redacted] / 15	[redacted] / 15
M15-741 /ABBV-951	1926.06		SC / CONTINUOUS	[redacted] / 16	[redacted] / 20
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted] / 21	
M15-741 /ABBV-951	1871.76		SC / CONTINUOUS	[redacted] / 21	[redacted] / 21
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 22	
M15-741 /ABBV-951	1841.36		SC / CONTINUOUS	[redacted] / 22	[redacted] / 22
M15-741 /ABBV-951	1826.17		SC / CONTINUOUS	[redacted] / 23	[redacted] / 23
M15-741 /ABBV-951	1926.06		SC / CONTINUOUS	[redacted] / 24	[redacted] / 26
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted] / 27	
M15-741 /ABBV-951	1898.74		SC / CONTINUOUS	[redacted] / 27	[redacted] / 27
M15-741 /ABBV-951		81.96	SC / ONCE	[redacted] / 28	
M15-741 /ABBV-951	1851.44		SC / CONTINUOUS	[redacted] / 28	[redacted] / 28
M15-741 /ABBV-951	1869.20		SC / CONTINUOUS	[redacted] / 29	[redacted] / 29
M15-741 /ABBV-951	1926.06		SC / CONTINUOUS	[redacted] / 30	[redacted] / 40
M15-741 /ABBV-951		81.96	SC / ONCE	[redacted] / 41	
M15-741 /ABBV-951	1953.55		SC / CONTINUOUS	[redacted] / 41	[redacted] / 41
M15-741 /ABBV-951		122.94	SC / ONCE	[redacted] / 42	
M15-741 /ABBV-951	1862.54		SC / CONTINUOUS	[redacted] / 42	[redacted] / 42
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted] / 43	
M15-741 /ABBV-951	2125.83		SC / CONTINUOUS	[redacted] / 43	[redacted] / 43
M15-741 /ABBV-951	2294.88		SC / CONTINUOUS	[redacted] / 44	[redacted] / 89
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted] / 90	
M15-741 /ABBV-951	2004.26		SC / CONTINUOUS	[redacted] / 90	[redacted] / 90
M15-741 /ABBV-951		81.96	SC / ONCE	[redacted] / 91	
M15-741 /ABBV-951	1819.17		SC / CONTINUOUS	[redacted] / 91	[redacted] / 91
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted] / 92	
M15-741 /ABBV-951	2165.79		SC / CONTINUOUS	[redacted] / 92	[redacted] / 92
M15-741 /ABBV-951	2294.88		SC / CONTINUOUS	[redacted] / 93	[redacted] / 180
M15-741 /ABBV-951	1829.92		SC / CONTINUOUS	[redacted] / 181	[redacted] / 181

M15-741 /ABBV-951		40.98	SC / ONCE	[redacted] / 182	
M15-741 /ABBV-951	1552.45		SC / CONTINUOUS	[redacted] / 182	[redacted] / 182
M15-741 /ABBV-951	1692.98		SC / CONTINUOUS	[redacted] / 183	[redacted] / 183
M15-741 /ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 184	[redacted] / 270
M15-741 /ABBV-951	1691.27		SC / CONTINUOUS	[redacted] / 271	[redacted] / 271
M15-741 /ABBV-951	1657.98		SC / CONTINUOUS	[redacted] / 272	[redacted] / 272
M15-741 /ABBV-951	1393.32		SC / CONTINUOUS	[redacted] / 273	[redacted] / 361
M15-741 /ABBV-951	1647.73		SC / CONTINUOUS	[redacted] / 362	[redacted] / 362
M15-741 /ABBV-951	1607.26		SC / CONTINUOUS	[redacted] / 363	[redacted] / 363
ABBV-951	937.41		SC / CONTINUOUS	[redacted] / 364	[redacted] / 364
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 365	[redacted] / 445
ABBV-951		40.98	SC / ONCE	[redacted] / 446	
ABBV-951	1821.04		SC / CONTINUOUS	[redacted] / 446	[redacted] / 447
ABBV-951		40.98	SC / ONCE	[redacted] / 448	
ABBV-951	1851.61		SC / CONTINUOUS	[redacted] / 448	[redacted] / 448
ABBV-951		40.98	SC / ONCE	[redacted] / 449	
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 449	[redacted] / 531
ABBV-951		81.96	SC / ONCE	[redacted] / 532	
ABBV-951	2024.07		SC / CONTINUOUS	[redacted] / 532	[redacted] / 532
ABBV-951		40.98	SC / ONCE	[redacted] / 533	
ABBV-951	2023.38		SC / CONTINUOUS	[redacted] / 533	[redacted] / 533
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 534	[redacted] / 614
ABBV-951	1851.78		SC / CONTINUOUS	[redacted] / 615	[redacted] / 615
ABBV-951	1827.87		SC / CONTINUOUS	[redacted] / 616	[redacted] / 616
ABBV-951	1803.12		SC / CONTINUOUS	[redacted] / 617	[redacted] / 683
ABBV-951		25.61	SC / ONCE	[redacted] / 684	
ABBV-951	1819.17		SC / CONTINUOUS	[redacted] / 684	[redacted] / 684
ABBV-951		25.61	SC / ONCE	[redacted] / 685	
ABBV-951	1795.26		SC / CONTINUOUS	[redacted] / 685	[redacted] / 685

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
BENZBROMARONE	50 mg	QD	Y-M: 20[redacted]
ESOMEPRAZOLE MAGNESIUM	20 mg	QD	Y-M: 20[redacted]
RIVAROXABAN	15 mg	QD	Y-M: 20[redacted]
GALANTAMINE HYDROBROMIDE	8 mg	BID	Y-M: 20[redacted]-[redacted]

LOXOPROFEN	100 mg	PRN	Y-M: 20[redacted]
ATRACTYLODES LANCEA RHIZOME;CITRUS AURANTIUM PEEL;GLYCYRRHIZA SPP. ROOT;PANAX GINSENG ROOT;PINELLIA TERNATA TUBER;PORIA COCOS SCLEROTIUM;ZINGIBER OFFICINALE RHIZOME;ZIZIPHUS JUJUBA FRUIT	2.5 g	QD	Y-M: 20[redacted]
FLUNITRAZEPAM	2 mg	QD	Y-M: 20[redacted]
SENNOSIDE A+B	36 mg	QD	Y-M: 20[redacted]
BISOPROLOL FUMARATE	1.25 mg	BID	Y-M: 20[redacted]
SILODOSIN	4 mg	BID	Y-M: 20[redacted]
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	APPROPRIATE AMOUNT OTHER: APPLICATION	PRN	Y-M: 20[redacted]
PRAMIPEXOLE	1.500 mg	QD	Y-M: 20[redacted]
DIMETICONE	40 mg	TID	Y-M: 20[redacted]
ANGELICA ACUTILOBA ROOT;ATRACTYLODES LANCEA RHIZOME;BUPLEURUM FALCATUM ROOT;CNIDIUM OFFICINALE RHIZOME;GLYCYRRHIZA SPP. ROOT;PORIA COCOS SCLEROTIUM;UNCARIA SPP. HOOK	2.5 g	TID	Y-M: 20[redacted]
RASAGILINE MESYLATE	1.000 mg	QD	Y-M: 20[redacted] / -344
SOLIFENACIN SUCCINATE	5 mg	QD	Y-M: 20[redacted] / -331
EPINASTINE HYDROCHLORIDE	20 mg	QD	Y-M: 20[redacted] / -191
CANDESARTAN	2 mg	BID	Y-M: 20[redacted] / -153
ZOLPIDEM	2.5 mg	QD	Y-M: 20[redacted] / -65
FUROSEMIDE	20 mg	QD	Y-M: 20[redacted] / 44
CAMPHOR;ENOXOLONE;LEVOMENTHOL;METHYL SALICYLATE	APPROPRIATE AMOUNT OTHER: APPROPRIATE AMOUNT	PRN	Y-M: 20[redacted] / 51
PITAVASTATIN	1 mg	QD	Y-M: 20[redacted] / 135
RUPATADINE FUMARATE	10 mg	QD	Y-M: 20[redacted] / 136
FLURBIPROFEN	40 mg	QD	Y-M: 20[redacted] / 190

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
ESOMEPRAZOLE MAGNESIUM	20 mg	QD	Y-M: 20[redacted]	NOT REPORTED
BENZBROMARONE	50 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 749
RIVAROXABAN	15 mg	QD	Y-M: 20[redacted]	NOT REPORTED
GALANTAMINE HYDROBROMIDE	8 mg	BID	Y-M: 20[redacted]	Y-M: 20[redacted] / 449

LOXOPROFEN	100 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
ATRACTYLODES LANCEA RHIZOME;CITRUS AURANTIUM PEEL;GLYCYRRHIZA SPP. ROOT;PANAX GINSENG ROOT;PINELLIA TERNATA TUBER;PORIA COCOS SCLEROTIUM;ZINGIBER OFFICINALE RHIZOME;ZIZIPHUS JUJUBA FRUIT	2.5 g	QD	Y-M: 20[redacted]	NOT REPORTED
FLUNITRAZEPAM	2 mg	QD	Y-M: 20[redacted]	NOT REPORTED
SENNOSIDE A+B	36 mg	QD	Y-M: 20[redacted]	NOT REPORTED
BISOPROLOL FUMARATE	1.25 mg	BID	Y-M: 20[redacted]	NOT REPORTED
SILODOSIN	4 mg	BID	Y-M: 20[redacted]	NOT REPORTED
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	APPROPRIATE AMOUNT OTHER: APPLICATION	PRN	Y-M: 20[redacted]	Y-M: 20[redacted] / 534
DIMETICONE	40 mg	TID	Y-M: 20[redacted]	Y-M: 20[redacted] / 446
ANGELICA ACUTILOBA ROOT;ATRACTYLODES LANCEA RHIZOME;BUPLEURUM FALCATUM ROOT;CNIDIUM OFFICINALE RHIZOME;GLYCYRRHIZA SPP. ROOT;PORIA COCOS SCLEROTIUM;UNCARIA SPP. HOOK	2.5 g	TID	Y-M: 20[redacted]	Y-M: 20[redacted] / 449
SOLIFENACIN SUCCINATE	5 mg	QD	Y-M: 20[redacted] / -331	NOT REPORTED
EPINASTINE HYDROCHLORIDE	20 mg	QD	Y-M: 20[redacted] / -191	NOT REPORTED
CANDESARTAN	2 mg	BID	Y-M: 20[redacted] / -153	NOT REPORTED
ZOLPIDEM	2.5 mg	QD	Y-M: 20[redacted] / -65	NOT REPORTED
FUROSEMIDE	20 mg	QD	Y-M: 20[redacted] / 44	NOT REPORTED
CAMPHOR;ENOXOLONE;LEVOMENTHOL; METHYL SALICYLATE	APPROPRIATE AMOUNT OTHER: APPROPRIATE AMOUNT	PRN	Y-M: 20[redacted] / 51	NOT REPORTED
PITAVASTATIN	1 mg	QD	Y-M: 20[redacted] / 135	NOT REPORTED
RUPATADINE FUMARATE	10 mg	QD	Y-M: 20[redacted] / 136	Y-M: 20[redacted] / 446
FLURBIPROFEN	40 mg	QD	Y-M: 20[redacted] / 190	NOT REPORTED
PARACETAMOL	200 mg	TID	Y-M: 20[redacted] / 436	Y-M: 20[redacted] / 439
PRANOPROFEN	APPROPRIATE AMOUNT OTHER: APPROPRIATE AMOUNT	BID	Y-M: 20[redacted] / 457	Y-M: 20[redacted] / 478

Event #1: Event of Interest - Falls and Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred Term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 436
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped Rx Day	436
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Serious Adverse Event, Event of Interest - Falls and Associated Injuries

Event Description	RIGHT SCAPULA FRACTURE
Preferred Term	肩甲骨骨折
AE Onset Date / Rx Day	[redacted]20[redacted] / 436
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
SAE Supplemental Procedure	
[redacted]20[redacted] (RX DAY 436): CT:RIGHT SCAPULA FRACTURE; X-RAY:RIGHT SCAPULA FRACTURE	
AE Stopped Rx Day	460
Duration of AE	25 DAYS

Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	ACCIDENTAL FALL
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Generated: [redacted] 20[redacted]:09:38
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者は日本の 7[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に右肩甲骨骨折を発現した。

Event 2 の臨床経過：

関連する病歴は，心房細動，高血圧，パーキンソン病，パーキンソン病による衝動制御障害，パーキンソン病による頻尿，元喫煙者（1 日 1 本を 37 年間），及び飲酒者（1 日 2 杯未満）であった。

投与 436 日目，被験者は右肩甲骨骨折を発現した。

投与 436 日目，被験者は自宅で入浴中に転倒し，右肩甲骨が陥没したため，救急車により病院へ搬送された。検査の結果，被験者は右肩甲骨骨折と診断された。被験者の関節可動域が正常であったため，吊り包帯による保存療法が実施され，被験者は帰宅した。

投与 439 日目，被験者は右肩甲骨の動きが限られており，安静にする必要があると訴えた。同日，右肩甲骨の安静及びリハビリテーションのため，被験者は入院した。投与 460 日目，被験者は退院した。投与 460 日目，右肩甲骨骨折は消失した。

被験者にアセトアミノフェンが投与された。

Causality for ABBV-951 (Open Label)

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1) Scapula fracture (10039579) (Scapula fracture (10039579)) [v.23.1] [10039579]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of RIGHT SCAPULA FRACTURE

- Investigator: Accidental fall.

- AbbVie: More likely related to reported accidental fall in an advanced age subject with Parkinson's disease

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] CT:** Right scapula fracture

[redacted] **20[redacted] X-RAY:** Right scapula fracture

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
窒息	X	X	X	
誤嚥	X	X	X	
注入部位皮膚炎				X
** Disc. due to adverse event				X

Disc = Discontinued.

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	7[redacted]	FEMALE	ASIAN

Medical History	Onset Year
DUODENAL ULCER	19[redacted]
ECTOPIC PREGNANCY	19[redacted]
HULLUCINATION	19[redacted]
RIGHT HAND FRECTURE	19[redacted]
SCHIZOPHRENIA	19[redacted]
HEPATIC STEATOSIS	20[redacted]
INSOMNIA	20[redacted]
RIGHT TROCHANTERIC FEMORAL FRACTURE	20[redacted]
MISSING TOOTH	20[redacted]
LEFT FEMUR FRACTURE	20[redacted]
LOW BACK PAIN	20[redacted]
OVARIAN CYSTOMA	20[redacted]
UTERINE MYOMA	20[redacted]
OSTEOPOROSIS	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	19[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]

Prior Procedures	Procedure Year
UNILATERAL OVARIECTOMY	19[redacted]
TOTAL HIP ARTHROPLASTY	20[redacted]
TOTAL HIP ARTHROPLASTY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	FORMER	MORE THAN 4 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.34	0.40	0.28	60	0.11	[redacted]20[redacted] / 366
ABBV-951	0.32	0.37	0.26	60	0.11	[redacted]20[redacted] / 478
ABBV-951	0.30	0.34	0.24	60	0.11	[redacted]20[redacted] / 506
ABBV-951	0.30	0.34	0.24	60	0.11	[redacted]20[redacted] / 534
ABBV-951	0.30	0.32	0.22	60	0.11	[redacted]20[redacted] / 591

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 1	
M15-741 /ABBV-951	833.26		SC / CONTINUOUS	[redacted]20[redacted] / 1	[redacted]20[redacted] / 1
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 2	
M15-741 /ABBV-951	1482.11		SC / CONTINUOUS	[redacted]20[redacted] / 2	[redacted]20[redacted] / 2
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 3	
M15-741 /ABBV-951	1488.94		SC / CONTINUOUS	[redacted]20[redacted] / 3	[redacted]20[redacted] / 3
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 4	
M15-741 /ABBV-951	1475.28		SC / CONTINUOUS	[redacted]20[redacted] / 4	[redacted]20[redacted] / 5
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 5	
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 6	

M15-741 /ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 6	[redacted]20[redacted] / 6
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 7	
M15-741 /ABBV-951	1651.49		SC / CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 7
M15-741 /ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 14
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 15	
M15-741 /ABBV-951	1740.11		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
M15-741 /ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 16	
M15-741 /ABBV-951	1710.06		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
M15-741 /ABBV-951	1434.3		SC / CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 19
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 20	
M15-741 /ABBV-951	1473.57		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 21	
M15-741 /ABBV-951	1765.55		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
M15-741 /ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 22	
M15-741 /ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 24
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 23	
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 24	
M15-741 /ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 25	
M15-741 /ABBV-951	1901.98		SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 26	
M15-741 /ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
M15-741 /ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 27	
M15-741 /ABBV-951	1837.78		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 28	
M15-741 /ABBV-951	1918.03		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 29
M15-741 /ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 29	
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 30	
M15-741 /ABBV-951	1772.38		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 31	
M15-741 /ABBV-951	1689.05		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 32	
M15-741 /ABBV-951	1550.75		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 33	
M15-741 /ABBV-951	1801.24		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 34	
M15-741 /ABBV-951	1791.67		SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 35	

M15-741 /ABBV-951	1784.33		SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 36	
M15-741 /ABBV-951	1805.85		SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 37	
M15-741 /ABBV-951	1550.75		SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 38
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 38	
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 39	
M15-741 /ABBV-951	1789.28		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 40	
M15-741 /ABBV-951	1550.75		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 41	
M15-741 /ABBV-951	1793.55		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 42	
M15-741 /ABBV-951	1557.24		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 43	
M15-741 /ABBV-951	1793.55		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 44	
M15-741 /ABBV-951	1672.83		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 45	
M15-741 /ABBV-951	1883.71		SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
M15-741 /ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 46	
M15-741 /ABBV-951	1985.65		SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 47	
M15-741 /ABBV-951	2002.04		SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 48	
M15-741 /ABBV-951	1969.25		SC / CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
M15-741 /ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 49	
M15-741 /ABBV-951	1961.06		SC / CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 50	
M15-741 /ABBV-951	1992.99		SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
M15-741 /ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 51	
M15-741 /ABBV-951	1999.31		SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
M15-741 /ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 52	
M15-741 /ABBV-951	2003.92		SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 53	
M15-741 /ABBV-951	1927.76		SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 54	

M15-741 /ABBV-951	1993.84		SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
M15-741 /ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 55	
M15-741 /ABBV-951	1952.86		SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
M15-741 /ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 56	
M15-741 /ABBV-951	2027.99		SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 57	
M15-741 /ABBV-951	1754.79		SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 58	
M15-741 /ABBV-951	1967.04		SC / CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 59	
M15-741 /ABBV-951	1986.16		SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 60	
M15-741 /ABBV-951	1936.98		SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
M15-741 /ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 62	
M15-741 /ABBV-951	1954.23		SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
M15-741 /ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 63	
M15-741 /ABBV-951	1978.30		SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 64	
M15-741 /ABBV-951	1971.13		SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 65	
M15-741 /ABBV-951	1871.42		SC / CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 66	
M15-741 /ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 67	
M15-741 /ABBV-951	1747.45		SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 68	
M15-741 /ABBV-951	1754.79		SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 69
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 69	
M15-741 /ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 70	
M15-741 /ABBV-951	1747.45		SC / CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 71	
M15-741 /ABBV-951	1754.79		SC / CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 72
M15-741 /ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 72	
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 73	
M15-741 /ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 75
M15-741 /ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 74	

M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]	20	/ 75	
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]	20	/ 76	
M15-741 /ABBV-951	1754.79		SC / CONTINUOUS	[redacted]	20	/ 76	[redacted] 20 / 78
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]	20	/ 77	
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]	20	/ 78	
M15-741 /ABBV-951	1762.14		SC / CONTINUOUS	[redacted]	20	/ 79	[redacted] 20 / 79
M15-741 /ABBV-951		128.06	SC / ONCE	[redacted]	20	/ 80	
M15-741 /ABBV-951	1754.79		SC / CONTINUOUS	[redacted]	20	/ 80	[redacted] 20 / 81
M15-741 /ABBV-951		153.67	SC / ONCE	[redacted]	20	/ 81	
M15-741 /ABBV-951		128.06	SC / ONCE	[redacted]	20	/ 82	
M15-741 /ABBV-951	1747.45		SC / CONTINUOUS	[redacted]	20	/ 82	[redacted] 20 / 82
M15-741 /ABBV-951		128.06	SC / ONCE	[redacted]	20	/ 83	
M15-741 /ABBV-951	1754.79		SC / CONTINUOUS	[redacted]	20	/ 83	[redacted] 20 / 84
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]	20	/ 84	
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]	20	/ 85	
M15-741 /ABBV-951	1747.45		SC / CONTINUOUS	[redacted]	20	/ 85	[redacted] 20 / 85
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]	20	/ 86	
M15-741 /ABBV-951	1762.14		SC / CONTINUOUS	[redacted]	20	/ 86	[redacted] 20 / 86
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M15-741 /ABBV-951		153.67	SC / ONCE	[redacted]	20	/ 88	
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M15-741 /ABBV-951	1762.14		SC / CONTINUOUS	[redacted]	20	/ 90	[redacted] 20 / 90
M15-741 /ABBV-951		153.67	SC / ONCE	[redacted]	20	/ 91	
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M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]	20	/ 92	
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M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]	20	/ 93	
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M15-741 /ABBV-951		153.67	SC / ONCE	[redacted]	20	/ 94	
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M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]	20	/ 97	
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M15-741 /ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 113		
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M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 119		
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M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 127			
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M15-741 /ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 141	
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M15-741 /ABBV-951		93.91	SC / ONCE	[redacted]20[redacted] / 188	
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M15-741 /ABBV-951		93.91	SC / ONCE	[redacted]20[redacted] / 189	
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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 292	
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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 293	
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M15-741 /ABBV-951		93.91	SC / ONCE	[redacted]20[redacted] / 316	
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M15-741 /ABBV-951		93.91	SC / ONCE	[redacted]20[redacted] / 317	
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M15-741 /ABBV-951		93.91	SC / ONCE	[redacted]20[redacted] / 321	
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M15-741 /ABBV-951		93.91	SC / ONCE	[redacted]20[redacted] / 324	
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M15-741 /ABBV-951		112.69	SC / ONCE	[redacted]20[redacted] / 330	
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M15-741 /ABBV-951	1393.32		SC / CONTINUOUS	[redacted]20[redacted] / 332	[redacted]20[redacted] / 333

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M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 344	
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M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 351	
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ABBV-951		75.13	SC / ONCE	[redacted]20[redacted] / 374	
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ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 384	
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ABBV-951		93.91	SC / ONCE	[redacted]20[redacted] / 385	
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ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 386	
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ABBV-951		93.91	SC / ONCE	[redacted]20[redacted] / 388	
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ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 389	
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ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 391	
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ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 392	
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ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 393	
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ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 395	
ABBV-951	1555.19		SC / CONTINUOUS	[redacted]20[redacted] / 395	[redacted]20[redacted] / 395
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ABBV-951	1538.79		SC / CONTINUOUS	[redacted]20[redacted] / 397	[redacted]20[redacted] / 397
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ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 545	
ABBV-951	1215.74		SC / CONTINUOUS	[redacted]20[redacted] / 545	[redacted]20[redacted] / 545
ABBV-951	983.52		SC / CONTINUOUS	[redacted]20[redacted] / 546	[redacted]20[redacted] / 555
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 555	
ABBV-951		75.13	SC / ONCE	[redacted]20[redacted] / 556	
ABBV-951	1257.74		SC / CONTINUOUS	[redacted]20[redacted] / 556	[redacted]20[redacted] / 556
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 557	
ABBV-951	1290.87		SC / CONTINUOUS	[redacted]20[redacted] / 557	[redacted]20[redacted] / 557
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 558	
ABBV-951	1348.24		SC / CONTINUOUS	[redacted]20[redacted] / 558	[redacted]20[redacted] / 558
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 559	
ABBV-951	1230.42		SC / CONTINUOUS	[redacted]20[redacted] / 559	[redacted]20[redacted] / 559
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 560	
ABBV-951	1210.61		SC / CONTINUOUS	[redacted]20[redacted] / 560	[redacted]20[redacted] / 560
ABBV-951	983.52		SC / CONTINUOUS	[redacted]20[redacted] / 561	[redacted]20[redacted] / 564

ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 565	
ABBV-951	1217.44		SC / CONTINUOUS	[redacted]20[redacted] / 565	[redacted]20[redacted] / 565
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 566	
ABBV-951	1209.93		SC / CONTINUOUS	[redacted]20[redacted] / 566	[redacted]20[redacted] / 566
ABBV-951		75.13	SC / ONCE	[redacted]20[redacted] / 567	
ABBV-951	1215.74		SC / CONTINUOUS	[redacted]20[redacted] / 567	[redacted]20[redacted] / 567
ABBV-951		93.91	SC / ONCE	[redacted]20[redacted] / 568	
ABBV-951	1199.68		SC / CONTINUOUS	[redacted]20[redacted] / 568	[redacted]20[redacted] / 568
ABBV-951		93.91	SC / ONCE	[redacted]20[redacted] / 569	
ABBV-951	1208.91		SC / CONTINUOUS	[redacted]20[redacted] / 569	[redacted]20[redacted] / 569
ABBV-951	983.52		SC / CONTINUOUS	[redacted]20[redacted] / 570	[redacted]20[redacted] / 570
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 571	
ABBV-951	1294.28		SC / CONTINUOUS	[redacted]20[redacted] / 571	[redacted]20[redacted] / 571
ABBV-951	1314.09		SC / CONTINUOUS	[redacted]20[redacted] / 572	[redacted]20[redacted] / 572
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 573	
ABBV-951	1348.92		SC / CONTINUOUS	[redacted]20[redacted] / 573	[redacted]20[redacted] / 573
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 574	
ABBV-951	1173.05		SC / CONTINUOUS	[redacted]20[redacted] / 574	[redacted]20[redacted] / 574
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 575	
ABBV-951	1286.77		SC / CONTINUOUS	[redacted]20[redacted] / 575	[redacted]20[redacted] / 575
ABBV-951	1265.25		SC / CONTINUOUS	[redacted]20[redacted] / 576	[redacted]20[redacted] / 576
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 577	
ABBV-951	1291.89		SC / CONTINUOUS	[redacted]20[redacted] / 577	[redacted]20[redacted] / 577
ABBV-951	1393.32		SC / CONTINUOUS	[redacted]20[redacted] / 578	[redacted]20[redacted] / 578
ABBV-951	1355.75		SC / CONTINUOUS	[redacted]20[redacted] / 579	[redacted]20[redacted] / 579
ABBV-951	983.52		SC / CONTINUOUS	[redacted]20[redacted] / 580	[redacted]20[redacted] / 583
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 584	
ABBV-951	979.42		SC / CONTINUOUS	[redacted]20[redacted] / 584	[redacted]20[redacted] / 584
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 585	
ABBV-951	1174.07		SC / CONTINUOUS	[redacted]20[redacted] / 585	[redacted]20[redacted] / 585
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 586	
ABBV-951	1223.59		SC / CONTINUOUS	[redacted]20[redacted] / 586	[redacted]20[redacted] / 586
ABBV-951	1217.44		SC / CONTINUOUS	[redacted]20[redacted] / 587	[redacted]20[redacted] / 587
ABBV-951		112.69	SC / ONCE	[redacted]20[redacted] / 588	
ABBV-951	1259.45		SC / CONTINUOUS	[redacted]20[redacted] / 588	[redacted]20[redacted] / 588
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 589	
ABBV-951	1387.51		SC / CONTINUOUS	[redacted]20[redacted] / 589	[redacted]20[redacted] / 589

ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 590	
ABBV-951	1379.66		SC / CONTINUOUS	[redacted]20[redacted] / 590	[redacted]20[redacted] / 590
ABBV-951	1161.1		SC / CONTINUOUS	[redacted]20[redacted] / 591	[redacted]20[redacted] / 591
ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 592	[redacted]20[redacted] / 594
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 595	
ABBV-951	1142.31		SC / CONTINUOUS	[redacted]20[redacted] / 595	[redacted]20[redacted] / 595
ABBV-951		75.13	SC / ONCE	[redacted]20[redacted] / 596	
ABBV-951	1196.95		SC / CONTINUOUS	[redacted]20[redacted] / 596	[redacted]20[redacted] / 596
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 597	
ABBV-951	1194.90		SC / CONTINUOUS	[redacted]20[redacted] / 597	[redacted]20[redacted] / 597
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 598	
ABBV-951	1212.32		SC / CONTINUOUS	[redacted]20[redacted] / 598	[redacted]20[redacted] / 598
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 599	
ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 599	[redacted]20[redacted] / 599
ABBV-951	930.58		SC / CONTINUOUS	[redacted]20[redacted] / 600	[redacted]20[redacted] / 600

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
RAMELTEON	8 mg	QD	Y-M: 20[redacted]-[redacted]
MOSAPRIDE	5 mg	TID	Y-M: 20[redacted]-[redacted]
ESFLURBIPROFEN;MENTHA SPP. OIL	1 OTHER: SHEET	PRN	Y-M: 20[redacted]
ELDECALCITOL	0.75 mg	QD	Y-M: 20[redacted]-[redacted]
ETIZOLAM	0.5 mg	QD	Y-M: 20[redacted]-[redacted] / 1
CARBOCISTEINE	500 mg	TID	Y-M: 20[redacted]-[redacted] / 30
PARAFFIN	0.5 g	PRN	Y-M: 20[redacted]-[redacted] / 65
CLONAZEPAM	0.5 mg	QD	Y-M: 20[redacted]-[redacted] / 91
ANGELICA ACUTILOBA ROOT;ATRACTYLODES LANCEA RHIZOME;BUPLEURUM FALCATUM ROOT;CNIDIUM OFFICINALE RHIZOME;GLYCYRRHIZA SPP. ROOT;PORIA COCOS SCLEROTIUM;UNCARIA SPP. HOOK	2.5 g	BID	Y-M: 20[redacted]-[redacted] / 128
CARBOHYDRATES NOS;FATTY ACIDS NOS;MINERALS NOS;PROTEINS NOS;VITAMINS NOS	250 mL	BID	Y-M: 20[redacted]-[redacted] / 247
ZONISAMIDE	25.000 mg	QD	Y-M: 20[redacted]-[redacted] / 304
RIVASTIGMINE	9 mg	QD	Y-M: 20[redacted]-[redacted] / 332

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
RAMELTEON	8 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 607
ESFLURBIPROFEN;MENTHA SPP. OIL	1 OTHER: SHEET	PRN	Y-M: 20[redacted]	Y-M: 20[redacted] / 607
ELDECALCITOL	0.75 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 607
ETIZOLAM	0.5 mg	QD	Y-M: 20[redacted] / 1	Y-M: 20[redacted] / 607
CARBOCISTEINE	500 mg	TID	Y-M: 20[redacted] / 30	Y-M: 20[redacted] / 607
PARAFFIN	0.5 g	PRN	Y-M: 20[redacted] / 65	Y-M: 20[redacted] / 607
CLONAZEPAM	0.5 mg	QD	Y-M: 20[redacted] / 91	Y-M: 20[redacted] / 607
ANGELICA ACUTILOBA ROOT;ATRACTYLODES LANCEA RHIZOME;BUPLEURUM FALCATUM ROOT;CNIDIUM OFFICINALE RHIZOME;GLYCYRRHIZA SPP. ROOT;PORIA COCOS SCLEROTIUM;UNCARIA SPP. HOOK	2.5 g	BID	Y-M: 20[redacted] / 128	Y-M: 20[redacted] / 607
CARBOHYDRATES NOS;FATTY ACIDS NOS;MINERALS NOS;PROTEINS NOS;VITAMINS NOS	250 mL	BID	Y-M: 20[redacted] / 247	Y-M: 20[redacted] / 607
RIVASTIGMINE	9 mg	QD	Y-M: 20[redacted] / 332	Y-M: 20[redacted] / 607
BENFOTIAMINE;CYANOCOBALAMIN; PYRIDOXINE HYDROCHLORIDE	1 OTHER: CAPSULE	BID	Y-M: 20[redacted] / 395	Y-M: 20[redacted] / 478
MOSAPRIDE CITRATE	5 mg	QD	Y-M: 20[redacted] / 395	Y-M: 20[redacted] / 607
QUETIAPINE	25 mg	QD	Y-M: 20[redacted] / 423	Y-M: 20[redacted] / 607
BENFOTIAMINE;CYANOCOBALAMIN; PYRIDOXINE HYDROCHLORIDE	2 OTHER: CAPSULES	QD	Y-M: 20[redacted] / 479	Y-M: 20[redacted] / 562
BETAMETHASONE VALERATE	0.5 g	QD	Y-M: 20[redacted] / 506	Y-M: 20[redacted] / 607
GENTAMICIN SULFATE	0.5 g	QD	Y-M: 20[redacted] / 506	Y-M: 20[redacted] / 607
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 517	NOT REPORTED
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 538	NOT REPORTED
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	0.5 g	QD	Y-M: 20[redacted] / 592	Y-M: 20[redacted] / 607

Event #1: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	DERMATITIS(INFUSION SITE)
Preferred Term	注入部位皮膚炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 492

Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped Rx Day	608
Duration of AE	117 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, Death

Event Description	SUFFOCATION
Preferred Term	窒息
AE Onset Date / Rx Day	[redacted]20[redacted] / 608
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
SAE Supplemental Procedure	
NOT REPORTED	
AE Stopped Rx Day	608
Duration of AE	1 DAY
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	ASPIRATION ACCIDENTALLY
Discontinued Study Drug Due to the Event	YES
SAE Criteria	DEATH OF SUBJECT

Event #3: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, Death

Event Description	DUE TO ASPIRATION
Preferred Term	誤嚥
AE Onset Date / Rx Day	[redacted]20[redacted] / 608
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
SAE Supplemental Procedure	
NOT REPORTED	
AE Stopped Rx Day	608
Duration of AE	1 DAY
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	ASPIRATION ACCIDENTALLY
Discontinued Study Drug Due to the Event	YES
SAE Criteria	DEATH OF SUBJECT

Generated: [redacted]20[redacted]:09:38

Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者は日本の 7[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に誤嚥による死亡に至ったグレード 5 の窒息を発現した。

Event 2 及び 3 の臨床経過：

関連する病歴は，十二指腸潰瘍，パーキンソン病，統合失調症，不眠症，非喫煙者，及び元飲酒者（1 日 4 杯超）であった。

投与 608 日目，被験者は誤嚥による窒息を発現した。投与 608 日目，被験者は死亡した。死因は誤嚥による窒息と報告された。剖検が実施されたかは不明であった。

投与 608 日目の朝，被験者の介護者は 3 時間離れて戻ってきたとき，被験者がベッドの脇にあるごみ箱に頭を突っ込んで死んでいるのを発見した。

The patient's past medications include:

ZONISAMIDE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Suffocation (10042443) (Asphyxia (10003497)) [v.24.0] [10042443]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

2) Aspiration (10003504) (Aspiration (10003504)) [v.24.0] [10003504]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of SUFFOCATION DUE TO ASPIRATION

- **Investigator:** aspiration accidentally

- **AbbVie:** More likely related to accidental aspiration (per PI) in an elderly patient with a history of Parkinson's disease.

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
注入部位膿瘍	X			X

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	4[redacted]	FEMALE	WHITE

Medical History	Onset Year
HAY FEVER	20[redacted]
ANXIETY	20[redacted]
LOW VITAMIN B6	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
NOT REPORTED	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	LESS THAN 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.34	0.35	0.30	60	0.11	[redacted] / 368
ABBV-951	0.34	0.35	0.30	60	0.11	[redacted] / 549
ABBV-951	0.35	0.36	0.31	60	0.11	[redacted] / 708
ABBV-951	0.36	0.37	0.32	60	0.15	[redacted] / 731

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted] / 6	
M15-741 /ABBV-951	651.92		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 7	
M15-741 /ABBV-951	942.54		SC / CONTINUOUS	[redacted] / 7	[redacted] / 88
M15-741 /ABBV-951		93.91	SC / ONCE	[redacted] / 10	
M15-741 /ABBV-951		112.69	SC / ONCE	[redacted] / 11	
M15-741 /ABBV-951		93.91	SC / ONCE	[redacted] / 12	
M15-741 /ABBV-951		112.69	SC / ONCE	[redacted] / 13	
M15-741 /ABBV-951		93.91	SC / ONCE	[redacted] / 14	
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 15	
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 16	
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 17	
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 21	
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 27	
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 28	
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted] / 35	
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 36	
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 37	
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 38	
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 41	
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 42	
M15-741 /ABBV-951	1146.07		SC / CONTINUOUS	[redacted] / 89	[redacted] / 89
M15-741 /ABBV-951	1270.38		SC / CONTINUOUS	[redacted] / 90	[redacted] / 272
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted] / 273	
M15-741 /ABBV-951	1315.79		SC / CONTINUOUS	[redacted] / 273	[redacted] / 273
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted] / 274	
M15-741 /ABBV-951	1312.38		SC / CONTINUOUS	[redacted] / 274	[redacted] / 274

M15-741 /ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 275	[redacted]20[redacted] / 366
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 367	
M15-741 /ABBV-951	1323.99		SC / CONTINUOUS	[redacted]20[redacted] / 367	[redacted]20[redacted] / 367
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 368	
ABBV-951	551.52		SC / CONTINUOUS	[redacted]20[redacted] / 368	[redacted]20[redacted] / 368
M15-741 /ABBV-951	1371.12		SC / CONTINUOUS	[redacted]20[redacted] / 368	[redacted]20[redacted] / 368
ABBV-951	1393.32		SC / CONTINUOUS	[redacted]20[redacted] / 369	[redacted]20[redacted] / 456
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 457	
ABBV-951	1400.32		SC / CONTINUOUS	[redacted]20[redacted] / 457	[redacted]20[redacted] / 457
ABBV-951	1362.58		SC / CONTINUOUS	[redacted]20[redacted] / 458	[redacted]20[redacted] / 458
ABBV-951	1434.3		SC / CONTINUOUS	[redacted]20[redacted] / 459	[redacted]20[redacted] / 546
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 547	
ABBV-951	1395.02		SC / CONTINUOUS	[redacted]20[redacted] / 547	[redacted]20[redacted] / 547
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 548	[redacted]20[redacted] / 548
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 549	
ABBV-951	1354.04		SC / CONTINUOUS	[redacted]20[redacted] / 549	[redacted]20[redacted] / 549
ABBV-951	1434.3		SC / CONTINUOUS	[redacted]20[redacted] / 550	[redacted]20[redacted] / 631
ABBV-951	1423.03		SC / CONTINUOUS	[redacted]20[redacted] / 632	[redacted]20[redacted] / 632
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 633	
ABBV-951	1333.55		SC / CONTINUOUS	[redacted]20[redacted] / 633	[redacted]20[redacted] / 633
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 634	
ABBV-951	1362.58		SC / CONTINUOUS	[redacted]20[redacted] / 634	[redacted]20[redacted] / 634
ABBV-951	1434.3		SC / CONTINUOUS	[redacted]20[redacted] / 635	[redacted]20[redacted] / 704
ABBV-951	1400.15		SC / CONTINUOUS	[redacted]20[redacted] / 705	[redacted]20[redacted] / 705
ABBV-951	1320.75		SC / CONTINUOUS	[redacted]20[redacted] / 706	[redacted]20[redacted] / 706
ABBV-951	1340.38		SC / CONTINUOUS	[redacted]20[redacted] / 707	[redacted]20[redacted] / 707
ABBV-951	1388.19		SC / CONTINUOUS	[redacted]20[redacted] / 708	[redacted]20[redacted] / 708

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
RASAGILINE	1.000 mg	QD	Y-M: 20[redacted]-[redacted]
CETIRIZINE HYDROCHLORIDE	10 mg	PRN	Y-M: 20[redacted]
MOMETASONE FUROATE	50 ug	PRN	Y-M: 20[redacted]
PYRIDOXINE	25 mg	OTHER: WEEKLY	Y-M: 20[redacted]-[redacted] / 72
VENLAFAXINE HYDROCHLORIDE	75 mg	QD	Y-M: 20[redacted]-[redacted] / 305

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
CETIRIZINE HYDROCHLORIDE	10 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
MOMETASONE FUROATE	50 ug	PRN	Y-M: 20[redacted]	NOT REPORTED
PYRIDOXINE	25 mg	OTHER: WEEKLY	Y-M: 20[redacted] / 72	NOT REPORTED
BOTULINUM TOXIN TYPE A	75 OTHER: UNITS	OTHER: EVERY 3 MONTHS	Y-M: 20[redacted] / 458	ONGOING
LORAZEPAM	0.25 mg	PRN	Y-M: 20[redacted] / 503	NOT REPORTED
VENLAFAXINE HYDROCHLORIDE	150 mg	QD	Y-M: 20[redacted] / 507	NOT REPORTED
CLINDAMYCIN	250 mg	QID	Y-M: 20[redacted] / 634	Y-M: 20[redacted] / 637
AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	125 mg	BID	Y-M: 20[redacted] / 638	NOT REPORTED

Event #1: Event of Interest - Infusion Site Related Infections

Event Description	LEFT ABDOMINAL ABSCESS TO PREVIOUS INFUSION SITE.
Preferred Term	注入部位膿瘍
AE Onset Date / Rx Day	[redacted]20[redacted] / 636
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped Rx Day	637
Duration of AE	2 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE

Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Serious Adverse Event, Event of Interest - Infusion Site Related Infections

Event Description	WORSENING OF LEFT ABDOMINAL ABSCESS AT INFUSION SITE
Preferred Term	注入部位膿瘍
AE Onset Date / Rx Day	[redacted]20[redacted] / 637
Age at AE Onset	4[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 637): NPTST015-WOUND MICROSCOPY, CULTURE AND S: STAPHYLO [NOT REPORTED - NOT REPORTED] ISOLATED

Microbiology

[redacted]20[redacted] (RX DAY 637): WOUND MC & S: POSITIVE-STAPHYLOCOCCUS AUREUS ISOLATED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 637): INCISIONAL DRAINAGE OF LEFT ABDOMINAL ABSCESS TO PREVIOUS INFUSION SITE:SURGICAL REMOVAL OF ABDOMINAL ABSCESS

AE Stopped Rx Day	638
Duration of AE	2 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	CAUSAL RELATIONSHIP
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	UNLIKELY
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Generated: [redacted]20[redacted]:09:38

Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者はオーストラリアの 4[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に左腹部注入部位膿瘍の悪化を発現した。

Event 2 の臨床経過：

関連する病歴は，パーキンソン病，非喫煙者，及び飲酒者（1 日 2 杯未満）であった。

投与 637 日目，被験者は左腹部注入部位膿瘍の悪化を発現した。投与 638 日目，左腹部注入部位膿瘍の悪化は消失した。

投与 634 日目，被験者は左下腹部の疼痛及び紅斑のため近医を受診した。医師は腹部皮下結節の感染症（非重篤）であると確定し，クリンダマイシンの経口投与を開始した。

投与 636 日目，被験者は以前の注入部位にある左腹部結節の疼痛及び紅斑の悪化の検査を受けるために救急診療部に来院し，以前の注入部位の左腹部膿瘍（非重篤）と診断された。被験者は自宅に帰された。

投与 637 日目，被験者は再度来院し，以前の注入部位の左腹部膿瘍に対し，切開及びドレナージが実施された。被験者は一晩入院し，抗生物質を静脈内投与された。投与 638 日目，被験者は退院した。

被験者にクリンダマイシン及びオーグメンチンが投与された。

Causality for ABBV-951 (Open Label)

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1) Infusion site abscess (10058464) (Infusion site abscess (10058464)) [v.24.0] [10058464]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Yes

Rechallenge: No rechallenge was done, recurrence is not applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of WORSENING OF LEFT ABDOMINAL ABSCESS AT INFUSION SITE

- **Investigator:** Not applicable

- AbbVie: Not applicable

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] WOUND CULTURE AND SENSITIVITY:** Positive: Staphlococcus aureus

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
起立性低血圧	X			

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	6[redacted]	FEMALE	ASIAN

Medical History	Onset Year
ASPIRIN ALLERGY	NOT REPORTED
ASTHMA	19[redacted]
MIGRAINE	19[redacted]
DEPRESSION	20[redacted]
HYPERCHOLESTEROLEMIA	20[redacted]
CONSTIPATION	20[redacted]
POST MENOPAUSAL	20[redacted]
INFLAMMATORY ARTHRITIS	20[redacted]
CHRONIC OBSTRUCTIVE PULMONARY DISORDER	20[redacted]
GASTRO ESOPHOGEAL REFLUX DISEASE	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
LEFT KNEE ARTHROSCOPY	20[redacted]
COLONOSCOPY AND ENDOSCOPY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	25 CIGARETTE	28	20[redacted]

CIGARS	NEVER
E-CIGARETTES	NEVER
PIPES	NEVER

Alcohol Use	Status	Number/Day
ALCOHOL	FORMER	LESS THAN 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.34	0.40	0.15	60	0.19	[redacted] / 364
ABBV-951	0.24	0.25	0.15	60	0.19	[redacted] / 391

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted] / 13	
M15-741 /ABBV-951	448.73		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted] / 14	
M15-741 /ABBV-951	1014.25		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
M15-741 /ABBV-951	1475.28		SC / CONTINUOUS	[redacted] / 15	[redacted] / 19
M15-741 /ABBV-951		162.21	SC / ONCE	[redacted] / 20	
M15-741 /ABBV-951	1514.55		SC / CONTINUOUS	[redacted] / 20	[redacted] / 20
M15-741 /ABBV-951		129.77	SC / ONCE	[redacted] / 21	
M15-741 /ABBV-951	1518.30		SC / CONTINUOUS	[redacted] / 21	[redacted] / 21
M15-741 /ABBV-951	1557.24		SC / CONTINUOUS	[redacted] / 22	[redacted] / 27
M15-741 /ABBV-951		129.77	SC / ONCE	[redacted] / 28	
M15-741 /ABBV-951	1477.32		SC / CONTINUOUS	[redacted] / 28	[redacted] / 28
M15-741 /ABBV-951	1475.28		SC / CONTINUOUS	[redacted] / 29	[redacted] / 40
M15-741 /ABBV-951	1408.00		SC / CONTINUOUS	[redacted] / 41	[redacted] / 41
M15-741 /ABBV-951	1182.61		SC / CONTINUOUS	[redacted] / 42	[redacted] / 42
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted] / 43	[redacted] / 270
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 271	
M15-741 /ABBV-951	1356.60		SC / CONTINUOUS	[redacted] / 271	[redacted] / 271
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted] / 272	
M15-741 /ABBV-951	1515.91		SC / CONTINUOUS	[redacted] / 272	[redacted] / 272
M15-741 /ABBV-951	1557.24		SC / CONTINUOUS	[redacted] / 273	[redacted] / 361
M15-741 /ABBV-951	1167.93		SC / CONTINUOUS	[redacted] / 362	[redacted] / 362

ABBV-951	638.60	SC / CONTINUOUS	[redacted]20[redacted] / 364	[redacted]20[redacted] / 364
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 365	[redacted]20[redacted] / 450

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
INDACATEROL MALEATE	150 ug	QD	Y-M: 20[redacted]
SALBUTAMOL	100 ug	PRN	Y-M: 20[redacted]
EZETIMIBE;ROSUVASTATIN CALCIUM	10+10 mg	QD	Y-M: 20[redacted]
PARACETAMOL	1000 mg	PRN	Y-M: 20[redacted]-[redacted] / 2
FLUDROCORTISONE	0.1 mg	QD	Y-M: 20[redacted]-[redacted] / 56
DESVENLAFAXINE SUCCINATE MONOHYDRATE	200 mg	QD	Y-M: 20[redacted]-[redacted] / 231
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	1 OTHER: SACHET	TID	Y-M: 20[redacted]-[redacted] / 238
METFORMIN	1000 mg	QD	Y-M: 20[redacted]-[redacted] / 245
CLOZAPINE	100 mg	QD	Y-M: 20[redacted]-[redacted] / 252
PANTOPRAZOLE	40 mg	BID	Y-M: 20[redacted]-[redacted] / 259
FAMOTIDINE	40 mg	QD	Y-M: 20[redacted]-[redacted] / 285
ONDANSETRON	4 mg	PRN	Y-M: 20[redacted]-[redacted] / 285
INDACATEROL	150 ug	QD	Y-M: 20[redacted]-[redacted] / 293
CLOZAPINE	75 mg	QD	Y-M: 20[redacted]-[redacted] / 294
FLUDROCORTISONE	150 ug	QD	Y-M: 20[redacted]-[redacted] / 350
MIRTAZAPINE	30 mg	QD	Y-M: 20[redacted]-[redacted] / 357
CLOZAPINE	175 mg	QD	Y-M: 20[redacted]-[redacted] / 363

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
INDACATEROL MALEATE	150 ug	QD	Y-M: 20[redacted]	NOT REPORTED
SALBUTAMOL	100 ug	PRN	Y-M: 20[redacted]	NOT REPORTED
EZETIMIBE;ROSUVASTATIN CALCIUM	10+10 mg	QD	Y-M: 20[redacted]	NOT REPORTED
PARACETAMOL	1000 mg	PRN	Y-M: 20[redacted]-[redacted] / 2	NOT REPORTED
FLUDROCORTISONE	0.1 mg	QD	Y-M: 20[redacted]-[redacted] / 56	NOT REPORTED
DESVENLAFAXINE SUCCINATE MONOHYDRATE	200 mg	QD	Y-M: 20[redacted]-[redacted] / 231	NOT REPORTED

MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	1 OTHER: SACHET	TID	Y-M: 20[redacted] / 238	Y-M: 20[redacted] / 373
METFORMIN	1000 mg	QD	Y-M: 20[redacted] / 245	NOT REPORTED
CLOZAPINE	100 mg	QD	Y-M: 20[redacted] / 252	Y-M: 20[redacted] / 362
PANTOPRAZOLE	40 mg	BID	Y-M: 20[redacted] / 259	NOT REPORTED
FAMOTIDINE	40 mg	QD	Y-M: 20[redacted] / 285	NOT REPORTED
ONDANSETRON	4 mg	PRN	Y-M: 20[redacted] / 285	NOT REPORTED
INDACATEROL	150 ug	QD	Y-M: 20[redacted] / 293	NOT REPORTED
CLOZAPINE	75 mg	QD	Y-M: 20[redacted] / 294	Y-M: 20[redacted] / 362
FLUDROCORTISONE	150 ug	QD	Y-M: 20[redacted] / 350	NOT REPORTED
MIRTAZAPINE	30 mg	QD	Y-M: 20[redacted] / 357	NOT REPORTED
CLOZAPINE	175 mg	QD	Y-M: 20[redacted] / 363	NOT REPORTED

Event #1: Serious Adverse Event

Event Description	WORSENING OF ORTHOSTATIC HYPOTENSION
Preferred Term	起立性低血圧
AE Onset Date / Rx Day	[redacted]20[redacted] / 357
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
SAE Supplemental Procedure	
NOT REPORTED	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	POSSIBLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	POSSIBLY CONTRIBUTED TO INITIATION OF CLOZAPINE.
Discontinued Study Drug Due to the Event	NO

SAE Criteria HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Generated: [redacted]20[redacted]:09:38
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者はオーストラリアの 6[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に起立性低血圧の悪化を発現した。

Event 1 の臨床経過：

投与 1 日目から 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するための治験薬の調整を必要とした。投与 5 週時に，被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 357 日目，被験者は起立性低血圧の悪化を発現した。

被験者は本事象発現前の投与 15 日目非重篤の起立性低血圧を発現し，投与 356 日目に消失した。

投与 357 日目，被験者は起立性低血圧の悪化の訴え，逆流性食道炎，継続中のクロザピン治療抵抗性の幻覚及びうつ病の二次診断のため入院した。起立性低血圧の悪化は，詳しくは自宅で立ったり歩いたりしている間の浮動性めまいとされた。被験者は逆流性食道炎による悪心及び嘔吐に苦しみ，経口摂取が少なかった。被験者に静脈内輸液を投与し，注意深くモニタリングした。経口レボドパ療法を行っている間，被験者は入院した。その結果，悪心及び嘔吐が消失し，経口摂取をモニタリングした。被験者の起立性血圧は改善し，幻視は顕著な改善が認められたものの継続した。投与 373 日目，被験者は退院した。

治験責任医師によると，起立性低血圧の悪化のリスク因子はパーキンソン病と考えられた。

被験者にレボドパが投与された。

Causality for ABBV-951 (Open Label)

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1) Orthostatic hypotension (10031127) (Orthostatic hypotension (10031127)) [v.24.1] [10031127]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of WORSENING OF ORTHOSTATIC HYPOTENSION

- Investigator: Reflux oesophagitis

- AbbVie: More likely related to reported nausea, reflux esophagitis and history of Parkinson's disease

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20**[redacted] **BODY WEIGHT:** 6[redacted] KG

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
滑液包炎	X			
転倒				X
幻覚				X

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	7[redacted]	MALE	WHITE

Medical History	Onset Year
LIMITED NON-Q-WAVE ANTEROLATERAL MYOCARDINFACTION	19[redacted]
HYPERCHOLESTELOREMIA	20[redacted]
LUMBAL HERNIA	20[redacted]
HARD STOOLS	20[redacted]
CATARACT	20[redacted]
CATARACTS	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
LUMBAL HERNIA SURGERY	20[redacted]
CATARACT SURGERY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			

PIPES NEVER

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.44	0.45	0.43	120	0.30	[redacted] / 362
ABBV-951	0.47	0.46	0.45	120	0.30	[redacted] / 516

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	901.56		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
M15-741 /ABBV-951	1639.2		SC / CONTINUOUS	[redacted] / 2	[redacted] / 15
M15-741 /ABBV-951	1729.35		SC / CONTINUOUS	[redacted] / 16	[redacted] / 16

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
OMEPRAZOLE	20 mg	QD	Y-M: 19[redacted]
ATORVASTATIN CALCIUM	20 mg	QD	Y-M: 20[redacted]
ACETYLSALICYLIC ACID	80 mg	QD	Y-M: 20[redacted]
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	1 OTHER: SACHET	QD	Y-M: 20[redacted]
PRAMIPEXOLE	0.260 mg	QD	Y-M: 20[redacted]-[redacted]
ATORVASTATIN CALCIUM	20 mg	QD	Y-M: 20[redacted]-[redacted]
CLOPIDOGREL	75 mg	QD	Y-M: 20[redacted]-[redacted] / 343

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
OMEPRAZOLE	20 mg	QD	Y-M: 19[redacted]	NOT REPORTED
ATORVASTATIN CALCIUM	20 mg	QD	Y-M: 20[redacted]	NOT REPORTED
ACETYLSALICYLIC ACID	80 mg	QD	Y-M: 20[redacted]	NOT REPORTED

MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	1 OTHER: SACHET	QD	Y-M: 20[redacted]	NOT REPORTED
ATORVASTATIN CALCIUM	20 mg	QD	Y-M: 20[redacted]	NOT REPORTED
CLOPIDOGREL	75 mg	QD	Y-M: 20[redacted] / 343	NOT REPORTED
PARACETAMOL	1 g	OTHER: MAXIMUM 4/DAY	Y-M: 20[redacted] / 376	NOT REPORTED
FUROSEMIDE	20 mg	QD	Y-M: 20[redacted] / 376	Y-M: 20[redacted] / 602
CALCIUM CARBONATE;COLECALCIFEROL	880 mg	QD	Y-M: 20[redacted] / 386	NOT REPORTED
COVID-19 VACCINE	1 OTHER: INJECTION	OTHER: ONCE	Y-M: 20[redacted] / 442	Y-M: 20[redacted] / 442
COVID-19 VACCINE	1 OTHER: INJECTION	OTHER: ONCE	Y-M: 20[redacted] / 477	Y-M: 20[redacted] / 477
FLUDROCORTISONE ACETATE	0.1 mg	QD	Y-M: 20[redacted] / 517	NOT REPORTED
QUETIAPINE	12.5 mg	QD	Y-M: 20[redacted] / 517	Y-M: 20[redacted] / 522
FUROSEMIDE	30 mg	QD	Y-M: 20[redacted] / 603	NOT REPORTED

Event #1: Event of Interest - Falls and Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred Term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 366
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped Rx Day	366
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Serious Adverse Event

Event Description	TRONCHATERITIS LEFT
Preferred Term	滑液包炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 375
Age at AE Onset	7[redacted]

Laboratory Testing

NOT REPORTED

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 376): RX HIP:NO FRACTURE; RX PELVIS:NO FRACTURE; [redacted]20[redacted] (RX DAY 378): CT PELVIS:DISPLACED FRACTURE THROUGH TROCHANTER MAJOR; [redacted]20[redacted] (RX DAY 384): BONE DENSIOMETRY:OSTEOPOROSIS WAS DETECTED

AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	EVENT CAUSED BY FALL, THIS IS DUE TO PARKINSON DISEASE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #3: Event of Interest - Hallucinations/Psychosis

Event Description	HALLUCINATIONS
Preferred Term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 516
Age at AE Onset	7[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped Rx Day	522
Duration of AE	7 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	MIRAPEXIN
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Generated: [redacted] 20[redacted]:09:38

Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者はベルギーの 7[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に左転子炎を発現した。

Event 2 の臨床経過：

関連する病歴は，高コレステロール血症，パーキンソン病，腰椎ヘルニア手術，非喫煙者，及び非飲酒者であった。

投与 376 日目，被験者は左転子炎を発現した。

本事象発現前の投与 366 日目，被験者は偶発的な転倒（非重篤）を発現した。投与 375 日目，被験者は左転子の痛みが強くなり始め，歩行が困難となった。投与 376 日目，被験者は歩行困難のため入院した。X 線検査が実施され，骨折が認められた。投与 378 日目，骨盤 CT スキャンが

実施され，大転子に骨折が発見された。保存療法を開始した結果，被験者は直ちに回復した。投与 386 日目，被験者は退院した。
被験者にラシックス，VITAL FORTE，及び DAFALGAN が投与された。

The patient's past medications include:

RASAGILINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

MADOPAR for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

TRIHEXYPHENIDYL for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

PROLOPA HBS for PARKINSON'S DIESASE ([redacted] 20[redacted] - [redacted] 20[redacted])

SAFINAMIDE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

STALEVO for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Trochanteritis (10059077) (Osteitis (10031149)) [v.23.1] [10059077]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of TRONCHATERITIS LEFT

- Investigator: Event caused by fall, this is due to Parkinson disease.

- AbbVie: More likely related to reported fall in an advanced age subject with Parkinson's disease and cataract

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BONE DENSIOMETRY:** Osteoporosis was detected

[redacted] **20[redacted] CT PELVIS:** Displaced fracture through trochanter major

[redacted] **20[redacted] RX HIP:** No fracture

[redacted] **20[redacted] RX PELVIS:** No fracture

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
出血性腸憩室	X			
顔面骨骨折				X
転倒				X
幻覚	X			X
股関節部骨折	X			X
上腕骨骨折				X
パーキンソン病	X	X	X	
体重減少				X
** Disc. due to adverse event				X

Disc = Discontinued.

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	8[redacted]	MALE	WHITE

Medical History	Onset Year
GROIN RUPTURE RIGHT	20[redacted]
BENING HYPERTROPHY PROSTATE	20[redacted]
DIVERTICULAR BLEEDING	20[redacted]
VIT B DEFFICIENCY	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
TRANSVESICAL PROSTATECTOMY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	20 CIGARETTE	20	19[redacted]
CIGARS	FORMER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	LESS THAN 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.45	0.46	0.44	120	0.30	[redacted]20[redacted] / 362
ABBV-951	0.43	0.44	0.42	120	0.30	[redacted]20[redacted] / 516

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	963.03		SC / CONTINUOUS	[redacted]20[redacted] / 1	[redacted]20[redacted] / 1
M15-741 /ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 2	[redacted]20[redacted] / 15
M15-741 /ABBV-951	1884.05		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
QUETIAPINE	12.5 mg	QD	Y-M: 20[redacted]-[redacted] / 154

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
QUETIAPINE	12.5 mg	QD	Y-M: 20[redacted]-[redacted] / 154	Y-M: 20[redacted]-[redacted] / 421
PARACETAMOL	1 g	PRN	Y-M: 20[redacted]-[redacted] / 369	Y-M: 20[redacted]-[redacted] / 403
BLOOD CELLS, PACKED HUMAN	2 OTHER: UNITS	OTHER: ONCE	Y-M: 20[redacted]-[redacted] / 376	Y-M: 20[redacted]-[redacted] / 376
PANTOPRAZOLE SODIUM SESQUIHYDRATE	40 mg	BID	Y-M: 20[redacted]-[redacted] / 376	Y-M: 20[redacted]-[redacted] / 379
FLUDROCORTISONE ACETATE	0.1 mg	QD	Y-M: 20[redacted]-[redacted] / 376	Y-M: 20[redacted]-[redacted] / 380

CALCIUM CARBONATE;COLECALCIFEROL	1000 mg	QD	Y-M: 20[redacted] / 376	Y-M: 20[redacted] / 421
CALCIUM CARBONATE;COLECALCIFEROL	880 mg	QD	Y-M: 20[redacted] / 376	Y-M: 20[redacted] / 421
BLOOD CELLS, PACKED HUMAN	2 OTHER: UNITS	OTHER: ONCE	Y-M: 20[redacted] / 383	Y-M: 20[redacted] / 383
TRANEXAMIC ACID	1 g	OTHER: ONCE	Y-M: 20[redacted] / 383	Y-M: 20[redacted] / 383
CLOZAPINE	12.5 mg	QD	Y-M: 20[redacted] / 398	Y-M: 20[redacted] / 493
CALCIUM CARBONATE;COLECALCIFEROL	100 mg	QD	Y-M: 20[redacted] / 421	Y-M: 20[redacted] / 535
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	25 mL	BID	Y-M: 20[redacted] / 421	Y-M: 20[redacted] / 535
CLOZAPINE	37.5 mg	QD	Y-M: 20[redacted] / 493	Y-M: 20[redacted] / 505
CLOZAPINE	50 mg	QD	Y-M: 20[redacted] / 506	Y-M: 20[redacted] / 535
FLUDROCORTISONE ACETATE	0.1 mg	QD	Y-M: 20[redacted] / 517	Y-M: 20[redacted] / 535
LORMETAZEPAM	1 mg	QD	Y-M: 20[redacted] / 517	Y-M: 20[redacted] / 535

Event #1: Serious Adverse Event, Event of Interest - Hallucinations/Psychosis

Event Description	HALLUCINATIONS
Preferred Term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 158
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
SAE Supplemental Procedure	
NOT REPORTED	
AE Stopped Rx Day	535
Duration of AE	378 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to	POSSIBLE

Infusion Pump	
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #2: Event of Interest - Falls and Associated Injuries

Event Description	NOSE FRACTURE
Preferred Term	顔面骨骨折
AE Onset Date / Rx Day	[redacted]20[redacted] / 369
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped Rx Day	453
Duration of AE	85 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Event of Interest - Falls and Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred Term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 369

Age at AE Onset	8[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped Rx Day	369
Duration of AE	1 DAY
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Event of Interest - Falls and Associated Injuries

Event Description	SUBCAPITAL HUMERUS FRACTURE
Preferred Term	上腕骨骨折
AE Onset Date / Rx Day	[redacted]20[redacted] / 369
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped Rx Day	453
Duration of AE	85 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #5: Serious Adverse Event

Event Description	DIVERTICULAR HEMORRHAGE
Preferred Term	出血性腸憩室
AE Onset Date / Rx Day	[redacted]20[redacted] / 376
Age at AE Onset	8[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 379): Hemoglobin: 100 [126 - 174] G/L

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 379): GASTROSCOPY:NORMAL

AE Stopped Rx Day	380
Duration of AE	5 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	HISTORY OF DIVERTICULAR BLEEDING
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #6: Serious Adverse Event

Event Description	DIVERTICULAR HEMMORHAGE
Preferred Term	出血性腸憩室
AE Onset Date / Rx Day	[redacted]20[redacted] / 383
Age at AE Onset	8[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 383): Hemoglobin: 86 [126 - 170] G/L

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 386): ANGIOGRAPHY ABDOMEN:ACTIVE ARTERIAL BLEEDING, COLONDIVERTICULOSIS,; COLONSCOPY:DIVERTICULOSIS IN COLON DESCENDENS AND IN SIGMOID WITH BLEEDING.

AE Stopped Rx Day	495
Duration of AE	113 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	HISTORY OF DIVERTICULAR BLEEDING
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #7: Event of Interest - Falls and Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred Term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 393
Age at AE Onset	8[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped Rx Day	393
Duration of AE	1 DAY
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #8: Serious Adverse Event, Event of Interest - Falls and Associated Injuries

Event Description	HIP FRACTURE
Preferred Term	股関節部骨折
AE Onset Date / Rx Day	[redacted]20[redacted] / 393
Age at AE Onset	8[redacted]

Laboratory Testing

NOT REPORTED

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 393): SURGERY DUE TO HIP FRACTURE:SURGERY WENT WELL AND PATIENT RECOVERED, FRACTURE HEALED

AE Stopped Rx Day	393
Duration of AE	1 DAY
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	ACCIDENTAL FALL
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #9: Event of Interest - Weight Loss

Event Description	WEIGHT LOSS
Preferred Term	体重減少
AE Onset Date / Rx Day	[redacted]20[redacted] / 516
Age at AE Onset	8[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped Rx Day	535
Duration of AE	20 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #10: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, Death

Event Description	END STAGE PARKINSON DISEASE
Preferred Term	パーキンソン病
AE Onset Date / Rx Day	[redacted]20[redacted] / 535
Age at AE Onset	8[redacted]

Laboratory Testing

NOT REPORTED

Microbiology

NOT REPORTED

SAE Supplemental Procedure

NOT REPORTED

AE Stopped Rx Day	535
Duration of AE	1 DAY
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to	NOT REPORTED

[redacted] **Infusion Set**	
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
Other Cause of Event	CARDIO RESPIRATORY FAILURE
Discontinued Study Drug Due to the Event	YES
SAE Criteria	DEATH OF SUBJECT

Generated: [redacted]20[redacted]:09:38
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者はベルギーの 8[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に幻覚を発現した。

Event 1 の臨床経過：

関連する病歴は，パーキンソン病，ビタミン B 欠乏症，元喫煙者（1 日 20 本を 20 年間），及び飲酒者（1 日 2 杯未満）であった。

投与 1 日目から 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するための治験薬の調整を必要とした。投与 5 週時に，被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 158 日目，被験者は幻覚を発現した。投与 535 日目，幻覚は消失した。

投与 158 日目，被験者は幻覚のため入院した。被験者は自宅でそこにいない人々を見ており，被験者の家族は被験者のその状況を心配した。投与 161 日目，被験者は退院した。

被験者は同時に非重篤な尿路感染の治療も受けた。

被験者にクエチアピンが投与された。

The patient's past medications include:

MADOPAR for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

ENTACAPONE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

STALEVO for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

PROLOPA HBS for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

PRAMIPEXOLE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

PROLOPA DISPERSIBLE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

VIT B 12 INJECTION for VIT B 12 DEFFICIENCY ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Hallucinations (10019077) (Hallucination (10019063)) [v.24.0] [10019077]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of HALLUCINATIONS

- Investigator: Not applicable

- AbbVie: More likely related to reported urinary tract infection in a 8[redacted] year old male with Parkinson's disease.

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者はベルギーの 8[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中の投与 376 日目に出血性腸憩室，投与 383 日目に出血性腸憩室及び股関節部骨折を発現した。

Event 5，6，及び 8 の臨床経過：

関連する病歴は，パーキンソン病，憩室出血，ビタミン B 欠乏症，元喫煙者（1 日 20 本を 20 年間），及び飲酒者（1 日 2 杯未満）であった。

投与 376 日目，被験者は出血性腸憩室を発現した。投与 380 日目，出血性腸憩室は消失した。投与 383 日目，被験者は出血性腸憩室を発現した。投与 393 日目，被験者は股関節部骨折を発現した。投与 393 日目，股関節部骨折は消失した。投与 495 日目，出血性腸憩室は消失した。

本事象発現前の投与 369 日目に，被験者は転倒のため非重篤の上腕骨骨頭下骨折及び鼻骨骨折を発現した。

投与 376 日目，被験者は直腸出血のエピソード後に入院した。同日，被験者は赤血球濃厚液を投与された。投与 380 日目，被験者は退院した。投与 383 日目，被験者は自宅で直腸出血のエピソードを発現し，再度入院した。結腸内視鏡検査では，下行結腸及び S 状結腸に憩室症が認められた。腹部 CT では結腸憩室症が認められた。出血部位を閉塞し，被験者に赤血球濃厚液が 2 単位投与された。

入院期間中に，被験者は不慮の転倒を引き起こし，股関節を骨折したため，入院期間が延長となった。投与 393 日目，被験者は股関節部骨折の手術を受け，手術は成功した。投与 421 日目，被験者は退院した。

被験者に赤血球濃厚液，EXACYL，及びフルドロコルチゾン酢酸エステルが投与された。

Causality for ABBV-951 (Open Label)

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1) Diverticulum intestinal hemorrhagic (10055241) (Diverticulum intestinal haemorrhagic (10013560)) [v.24.0] [10055241]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

2) Diverticulum intestinal hemorrhagic (10055241) (Diverticulum intestinal haemorrhagic (10013560)) [v.24.0] [10055241]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

3) Hip fracture (10020100) (Hip fracture (10020100)) [v.24.0] [10020100]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of DIVERTICULAR HEMORRHAGE

- Investigator: HISTORY OF DIVERTICULAR BLEEDING

- AbbVie: More likely related to a history of diverticular bleeding and Parkinson's disease in an advanced aged patient

Event of DIVERTICULAR HEMORRHAGE

- Investigator: HISTORY OF DIVERTICULAR BLEEDING

- AbbVie: More likely related to a history of diverticular bleeding and Parkinson's disease in an advanced aged patient

Event of HIP FRACTURE

- Investigator: ACCIDENTAL FALL

- AbbVie: More likely related to reported fall in an advanced age patient with a history of Parkinson's disease

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ANGIOGRAPHY ABDOMEN:** ACTIVE ARTERIAL BLEEDING, COLONDIVERTICULOSIS.

[redacted] 20[redacted] **COLONSCOPY:** DIVERTICULOSIS IN COLON DESCENDENS AND IN SIGMOÏD WITH BLEEDING.

[redacted] 20[redacted] **GASTROSCOPY:** Normal

[redacted] 20[redacted] **HEMOLOBIN:** 10 G/DL (normal 12.6 to 17.4)

[redacted] 20[redacted] **HEMOGLOBIN:** 8.6 G/DL (normal 12.6 to 17.0)

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者はベルギーの 8[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に死亡に至った終末期のパーキンソン病を発現した。

Event 10 の臨床経過：

投与 535 日目，被験者は終末期のパーキンソン病を発現した。投与 535 日目，被験者は死亡した。死因は終末期のパーキンソン病による心肺不全及び終末期のパーキンソン病と報告された。剖検は実施されなかった。

本事象の発現前，死亡に至るまでに治験薬の注入部位に感染の徴候は認められなかった。被験者は非常に進行したパーキンソン病であった。被験者は飲食を拒んでおり，嚥下に関して協調した動作をすることがもはやできない徴候が認められた。レボドパの継続的な皮下投与によって被験者の生活の質が以前と比べとても改善されたので，最後の数週間であっても，被験者が本試験に参加できて本当に幸せであったと，介護者は繰り返し強調していた。

投与 535 日目，被験者の介護者は介護施設に電話し，被験者が投与 534 日目から何も食べず何も飲んでいないことを告げられた。同日，被験者の介護者が被験者を訪ね，午前 10 時に薬剤ポンプを交換した。被験者は口を開けて息をしており，調子が良さそうではなかったため，一般開業医に電話した。午前 11 時 52 分，被験者が呼吸困難となったため，病院の救急チームに電話することを決めた。午後 0 時 1 分にチームが到着したが，被験者はチームの到着前に息を引き取っており，救急チームは被験者の死亡を確認できただけであった。

治験責任医師によると，被験者は終末期のパーキンソン病に関連した心肺停止によって死亡した。

The patient's past medications include:

DAFALGAN for SUBCAPITAL HUMERUS FRACTURE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) End stage Parkinson's disease (10076917) (Parkinson's disease (10061536)) [v.24.0] [10076917]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of END STAGE PARKINSON DISEASE

- Investigator: Cardiorespiratory failure.

- AbbVie: More likely related to progression of underlying Parkinson disease in an elderly subject.

ADVERSE EVENTS OF SPECIAL INTEREST AND **OTHER AREAS OF SPECIAL INTEREST

Weight Decreased: Day 1 weight 5[redacted] kg. Weight at time of event 4[redacted] kg. Weight loss occurred over a period of 6 months. Change in diet or mobility level with pump/infusion therapy reported as immobilization due to hip fracture, in nursing home [redacted] - [redacted] 20[redacted]. Onset of weight loss did not coincide with worsening PD symptoms or eating difficulties. Subject experienced previous episode of cognitive decline and depression and/or other psychiatric disorders, temporal episodes of loss of appetite and dysphagia. No additional conditions or circumstances reported.

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
注入部位紅斑				X
注入部位腫瘤				X
注入部位浮腫				X
注入部位丘疹				X
四肢痛	X			

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	7[redacted]	FEMALE	WHITE

Medical History	Onset Year
NIGHT AKATHISIA	NOT REPORTED
DEPRESSION (INTERMITTENT)	19[redacted]
ARTHROSIS	19[redacted]
PERFORATED GASTRIC ULCUS	19[redacted]
HYPOTHYREOSIS	20[redacted]
PARKINSON DISEASE	20[redacted]
POST MENUPAUSAL STATUS	20[redacted]
PULMONARY EMBOLISM	20[redacted]
SLEEP APNEA	20[redacted]
DYSPNEA	20[redacted]
THORACIC SKIN HERPES	20[redacted]
SPINE DEGENERATIVE LESIONS INCREASED ON L4 L5	20[redacted]
LEFT CARPAL TUNNEL	20[redacted]
INTERMITTENT DYSSOMNIA	20[redacted]
RIGHT CARPAL TUNNEL	20[redacted]
LEFT WRIST EDEMA	20[redacted]
RIGHT HAND PARESTHESIAS	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED

PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
LOCAL RESECTION OF THE UTERUS	19[redacted]
OPERATED LEFT KNEE (PROTHESIS)	20[redacted]
OPERATED RIGHT KNEE (PROTHESIS)	20[redacted]
OPERATED LEFT CARPAL CANAL	20[redacted]
OPERATED RIGHT CARPAL CANAL	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	LESS THAN 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.36	0.40	0.32	120	0.19	[redacted]20[redacted] / 367
ABBV-951	0.38	0.40	0.36	120	0.19	[redacted]20[redacted] / 479
ABBV-951	0.40	0.42	0.36	120	0.19	[redacted]20[redacted] / 535

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 1	
M15-741 /ABBV-951	553.23		SC / CONTINUOUS	[redacted]20[redacted] / 1	[redacted]20[redacted] / 1
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 2	
M15-741 /ABBV-951	1092.62		SC / CONTINUOUS	[redacted]20[redacted] / 2	[redacted]20[redacted] / 2
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 3	
M15-741 /ABBV-951	1097.23		SC / CONTINUOUS	[redacted]20[redacted] / 3	[redacted]20[redacted] / 3

M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 4	
M15-741 /ABBV-951	1074.18		SC / CONTINUOUS	[redacted]20[redacted] / 4	[redacted]20[redacted] / 4
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 5	
M15-741 /ABBV-951	1108.50		SC / CONTINUOUS	[redacted]20[redacted] / 5	[redacted]20[redacted] / 5
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 6	
M15-741 /ABBV-951	1101.84		SC / CONTINUOUS	[redacted]20[redacted] / 6	[redacted]20[redacted] / 7
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 7	
M15-741 /ABBV-951	1318.70		SC / CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 8
M15-741 /ABBV-951	1381.70		SC / CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 9
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 10	
M15-741 /ABBV-951	1248.18		SC / CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 10
M15-741 /ABBV-951	1381.70		SC / CONTINUOUS	[redacted]20[redacted] / 11	[redacted]20[redacted] / 11
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 12	
M15-741 /ABBV-951	1414.83		SC / CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
M15-741 /ABBV-951	1430.88		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
M15-741 /ABBV-951	1387.51		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
M15-741 /ABBV-951	1416.88		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
M15-741 /ABBV-951	1402.54		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
M15-741 /ABBV-951	1420.64		SC / CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 18	
M15-741 /ABBV-951	1426.44		SC / CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 19	
M15-741 /ABBV-951	1386.14		SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
M15-741 /ABBV-951	1443.86		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
M15-741 /ABBV-951	1426.10		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
M15-741 /ABBV-951	1361.21		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
M15-741 /ABBV-951	1368.04		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
M15-741 /ABBV-951	1390.24		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
M15-741 /ABBV-951	1388.19		SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 26	
M15-741 /ABBV-951	1413.46		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 27	
M15-741 /ABBV-951	1422.68		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 28	
M15-741 /ABBV-951	1423.37		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
M15-741 /ABBV-951	1472.20		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 30	

M15-741 /ABBV-951	1432.59		SC / CONTINUOUS	[redacted] / 30	[redacted] / 30
M15-741 /ABBV-951	1403.56		SC / CONTINUOUS	[redacted] / 31	[redacted] / 31
M15-741 /ABBV-951	1416.54		SC / CONTINUOUS	[redacted] / 32	[redacted] / 32
M15-741 /ABBV-951	1419.95		SC / CONTINUOUS	[redacted] / 33	[redacted] / 33
M15-741 /ABBV-951	1454.10		SC / CONTINUOUS	[redacted] / 34	[redacted] / 34
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 35	
M15-741 /ABBV-951	1420.98		SC / CONTINUOUS	[redacted] / 35	[redacted] / 35
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 36	
M15-741 /ABBV-951	1458.54		SC / CONTINUOUS	[redacted] / 36	[redacted] / 36
M15-741 /ABBV-951	1398.78		SC / CONTINUOUS	[redacted] / 37	[redacted] / 37
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 38	
M15-741 /ABBV-951	1488.59		SC / CONTINUOUS	[redacted] / 38	[redacted] / 38
M15-741 /ABBV-951	1508.06		SC / CONTINUOUS	[redacted] / 39	[redacted] / 39
M15-741 /ABBV-951	1467.76		SC / CONTINUOUS	[redacted] / 40	[redacted] / 40
M15-741 /ABBV-951	1531.28		SC / CONTINUOUS	[redacted] / 41	[redacted] / 41
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted] / 42	
M15-741 /ABBV-951	1440.10		SC / CONTINUOUS	[redacted] / 42	[redacted] / 42
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted] / 43	
M15-741 /ABBV-951	1514.55		SC / CONTINUOUS	[redacted] / 43	[redacted] / 43
M15-741 /ABBV-951	1469.13		SC / CONTINUOUS	[redacted] / 44	[redacted] / 44
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 45	
M15-741 /ABBV-951	1438.39		SC / CONTINUOUS	[redacted] / 45	[redacted] / 45
M15-741 /ABBV-951	1431.05		SC / CONTINUOUS	[redacted] / 46	[redacted] / 46
M15-741 /ABBV-951	1475.28		SC / CONTINUOUS	[redacted] / 47	[redacted] / 51
M15-741 /ABBV-951	915.90		SC / CONTINUOUS	[redacted] / 52	[redacted] / 52
M15-741 /ABBV-951	534.78		SC / CONTINUOUS	[redacted] / 53	[redacted] / 53
M15-741 /ABBV-951	1475.28		SC / CONTINUOUS	[redacted] / 54	[redacted] / 89
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted] / 90	
M15-741 /ABBV-951	1480.74		SC / CONTINUOUS	[redacted] / 90	[redacted] / 90
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted] / 91	
M15-741 /ABBV-951	1457.52		SC / CONTINUOUS	[redacted] / 91	[redacted] / 91
M15-741 /ABBV-951	1417.90		SC / CONTINUOUS	[redacted] / 92	[redacted] / 92
M15-741 /ABBV-951	1475.28		SC / CONTINUOUS	[redacted] / 93	[redacted] / 180
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 181	
M15-741 /ABBV-951	1527.87		SC / CONTINUOUS	[redacted] / 181	[redacted] / 181
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted] / 182	
M15-741 /ABBV-951	1495.77		SC / CONTINUOUS	[redacted] / 182	[redacted] / 182

M15-741 /ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 183	[redacted]20[redacted] / 273
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 274	
M15-741 /ABBV-951	1508.06		SC / CONTINUOUS	[redacted]20[redacted] / 274	[redacted]20[redacted] / 274
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 275	
M15-741 /ABBV-951	1359.17		SC / CONTINUOUS	[redacted]20[redacted] / 275	[redacted]20[redacted] / 275
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 276	[redacted]20[redacted] / 364
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 365	
M15-741 /ABBV-951	1400.83		SC / CONTINUOUS	[redacted]20[redacted] / 365	[redacted]20[redacted] / 365
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 366	
M15-741 /ABBV-951	1462.98		SC / CONTINUOUS	[redacted]20[redacted] / 366	[redacted]20[redacted] / 366
ABBV-951	485.61		SC / CONTINUOUS	[redacted]20[redacted] / 367	[redacted]20[redacted] / 367
ABBV-951	1475.28		SC / CONTINUOUS	[redacted]20[redacted] / 368	[redacted]20[redacted] / 448
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 449	
ABBV-951	1469.13		SC / CONTINUOUS	[redacted]20[redacted] / 449	[redacted]20[redacted] / 449
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 450	
ABBV-951	1462.98		SC / CONTINUOUS	[redacted]20[redacted] / 450	[redacted]20[redacted] / 450
ABBV-951	1475.28		SC / CONTINUOUS	[redacted]20[redacted] / 451	[redacted]20[redacted] / 451
ABBV-951	1081.87		SC / CONTINUOUS	[redacted]20[redacted] / 452	[redacted]20[redacted] / 452
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 624	
ABBV-951	1004.01		SC / CONTINUOUS	[redacted]20[redacted] / 624	[redacted]20[redacted] / 624
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 625	
ABBV-951	1617.68		SC / CONTINUOUS	[redacted]20[redacted] / 625	[redacted]20[redacted] / 625
ABBV-951	1721.16		SC / CONTINUOUS	[redacted]20[redacted] / 626	[redacted]20[redacted] / 697

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
VENLAFAXINE HYDROCHLORIDE	75 mg	QD	Y-M: 19[redacted]
LEVOTHYROXINE	87.5 ug	QD	Y-M: 20[redacted]
ACETYLSALICYLIC ACID	80 mg	QD	Y-M: 20[redacted]
CLONAZEPAM	0.5 mg	PRN	Y-M: 20[redacted]
COLECALCIFEROL	1000 IU	QD	Y-M: 20[redacted]-[redacted] / -70
AMANTADINE	100.000 mg	BID	Y-M: 20[redacted]-[redacted] / 21
MELATONIN	2 mg	QD	Y-M: 20[redacted]-[redacted] / 22
ETILEFRINE HYDROCHLORIDE	10 gtt	TID	Y-M: 20[redacted]-[redacted] / 198

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
VENLAFAXINE HYDROCHLORIDE	75 mg	QD	Y-M: 19[redacted]	Y-M: 20[redacted]-[redacted] / 535
LEVOTHYROXINE	87.5 ug	QD	Y-M: 20[redacted]	NOT REPORTED
ACETYLSALICYLIC ACID	80 mg	QD	Y-M: 20[redacted]	NOT REPORTED
CLONAZEPAM	0.5 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
COLECALCIFEROL	1000 IU	QD	Y-M: 20[redacted]-[redacted] / -70	NOT REPORTED
MELATONIN	2 mg	QD	Y-M: 20[redacted]-[redacted] / 22	Y-M: 20[redacted]-[redacted] / 478
ETILEFRINE HYDROCHLORIDE	10 gtt	TID	Y-M: 20[redacted]-[redacted] / 198	NOT REPORTED
NITROFURANTOIN	100 mg	TID	Y-M: 20[redacted]-[redacted] / 451	Y-M: 20[redacted]-[redacted] / 456
D-MANNOSE;VACCINIUM MACROCARPON	1 OTHER: BAG	PRN	Y-M: 20[redacted]-[redacted] / 456	NOT REPORTED
CIPROFLOXACIN HYDROCHLORIDE	500 mg	BID	Y-M: 20[redacted]-[redacted] / 457	Y-M: 20[redacted]-[redacted] / 460
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted]-[redacted] / 472	NOT REPORTED
MELATONIN	3 mg	QD	Y-M: 20[redacted]-[redacted] / 479	ONGOING
VALERIANA OFFICINALIS	300 mg	QD	Y-M: 20[redacted]-[redacted] / 479	ONGOING
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted]-[redacted] / 507	NOT REPORTED
NITROFURANTOIN	50 mg	TID	Y-M: 20[redacted]-[redacted] / 518	Y-M: 20[redacted]-[redacted] / 525
NITROFURANTOIN	50 mg	TID	Y-M: 20[redacted]-[redacted] / 531	Y-M: 20[redacted]-[redacted] / 538
VENLAFAXINE HYDROCHLORIDE	112.50 mg	QD	Y-M: 20[redacted]-[redacted] / 535	ONGOING
CYANOCOBALAMIN;FOLIC ACID;PYRIDOXINE HYDROCHLORIDE	1 OTHER: PILL	QD	Y-M: 20[redacted]-[redacted] / 550	ONGOING
AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	875 mg	QID	Y-M: 20[redacted]-[redacted] / 554	Y-M: 20[redacted]-[redacted] / 560
NITROFURANTOIN	100 mg	TID	Y-M: 20[redacted]-[redacted] / 565	Y-M: 20[redacted]-[redacted] / 572
AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	875 mg	TID	Y-M: 20[redacted]-[redacted] / 584	Y-M: 20[redacted]-[redacted] / 590
NITROFURANTOIN	100 mg	TID	Y-M: 20[redacted]-[redacted] / 616	Y-M: 20[redacted]-[redacted] / 622

AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	875 mg	TID	Y-M: 20[redacted] / 620	Y-M: 20[redacted] / 625
AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	875 mg	TID	Y-M: 20[redacted] / 629	Y-M: 20[redacted] / 641
CIPROFLOXACIN	500 mg	BID	Y-M: 20[redacted] / 644	Y-M: 20[redacted] / 647
PARACETAMOL	1 g	PRN	Y-M: 20[redacted] / 660	NOT REPORTED
PANTOPRAZOLE SODIUM SESQUIHYDRATE	40 mg	QD	Y-M: 20[redacted] / 676	NOT REPORTED
FLUOXETINE HYDROCHLORIDE	20 mg	QD	Y-M: 20[redacted] / 681	NOT REPORTED
NITROFURANTOIN	100 mg	TID	Y-M: 20[redacted] / 690	Y-M: 20[redacted] / 697
FLUCLOXACILLIN SODIUM	500 mg	QID	Y-M: 20[redacted] / 694	Y-M: 20[redacted] / 697
AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	875 mg	TID	Y-M: 20[redacted] / 697	NOT REPORTED

Event #1: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	SKIN DEFINITE EDEMA AT INFUSION SITE (ABDOMEN)
Preferred Term	注入部位浮腫
AE Onset Date / Rx Day	[redacted]20[redacted] / 367
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped Rx Day	372
Duration of AE	6 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to	NOT APPLICABLE

[redacted] **Infusion Set**	
SAE: Investigator Opinion of Relationship to [redacted] **Infusion Set**	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	MULTIPLE SKIN MINIMAL PAPULAR RESPONSE AT INFUSION SITE (ABDOMEN)
Preferred Term	注入部位丘疹
AE Onset Date / Rx Day	[redacted]20[redacted] / 367
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] **Infusion Set**	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] **Infusion Set**	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	PANNICULUS ADIPOSUS AT INFUSION SITE
Preferred Term	注入部位腫瘤
AE Onset Date / Rx Day	[redacted]20[redacted] / 554
Age at AE Onset	8[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped Rx Day	562
Duration of AE	9 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	SKIN DEFINITE EDEMA AT INFUSION SITE (LEG)
Preferred Term	注入部位浮腫
AE Onset Date / Rx Day	[redacted]20[redacted] / 584
Age at AE Onset	8[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped Rx Day	591
Duration of AE	8 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to	NOT APPLICABLE

[redacted] **Infusion Set**	
SAE: Investigator Opinion of Relationship to [redacted] **Infusion Set**	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #5: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	SKIN DEFINITE EDEMA AT INFUSION SITE (LEG)
Preferred Term	注入部位浮腫
AE Onset Date / Rx Day	[redacted]20[redacted] / 620
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped Rx Day	638
Duration of AE	19 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] **Infusion Set**	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] **Infusion Set**	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #6: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	SKIN DEFINITE EDEMA ON INFUSION SITE (ABDOMEN)
Preferred Term	注入部位浮腫
AE Onset Date / Rx Day	[redacted]20[redacted] / 629
Age at AE Onset	8[redacted]
Laboratory Testing	

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped Rx Day	653
Duration of AE	25 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #7: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	MINIMAL ERYTHEMA ON INFUSION SITE (ABDOMEN)
Preferred Term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 643
Age at AE Onset	8[redacted]
Laboratory Testing	

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped Rx Day	653
Duration of AE	11 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #8: Serious Adverse Event

Event Description	PAIN LEFT LEG
Preferred Term	四肢痛
AE Onset Date / Rx Day	[redacted]20[redacted] / 660
Age at AE Onset	8[redacted]

Laboratory Testing

NOT REPORTED

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 666): HIP RADIOGRAPHY:ARTHROSIS (KNOWN IN MEDICAL HISTORY); [redacted]20[redacted] (RX DAY 676): LUMBAR CT SCAN:OSTEOPOROSIS ARTHROSIS NO INTRACANALAR COMPRESSION. SIGNIFICANT FORAMINAL NAROWNESS AT L1-L2, L2-L3, L3-L4 AND FORAMINAL NAROWNESS AT D11-D12 AND D12-L1; [redacted]20[redacted] (RX DAY 679): ELECTROCARDIOGRAM:SINUSAL RHYTHM

AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
Other Cause of Event	PATIENT HOSPITALIZED IN ORDER TO BE EVALUATED BY KINESIOLOGIST AND LOGOPEDE. THIS IS MORE LIKE AND HOSPITALIZATION TO REVIEW THE PATIENT'S CONDITION THEN A SEVERE AE THAT NEEDED TO BE HOSPITALIZED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION, PERSISTENT OR SIGNIFICANT DISABILITY

Event #9: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	SKIN DEFINITE EDEMA ON INFUSION SITE (ABDOMEN, PATIENT'S RIGHT SIDE)
Preferred Term	注入部位浮腫
AE Onset Date / Rx Day	[redacted]20[redacted] / 674
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped Rx Day	681
Duration of AE	8 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #10: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	DEFINITE EDEMA ON INFUSION SITE (ABDOMEN)
Preferred Term	注入部位浮腫
AE Onset Date / Rx Day	[redacted]20[redacted] / 692
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped Rx Day	692

Duration of AE	1 DAY
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Generated: [redacted] 20[redacted]:09:38
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者はベルギーの 8[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に左下肢の疼痛を発現した。

Event 8 の臨床経過：

関連する病歴は，うつ病，関節症，甲状腺機能低下症，パーキンソン病，肺塞栓症，睡眠時無呼吸，呼吸困難，左膝の手術（補装具），右膝の手術（補装具），骨粗鬆症，間欠性睡眠異常，及び現飲酒者（1 日 2 杯未満）であった。

投与 660 日目，被験者は左下肢の疼痛を発現した。

投与 674 日目，被験者は左下肢の疼痛のため入院した。被験者の左下肢の状態を評価するために運動機能学者（Kinesiologist）及び言語療法士に相談した。投与から約 22 ヵ月後，股関節の X 線検査が実施され，関節症が認められた。投与 676 日目，腰部の CT スキャンが実施され，骨粗鬆症及び関節症が認められた。予定された股関節超音波検査が完了するまでに，理学療法チームは中臀筋腱炎の疑いと最終診断を下した。投与 684 日目，被験者は自宅療養のため退院した。

治験責任医師によると，被験者には関連するリスク因子としてパーキンソン病及び股関節関節症の病歴があった。

被験者に DAFALGAN が投与された。

The patient's past medications include:

COVID-19 VACCINE (Pfizer) for PROPHYLAXIS ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Leg pain (10024130) (Pain in extremity (10033425)) [v.24.1] [10024130]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of PAIN LEFT LEG

- Investigator: PATIENT HOSPITALIZED IN ORDER TO BE EVALUATED BY KINESIOLOGIST AND LOGOPEDE. THIS IS MORE LIKE AND HOSPITALIZATION TO REVIEW THE PATIENT'S CONDITION THEN A SEVERE AE THAT NEEDED TO BE HOSPITALIZED

- AbbVie: More likely related to elderly age, hip arthrosis and underlying Parkinson disease.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ELECTROCARDIOGRAM:** SINUSAL RHYTHM

[redacted] **20[redacted] HIP RADIOGRAPHY:** Arthrosis
[redacted] **20[redacted] LUMBAR CT SCAN:** OSTEOPOROSIS ARTHROSIS NO INTRACANALAR COMPRESSION. SIGNIFICANT FORAMINAL NAROWNESS AT L1-L2, L2-L3, L3-L4 AND FORAMINAL NAROWNESS AT D11-D12 AND D12-L1

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
注入部位炎症				X
一過性脳虚血発作	X			

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	7[redacted]	MALE	WHITE

Medical History	Onset Year
PARKINSONS DISEASE	20[redacted]
DISCUS PROLAPS L5 DEX	20[redacted]
OBSTIPATION	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
HEMILAMINEKTOMI L4/L5	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	LESS THAN 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.55	0.60	0.50	60	0.15	[redacted] / 365
ABBV-951	0.55	0.6	0.5		0.15	[redacted] / 522

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	496.88		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted] / 2	
M15-741 /ABBV-951	1229.4		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted] / 3	
M15-741 /ABBV-951	1354.38		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted] / 4	
M15-741 /ABBV-951	1401.51		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted] / 5	
M15-741 /ABBV-951	1475.28		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted] / 6	
M15-741 /ABBV-951	1462.98		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted] / 7	
M15-741 /ABBV-951	1413.81		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted] / 8	
M15-741 /ABBV-951	1652.51		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted] / 9	
M15-741 /ABBV-951	1678.13		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted] / 10	
M15-741 /ABBV-951	1706.81		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted] / 11	
M15-741 /ABBV-951	1709.89		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
M15-741 /ABBV-951	1635.10		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted] / 13	
M15-741 /ABBV-951	1706.81		SC / CONTINUOUS	[redacted] / 13	[redacted] / 14
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted] / 14	
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted] / 15	
M15-741 /ABBV-951	1728.33		SC / CONTINUOUS	[redacted] / 15	[redacted] / 15
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted] / 16	
M15-741 /ABBV-951	1795.60		SC / CONTINUOUS	[redacted] / 16	[redacted] / 16

M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 17	
M15-741 /ABBV-951	1788.09		SC / CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 18	
M15-741 /ABBV-951	1712.96		SC / CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 19	
M15-741 /ABBV-951	1757.35		SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 20	
M15-741 /ABBV-951	1788.09		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
M15-741 /ABBV-951	1873.46		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 22	
M15-741 /ABBV-951	2072.90		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 23	
M15-741 /ABBV-951	2023.38		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 24	
M15-741 /ABBV-951	2040.46		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
M15-741 /ABBV-951	2049		SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
M15-741 /ABBV-951	2040.46		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 27
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 27	
M15-741 /ABBV-951	1955.08		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 29	
M15-741 /ABBV-951	2023.38		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 30	
M15-741 /ABBV-951	2161.69		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 31	
M15-741 /ABBV-951	2112.17		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 32	
M15-741 /ABBV-951	2192.43		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 33	
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 36
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 34	
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 35	
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 36	
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M15-741 /ABBV-951	2304.27		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 45	
M15-741 /ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
M15-741 /ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 48
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 48	
M15-741 /ABBV-951	2188.16		SC / CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 51
M15-741 /ABBV-951	2178.77		SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
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M15-741 /ABBV-951	2225.72		SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 57
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M15-741 /ABBV-951	2141.20		SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
M15-741 /ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 64
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M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 67
M15-741 /ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 69	
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M15-741 /ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
M15-741 /ABBV-951	2159.98		SC / CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
M15-741 /ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 74	[redacted]20[redacted] / 74
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M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
M15-741 /ABBV-951	2325.61		SC / CONTINUOUS	[redacted]20[redacted] / 85	[redacted]20[redacted] / 85
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M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 86	[redacted]20[redacted] / 86
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M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 88	[redacted]20[redacted] / 89
M15-741 /ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 91
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 92	
M15-741 /ABBV-951	2169.37		SC / CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 92
M15-741 /ABBV-951	2225.72		SC / CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 93
M15-741 /ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 94	[redacted]20[redacted] / 94
M15-741 /ABBV-951	2169.37		SC / CONTINUOUS	[redacted]20[redacted] / 95	[redacted]20[redacted] / 95
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 96	[redacted]20[redacted] / 97
M15-741 /ABBV-951	2178.77		SC / CONTINUOUS	[redacted]20[redacted] / 98	[redacted]20[redacted] / 98
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 99	[redacted]20[redacted] / 100
M15-741 /ABBV-951	2150.59		SC / CONTINUOUS	[redacted]20[redacted] / 101	[redacted]20[redacted] / 101
M15-741 /ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 102	[redacted]20[redacted] / 102
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 103	
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 103	[redacted]20[redacted] / 103
M15-741 /ABBV-951	2141.20		SC / CONTINUOUS	[redacted]20[redacted] / 104	[redacted]20[redacted] / 104
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 105	[redacted]20[redacted] / 106
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 107	
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M15-741 /ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 109	[redacted]20[redacted] / 109
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M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 112	
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M15-741 /ABBV-951	2159.98		SC / CONTINUOUS	[redacted]20[redacted] / 116	[redacted]20[redacted] / 116
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 117	[redacted]20[redacted] / 118
M15-741 /ABBV-951	2159.98		SC / CONTINUOUS	[redacted]20[redacted] / 119	[redacted]20[redacted] / 119
M15-741 /ABBV-951	2216.33		SC / CONTINUOUS	[redacted]20[redacted] / 120	[redacted]20[redacted] / 120
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 121	[redacted]20[redacted] / 121
M15-741 /ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 122	[redacted]20[redacted] / 122
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 123	[redacted]20[redacted] / 123
M15-741 /ABBV-951	2188.16		SC / CONTINUOUS	[redacted]20[redacted] / 124	[redacted]20[redacted] / 124
M15-741 /ABBV-951	2216.33		SC / CONTINUOUS	[redacted]20[redacted] / 125	[redacted]20[redacted] / 125
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 126	
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 126	[redacted]20[redacted] / 127
M15-741 /ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 128	[redacted]20[redacted] / 128
M15-741 /ABBV-951	2206.94		SC / CONTINUOUS	[redacted]20[redacted] / 129	[redacted]20[redacted] / 129
M15-741 /ABBV-951	2225.72		SC / CONTINUOUS	[redacted]20[redacted] / 130	[redacted]20[redacted] / 130
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M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 149	

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M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 150	[redacted]20[redacted] / 150
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M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 153	
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M15-741 /ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 154	[redacted]20[redacted] / 154
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 155	[redacted]20[redacted] / 155
M15-741 /ABBV-951	2225.72		SC / CONTINUOUS	[redacted]20[redacted] / 156	[redacted]20[redacted] / 156
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 157	[redacted]20[redacted] / 158
M15-741 /ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 159	[redacted]20[redacted] / 159
M15-741 /ABBV-951	2169.37		SC / CONTINUOUS	[redacted]20[redacted] / 160	[redacted]20[redacted] / 160
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 161	
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M15-741 /ABBV-951	2169.37		SC / CONTINUOUS	[redacted]20[redacted] / 163	[redacted]20[redacted] / 163
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M15-741 /ABBV-951	2159.98		SC / CONTINUOUS	[redacted]20[redacted] / 170	[redacted]20[redacted] / 170
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M15-741 /ABBV-951	2169.37		SC / CONTINUOUS	[redacted]20[redacted] / 193	[redacted]20[redacted] / 193
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 194	[redacted]20[redacted] / 195
M15-741 /ABBV-951	2159.98		SC / CONTINUOUS	[redacted]20[redacted] / 196	[redacted]20[redacted] / 196
M15-741 /ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 197	[redacted]20[redacted] / 197
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M15-741 /ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 201	[redacted]20[redacted] / 202
M15-741 /ABBV-951	2225.72		SC / CONTINUOUS	[redacted]20[redacted] / 203	[redacted]20[redacted] / 203
M15-741 /ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 204	[redacted]20[redacted] / 204
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 205	[redacted]20[redacted] / 205
M15-741 /ABBV-951	2206.94		SC / CONTINUOUS	[redacted]20[redacted] / 206	[redacted]20[redacted] / 206
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 207	[redacted]20[redacted] / 209
M15-741 /ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 210	[redacted]20[redacted] / 210
M15-741 /ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 211	[redacted]20[redacted] / 212
M15-741 /ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 213	[redacted]20[redacted] / 213
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M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 228	[redacted]20[redacted] / 228
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M15-741 /ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 242	[redacted]20[redacted] / 243
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M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 245	[redacted]20[redacted] / 245
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M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 252	[redacted]20[redacted] / 255
M15-741 /ABBV-951	2197.55		SC / CONTINUOUS	[redacted]20[redacted] / 256	[redacted]20[redacted] / 256
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 257	[redacted]20[redacted] / 257
M15-741 /ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 258	[redacted]20[redacted] / 258
M15-741 /ABBV-951	2206.94		SC / CONTINUOUS	[redacted]20[redacted] / 259	[redacted]20[redacted] / 259
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 260	[redacted]20[redacted] / 260
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M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 263	[redacted]20[redacted] / 263
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M15-741 /ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 268	[redacted]20[redacted] / 268
M15-741 /ABBV-951	2225.72		SC / CONTINUOUS	[redacted]20[redacted] / 269	[redacted]20[redacted] / 270
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 271	[redacted]20[redacted] / 271
M15-741 /ABBV-951	2225.72		SC / CONTINUOUS	[redacted]20[redacted] / 272	[redacted]20[redacted] / 272
M15-741 /ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 273	[redacted]20[redacted] / 273
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M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 277	[redacted]20[redacted] / 278
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M15-741 /ABBV-951	2216.33		SC / CONTINUOUS	[redacted]20[redacted] / 283	[redacted]20[redacted] / 283
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 284	[redacted]20[redacted] / 284
M15-741 /ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 285	[redacted]20[redacted] / 285
M15-741 /ABBV-951	2225.72		SC / CONTINUOUS	[redacted]20[redacted] / 286	[redacted]20[redacted] / 286
M15-741 /ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 287	[redacted]20[redacted] / 287
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 288	
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M15-741 /ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 292	[redacted]20[redacted] / 293
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M15-741 /ABBV-951	2206.94		SC / CONTINUOUS	[redacted]20[redacted] / 335	[redacted]20[redacted] / 335
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ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 385	[redacted]20[redacted] / 385
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ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 413	[redacted]20[redacted] / 413
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ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 429	[redacted]20[redacted] / 429
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ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 432	[redacted]20[redacted] / 432
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 433	[redacted]20[redacted] / 433
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 434	[redacted]20[redacted] / 435
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 436	[redacted]20[redacted] / 436
ABBV-951	2216.33		SC / CONTINUOUS	[redacted]20[redacted] / 437	[redacted]20[redacted] / 438
ABBV-951	2206.94		SC / CONTINUOUS	[redacted]20[redacted] / 439	[redacted]20[redacted] / 439
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 440	[redacted]20[redacted] / 446
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 447	[redacted]20[redacted] / 447
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 448	[redacted]20[redacted] / 448
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 449	[redacted]20[redacted] / 449
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 450	[redacted]20[redacted] / 451
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 452	[redacted]20[redacted] / 452
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 453	[redacted]20[redacted] / 455
ABBV-951	2206.94		SC / CONTINUOUS	[redacted]20[redacted] / 456	[redacted]20[redacted] / 456
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 457	[redacted]20[redacted] / 457
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 458	[redacted]20[redacted] / 458
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 459	[redacted]20[redacted] / 459
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 460	[redacted]20[redacted] / 460
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 461	[redacted]20[redacted] / 461
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 462	[redacted]20[redacted] / 463
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 464	[redacted]20[redacted] / 464
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 465	[redacted]20[redacted] / 466
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 467	
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 467	[redacted]20[redacted] / 467
ABBV-951	2197.55		SC / CONTINUOUS	[redacted]20[redacted] / 468	[redacted]20[redacted] / 468
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 469	[redacted]20[redacted] / 469

ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 470	[redacted]20[redacted] / 470
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 471	[redacted]20[redacted] / 471
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 472	[redacted]20[redacted] / 472
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 473	[redacted]20[redacted] / 473
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 474	[redacted]20[redacted] / 475
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 476	[redacted]20[redacted] / 476
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 477	[redacted]20[redacted] / 478
ABBV-951	1972.16		SC / CONTINUOUS	[redacted]20[redacted] / 479	[redacted]20[redacted] / 479
ABBV-951	2225.72		SC / CONTINUOUS	[redacted]20[redacted] / 480	[redacted]20[redacted] / 480
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 481	[redacted]20[redacted] / 482
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 483	[redacted]20[redacted] / 483
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 484	[redacted]20[redacted] / 485
ABBV-951	2225.72		SC / CONTINUOUS	[redacted]20[redacted] / 486	[redacted]20[redacted] / 486
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 487	[redacted]20[redacted] / 487
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 488	[redacted]20[redacted] / 490
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 491	
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 491	[redacted]20[redacted] / 491
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 492	[redacted]20[redacted] / 494
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 495	[redacted]20[redacted] / 495
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 496	
ABBV-951	2159.98		SC / CONTINUOUS	[redacted]20[redacted] / 496	[redacted]20[redacted] / 496
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 497	[redacted]20[redacted] / 498
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 499	[redacted]20[redacted] / 499
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 500	[redacted]20[redacted] / 500
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 501	
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 501	[redacted]20[redacted] / 502
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 503	
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 503	[redacted]20[redacted] / 503
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 504	[redacted]20[redacted] / 504
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 505	[redacted]20[redacted] / 506
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 507	[redacted]20[redacted] / 507
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 508	[redacted]20[redacted] / 509
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 510	[redacted]20[redacted] / 511
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 512	
ABBV-951	2197.55		SC / CONTINUOUS	[redacted]20[redacted] / 512	[redacted]20[redacted] / 512
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 513	[redacted]20[redacted] / 513
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 514	[redacted]20[redacted] / 514

ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 515	[redacted]20[redacted] / 517
ABBV-951	2216.33		SC / CONTINUOUS	[redacted]20[redacted] / 518	[redacted]20[redacted] / 518
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 519	[redacted]20[redacted] / 521
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 522	[redacted]20[redacted] / 522
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 523	[redacted]20[redacted] / 523
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 524	[redacted]20[redacted] / 524
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 525	
ABBV-951	2206.94		SC / CONTINUOUS	[redacted]20[redacted] / 525	[redacted]20[redacted] / 525
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 526	[redacted]20[redacted] / 529
ABBV-951	2216.33		SC / CONTINUOUS	[redacted]20[redacted] / 530	[redacted]20[redacted] / 530
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 531	[redacted]20[redacted] / 534
ABBV-951	2216.33		SC / CONTINUOUS	[redacted]20[redacted] / 535	[redacted]20[redacted] / 535
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 536	[redacted]20[redacted] / 538
ABBV-951	2216.33		SC / CONTINUOUS	[redacted]20[redacted] / 539	[redacted]20[redacted] / 539
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 540	[redacted]20[redacted] / 544
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 542	
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 545	[redacted]20[redacted] / 545
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 546	[redacted]20[redacted] / 546
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 547	
ABBV-951	2240.24		SC / CONTINUOUS	[redacted]20[redacted] / 547	[redacted]20[redacted] / 547
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 548	[redacted]20[redacted] / 550
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 551	[redacted]20[redacted] / 551
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 552	[redacted]20[redacted] / 552
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 553	[redacted]20[redacted] / 553
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 554	[redacted]20[redacted] / 554
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 555	[redacted]20[redacted] / 555
ABBV-951	2216.33		SC / CONTINUOUS	[redacted]20[redacted] / 556	[redacted]20[redacted] / 556
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 557	[redacted]20[redacted] / 558
ABBV-951	2225.72		SC / CONTINUOUS	[redacted]20[redacted] / 559	[redacted]20[redacted] / 559
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 560	[redacted]20[redacted] / 560
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 561	[redacted]20[redacted] / 561
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 562	
ABBV-951	2225.72		SC / CONTINUOUS	[redacted]20[redacted] / 562	[redacted]20[redacted] / 562
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 563	[redacted]20[redacted] / 563
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 564	[redacted]20[redacted] / 564
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 565	[redacted]20[redacted] / 565
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 566	[redacted]20[redacted] / 566

ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 567	[redacted]20[redacted] / 567
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 568	[redacted]20[redacted] / 568
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 569	
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 569	[redacted]20[redacted] / 569
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 570	[redacted]20[redacted] / 570
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 571	[redacted]20[redacted] / 571
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 572	[redacted]20[redacted] / 572
ABBV-951	2225.72		SC / CONTINUOUS	[redacted]20[redacted] / 573	[redacted]20[redacted] / 573
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 574	[redacted]20[redacted] / 574
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 575	[redacted]20[redacted] / 575
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 576	[redacted]20[redacted] / 576
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 577	[redacted]20[redacted] / 577
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 578	
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ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 579	
ABBV-951	2206.94		SC / CONTINUOUS	[redacted]20[redacted] / 579	[redacted]20[redacted] / 579
ABBV-951	2225.72		SC / CONTINUOUS	[redacted]20[redacted] / 580	[redacted]20[redacted] / 580
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 581	[redacted]20[redacted] / 583
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 584	
ABBV-951	2216.33		SC / CONTINUOUS	[redacted]20[redacted] / 584	[redacted]20[redacted] / 584
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 585	[redacted]20[redacted] / 585
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 586	[redacted]20[redacted] / 586
ABBV-951	2216.33		SC / CONTINUOUS	[redacted]20[redacted] / 587	[redacted]20[redacted] / 587
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 588	[redacted]20[redacted] / 588
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 589	[redacted]20[redacted] / 589
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 590	[redacted]20[redacted] / 590
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 591	[redacted]20[redacted] / 591
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 592	[redacted]20[redacted] / 597
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 598	
ABBV-951	2188.16		SC / CONTINUOUS	[redacted]20[redacted] / 598	[redacted]20[redacted] / 598
ABBV-951	2225.72		SC / CONTINUOUS	[redacted]20[redacted] / 599	[redacted]20[redacted] / 599
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 600	[redacted]20[redacted] / 600
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 601	
ABBV-951	2225.72		SC / CONTINUOUS	[redacted]20[redacted] / 601	[redacted]20[redacted] / 601
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 602	[redacted]20[redacted] / 602
ABBV-951	2225.72		SC / CONTINUOUS	[redacted]20[redacted] / 603	[redacted]20[redacted] / 603
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 604	[redacted]20[redacted] / 605

ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 606	[redacted]20[redacted] / 606
ABBV-951	2225.72		SC / CONTINUOUS	[redacted]20[redacted] / 607	[redacted]20[redacted] / 607
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 608	[redacted]20[redacted] / 609
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 610	[redacted]20[redacted] / 610
ABBV-951	2197.55		SC / CONTINUOUS	[redacted]20[redacted] / 611	[redacted]20[redacted] / 611
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 612	[redacted]20[redacted] / 612
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 613	[redacted]20[redacted] / 614
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 615	[redacted]20[redacted] / 615
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 616	[redacted]20[redacted] / 616
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 617	[redacted]20[redacted] / 617
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 618	[redacted]20[redacted] / 618
ABBV-951	2216.33		SC / CONTINUOUS	[redacted]20[redacted] / 619	[redacted]20[redacted] / 619
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 620	[redacted]20[redacted] / 621
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 622	[redacted]20[redacted] / 622
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 623	[redacted]20[redacted] / 623
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 624	[redacted]20[redacted] / 627
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 628	[redacted]20[redacted] / 628
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 629	[redacted]20[redacted] / 629
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 630	[redacted]20[redacted] / 630
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 631	[redacted]20[redacted] / 633
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 634	[redacted]20[redacted] / 634
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 635	[redacted]20[redacted] / 636
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 637	[redacted]20[redacted] / 637
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 638	[redacted]20[redacted] / 641
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 642	[redacted]20[redacted] / 642
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 643	
ABBV-951	2206.94		SC / CONTINUOUS	[redacted]20[redacted] / 643	[redacted]20[redacted] / 643
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 644	[redacted]20[redacted] / 644
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 645	
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 645	[redacted]20[redacted] / 645
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 646	[redacted]20[redacted] / 646
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 647	[redacted]20[redacted] / 647
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 648	[redacted]20[redacted] / 648

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
SODIUM CITRATE;SODIUM LAURYL SULFOACETATE	9 MG/ML + 90 MG/ML OTHER: MG/ML + MG/ML	PRN	Y-M: 20[redacted] / -98
CARBIDOPA;LEVODOPA	100.000 mg	PRN	Y-M: 20[redacted] / -39
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	1 OTHER: UNIT	PRN	Y-M: 20[redacted] / 135

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
SODIUM CITRATE;SODIUM LAURYL SULFOACETATE	9 MG/ML + 90 MG/ML OTHER: MG/ML + MG/ML	PRN	Y-M: 20[redacted] / -98	NOT REPORTED
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	1 OTHER: UNIT	PRN	Y-M: 20[redacted] / 135	NOT REPORTED
ACETYLSALICYLIC ACID	300 mg	OTHER: SD	Y-M: 20[redacted] / 423	Y-M: 20[redacted] / 423
CLOPIDOGREL	75 mg	QD	Y-M: 20[redacted] / 424	NOT REPORTED
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 431	NOT REPORTED
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 452	NOT REPORTED
SILDENAFIL	20 mg	PRN	Y-M: 20[redacted] / 497	ONGOING
DICLOXACILLIN	1000 mg	QID	Y-M: 20[redacted] / 519	Y-M: 20[redacted] / 526
INFLUENZA VACCINE INACT SAG 4V	1 OTHER: UNIT	OTHER: ONCE	Y-M: 20[redacted] / 613	Y-M: 20[redacted] / 613

Event #1: Serious Adverse Event

Event Description	TRANSIENT ISCHEMIC ATTACK
Preferred Term	一過性脳虚血発作
AE Onset Date / Rx Day	[redacted]20[redacted] / 423
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 424): Albumin: 36 [34 - 45] G/L; Alkaline Phosphatase: 61 [35 - 105] U/L; Bilirubin: 16 [5 - 25] UMOL/L; Cholesterol: 3.4 [NOT REPORTED - 5] mmol/L; Creatinine: 63 [60 - 105] UMOL/L; Ery. Mean Corpuscular

HGB Concentration: 359.33 [317.43 - 357.72] G/L; Glucose: 6.2 [4.2 - 7.8] MMOL/L; Hemoglobin: 158 [134 - 169] G/L; NPTST001-ALANINE TRANSAMINASE ALAT: 9 [10 - 70] U/L; NPTST005-C-REACTIVE PROTEIN (CRP): 1.5 [NOT REPORTED - 8] mg/L; NPTST006-CHELESTEROL LDL: 1.8 [NOT REPORTED - 3] mmol/L; NPTST007-CHOLESTEROL HDL: 1.2 [1 - NOT REPORTED] mmol/L; NPTST010-GLOMERULAR FILTRATION RATE (GFR: 90 [60 - NOT REPORTED] ML/MIN; NPTST011-INR: 1.2 [NOT REPORTED - 1.2] RATIO; Potassium: 3.8 [3.5 - 4.6] MMOL/L; Sodium: 141 [137 - 145] MMOL/L; Triglycerides: 1.0 [NOT REPORTED - 2] mmol/L

Microbiology

[redacted]20[redacted] (RX DAY 424): OTHER PHARYNGEAL SWAB CORONAVIRUS SARS-CO-V-2 DNA/RNA: NEGATIVE

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 423): CT CEREBRUM:DISCRETE CENTRAL ATROPHY. THERE ARE NO SIGNS OF INFARCTION, BLEEDING OR SPACE-FILLING PROCESSES. THE VENTRICULAR SYSTEM IS CENTRALIZED AND NORMALLY CALIBRATED. THERE ARE INCONSPICUOUS SURFACE SULCI.; [redacted]20[redacted] (RX DAY 424): CARDIAC MONITORING AT HOME FOR 3 DAYS.:NORMAL HEART RHYTHM; CT ANGIOGRAHPY OF HEAD AND NECK:NORMAL CONTRAST FILLING IN THE VESSELS. OPEN CAROTID ARTERIES AND CENTRAL CEREBRAL ARTERIES. THERE ARE NO STENOSES OR CALIBER DIFFERENCES. NO INFILTRATES IN CO-SCANNED LUNGS. DEGENERATIVE CHANGES IN THE CULUMNA CERVICALIS.

AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	AGE AND STRESED AT THE TIME OF EVENT,
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #2: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	ABDOMEN INFUSION SITE INFLAMMATION.
Preferred Term	注入部位炎症
AE Onset Date / Rx Day	[redacted]20[redacted] / 519
Age at AE Onset	7[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped Rx Day	526
Duration of AE	8 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Generated: [redacted]20[redacted]:09:38

Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者はデンマークの 7[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に一過性脳虚血発作を発現した。

Event 1 の臨床経過：

関連する病歴は，パーキンソン病，非喫煙者，及び飲酒者（1 日 2 杯未満）であった。

投与 423 日目，被験者は一過性脳虚血発作を発現した。本事象発現前に，被験者は手首にわずかに締め付けられるような感覚及び右親指と人差し指にわずかに眠ったような感覚があった。しかし，これらの症状は軽減した。

投与 423 日目，被験者は胸部圧迫感を伴った失語症の突然の発症により入院した。約 1 時間症状が持続した後に，被験者は習慣的状態を感じた。大脳の CT スキャンの結果，軽度の中心性萎縮症及び頸動脈と中心動脈の開放が認められた。神経学的検査の結果，被験者は客観的に見て習慣的状態であった。脳神経：I.a。上肢：力及び感受性は正常。深部反射は均衡。指鼻試験は正常。下肢：右足首の屈曲によるわずかな力の減少を除き力は正常，深部反射なし。踵膝試験は正常。歩行 / 起立：正常な歩行で右側にやや下垂足，ただし以前より認められていた。一過

性血栓症の疑いがあり，クロピドグレルの予防投与を開始した。投与 424 日目，被験者は習慣的状態で退院した。
治験責任医師によると，被験者の母親は 5[redacted] 歳で心臓発作によって死亡した。
被験者にクロピドグレル及びアセチルサリチル酸が投与された。

Causality for ABBV-951 (Open Label)

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1) Transient ischemic attack (10072760) (Transient ischaemic attack (10044390)) [v.23.1] [10072760]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of TRANSIENT ISCHEMIC ATTACK

- Investigator: Age and stressed at the time of event

- AbbVie: More likely related to advanced age.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ALANINE TRANSAMINASE ALAT:** <9 U/L

[redacted] **20[redacted] ALBUMIN:** 36 G/L (normal 34 to 45)

[redacted] **20[redacted] ALKALINE PHOSPHATASE:** 61 U/L (normal 35 to 105)

[redacted] **20[redacted] BILIRUBIN:** 16 umol/L (normal 5 to 25)

[redacted] **20[redacted] C-REACTIVE PROTEIN:** 1.5 MG/L (normal <8.0)

[redacted] **20[redacted] CARDIAC MONITORING AT HOME FOR 3 DAYS:** Normal heart rhythm

[redacted] **20[redacted] CHOLESTEROL:** 3.4 MMOL/L (normal <5.0)

[redacted] **20[redacted] CHOLESTEROL HDL:** 1.2 MMOL/L (normal >1.0)

[redacted] **20[redacted] CHOLESTEROL LDL:** 1.8 MMOL/L (normal <3.0)

[redacted] **20[redacted] CREATININE:** 63 umol/L (normal 60 to 105)

[redacted] **20[redacted] CT ANGIOGRAPHY OF HEAD AND NECK:** Normal contrast filling in the vessels. Open carotid arteries and central cerebral arteries. There are no stenoses or caliber differences. No infiltrates in co-scanned lungs. Degenerative changes in the culumna cervicalis.

[redacted] **20[redacted] CT CEREBRUM:** Discrete central atrophy. There are no signs of infarction, bleeding or space-filling processes. The ventricular system is centralized and normally calibrated. There are inconspicuous surface sulci.

[redacted] **20[redacted] GLOMERULAR FILTRATION RATE:** 90 mL/min (normal >60)

[redacted] **20[redacted] GLUCOSE:** 6.2 MMOL/L (normal 4.2 to 7.8)

[redacted] **20[redacted] HEMOGLOBIN:** 9.8 MMOL/L (normal 8.3 to 10.5)

[redacted] **20[redacted] INR:** 1.2 NO UNITS (normal <1.2)

[redacted] **20[redacted] MCHC:** 22.3 MMOL/L (normal 19.7 to 22.2)

[redacted] **20[redacted] POTASSIUM:** 3.8 MMOL/L (normal 3.5 to 4.6)

[redacted] **20[redacted] SARS-COV-2 TEST:** Pharyngeal swab: Negative

[redacted] **20[redacted] SODIUM:** 141 MMOL/L (normal 137 to 145)

[redacted] **20[redacted] TRIGLYCERIDES:** 1.0 MMOL/L (normal <2.0)

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
幻覚				X
注入部位蜂巣炎				X
精神病性障害	X			X

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	6[redacted]	FEMALE	WHITE

Medical History	Onset Year
ALLERGY FOR WASP STING. HAD ONCE AN ANAPHYLACTIC SHOCK AFTER A WASP STING	NOT REPORTED
EMOTION REGULATION DISORDER	NOT REPORTED
OBSESSIVE THOUGHTS	NOT REPORTED
PARANOID THOUGHTS	NOT REPORTED
HYPERCHOLESTEROLEMIA	20[redacted]
ANGINA PECTORIS	20[redacted]
TRANSIENT ISCHEMIC ATTACK	20[redacted]
IMPINGEMENT SYNDROME	20[redacted]
DEPRESSION AND ANXIETY DISORDER	20[redacted]
OBSTIPATION	20[redacted]
OCCASIONALLY DIFFICULTIES FALLING ASLEEP	20[redacted]
PERSISTENT PAIN AFTER HALLUX VALGUS OSTEOTOMY LEFT SIDE	20[redacted]
DELAYED GASTRIC EMPTYING	20[redacted]
NEGATIVE SELF-IMAGE	20[redacted]
ORTHOSTATIC HYPOTENSION	20[redacted]
URINARY TRACT INFECTION	20[redacted]
VITAMIN B6 DEFICIENCT	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]

ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
RIGHT SHOULDER SURGERY	20[redacted]
LEFT SHOULDER SURGERY	20[redacted]
CHEVRON OSTEOTOMY HALLUX VALGUS LEFT SIDE	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	LESS THAN 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.31	0.33	0.28	60	0.15	[redacted]20[redacted] / 364
ABBV-951	0.31	0.31	0.28	60	0.15	[redacted]20[redacted] / 525
ABBV-951	0.31	0.31	0.28	60	0.00	[redacted]20[redacted] / 531
ABBV-951	0.27	0.30	0.27	60	0.00	[redacted]20[redacted] / 588
ABBV-951	0.24	0.27	0.24	60	0.00	[redacted]20[redacted] / 616
ABBV-951	0.24	0.27	0.24	60	0.11	[redacted]20[redacted] / 657

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 1	
M15-741 /ABBV-951	1343.97		SC / CONTINUOUS	[redacted]20[redacted] / 1	[redacted]20[redacted] / 1
M15-741 /ABBV-951	2792.95		SC / CONTINUOUS	[redacted]20[redacted] / 2	[redacted]20[redacted] / 2
M15-741 /ABBV-951	2691.02		SC / CONTINUOUS	[redacted]20[redacted] / 3	[redacted]20[redacted] / 3
M15-741 /ABBV-951	2523.85		SC / CONTINUOUS	[redacted]20[redacted] / 4	[redacted]20[redacted] / 4
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 5	
M15-741 /ABBV-951	2413.72		SC / CONTINUOUS	[redacted]20[redacted] / 5	[redacted]20[redacted] / 5

M15-741 /ABBV-951	2054.12		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
M15-741 /ABBV-951	2049		SC / CONTINUOUS	[redacted] / 7	[redacted] / 10
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted] / 11	
M15-741 /ABBV-951	2253.55		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted] / 12	
M15-741 /ABBV-951	2296.92		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 13	
M15-741 /ABBV-951	2392.20		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
M15-741 /ABBV-951	2663.7		SC / CONTINUOUS	[redacted] / 14	[redacted] / 18
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted] / 19	
M15-741 /ABBV-951	2483.04		SC / CONTINUOUS	[redacted] / 19	[redacted] / 19
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted] / 20	
M15-741 /ABBV-951	2297.09		SC / CONTINUOUS	[redacted] / 20	[redacted] / 20
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 21	
M15-741 /ABBV-951	2359.76		SC / CONTINUOUS	[redacted] / 21	[redacted] / 21
M15-741 /ABBV-951	2540.76		SC / CONTINUOUS	[redacted] / 22	[redacted] / 25
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 26	
M15-741 /ABBV-951	2529.66		SC / CONTINUOUS	[redacted] / 26	[redacted] / 26
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 27	
M15-741 /ABBV-951	2370.52		SC / CONTINUOUS	[redacted] / 27	[redacted] / 27
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 28	
M15-741 /ABBV-951	2555.10		SC / CONTINUOUS	[redacted] / 28	[redacted] / 28
M15-741 /ABBV-951	2663.7		SC / CONTINUOUS	[redacted] / 29	[redacted] / 39
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted] / 40	
M15-741 /ABBV-951	2465.97		SC / CONTINUOUS	[redacted] / 40	[redacted] / 40
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 41	
M15-741 /ABBV-951	2377.52		SC / CONTINUOUS	[redacted] / 41	[redacted] / 41
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 42	
M15-741 /ABBV-951	2275.75		SC / CONTINUOUS	[redacted] / 42	[redacted] / 42
M15-741 /ABBV-951	2171.94		SC / CONTINUOUS	[redacted] / 43	[redacted] / 59
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted] / 60	
M15-741 /ABBV-951	2140.18		SC / CONTINUOUS	[redacted] / 60	[redacted] / 60
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted] / 61	
M15-741 /ABBV-951	2085.71		SC / CONTINUOUS	[redacted] / 61	[redacted] / 61
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted] / 62	
M15-741 /ABBV-951	1775.8		SC / CONTINUOUS	[redacted] / 62	[redacted] / 62
M15-741 /ABBV-951	1639.2		SC / CONTINUOUS	[redacted] / 63	[redacted] / 88

M15-741 /ABBV-951	1474.25		SC / CONTINUOUS	20[redacted] / 89	20[redacted] / 89
M15-741 /ABBV-951		51.22	SC / ONCE	20[redacted] / 90	
M15-741 /ABBV-951	1330.14		SC / CONTINUOUS	20[redacted] / 90	20[redacted] / 90
M15-741 /ABBV-951	1339.53		SC / CONTINUOUS	20[redacted] / 91	20[redacted] / 91
M15-741 /ABBV-951	1434.3		SC / CONTINUOUS	20[redacted] / 92	20[redacted] / 179
M15-741 /ABBV-951	1422.17		SC / CONTINUOUS	20[redacted] / 180	20[redacted] / 180
M15-741 /ABBV-951	1066.67		SC / CONTINUOUS	20[redacted] / 181	20[redacted] / 181
M15-741 /ABBV-951	1379.66		SC / CONTINUOUS	20[redacted] / 182	20[redacted] / 182
M15-741 /ABBV-951	1434.3		SC / CONTINUOUS	20[redacted] / 183	20[redacted] / 270
M15-741 /ABBV-951		25.61	SC / ONCE	20[redacted] / 271	
M15-741 /ABBV-951	1426.61		SC / CONTINUOUS	20[redacted] / 271	20[redacted] / 271
M15-741 /ABBV-951	1434.3		SC / CONTINUOUS	20[redacted] / 272	20[redacted] / 272
M15-741 /ABBV-951	1354.21		SC / CONTINUOUS	20[redacted] / 273	20[redacted] / 273
M15-741 /ABBV-951	1352.34		SC / CONTINUOUS	20[redacted] / 274	20[redacted] / 361
M15-741 /ABBV-951	1261.33		SC / CONTINUOUS	20[redacted] / 362	20[redacted] / 362
M15-741 /ABBV-951	1249.20		SC / CONTINUOUS	20[redacted] / 363	20[redacted] / 363
ABBV-951	476.39		SC / CONTINUOUS	20[redacted] / 364	20[redacted] / 364
M15-741 /ABBV-951	1238.62		SC / CONTINUOUS	20[redacted] / 364	20[redacted] / 364
ABBV-951	1270.38		SC / CONTINUOUS	20[redacted] / 365	20[redacted] / 445
ABBV-951	449.92		SC / CONTINUOUS	20[redacted] / 446	20[redacted] / 446
ABBV-951	805.76		SC / CONTINUOUS	20[redacted] / 447	20[redacted] / 447
ABBV-951	1324.16		SC / CONTINUOUS	20[redacted] / 448	20[redacted] / 448
ABBV-951	1352.34		SC / CONTINUOUS	20[redacted] / 449	20[redacted] / 522
ABBV-951		25.61	SC / ONCE	20[redacted] / 523	
ABBV-951	1341.07		SC / CONTINUOUS	20[redacted] / 523	20[redacted] / 523
ABBV-951	1329.80		SC / CONTINUOUS	20[redacted] / 524	20[redacted] / 524
ABBV-951	1285.23		SC / CONTINUOUS	20[redacted] / 525	20[redacted] / 525
ABBV-951	1270.38		SC / CONTINUOUS	20[redacted] / 526	20[redacted] / 620
ABBV-951	1072.82		SC / CONTINUOUS	20[redacted] / 621	20[redacted] / 621
ABBV-951	389.31		SC / CONTINUOUS	20[redacted] / 622	20[redacted] / 622

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
EPINEPHRINE	0.3 mg	PRN	Y-M: 20[redacted]
ROSUVASTATIN	10 mg	QD	Y-M: 20[redacted]-[redacted]
TEMAZEPAM	10 mg	PRN	Y-M: 20[redacted]-[redacted]
CLOPIDOGREL	75 mg	QD	Y-M: 20[redacted]-[redacted]

CITALOPRAM	20 mg	QD	Y-M: 20[redacted]
PYRIDOXINE	50 mg	QD	Y-M: 20[redacted] / 63
FLUTICASONE	0.5 OTHER: MG/G	QD	Y-M: 20[redacted] / 133
ISOSORBIDE MONONITRATE	60 mg	QD	Y-M: 20[redacted] / 187
GLYCERYL TRINITRATE	0.4 mg	PRN	Y-M: 20[redacted] / 212
METFORMIN	500 mg	QD	Y-M: 20[redacted] / 212
IBUPROFEN	400 mg	PRN	Y-M: 20[redacted] / 258
TRAMADOL	50 mg	PRN	Y-M: 20[redacted] / 258
CLOZAPINE	25 mg	QD	Y-M: 20[redacted] / 361

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
EPINEPHRINE	0.3 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
ROSUVASTATIN	10 mg	QD	Y-M: 20[redacted]	NOT REPORTED
TEMAZEPAM	10 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
CLOPIDOGREL	75 mg	QD	Y-M: 20[redacted]	NOT REPORTED
CITALOPRAM	20 mg	QD	Y-M: 20[redacted]	NOT REPORTED
PYRIDOXINE	50 mg	QD	Y-M: 20[redacted] / 63	NOT REPORTED
FLUTICASONE	0.5 OTHER: MG/G	QD	Y-M: 20[redacted] / 133	NOT REPORTED
ISOSORBIDE MONONITRATE	60 mg	QD	Y-M: 20[redacted] / 187	NOT REPORTED
GLYCERYL TRINITRATE	0.4 mg	PRN	Y-M: 20[redacted] / 212	NOT REPORTED
METFORMIN	500 mg	QD	Y-M: 20[redacted] / 212	NOT REPORTED
IBUPROFEN	400 mg	PRN	Y-M: 20[redacted] / 258	NOT REPORTED
TRAMADOL	50 mg	PRN	Y-M: 20[redacted] / 258	NOT REPORTED
CLOZAPINE	25 mg	QD	Y-M: 20[redacted] / 361	Y-M: 20[redacted] / 471
FLUDROCORTISONE	0.100 mg	QD	Y-M: 20[redacted] / 372	Y-M: 20[redacted] / 448
TRIAMCINOLONE ACETONIDE	80 mg	OTHER: ONCE	Y-M: 20[redacted] / 400	Y-M: 20[redacted] / 400
LIDOCAINE	2 mL	OTHER: ONCE	Y-M: 20[redacted] / 408	Y-M: 20[redacted] / 408
CLINDAMYCIN	600 mg	TID	Y-M: 20[redacted] / 418	Y-M: 20[redacted] / 428
PANTOPRAZOLE	40 mg	QD	Y-M: 20[redacted] / 439	Y-M: 20[redacted] / 611
FLUDROCORTISONE	0.200 mg	QD	Y-M: 20[redacted] / 448	NOT REPORTED
AMOXICILLIN	1000 mg	BID	Y-M: 20[redacted] / 448	Y-M: 20[redacted] / 455
METRONIDAZOLE	500 mg	BID	Y-M: 20[redacted] / 448	Y-M: 20[redacted] / 455
OXAZEPAM	10 mg	BID	Y-M: 20[redacted] / 471	Y-M: 20[redacted] / 579

CLOZAPINE	31.25 mg	QD	Y-M: 20[redacted] / 472	NOT REPORTED
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 503	NOT REPORTED
AMOXICILLIN	1000 mg	BID	Y-M: 20[redacted] / 520	Y-M: 20[redacted] / 530
METRONIDAZOLE	500 mg	BID	Y-M: 20[redacted] / 520	Y-M: 20[redacted] / 530
DOMPERIDONE	10 mg	TID	Y-M: 20[redacted] / 526	Y-M: 20[redacted] / 539
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 538	NOT REPORTED
OXAZEPAM	10 mg	TID	Y-M: 20[redacted] / 579	NOT REPORTED
PANTOPRAZOLE	40 mg	PRN	Y-M: 20[redacted] / 611	NOT REPORTED
CLINDAMYCIN	600 mg	TID	Y-M: 20[redacted] / 642	Y-M: 20[redacted] / 656

Event #1: Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS AT INFUSION SITE AT RIGHT LOWER QUADRANT
Preferred Term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 413
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped Rx Day	428
Duration of AE	16 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest - Hallucinations/Psychosis

Event Description	WORSENING HALLUCINATIONS
Preferred Term	幻覚

AE Onset Date / Rx Day	[redacted]20[redacted] / 471
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped Rx Day	525
Duration of AE	55 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Serious Adverse Event, Event of Interest - Hallucinations/Psychosis

Event Description	WORSENING PSYCHOSIS
Preferred Term	精神病性障害
AE Onset Date / Rx Day	[redacted]20[redacted] / 525
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
SAE Supplemental Procedure	
[redacted]20[redacted] (RX DAY 526): MONTRAL COGNITIVE ASSESSMENT:25 POINTS OUT OF 30	
AE Stopped Rx Day	539
Duration of AE	15 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to	NOT RELATED

Infusion Pump	
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
Other Cause of Event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #4: Event of Interest - Hallucinations/Psychosis

Event Description	WORSENING PSYCHOSIS
Preferred Term	精神病性障害
AE Onset Date / Rx Day	[redacted]20[redacted] / 579
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #5: Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS AT INFUSION SITE LEFT UPPER QUADRANT ABDOMEN
Preferred Term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 642

Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped Rx Day	656
Duration of AE	15 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Generated: [redacted]20[redacted]:09:38
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者はオランダの 6[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に精神病性障害を発現した。

Event 3 の臨床経過：

関連する病歴は，パーキンソン病，うつ病及び不安障害，強迫観念，妄想観念，非喫煙者，及び飲酒者（1 日 2 杯未満）であった。

投与 525 日目，被験者は精神病性障害を発現した。

本事象発現前に，被験者は娘の声及び男性の合唱隊の音楽が聞こえることを含む精神病性症状を約 1.5 年発現していた。

投与 525 日目，被験者は症状が増強したため入院し，試験での dF2 の注入速度を落とした。投与 531 日目，治験薬のボーラス投与を 0.0 mL に減量したところ，硬直が増強するとともに精神病的な現象が減少した。投与 539 日目，被験者は退院した。

治験責任医師によると，本事象に関連する被験者のリスク因子はパーキンソン病であった。

Causality for ABBV-951 (Open Label)

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1) Psychosis aggravated (10048343) (Psychotic disorder (10061920)) [v.24.0] [10048343]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of WORSENING PSYCHOSIS

- Investigator: Not applicable

- AbbVie: More likely related to Parkinson disease, with reported ongoing psychotic symptoms and history of paranoid and obsessive thoughts, depression and anxiety in a 6[redacted] year old subject.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] MONTRAL COGNITIVE ASSESSMENT:** 25 points out of 30

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
処置による疼痛	X			

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	5[redacted]	MALE	WHITE

Medical History	Onset Year
DYSLIPIDEMIA	19[redacted]
HYPERTENSION	19[redacted]
ISCHEMIC HEART DISEASE	19[redacted]
STENOSIS SPINAL CANAL IN THE LUMBAR	20[redacted]
BLEPHAROSPASM	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
CORONARY BYPASS	19[redacted]
VASECTOMY	19[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	40 CIGARETTE	9	19[redacted]
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.60	0.70	0	60	0.30	[redacted] / 372
ABBV-951	0.6	0.7	0	60	0.30	[redacted] / 555
ABBV-951	0.6	0.7	0	60	0.30	[redacted] / 705

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	725.68		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
M15-741 /ABBV-951	2049		SC / CONTINUOUS	[redacted] / 2	[redacted] / 4
M15-741 /ABBV-951	1980.7		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted] / 6	
M15-741 /ABBV-951	1989.23		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
M15-741 /ABBV-951	2049		SC / CONTINUOUS	[redacted] / 7	[redacted] / 10
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted] / 11	
M15-741 /ABBV-951	2023.38		SC / CONTINUOUS	[redacted] / 11	[redacted] / 12
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted] / 12	
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted] / 13	
M15-741 /ABBV-951	2014.85		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
M15-741 /ABBV-951	2049		SC / CONTINUOUS	[redacted] / 14	[redacted] / 16
M15-741 /ABBV-951	2006.31		SC / CONTINUOUS	[redacted] / 17	[redacted] / 17
M15-741 /ABBV-951	2023.38		SC / CONTINUOUS	[redacted] / 18	[redacted] / 18
M15-741 /ABBV-951	2049		SC / CONTINUOUS	[redacted] / 19	[redacted] / 19
M15-741 /ABBV-951	2006.31		SC / CONTINUOUS	[redacted] / 20	[redacted] / 21
M15-741 /ABBV-951	2049		SC / CONTINUOUS	[redacted] / 22	[redacted] / 25
M15-741 /ABBV-951	2006.31		SC / CONTINUOUS	[redacted] / 26	[redacted] / 27
M15-741 /ABBV-951	1997.77		SC / CONTINUOUS	[redacted] / 28	[redacted] / 28
M15-741 /ABBV-951	2049		SC / CONTINUOUS	[redacted] / 29	[redacted] / 37
M15-741 /ABBV-951	2014.85		SC / CONTINUOUS	[redacted] / 38	[redacted] / 38
M15-741 /ABBV-951	2006.31		SC / CONTINUOUS	[redacted] / 39	[redacted] / 39
M15-741 /ABBV-951	2023.38		SC / CONTINUOUS	[redacted] / 40	[redacted] / 40
M15-741 /ABBV-951	2049		SC / CONTINUOUS	[redacted] / 41	[redacted] / 93
M15-741 /ABBV-951	1989.23		SC / CONTINUOUS	[redacted] / 94	[redacted] / 94
M15-741 /ABBV-951	2049		SC / CONTINUOUS	[redacted] / 95	[redacted] / 102
M15-741 /ABBV-951	2014.85		SC / CONTINUOUS	[redacted] / 103	[redacted] / 103
M15-741 /ABBV-951	2023.38		SC / CONTINUOUS	[redacted] / 104	[redacted] / 104

M15-741 /ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 105	[redacted]20[redacted] / 116
M15-741 /ABBV-951	2057.53	SC / CONTINUOUS	[redacted]20[redacted] / 117	[redacted]20[redacted] / 117
M15-741 /ABBV-951	2428.06	SC / CONTINUOUS	[redacted]20[redacted] / 118	[redacted]20[redacted] / 118
M15-741 /ABBV-951	2387.08	SC / CONTINUOUS	[redacted]20[redacted] / 119	[redacted]20[redacted] / 119
M15-741 /ABBV-951	2397.33	SC / CONTINUOUS	[redacted]20[redacted] / 120	[redacted]20[redacted] / 120
M15-741 /ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 121	[redacted]20[redacted] / 186
M15-741 /ABBV-951	1219.15	SC / CONTINUOUS	[redacted]20[redacted] / 187	[redacted]20[redacted] / 187
M15-741 /ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 188	[redacted]20[redacted] / 270
M15-741 /ABBV-951	2397.33	SC / CONTINUOUS	[redacted]20[redacted] / 271	[redacted]20[redacted] / 271
M15-741 /ABBV-951	2387.08	SC / CONTINUOUS	[redacted]20[redacted] / 272	[redacted]20[redacted] / 272
M15-741 /ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 273	[redacted]20[redacted] / 369
M15-741 /ABBV-951	2417.82	SC / CONTINUOUS	[redacted]20[redacted] / 370	[redacted]20[redacted] / 370
M15-741 /ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 371	[redacted]20[redacted] / 371
ABBV-951	40.98	SC / CONTINUOUS	[redacted]20[redacted] / 467	[redacted]20[redacted] / 468
ABBV-951	901.56	SC / CONTINUOUS	[redacted]20[redacted] / 469	[redacted]20[redacted] / 469
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 470	[redacted]20[redacted] / 553
ABBV-951	2428.06	SC / CONTINUOUS	[redacted]20[redacted] / 554	[redacted]20[redacted] / 554
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 555	[redacted]20[redacted] / 702
ABBV-951	2554.42	SC / CONTINUOUS	[redacted]20[redacted] / 703	[redacted]20[redacted] / 703
ABBV-951	2832.74	SC / CONTINUOUS	[redacted]20[redacted] / 704	[redacted]20[redacted] / 704

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
ACETYLSALICYLIC ACID	100 mg	QD	Y-M: 20[redacted]-[redacted]
OLMESARTAN MEDOXOMIL	40 mg	QD	Y-M: 20[redacted]-[redacted]
ROSUVASTATIN CALCIUM	20 mg	QD	Y-M: 20[redacted]-[redacted]
ROPINIROLE	8.000 mg	QD	Y-M: 20[redacted]-[redacted]

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
ACETYLSALICYLIC ACID	100 mg	QD	Y-M: 20[redacted]-[redacted]	NOT REPORTED
OLMESARTAN MEDOXOMIL	40 mg	QD	Y-M: 20[redacted]-[redacted]	NOT REPORTED
ROSUVASTATIN CALCIUM	20 mg	QD	Y-M: 20[redacted]-[redacted]	NOT REPORTED
FENTANYL	50 OTHER: MCG/H	OTHER: C/72H	Y-M: 20[redacted]-[redacted] / 519	NOT REPORTED

METAMIZOLE MAGNESIUM	575 mg	TID	Y-M: 20[redacted] / 519	NOT REPORTED
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 580	NOT REPORTED
CYANOCOBALAMIN; FOLIC ACID	1 OTHER: CAPSULE	QD	Y-M: 20[redacted] / 602	NOT REPORTED
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 603	NOT REPORTED
BOTULINUM TOXIN TYPE A	5 IU	QD	Y-M: 20[redacted] / 623	Y-M: 20[redacted] / 623
DEXKETOPROFEN TROMETAMOL	25 mg	BID	Y-M: 20[redacted] / 686	NOT REPORTED

Event #1: Serious Adverse Event

Event Description	POSTOPERATIVE/PROCEDURAL PAIN
Preferred Term	処置による疼痛
AE Onset Date / Rx Day	[redacted]20[redacted] / 519
Age at AE Onset	5[redacted]

Laboratory Testing

NOT REPORTED

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 686): PEDICULAR SCREWS FROM THE FIRST SURGERY ON MARCH WERE REPLACED:MILD BACK PAIN

AE Stopped Rx Day	686
Duration of AE	168 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
Other Cause of Event	THIS WAS A CONSEQUENCE OF THE FIRST SURGERY
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Generated: [redacted]20[redacted]:09:38

Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者はスペインの 5[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に術後 / 処置による疼痛を発現した。

Event 1 の臨床経過：

関連する病歴は，虚血性心疾患，パーキンソン病，腰部脊柱管狭窄症，及び元喫煙者（1 日 40 本を 9 年間）であった。

投与 519 日目，被験者は術後 / 処置による疼痛を発現した。投与 686 日目，術後 / 処置による疼痛は消失した。

投与の約 18 ヵ月前，被験者は腰部脊柱管狭窄症を発現した。投与の約 17 ヵ月後，狭窄症に対して手術が実施された。L2～L5 及び S1 に椎弓根スクリューが埋め込まれ，L4～S4 の椎弓切除術が実施された。手術後，被験者は背部痛に苦しんだ。

投与 686 日目，被験者は入院し，椎弓根スクリューが交換された。手術後の疼痛は軽度であった。投与 689 日目，被験者は退院した。

被験者に ENANTYUM 及びロピニロールが投与された。

Causality for ABBV-951 (Open Label)

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1) Postoperative pain (10054711) (Procedural pain (10064882)) [v.24.0] [10054711]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of POSTOPERATIVE/PROCEDURAL PAIN

- Investigator: This was a consequence of the first surgery.

- **AbbVie:** More likely related to reported first lumbar surgery and history of stenosis spinal canal in the lumbar

M15-737 試験（更新時）

治験の標題： パーキンソン病患者を対象とした ABBV-951 の持続皮下注入による 1 日 24 時間投与時の安全性及び忍容性を評価する M15-741 試験の非盲検継続試験	
施設数 / 実施国名： 44 施設 / オーストラリア，ベルギー，カナダ，デンマーク，ドイツ，イタリア，日本，オランダ，スペイン，スウェーデン，イギリス及び米国	
治験責任医師： [redacted], MD，他	
公表文献 (参考資料) ： なし	
治験期間： 最初の被験者の初回来院日：20[redacted] 年 [redacted] 月 [redacted] 日 最後の被験者の最終来院日：20[redacted] 年 [redacted] 月 [redacted] 日（データカットオフ日）	開発のフェーズ：III
目的： 持続皮下注入（以下「CSCI」）として 1 日 24 時間，ABBV-951 を持続投与した場合の局所及び全身の安全性及び忍容性の評価	
被験者数 (計画時と解析時) ： 計画時：約 130 例，解析時：116 例	
診断と主要な組入れ基準： 親試験（M15-741 試験）の完了時に治験薬を継続中のパーキンソン病患者	
治験方法： 本試験は，親試験である M15-741 試験を完了したパーキンソン病患者を対象とし，ABBV-951 を 1 日 24 時間 CSCI 投与した場合の局所及び全身の安全性及び忍容性の評価を継続する非盲検，単群，多施設共同継続試験であった。 本試験にスクリーニング期は設定しなかった。親試験（M15-741 試験）の最終来院を本継続試験（M15-737 試験）の組入れ来院（投与 1 日目）とした。親試験の最終来院は，本継続試験の投与 1 日目と同日に実施し，被験者は直ちに M15-737 試験の投与期を開始することとした。投与 1 日目に適格性が確認された後，被験者は親試験の未使用の治験薬及び付属品を返却した。M15-737 試験用の治験薬のバイアルが入った箱及び注入セットが新たに提供された。何らかの理由で交換が必要でない限り，ポンプは交換されなかった（被験者は親試験で提供されたポンプを使用し続けた）。投与期間中，被験者は 1 日 24 時間，最適治療用量の ABBV-951 の CSCI 投与を受けた。試験期間を通じて，ABBV-951 の投与量は治験責任医師の判断に基づき調節してもよいこととした。96 週間の投与期は 5 回の治験来院と 4 回の遠隔評価から構成され，48 週間の延長投与期は 2 回の治験来院と 2 回の遠隔評価から構成された。 96 週間の投与期を終えた被験者で，投与 96 週時の治験来院時に治験薬投与を継続しており，治験責任医師により ABBV-951 の投与を継続することが適切であると判断された被験者については，延長投与期に移行し投与を継続してよいこととした。延長投与期の目的は，長期的安全性データの追加収集，及び ABBV-951 の市販薬の使用が可能になるまで治療を継続できるようにするためである。延長投与期は，96 週間の投与期の終了後最大 48 週間又は各地域で ABBV-951 の市販薬の使用が可能になった後最大 12 週間のいずれか短い方の期間とした。最終来院前に被験者が ABBV-951 の市販薬に移行する場合，最後の来院時に早期中止の評価を完了することとした。	

被験薬，用量，投与方法及びバッチ番号： ABBV-951 12/240 mg/mL（カルビドパ-4′-リン酸塩 / レボドパ-4′-リン酸塩）注入用溶液を個々の患者に合わせた用量でポンプに接続した注入セットを介して 1 日 24 時間 CSCI 投与 バルクロット番号：[redacted], [redacted], [redacted], [redacted], [redacted], [redacted], [redacted], [redacted] [redacted] delivery system 治療期間：最大 144 週間（96 週間の投与期 + 48 週間の延長投与期）
対照薬，用量，投与方法及びバッチ番号： 該当なし
評価基準： 有効性： 有効性評価項目は本試験における副次評価項目であり，パーキンソン病日誌により評価した標準化した 1 日あたりの平均オフ時間及びオン時間，国際パーキンソン病・運動障害学会統一パーキンソン病評価尺度（以下「MDS-UPDRS」）Part I-IV により評価したパーキンソン病症状，パーキンソン病質問票（以下「PDQ-39」）により評価した生活の質，EuroQol 5 項目質問票（以下「EQ-5D-5L」）により評価した健康に関連した生活の質並びにミニメンタルステート検査（以下「MMSE」）により評価した認知障害のベースラインから試験終了時までの変化量を評価した。 安全性： 安全性評価項目は本試験における主要評価項目であり，有害事象の発現割合並びに臨床検査値，バイタルサイン測定値及び心電図のベースラインから試験終了時までの変化量により評価した。局所刺激性についても注入部位評価尺度により評価した。自殺傾向及び衝動的強迫性行動をそれぞれコロンビア自殺評価スケール（以下「C-SSRS」）及びパーキンソン病における衝動制御障害の評価尺度（以下「QUIP-RS」）により評価した。
統計手法： 有効性： すべての有効性解析は，ABBV-951 を注入し，1 つ以上の有効性評価項目に関してベースライン及びベースライン後の所見が得られているすべての被験者から構成された最大の解析対象集団（以下「FAS」）を用いて実施した。 各被験者は，投与期における 1 日あたりの最頻投与量に基づき用量群別に分類された。すべての有効性評価項目について，各用量群及び被験者全体における各評価時点でのベースラインからの変化量を記述的に要約した。統計量には観測数，平均値，標準偏差，最小値，中央値及び最大値を含めた。 安全性： すべての安全性解析は，ABBV-951 を注入したすべての被験者から構成された安全性解析対象集団を用いて実施した。有害事象は，ABBV-951 の CSCI 投与開始日以降，最終注入後 30 日までに発現又は悪化したすべての事象と定義した。有害事象及び注入部位評価尺度を除く安全性評価項目に関するすべての解析は，ABBV-951 の注入終了後 1 日目までに収集されたデータを用いて実施した。すべての有害事象は ICH 国際医薬用語集（以下「MedDRA」）version 24.0 を用いて要約した。 安全性転帰に関する連続変数について，各用量群及び被験者全体におけるベースラインからの変化量を評価時点別に記述的に解析した。安全性転帰に関するカテゴリー変数について，各用量群及び被験者全体における各カテゴリーの数及び割合を評価時点別に要約した。仮説検定は実施しなかった。

表 1.　　治験実施スケジュール

実施項目	投与期				
	組入れ来院 (D1)	**遠隔評価 (W12,W36, W60,W84, +W12, +W36)**	**治験来院 (W24,W48, W72,W96, +W24)**	**最終治験来院 (+W48) 又は 治験の早期中止** [a]	**交付のための来院** [b]
問診及び質問票					
被験者への情報提供及び同意取得	√				
適格基準	√				
最新の病歴聴取	√				
注入部位の評価 (適切な場合は皮膚科学的評価)	M15-741 試験の評価		√	√	
有害事象の評価		√	√	√	
特に注目すべき有害事象		√	√	√	
製品の苦情・不具合		√	√	√	
前治療 / 併用療法		√	√	√	
患者報告アウトカム： 患者報告による評価 (特定の時点)					
被験者投与日誌		評価の 2 日前 √	来院の 2 日前 √	来院の 2 日前 √	
パーキンソン病日誌		評価の 2 日前 √	来院の 2 日前 √	来院の 2 日前 √	
EQ-5D-5L	M15-741 試験の評価		√	√	
患者報告アウトカム： 評価者報告による評価 (特定の時点)					
C-SSRS	M15-741 試験の評価		√	√	
QUIP-RS			√	√	
MDS-UPDRS			√	√	
MMSE	√		√	√	
PDQ-39	M15-741 試験の評価		√	√	

表 1. 治験実施スケジュール（続き）

実施項目	投与期				
	組入れ来院 (D1)	遠隔評価 (W12,W36, W60,W84, +W12, +W36)	治験来院 (W24,W48, W72,W96, +W24)	最終治験来院 (+W48) 又は 治験の早期中止 [a]	交付のための来院 [b]
検査及び診察					
臨床検査	M15-741 試験の評価		√	√	
特殊な臨床検査 (ビタミン B_6 及び B_{12}, 葉酸，メチルマロン酸，ホモシステイン)			√	√	
12 誘導心電図			√	√	
体重			√	√	
バイタルサイン			√	√	
身体検査			√	√	
神経学的検査			√	√	
妊娠検査 (尿) [c]			√	√	
治療					
治験薬投与システムに関するトレーニング	必要に応じて				
治験薬の注入	√		√		
薬剤，治験機器，及び付属品の供給の確認	√		√		√
薬剤及び治験機器処方の確認			√	√	√
治験薬投与システムの交付 / 返却	√		√	√	√
治験薬の処方記録	√		√	√	

D = 投与日，W = 投与週

a. 被験者が早期中止し，被験者から了承が得られた場合，治験薬の注入終了 30 日後にも治験実施医療機関スタッフから電話することとした。

b. 治験来院を実施したか否かに関わらず，治験薬は最低でも 2 週間に 1 回交付された。

c. 妊娠可能な女性には，妊娠検査（尿）を月 1 回実施した。治験来院の予定がある場合，検査は実施医療機関で実施することとした。治験来院の予定がない場合，規定外の治験来院又は自宅で実施してもよいこととした。

M15-741 試験ですべての日本人被験者が 52 週間の投与期を完了又は早期中止した時点でデータカットオフし，中間解析を実施した。

被験者の内訳

被験者の内訳を表 2 に示す。
本試験では，M15-741 試験を完了した 116 例が登録された。
解析対象集団については，FAS が 106 例であった。
治験薬の投与を完了した被験者はおらず，治験薬投与継続中は 105 例（90.5%），治験薬投与中止は 11 例（9.5%）であった。治験薬の投与を中止した主な理由で最も多かったのは有害事象 7 例（6.0%）であった。

日本人部分集団における被験者の内訳を表 3 に示す。
本試験には M15-741 試験を完了した 12 例の日本人が登録され，日本人解析対象集団の FAS は 11 例であった。
治験薬の投与を完了した被験者はおらず，治験薬投与継続中は 11 例（91.7%），治験薬投与中止は 1 例（8.3%）であり，治験薬の投与を中止した主な理由は有害事象であった。

被験者背景

人口統計学的特性及びその他のベースラインの特性

人口統計学的特性及びその他のベースラインの特性を表 4 に，パーキンソン病の病歴を表 5 に示す。
安全性解析対象集団では，年齢の平均値が 62.7 歳（範囲：34～86 歳），65 歳以上の割合が 44.8%，体重の平均値が 74.34 kg（範囲：38.9～110.9 kg），居住地域は欧米及びオーストラリア合わせて 89.7%，女性が 36.2%，民族は非ヒスパニック（非ラテン含む）が 92.2%，人種は白人が 85.3%，アジア人が 13.8%，パーキンソン病罹病期間は 10 年以上が 44.0%であった。

日本人部分集団における人口統計学的特性及びその他のベースラインの特性を表 6 に示す。
安全性解析対象集団では，年齢の平均値が 61.1 歳（範囲：47～72 歳），65 歳以上の割合が 33.3%，体重の平均値が 61.52 kg（範囲：38.9～82.5 kg），女性が 33.3%であった。

併用薬

パーキンソン病の前治療歴は，親試験（M15-741 試験）のスクリーニング期に収集した。ベースラインのデータは，M15-741 試験における投与 1 日目の ABBV-951 の注入開始前までに収集されたものである。
治験実施計画書の規定に基づき，すべての被験者は親試験（M15-741 試験）の登録時に経口パーキンソン病治療薬を使用していた。

M15-737 試験の試験期間中，他のパーキンソン病治療薬を使用していなかった被験者は 29 例（25.0%），1 種類の他のパーキンソン病治療薬を使用していた被験者は 51 例（44.0%），2 種類の他のパーキンソン病治療薬を使用していた被験者は 23 例（19.8%），3 種類の他のパーキンソン病薬を使用していた被験者は 11 例（9.5%）であった（M15-737 試験 CSR update Table 14.1__3.2.3）。

曝露状況

処方用量

本試験における開始時の標準及び追加の持続注入速度，追加投与量並びに追加投与間のロックアウト時間は，調節が必要であると治験責任医師が判断しない限り，親試験である M15-741 試験の最終投与日に処方されたものと同様とした。

特に明記されていない限り，ABBV-951 の投与量は，ホスレボドパを分子量に基づきレボドパに換算したレボドパ換算投与量として示す（ホスレボドパ 100 mg はレボドパ 71 mg に相当）。

1 日あたりの総投与量，標準注入速度及び追加の注入速度を表 7 及び表 8 に示す。また，追加の高い注入速度及び追加の低い注入速度を標準注入速度の割合として表したものを M15-737 試験 CSR update Table 14.1__6.2 に示す。データカットオフ時点（20[redacted]年[redacted]月[redacted]日）で，標準注入速度の変化量は小さかった（レボドパの平均変化量は 2.6 mg/時間又は 62.4 mg/日に相当）。

日本人部分集団における 1 日あたりの総投与量，標準注入速度及び追加の注入速度を表 9 に示す。全体集団と同様に，標準注入速度の変化量は小さかった（レボドパの平均変化量は 1.3 mg/時間又は 30.7 mg/日に相当）。

1 日あたりの総投与量

救済療法が必要となった場合に備え，治験責任医師又はかかりつけ医によりレボドパ及びドパ脱炭酸酵素阻害薬の速放性経口錠剤又はレボドパ吸入パウダーがすべての被験者に処方されることとした。ABBV-951 の投与期間中，ABBV-951 の追加投与又は注入速度の増加では反応がないような急激な運動症状の悪化など，重大な医療上の必要性が生じた場合のみ，救済療法を使用することとした。

ABBV-951 及び併用薬のレボドパ換算 1 日投与量を表 10 に示す。また，レボドパの 1 日あたりの最頻投与量の分布を表 11 及び M15-737 試験 CSR update Figure 14.1__13.2 に示す。レボドパ換算投与量を 100 mg 間隔で表した各被験者の 1 日あたりの最頻投与量を，被験者が実際に使用した注入速度及び注入持続時間から計算し，レボドパ換算投与量として示した。1 日あたりの最頻レボドパ換算投与量は約 700 mg から 4200 mg の範囲で分布しており，第 I 相試験及び他の第 III 相試験でみられた投与量の分布と同様であることから，ABBV-951 が進行期パーキンソン病患者における運動症状を十分にコントロールするために必要な広範囲のレボドパ投与量に対応できることが確認された。

治験薬の曝露期間及び投与中断

データカットオフ時点（20[redacted] 年 [redacted] 月 [redacted] 日）で，治験薬への平均曝露日数は 320.8 日であった（表 12）。約 71.6%の被験者が治験薬の曝露を 169 日以上受けた。

投与中断した被験者は 15 例であった。投与中断理由はその他（8 例），ポンプの故障（5 例）及び COVID-19 以外の有害事象（2 例）であった（表 13）。投与中断期間は 1 日未満から 30 日以上までの日数間隔により分類された。投与中断した 15 例中 10 例（66.7%）の投与中断期間は，1 日未満であった（表 14）。いずれの時点においても，経口負荷投与した被験者は 3 例以下であった（表 15）。

日本人部分集団における治験薬への平均曝露日数は 274.1 日であった（表 16）。約 58.3%の被験者が治験薬の曝露を 169 日以上受けた。

投与中断した日本人被験者は 1 例で，投与中断理由はその他であった（表 17）。投与中断期間は 1 日未満であった（M15-737 試験 CSR update Table 14.1__12.2.J）。経口負荷投与した被験者は投与 60 週時に 1 例であった（表 18）。

有効性の結果

パーキンソン病日誌

各被験者は，起床時及び起きている時間は 30 分ごとに，睡眠，ジスキネジアを伴わないオン時間，日常生活に支障のないジスキネジアを伴うオン時間，日常生活に支障のあるジスキネジアを伴うオン時間又はオフ時間をパーキンソン病日誌に記録した。パーキンソン病日誌は 24 時間を 1 日と定義し（午前 6 時から翌日の午前 5 時 30 分まで），各被験者は 1 日に 48 回，各記録が 0.5 時間に相当するように各規定日に記入することとした。被験者ごとに睡眠パターンが異なることを考慮し，1 日あたりのオン時間とオフ時間を一般的な覚醒期間（16 時間）に標準化した。

標準化した 1 日あたりの平均オフ時間，日常生活に支障のないジスキネジアを伴うオン時間及び日常生活に支障のあるジスキネジアを伴うオン時間の M15-737 試験のベースライン（親試験である M15-741 試験の最終評価）からの変化量は小さく，M15-741 試験における 12 ヵ月間の ABBV-951 投与後も，治療効果の経時的な低下は認められなかった（表 19）。1 日あたりの時間を絶対値で解析した場合の結果も同様であった（M15-737 試験 CSR update Table 14.2__1.2）。

日本人部分集団においても同様に，標準化した 1 日あたりの平均オフ時間，日常生活に支障のないジスキネジアを伴うオン時間及び日常生活に支障のあるジスキネジアを伴うオン時間のベースラインからの変化量は小さかった（M15-737 試験 CSR update Figure 14.2__6.1.J）。

部分集団解析結果（用量別［低用量又は高用量］，性別［男性又は女性］，人種別［白人又はアジア人］，年齢別［65 歳未満又は 65 歳以上］，地域別［北米，欧州及びオーストラリア，

又は日本］，パーキンソン病罹病期間［10 年未満又は 10 年以上］）は全体集団の結果とおおむね同様であった（表 20）。

ベースライン（親試験である M15-741 試験の最終評価）から投与 96 週時までの期間に早朝の非睡眠症状を報告した被験者の割合を表 21 に示す。データカットオフ時点において，投与 84 週時及び投与 96 週時まで達している被験者数は少なかった。

日本人部分集団においてベースラインから投与 84 週時までの期間に早朝の非睡眠症状を報告した被験者の割合を表 22 に示す。データカットオフ時点において，投与 84 週時まで達している被験者数は 1 例であった。投与 96 週時まで達している被験者はいなかった。

MDS-UPDRS

MDS-UPDRS は以下の項から構成される。

- Part I：日常生活における非運動症状
- Part II：日常生活における運動症状
- Part III：運動症状の検査（Hoehn-Yahr 重症度分類を含む）
- Part IV：運動合併症

MDS-UPDRS の総スコア（Part I～III）は 0 から 236 の範囲であり，236 が最も重症度の高い（合計）障害を示し，0 は障害がないことを示す。MDS-UPDRS は，ABBV-951 の投与開始前に被験者の実質的なオフ状態で実施された親試験（M15-741 試験）の投与 1 日目を除き，被験者の最良のオン状態で実施することとした。

MDS-UPDRS スコアはベースラインから投与 72 週時まで安定しており，M15-741 試験における 12 ヵ月間の ABBV-951 投与後も治療効果が持続することを示した（表 23）。

日本人部分集団においても同様に，MDS-UPDRS スコアはベースラインから投与 72 週時まで安定していた（表 24）。

全体集団及び日本人部分集団の MDS-UPDRS スコア（Hoehn-Yahr 重症度分類）をそれぞれ表 25 及び表 26 に示す。

生活の質

PDQ-39 は，パーキンソン病患者に関連する健康面を評価するためにデザインされた 39 項目の疾患特異的評価尺度である。要約指標及び各構成要素のスコアは 0 から 100 までの点数で評価され，スコアが低いほど健康状態が良好であることを意味する。

EQ-5D-5L は，EQ-5D 記述式評価と EQ 視覚的評価尺度（以下「EQ VAS」）の 2 部から構成された標準化尺度である。記述式評価は「移動の程度」，「身の回りの管理」，「ふだんの活動」，「痛み / 不快感」及び「不安 / ふさぎ込み」の 5 項目から構成される。5 項目の機能状

態それぞれを 5 段階尺度（1 = 問題はない，2 = 少し問題がある，3 = 中程度の問題がある，4 = かなり問題がある，5 = 極度の問題がある）で評価する。健康状態は，米国固有の重み付けをした評価アルゴリズム（最低値–0.109～最高値 1）を用いて要約指標に変換した。EQ VAS は，被験者の自己評価による健康状態を，「想像できる最良の健康状態」から「想像できる最悪の健康状態」までの範囲が表記された縦軸視覚的評価尺度に記録する。

PDQ-39 及び EQ-5D-5L 評価の全体的な結果は，ベースラインから投与 72 週時まで安定しており，M15-741 試験における 12 ヵ月間の ABBV-951 投与後も治療効果が持続することを示した（表 27 及び表 28）。

日本人部分集団においても同様に，PDQ-39 及び EQ-5D-5L 評価の全体的な結果は，ベースラインから投与 72 週時まで安定していた（表 29 及び表 30）。

認知機能障害

MMSE は，成人の認知機能を定量的に評価するための 30 点満点の質問票であり，認知機能障害のスクリーニング又は特定時点の認知機能障害の重症度を推定し，患者の認知機能の経時的な変化を追跡し，治療への反応を記録するために広く使用されている。MMSE のスコアは 0 から 30 点の範囲であり，低いスコアほど認知機能障害が大きいことを示す。

MMSE 評価の結果は，M15-737 試験のベースラインから投与 72 週時までの MMSE 総スコアに変化がないことを示し，ABBV-951 の作用機序から期待されるとおりであった（表 31）。

日本人部分集団においても同様に，ベースラインから投与 72 週時までの MMSE 総スコアに大きな変化は認められなかった（表 32）。

安全性の結果

全体集団の有害事象の発現状況を以下に示す。

有害事象の発現割合は 75.9%（88 / 116 例）であった。ほとんどの有害事象は非重篤で，軽度又は中等度であった。有害事象の全体的な発現割合は，ABBV-951 の用量別及び部分集団間で同様であった。発現割合が 10%以上の有害事象は，注入部位紅斑（16.4%［19 / 116 例］），注入部位蜂巣炎（13.8%［16 / 116 例］），及び転倒（12.1%［14 / 116 例］）であった。ほとんどの注入部位の有害事象は回復した。

治験薬と関連ありの有害事象の発現割合は 51.7%（60 / 116 例）であった。発現割合が 5%以上の治験薬と関連ありの有害事象は，注入部位紅斑（13.8%［16 / 116 例］），注入部位蜂巣炎（12.9%［15 / 116 例］），及びオンオフ現象（6.0%［7 / 116 例］）であった。

死亡に至った有害事象を発現した被験者は 3 例であった。死亡に至った有害事象はいずれも，治験責任医師により治験薬と関連なしと判断された。

重篤な有害事象の発現割合は 22.4%（26 / 116 例）であった。2 例以上に発現した重篤な有害事象は，注入部位蜂巣炎（4.3%［5 / 116 例］），転倒及びパーキンソン病（各 2.6%［3 / 116

例］），並びに股関節部骨折，変形性関節症及び精神病性障害（各 1.7%［2 / 116 例］）であった。

中止に至った有害事象の発現割合は 6.0%（7 / 116 例）であった。中止に至った有害事象は，注入部位蜂巣炎及びパーキンソン病（各 1.7%［2 / 116 例］），並びに注入部位発疹，注入部位膿瘍，窒息及び誤嚥（各 0.9%［1 / 116 例］）であった。

有害事象の 90 日間ごとの初回発現割合は，投与開始後 90 日までが 49.1%（57 / 116 例）と最も高く，その後，発現割合は減少した。90 日間ごとの有病割合は，投与開始後 90 日までが 49.1%（57 / 116 例），91 日～180 日が 58.0%（65 / 112 例），181 日～270 日が 73.1%（57 / 78 例），271 日～360 日が 75.4%（52 / 69 例）であった。

臨床検査値，バイタルサイン，心電図，C-SSRS 又は QUIP-RS の評価において，安全性の懸念は認められなかった。

日本人部分集団の有害事象の発現状況を以下に示す。

日本人部分集団の有害事象の発現割合は 75.0%（9 / 12 例）であった。認められた有害事象は，注入部位蜂巣炎（25.0%［3 / 12 例］），注入部位硬結及び注射部位紅斑（各 16.7%［2 / 12 例］），並びに眼充血，便秘，注入部位皮膚炎，注射部位硬結，ＣＯＶＩＤ－１９，注射部位蜂巣炎，転倒，肩甲骨骨折，血中ホモシステイン増加，ビタミンＢ１２欠乏，腱鞘炎，感覚鈍麻，錯感覚，妄想，幻覚，尿失禁，窒息，誤嚥，痰貯留及び湿疹（各 8.3%［1 / 12 例］）であった。

治験薬と関連ありの有害事象の発現割合は 58.3%（7 / 12 例）であった。認められた治験薬と関連ありの有害事象は，注入部位蜂巣炎（25.0%［3 / 12 例］），注入部位硬結及び注射部位紅斑（各 16.7%［2 / 12 例］），並びに注入部位皮膚炎，注射部位硬結，注射部位蜂巣炎，血中ホモシステイン増加，ビタミンＢ１２欠乏及び幻覚（各 8.3%［1 / 12 例］）であった。

死亡に至った有害事象を発現した被験者は 1 例であった。認められた死亡に至った有害事象は窒息及び誤嚥で，いずれも治験責任医師により治験薬と関連なしと判断された。

重篤な有害事象の発現割合は 33.3%（4 / 12 例）であった。認められた重篤な有害事象は，ＣＯＶＩＤ－１９，注入部位蜂巣炎，肩甲骨骨折，窒息及び誤嚥（各 8.3%［1 / 12 例］）であった。

中止に至った有害事象の発現割合は 8.3%（1 / 12 例）であった。認められた中止に至った有害事象は，窒息及び誤嚥（各 8.3%［1 / 12 例］）であった。

本試験で発現した有害事象を以下のとおり示す。

項目	全体集団	日本人部分集団
有害事象の概要	表 33	表 41
すべての有害事象	表 34	表 42
治験薬との因果関係別の有害事象	表 35	表 43
死亡した被験者一覧	表 36	–
重篤な有害事象	表 37	表 44
中止に至った有害事象	表 38	表 45
有害事象の 90 日間ごとの初回発現割合の推移	表 39	–
有害事象の 90 日間ごとの有病割合の推移	表 40	–

結論

データカットオフ時点（20[redacted] 年 [redacted] 月 [redacted] 日）で，オフ時間，日常生活に支障のないジスキネジアを伴うオン時間及び日常生活に支障のあるジスキネジアを伴うオン時間の M15-737 試験のベースライン（親試験である M15-741 試験の最終評価）からの平均変化量は小さかった。PDQ-39 及び EQ-5D-5L 評価の全体的な結果は，ベースラインから投与 72 週時まで安定していた。MMSE 評価の結果は，M15-737 試験のベースラインから投与 72 週時までの MMSE 総スコアに大きな変化がなかったことを示した。これらの結果は，M15-741 試験における 12 ヵ月間の ABBV-951 投与後も有効性が持続することを示した。

ABBV-951 はおおむね安全で，忍容性は良好であった。ABBV-951 の全身性の安全性プロファイルは，レボドパ / カルビドパ薬剤の確立された安全性プロファイルとおおむね一致していた。ほとんどの注入部位の有害事象は非重篤で，重症度は軽度又は中等度であり，回復した。ABBV-951 に関する新たな安全性の懸念は認められなかった。

表2　被験者の内訳　（All Enrolled Subjects）：M15-737試験

[redacted]20[redacted] 10:46 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.1__1.1

Subject Disposition
(All Enrolled Subjects)

	Dose Category		
	Low Dose (N=55) n (%)	High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Total subjects enrolled	55 (100)	61 (100)	116 (100)
Analysis population			
Full analysis set	48 (87.3)	58 (95.1)	106 (91.4)
Safety analysis set	55 (100)	61 (100)	116 (100)
ABBV-951 ongoing	52 (94.5)	53 (86.9)	105 (90.5)
ABBV-951 completed	0	0	0
ABBV-951 prematurely discontinued	3 (5.5)	8 (13.1)	11 (9.5)

One subject can be only counted once.
$ All reasons that are contributing to the disposition event, including the primary reason. One subject can be counted multiple times.

Program Source Code: [redacted]

TABLE 14.1 1.1

Subject Disposition
(All Enrolled Subjects)

	Dose Category: Low Dose (N=55) n (%)	Dose Category: High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Primary reasons for ABBV-951 prematurely discontinuation #			
Adverse event	3 (5.5)	4 (6.6)	7 (6.0)
Infusion site related infections	2 (3.6)	1 (1.6)	3 (2.6)
Infusion site related non infection reactions	0	1 (1.6)	1 (0.9)
Polyneuropathy	0	0	0
Weight loss	0	0	0
Hallucinations/psychosis	0	0	0
Somnolence	0	0	0
Falls and associated injuries	0	0	0
Withdrew consent	0	1 (1.6)	1 (0.9)
Lost to follow-up	0	0	0
Lack of efficacy	0	1 (1.6)	1 (0.9)
COVID-19 infection	0	0	0
COVID-19 logistical restrictions	0	0	0
Difficulty with drug delivery system	0	0	0
Other	0	2 (3.3)	2 (1.7)

One subject can be only counted once.
$ All reasons that are contributing to the disposition event, including the primary reason. One subject can be counted multiple times.

Program Source Code: [redacted]

TABLE 14.1 1.1

Subject Disposition
(All Enrolled Subjects)

	Dose Category: Low Dose (N=55) n (%)	Dose Category: High Dose (N=61) n (%)	All Subjects (N=116) n (%)
All reasons for ABBV-951 prematurely discontinuation $			
Adverse event	3 (5.5)	4 (6.6)	7 (6.0)
Infusion site related infections	2 (3.6)	1 (1.6)	3 (2.6)
Infusion site related non infection reactions	0	1 (1.6)	1 (0.9)
Polyneuropathy	0	0	0
Weight loss	0	0	0
Hallucinations/psychosis	0	0	0
Somnolence	0	0	0
Falls and associated injuries	0	0	0
Withdrew consent	0	1 (1.6)	1 (0.9)
Lost to follow-up	0	0	0
Lack of efficacy	0	1 (1.6)	1 (0.9)
COVID-19 infection	0	0	0
COVID-19 logistical restrictions	0	0	0
Difficulty with drug delivery system	0	0	0
Other	0	4 (6.6)	4 (3.4)
Study ongoing	53 (96.4)	53 (86.9)	106 (91.4)
Study completed	0	0	0
Study prematurely discontinued	2 (3.6)	8 (13.1)	10 (8.6)

One subject can be only counted once.
$ All reasons that are contributing to the disposition event, including the primary reason. One subject can be counted multiple times.

Program Source Code: [redacted]

TABLE 14.1 1.1

Subject Disposition
(All Enrolled Subjects)

	Dose Category: Low Dose (N=55) n (%)	Dose Category: High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Primary reasons for study discontinuation #			
Adverse event	2 (3.6)	4 (6.6)	6 (5.2)
Withdrew consent	0	1 (1.6)	1 (0.9)
Lost to follow-up	0	0	0
Lack of efficacy	0	1 (1.6)	1 (0.9)
COVID-19 infection	0	0	0
COVID-19 logistical restrictions	0	0	0
Difficulty with drug delivery system	0	0	0
Other	0	2 (3.3)	2 (1.7)
All reasons for study discontinuation $			
Adverse event	2 (3.6)	4 (6.6)	6 (5.2)
Withdrew consent	0	1 (1.6)	1 (0.9)
Lost to follow-up	0	0	0
Lack of efficacy	2 (3.6)	8 (13.1)	10 (8.6)
COVID-19 infection	2 (3.6)	8 (13.1)	10 (8.6)
COVID-19 logistical restrictions	2 (3.6)	8 (13.1)	10 (8.6)
Difficulty with drug delivery system	0	0	0
Other	0	5 (8.2)	5 (4.3)
Number of sites that enrolled at least 1 subject			44
Number of country that enrolled at least 1 subject			12

One subject can be only counted once.
$ All reasons that are contributing to the disposition event, including the primary reason. One subject can be counted multiple times.

Program Source Code: [redacted]

表3　被験者の内訳（All Enrolled Subjects，日本人部分集団）：M15-737試験

[redacted]20[redacted] 10:45 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.1__1.1.J

Subject Disposition
(Enrolled Japan Subjects)

	Dose Category		
	Low Dose (N=8) n (%)	High Dose (N=4) n (%)	All Subjects (N=12) n (%)
Total subjects enrolled	8 (100)	4 (100)	12 (100)
Analysis population			
Full analysis set	7 (87.5)	4 (100)	11 (91.7)
Safety analysis set	8 (100)	4 (100)	12 (100)
ABBV-951 ongoing	7 (87.5)	4 (100)	11 (91.7)
ABBV-951 completed	0	0	0
ABBV-951 prematurely discontinued	1 (12.5)	0	1 (8.3)

One subject can be only counted once.
$ All reasons that are contributing to the disposition event, including the primary reason. One subject can be counted multiple times.

Program Source Code: [redacted]

TABLE 14.1 1.1.J

Subject Disposition
(Enrolled Japan Subjects)

	Dose Category: Low Dose (N=8) n (%)	Dose Category: High Dose (N=4) n (%)	All Subjects (N=12) n (%)
Primary reasons for ABBV-951 prematurely discontinuation #			
Adverse event	1 (12.5)	0	1 (8.3)
Infusion site related infections	0	0	0
Infusion site related non infection reactions	0	0	0
Polyneuropathy	0	0	0
Weight loss	0	0	0
Hallucinations/psychosis	0	0	0
Somnolence	0	0	0
Falls and associated injuries	0	0	0
Withdrew consent	0	0	0
Lost to follow-up	0	0	0
Lack of efficacy	0	0	0
COVID-19 infection	0	0	0
COVID-19 logistical restrictions	0	0	0
Difficulty with drug delivery system	0	0	0
Other	0	0	0

One subject can be only counted once.
$ All reasons that are contributing to the disposition event, including the primary reason. One subject can be counted multiple times.

Program Source Code: [redacted]

TABLE 14.1 1.1.J

Subject Disposition
(Enrolled Japan Subjects)

	Dose Category: Low Dose (N=8) n (%)	Dose Category: High Dose (N=4) n (%)	All Subjects (N=12) n (%)
All reasons for ABBV-951 prematurely discontinuation $			
Adverse event	1 (12.5)	0	1 (8.3)
Infusion site related infections	0	0	0
Infusion site related non infection reactions	0	0	0
Polyneuropathy	0	0	0
Weight loss	0	0	0
Hallucinations/psychosis	0	0	0
Somnolence	0	0	0
Falls and associated injuries	0	0	0
Withdrew consent	0	0	0
Lost to follow-up	0	0	0
Lack of efficacy	0	0	0
COVID-19 infection	0	0	0
COVID-19 logistical restrictions	0	0	0
Difficulty with drug delivery system	0	0	0
Other	0	0	0
Study ongoing	7 (87.5)	4 (100)	11 (91.7)
Study completed	0	0	0
Study prematurely discontinued	1 (12.5)	0	1 (8.3)

One subject can be only counted once.
$ All reasons that are contributing to the disposition event, including the primary reason. One subject can be counted multiple times.

Program Source Code: [redacted]

TABLE 14.1 1.1.J

Subject Disposition
(Enrolled Japan Subjects)

	Dose Category		
	Low Dose (N=8) n (%)	High Dose (N=4) n (%)	All Subjects (N=12) n (%)
Primary reasons for study discontinuation #			
Adverse event	1 (12.5)	0	1 (8.3)
Withdrew consent	0	0	0
Lost to follow-up	0	0	0
Lack of efficacy	0	0	0
COVID-19 infection	0	0	0
COVID-19 logistical restrictions	0	0	0
Difficulty with drug delivery system	0	0	0
Other	0	0	0
All reasons for study discontinuation $			
Adverse event	1 (12.5)	0	1 (8.3)
Withdrew consent	0	0	0
Lost to follow-up	0	0	0
Lack of efficacy	1 (12.5)	0	1 (8.3)
COVID-19 infection	1 (12.5)	0	1 (8.3)
COVID-19 logistical restrictions	1 (12.5)	0	1 (8.3)
Difficulty with drug delivery system	0	0	0
Other	0	0	0
Number of sites that enrolled at least 1 subject			3
Number of country that enrolled at least 1 subject			1

One subject can be only counted once.
$ All reasons that are contributing to the disposition event, including the primary reason. One subject can be counted multiple times.

Program Source Code: [redacted]

表4　人口統計学的特性及びその他のベースラインの特性（安全性解析対象集団）：M15-737試験

[redacted]20[redacted] 10:45 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.1__2

Demographic and Baseline Characteristics
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=55)	High Dose (N=61)	All Subjects (N=116)
Age (year)			
n	55	61	116
Mean (SD)	62.5 (8.95)	62.8 (9.85)	62.7 (9.39)
Median	63.0	63.0	63.0
Min, Max	34, 78	43, 86	34, 86
Age (year) - n (%)			
< 65	29 (52.7)	35 (57.4)	64 (55.2)
>= 65	26 (47.3)	26 (42.6)	52 (44.8)
Age (year) - n (%)			
< 75	52 (94.5)	53 (86.9)	105 (90.5)
>= 75	3 (5.5)	8 (13.1)	11 (9.5)
Weight (kg)			
n	55	61	116
Mean (SD)	70.04 (17.538)	78.22 (16.486)	74.34 (17.409)
Median	68.04	79.60	75.65
Min, Max	38.9, 110.6	44.5, 110.9	38.9, 110.9
Height (cm)			
n	55	61	116
Mean (SD)	167.08 (11.039)	174.23 (8.927)	170.84 (10.567)
Median	166.10	175.00	172.00
Min, Max	140.1, 187.9	155.0, 196.0	140.1, 196.0

Note: Percentages calculated on non-missing or non-unknown values.
For categorical variables, 'Missing' row is only presented when there are missing data presented.

Program Source Code: [redacted]

TABLE 14.1 2

Demographic and Baseline Characteristics
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=55)	High Dose (N=61)	All Subjects (N=116)
BMI (kg/m^2)			
n	55	61	116
Mean (SD)	24.90 (5.196)	25.65 (4.668)	25.30 (4.918)
Median	23.61	26.31	24.68
Min, Max	17.6, 39.9	16.1, 35.0	16.1, 39.9
BMI (kg/m^2) - n (%)			
< 18.5	2 (3.6)	3 (4.9)	5 (4.3)
18.5 - < 25.0	31 (56.4)	24 (39.3)	55 (47.4)
25.0 - < 30.0	11 (20.0)	21 (34.4)	32 (27.6)
>= 30.0	11 (20.0)	13 (21.3)	24 (20.7)
Mini-Mental State Examination (MMSE) total score			
n	55	60	115
Mean (SD)	29.05 (1.113)	28.52 (1.927)	28.77 (1.606)
Median	29.00	29.00	29.00
Min, Max	26.0, 30.0	21.0, 30.0	21.0, 30.0

Note: Percentages calculated on non-missing or non-unknown values.
For categorical variables, 'Missing' row is only presented when there are missing data presented.

Program Source Code: [redacted]

TABLE 14.1 2

Demographic and Baseline Characteristics
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=55)	High Dose (N=61)	All Subjects (N=116)
Country - n (%)			
AUSTRALIA	7 (12.7)	10 (16.4)	17 (14.7)
BELGIUM	3 (5.5)	1 (1.6)	4 (3.4)
CANADA	1 (1.8)	3 (4.9)	4 (3.4)
DENMARK	2 (3.6)	5 (8.2)	7 (6.0)
GERMANY	2 (3.6)	0	2 (1.7)
ITALY	3 (5.5)	1 (1.6)	4 (3.4)
JAPAN	8 (14.5)	4 (6.6)	12 (10.3)
NETHERLANDS	2 (3.6)	0	2 (1.7)
SPAIN	5 (9.1)	6 (9.8)	11 (9.5)
SWEDEN	1 (1.8)	0	1 (0.9)
UNITED KINGDOM	2 (3.6)	5 (8.2)	7 (6.0)
UNITED STATES	19 (34.5)	26 (42.6)	45 (38.8)
Geographic region - n (%)			
North America	20 (36.4)	29 (47.5)	49 (42.2)
Europe and Australia	27 (49.1)	28 (45.9)	55 (47.4)
Japan	8 (14.5)	4 (6.6)	12 (10.3)
Sex - n (%)			
Female	27 (49.1)	15 (24.6)	42 (36.2)
Male	28 (50.9)	46 (75.4)	74 (63.8)
Ethnicity - n (%)			
Hispanic or Latino	5 (9.1)	4 (6.6)	9 (7.8)
Not Hispanic or Latino	50 (90.9)	57 (93.4)	107 (92.2)

Note: Percentages calculated on non-missing or non-unknown values.
For categorical variables, 'Missing' row is only presented when there are missing data presented.

Program Source Code: [redacted]

TABLE 14.1 2

Demographic and Baseline Characteristics
(Safety Analysis Set)

	Dose Category: Low Dose (N=55)	Dose Category: High Dose (N=61)	All Subjects (N=116)
Race - n (%)			
White	44 (80.0)	55 (90.2)	99 (85.3)
Black or African American	0	0	0
Asian	10 (18.2)	6 (9.8)	16 (13.8)
American Indian or Alaska Native	1 (1.8)	0	1 (0.9)
Native Hawaiian or Other Pacific Islander	0	0	0
Tobacco - n (%)			
Current	4 (7.3)	1 (1.6)	5 (4.3)
Former	13 (23.6)	21 (34.4)	34 (29.3)
Never	38 (69.1)	39 (63.9)	77 (66.4)
Unknown	0	0	0
Alcohol - n (%)			
Current	40 (72.7)	35 (57.4)	75 (64.7)
Former	5 (9.1)	12 (19.7)	17 (14.7)
Never	10 (18.2)	14 (23.0)	24 (20.7)
Unknown	0	0	0
Brief neurological examination			
Mental status - n (%)			
Normal	55 (100)	59 (96.7)	114 (98.3)
Abnormal	0	2 (3.3)	2 (1.7)
Cranial nerves - n (%)			
Normal	49 (89.1)	57 (93.4)	106 (91.4)
Abnormal	6 (10.9)	4 (6.6)	10 (8.6)

Note: Percentages calculated on non-missing or non-unknown values.
For categorical variables, 'Missing' row is only presented when there are missing data presented.

Program Source Code: [redacted]

TABLE 14.1 2

Demographic and Baseline Characteristics
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=55)	High Dose (N=61)	All Subjects (N=116)
Motor system - n (%)			
Normal	29 (52.7)	39 (63.9)	68 (58.6)
Abnormal	26 (47.3)	22 (36.1)	48 (41.4)
Sensory system - n (%)			
Normal	50 (92.6)	54 (88.5)	104 (90.4)
Abnormal	4 (7.4)	7 (11.5)	11 (9.6)
Missing	1	0	1
Reflexes - n (%)			
Normal	51 (94.4)	52 (85.2)	103 (89.6)
Abnormal	3 (5.6)	9 (14.8)	12 (10.4)
Missing	1	0	1
Coordination - n (%)			
Normal	45 (83.3)	51 (83.6)	96 (83.5)
Abnormal	9 (16.7)	10 (16.4)	19 (16.5)
Missing	1	0	1
Gait - n (%)			
Normal	25 (45.5)	28 (45.9)	53 (45.7)
Abnormal	30 (54.5)	33 (54.1)	63 (54.3)
Station - n (%)			
Normal	42 (79.2)	45 (76.3)	87 (77.7)
Abnormal	11 (20.8)	14 (23.7)	25 (22.3)
Missing	2	2	4

Note: Percentages calculated on non-missing or non-unknown values.
For categorical variables, 'Missing' row is only presented when there are missing data presented.

Program Source Code: [redacted]

表5　パーキンソン病の病歴（安全性解析対象集団）：M15-737試験

[redacted]20[redacted] 10:46 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.1__3.1

Parkinson's Disease History
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=55)	High Dose (N=61)	All Subjects (N=116)
Duration of PD since diagnosis - n (%)			
< 10 years	30 (54.5)	35 (57.4)	65 (56.0)
>= 10 years	25 (45.5)	26 (42.6)	51 (44.0)
History of levodopa induced dyskinesia - n (%)			
Yes	44 (80.0)	43 (70.5)	87 (75.0)
No	11 (20.0)	18 (29.5)	29 (25.0)
Levodopa response for more than 5 years - n (%)			
Yes	50 (90.9)	47 (77.0)	97 (83.6)
No	5 (9.1)	14 (23.0)	19 (16.4)
Baseline parkinson's disease Hoehn and Yahr Stage (MDS-UPDRS) - n (%)			
0	0	0	0
1	0	0	0
2	30 (54.5)	34 (55.7)	64 (55.2)
3	14 (25.5)	11 (18.0)	25 (21.6)
4	9 (16.4)	8 (13.1)	17 (14.7)
5	2 (3.6)	8 (13.1)	10 (8.6)
Age at PD onset (years)			
n	55	61	116
Mean (SD)	50.5 (9.16)	51.8 (9.43)	51.2 (9.28)
Median	52.0	52.9	52.0
Min, Max	21, 69	34, 70	21, 70

Note: Percentages calculated on non-missing or non-unknown values.

Program Source Code: [redacted]

TABLE 14.1 3.1

Parkinson's Disease History
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=55)	High Dose (N=61)	All Subjects (N=116)
Duration of PD since onset (years)			
n	55	61	116
Mean (SD)	12.61 (5.308)	11.57 (5.252)	12.07 (5.281)
Median	12.10	10.07	11.63
Min, Max	3.1, 29.7	2.1, 24.8	2.1, 29.7
Age at first diagnosis by a physician (years)			
n	55	61	116
Mean (SD)	52.6 (9.08)	53.3 (8.97)	53.0 (8.99)
Median	55.0	53.1	54.0
Min, Max	27, 70	37, 70	27, 70
Duration of PD since first diagnosis by a physician (years)			
n	55	61	116
Mean (SD)	10.47 (5.181)	10.07 (4.924)	10.26 (5.030)
Median	9.46	9.07	9.24
Min, Max	1.6, 25.8	2.1, 20.9	1.6, 25.8
Age at onset of motor fluctuation (years)			
n	55	60	115
Mean (SD)	56.3 (9.19)	56.9 (9.92)	56.6 (9.54)
Median	58.0	57.7	58.0
Min, Max	34, 74	39, 77	34, 77
Duration since onset of motor fluctuation (years)			
n	55	60	115
Mean (SD)	6.79 (4.819)	6.53 (4.201)	6.65 (4.489)
Median	6.29	5.61	5.92
Min, Max	1.0, 25.8	0.4, 20.4	0.4, 25.8

Note: Percentages calculated on non-missing or non-unknown values.

Program Source Code: [redacted]

TABLE 14.1 3.1

Parkinson's Disease History
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=55)	High Dose (N=61)	All Subjects (N=116)
MDS-UPDRS - Part III score during 'Off' state			
n	55	61	116
Mean (SD)	46.9 (14.20)	45.8 (14.27)	46.3 (14.18)
Median	47.0	42.0	44.0
Min, Max	11, 87	19, 81	11, 87

Note: Percentages calculated on non-missing or non-unknown values.

Program Source Code: [redacted]

表6　人口統計学的特性及びその他のベースラインの特性（安全性解析対象集団，日本人部分集団）：M15-737試験

[redacted]20[redacted] 10:45 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.1__2.J

Demographic and Baseline Characteristics
(Safety Analysis Set - Japan Subjects)

	Dose Category		
	Low Dose (N=8)	High Dose (N=4)	All Subjects (N=12)
Age (year)			
n	8	4	12
Mean (SD)	61.5 (7.73)	60.3 (10.75)	61.1 (8.36)
Median	61.5	61.0	61.5
Min, Max	49, 72	47, 72	47, 72
Age (year) - n (%)			
< 65	6 (75.0)	2 (50.0)	8 (66.7)
>= 65	2 (25.0)	2 (50.0)	4 (33.3)
Age (year) - n (%)			
< 75	8 (100)	4 (100)	12 (100)
>= 75	0	0	0
Weight (kg)			
n	8	4	12
Mean (SD)	53.75 (12.796)	77.05 (4.665)	61.52 (15.548)
Median	53.25	77.15	66.05
Min, Max	38.9, 67.7	71.4, 82.5	38.9, 82.5
Height (cm)			
n	8	4	12
Mean (SD)	160.68 (14.815)	168.15 (4.276)	163.17 (12.578)
Median	161.95	167.55	167.55
Min, Max	140.1, 177.4	164.2, 173.3	140.1, 177.4

Note: Percentages calculated on non-missing or non-unknown values.
For categorical variables, 'Missing' row is only presented when there are missing data presented.

Program Source Code: [redacted]

TABLE 14.1 2.J

Demographic and Baseline Characteristics
(Safety Analysis Set - Japan Subjects)

	Dose Category: Low Dose (N=8)	Dose Category: High Dose (N=4)	All Subjects (N=12)
BMI (kg/m^2)			
n	8	4	12
Mean (SD)	20.50 (1.551)	27.29 (2.140)	22.76 (3.735)
Median	20.54	26.82	21.59
Min, Max	18.0, 22.6	25.2, 30.3	18.0, 30.3
BMI (kg/m^2) - n (%)			
< 18.5	1 (12.5)	0	1 (8.3)
18.5 - < 25.0	7 (87.5)	0	7 (58.3)
25.0 - < 30.0	0	3 (75.0)	3 (25.0)
>= 30.0	0	1 (25.0)	1 (8.3)
Mini-Mental State Examination (MMSE) total score			
n	8	4	12
Mean (SD)	29.25 (1.165)	29.00 (0.816)	29.17 (1.030)
Median	30.00	29.00	29.50
Min, Max	27.0, 30.0	28.0, 30.0	27.0, 30.0
Country - n (%)			
JAPAN	8 (100)	4 (100)	12 (100)
Geographic region - n (%)			
Japan	8 (100)	4 (100)	12 (100)
Sex - n (%)			
Female	4 (50.0)	0	4 (33.3)
Male	4 (50.0)	4 (100)	8 (66.7)

Note: Percentages calculated on non-missing or non-unknown values.
For categorical variables, 'Missing' row is only presented when there are missing data presented.

Program Source Code: [redacted]

TABLE 14.1 2.J

Demographic and Baseline Characteristics
(Safety Analysis Set - Japan Subjects)

	Dose Category: Low Dose (N=8)	Dose Category: High Dose (N=4)	All Subjects (N=12)
Ethnicity - n (%)			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	8 (100)	4 (100)	12 (100)
Race - n (%)			
White	0	0	0
Black or African American	0	0	0
Asian	8 (100)	4 (100)	12 (100)
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Tobacco - n (%)			
Current	0	0	0
Former	2 (25.0)	2 (50.0)	4 (33.3)
Never	6 (75.0)	2 (50.0)	8 (66.7)
Unknown	0	0	0
Alcohol - n (%)			
Current	5 (62.5)	2 (50.0)	7 (58.3)
Former	1 (12.5)	1 (25.0)	2 (16.7)
Never	2 (25.0)	1 (25.0)	3 (25.0)
Unknown	0	0	0
Brief neurological examination			
Mental status - n (%)			
Normal	8 (100)	3 (75.0)	11 (91.7)
Abnormal	0	1 (25.0)	1 (8.3)

Note: Percentages calculated on non-missing or non-unknown values.
For categorical variables, 'Missing' row is only presented when there are missing data presented.

Program Source Code: [redacted]

TABLE 14.1 2.J

Demographic and Baseline Characteristics
(Safety Analysis Set - Japan Subjects)

	Dose Category: Low Dose (N=8)	Dose Category: High Dose (N=4)	All Subjects (N=12)
Cranial nerves - n (%)			
Normal	7 (87.5)	4 (100)	11 (91.7)
Abnormal	1 (12.5)	0	1 (8.3)
Motor system - n (%)			
Normal	5 (62.5)	2 (50.0)	7 (58.3)
Abnormal	3 (37.5)	2 (50.0)	5 (41.7)
Sensory system - n (%)			
Normal	8 (100)	4 (100)	12 (100)
Abnormal	0	0	0
Reflexes - n (%)			
Normal	7 (87.5)	4 (100)	11 (91.7)
Abnormal	1 (12.5)	0	1 (8.3)
Coordination - n (%)			
Normal	4 (50.0)	3 (75.0)	7 (58.3)
Abnormal	4 (50.0)	1 (25.0)	5 (41.7)
Gait - n (%)			
Normal	2 (25.0)	1 (25.0)	3 (25.0)
Abnormal	6 (75.0)	3 (75.0)	9 (75.0)
Station - n (%)			
Normal	4 (50.0)	2 (50.0)	6 (50.0)
Abnormal	4 (50.0)	2 (50.0)	6 (50.0)

Note: Percentages calculated on non-missing or non-unknown values.
For categorical variables, 'Missing' row is only presented when there are missing data presented.

Program Source Code: [redacted]

表7　レボドパの1日あたりの規定投与量（安全性解析対象集団）：M15-737試験

[redacted]20[redacted] 10:45 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.1__6.1

Daily Prescribed Dose
(Safety Analysis Set)

	N	Mean	SD	25% Quantile	Median	75% Quantile	Min / Max
ABBV-951 continuous infusion rate ('base') - LD mg/HR							
Initial CSCI prescription	116	79.1	30.59	56.3	76.8	97.3	29.0 / 163.9
Final prescription in study	115	81.8	32.41	52.9	80.3	102.5	29.0 / 162.2
Change from initial to final	115	2.6	8.11	0.0	0.0	5.1	-34.1 / 35.9
ABBV-951 continuous infusion rate ('high') & - LD mg/HR							
Initial CSCI prescription	105	86.2	32.58	63.2	82.0	104.2	34.2 / 177.6
Final prescription in study	103	89.1	34.93	59.8	88.8	111.0	34.2 / 177.6
Change from initial to final	102	2.8	9.17	0.0	0.0	5.1	-34.1 / 42.7
ABBV-951 continuous infusion rate ('low') & - LD mg/HR							
Initial CSCI prescription	103	70.8	29.40	46.1	66.6	85.4	25.6 / 141.7
Final prescription in study	101	73.9	31.21	46.1	73.4	90.5	25.6 / 157.1
Change from initial to final	100	2.3	8.09	0.0	0.0	4.3	-34.2 / 37.6
Extra dose $ - LD mg/use							
Initial prescription	109	33.38	11.820	25.61	32.44	40.98	18.78 / 51.23
Final prescription in study	105	33.34	12.021	25.61	32.44	40.98	18.78 / 51.23
Change from initial to final	104	-0.13	7.061	0.00	0.00	0.00	-32.44 / 32.44
Total daily dose # - LD mg/day							
Initial prescription	116	1897.4	734.11	1352.3	1844.1	2335.9	696.7 / 3934.1
Final prescription in study	115	1963.5	777.91	1270.4	1926.1	2458.8	696.7 / 3893.1
Change from initial to final	115	62.4	194.53	0.0	0.0	122.9	-819.6 / 860.6

& Only for subjects whose 'high' or 'low' flow rates are allowed, non-zero and different from 'base'.
$ Only for subjects whose extra dose function is allowed (volume > 0 mL).
# Calculated as 'base' (mL/HR) * 24 HR/day * 170.75 mg LD/mL.

Program Source Code: [redacted]

表8　規定注入速度（安全性解析対象集団）：M15-737試験

[redacted]20[redacted] 10:45 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.1__6.3

Prescribed Pump Infusion Flow Rate by Category
(Safety Analysis Set)

	Base n (%)	High n (%)	Low n (%)
Modal prescribed pump infusion flow rate	N=116	N=106	N=103
FLOW RATE < 0.17 mL/hr	0	0	1 (1.0)
0.17 <= FLOW RATE < 0.20 mL/hr	2 (1.7)	0	7 (6.8)
0.20 <= FLOW RATE < 0.23 mL/hr	6 (5.2)	4 (3.8)	4 (3.9)
0.23 <= FLOW RATE < 0.26 mL/hr	2 (1.7)	3 (2.8)	8 (7.8)
0.26 <= FLOW RATE < 0.29 mL/hr	10 (8.6)	5 (4.7)	8 (7.8)
0.29 <= FLOW RATE < 0.32 mL/hr	8 (6.9)	8 (7.5)	5 (4.9)
0.32 <= FLOW RATE < 0.35 mL/hr	9 (7.8)	2 (1.9)	5 (4.9)
0.35 <= FLOW RATE < 0.38 mL/hr	3 (2.6)	7 (6.6)	4 (3.9)
0.38 <= FLOW RATE < 0.41 mL/hr	7 (6.0)	6 (5.7)	9 (8.7)
0.41 <= FLOW RATE < 0.44 mL/hr	6 (5.2)	5 (4.7)	5 (4.9)
0.44 <= FLOW RATE < 0.47 mL/hr	6 (5.2)	8 (7.5)	9 (8.7)
0.47 <= FLOW RATE < 0.50 mL/hr	7 (6.0)	6 (5.7)	7 (6.8)
0.50 <= FLOW RATE < 0.53 mL/hr	10 (8.6)	6 (5.7)	7 (6.8)
0.53 <= FLOW RATE < 0.56 mL/hr	10 (8.6)	7 (6.6)	2 (1.9)

Note: High and low columns only contain subjects whose high/low prescription is not 0.

Program Source Code: [redacted]

TABLE 14.1 6.3

Prescribed Pump Infusion Flow Rate by Category
(Safety Analysis Set)

	Base n (%)	High n (%)	Low n (%)
0.56 <= FLOW RATE < 0.59 mL/hr	3 (2.6)	7 (6.6)	2 (1.9)
0.59 <= FLOW RATE < 0.62 mL/hr	4 (3.4)	5 (4.7)	5 (4.9)
0.62 <= FLOW RATE < 0.65 mL/hr	3 (2.6)	4 (3.8)	1 (1.0)
0.65 <= FLOW RATE < 0.68 mL/hr	3 (2.6)	2 (1.9)	2 (1.9)
0.68 <= FLOW RATE < 0.71 mL/hr	7 (6.0)	5 (4.7)	5 (4.9)
0.71 <= FLOW RATE < 0.74 mL/hr	0	6 (5.7)	0
0.74 <= FLOW RATE < 0.77 mL/hr	0	0	4 (3.9)
0.77 <= FLOW RATE < 0.80 mL/hr	2 (1.7)	0	0
0.80 <= FLOW RATE < 0.83 mL/hr	1 (0.9)	1 (0.9)	1 (1.0)
0.83 <= FLOW RATE < 0.86 mL/hr	2 (1.7)	3 (2.8)	0
0.86 <= FLOW RATE < 0.89 mL/hr	2 (1.7)	0	0
0.89 <= FLOW RATE < 0.92 mL/hr	0	0	2 (1.9)
0.92 <= FLOW RATE < 0.95 mL/hr	2 (1.7)	2 (1.9)	0
0.95 <= FLOW RATE < 0.98 mL/hr	1 (0.9)	1 (0.9)	0
0.98 <= FLOW RATE < 1.01 mL/hr	0	2 (1.9)	0
FLOW RATE >= 1.01 mL/hr	0	1 (0.9)	0

Note: High and low columns only contain subjects whose high/low prescription is not 0.

Program Source Code: [redacted]

表9　レボドパの1日あたりの規定投与量（安全性解析対象集団，日本人部分集団）：M15-737試験

[redacted]20[redacted] 10:45 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.1__6.1.J

Daily Prescribed Dose
(Safety Analysis Set - Japan Subjects)

	N	Mean	SD	25% Quantile	Median	75% Quantile	Min / Max
ABBV-951 continuous infusion rate ('base') - LD mg/HR							
Initial CSCI prescription	12	58.6	19.00	47.0	53.8	78.5	29.0 / 87.1
Final prescription in study	12	59.9	23.88	41.8	50.4	87.1	29.0 / 93.9
Change from initial to final	12	1.3	7.29	0.0	0.0	5.1	-13.7 / 13.7
ABBV-951 continuous infusion rate ('high') & - LD mg/HR							
Initial CSCI prescription	12	63.9	20.20	50.4	58.1	85.4	34.2 / 93.9
Final prescription in study	12	64.7	23.59	50.4	53.8	92.2	34.2 / 99.0
Change from initial to final	12	0.9	6.24	-0.9	0.0	3.4	-13.7 / 12.0
ABBV-951 continuous infusion rate ('low') & - LD mg/HR							
Initial CSCI prescription	11	50.0	15.27	34.2	47.8	61.5	29.0 / 80.3
Final prescription in study	11	52.8	21.40	34.2	46.1	78.5	34.2 / 87.1
Change from initial to final	11	2.8	9.36	0.0	0.0	6.8	-10.2 / 20.5
Extra dose $ - LD mg/use							
Initial prescription	12	31.16	11.515	22.20	29.03	36.71	18.78 / 51.23
Final prescription in study	12	30.59	11.614	22.20	25.61	36.71	18.78 / 51.23
Change from initial to final	12	-0.57	5.267	0.00	0.00	0.00	-15.37 / 8.54
Total daily dose # - LD mg/day							
Initial prescription	12	1407.0	456.11	1127.0	1290.9	1885.1	696.7 / 2090.0
Final prescription in study	12	1437.7	573.04	1004.0	1208.9	2090.0	696.7 / 2253.9
Change from initial to final	12	30.7	174.85	0.0	0.0	122.9	-327.8 / 327.8

& Only for subjects whose 'high' or 'low' flow rates are allowed, non-zero and different from 'base'.
$ Only for subjects whose extra dose function is allowed (volume > 0 mL).
# Calculated as 'base' (mL/HR) * 24 HR/day * 170.75 mg LD/mL.

Program Source Code: [redacted]

表10　ABBV-951及び併用薬のレボドパ換算1日投与量（安全性解析対象集団）：M15-737試験

[redacted]20[redacted] 10:46 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.1__8.3

Daily Levodopa Equivalent Dose (mg) from ABBV-951 and All Concomitant Medications
(Safety Analysis Set)

Week		ABBV-951 (CSCI + Extra)	LED from Concomitant Medications	Total
WEEK 12	n	88	12	88
	Mean	1914.3	318.9	1957.8
	SD	799.00	505.24	803.38
	Median	1836.5	126.0	1874.2
	Min	753.9	25.0	753.9
	Max	4116.8	1800.0	4116.8
WEEK 24	n	85	9	85
	Mean	1973.2	289.9	2003.9
	SD	737.01	481.04	766.98
	Median	1949.2	112.5	1949.2
	Min	688.0	25.0	688.0
	Max	3942.6	1552.0	3942.6
WEEK 36	n	67	7	67
	Mean	2049.9	613.6	2114.0
	SD	719.12	990.44	830.91
	Median	1998.0	80.0	1998.0
	Min	954.2	25.0	954.2
	Max	3725.4	2500.0	5034.8
WEEK 48	n	59	8	59
	Mean	2052.9	1323.3	2232.4
	SD	729.76	1557.25	993.75
	Median	2031.8	350.0	2158.4
	Min	953.1	87.5	953.1
	Max	4040.1	3391.5	5208.8

Program Source Code: [redacted]

TABLE 14.1 8.3

Daily Levodopa Equivalent Dose (mg) from ABBV-951 and All Concomitant Medications
(Safety Analysis Set)

Week		ABBV-951 (CSCI + Extra)	LED from Concomitant Medications	Total
WEEK 60	n	44	0	44
	Mean	2020.6		2020.6
	SD	714.52		714.52
	Median	1978.1		1978.1
	Min	872.9		872.9
	Max	4012.6		4012.6
WEEK 72	n	26	0	26
	Mean	1844.9		1844.9
	SD	669.82		669.82
	Median	1864.6		1864.6
	Min	819.6		819.6
	Max	3845.3		3845.3
WEEK 84	n	3	0	3
	Mean	1681.1		1681.1
	SD	606.13		606.13
	Median	1389.9		1389.9
	Min	1275.5		1275.5
	Max	2377.9		2377.9
WEEK 96	n	2	0	2
	Mean	1946.8		1946.8
	SD	617.88		617.88
	Median	1946.8		1946.8
	Min	1509.9		1509.9
	Max	2383.8		2383.8

Program Source Code: [redacted]

表11　レボドパの1日あたりの最頻投与量（安全性解析対象集団）：M15-737試験

[redacted]20[redacted] 10:46 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.1__8.2

Modal Daily Levodopa Dose by Dose Range Category
(Safety Analysis Set)

Categories (mg LD)	CSCI + Extra (N=116) n (%)	CSCI + Extra + Rescue + Loading Oral (N=116) n (%)
< 500	0	0
500 - < 600	0	0
600 - < 700	3 (2.6)	3 (2.6)
700 - < 800	1 (0.9)	1 (0.9)
800 - < 900	4 (3.4)	4 (3.4)
900 - < 1000	6 (5.2)	6 (5.2)
1000 - < 1100	3 (2.6)	3 (2.6)
1100 - < 1200	7 (6.0)	7 (6.0)
1200 - < 1300	6 (5.2)	6 (5.2)
1300 - < 1400	8 (6.9)	8 (6.9)
1400 - < 1500	4 (3.4)	4 (3.4)
1500 - < 1600	4 (3.4)	4 (3.4)
1600 - < 1700	6 (5.2)	6 (5.2)
1700 - < 1800	3 (2.6)	3 (2.6)
1800 - < 1900	6 (5.2)	6 (5.2)
1900 - < 2000	7 (6.0)	7 (6.0)
2000 - < 2100	6 (5.2)	6 (5.2)
2100 - < 2200	3 (2.6)	3 (2.6)
2200 - < 2300	8 (6.9)	8 (6.9)
2300 - < 2400	5 (4.3)	5 (4.3)
2400 - < 2500	4 (3.4)	3 (2.6)
2500 - < 2600	3 (2.6)	4 (3.4)
2600 - < 2700	2 (1.7)	2 (1.7)
2700 - < 2800	4 (3.4)	4 (3.4)
2800 - < 2900	3 (2.6)	3 (2.6)
2900 - < 3000	0	0
3000 - < 3100	0	0
3100 - < 3200	2 (1.7)	2 (1.7)

Program Source Code: [redacted]

TABLE 14.1 8.2

Modal Daily Levodopa Dose by Dose Range Category
(Safety Analysis Set)

Categories (mg LD)	CSCI + Extra (N=116) n (%)	CSCI + Extra + Rescue + Loading Oral (N=116) n (%)
3200 - < 3300	0	0
3300 - < 3400	0	0
3400 - < 3500	3 (2.6)	3 (2.6)
3500 - < 3600	1 (0.9)	1 (0.9)
3600 - < 3700	0	0
3700 - < 3800	1 (0.9)	1 (0.9)
3800 - < 3900	0	0
3900 - < 4000	0	0
4000 - < 4100	2 (1.7)	2 (1.7)
4100 - < 4200	0	0
4200 - < 4300	1 (0.9)	1 (0.9)
>= 4300	0	0

Program Source Code: [redacted]

表12　治験薬曝露期間（安全性解析対象集団）：M15-737試験

[redacted]20[redacted] 10:45 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.1__10

Duration of Study Drug Exposure
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=55)	High Dose (N=61)	All Subjects (N=116)
Duration of ABBV-951 exposure (days) &			
n	55	61	116
Mean (SD)	293.7 (166.04)	345.1 (164.00)	320.8 (166.26)
Median	314.0	406.0	392.0
Min, Max	3, 626	70, 633	3, 633
By time intervals - n(%) &			
1 - 84 Days	4 (7.3)	2 (3.3)	6 (5.2)
85 - 168 Days	14 (25.5)	13 (21.3)	27 (23.3)
169 - 252 Days	8 (14.5)	7 (11.5)	15 (12.9)
253 - 336 Days	3 (5.5)	1 (1.6)	4 (3.4)
337 - 420 Days	9 (16.4)	15 (24.6)	24 (20.7)
421 - 504 Days	13 (23.6)	15 (24.6)	28 (24.1)
505 - 588 Days	3 (5.5)	5 (8.2)	8 (6.9)
589 - 672 Days	1 (1.8)	3 (4.9)	4 (3.4)
>= 673 Days	0	0	0
Patient-years of exposure &	44.2	57.6	101.9

Note: Percentages calculated on non-missing values.
&: Duration of ABBV-951 exposure (days) = Date of ABBV-951 stopped - Date of ABBV-951 started + 1.
*: Duration of ABBV-951 exposure (days) excluding study drug interruption = Duration of ABBV-951 exposure (days) - Duration of interruption (days).

Program Source Code: [redacted]

TABLE 14.1 10

Duration of Study Drug Exposure
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=55)	High Dose (N=61)	All Subjects (N=116)
Duration of ABBV-951 exposure (days) without interruption *			
n	55	61	116
Mean (SD)	293.1 (166.30)	344.5 (163.83)	320.1 (166.29)
Median	314.0	405.0	392.0
Min, Max	3, 626	70, 633	3, 633
By time intervals - n(%) *			
1 - 84 Days	4 (7.3)	2 (3.3)	6 (5.2)
85 - 168 Days	14 (25.5)	13 (21.3)	27 (23.3)
169 - 252 Days	8 (14.5)	7 (11.5)	15 (12.9)
253 - 336 Days	3 (5.5)	1 (1.6)	4 (3.4)
337 - 420 Days	9 (16.4)	15 (24.6)	24 (20.7)
421 - 504 Days	13 (23.6)	15 (24.6)	28 (24.1)
505 - 588 Days	3 (5.5)	5 (8.2)	8 (6.9)
589 - 672 Days	1 (1.8)	3 (4.9)	4 (3.4)
>= 673 Days	0	0	0
Patient-years of exposure *	44.1	57.5	101.7

Note: Percentages calculated on non-missing values.
&: Duration of ABBV-951 exposure (days) = Date of ABBV-951 stopped - Date of ABBV-951 started + 1.
*: Duration of ABBV-951 exposure (days) excluding study drug interruption = Duration of ABBV-951 exposure (days) - Duration of interruption (days).

Program Source Code: [redacted]

表13　治験薬投与中断理由（安全性解析対象集団）：M15-737試験

[redacted]20[redacted] 10:45 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.1__12.1

All Reasons for Infusion Interruption
(Safety Analysis Set)

	Total
Total number of subjects with any interruptions	15
By all reasons	
COVID-19 infection	0
COVID-19 logistical restrictions	0
Pump malfunction	5
Adverse event (not COVID-19 infection)	2
Other	8

Note: One subject can be counted multiple times.

Program Source Code: [redacted]

表14　治験薬投与中断期間（安全性解析対象集団）：M15-737試験

[redacted]20[redacted] 10:45 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.1__12.2

Duration of Infusion Interruption
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=55)	High Dose (N=61)	All Subjects (N=116)
Duration of ABBV-951 interruption (days)			
n	5	10	15
Mean (SD)	5.70 (11.450)	2.02 (4.346)	3.25 (7.268)
Median	0.59	0.53	0.59
Min, Max	0.3, 26.2	0.1, 14.3	0.1, 26.2
By time intervals - n(%)			
< 1 day	3 (60.0)	7 (70.0)	10 (66.7)
1 - < 2 days	1 (20.0)	2 (20.0)	3 (20.0)
2 - < 3 days	0	0	0
3 - < 4 days	0	0	0
4 - < 5 days	0	0	0
5 - < 10 days	0	0	0
10 - < 20 days	0	1 (10.0)	1 (6.7)
20 - < 30 days	1 (20.0)	0	1 (6.7)
>= 30 days	0	0	0

Program Source Code: [redacted]

表15　レボドパの1日あたりの投与量（安全性解析対象集団）：M15-737試験

[redacted]20[redacted] 10:45 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.1__8.1

Daily Levodopa Dose (mg LD)
(Safety Analysis Set)

		ABBV-951 CSCI			Oral			
Week		Continuous Infusion	Extra Dose	Total	Rescue Dose	Loading Dose	Total	Overall Total
WEEK 12	n	88	48	88	16	0	16	88
	Mean	1872.6	76.5	1914.3	115.6		115.6	1935.3
	SD	795.71	63.65	799.00	35.21		35.21	801.28
	Median	1752.4	56.3	1836.5	100.0		100.0	1836.5
	Min	685.0	18.8	753.9	100.0		100.0	753.9
	Max	4098.0	307.4	4116.8	200.0		200.0	4216.8
WEEK 24	n	85	49	85	11	3	14	85
	Mean	1926.1	81.7	1973.2	154.5	158.3	155.4	1998.8
	SD	731.56	69.07	737.01	82.02	80.36	78.56	744.65
	Median	1885.1	61.5	1949.2	100.0	125.0	100.0	1952.3
	Min	688.0	18.8	688.0	100.0	100.0	100.0	688.0
	Max	3886.3	333.0	3942.6	300.0	250.0	300.0	3942.6
WEEK 36	n	67	30	67	6	1	7	67
	Mean	2020.3	66.1	2049.9	108.3	250.0	128.6	2063.3
	SD	719.70	54.18	719.12	20.41	N/A	56.69	716.65
	Median	1967.0	51.2	1998.0	100.0	250.0	100.0	1998.0
	Min	857.5	18.8	954.2	100.0	250.0	100.0	954.2
	Max	3725.4	256.1	3725.4	150.0	250.0	250.0	3725.4
WEEK 48	n	59	32	59	2	1	3	59
	Mean	2011.8	75.9	2052.9	150.0	250.0	183.3	2062.3
	SD	719.27	71.90	729.76	70.71	N/A	76.38	736.05
	Median	1959.4	41.0	2031.8	150.0	250.0	200.0	2031.8
	Min	855.8	18.8	953.1	100.0	250.0	100.0	953.1
	Max	4014.5	307.4	4040.1	200.0	250.0	250.0	4040.1

Program Source Code: [redacted]

TABLE 14.1 8.1

Daily Levodopa Dose (mg LD)
(Safety Analysis Set)

Week		ABBV-951 CSCI			Oral			Overall Total
		Continuous Infusion	Extra Dose	Total	Rescue Dose	Loading Dose	Total	
WEEK 60	n	44	23	44	6	1	6	44
	Mean	1982.4	73.2	2020.6	150.0	200.0	183.3	2045.6
	SD	700.53	72.20	714.52	63.25	N/A	81.65	718.81
	Median	1978.1	48.7	1978.1	125.0	200.0	175.0	1994.4
	Min	847.3	18.8	872.9	100.0	200.0	100.0	872.9
	Max	3961.4	307.4	4012.6	250.0	200.0	300.0	4012.6
WEEK 72	n	26	13	26	1	0	1	26
	Mean	1824.7	40.5	1844.9	100.0		100.0	1848.8
	SD	669.28	18.37	669.82	N/A		N/A	668.01
	Median	1855.1	32.4	1864.6	100.0		100.0	1864.6
	Min	819.6	18.8	819.6	100.0		100.0	819.6
	Max	3794.1	76.8	3845.3	100.0		100.0	3845.3
WEEK 84	n	3	3	3	0	0	0	3
	Mean	1631.0	50.1	1681.1				1681.1
	SD	597.01	11.99	606.13				606.13
	Median	1352.3	51.2	1389.9				1389.9
	Min	1224.3	37.6	1275.5				1275.5
	Max	2316.4	61.5	2377.9				2377.9
WEEK 96	n	2	1	2	1	0	1	2
	Mean	1905.9	82.0	1946.8	100.0		100.0	1996.8
	SD	559.92	N/A	617.88	N/A		N/A	547.17
	Median	1905.9	82.0	1946.8	100.0		100.0	1996.8
	Min	1509.9	82.0	1509.9	100.0		100.0	1609.9
	Max	2301.8	82.0	2383.8	100.0		100.0	2383.8

Program Source Code: [redacted]

表16　治験薬曝露期間（安全性解析対象集団，日本人部分集団）：M15-737試験

[redacted]20[redacted] 10:45 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.1__10.J

Duration of Study Drug Exposure
(Safety Analysis Set - Japan Subjects)

	Dose Category		
	Low Dose (N=8)	High Dose (N=4)	All Subjects (N=12)
Duration of ABBV-951 exposure (days) &			
n	8	4	12
Mean (SD)	198.0 (124.31)	426.3 (181.61)	274.1 (177.37)
Median	163.5	512.5	176.5
Min, Max	79, 483	154, 526	79, 526
By time intervals - n(%) &			
1 - 84 Days	1 (12.5)	0	1 (8.3)
85 - 168 Days	3 (37.5)	1 (25.0)	4 (33.3)
169 - 252 Days	3 (37.5)	0	3 (25.0)
253 - 336 Days	0	0	0
337 - 420 Days	0	0	0
421 - 504 Days	1 (12.5)	0	1 (8.3)
505 - 588 Days	0	3 (75.0)	3 (25.0)
589 - 672 Days	0	0	0
>= 673 Days	0	0	0
Patient-years of exposure &	4.3	4.7	9.0

Note: Percentages calculated on non-missing values.
&: Duration of ABBV-951 exposure (days) = Date of ABBV-951 stopped - Date of ABBV-951 started + 1.
*: Duration of ABBV-951 exposure (days) excluding study drug interruption = Duration of ABBV-951 exposure (days) - Duration of interruption (days).

Program Source Code: [redacted]

TABLE 14.1 10.J

Duration of Study Drug Exposure
(Safety Analysis Set - Japan Subjects)

	Dose Category		
	Low Dose (N=8)	High Dose (N=4)	All Subjects (N=12)
Duration of ABBV-951 exposure (days) without interruption *			
n	8	4	12
Mean (SD)	198.0 (124.31)	426.0 (181.45)	274.0 (177.24)
Median	163.5	512.0	176.5
Min, Max	79, 483	154, 526	79, 526
By time intervals - n(%) *			
1 - 84 Days	1 (12.5)	0	1 (8.3)
85 - 168 Days	3 (37.5)	1 (25.0)	4 (33.3)
169 - 252 Days	3 (37.5)	0	3 (25.0)
253 - 336 Days	0	0	0
337 - 420 Days	0	0	0
421 - 504 Days	1 (12.5)	0	1 (8.3)
505 - 588 Days	0	3 (75.0)	3 (25.0)
589 - 672 Days	0	0	0
>= 673 Days	0	0	0
Patient-years of exposure *	4.3	4.7	9.0

Note: Percentages calculated on non-missing values.
&: Duration of ABBV-951 exposure (days) = Date of ABBV-951 stopped - Date of ABBV-951 started + 1.
*: Duration of ABBV-951 exposure (days) excluding study drug interruption = Duration of ABBV-951 exposure (days) - Duration of interruption (days).

Program Source Code: [redacted]

表17　治験薬投与中断理由（安全性解析対象集団，日本人部分集団）：M15-737試験

[redacted]20[redacted] 10:46 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.1__12.1.J

All Reasons for Infusion Interruption
(Safety Analysis Set - Japan Subjects)

	Total
Total number of subjects with any interruptions	1
By all reasons	
COVID-19 infection	0
COVID-19 logistical restrictions	0
Pump malfunction	0
Adverse event (not COVID-19 infection)	0
Other	1

Note: One subject can be counted multiple times.

Program Source Code: [redacted]

表18　レボドパの1日あたりの投与量（安全性解析対象集団，日本人部分集団）：M15-737試験

[redacted]20[redacted] 10:45 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.1__8.1.J

Daily Levodopa Dose (mg LD)
(Safety Analysis Set - Japan Subjects)

		ABBV-951 CSCI			Oral			
Week		Continuous Infusion	Extra Dose	Total	Rescue Dose	Loading Dose	Total	Overall Total
WEEK 12	n	11	9	11	4	0	4	11
	Mean	1409.5	90.9	1483.8	112.5		112.5	1524.7
	SD	501.86	40.67	498.58	25.00		25.00	488.74
	Median	1363.2	93.9	1465.6	100.0		100.0	1465.6
	Min	685.0	41.0	779.0	100.0		100.0	879.0
	Max	2178.8	179.3	2243.7	150.0		150.0	2243.7
WEEK 24	n	11	8	11	2	0	2	11
	Mean	1407.9	102.2	1482.3	100.0		100.0	1500.4
	SD	559.36	45.25	567.59	0.00		0.00	560.19
	Median	1293.9	93.5	1359.7	100.0		100.0	1459.7
	Min	688.0	61.5	688.0	100.0		100.0	688.0
	Max	2183.5	204.9	2264.6	100.0		100.0	2264.6
WEEK 36	n	6	4	6	0	0	0	6
	Mean	1558.7	70.9	1605.9				1605.9
	SD	534.05	31.07	522.28				522.28
	Median	1582.1	74.3	1607.7				1607.7
	Min	857.5	37.6	954.8				954.8
	Max	2183.5	97.3	2280.8				2280.8
WEEK 48	n	4	3	4	0	0	0	4
	Mean	1743.1	57.2	1786.0				1786.0
	SD	621.90	36.61	591.05				591.05
	Median	1919.5	48.7	1932.3				1932.3
	Min	855.8	25.6	953.1				953.1
	Max	2277.5	97.3	2326.1				2326.1

Program Source Code: [redacted]

TABLE 14.1 8.1.J

Daily Levodopa Dose (mg LD)
(Safety Analysis Set - Japan Subjects)

		ABBV-951 CSCI			Oral			
Week		Continuous Infusion	Extra Dose	Total	Rescue Dose	Loading Dose	Total	Overall Total
WEEK 60	n	4	2	4	1	1	1	4
	Mean	1721.1	64.9	1753.5	100.0	200.0	300.0	1828.5
	SD	603.76	45.88	567.65	N/A	N/A	N/A	622.69
	Median	1885.8	64.9	1885.8	100.0	200.0	300.0	2035.8
	Min	859.4	32.4	956.7	100.0	200.0	300.0	956.7
	Max	2253.1	97.3	2285.6	100.0	200.0	300.0	2285.6
WEEK 72	n	4	2	4	0	0	0	4
	Mean	1810.7	29.0	1825.2				1825.2
	SD	684.05	4.83	693.70				693.70
	Median	2043.6	29.0	2056.4				2056.4
	Min	819.6	25.6	819.6				819.6
	Max	2335.9	32.4	2368.3				2368.3

Program Source Code: [redacted]

表19　パーキンソン病日誌に基づく，標準化した1日あたりの平均オフ時間及びオン時間の要約（FAS）：M15-737試験

[redacted]20[redacted] 10:46 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.2__1.1

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	Change from Baseline: P-Value &
Average Daily Normalized 'Off' Time									
BASELINE	97		2.55 (2.96)	1.2	0.0, 11.5				
Low Dose	45		2.94 (2.91)	2.6	0.0, 10.9				
High Dose	52		2.21 (2.98)	0.5	0.0, 11.5				
WEEK 12	75	2.84 (3.14)	2.98 (2.83)	2.3	0.0, 10.9	0.14 (2.59)	0.0	-8.2, 10.9	0.6297
Low Dose	38	3.00 (3.09)	2.64 (2.35)	2.5	0.0, 8.0	-0.36 (2.26)	0.0	-8.2, 3.8	0.3332
High Dose	37	2.67 (3.22)	3.33 (3.25)	2.3	0.0, 10.9	0.66 (2.83)	0.0	-6.4, 10.9	0.1630
WEEK 24	75	2.35 (2.64)	3.12 (3.58)	2.3	0.0, 16.0	0.76 (2.99)	0.0	-6.1, 13.3	0.0301*
Low Dose	36	3.03 (2.70)	3.23 (3.75)	2.5	0.0, 16.0	0.20 (3.48)	0.0	-6.1, 13.3	0.7311
High Dose	39	1.73 (2.45)	3.01 (3.47)	2.3	0.0, 13.4	1.28 (2.38)	0.6	-3.3, 7.7	0.0018**
WEEK 36	39	2.27 (2.65)	2.34 (2.66)	1.7	0.0, 12.1	0.07 (1.91)	0.0	-5.5, 5.6	0.8096
Low Dose	21	2.48 (2.52)	2.65 (3.15)	1.9	0.0, 12.1	0.16 (1.87)	0.0	-5.5, 5.6	0.6950
High Dose	18	2.02 (2.85)	1.99 (1.97)	1.7	0.0, 6.1	-0.03 (2.00)	0.0	-3.9, 3.9	0.9516

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours
(i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.1

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary
(FAS)

Parameter Time Point Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	Change from Baseline P-Value &
Average Daily Normalized 'Off' Time (Cont.)									
WEEK 48	52	2.01 (2.42)	2.81 (3.58)	1.2	0.0, 14.3	0.79 (2.27)	0.0	-3.0, 7.4	0.0149*
Low Dose	21	2.11 (2.30)	2.32 (3.11)	0.7	0.0, 10.1	0.21 (2.12)	0.0	-3.0, 7.4	0.6586
High Dose	31	1.95 (2.53)	3.14 (3.88)	1.2	0.0, 14.3	1.19 (2.32)	0.2	-2.0, 6.6	0.0077**
WEEK 60	29	2.54 (2.68)	3.04 (2.84)	2.4	0.0, 10.4	0.50 (1.62)	0.0	-3.0, 3.9	0.1088
Low Dose	16	2.70 (2.44)	2.86 (3.13)	2.2	0.0, 10.4	0.16 (1.59)	-0.0	-3.0, 3.9	0.6897
High Dose	13	2.34 (3.05)	3.26 (2.53)	3.0	0.0, 7.1	0.91 (1.63)	0.9	-2.0, 3.9	0.0660
WEEK 72	12	2.46 (2.66)	3.36 (3.37)	2.8	0.0, 10.4	0.90 (2.48)	-0.0	-2.2, 5.5	0.2342
Low Dose	6	2.16 (2.50)	1.69 (1.66)	1.3	0.0, 3.7	-0.47 (1.03)	-0.2	-2.2, 0.8	0.3183
High Dose	6	2.76 (3.02)	5.03 (3.94)	4.7	0.0, 10.4	2.27 (2.83)	3.0	-1.7, 5.5	0.1064
WEEK 84	2	3.06 (4.33)	5.71 (8.08)	5.7	0.0, 11.4	2.65 (3.75)	2.7	0.0, 5.3	0.5000
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	1	6.13 (N/A)	11.43 (N/A)	11.4	11.4, 11.4	5.30 (N/A)	5.3	5.3, 5.3	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.1

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Average Daily Normalized 'Off' Time (Cont.)									
WEEK 96	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								
Average Daily Normalized 'On' Time Without Dyskinesia									
BASELINE	97		10.66 (4.84)	11.6	0.0, 16.0				
Low Dose	45		10.82 (4.46)	11.7	0.0, 16.0				
High Dose	52		10.52 (5.19)	11.5	0.0, 16.0				
WEEK 12	75	10.66 (4.91)	10.83 (4.63)	11.7	0.0, 16.0	0.17 (3.71)	0.0	-10.9, 14.2	0.6998
Low Dose	38	10.94 (4.51)	11.18 (4.68)	12.8	0.0, 16.0	0.24 (3.79)	0.0	-6.7, 14.2	0.6931
High Dose	37	10.38 (5.33)	10.47 (4.62)	10.8	0.0, 16.0	0.09 (3.69)	0.0	-10.9, 9.0	0.8886
WEEK 24	75	10.66 (4.81)	10.58 (4.76)	10.7	0.0, 16.0	-0.09 (4.47)	0.0	-13.3, 14.2	0.8695
Low Dose	36	10.64 (4.39)	10.50 (5.14)	10.7	0.0, 16.0	-0.14 (4.57)	0.0	-13.3, 14.2	0.8590
High Dose	39	10.69 (5.22)	10.65 (4.44)	10.6	0.0, 16.0	-0.04 (4.43)	0.0	-9.6, 13.7	0.9578

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.1

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary
(FAS)

Parameter Time Point Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	Change from Baseline P-Value &
Average Daily Normalized 'On' Time Without Dyskinesia (Cont.)									
WEEK 36	39	11.45 (4.51)	11.47 (4.73)	12.1	0.0, 16.0	0.02 (4.39)	0.0	-11.2, 14.2	0.9723
Low Dose	21	12.11 (3.82)	12.28 (4.45)	14.0	1.3, 16.0	0.16 (3.99)	0.0	-5.9, 14.2	0.8524
High Dose	18	10.67 (5.21)	10.53 (4.99)	11.9	0.0, 16.0	-0.14 (4.94)	0.1	-11.2, 14.0	0.9070
WEEK 48	52	10.49 (5.06)	10.98 (4.69)	11.4	0.0, 16.0	0.49 (4.82)	0.0	-9.4, 14.9	0.4648
Low Dose	21	10.83 (5.04)	11.33 (4.75)	12.4	1.1, 16.0	0.50 (5.34)	0.0	-8.0, 13.7	0.6710
High Dose	31	10.26 (5.15)	10.74 (4.71)	10.7	0.0, 16.0	0.49 (4.53)	0.0	-9.4, 14.9	0.5549
WEEK 60	29	10.16 (4.90)	10.85 (4.09)	10.3	0.8, 16.0	0.69 (4.13)	0.0	-6.1, 13.9	0.3752
Low Dose	16	10.42 (4.59)	10.73 (4.54)	10.2	0.8, 16.0	0.31 (4.96)	-0.7	-6.1, 13.9	0.8086
High Dose	13	9.83 (5.43)	10.99 (3.63)	12.1	4.3, 16.0	1.16 (2.92)	0.3	-3.9, 6.3	0.1757
WEEK 72	12	10.96 (4.52)	11.11 (4.62)	12.2	1.4, 16.0	0.15 (4.68)	0.0	-9.9, 9.8	0.9155
Low Dose	6	13.60 (2.96)	14.03 (1.84)	14.1	11.9, 16.0	0.42 (1.43)	0.0	-0.8, 3.2	0.5010
High Dose	6	8.32 (4.40)	8.19 (4.81)	8.6	1.4, 14.1	-0.13 (6.78)	-0.2	-9.9, 9.8	0.9641

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.1

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary
(FAS)

Parameter Time Point Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	Change from Baseline P-Value &
Average Daily Normalized 'On' Time Without Dyskinesia (Cont.)									
WEEK 84	2	12.03 (5.62)	10.29 (8.08)	10.3	4.6, 16.0	-1.74 (2.46)	-1.7	-3.5, 0.0	0.5000
Low Dose	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	1	8.05 (N/A)	4.57 (N/A)	4.6	4.6, 4.6	-3.48 (N/A)	-3.5	-3.5, -3.5	
WEEK 96	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia									
BASELINE	97		2.31 (4.14)	0.3	0.0, 16.0				
Low Dose	45		1.75 (3.51)	0.0	0.0, 16.0				
High Dose	52		2.78 (4.60)	0.4	0.0, 16.0				
WEEK 12	75	1.98 (3.99)	1.83 (3.55)	0.0	0.0, 16.0	-0.15 (3.77)	0.0	-15.8, 11.6	0.7321
Low Dose	38	1.49 (3.32)	1.75 (3.28)	0.0	0.0, 12.4	0.26 (3.82)	0.0	-11.6, 11.6	0.6791
High Dose	37	2.49 (4.56)	1.92 (3.85)	0.0	0.0, 16.0	-0.57 (3.72)	0.0	-15.8, 6.7	0.3589

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.1

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary
(FAS)

Parameter Time Point Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	Change from Baseline P-Value &
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia (Cont.)									
WEEK 24	75	2.57 (4.21)	1.90 (3.44)	0.0	0.0, 16.0	-0.67 (3.87)	0.0	-16.0, 6.2	0.1385
Low Dose	36	2.11 (3.84)	1.94 (3.56)	0.0	0.0, 16.0	-0.17 (3.49)	0.0	-12.0, 6.2	0.7708
High Dose	39	2.99 (4.52)	1.86 (3.37)	0.0	0.0, 16.0	-1.13 (4.18)	0.0	-16.0, 6.1	0.0997
WEEK 36	39	2.01 (3.45)	2.01 (4.01)	0.0	0.0, 16.0	-0.00 (3.83)	0.0	-12.9, 11.2	0.9937
Low Dose	21	1.26 (2.89)	1.00 (2.49)	0.0	0.0, 11.1	-0.27 (2.83)	0.0	-11.6, 4.4	0.6718
High Dose	18	2.88 (3.92)	3.18 (5.10)	0.1	0.0, 16.0	0.30 (4.81)	0.0	-12.9, 11.2	0.7954
WEEK 48	52	3.16 (4.69)	1.90 (3.31)	0.1	0.0, 14.9	-1.25 (4.17)	0.0	-12.9, 8.0	0.0351*
Low Dose	21	2.76 (4.75)	2.30 (4.26)	0.0	0.0, 14.9	-0.47 (4.14)	0.0	-11.1, 8.0	0.6105
High Dose	31	3.42 (4.70)	1.64 (2.53)	0.2	0.0, 9.8	-1.78 (4.17)	0.0	-12.9, 4.9	0.0238*
WEEK 60	29	2.71 (4.41)	1.98 (2.73)	0.9	0.0, 11.6	-0.73 (3.81)	0.0	-11.3, 5.7	0.3101
Low Dose	16	2.51 (4.11)	2.36 (3.21)	1.0	0.0, 11.6	-0.15 (4.24)	0.0	-11.3, 5.7	0.8919
High Dose	13	2.95 (4.91)	1.50 (2.01)	0.0	0.0, 5.8	-1.45 (3.21)	-0.2	-10.2, 1.1	0.1298

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.1

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia (Cont.)									
WEEK 72	12	2.06 (4.60)	0.94 (1.30)	0.2	0.0, 4.2	-1.12 (4.18)	0.0	-14.2, 1.4	0.3725
Low Dose	6	0.24 (0.59)	0.28 (0.50)	0.0	0.0, 1.2	0.04 (0.71)	0.0	-1.0, 1.2	0.8905
High Dose	6	3.88 (6.19)	1.59 (1.55)	1.6	0.0, 4.2	-2.29 (5.90)	-0.2	-14.2, 1.4	0.3855
WEEK 84	2	0.91 (1.29)	0.00 (0.00)	0.0	0.0, 0.0	-0.91 (1.29)	-0.9	-1.8, 0.0	0.5000
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	1	1.82 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	-1.82 (N/A)	-1.8	-1.8, -1.8	
WEEK 96	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								
Average Daily Normalized 'On' Time With Troublesome Dyskinesia									
BASELINE	97		0.48 (1.69)	0.0	0.0, 13.5				
Low Dose	45		0.48 (2.09)	0.0	0.0, 13.5				
High Dose	52		0.49 (1.27)	0.0	0.0, 6.3				

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.1

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary
(FAS)

Parameter Time Point Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	Change from Baseline P-Value &
Average Daily Normalized 'On' Time With Troublesome Dyskinesia (Cont.)									
WEEK 12	75	0.52 (1.79)	0.36 (1.49)	0.0	0.0, 11.0	-0.16 (2.31)	0.0	-13.5, 11.0	0.5486
Low Dose	38	0.57 (2.27)	0.43 (1.90)	0.0	0.0, 11.0	-0.14 (3.04)	0.0	-13.5, 11.0	0.7716
High Dose	37	0.46 (1.12)	0.28 (0.92)	0.0	0.0, 4.4	-0.18 (1.24)	0.0	-5.3, 3.0	0.3861
WEEK 24	75	0.41 (1.17)	0.41 (1.36)	0.0	0.0, 7.8	-0.01 (1.32)	0.0	-5.3, 6.4	0.9538
Low Dose	36	0.22 (0.73)	0.33 (1.31)	0.0	0.0, 7.8	0.11 (1.32)	0.0	-3.3, 6.4	0.6330
High Dose	39	0.59 (1.45)	0.48 (1.42)	0.0	0.0, 7.2	-0.12 (1.33)	0.0	-5.3, 4.3	0.5931
WEEK 36	39	0.27 (1.00)	0.18 (0.57)	0.0	0.0, 2.8	-0.09 (1.04)	0.0	-5.3, 1.8	0.5758
Low Dose	21	0.14 (0.58)	0.08 (0.28)	0.0	0.0, 1.2	-0.06 (0.66)	0.0	-2.7, 1.2	0.6773
High Dose	18	0.42 (1.34)	0.29 (0.77)	0.0	0.0, 2.8	-0.13 (1.37)	0.0	-5.3, 1.8	0.6888
WEEK 48	52	0.34 (0.86)	0.31 (1.00)	0.0	0.0, 6.2	-0.03 (1.26)	0.0	-3.3, 6.2	0.8428
Low Dose	21	0.30 (0.90)	0.06 (0.17)	0.0	0.0, 0.7	-0.24 (0.94)	0.0	-3.3, 0.7	0.2516
High Dose	31	0.37 (0.85)	0.48 (1.27)	0.0	0.0, 6.2	0.11 (1.44)	0.0	-3.0, 6.2	0.6876

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.1

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	Change from Baseline: P-Value &
Average Daily Normalized 'On' Time With Troublesome Dyskinesia (Cont.)									
WEEK 60	29	0.60 (1.42)	0.14 (0.36)	0.0	0.0, 1.5	-0.46 (1.46)	0.0	-6.3, 1.5	0.1021
Low Dose	16	0.37 (1.03)	0.05 (0.16)	0.0	0.0, 0.6	-0.32 (1.06)	0.0	-3.3, 0.6	0.2452
High Dose	13	0.88 (1.79)	0.25 (0.50)	0.0	0.0, 1.5	-0.63 (1.88)	0.0	-6.3, 1.5	0.2504
WEEK 72	12	0.52 (1.80)	0.60 (1.46)	0.0	0.0, 5.0	0.08 (2.04)	0.0	-4.6, 5.0	0.9006
Low Dose	6	0.00 (0.00)	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
High Dose	6	1.04 (2.55)	1.19 (1.96)	0.3	0.0, 5.0	0.15 (3.02)	0.0	-4.6, 5.0	0.9077
WEEK 84	2	0.00 (0.00)	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
WEEK 96	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.1

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary
(FAS)

Parameter Time Point Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	Change from Baseline P-Value &
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia									
BASELINE	97		12.96 (3.22)	13.7	2.5, 16.0				
Low Dose	45		12.57 (3.24)	13.3	2.5, 16.0				
High Dose	52		13.30 (3.19)	15.1	4.5, 16.0				
WEEK 12	75	12.65 (3.40)	12.66 (3.09)	13.5	5.0, 16.0	0.02 (3.35)	0.0	-11.0, 11.6	0.9662
Low Dose	38	12.43 (3.44)	12.93 (2.86)	13.4	5.0, 16.0	0.50 (3.57)	0.0	-11.0, 11.6	0.3906
High Dose	37	12.87 (3.39)	12.38 (3.33)	13.7	5.1, 16.0	-0.48 (3.07)	0.0	-10.9, 6.4	0.3455
WEEK 24	75	13.23 (2.75)	12.48 (3.78)	13.6	0.0, 16.0	-0.75 (3.10)	-0.1	-13.3, 6.1	0.0386*
Low Dose	36	12.75 (2.66)	12.45 (3.98)	13.5	0.0, 16.0	-0.31 (3.57)	0.0	-13.3, 6.1	0.6089
High Dose	39	13.67 (2.79)	12.51 (3.64)	13.7	2.6, 16.0	-1.17 (2.57)	-0.7	-7.7, 3.3	0.0074**
WEEK 36	39	13.46 (2.72)	13.48 (2.68)	14.1	3.9, 16.0	0.02 (2.10)	0.0	-5.6, 5.5	0.9535
Low Dose	21	13.38 (2.45)	13.28 (3.21)	14.1	3.9, 16.0	-0.10 (2.03)	0.0	-5.6, 5.5	0.8212
High Dose	18	13.55 (3.08)	13.72 (1.96)	14.1	9.9, 16.0	0.16 (2.23)	0.0	-3.9, 4.3	0.7629

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.1

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia (Cont.)									
WEEK 48	52	13.64 (2.54)	12.88 (3.63)	14.4	1.7, 16.0	-0.76 (2.66)	0.0	-7.4, 3.8	0.0445*
Low Dose	21	13.59 (2.24)	13.63 (3.15)	15.3	5.9, 16.0	0.03 (2.41)	0.0	-7.4, 3.8	0.9491
High Dose	31	13.68 (2.76)	12.38 (3.88)	13.8	1.7, 16.0	-1.30 (2.72)	-0.3	-6.6, 2.3	0.0125*
WEEK 60	29	12.86 (2.80)	12.82 (2.87)	13.0	5.6, 16.0	-0.04 (2.02)	0.0	-3.9, 5.3	0.9148
Low Dose	16	12.93 (2.26)	13.09 (3.12)	13.8	5.6, 16.0	0.16 (1.70)	0.0	-3.9, 3.0	0.7135
High Dose	13	12.78 (3.45)	12.49 (2.60)	12.9	7.8, 16.0	-0.29 (2.41)	-0.5	-3.9, 5.3	0.6761
WEEK 72	12	13.02 (2.85)	12.04 (3.79)	13.2	5.6, 16.0	-0.98 (3.98)	0.0	-10.4, 5.1	0.4138
Low Dose	6	13.84 (2.50)	14.31 (1.66)	14.7	12.3, 16.0	0.47 (1.03)	0.2	-0.8, 2.2	0.3183
High Dose	6	12.20 (3.15)	9.78 (4.07)	9.5	5.6, 14.3	-2.42 (5.37)	-3.2	-10.4, 5.1	0.3201
WEEK 84	2	12.94 (4.33)	10.29 (8.08)	10.3	4.6, 16.0	-2.65 (3.75)	-2.7	-5.3, 0.0	0.5000
Low Dose	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	1	9.87 (N/A)	4.57 (N/A)	4.6	4.6, 4.6	-5.30 (N/A)	-5.3	-5.3, -5.3	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.1

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia (Cont.)									
WEEK 96	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

表20　パーキンソン病日誌に基づく，標準化した1日あたりの平均オフ時間及びオン時間の要約（FAS，部分集団別）：M15-737試験

[redacted]20[redacted] 10:46 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.2__1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	Change from Baseline: P-Value &
Gender:Female									
Average Daily Normalized 'Off' Time									
BASELINE	33		1.91 (2.35)	0.9	0.0, 8.8				
Low Dose	23		2.05 (2.24)	1.2	0.0, 6.7				
High Dose	10		1.58 (2.68)	0.7	0.0, 8.8				
WEEK 12	29	2.06 (2.43)	2.63 (2.49)	2.2	0.0, 10.9	0.56 (2.90)	0.0	-6.4, 10.9	0.3045
Low Dose	22	2.02 (2.29)	2.21 (1.98)	2.0	0.0, 6.1	0.18 (1.64)	0.0	-4.2, 3.8	0.6081
High Dose	7	2.19 (3.05)	3.95 (3.56)	2.3	0.3, 10.9	1.76 (5.25)	1.3	-6.4, 10.9	0.4094
WEEK 24	27	2.12 (2.44)	3.70 (4.35)	2.5	0.0, 16.0	1.58 (3.33)	0.1	-3.0, 13.3	0.0208*
Low Dose	18	2.30 (2.32)	3.61 (4.50)	1.9	0.0, 16.0	1.31 (3.79)	0.0	-3.0, 13.3	0.1621
High Dose	9	1.76 (2.78)	3.88 (4.30)	2.7	0.0, 13.4	2.12 (2.24)	2.2	0.0, 6.2	0.0217*
WEEK 36	15	1.87 (2.89)	1.41 (1.95)	0.5	0.0, 6.5	-0.46 (1.87)	0.0	-5.5, 1.4	0.3596
Low Dose	10	1.50 (2.58)	1.07 (2.04)	0.1	0.0, 6.5	-0.43 (1.87)	0.0	-5.5, 1.4	0.4853
High Dose	5	2.62 (3.63)	2.11 (1.76)	2.0	0.0, 4.9	-0.51 (2.10)	0.0	-3.9, 1.2	0.6134

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Gender:Female (Cont.)									
Average Daily Normalized 'Off' Time (Cont.)									
WEEK 48	17	1.70 (2.39)	2.44 (4.08)	0.7	0.0, 14.3	0.74 (2.46)	0.0	-2.0, 7.4	0.2338
Low Dose	10	1.36 (1.91)	2.19 (3.43)	0.4	0.0, 10.1	0.83 (2.53)	0.0	-1.2, 7.4	0.3276
High Dose	7	2.19 (3.05)	2.79 (5.15)	1.1	0.0, 14.3	0.60 (2.53)	0.0	-2.0, 5.5	0.5509
WEEK 60	11	1.79 (2.92)	1.62 (2.67)	0.2	0.0, 6.9	-0.18 (0.86)	0.0	-2.0, 1.0	0.5137
Low Dose	7	1.43 (2.20)	1.31 (2.59)	0.0	0.0, 6.9	-0.12 (0.69)	0.0	-1.2, 1.0	0.6523
High Dose	4	2.43 (4.23)	2.16 (3.12)	0.9	0.0, 6.8	-0.27 (1.23)	0.0	-2.0, 0.9	0.6922
WEEK 72	5	1.33 (2.56)	0.94 (1.56)	0.2	0.0, 3.7	-0.39 (1.13)	-0.0	-2.2, 0.8	0.4827
Low Dose	4	1.53 (2.91)	1.17 (1.69)	0.5	0.0, 3.7	-0.36 (1.30)	-0.0	-2.2, 0.8	0.6160
High Dose	1	0.50 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	-0.50 (N/A)	-0.5	-0.5, -0.5	
WEEK 84	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								
WEEK 96	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Gender:Female (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia									
BASELINE	33		11.60 (4.92)	13.3	0.0, 16.0				
Low Dose	23		11.61 (4.88)	13.0	1.3, 16.0				
High Dose	10		11.56 (5.26)	13.9	0.0, 16.0				
WEEK 12	29	11.75 (4.70)	11.71 (4.13)	12.9	2.5, 16.0	-0.04 (4.15)	-0.0	-10.9, 14.2	0.9586
Low Dose	22	12.08 (4.44)	12.12 (4.07)	13.4	2.5, 16.0	0.04 (3.84)	-0.2	-6.6, 14.2	0.9599
High Dose	7	10.73 (5.70)	10.43 (4.37)	11.3	4.2, 15.8	-0.30 (5.34)	0.4	-10.9, 5.4	0.8874
WEEK 24	27	11.36 (4.92)	11.05 (5.29)	13.5	0.0, 16.0	-0.31 (4.99)	0.0	-13.3, 14.2	0.7509
Low Dose	18	11.51 (4.85)	11.06 (5.52)	14.0	0.0, 16.0	-0.44 (5.38)	0.0	-13.3, 14.2	0.7315
High Dose	9	11.07 (5.32)	11.03 (5.14)	13.3	2.6, 16.0	-0.04 (4.40)	0.0	-4.5, 10.6	0.9789
WEEK 36	15	11.67 (5.44)	14.27 (2.61)	15.5	8.0, 16.0	2.60 (5.01)	0.0	-1.4, 14.2	0.0638
Low Dose	10	12.91 (4.89)	14.79 (2.36)	15.7	8.4, 16.0	1.88 (4.71)	0.0	-1.4, 14.2	0.2382
High Dose	5	9.17 (6.17)	13.22 (3.04)	14.0	8.0, 16.0	4.05 (5.83)	1.0	0.0, 14.0	0.1957

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Gender:Female (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia (Cont.)									
WEEK 48	17	11.39 (5.68)	12.80 (4.33)	14.9	1.4, 16.0	1.41 (6.67)	0.0	-8.0, 14.9	0.3952
Low Dose	10	11.85 (5.92)	12.63 (3.82)	14.0	5.9, 16.0	0.78 (7.00)	-0.0	-8.0, 13.7	0.7330
High Dose	7	10.73 (5.70)	13.05 (5.28)	14.9	1.4, 16.0	2.32 (6.61)	0.0	-5.6, 14.9	0.3884
WEEK 60	11	10.81 (5.72)	13.49 (3.14)	15.5	8.2, 16.0	2.68 (4.52)	0.3	-0.5, 13.9	0.0777
Low Dose	7	10.58 (6.76)	13.82 (3.48)	15.8	8.2, 16.0	3.24 (5.57)	0.0	-0.5, 13.9	0.1748
High Dose	4	11.21 (4.16)	12.90 (2.81)	13.2	9.2, 16.0	1.69 (1.94)	1.3	0.0, 4.2	0.1798
WEEK 72	5	12.98 (4.02)	14.20 (2.02)	15.2	11.9, 16.0	1.22 (2.06)	0.0	-0.8, 3.6	0.2559
Low Dose	4	14.10 (3.63)	14.71 (1.92)	15.5	11.9, 16.0	0.61 (1.78)	0.0	-0.8, 3.2	0.5424
High Dose	1	8.50 (N/A)	12.15 (N/A)	12.1	12.1, 12.1	3.65 (N/A)	3.6	3.6, 3.6	
WEEK 84	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								
WEEK 96	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Gender:Female (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia									
BASELINE	33		1.76 (3.62)	0.0	0.0, 12.9				
Low Dose	23		1.56 (3.43)	0.0	0.0, 12.0				
High Dose	10		2.23 (4.16)	0.4	0.0, 12.9				
WEEK 12	29	1.57 (3.30)	1.63 (3.12)	0.0	0.0, 11.6	0.06 (3.84)	0.0	-11.6, 11.6	0.9292
Low Dose	22	1.08 (2.63)	1.63 (3.36)	0.0	0.0, 11.6	0.55 (4.09)	0.0	-11.6, 11.6	0.5357
High Dose	7	3.08 (4.80)	1.62 (2.46)	0.0	0.0, 6.1	-1.46 (2.62)	-0.6	-6.9, 1.0	0.1903
WEEK 24	27	2.13 (3.91)	0.66 (1.45)	0.0	0.0, 5.7	-1.47 (4.06)	0.0	-12.9, 4.5	0.0717
Low Dose	18	1.95 (3.81)	0.84 (1.71)	0.0	0.0, 5.7	-1.11 (4.04)	0.0	-12.0, 4.5	0.2605
High Dose	9	2.48 (4.33)	0.29 (0.63)	0.0	0.0, 1.8	-2.19 (4.25)	-0.2	-12.9, 0.1	0.1613
WEEK 36	15	2.28 (4.37)	0.29 (0.80)	0.0	0.0, 3.1	-2.00 (4.52)	0.0	-12.9, 2.9	0.1090
Low Dose	10	1.33 (3.71)	0.09 (0.22)	0.0	0.0, 0.7	-1.23 (3.63)	0.0	-11.6, 0.0	0.3120
High Dose	5	4.20 (5.39)	0.67 (1.37)	0.0	0.0, 3.1	-3.53 (6.12)	-2.0	-12.9, 2.9	0.2661

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Gender:Female (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia (Cont.)									
WEEK 48	17	2.75 (4.75)	0.75 (1.94)	0.0	0.0, 8.0	-2.01 (5.16)	0.0	-12.9, 8.0	0.1281
Low Dose	10	2.53 (4.96)	1.16 (2.48)	0.0	0.0, 8.0	-1.36 (5.51)	0.0	-11.1, 8.0	0.4539
High Dose	7	3.08 (4.80)	0.15 (0.29)	0.0	0.0, 0.8	-2.93 (4.87)	-0.6	-12.9, 0.1	0.1627
WEEK 60	11	2.58 (4.67)	0.83 (1.42)	0.0	0.0, 4.7	-1.76 (3.87)	0.0	-11.3, 1.1	0.1634
Low Dose	7	3.61 (5.69)	0.87 (1.71)	0.0	0.0, 4.7	-2.74 (4.63)	0.0	-11.3, 0.0	0.1689
High Dose	4	0.79 (1.01)	0.75 (0.92)	0.6	0.0, 1.9	-0.04 (0.91)	-0.1	-1.1, 1.1	0.9405
WEEK 72	5	0.44 (0.65)	0.53 (0.94)	0.0	0.0, 2.2	0.09 (0.86)	0.0	-1.0, 1.4	0.8309
Low Dose	4	0.36 (0.72)	0.11 (0.23)	0.0	0.0, 0.5	-0.25 (0.49)	0.0	-1.0, 0.0	0.3910
High Dose	1	0.75 (N/A)	2.18 (N/A)	2.2	2.2, 2.2	1.43 (N/A)	1.4	1.4, 1.4	
WEEK 84	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								
WEEK 96	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Gender:Female (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia									
BASELINE	33		0.73 (2.58)	0.0	0.0, 13.5				
Low Dose	23		0.78 (2.85)	0.0	0.0, 13.5				
High Dose	10		0.63 (1.98)	0.0	0.0, 6.3				
WEEK 12	29	0.62 (2.54)	0.03 (0.13)	0.0	0.0, 0.7	-0.59 (2.55)	0.0	-13.5, 0.7	0.2265
Low Dose	22	0.81 (2.91)	0.04 (0.15)	0.0	0.0, 0.7	-0.77 (2.92)	0.0	-13.5, 0.7	0.2285
High Dose	7	0.00 (0.00)	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
WEEK 24	27	0.39 (1.30)	0.59 (2.00)	0.0	0.0, 7.8	0.20 (1.36)	0.0	-2.7, 6.4	0.4550
Low Dose	18	0.24 (0.70)	0.49 (1.84)	0.0	0.0, 7.8	0.25 (1.66)	0.0	-2.7, 6.4	0.5389
High Dose	9	0.69 (2.08)	0.80 (2.39)	0.0	0.0, 7.2	0.10 (0.31)	0.0	0.0, 0.9	0.3466
WEEK 36	15	0.18 (0.69)	0.03 (0.12)	0.0	0.0, 0.5	-0.15 (0.71)	0.0	-2.7, 0.5	0.4331
Low Dose	10	0.27 (0.84)	0.05 (0.14)	0.0	0.0, 0.5	-0.22 (0.87)	0.0	-2.7, 0.5	0.4432
High Dose	5	0.00 (0.00)	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Gender:Female (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia (Cont.)									
WEEK 48	17	0.16 (0.65)	0.01 (0.06)	0.0	0.0, 0.2	-0.14 (0.65)	0.0	-2.7, 0.2	0.3783
Low Dose	10	0.27 (0.84)	0.02 (0.07)	0.0	0.0, 0.2	-0.24 (0.85)	0.0	-2.7, 0.2	0.3903
High Dose	7	0.00 (0.00)	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
WEEK 60	11	0.81 (1.97)	0.07 (0.22)	0.0	0.0, 0.7	-0.74 (2.02)	0.0	-6.3, 0.7	0.2485
Low Dose	7	0.38 (1.01)	0.00 (0.00)	0.0	0.0, 0.0	-0.38 (1.01)	0.0	-2.7, 0.0	0.3559
High Dose	4	1.56 (3.13)	0.18 (0.36)	0.0	0.0, 0.7	-1.38 (3.26)	0.0	-6.3, 0.7	0.4597
WEEK 72	5	1.25 (2.80)	0.34 (0.75)	0.0	0.0, 1.7	-0.91 (2.05)	0.0	-4.6, 0.0	0.3739
Low Dose	4	0.00 (0.00)	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
High Dose	1	6.25 (N/A)	1.68 (N/A)	1.7	1.7, 1.7	-4.57 (N/A)	-4.6	-4.6, -4.6	
WEEK 84	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								
WEEK 96	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Gender:Female (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia									
BASELINE	33		13.36 (3.17)	14.8	2.5, 16.0				
Low Dose	23		13.17 (3.26)	13.3	2.5, 16.0				
High Dose	10		13.79 (3.10)	15.1	7.2, 16.0				
WEEK 12	29	13.32 (3.23)	13.34 (2.47)	13.8	5.1, 16.0	0.02 (3.73)	-0.0	-10.9, 11.6	0.9731
Low Dose	22	13.16 (3.33)	13.75 (1.94)	14.0	9.9, 16.0	0.59 (3.05)	0.0	-3.8, 11.6	0.3739
High Dose	7	13.81 (3.05)	12.05 (3.56)	13.7	5.1, 15.8	-1.76 (5.25)	-1.3	-10.9, 6.4	0.4094
WEEK 24	27	13.49 (2.63)	11.71 (4.75)	13.5	0.0, 16.0	-1.78 (3.35)	-0.2	-13.3, 2.7	0.0107*
Low Dose	18	13.46 (2.40)	11.91 (4.82)	14.1	0.0, 16.0	-1.55 (3.81)	-0.0	-13.3, 2.7	0.1024
High Dose	9	13.55 (3.18)	11.32 (4.86)	13.3	2.6, 16.0	-2.23 (2.31)	-2.2	-6.2, 0.0	0.0202*
WEEK 36	15	13.95 (2.85)	14.56 (2.04)	15.5	9.1, 16.0	0.61 (1.98)	0.0	-1.4, 5.5	0.2550
Low Dose	10	14.24 (2.55)	14.89 (2.17)	15.9	9.1, 16.0	0.65 (2.03)	0.0	-1.4, 5.5	0.3359
High Dose	5	13.38 (3.63)	13.89 (1.76)	14.0	11.1, 16.0	0.51 (2.10)	0.0	-1.2, 3.9	0.6134

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Gender:Female (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia (Cont.)									
WEEK 48	17	14.14 (2.36)	13.55 (4.09)	15.3	1.7, 16.0	-0.59 (2.59)	0.0	-7.4, 2.7	0.3580
Low Dose	10	14.37 (1.89)	13.79 (3.45)	15.6	5.9, 16.0	-0.59 (2.76)	0.0	-7.4, 2.7	0.5188
High Dose	7	13.81 (3.05)	13.21 (5.15)	14.9	1.7, 16.0	-0.60 (2.53)	0.0	-5.5, 2.0	0.5509
WEEK 60	11	13.40 (3.14)	14.32 (2.65)	15.8	9.1, 16.0	0.92 (1.84)	0.0	-1.0, 5.3	0.1277
Low Dose	7	14.19 (2.14)	14.69 (2.59)	16.0	9.1, 16.0	0.50 (1.18)	0.0	-1.0, 2.7	0.2995
High Dose	4	12.00 (4.42)	13.65 (3.01)	14.7	9.2, 16.0	1.65 (2.72)	1.0	-0.7, 5.3	0.3119
WEEK 72	5	13.42 (3.43)	14.73 (1.48)	15.2	12.3, 16.0	1.31 (2.39)	0.0	-0.8, 5.1	0.2890
Low Dose	4	14.47 (2.91)	14.83 (1.69)	15.5	12.3, 16.0	0.36 (1.30)	0.0	-0.8, 2.2	0.6160
High Dose	1	9.25 (N/A)	14.32 (N/A)	14.3	14.3, 14.3	5.07 (N/A)	5.1	5.1, 5.1	
WEEK 84	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								
WEEK 96	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Gender:Male									
Average Daily Normalized 'Off' Time									
BASELINE	64		2.88 (3.19)	1.6	0.0, 11.5				
Low Dose	22		3.87 (3.27)	2.8	0.0, 10.9				
High Dose	42		2.36 (3.06)	0.5	0.0, 11.5				
WEEK 12	46	3.33 (3.45)	3.21 (3.03)	2.6	0.0, 10.8	-0.12 (2.37)	0.0	-8.2, 6.8	0.7345
Low Dose	16	4.34 (3.59)	3.23 (2.73)	2.7	0.0, 8.0	-1.10 (2.78)	-0.1	-8.2, 2.7	0.1340
High Dose	30	2.79 (3.30)	3.19 (3.23)	2.2	0.0, 10.8	0.41 (1.96)	0.0	-4.3, 6.8	0.2673
WEEK 24	48	2.49 (2.76)	2.79 (3.07)	2.3	0.0, 10.9	0.30 (2.71)	0.0	-6.1, 7.7	0.4402
Low Dose	18	3.75 (2.91)	2.85 (2.89)	2.5	0.0, 10.8	-0.90 (2.83)	-0.3	-6.1, 4.3	0.1923
High Dose	30	1.73 (2.40)	2.75 (3.22)	2.3	0.0, 10.9	1.03 (2.39)	0.0	-3.3, 7.7	0.0256*
WEEK 36	24	2.52 (2.52)	2.93 (2.90)	2.7	0.0, 12.1	0.41 (1.89)	0.1	-3.5, 5.6	0.3029
Low Dose	11	3.38 (2.20)	4.08 (3.36)	3.6	0.0, 12.1	0.70 (1.78)	0.3	-1.1, 5.6	0.2214
High Dose	13	1.79 (2.63)	1.95 (2.11)	1.0	0.0, 6.1	0.16 (2.01)	0.0	-3.5, 3.9	0.7829

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Gender:Male (Cont.)									
Average Daily Normalized 'Off' Time (Cont.)									
WEEK 48	35	2.17 (2.45)	2.99 (3.36)	1.7	0.0, 11.0	0.82 (2.22)	0.0	-3.0, 6.6	0.0352*
Low Dose	11	2.79 (2.50)	2.43 (2.96)	1.7	0.0, 9.0	-0.36 (1.57)	-0.0	-3.0, 2.5	0.4685
High Dose	24	1.88 (2.42)	3.24 (3.56)	1.9	0.0, 11.0	1.36 (2.28)	0.5	-1.1, 6.6	0.0076**
WEEK 60	18	2.99 (2.50)	3.90 (2.64)	3.4	0.0, 10.4	0.91 (1.85)	1.1	-3.0, 3.9	0.0519
Low Dose	9	3.68 (2.24)	4.07 (3.11)	3.7	0.0, 10.4	0.38 (2.06)	-0.2	-3.0, 3.9	0.5918
High Dose	9	2.30 (2.69)	3.74 (2.25)	3.1	0.0, 7.1	1.44 (1.55)	2.0	-1.3, 3.9	0.0238*
WEEK 72	7	3.27 (2.60)	5.09 (3.29)	3.9	1.7, 10.4	1.82 (2.84)	2.2	-1.7, 5.5	0.1397
Low Dose	2	3.40 (1.10)	2.73 (1.40)	2.7	1.7, 3.7	-0.67 (0.29)	-0.7	-0.9, -0.5	0.1909
High Dose	5	3.21 (3.14)	6.04 (3.44)	5.5	1.9, 10.4	2.82 (2.77)	3.9	-1.7, 5.5	0.0851
WEEK 84	1	6.13 (N/A)	11.43 (N/A)	11.4	11.4, 11.4	5.30 (N/A)	5.3	5.3, 5.3	
Low Dose	0								
High Dose	1	6.13 (N/A)	11.43 (N/A)	11.4	11.4, 11.4	5.30 (N/A)	5.3	5.3, 5.3	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Gender:Male (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia									
BASELINE	64		10.17 (4.77)	11.0	0.0, 16.0				
Low Dose	22		9.99 (3.91)	10.6	0.0, 15.3				
High Dose	42		10.27 (5.21)	11.2	0.0, 16.0				
WEEK 12	46	9.98 (4.96)	10.27 (4.89)	10.8	0.0, 16.0	0.30 (3.46)	0.0	-9.6, 9.0	0.5639
Low Dose	16	9.37 (4.24)	9.89 (5.29)	11.1	0.0, 16.0	0.52 (3.81)	0.6	-6.7, 8.2	0.5913
High Dose	30	10.30 (5.34)	10.48 (4.74)	10.8	0.0, 16.0	0.18 (3.31)	0.0	-9.6, 9.0	0.7740
WEEK 24	48	10.27 (4.75)	10.31 (4.46)	10.4	0.0, 16.0	0.04 (4.19)	0.0	-9.6, 13.7	0.9469
Low Dose	18	9.78 (3.81)	9.95 (4.83)	10.5	0.0, 16.0	0.17 (3.71)	-0.1	-5.9, 7.4	0.8484
High Dose	30	10.57 (5.28)	10.53 (4.30)	10.4	0.0, 16.0	-0.04 (4.52)	0.0	-9.6, 13.7	0.9644
WEEK 36	24	11.31 (3.94)	9.73 (4.95)	11.0	0.0, 16.0	-1.59 (3.09)	-0.4	-11.2, 2.4	0.0193*
Low Dose	11	11.39 (2.53)	9.99 (4.74)	11.1	1.3, 16.0	-1.40 (2.48)	-0.4	-5.9, 1.4	0.0910
High Dose	13	11.25 (4.94)	9.50 (5.30)	9.9	0.0, 16.0	-1.75 (3.62)	-0.2	-11.2, 2.4	0.1077

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Gender:Male (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia (Cont.)									
WEEK 48	35	10.05 (4.76)	10.09 (4.66)	10.2	0.0, 16.0	0.04 (3.64)	0.2	-9.4, 7.9	0.9428
Low Dose	11	9.90 (4.15)	10.15 (5.38)	10.2	1.1, 16.0	0.25 (3.57)	0.4	-5.1, 7.4	0.8208
High Dose	24	10.12 (5.10)	10.07 (4.42)	10.4	0.0, 16.0	-0.05 (3.75)	0.0	-9.4, 7.9	0.9487
WEEK 60	18	9.75 (4.46)	9.23 (3.80)	9.3	0.8, 16.0	-0.52 (3.45)	-1.1	-6.1, 6.3	0.5291
Low Dose	9	10.30 (2.29)	8.32 (3.82)	9.5	0.8, 13.6	-1.98 (3.07)	-2.5	-6.1, 4.9	0.0896
High Dose	9	9.21 (6.03)	10.14 (3.76)	9.1	4.3, 16.0	0.93 (3.34)	0.3	-3.9, 6.3	0.4268
WEEK 72	7	9.52 (4.56)	8.90 (4.78)	9.8	1.4, 14.1	-0.62 (5.97)	-0.4	-9.9, 9.8	0.7934
Low Dose	2	12.60 (1.10)	12.66 (0.52)	12.7	12.3, 13.0	0.05 (0.58)	0.1	-0.4, 0.5	0.9198
High Dose	5	8.28 (4.92)	7.39 (4.93)	7.5	1.4, 14.1	-0.89 (7.29)	-2.2	-9.9, 9.8	0.7991
WEEK 84	1	8.05 (N/A)	4.57 (N/A)	4.6	4.6, 4.6	-3.48 (N/A)	-3.5	-3.5, -3.5	
Low Dose	0								
High Dose	1	8.05 (N/A)	4.57 (N/A)	4.6	4.6, 4.6	-3.48 (N/A)	-3.5	-3.5, -3.5	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Gender:Male (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia									
BASELINE	64		2.59 (4.39)	0.5	0.0, 16.0				
Low Dose	22		1.96 (3.66)	0.6	0.0, 16.0				
High Dose	42		2.91 (4.74)	0.4	0.0, 16.0				
WEEK 12	46	2.24 (4.38)	1.96 (3.82)	0.0	0.0, 16.0	-0.28 (3.76)	0.0	-15.8, 6.7	0.6107
Low Dose	16	2.05 (4.11)	1.91 (3.26)	0.2	0.0, 12.4	-0.14 (3.51)	0.0	-11.0, 5.7	0.8746
High Dose	30	2.35 (4.58)	1.99 (4.14)	0.0	0.0, 16.0	-0.36 (3.94)	0.0	-15.8, 6.7	0.6202
WEEK 24	48	2.82 (4.38)	2.60 (4.01)	0.8	0.0, 16.0	-0.22 (3.72)	0.0	-16.0, 6.2	0.6850
Low Dose	18	2.27 (3.98)	3.04 (4.54)	1.5	0.0, 16.0	0.77 (2.63)	0.0	-4.2, 6.2	0.2329
High Dose	30	3.14 (4.64)	2.33 (3.71)	0.0	0.0, 16.0	-0.81 (4.17)	0.0	-16.0, 6.1	0.2959
WEEK 36	24	1.84 (2.83)	3.08 (4.81)	0.5	0.0, 16.0	1.24 (2.75)	0.0	-1.4, 11.2	0.0372*
Low Dose	11	1.21 (2.06)	1.82 (3.28)	0.5	0.0, 11.1	0.61 (1.52)	0.2	-1.4, 4.4	0.2116
High Dose	13	2.37 (3.33)	4.15 (5.71)	0.5	0.0, 16.0	1.77 (3.45)	0.0	-1.0, 11.2	0.0885

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Gender:Male (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia (Cont.)									
WEEK 48	35	3.35 (4.71)	2.47 (3.70)	0.7	0.0, 14.9	-0.88 (3.62)	0.0	-12.8, 5.2	0.1577
Low Dose	11	2.98 (4.79)	3.33 (5.31)	0.9	0.0, 14.9	0.35 (2.33)	-0.3	-3.5, 5.2	0.6322
High Dose	24	3.52 (4.77)	2.07 (2.74)	0.6	0.0, 9.8	-1.45 (4.00)	0.0	-12.8, 4.9	0.0889
WEEK 60	18	2.78 (4.38)	2.68 (3.12)	2.0	0.0, 11.6	-0.10 (3.74)	0.0	-10.2, 5.7	0.9068
Low Dose	9	1.65 (2.35)	3.52 (3.70)	2.1	0.0, 11.6	1.87 (2.68)	2.1	-3.5, 5.7	0.0700
High Dose	9	3.91 (5.69)	1.83 (2.31)	0.0	0.0, 5.8	-2.08 (3.71)	-0.7	-10.2, 1.0	0.1312
WEEK 72	7	3.22 (5.90)	1.23 (1.50)	1.2	0.0, 4.2	-1.99 (5.43)	0.0	-14.2, 1.2	0.3703
Low Dose	2	0.00 (0.00)	0.62 (0.88)	0.6	0.0, 1.2	0.62 (0.88)	0.6	0.0, 1.2	0.5000
High Dose	5	4.51 (6.71)	1.48 (1.71)	1.5	0.0, 4.2	-3.03 (6.27)	-0.4	-14.2, 0.0	0.3406
WEEK 84	1	1.82 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	-1.82 (N/A)	-1.8	-1.8, -1.8	
Low Dose	0								
High Dose	1	1.82 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	-1.82 (N/A)	-1.8	-1.8, -1.8	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Gender:Male (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia									
BASELINE	64		0.36 (0.97)	0.0	0.0, 5.3				
Low Dose	22		0.17 (0.71)	0.0	0.0, 3.3				
High Dose	42		0.45 (1.07)	0.0	0.0, 5.3				
WEEK 12	46	0.45 (1.10)	0.56 (1.88)	0.0	0.0, 11.0	0.11 (2.14)	0.0	-5.3, 11.0	0.7355
Low Dose	16	0.24 (0.82)	0.96 (2.90)	0.0	0.0, 11.0	0.72 (3.07)	0.0	-3.3, 11.0	0.3625
High Dose	30	0.57 (1.23)	0.35 (1.02)	0.0	0.0, 4.4	-0.22 (1.38)	0.0	-5.3, 3.0	0.3878
WEEK 24	48	0.43 (1.10)	0.30 (0.83)	0.0	0.0, 4.3	-0.13 (1.31)	0.0	-5.3, 4.3	0.5102
Low Dose	18	0.20 (0.78)	0.17 (0.35)	0.0	0.0, 1.1	-0.03 (0.90)	0.0	-3.3, 1.1	0.8776
High Dose	30	0.56 (1.24)	0.38 (1.01)	0.0	0.0, 4.3	-0.18 (1.51)	0.0	-5.3, 4.3	0.5186
WEEK 36	24	0.33 (1.16)	0.27 (0.71)	0.0	0.0, 2.8	-0.06 (1.21)	0.0	-5.3, 1.8	0.8097
Low Dose	11	0.03 (0.09)	0.11 (0.37)	0.0	0.0, 1.2	0.08 (0.38)	0.0	-0.3, 1.2	0.4834
High Dose	13	0.59 (1.56)	0.40 (0.89)	0.0	0.0, 2.8	-0.18 (1.63)	0.0	-5.3, 1.8	0.6936

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Gender:Male (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia (Cont.)									
WEEK 48	35	0.43 (0.94)	0.45 (1.20)	0.0	0.0, 6.2	0.02 (1.48)	0.0	-3.3, 6.2	0.9437
Low Dose	11	0.33 (0.99)	0.09 (0.22)	0.0	0.0, 0.7	-0.24 (1.05)	0.0	-3.3, 0.7	0.4665
High Dose	24	0.48 (0.94)	0.62 (1.42)	0.0	0.0, 6.2	0.14 (1.64)	0.0	-3.0, 6.2	0.6897
WEEK 60	18	0.47 (0.98)	0.19 (0.42)	0.0	0.0, 1.5	-0.28 (1.02)	0.0	-3.3, 1.5	0.2545
Low Dose	9	0.37 (1.10)	0.09 (0.21)	0.0	0.0, 0.6	-0.27 (1.16)	0.0	-3.3, 0.6	0.4984
High Dose	9	0.57 (0.90)	0.28 (0.56)	0.0	0.0, 1.5	-0.29 (0.94)	0.0	-1.5, 1.5	0.3733
WEEK 72	7	0.00 (0.00)	0.78 (1.85)	0.0	0.0, 5.0	0.78 (1.85)	0.0	0.0, 5.0	0.3065
Low Dose	2	0.00 (0.00)	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
High Dose	5	0.00 (0.00)	1.10 (2.17)	0.0	0.0, 5.0	1.10 (2.17)	0.0	0.0, 5.0	0.3226
WEEK 84	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	0								
High Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Gender:Male (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia									
BASELINE	64		12.76 (3.25)	13.6	4.5, 16.0				
Low Dose	22		11.95 (3.18)	12.7	5.1, 16.0				
High Dose	42		13.18 (3.24)	14.9	4.5, 16.0				
WEEK 12	46	12.22 (3.47)	12.23 (3.39)	12.9	5.0, 16.0	0.01 (3.13)	0.0	-11.0, 8.2	0.9794
Low Dose	16	11.42 (3.44)	11.81 (3.55)	12.9	5.0, 16.0	0.38 (4.28)	0.2	-11.0, 8.2	0.7263
High Dose	30	12.65 (3.47)	12.46 (3.34)	13.0	5.2, 16.0	-0.19 (2.36)	0.0	-6.8, 5.3	0.6695
WEEK 24	48	13.09 (2.83)	12.91 (3.08)	13.7	5.1, 16.0	-0.18 (2.82)	0.0	-7.7, 6.1	0.6630
Low Dose	18	12.05 (2.79)	12.99 (2.95)	13.5	5.2, 16.0	0.94 (2.90)	0.5	-4.3, 6.1	0.1884
High Dose	30	13.71 (2.72)	12.86 (3.20)	13.7	5.1, 16.0	-0.85 (2.60)	-0.5	-7.7, 3.3	0.0843
WEEK 36	24	13.15 (2.65)	12.81 (2.85)	12.5	3.9, 16.0	-0.35 (2.13)	0.0	-5.6, 4.3	0.4334
Low Dose	11	12.59 (2.18)	11.81 (3.37)	12.4	3.9, 16.0	-0.79 (1.86)	-0.3	-5.6, 1.1	0.1905
High Dose	13	13.62 (3.00)	13.65 (2.10)	14.2	9.9, 16.0	0.03 (2.34)	0.0	-3.9, 4.3	0.9695

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Gender:Male (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia (Cont.)									
WEEK 48	35	13.40 (2.62)	12.56 (3.39)	13.7	5.0, 16.0	-0.84 (2.73)	-0.2	-6.6, 3.8	0.0771
Low Dose	11	12.88 (2.38)	13.48 (3.00)	14.1	7.0, 16.0	0.60 (2.02)	0.0	-2.5, 3.8	0.3491
High Dose	24	13.64 (2.74)	12.14 (3.53)	12.8	5.0, 16.0	-1.50 (2.79)	-0.5	-6.6, 2.3	0.0148*
WEEK 60	18	12.54 (2.62)	11.91 (2.66)	12.2	5.6, 16.0	-0.63 (1.95)	-0.5	-3.9, 3.0	0.1890
Low Dose	9	11.95 (1.91)	11.84 (3.04)	12.3	5.6, 16.0	-0.11 (2.05)	-0.1	-3.9, 3.0	0.8768
High Dose	9	13.12 (3.18)	11.98 (2.41)	12.1	7.8, 16.0	-1.15 (1.80)	-0.7	-3.9, 1.3	0.0926
WEEK 72	7	12.73 (2.60)	10.13 (3.83)	11.6	5.6, 14.3	-2.61 (4.22)	-2.2	-10.4, 1.7	0.1535
Low Dose	2	12.60 (1.10)	13.27 (1.40)	13.3	12.3, 14.3	0.67 (0.29)	0.7	0.5, 0.9	0.1909
High Dose	5	12.79 (3.14)	8.87 (3.81)	7.5	5.6, 14.1	-3.92 (4.38)	-4.3	-10.4, 1.7	0.1162
WEEK 84	1	9.87 (N/A)	4.57 (N/A)	4.6	4.6, 4.6	-5.30 (N/A)	-5.3	-5.3, -5.3	
Low Dose	0								
High Dose	1	9.87 (N/A)	4.57 (N/A)	4.6	4.6, 4.6	-5.30 (N/A)	-5.3	-5.3, -5.3	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Race:WHITE									
Average Daily Normalized 'Off' Time									
BASELINE	82		2.17 (2.85)	0.7	0.0, 11.5				
Low Dose	36		2.52 (2.76)	2.0	0.0, 10.9				
High Dose	46		1.90 (2.92)	0.5	0.0, 11.5				
WEEK 12	60	2.39 (3.09)	2.49 (2.74)	2.0	0.0, 10.9	0.10 (2.69)	0.0	-8.2, 10.9	0.7750
Low Dose	29	2.49 (2.98)	2.04 (1.97)	1.9	0.0, 7.3	-0.45 (2.19)	0.0	-8.2, 2.8	0.2779
High Dose	31	2.29 (3.24)	2.91 (3.28)	2.0	0.0, 10.9	0.61 (3.03)	0.0	-6.4, 10.9	0.2676
WEEK 24	64	1.93 (2.39)	2.74 (3.58)	1.2	0.0, 16.0	0.82 (2.97)	0.0	-6.0, 13.3	0.0312*
Low Dose	29	2.53 (2.47)	2.78 (3.91)	1.2	0.0, 16.0	0.25 (3.57)	0.0	-6.0, 13.3	0.7082
High Dose	35	1.43 (2.23)	2.71 (3.35)	1.7	0.0, 13.4	1.29 (2.31)	0.0	-3.1, 7.7	0.0023**
WEEK 36	33	1.87 (2.48)	2.17 (2.77)	1.2	0.0, 12.1	0.30 (1.46)	0.0	-3.9, 5.6	0.2546
Low Dose	19	2.27 (2.45)	2.67 (3.29)	1.9	0.0, 12.1	0.41 (1.40)	0.0	-1.1, 5.6	0.2227
High Dose	14	1.34 (2.51)	1.49 (1.74)	0.9	0.0, 4.9	0.15 (1.59)	0.0	-3.9, 3.6	0.7357

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Race:WHITE (Cont.)									
Average Daily Normalized 'Off' Time (Cont.)									
WEEK 48	47	1.80 (2.31)	2.62 (3.69)	0.9	0.0, 14.3	0.82 (2.31)	0.0	-3.0, 7.4	0.0187*
Low Dose	20	2.10 (2.36)	2.32 (3.19)	0.5	0.0, 10.1	0.22 (2.18)	0.0	-3.0, 7.4	0.6560
High Dose	27	1.59 (2.29)	2.85 (4.07)	1.1	0.0, 14.3	1.27 (2.35)	0.2	-2.0, 6.6	0.0094**
WEEK 60	25	2.40 (2.70)	2.74 (2.90)	2.4	0.0, 10.4	0.34 (1.52)	0.0	-3.0, 3.9	0.2685
Low Dose	15	2.72 (2.52)	2.80 (3.24)	2.0	0.0, 10.4	0.09 (1.61)	-0.0	-3.0, 3.9	0.8399
High Dose	10	1.92 (3.02)	2.65 (2.48)	2.5	0.0, 6.9	0.73 (1.36)	0.7	-2.0, 2.4	0.1220
WEEK 72	10	1.70 (2.19)	2.14 (1.93)	1.8	0.0, 5.5	0.44 (2.42)	-0.2	-2.2, 5.5	0.5796
Low Dose	6	2.16 (2.50)	1.69 (1.66)	1.3	0.0, 3.7	-0.47 (1.03)	-0.2	-2.2, 0.8	0.3183
High Dose	4	1.01 (1.71)	2.81 (2.37)	2.9	0.0, 5.5	1.80 (3.42)	1.7	-1.7, 5.5	0.3700
WEEK 84	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								
WEEK 96	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Race:WHITE (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia									
BASELINE	82		10.87 (5.00)	12.4	0.0, 16.0				
Low Dose	36		11.18 (4.57)	12.7	0.0, 16.0				
High Dose	46		10.63 (5.35)	12.0	0.0, 16.0				
WEEK 12	60	10.96 (5.13)	11.52 (4.43)	12.6	0.0, 16.0	0.56 (3.76)	0.0	-10.9, 14.2	0.2564
Low Dose	29	11.42 (4.64)	12.15 (4.16)	13.3	0.0, 16.0	0.73 (3.79)	0.0	-6.6, 14.2	0.3075
High Dose	31	10.53 (5.59)	10.92 (4.65)	11.1	0.0, 16.0	0.39 (3.78)	0.0	-10.9, 9.0	0.5685
WEEK 24	64	10.98 (4.91)	11.14 (4.69)	11.9	0.0, 16.0	0.16 (4.60)	0.0	-13.3, 14.2	0.7802
Low Dose	29	11.16 (4.49)	11.40 (5.03)	13.6	0.0, 16.0	0.25 (4.70)	0.0	-13.3, 14.2	0.7804
High Dose	35	10.83 (5.30)	10.92 (4.45)	11.3	0.0, 16.0	0.09 (4.59)	0.0	-9.6, 13.7	0.9070
WEEK 36	33	11.90 (4.50)	11.96 (4.63)	14.0	0.0, 16.0	0.06 (4.51)	0.0	-11.2, 14.2	0.9349
Low Dose	19	12.54 (3.75)	12.72 (3.84)	14.0	3.4, 16.0	0.19 (3.77)	0.0	-5.9, 14.2	0.8321
High Dose	14	11.03 (5.39)	10.93 (5.52)	12.9	0.0, 16.0	-0.10 (5.51)	0.0	-11.2, 14.0	0.9469

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours
(i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Race:WHITE (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia (Cont.)									
WEEK 48	47	10.65 (5.14)	11.40 (4.58)	12.4	0.0, 16.0	0.74 (4.92)	0.0	-9.4, 14.9	0.3070
Low Dose	20	11.03 (5.09)	11.81 (4.33)	12.6	1.1, 16.0	0.78 (5.31)	0.1	-8.0, 13.7	0.5180
High Dose	27	10.38 (5.25)	11.09 (4.82)	12.4	0.0, 16.0	0.71 (4.72)	0.0	-9.4, 14.9	0.4401
WEEK 60	25	10.38 (4.94)	11.56 (3.55)	10.9	4.5, 16.0	1.18 (4.10)	0.0	-4.7, 13.9	0.1627
Low Dose	15	10.66 (4.66)	11.39 (3.81)	10.3	4.5, 16.0	0.74 (4.82)	-0.5	-4.7, 13.9	0.5641
High Dose	10	9.97 (5.57)	11.82 (3.30)	12.9	6.3, 16.0	1.85 (2.79)	1.2	-2.0, 6.3	0.0659
WEEK 72	10	11.39 (4.86)	12.17 (4.25)	12.7	1.4, 16.0	0.78 (4.89)	0.2	-9.9, 9.8	0.6255
Low Dose	6	13.60 (2.96)	14.03 (1.84)	14.1	11.9, 16.0	0.42 (1.43)	0.0	-0.8, 3.2	0.5010
High Dose	4	8.06 (5.62)	9.38 (5.58)	11.0	1.4, 14.1	1.32 (8.22)	2.7	-9.9, 9.8	0.7699
WEEK 84	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								
WEEK 96	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Race:WHITE (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia									
BASELINE	82		2.44 (4.41)	0.1	0.0, 16.0				
Low Dose	36		1.74 (3.77)	0.0	0.0, 16.0				
High Dose	46		2.99 (4.83)	0.3	0.0, 16.0				
WEEK 12	60	2.08 (4.34)	1.70 (3.55)	0.0	0.0, 16.0	-0.39 (4.01)	0.0	-15.8, 11.6	0.4585
Low Dose	29	1.40 (3.59)	1.40 (2.82)	0.0	0.0, 11.6	-0.00 (4.15)	0.0	-11.6, 11.6	0.9982
High Dose	31	2.73 (4.91)	1.98 (4.14)	0.0	0.0, 16.0	-0.75 (3.92)	0.0	-15.8, 6.7	0.2968
WEEK 24	64	2.67 (4.45)	1.80 (3.41)	0.0	0.0, 16.0	-0.86 (4.09)	0.0	-16.0, 6.2	0.0958
Low Dose	29	2.09 (4.13)	1.69 (3.34)	0.0	0.0, 16.0	-0.40 (3.73)	0.0	-12.0, 6.2	0.5679
High Dose	35	3.15 (4.71)	1.90 (3.52)	0.0	0.0, 16.0	-1.25 (4.37)	0.0	-16.0, 6.1	0.1007
WEEK 36	33	1.98 (3.59)	1.75 (3.95)	0.0	0.0, 16.0	-0.23 (4.07)	0.0	-12.9, 11.2	0.7450
Low Dose	19	1.04 (2.73)	0.52 (0.96)	0.0	0.0, 3.0	-0.52 (2.76)	0.0	-11.6, 1.8	0.4188
High Dose	14	3.25 (4.29)	3.41 (5.66)	0.1	0.0, 16.0	0.16 (5.47)	0.0	-12.9, 11.2	0.9127

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Race:WHITE (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia (Cont.)									
WEEK 48	47	3.21 (4.85)	1.70 (3.11)	0.0	0.0, 14.9	-1.52 (4.24)	0.0	-12.9, 8.0	0.0180*
Low Dose	20	2.57 (4.79)	1.82 (3.74)	0.0	0.0, 14.9	-0.75 (4.04)	0.0	-11.1, 8.0	0.4174
High Dose	27	3.69 (4.94)	1.61 (2.62)	0.2	0.0, 9.8	-2.08 (4.36)	-0.6	-12.9, 4.9	0.0199*
WEEK 60	25	2.61 (4.64)	1.57 (2.10)	0.5	0.0, 5.8	-1.04 (3.92)	0.0	-11.3, 5.7	0.1969
Low Dose	15	2.23 (4.09)	1.75 (2.15)	0.9	0.0, 5.8	-0.48 (4.17)	0.0	-11.3, 5.7	0.6634
High Dose	10	3.20 (5.54)	1.31 (2.11)	0.0	0.0, 5.8	-1.88 (3.56)	-0.4	-10.2, 1.1	0.1281
WEEK 72	10	2.29 (5.04)	0.98 (1.39)	0.2	0.0, 4.2	-1.31 (4.60)	0.0	-14.2, 1.4	0.3910
Low Dose	6	0.24 (0.59)	0.28 (0.50)	0.0	0.0, 1.2	0.04 (0.71)	0.0	-1.0, 1.2	0.8905
High Dose	4	5.36 (7.39)	2.02 (1.71)	2.0	0.0, 4.2	-3.34 (7.31)	-0.3	-14.2, 1.4	0.4285
WEEK 84	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								
WEEK 96	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Race:WHITE (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia									
BASELINE	82		0.52 (1.82)	0.0	0.0, 13.5				
Low Dose	36		0.56 (2.33)	0.0	0.0, 13.5				
High Dose	46		0.48 (1.32)	0.0	0.0, 6.3				
WEEK 12	60	0.57 (1.97)	0.30 (1.49)	0.0	0.0, 11.0	-0.27 (2.50)	0.0	-13.5, 11.0	0.4084
Low Dose	29	0.69 (2.59)	0.41 (2.05)	0.0	0.0, 11.0	-0.28 (3.39)	0.0	-13.5, 11.0	0.6596
High Dose	31	0.45 (1.17)	0.19 (0.65)	0.0	0.0, 3.0	-0.26 (1.28)	0.0	-5.3, 3.0	0.2679
WEEK 24	64	0.43 (1.23)	0.31 (1.10)	0.0	0.0, 7.2	-0.12 (1.18)	0.0	-5.3, 4.3	0.4374
Low Dose	29	0.22 (0.77)	0.13 (0.30)	0.0	0.0, 1.1	-0.10 (0.86)	0.0	-3.3, 1.1	0.5532
High Dose	35	0.60 (1.49)	0.46 (1.45)	0.0	0.0, 7.2	-0.13 (1.41)	0.0	-5.3, 4.3	0.5830
WEEK 36	33	0.25 (1.02)	0.12 (0.39)	0.0	0.0, 1.8	-0.13 (1.12)	0.0	-5.3, 1.8	0.5181
Low Dose	19	0.16 (0.61)	0.09 (0.29)	0.0	0.0, 1.2	-0.07 (0.70)	0.0	-2.7, 1.2	0.6785
High Dose	14	0.38 (1.43)	0.17 (0.50)	0.0	0.0, 1.8	-0.21 (1.56)	0.0	-5.3, 1.8	0.6225

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Race:WHITE (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia (Cont.)									
WEEK 48	47	0.33 (0.85)	0.28 (0.99)	0.0	0.0, 6.2	-0.05 (1.33)	0.0	-3.3, 6.2	0.8040
Low Dose	20	0.31 (0.92)	0.06 (0.17)	0.0	0.0, 0.7	-0.25 (0.96)	0.0	-3.3, 0.7	0.2521
High Dose	27	0.34 (0.82)	0.45 (1.28)	0.0	0.0, 6.2	0.10 (1.55)	0.0	-3.0, 6.2	0.7302
WEEK 60	25	0.60 (1.47)	0.12 (0.34)	0.0	0.0, 1.5	-0.48 (1.56)	0.0	-6.3, 1.5	0.1350
Low Dose	15	0.40 (1.06)	0.06 (0.16)	0.0	0.0, 0.6	-0.34 (1.09)	0.0	-3.3, 0.6	0.2460
High Dose	10	0.91 (1.97)	0.22 (0.49)	0.0	0.0, 1.5	-0.69 (2.14)	0.0	-6.3, 1.5	0.3303
WEEK 72	10	0.63 (1.98)	0.72 (1.58)	0.0	0.0, 5.0	0.09 (2.25)	0.0	-4.6, 5.0	0.9020
Low Dose	6	0.00 (0.00)	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
High Dose	4	1.56 (3.13)	1.79 (2.23)	1.1	0.0, 5.0	0.23 (3.90)	0.3	-4.6, 5.0	0.9151
WEEK 84	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								
WEEK 96	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Race:WHITE (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia									
BASELINE	82		13.31 (3.16)	14.6	2.5, 16.0				
Low Dose	36		12.92 (3.21)	13.4	2.5, 16.0				
High Dose	46		13.62 (3.12)	15.3	4.5, 16.0				
WEEK 12	60	13.04 (3.42)	13.21 (2.88)	13.9	5.0, 16.0	0.17 (3.52)	0.0	-11.0, 11.6	0.7106
Low Dose	29	12.82 (3.49)	13.55 (2.52)	13.9	5.0, 16.0	0.73 (3.74)	0.0	-11.0, 11.6	0.3021
High Dose	31	13.26 (3.39)	12.90 (3.20)	13.9	5.1, 16.0	-0.36 (3.28)	0.0	-10.9, 6.4	0.5509
WEEK 24	64	13.65 (2.52)	12.94 (3.69)	14.1	0.0, 16.0	-0.70 (3.12)	0.0	-13.3, 5.7	0.0765
Low Dose	29	13.25 (2.39)	13.09 (3.97)	14.8	0.0, 16.0	-0.16 (3.68)	0.0	-13.3, 5.7	0.8222
High Dose	35	13.98 (2.60)	12.82 (3.50)	13.7	2.6, 16.0	-1.16 (2.53)	-0.6	-7.7, 3.3	0.0107*
WEEK 36	33	13.88 (2.50)	13.71 (2.79)	14.3	3.9, 16.0	-0.17 (1.79)	0.0	-5.6, 4.3	0.5948
Low Dose	19	13.58 (2.38)	13.24 (3.35)	14.1	3.9, 16.0	-0.34 (1.63)	0.0	-5.6, 2.7	0.3791
High Dose	14	14.28 (2.69)	14.34 (1.67)	14.5	11.1, 16.0	0.06 (2.03)	0.0	-3.6, 4.3	0.9088

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Race:WHITE (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia (Cont.)									
WEEK 48	47	13.87 (2.40)	13.09 (3.71)	14.9	1.7, 16.0	-0.77 (2.73)	0.0	-7.4, 3.8	0.0585
Low Dose	20	13.59 (2.30)	13.62 (3.23)	15.5	5.9, 16.0	0.03 (2.48)	0.0	-7.4, 3.8	0.9522
High Dose	27	14.07 (2.50)	12.70 (4.05)	14.8	1.7, 16.0	-1.37 (2.81)	-0.3	-6.6, 2.3	0.0174*
WEEK 60	25	13.00 (2.75)	13.14 (2.88)	13.6	5.6, 16.0	0.14 (1.99)	0.0	-3.9, 5.3	0.7302
Low Dose	15	12.88 (2.33)	13.14 (3.23)	14.0	5.6, 16.0	0.26 (1.71)	0.0	-3.9, 3.0	0.5717
High Dose	10	13.17 (3.42)	13.13 (2.44)	13.3	9.1, 16.0	-0.04 (2.43)	-0.3	-3.9, 5.3	0.9621
WEEK 72	10	13.68 (2.65)	13.15 (3.05)	14.2	5.6, 16.0	-0.53 (4.22)	0.2	-10.4, 5.1	0.7006
Low Dose	6	13.84 (2.50)	14.31 (1.66)	14.7	12.3, 16.0	0.47 (1.03)	0.2	-0.8, 2.2	0.3183
High Dose	4	13.42 (3.25)	11.40 (4.07)	12.8	5.6, 14.3	-2.02 (6.83)	-1.4	-10.4, 5.1	0.5954
WEEK 84	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								
WEEK 96	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Race:ASIAN									
Average Daily Normalized 'Off' Time									
BASELINE	15		4.63 (2.73)	5.3	0.0, 10.1				
Low Dose	9		4.63 (3.02)	5.3	0.0, 10.1				
High Dose	6		4.64 (2.49)	5.6	0.0, 6.4				
WEEK 12	15	4.63 (2.73)	4.96 (2.37)	5.5	0.0, 8.0	0.32 (2.20)	0.6	-4.2, 3.8	0.5779
Low Dose	9	4.63 (3.02)	4.56 (2.53)	4.5	0.0, 8.0	-0.06 (2.57)	0.0	-4.2, 3.8	0.9428
High Dose	6	4.64 (2.49)	5.54 (2.19)	5.6	2.1, 8.0	0.91 (1.55)	1.5	-2.1, 2.1	0.2112
WEEK 24	11	4.84 (2.76)	5.28 (2.84)	4.3	2.5, 10.9	0.44 (3.22)	2.0	-6.1, 4.5	0.6594
Low Dose	7	5.08 (2.83)	5.08 (2.39)	4.3	2.5, 8.8	-0.01 (3.33)	2.0	-6.1, 2.5	0.9967
High Dose	4	4.41 (2.99)	5.64 (3.89)	4.5	2.6, 10.9	1.22 (3.35)	1.8	-3.3, 4.5	0.5178
WEEK 36	6	4.46 (2.70)	3.32 (1.77)	3.5	1.2, 6.1	-1.14 (3.44)	-1.5	-5.5, 3.9	0.4526
Low Dose	2	4.55 (3.09)	2.41 (1.71)	2.4	1.2, 3.6	-2.15 (4.80)	-2.1	-5.5, 1.2	0.6410
High Dose	4	4.41 (2.99)	3.77 (1.85)	3.7	1.6, 6.1	-0.64 (3.32)	-1.5	-3.5, 3.9	0.7249

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Race:ASIAN (Cont.)									
Average Daily Normalized 'Off' Time (Cont.)									
WEEK 48	5	4.00 (2.75)	4.54 (1.70)	4.1	2.3, 6.9	0.53 (2.08)	-0.0	-1.0, 4.0	0.5993
Low Dose	1	2.37 (N/A)	2.32 (N/A)	2.3	2.3, 2.3	-0.04 (N/A)	-0.0	-0.0, -0.0	
High Dose	4	4.41 (2.99)	5.09 (1.35)	4.7	4.0, 6.9	0.67 (2.38)	-0.1	-1.0, 4.0	0.6101
WEEK 60	4	3.41 (2.78)	4.88 (1.57)	4.4	3.7, 7.1	1.47 (2.16)	1.6	-1.3, 3.9	0.2671
Low Dose	1	2.37 (N/A)	3.66 (N/A)	3.7	3.7, 3.7	1.30 (N/A)	1.3	1.3, 1.3	
High Dose	3	3.76 (3.29)	5.28 (1.65)	4.8	3.9, 7.1	1.52 (2.64)	2.0	-1.3, 3.9	0.4229
WEEK 72	2	6.26 (0.18)	9.47 (1.31)	9.5	8.5, 10.4	3.21 (1.49)	3.2	2.2, 4.3	0.2021
Low Dose	0								
High Dose	2	6.26 (0.18)	9.47 (1.31)	9.5	8.5, 10.4	3.21 (1.49)	3.2	2.2, 4.3	0.2021
WEEK 84	1	6.13 (N/A)	11.43 (N/A)	11.4	11.4, 11.4	5.30 (N/A)	5.3	5.3, 5.3	
Low Dose	0								
High Dose	1	6.13 (N/A)	11.43 (N/A)	11.4	11.4, 11.4	5.30 (N/A)	5.3	5.3, 5.3	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Race:ASIAN (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia									
BASELINE	15		9.49 (3.80)	9.3	4.0, 16.0				
Low Dose	9		9.39 (3.87)	9.3	4.2, 16.0				
High Dose	6		9.63 (4.06)	8.9	4.0, 16.0				
WEEK 12	15	9.49 (3.80)	8.09 (4.57)	8.0	1.0, 16.0	-1.39 (3.18)	-1.1	-6.7, 4.2	0.1113
Low Dose	9	9.39 (3.87)	8.06 (5.14)	8.0	1.0, 16.0	-1.33 (3.51)	-1.1	-6.7, 4.2	0.2893
High Dose	6	9.63 (4.06)	8.13 (4.00)	7.0	3.6, 13.9	-1.50 (2.93)	-1.3	-6.4, 2.1	0.2661
WEEK 24	11	8.83 (3.84)	7.31 (3.89)	8.1	1.0, 13.4	-1.52 (3.41)	-2.5	-5.9, 6.6	0.1713
Low Dose	7	8.49 (3.42)	6.78 (4.02)	8.1	1.0, 10.8	-1.72 (3.88)	-2.5	-5.9, 6.6	0.2859
High Dose	4	9.42 (4.99)	8.25 (4.04)	7.3	5.0, 13.4	-1.17 (2.91)	-0.8	-4.5, 1.6	0.4816
WEEK 36	6	8.97 (3.99)	8.78 (4.70)	9.0	1.3, 14.8	-0.20 (4.07)	0.2	-5.6, 5.5	0.9110
Low Dose	2	8.09 (1.66)	8.05 (9.55)	8.0	1.3, 14.8	-0.04 (7.89)	-0.0	-5.6, 5.5	0.9950
High Dose	4	9.42 (4.99)	9.14 (2.43)	9.0	6.4, 12.1	-0.27 (2.62)	0.2	-3.9, 2.4	0.8494

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Race:ASIAN (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia (Cont.)									
WEEK 48	5	8.92 (4.46)	7.06 (4.21)	5.9	1.8, 12.0	-1.85 (3.15)	-3.1	-5.1, 1.9	0.2589
Low Dose	1	6.92 (N/A)	1.81 (N/A)	1.8	1.8, 1.8	-5.11 (N/A)	-5.1	-5.1, -5.1	
High Dose	4	9.42 (4.99)	8.38 (3.48)	8.3	4.9, 12.0	-1.04 (2.97)	-1.0	-4.0, 1.9	0.5347
WEEK 60	4	8.74 (5.13)	6.37 (4.91)	6.3	0.8, 12.1	-2.37 (3.20)	-1.8	-6.1, 0.3	0.2349
Low Dose	1	6.92 (N/A)	0.78 (N/A)	0.8	0.8, 0.8	-6.13 (N/A)	-6.1	-6.1, -6.1	
High Dose	3	9.35 (6.10)	8.24 (3.91)	8.4	4.3, 12.1	-1.11 (2.42)	0.3	-3.9, 0.3	0.5094
WEEK 72	2	8.83 (1.10)	5.81 (2.34)	5.8	4.2, 7.5	-3.03 (1.23)	-3.0	-3.9, -2.2	0.1783
Low Dose	0								
High Dose	2	8.83 (1.10)	5.81 (2.34)	5.8	4.2, 7.5	-3.03 (1.23)	-3.0	-3.9, -2.2	0.1783
WEEK 84	1	8.05 (N/A)	4.57 (N/A)	4.6	4.6, 4.6	-3.48 (N/A)	-3.5	-3.5, -3.5	
Low Dose	0								
High Dose	1	8.05 (N/A)	4.57 (N/A)	4.6	4.6, 4.6	-3.48 (N/A)	-3.5	-3.5, -3.5	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Race:ASIAN (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia									
BASELINE	15		1.57 (2.12)	0.6	0.0, 6.7				
Low Dose	9		1.80 (2.40)	0.6	0.0, 6.7				
High Dose	6		1.23 (1.77)	0.5	0.0, 4.6				
WEEK 12	15	1.57 (2.12)	2.37 (3.63)	0.0	0.0, 12.4	0.80 (2.45)	0.0	-2.7, 5.7	0.2271
Low Dose	9	1.80 (2.40)	2.89 (4.45)	0.0	0.0, 12.4	1.10 (2.49)	0.0	-2.7, 5.7	0.2230
High Dose	6	1.23 (1.77)	1.58 (1.98)	1.1	0.0, 4.9	0.35 (2.54)	0.0	-2.3, 4.6	0.7482
WEEK 24	11	1.99 (2.35)	2.46 (3.68)	1.2	0.0, 12.4	0.46 (1.97)	0.0	-2.1, 5.7	0.4525
Low Dose	7	2.22 (2.59)	3.00 (4.48)	1.2	0.0, 12.4	0.78 (2.21)	0.0	-0.5, 5.7	0.3861
High Dose	4	1.60 (2.16)	1.51 (1.80)	1.2	0.0, 3.6	-0.09 (1.59)	0.0	-2.1, 1.8	0.9172
WEEK 36	6	2.19 (2.85)	3.43 (4.42)	2.2	0.0, 11.1	1.25 (1.82)	0.3	0.0, 4.4	0.1551
Low Dose	2	3.36 (4.75)	5.55 (7.85)	5.5	0.0, 11.1	2.19 (3.10)	2.2	0.0, 4.4	0.5000
High Dose	4	1.60 (2.16)	2.37 (2.76)	2.2	0.0, 5.1	0.77 (1.20)	0.3	0.0, 2.5	0.2893

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Race:ASIAN (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia (Cont.)									
WEEK 48	5	2.62 (2.96)	3.85 (4.86)	3.2	0.0, 11.9	1.23 (2.57)	0.0	-1.4, 5.2	0.3451
Low Dose	1	6.72 (N/A)	11.87 (N/A)	11.9	11.9, 11.9	5.15 (N/A)	5.2	5.2, 5.2	
High Dose	4	1.60 (2.16)	1.85 (2.17)	1.6	0.0, 4.2	0.25 (1.56)	0.0	-1.4, 2.4	0.7689
WEEK 60	4	3.28 (2.96)	4.48 (4.96)	3.2	0.0, 11.6	1.21 (2.56)	0.5	-1.0, 4.8	0.4147
Low Dose	1	6.72 (N/A)	11.55 (N/A)	11.6	11.6, 11.6	4.83 (N/A)	4.8	4.8, 4.8	
High Dose	3	2.13 (2.30)	2.13 (1.88)	2.8	0.0, 3.6	-0.00 (1.01)	0.0	-1.0, 1.0	0.9967
WEEK 72	2	0.91 (1.29)	0.73 (1.03)	0.7	0.0, 1.5	-0.18 (0.26)	-0.2	-0.4, 0.0	0.5000
Low Dose	0								
High Dose	2	0.91 (1.29)	0.73 (1.03)	0.7	0.0, 1.5	-0.18 (0.26)	-0.2	-0.4, 0.0	0.5000
WEEK 84	1	1.82 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	-1.82 (N/A)	-1.8	-1.8, -1.8	
Low Dose	0								
High Dose	1	1.82 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	-1.82 (N/A)	-1.8	-1.8, -1.8	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Race:ASIAN (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia									
BASELINE	15		0.31 (0.68)	0.0	0.0, 2.3				
Low Dose	9		0.19 (0.48)	0.0	0.0, 1.5				
High Dose	6		0.50 (0.92)	0.0	0.0, 2.3				
WEEK 12	15	0.31 (0.68)	0.58 (1.54)	0.0	0.0, 4.4	0.27 (1.28)	0.0	-1.5, 4.1	0.4255
Low Dose	9	0.19 (0.48)	0.48 (1.44)	0.0	0.0, 4.3	0.29 (1.50)	0.0	-1.5, 4.1	0.5746
High Dose	6	0.50 (0.92)	0.74 (1.81)	0.0	0.0, 4.4	0.24 (0.98)	0.0	-0.7, 2.2	0.5787
WEEK 24	11	0.34 (0.78)	0.95 (2.39)	0.0	0.0, 7.8	0.61 (1.91)	0.0	0.0, 6.4	0.3138
Low Dose	7	0.21 (0.55)	1.15 (2.95)	0.0	0.0, 7.8	0.94 (2.40)	0.0	0.0, 6.4	0.3383
High Dose	4	0.57 (1.14)	0.60 (1.21)	0.0	0.0, 2.4	0.03 (0.07)	0.0	0.0, 0.1	0.3910
WEEK 36	6	0.38 (0.93)	0.47 (1.16)	0.0	0.0, 2.8	0.09 (0.23)	0.0	0.0, 0.6	0.3632
Low Dose	2	0.00 (0.00)	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
High Dose	4	0.57 (1.14)	0.71 (1.42)	0.0	0.0, 2.8	0.14 (0.28)	0.0	0.0, 0.6	0.3910

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Race:ASIAN (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia (Cont.)									
WEEK 48	5	0.46 (1.02)	0.55 (1.23)	0.0	0.0, 2.7	0.09 (0.20)	0.0	0.0, 0.5	0.3739
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	4	0.57 (1.14)	0.69 (1.37)	0.0	0.0, 2.7	0.11 (0.23)	0.0	0.0, 0.5	0.3910
WEEK 60	4	0.57 (1.14)	0.27 (0.53)	0.0	0.0, 1.1	-0.30 (0.61)	0.0	-1.2, 0.0	0.3910
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	3	0.76 (1.32)	0.36 (0.62)	0.0	0.0, 1.1	-0.41 (0.70)	0.0	-1.2, 0.0	0.4226
WEEK 72	2	0.00 (0.00)	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
Low Dose	0								
High Dose	2	0.00 (0.00)	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
WEEK 84	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	0								
High Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Race:ASIAN (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia									
BASELINE	15		11.06 (2.92)	9.9	5.9, 16.0				
Low Dose	9		11.19 (3.14)	10.7	5.9, 16.0				
High Dose	6		10.86 (2.84)	9.7	8.6, 16.0				
WEEK 12	15	11.06 (2.92)	10.46 (3.01)	10.5	5.8, 16.0	-0.60 (2.54)	-1.5	-3.8, 4.2	0.3796
Low Dose	9	11.19 (3.14)	10.96 (3.14)	11.5	5.8, 16.0	-0.23 (3.02)	-0.2	-3.8, 4.2	0.8248
High Dose	6	10.86 (2.84)	9.72 (2.91)	9.4	5.8, 13.9	-1.14 (1.71)	-1.6	-2.8, 2.1	0.1630
WEEK 24	11	10.82 (2.94)	9.77 (3.20)	10.7	5.1, 13.5	-1.05 (3.12)	-2.3	-4.5, 6.1	0.2883
Low Dose	7	10.71 (2.94)	9.77 (2.89)	10.7	5.4, 13.5	-0.94 (3.25)	-2.3	-3.3, 6.1	0.4737
High Dose	4	11.01 (3.37)	9.76 (4.18)	10.3	5.1, 13.4	-1.26 (3.35)	-1.9	-4.5, 3.3	0.5073
WEEK 36	6	11.16 (2.96)	12.21 (1.60)	12.2	9.9, 14.8	1.05 (3.37)	1.5	-3.9, 5.5	0.4798
Low Dose	2	11.45 (3.09)	13.59 (1.71)	13.6	12.4, 14.8	2.15 (4.80)	2.1	-1.2, 5.5	0.6410
High Dose	4	11.01 (3.37)	11.52 (1.18)	11.8	9.9, 12.6	0.50 (3.17)	1.5	-3.9, 2.9	0.7722

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Race:ASIAN (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia (Cont.)									
WEEK 48	5	11.54 (3.15)	10.92 (1.96)	10.7	9.1, 13.7	-0.62 (2.01)	0.0	-4.0, 1.0	0.5261
Low Dose	1	13.63 (N/A)	13.68 (N/A)	13.7	13.7, 13.7	0.04 (N/A)	0.0	0.0, 0.0	
High Dose	4	11.01 (3.37)	10.23 (1.39)	9.9	9.1, 12.0	-0.79 (2.28)	-0.1	-4.0, 1.0	0.5382
WEEK 60	4	12.02 (3.41)	10.86 (2.08)	11.6	7.8, 12.3	-1.16 (2.15)	-1.0	-3.9, 1.3	0.3587
Low Dose	1	13.63 (N/A)	12.34 (N/A)	12.3	12.3, 12.3	-1.30 (N/A)	-1.3	-1.3, -1.3	
High Dose	3	11.48 (3.97)	10.37 (2.25)	11.2	7.8, 12.1	-1.12 (2.63)	-0.7	-3.9, 1.3	0.5388
WEEK 72	2	9.74 (0.18)	6.53 (1.31)	6.5	5.6, 7.5	-3.21 (1.49)	-3.2	-4.3, -2.2	0.2021
Low Dose	0								
High Dose	2	9.74 (0.18)	6.53 (1.31)	6.5	5.6, 7.5	-3.21 (1.49)	-3.2	-4.3, -2.2	0.2021
WEEK 84	1	9.87 (N/A)	4.57 (N/A)	4.6	4.6, 4.6	-5.30 (N/A)	-5.3	-5.3, -5.3	
Low Dose	0								
High Dose	1	9.87 (N/A)	4.57 (N/A)	4.6	4.6, 4.6	-5.30 (N/A)	-5.3	-5.3, -5.3	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Age category:< 65 years									
Average Daily Normalized 'Off' Time									
BASELINE	57		2.69 (3.23)	1.2	0.0, 11.5				
Low Dose	25		3.23 (3.40)	2.3	0.0, 10.9				
High Dose	32		2.27 (3.08)	0.5	0.0, 11.5				
WEEK 12	43	3.06 (3.47)	3.40 (3.10)	2.7	0.0, 10.9	0.33 (3.07)	0.0	-8.2, 10.9	0.4795
Low Dose	20	3.37 (3.68)	3.09 (2.44)	2.7	0.0, 8.0	-0.28 (2.77)	0.0	-8.2, 3.8	0.6583
High Dose	23	2.80 (3.35)	3.67 (3.62)	2.3	0.0, 10.9	0.87 (3.27)	0.0	-6.4, 10.9	0.2169
WEEK 24	43	2.56 (2.87)	2.73 (3.02)	2.3	0.0, 13.4	0.17 (2.77)	0.0	-6.1, 7.7	0.6954
Low Dose	20	3.12 (3.12)	2.26 (2.17)	2.2	0.0, 7.8	-0.86 (2.54)	0.0	-6.1, 2.5	0.1455
High Dose	23	2.07 (2.60)	3.13 (3.60)	2.3	0.0, 13.4	1.06 (2.70)	0.0	-3.3, 7.7	0.0723
WEEK 36	24	2.11 (2.60)	1.97 (2.10)	1.8	0.0, 7.7	-0.15 (1.55)	0.0	-3.9, 3.6	0.6476
Low Dose	14	1.90 (2.17)	2.15 (2.31)	1.9	0.0, 7.7	0.25 (0.68)	0.0	-0.9, 1.4	0.1844
High Dose	10	2.41 (3.21)	1.70 (1.85)	1.2	0.0, 4.9	-0.71 (2.20)	0.0	-3.9, 3.6	0.3358

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Age category:< 65 years (Cont.)									
Average Daily Normalized 'Off' Time (Cont.)									
WEEK 48	31	2.26 (2.50)	2.94 (3.60)	1.2	0.0, 14.3	0.69 (2.11)	0.0	-2.3, 6.1	0.0798
Low Dose	12	1.91 (2.23)	1.84 (2.02)	1.2	0.0, 5.9	-0.08 (1.32)	0.0	-2.3, 2.7	0.8462
High Dose	19	2.47 (2.70)	3.64 (4.22)	1.2	0.0, 14.3	1.17 (2.39)	0.4	-2.0, 6.1	0.0472*
WEEK 60	19	2.62 (2.85)	2.87 (2.55)	2.5	0.0, 7.1	0.25 (1.31)	0.0	-2.0, 2.4	0.4214
Low Dose	9	2.26 (2.47)	2.00 (2.24)	1.2	0.0, 5.8	-0.26 (0.76)	-0.2	-1.2, 1.3	0.3320
High Dose	10	2.95 (3.25)	3.65 (2.66)	3.0	0.0, 7.1	0.71 (1.55)	0.8	-2.0, 2.4	0.1846
WEEK 72	6	2.09 (2.48)	3.03 (3.87)	1.8	0.0, 10.4	0.93 (2.52)	-0.0	-1.7, 4.3	0.4054
Low Dose	3	0.96 (1.44)	0.66 (0.94)	0.2	0.0, 1.7	-0.30 (0.50)	-0.0	-0.9, 0.0	0.4087
High Dose	3	3.23 (3.08)	5.39 (4.44)	3.9	1.9, 10.4	2.17 (3.32)	3.9	-1.7, 4.3	0.3757
WEEK 84	2	3.06 (4.33)	5.71 (8.08)	5.7	0.0, 11.4	2.65 (3.75)	2.7	0.0, 5.3	0.5000
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	1	6.13 (N/A)	11.43 (N/A)	11.4	11.4, 11.4	5.30 (N/A)	5.3	5.3, 5.3	
WEEK 96	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Age category:< 65 years (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia									
BASELINE	57		10.09 (5.26)	11.0	0.0, 16.0				
Low Dose	25		10.53 (4.54)	11.0	1.5, 16.0				
High Dose	32		9.74 (5.81)	10.8	0.0, 16.0				
WEEK 12	43	9.81 (5.37)	10.28 (4.75)	11.1	0.0, 16.0	0.47 (4.20)	0.0	-10.9, 14.2	0.4664
Low Dose	20	10.05 (4.93)	10.29 (4.87)	11.8	1.0, 15.8	0.24 (4.50)	-0.5	-6.7, 14.2	0.8142
High Dose	23	9.59 (5.83)	10.27 (4.75)	10.1	0.0, 16.0	0.67 (4.02)	0.3	-10.9, 9.0	0.4311
WEEK 24	43	10.21 (5.16)	10.58 (4.62)	10.7	0.0, 16.0	0.37 (4.64)	0.0	-9.6, 14.2	0.6037
Low Dose	20	10.86 (4.36)	10.88 (4.70)	10.7	1.0, 16.0	0.01 (4.37)	-0.4	-5.9, 14.2	0.9885
High Dose	23	9.64 (5.81)	10.32 (4.64)	10.6	0.0, 16.0	0.68 (4.95)	0.0	-9.6, 13.7	0.5164
WEEK 36	24	11.41 (4.93)	12.14 (4.25)	13.9	1.3, 16.0	0.72 (4.45)	0.0	-5.6, 14.2	0.4339
Low Dose	14	12.12 (4.21)	12.35 (4.48)	13.9	1.3, 16.0	0.23 (4.39)	-0.2	-5.6, 14.2	0.8455
High Dose	10	10.43 (5.90)	11.84 (4.13)	12.9	6.4, 16.0	1.41 (4.68)	0.1	-3.6, 14.0	0.3653

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Age category:< 65 years (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia (Cont.)									
WEEK 48	31	9.68 (5.32)	10.62 (4.78)	10.7	0.0, 16.0	0.94 (4.61)	0.2	-5.6, 14.9	0.2670
Low Dose	12	11.77 (4.41)	12.21 (4.31)	13.8	1.8, 16.0	0.44 (4.80)	0.1	-5.1, 13.7	0.7560
High Dose	19	8.36 (5.53)	9.61 (4.89)	9.4	0.0, 16.0	1.25 (4.59)	0.4	-5.6, 14.9	0.2508
WEEK 60	19	9.90 (5.26)	10.75 (4.53)	9.5	0.8, 16.0	0.85 (4.23)	0.0	-6.1, 13.9	0.3934
Low Dose	9	10.90 (4.81)	11.08 (5.29)	10.9	0.8, 16.0	0.18 (5.58)	-0.9	-6.1, 13.9	0.9239
High Dose	10	8.99 (5.73)	10.44 (4.00)	9.2	4.3, 16.0	1.45 (2.70)	0.7	-2.0, 6.3	0.1239
WEEK 72	6	10.94 (6.08)	12.15 (4.51)	13.6	4.2, 16.0	1.21 (4.60)	0.0	-3.9, 9.8	0.5482
Low Dose	3	15.04 (1.44)	14.93 (1.66)	15.8	13.0, 16.0	-0.11 (0.21)	0.0	-0.4, 0.0	0.4580
High Dose	3	6.83 (6.31)	9.36 (4.99)	9.8	4.2, 14.1	2.53 (6.90)	1.7	-3.9, 9.8	0.5904
WEEK 84	2	12.03 (5.62)	10.29 (8.08)	10.3	4.6, 16.0	-1.74 (2.46)	-1.7	-3.5, 0.0	0.5000
Low Dose	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	1	8.05 (N/A)	4.57 (N/A)	4.6	4.6, 4.6	-3.48 (N/A)	-3.5	-3.5, -3.5	
WEEK 96	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Age category:< 65 years (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia									
BASELINE	57		2.69 (4.49)	0.6	0.0, 16.0				
Low Dose	25		1.52 (2.69)	0.6	0.0, 11.8				
High Dose	32		3.60 (5.38)	0.6	0.0, 16.0				
WEEK 12	43	2.47 (4.39)	2.03 (3.67)	0.2	0.0, 16.0	-0.44 (4.23)	0.0	-15.8, 11.6	0.5037
Low Dose	20	1.67 (2.94)	2.37 (3.85)	0.3	0.0, 12.4	0.70 (4.18)	0.0	-11.6, 11.6	0.4646
High Dose	23	3.16 (5.32)	1.74 (3.57)	0.0	0.0, 16.0	-1.42 (4.12)	0.0	-15.8, 4.6	0.1125
WEEK 24	43	2.88 (4.44)	2.27 (3.55)	0.3	0.0, 16.0	-0.60 (4.53)	0.0	-16.0, 6.2	0.3886
Low Dose	20	1.79 (2.94)	2.32 (3.08)	1.5	0.0, 12.4	0.53 (3.46)	0.1	-11.6, 6.2	0.5038
High Dose	23	3.82 (5.31)	2.23 (3.98)	0.0	0.0, 16.0	-1.58 (5.16)	0.0	-16.0, 6.1	0.1555
WEEK 36	24	2.26 (3.84)	1.70 (2.91)	0.1	0.0, 11.1	-0.55 (3.83)	0.0	-12.9, 4.4	0.4862
Low Dose	14	1.77 (3.44)	1.41 (2.99)	0.1	0.0, 11.1	-0.36 (3.50)	0.0	-11.6, 4.4	0.7031
High Dose	10	2.93 (4.44)	2.11 (2.90)	0.2	0.0, 8.1	-0.82 (4.44)	0.0	-12.9, 2.9	0.5742

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Age category:< 65 years (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia (Cont.)									
WEEK 48	31	3.62 (4.95)	2.01 (3.06)	0.7	0.0, 11.9	-1.60 (4.58)	0.0	-12.9, 5.2	0.0606
Low Dose	12	2.07 (3.65)	1.87 (3.58)	0.4	0.0, 11.9	-0.20 (3.87)	0.0	-11.1, 5.2	0.8608
High Dose	19	4.60 (5.48)	2.11 (2.79)	0.7	0.0, 9.8	-2.49 (4.87)	-0.7	-12.9, 4.9	0.0386*
WEEK 60	19	3.07 (4.79)	2.21 (3.06)	0.5	0.0, 11.6	-0.86 (4.12)	0.0	-11.3, 4.8	0.3744
Low Dose	9	2.55 (4.14)	2.83 (3.81)	1.9	0.0, 11.6	0.28 (4.61)	1.9	-11.3, 4.8	0.8595
High Dose	10	3.54 (5.49)	1.65 (2.26)	0.0	0.0, 5.8	-1.89 (3.55)	-0.4	-10.2, 1.0	0.1263
WEEK 72	6	2.97 (6.42)	0.74 (0.83)	0.6	0.0, 1.8	-2.23 (5.91)	0.0	-14.2, 1.2	0.3981
Low Dose	3	0.00 (0.00)	0.41 (0.71)	0.0	0.0, 1.2	0.41 (0.71)	0.0	0.0, 1.2	0.4226
High Dose	3	5.94 (8.76)	1.07 (0.94)	1.5	0.0, 1.8	-4.87 (8.12)	-0.4	-14.2, 0.0	0.4079
WEEK 84	2	0.91 (1.29)	0.00 (0.00)	0.0	0.0, 0.0	-0.91 (1.29)	-0.9	-1.8, 0.0	0.5000
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	1	1.82 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	-1.82 (N/A)	-1.8	-1.8, -1.8	
WEEK 96	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Age category:< 65 years (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia									
BASELINE	57		0.53 (1.90)	0.0	0.0, 13.5				
Low Dose	25		0.73 (2.73)	0.0	0.0, 13.5				
High Dose	32		0.38 (0.84)	0.0	0.0, 3.0				
WEEK 12	43	0.66 (2.17)	0.29 (0.98)	0.0	0.0, 4.4	-0.37 (2.30)	0.0	-13.5, 4.1	0.2970
Low Dose	20	0.91 (3.04)	0.25 (0.97)	0.0	0.0, 4.3	-0.66 (3.25)	0.0	-13.5, 4.1	0.3764
High Dose	23	0.44 (0.93)	0.32 (1.01)	0.0	0.0, 4.4	-0.12 (0.89)	0.0	-3.0, 2.2	0.5302
WEEK 24	43	0.35 (0.83)	0.42 (1.31)	0.0	0.0, 7.8	0.06 (1.29)	0.0	-3.0, 6.4	0.7432
Low Dose	20	0.22 (0.66)	0.54 (1.75)	0.0	0.0, 7.8	0.32 (1.60)	0.0	-2.7, 6.4	0.3806
High Dose	23	0.47 (0.96)	0.31 (0.76)	0.0	0.0, 2.4	-0.16 (0.93)	0.0	-3.0, 1.9	0.4250
WEEK 36	24	0.22 (0.70)	0.19 (0.63)	0.0	0.0, 2.8	-0.02 (0.64)	0.0	-2.7, 1.2	0.8522
Low Dose	14	0.21 (0.71)	0.09 (0.32)	0.0	0.0, 1.2	-0.12 (0.81)	0.0	-2.7, 1.2	0.5738
High Dose	10	0.23 (0.72)	0.34 (0.90)	0.0	0.0, 2.8	0.12 (0.24)	0.0	0.0, 0.6	0.1680

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Age category:< 65 years (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia (Cont.)									
WEEK 48	31	0.44 (0.94)	0.42 (1.22)	0.0	0.0, 6.2	-0.02 (1.46)	0.0	-3.0, 6.2	0.9449
Low Dose	12	0.25 (0.77)	0.08 (0.21)	0.0	0.0, 0.7	-0.17 (0.82)	0.0	-2.7, 0.7	0.4999
High Dose	19	0.57 (1.03)	0.64 (1.53)	0.0	0.0, 6.2	0.07 (1.77)	0.0	-3.0, 6.2	0.8562
WEEK 60	19	0.41 (0.86)	0.18 (0.41)	0.0	0.0, 1.5	-0.23 (0.89)	0.0	-2.7, 1.5	0.2651
Low Dose	9	0.30 (0.89)	0.09 (0.21)	0.0	0.0, 0.6	-0.20 (0.95)	0.0	-2.7, 0.6	0.5402
High Dose	10	0.52 (0.86)	0.25 (0.54)	0.0	0.0, 1.5	-0.26 (0.89)	0.0	-1.5, 1.5	0.3700
WEEK 72	6	0.00 (0.00)	0.09 (0.21)	0.0	0.0, 0.5	0.09 (0.21)	0.0	0.0, 0.5	0.3632
Low Dose	3	0.00 (0.00)	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
High Dose	3	0.00 (0.00)	0.17 (0.30)	0.0	0.0, 0.5	0.17 (0.30)	0.0	0.0, 0.5	0.4226
WEEK 84	2	0.00 (0.00)	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
WEEK 96	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Age category:< 65 years (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia									
BASELINE	57		12.78 (3.59)	13.9	2.5, 16.0				
Low Dose	25		12.05 (3.87)	13.4	2.5, 16.0				
High Dose	32		13.35 (3.31)	15.1	4.5, 16.0				
WEEK 12	43	12.28 (3.86)	12.31 (3.32)	13.3	5.1, 16.0	0.04 (3.66)	0.0	-10.9, 11.6	0.9491
Low Dose	20	11.72 (4.17)	12.66 (2.82)	13.3	5.8, 16.0	0.94 (3.90)	-0.1	-3.8, 11.6	0.2960
High Dose	23	12.76 (3.59)	12.01 (3.73)	13.7	5.1, 16.0	-0.75 (3.33)	0.0	-10.9, 6.4	0.2928
WEEK 24	43	13.09 (2.99)	12.85 (3.28)	13.7	2.6, 16.0	-0.23 (2.77)	0.0	-7.7, 6.1	0.5874
Low Dose	20	12.66 (3.11)	13.20 (2.94)	13.8	5.4, 16.0	0.54 (2.67)	0.0	-3.3, 6.1	0.3758
High Dose	23	13.46 (2.90)	12.56 (3.59)	13.7	2.6, 16.0	-0.90 (2.74)	-0.2	-7.7, 3.3	0.1283
WEEK 36	24	13.67 (2.71)	13.84 (2.20)	14.1	8.3, 16.0	0.17 (1.65)	0.0	-3.6, 3.9	0.6181
Low Dose	14	13.89 (2.10)	13.76 (2.39)	14.1	8.3, 16.0	-0.13 (1.17)	0.0	-2.3, 2.7	0.6828
High Dose	10	13.36 (3.49)	13.95 (2.02)	14.3	11.1, 16.0	0.59 (2.16)	0.0	-3.6, 3.9	0.4091

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Age category:< 65 years (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia (Cont.)									
WEEK 48	31	13.30 (2.67)	12.63 (3.62)	13.8	1.7, 16.0	-0.67 (2.54)	0.0	-6.2, 2.7	0.1526
Low Dose	12	13.84 (2.15)	14.08 (2.10)	14.7	10.1, 16.0	0.24 (1.64)	0.0	-2.7, 2.7	0.6199
High Dose	19	12.96 (2.96)	11.72 (4.11)	13.5	1.7, 16.0	-1.24 (2.86)	-0.4	-6.2, 2.3	0.0743
WEEK 60	19	12.97 (2.97)	12.95 (2.65)	13.0	7.8, 16.0	-0.01 (1.47)	0.0	-3.9, 2.7	0.9718
Low Dose	9	13.44 (2.32)	13.91 (2.25)	14.5	10.2, 16.0	0.46 (1.15)	0.0	-1.3, 2.7	0.2593
High Dose	10	12.54 (3.53)	12.09 (2.79)	12.5	7.8, 16.0	-0.44 (1.65)	-0.3	-3.9, 2.0	0.4204
WEEK 72	6	13.91 (2.48)	12.89 (3.90)	14.2	5.6, 16.0	-1.02 (2.65)	0.0	-4.4, 1.7	0.3884
Low Dose	3	15.04 (1.44)	15.34 (0.94)	15.8	14.3, 16.0	0.30 (0.50)	0.0	0.0, 0.9	0.4087
High Dose	3	12.77 (3.08)	10.43 (4.36)	11.6	5.6, 14.1	-2.34 (3.47)	-4.3	-4.4, 1.7	0.3629
WEEK 84	2	12.94 (4.33)	10.29 (8.08)	10.3	4.6, 16.0	-2.65 (3.75)	-2.7	-5.3, 0.0	0.5000
Low Dose	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	1	9.87 (N/A)	4.57 (N/A)	4.6	4.6, 4.6	-5.30 (N/A)	-5.3	-5.3, -5.3	
WEEK 96	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Age category:>= 65 years									
Average Daily Normalized 'Off' Time									
BASELINE	40		2.35 (2.54)	1.3	0.0, 8.1				
Low Dose	20		2.59 (2.18)	2.7	0.0, 6.7				
High Dose	20		2.12 (2.90)	0.5	0.0, 8.1				
WEEK 12	32	2.53 (2.64)	2.42 (2.36)	2.1	0.0, 8.0	-0.11 (1.76)	0.0	-4.3, 4.2	0.7273
Low Dose	18	2.59 (2.30)	2.14 (2.19)	1.7	0.0, 7.3	-0.45 (1.57)	0.0	-4.2, 1.5	0.2420
High Dose	14	2.46 (3.12)	2.79 (2.59)	2.1	0.0, 8.0	0.32 (1.96)	0.3	-4.3, 4.2	0.5454
WEEK 24	32	2.07 (2.31)	3.64 (4.22)	2.4	0.0, 16.0	1.56 (3.13)	0.3	-3.0, 13.3	0.0081**
Low Dose	16	2.90 (2.16)	4.43 (4.90)	2.5	0.0, 16.0	1.53 (4.09)	0.0	-3.0, 13.3	0.1552
High Dose	16	1.24 (2.21)	2.84 (3.38)	2.0	0.0, 10.9	1.60 (1.87)	1.2	-0.2, 6.2	0.0037**
WEEK 36	15	2.52 (2.81)	2.95 (3.36)	1.7	0.0, 12.1	0.43 (2.39)	0.0	-5.5, 5.6	0.5010
Low Dose	7	3.65 (2.93)	3.63 (4.45)	1.2	0.0, 12.1	-0.02 (3.26)	0.0	-5.5, 5.6	0.9860
High Dose	8	1.54 (2.45)	2.36 (2.18)	1.8	0.0, 6.1	0.82 (1.41)	0.5	-0.3, 3.9	0.1430

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Age category:>= 65 years (Cont.)									
Average Daily Normalized 'Off' Time (Cont.)									
WEEK 48	21	1.66 (2.30)	2.61 (3.63)	0.6	0.0, 11.0	0.95 (2.54)	0.0	-3.0, 7.4	0.1014
Low Dose	9	2.37 (2.51)	2.95 (4.22)	0.0	0.0, 10.1	0.59 (2.93)	0.0	-3.0, 7.4	0.5652
High Dose	12	1.12 (2.07)	2.35 (3.30)	0.9	0.0, 11.0	1.23 (2.31)	0.0	-1.0, 6.6	0.0924
WEEK 60	10	2.38 (2.47)	3.36 (3.45)	2.2	0.0, 10.4	0.98 (2.09)	1.0	-3.0, 3.9	0.1735
Low Dose	7	3.26 (2.47)	3.97 (3.91)	2.4	0.0, 10.4	0.71 (2.21)	1.0	-3.0, 3.9	0.4305
High Dose	3	0.32 (0.28)	1.94 (1.77)	1.4	0.5, 3.9	1.61 (2.04)	0.9	0.0, 3.9	0.3045
WEEK 72	6	2.83 (3.01)	3.69 (3.12)	3.7	0.0, 8.5	0.87 (2.68)	0.2	-2.2, 5.5	0.4634
Low Dose	3	3.36 (3.03)	2.72 (1.67)	3.7	0.8, 3.7	-0.63 (1.52)	-0.5	-2.2, 0.8	0.5470
High Dose	3	2.30 (3.55)	4.66 (4.33)	5.5	0.0, 8.5	2.37 (2.98)	2.2	-0.5, 5.5	0.3026
Average Daily Normalized 'On' Time Without Dyskinesia									
BASELINE	40		11.47 (4.10)	11.8	0.0, 16.0				
Low Dose	20		11.19 (4.45)	12.4	0.0, 16.0				
High Dose	20		11.75 (3.82)	11.5	1.3, 16.0				

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Age category:>= 65 years (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia (Cont.)									
WEEK 12	32	11.82 (4.00)	11.57 (4.44)	12.5	0.0, 16.0	-0.24 (2.95)	0.0	-9.6, 6.1	0.6428
Low Dose	18	11.93 (3.89)	12.17 (4.39)	13.2	0.0, 16.0	0.25 (2.93)	0.0	-6.6, 6.1	0.7223
High Dose	14	11.68 (4.27)	10.80 (4.54)	11.0	0.0, 16.0	-0.88 (2.96)	-0.6	-9.6, 2.8	0.2865
WEEK 24	32	11.27 (4.29)	10.58 (5.01)	11.2	0.0, 16.0	-0.70 (4.21)	0.0	-13.3, 7.4	0.3562
Low Dose	16	10.36 (4.55)	10.04 (5.77)	11.2	0.0, 16.0	-0.32 (4.94)	0.5	-13.3, 7.4	0.7963
High Dose	16	12.18 (3.94)	11.11 (4.24)	11.5	4.4, 16.0	-1.07 (3.46)	-1.0	-9.2, 6.5	0.2348
WEEK 36	15	11.50 (3.90)	10.41 (5.39)	11.9	0.0, 16.0	-1.09 (4.20)	0.0	-11.2, 5.5	0.3301
Low Dose	7	12.11 (3.19)	12.13 (4.75)	14.8	3.4, 16.0	0.03 (3.33)	0.0	-5.9, 5.5	0.9847
High Dose	8	10.98 (4.58)	8.90 (5.75)	10.9	0.0, 14.1	-2.07 (4.84)	-0.5	-11.2, 4.5	0.2647
WEEK 48	21	11.68 (4.52)	11.51 (4.62)	12.4	1.1, 16.0	-0.16 (5.16)	0.0	-9.4, 11.4	0.8863
Low Dose	9	9.57 (5.80)	10.16 (5.32)	8.6	1.1, 16.0	0.58 (6.28)	0.0	-8.0, 11.4	0.7880
High Dose	12	13.26 (2.50)	12.53 (3.96)	13.6	5.0, 16.0	-0.72 (4.35)	-0.0	-9.4, 6.5	0.5769
WEEK 60	10	10.65 (4.38)	11.04 (3.28)	11.2	4.5, 16.0	0.39 (4.12)	-0.2	-4.7, 8.0	0.7722
Low Dose	7	9.81 (4.60)	10.27 (3.70)	10.0	4.5, 16.0	0.46 (4.47)	-0.5	-4.7, 8.0	0.7931
High Dose	3	12.60 (3.80)	12.82 (0.79)	12.7	12.1, 13.7	0.22 (4.06)	0.3	-3.9, 4.2	0.9352

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Age category:>= 65 years (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia (Cont.)									
WEEK 72	6	10.98 (2.81)	10.07 (4.91)	12.0	1.4, 15.2	-0.92 (4.93)	-0.2	-9.9, 3.6	0.6683
Low Dose	3	12.16 (3.68)	13.12 (1.81)	12.3	11.9, 15.2	0.96 (2.06)	0.5	-0.8, 3.2	0.5031
High Dose	3	9.80 (1.41)	7.01 (5.37)	7.5	1.4, 12.1	-2.79 (6.78)	-2.2	-9.9, 3.6	0.5497
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia									
BASELINE	40		1.76 (3.57)	0.0	0.0, 16.0				
Low Dose	20		2.04 (4.38)	0.0	0.0, 16.0				
High Dose	20		1.48 (2.60)	0.0	0.0, 9.3				
WEEK 12	32	1.33 (3.32)	1.56 (3.42)	0.0	0.0, 16.0	0.23 (3.06)	0.0	-11.0, 7.4	0.6679
Low Dose	18	1.29 (3.78)	1.06 (2.42)	0.0	0.0, 8.7	-0.23 (3.44)	0.0	-11.0, 7.4	0.7811
High Dose	14	1.37 (2.76)	2.20 (4.40)	0.0	0.0, 16.0	0.83 (2.50)	0.0	-2.2, 6.7	0.2361
WEEK 24	32	2.15 (3.90)	1.40 (3.27)	0.0	0.0, 16.0	-0.76 (2.81)	0.0	-12.0, 5.1	0.1369
Low Dose	16	2.51 (4.81)	1.47 (4.14)	0.0	0.0, 16.0	-1.04 (3.44)	0.0	-12.0, 4.5	0.2442
High Dose	16	1.80 (2.82)	1.32 (2.22)	0.0	0.0, 5.8	-0.48 (2.08)	0.0	-3.9, 5.1	0.3755

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Age category:>= 65 years (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia (Cont.)									
WEEK 36	15	1.62 (2.81)	2.49 (5.42)	0.0	0.0, 16.0	0.87 (3.79)	0.0	-5.7, 11.2	0.3876
Low Dose	7	0.24 (0.54)	0.17 (0.30)	0.0	0.0, 0.7	-0.07 (0.32)	0.0	-0.8, 0.3	0.5975
High Dose	8	2.82 (3.47)	4.51 (6.98)	0.1	0.0, 16.0	1.69 (5.19)	0.0	-5.7, 11.2	0.3866
WEEK 48	21	2.47 (4.30)	1.74 (3.73)	0.0	0.0, 14.9	-0.73 (3.51)	0.0	-10.3, 8.0	0.3521
Low Dose	9	3.69 (6.04)	2.86 (5.20)	0.0	0.0, 14.9	-0.82 (4.70)	-0.3	-10.3, 8.0	0.6130
High Dose	12	1.56 (2.22)	0.90 (1.95)	0.0	0.0, 5.5	-0.66 (2.52)	0.0	-5.7, 4.0	0.3842
WEEK 60	10	2.02 (3.70)	1.53 (2.03)	1.0	0.0, 5.7	-0.48 (3.32)	0.0	-7.3, 5.7	0.6564
Low Dose	7	2.46 (4.40)	1.76 (2.39)	0.9	0.0, 5.7	-0.70 (4.00)	0.0	-7.3, 5.7	0.6609
High Dose	3	0.99 (1.13)	1.00 (0.95)	1.1	0.0, 1.9	0.01 (1.11)	0.0	-1.1, 1.1	0.9844
WEEK 72	6	1.15 (1.84)	1.13 (1.71)	0.2	0.0, 4.2	-0.02 (0.81)	0.0	-1.0, 1.4	0.9593
Low Dose	3	0.48 (0.83)	0.15 (0.26)	0.0	0.0, 0.5	-0.33 (0.57)	0.0	-1.0, 0.0	0.4226
High Dose	3	1.82 (2.53)	2.11 (2.08)	2.2	0.0, 4.2	0.29 (1.02)	0.0	-0.5, 1.4	0.6671

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Age category:>= 65 years (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia									
BASELINE	40		0.42 (1.37)	0.0	0.0, 6.3				
Low Dose	20		0.18 (0.74)	0.0	0.0, 3.3				
High Dose	20		0.65 (1.78)	0.0	0.0, 6.3				
WEEK 12	32	0.33 (1.10)	0.44 (2.00)	0.0	0.0, 11.0	0.12 (2.35)	0.0	-5.3, 11.0	0.7758
Low Dose	18	0.20 (0.78)	0.63 (2.60)	0.0	0.0, 11.0	0.43 (2.76)	0.0	-3.3, 11.0	0.5205
High Dose	14	0.49 (1.42)	0.21 (0.79)	0.0	0.0, 3.0	-0.28 (1.69)	0.0	-5.3, 3.0	0.5521
WEEK 24	32	0.50 (1.52)	0.39 (1.45)	0.0	0.0, 7.2	-0.11 (1.38)	0.0	-5.3, 4.3	0.6620
Low Dose	16	0.22 (0.83)	0.06 (0.14)	0.0	0.0, 0.5	-0.16 (0.85)	0.0	-3.3, 0.3	0.4566
High Dose	16	0.77 (1.98)	0.72 (2.03)	0.0	0.0, 7.2	-0.05 (1.80)	0.0	-5.3, 4.3	0.9055
WEEK 36	15	0.36 (1.38)	0.15 (0.47)	0.0	0.0, 1.8	-0.20 (1.49)	0.0	-5.3, 1.8	0.6043
Low Dose	7	0.00 (0.00)	0.07 (0.17)	0.0	0.0, 0.5	0.07 (0.17)	0.0	0.0, 0.5	0.3559
High Dose	8	0.67 (1.89)	0.23 (0.64)	0.0	0.0, 1.8	-0.44 (2.08)	0.0	-5.3, 1.8	0.5669

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Age category:>= 65 years (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia (Cont.)									
WEEK 48	21	0.19 (0.73)	0.14 (0.51)	0.0	0.0, 2.3	-0.06 (0.92)	0.0	-3.3, 2.3	0.7712
Low Dose	9	0.37 (1.10)	0.03 (0.08)	0.0	0.0, 0.2	-0.34 (1.12)	0.0	-3.3, 0.2	0.3840
High Dose	12	0.07 (0.23)	0.22 (0.67)	0.0	0.0, 2.3	0.15 (0.73)	0.0	-0.8, 2.3	0.4805
WEEK 60	10	0.96 (2.13)	0.07 (0.23)	0.0	0.0, 0.7	-0.88 (2.18)	0.0	-6.3, 0.7	0.2319
Low Dose	7	0.47 (1.25)	0.00 (0.00)	0.0	0.0, 0.0	-0.47 (1.25)	0.0	-3.3, 0.0	0.3559
High Dose	3	2.08 (3.61)	0.24 (0.42)	0.0	0.0, 0.7	-1.84 (3.84)	0.0	-6.3, 0.7	0.4933
WEEK 72	6	1.04 (2.55)	1.11 (2.00)	0.0	0.0, 5.0	0.06 (3.02)	0.0	-4.6, 5.0	0.9603
Low Dose	3	0.00 (0.00)	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
High Dose	3	2.08 (3.61)	2.21 (2.52)	1.7	0.0, 5.0	0.13 (4.77)	0.0	-4.6, 5.0	0.9669
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia									
BASELINE	40		13.23 (2.62)	13.4	7.9, 16.0				
Low Dose	20		13.23 (2.14)	13.2	9.3, 16.0				
High Dose	20		13.23 (3.08)	15.0	7.9, 16.0				

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Age category:>= 65 years (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia (Cont.)									
WEEK 12	32	13.14 (2.64)	13.13 (2.75)	13.7	5.0, 16.0	-0.01 (2.93)	0.0	-11.0, 5.3	0.9854
Low Dose	18	13.21 (2.26)	13.24 (2.96)	13.7	5.0, 16.0	0.02 (3.20)	0.0	-11.0, 4.2	0.9785
High Dose	14	13.05 (3.15)	13.00 (2.56)	13.1	8.0, 16.0	-0.05 (2.67)	-0.3	-4.2, 5.3	0.9468
WEEK 24	32	13.43 (2.42)	11.97 (4.36)	13.5	0.0, 16.0	-1.46 (3.41)	-0.4	-13.3, 3.8	0.0219*
Low Dose	16	12.87 (2.08)	11.51 (4.93)	13.4	0.0, 16.0	-1.37 (4.31)	-0.0	-13.3, 3.8	0.2231
High Dose	16	13.98 (2.67)	12.44 (3.82)	13.5	5.1, 16.0	-1.55 (2.35)	-1.2	-6.2, 3.0	0.0189*
WEEK 36	15	13.12 (2.80)	12.90 (3.31)	14.2	3.9, 16.0	-0.22 (2.71)	0.0	-5.6, 5.5	0.7556
Low Dose	7	12.35 (2.93)	12.31 (4.50)	14.8	3.9, 16.0	-0.04 (3.28)	0.0	-5.6, 5.5	0.9736
High Dose	8	13.80 (2.69)	13.42 (1.98)	14.1	9.9, 16.0	-0.38 (2.33)	-0.6	-3.9, 4.3	0.6592
WEEK 48	21	14.15 (2.31)	13.26 (3.69)	15.4	5.0, 16.0	-0.89 (2.89)	0.0	-7.4, 3.8	0.1714
Low Dose	9	13.26 (2.45)	13.02 (4.24)	16.0	5.9, 16.0	-0.24 (3.27)	0.0	-7.4, 3.8	0.8298
High Dose	12	14.82 (2.04)	13.43 (3.40)	15.1	5.0, 16.0	-1.38 (2.60)	-0.1	-6.6, 1.0	0.0925
WEEK 60	10	12.67 (2.59)	12.57 (3.39)	13.8	5.6, 16.0	-0.09 (2.90)	-0.4	-3.9, 5.3	0.9200
Low Dose	7	12.27 (2.16)	12.03 (3.91)	13.6	5.6, 16.0	-0.23 (2.27)	0.0	-3.9, 3.0	0.7948
High Dose	3	13.59 (3.77)	13.82 (1.50)	14.6	12.1, 14.8	0.23 (4.70)	-0.7	-3.9, 5.3	0.9403

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Age category:>= 65 years (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia (Cont.)									
WEEK 72	6	12.13 (3.12)	11.20 (3.84)	12.3	5.6, 15.2	-0.93 (5.28)	-0.2	-10.4, 5.1	0.6832
Low Dose	3	12.64 (3.03)	13.28 (1.67)	12.3	12.3, 15.2	0.63 (1.52)	0.5	-0.8, 2.2	0.5470
High Dose	3	11.62 (3.80)	9.12 (4.60)	7.5	5.6, 14.3	-2.50 (7.75)	-2.2	-10.4, 5.1	0.6328
Geographic region:NORTH AMERICA									
Average Daily Normalized 'Off' Time									
BASELINE	40		1.86 (2.44)	0.5	0.0, 8.8				
Low Dose	16		2.65 (2.41)	2.6	0.0, 8.8				
High Dose	24		1.32 (2.35)	0.1	0.0, 8.1				
WEEK 12	27	2.15 (2.68)	2.35 (2.19)	2.1	0.0, 6.8	0.20 (2.30)	0.0	-4.3, 6.8	0.6488
Low Dose	12	2.88 (2.69)	2.42 (1.83)	2.5	0.0, 5.9	-0.47 (1.88)	-0.3	-3.8, 2.8	0.4095
High Dose	15	1.56 (2.60)	2.30 (2.50)	2.0	0.0, 6.8	0.74 (2.52)	0.0	-4.3, 6.8	0.2753
WEEK 24	33	1.63 (2.19)	2.42 (2.92)	1.2	0.0, 10.3	0.79 (2.68)	0.0	-6.0, 7.7	0.0990
Low Dose	13	2.91 (2.43)	2.74 (3.09)	2.4	0.0, 10.3	-0.17 (3.13)	-0.0	-6.0, 7.6	0.8452
High Dose	20	0.79 (1.57)	2.21 (2.86)	0.4	0.0, 8.3	1.42 (2.20)	0.3	-0.5, 7.7	0.0094**

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Geographic region:NORTH AMERICA (Cont.)									
Average Daily Normalized 'Off' Time (Cont.)									
WEEK 36	14	1.32 (1.88)	1.72 (1.98)	1.4	0.0, 6.5	0.40 (0.69)	0.3	-1.1, 1.4	0.0496*
Low Dose	6	2.30 (2.37)	2.85 (2.52)	3.0	0.0, 6.5	0.55 (0.57)	0.4	-0.0, 1.4	0.0639
High Dose	8	0.57 (1.05)	0.86 (0.92)	0.6	0.0, 2.0	0.29 (0.79)	0.1	-1.1, 1.2	0.3349
WEEK 48	20	1.23 (1.66)	1.58 (1.88)	0.8	0.0, 6.0	0.35 (1.77)	0.0	-3.0, 4.5	0.3832
Low Dose	8	1.99 (1.98)	2.00 (2.31)	1.1	0.0, 6.0	0.01 (1.72)	0.1	-3.0, 2.7	0.9839
High Dose	12	0.72 (1.24)	1.30 (1.57)	0.8	0.0, 4.5	0.58 (1.84)	0.0	-2.0, 4.5	0.2982
WEEK 60	12	1.68 (1.96)	2.03 (2.31)	1.7	0.0, 6.9	0.35 (1.45)	0.0	-3.0, 2.4	0.4228
Low Dose	8	2.40 (2.06)	2.50 (2.67)	2.2	0.0, 6.9	0.10 (1.59)	-0.0	-3.0, 1.9	0.8593
High Dose	4	0.24 (0.28)	1.08 (1.07)	0.9	0.0, 2.4	0.84 (1.14)	0.5	0.0, 2.4	0.2382
WEEK 72	9	1.89 (2.23)	2.29 (1.99)	1.9	0.0, 5.5	0.40 (2.56)	-0.5	-2.2, 5.5	0.6524
Low Dose	5	2.59 (2.53)	1.87 (1.79)	1.7	0.0, 3.7	-0.72 (0.92)	-0.5	-2.2, 0.0	0.1553
High Dose	4	1.01 (1.71)	2.81 (2.37)	2.9	0.0, 5.5	1.80 (3.42)	1.7	-1.7, 5.5	0.3700
WEEK 84	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Geographic region:NORTH AMERICA (Cont.)									
Average Daily Normalized 'Off' Time (Cont.)									
WEEK 96	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								
Average Daily Normalized 'On' Time Without Dyskinesia									
BASELINE	40		10.81 (5.02)	11.8	0.0, 16.0				
Low Dose	16		11.44 (4.00)	12.4	1.3, 16.0				
High Dose	24		10.39 (5.65)	11.2	0.0, 16.0				
WEEK 12	27	10.68 (5.23)	10.79 (4.64)	11.3	0.0, 16.0	0.11 (3.62)	0.3	-9.6, 9.0	0.8742
Low Dose	12	12.18 (3.08)	12.12 (3.56)	13.1	4.5, 16.0	-0.06 (3.44)	0.4	-6.6, 6.1	0.9549
High Dose	15	9.48 (6.31)	9.73 (5.23)	10.1	0.0, 16.0	0.25 (3.87)	0.0	-9.6, 9.0	0.8087
WEEK 24	33	10.74 (5.19)	11.31 (4.61)	11.8	0.0, 16.0	0.57 (4.74)	0.0	-9.6, 13.7	0.4961
Low Dose	13	10.92 (4.23)	11.80 (4.57)	13.6	3.4, 16.0	0.88 (3.68)	1.1	-7.7, 7.4	0.4068
High Dose	20	10.62 (5.84)	10.99 (4.72)	11.2	0.0, 16.0	0.37 (5.41)	0.0	-9.6, 13.7	0.7642

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Geographic region:NORTH AMERICA (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia (Cont.)									
WEEK 36	14	11.66 (5.26)	11.39 (5.41)	13.9	0.0, 16.0	-0.28 (5.45)	-0.3	-11.2, 14.0	0.8530
Low Dose	6	13.46 (2.83)	12.72 (2.99)	12.6	8.4, 16.0	-0.74 (1.01)	-0.3	-2.5, 0.0	0.1319
High Dose	8	10.32 (6.40)	10.40 (6.73)	14.0	0.0, 16.0	0.07 (7.36)	-0.1	-11.2, 14.0	0.9784
WEEK 48	20	11.05 (5.20)	13.07 (3.18)	14.2	5.8, 16.0	2.01 (5.47)	0.2	-9.4, 14.9	0.1168
Low Dose	8	11.48 (5.02)	13.41 (2.89)	14.0	8.6, 16.0	1.93 (5.09)	-0.0	-3.2, 11.4	0.3193
High Dose	12	10.77 (5.52)	12.84 (3.46)	14.2	5.8, 16.0	2.07 (5.94)	0.8	-9.4, 14.9	0.2535
WEEK 60	12	10.53 (5.37)	11.90 (3.22)	11.8	6.3, 16.0	1.37 (3.57)	0.0	-2.6, 8.0	0.2112
Low Dose	8	11.07 (4.81)	11.76 (2.98)	10.6	8.2, 16.0	0.69 (3.80)	-0.2	-2.6, 8.0	0.6215
High Dose	4	9.45 (7.02)	12.17 (4.15)	13.2	6.3, 16.0	2.71 (3.06)	2.3	0.0, 6.3	0.1740
WEEK 72	9	10.87 (4.86)	11.83 (4.36)	12.3	1.4, 16.0	0.96 (5.15)	0.5	-9.9, 9.8	0.5927
Low Dose	5	13.12 (3.03)	13.79 (1.95)	13.0	11.9, 16.0	0.67 (1.46)	0.0	-0.4, 3.2	0.3621
High Dose	4	8.06 (5.62)	9.38 (5.58)	11.0	1.4, 14.1	1.32 (8.22)	2.7	-9.9, 9.8	0.7699
WEEK 84	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Geographic region:NORTH AMERICA (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia (Cont.)									
WEEK 96	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia									
BASELINE	40		2.88 (4.65)	0.6	0.0, 16.0				
Low Dose	16		1.68 (3.17)	0.4	0.0, 12.0				
High Dose	24		3.67 (5.33)	0.6	0.0, 16.0				
WEEK 12	27	2.75 (4.93)	2.66 (4.54)	0.0	0.0, 16.0	-0.08 (4.25)	0.0	-15.8, 7.4	0.9188
Low Dose	12	0.64 (1.05)	1.44 (2.70)	0.0	0.0, 8.7	0.80 (2.67)	0.0	-3.5, 7.4	0.3202
High Dose	15	4.43 (6.12)	3.64 (5.50)	0.7	0.0, 16.0	-0.79 (5.17)	0.0	-15.8, 6.7	0.5622
WEEK 24	33	3.10 (4.81)	1.82 (3.37)	0.0	0.0, 16.0	-1.28 (4.61)	0.0	-16.0, 6.2	0.1213
Low Dose	13	1.90 (3.49)	1.24 (2.35)	0.0	0.0, 6.9	-0.66 (4.38)	0.0	-12.0, 6.2	0.5985
High Dose	20	3.88 (5.45)	2.20 (3.90)	0.0	0.0, 16.0	-1.68 (4.82)	0.0	-16.0, 5.1	0.1353

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Geographic region:NORTH AMERICA (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia (Cont.)									
WEEK 36	14	2.64 (4.11)	2.65 (5.59)	0.0	0.0, 16.0	0.01 (5.41)	0.0	-12.9, 11.2	0.9961
Low Dose	6	0.24 (0.59)	0.15 (0.28)	0.0	0.0, 0.7	-0.09 (0.34)	0.0	-0.8, 0.2	0.5663
High Dose	8	4.44 (4.75)	4.51 (6.98)	0.1	0.0, 16.0	0.08 (7.36)	0.0	-12.9, 11.2	0.9771
WEEK 48	20	3.42 (4.84)	1.14 (1.87)	0.0	0.0, 5.5	-2.28 (4.72)	0.0	-12.9, 4.0	0.0434*
Low Dose	8	2.12 (4.18)	0.47 (0.69)	0.0	0.0, 1.7	-1.65 (3.72)	0.0	-10.3, 0.9	0.2503
High Dose	12	4.29 (5.23)	1.59 (2.28)	0.0	0.0, 5.5	-2.70 (5.40)	-0.4	-12.9, 4.0	0.1105
WEEK 60	12	2.99 (5.33)	1.84 (2.27)	1.0	0.0, 5.8	-1.15 (4.19)	0.0	-10.2, 5.7	0.3622
Low Dose	8	2.12 (4.18)	1.66 (2.29)	0.4	0.0, 5.7	-0.46 (3.80)	0.0	-7.3, 5.7	0.7438
High Dose	4	4.74 (7.56)	2.21 (2.53)	1.5	0.0, 5.8	-2.53 (5.18)	-0.5	-10.2, 1.1	0.3998
WEEK 72	9	2.54 (5.27)	1.09 (1.42)	0.5	0.0, 4.2	-1.46 (4.85)	0.0	-14.2, 1.4	0.3944
Low Dose	5	0.29 (0.65)	0.34 (0.54)	0.0	0.0, 1.2	0.05 (0.79)	0.0	-1.0, 1.2	0.8939
High Dose	4	5.36 (7.39)	2.02 (1.71)	2.0	0.0, 4.2	-3.34 (7.31)	-0.3	-14.2, 1.4	0.4285
WEEK 84	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Geographic region:NORTH AMERICA (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia (Cont.)									
WEEK 96	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								
Average Daily Normalized 'On' Time With Troublesome Dyskinesia									
BASELINE	40		0.45 (1.41)	0.0	0.0, 6.3				
Low Dose	16		0.22 (0.83)	0.0	0.0, 3.3				
High Dose	24		0.61 (1.69)	0.0	0.0, 6.3				
WEEK 12	27	0.42 (1.26)	0.19 (0.68)	0.0	0.0, 3.0	-0.23 (1.35)	0.0	-5.3, 3.0	0.3809
Low Dose	12	0.30 (0.95)	0.02 (0.06)	0.0	0.0, 0.2	-0.28 (0.96)	0.0	-3.3, 0.2	0.3362
High Dose	15	0.53 (1.48)	0.33 (0.90)	0.0	0.0, 3.0	-0.19 (1.63)	0.0	-5.3, 3.0	0.6530
WEEK 24	33	0.54 (1.54)	0.45 (1.44)	0.0	0.0, 7.2	-0.08 (1.43)	0.0	-5.3, 4.3	0.7392
Low Dose	13	0.27 (0.92)	0.23 (0.37)	0.0	0.0, 1.1	-0.05 (1.05)	0.0	-3.3, 1.1	0.8765
High Dose	20	0.71 (1.84)	0.60 (1.82)	0.0	0.0, 7.2	-0.11 (1.65)	0.0	-5.3, 4.3	0.7741

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Geographic region:NORTH AMERICA (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia (Cont.)									
WEEK 36	14	0.38 (1.43)	0.25 (0.56)	0.0	0.0, 1.8	-0.13 (1.60)	0.0	-5.3, 1.8	0.7608
Low Dose	6	0.00 (0.00)	0.28 (0.49)	0.0	0.0, 1.2	0.28 (0.49)	0.0	0.0, 1.2	0.2252
High Dose	8	0.67 (1.89)	0.23 (0.64)	0.0	0.0, 1.8	-0.44 (2.08)	0.0	-5.3, 1.8	0.5669
WEEK 48	20	0.29 (0.91)	0.21 (0.53)	0.0	0.0, 2.3	-0.08 (1.09)	0.0	-3.3, 2.3	0.7367
Low Dose	8	0.41 (1.17)	0.12 (0.26)	0.0	0.0, 0.7	-0.30 (1.25)	0.0	-3.3, 0.7	0.5238
High Dose	12	0.21 (0.74)	0.27 (0.66)	0.0	0.0, 2.3	0.06 (1.00)	0.0	-2.3, 2.3	0.8438
WEEK 60	12	0.80 (1.96)	0.23 (0.46)	0.0	0.0, 1.5	-0.57 (2.11)	0.0	-6.3, 1.5	0.3739
Low Dose	8	0.41 (1.17)	0.07 (0.21)	0.0	0.0, 0.6	-0.34 (1.22)	0.0	-3.3, 0.6	0.4560
High Dose	4	1.56 (3.13)	0.55 (0.70)	0.4	0.0, 1.5	-1.02 (3.54)	0.4	-6.3, 1.5	0.6057
WEEK 72	9	0.69 (2.08)	0.79 (1.66)	0.0	0.0, 5.0	0.10 (2.39)	0.0	-4.6, 5.0	0.9029
Low Dose	5	0.00 (0.00)	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
High Dose	4	1.56 (3.13)	1.79 (2.23)	1.1	0.0, 5.0	0.23 (3.90)	0.3	-4.6, 5.0	0.9151
WEEK 84	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Geographic region:NORTH AMERICA (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia (Cont.)									
WEEK 96	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia									
BASELINE	40		13.69 (2.55)	14.7	7.2, 16.0				
Low Dose	16		13.12 (2.37)	13.2	7.2, 16.0				
High Dose	24		14.07 (2.65)	15.5	7.9, 16.0				
WEEK 12	27	13.43 (2.66)	13.45 (2.14)	13.8	9.2, 16.0	0.03 (2.69)	0.0	-6.8, 5.3	0.9586
Low Dose	12	12.82 (2.60)	13.57 (1.82)	13.5	10.1, 16.0	0.74 (1.95)	0.7	-2.8, 3.8	0.2139
High Dose	15	13.91 (2.69)	13.37 (2.42)	13.9	9.2, 16.0	-0.55 (3.11)	0.0	-6.8, 5.3	0.5072
WEEK 24	33	13.84 (2.39)	13.13 (3.26)	13.7	5.2, 16.0	-0.71 (2.93)	0.0	-7.8, 4.9	0.1740
Low Dose	13	12.82 (2.34)	13.03 (3.20)	13.6	5.5, 16.0	0.22 (3.25)	0.0	-7.8, 4.9	0.8118
High Dose	20	14.50 (2.24)	13.19 (3.38)	14.4	5.2, 16.0	-1.31 (2.61)	-0.3	-7.7, 3.0	0.0365*

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Geographic region:NORTH AMERICA (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia (Cont.)									
WEEK 36	14	14.30 (2.12)	14.04 (2.11)	14.3	9.1, 16.0	-0.27 (1.57)	-0.3	-2.3, 4.3	0.5345
Low Dose	6	13.70 (2.37)	12.87 (2.77)	12.6	9.1, 16.0	-0.83 (0.91)	-0.7	-2.3, 0.0	0.0758
High Dose	8	14.76 (1.94)	14.91 (0.90)	14.6	14.0, 16.0	0.15 (1.88)	-0.1	-1.6, 4.3	0.8278
WEEK 48	20	14.48 (1.73)	14.21 (2.14)	15.2	9.7, 16.0	-0.27 (2.38)	-0.1	-5.4, 3.8	0.6167
Low Dose	8	13.60 (1.98)	13.88 (2.48)	14.9	9.7, 16.0	0.28 (2.31)	-0.2	-2.7, 3.8	0.7399
High Dose	12	15.06 (1.32)	14.42 (1.97)	15.2	10.4, 16.0	-0.64 (2.44)	-0.1	-5.4, 2.3	0.3843
WEEK 60	12	13.52 (2.38)	13.74 (2.35)	14.3	9.1, 16.0	0.22 (2.33)	0.0	-3.9, 5.3	0.7528
Low Dose	8	13.19 (1.96)	13.42 (2.68)	13.8	9.1, 16.0	0.24 (1.51)	0.0	-1.8, 3.0	0.6710
High Dose	4	14.19 (3.30)	14.37 (1.63)	14.7	12.1, 16.0	0.18 (3.83)	-0.4	-3.9, 5.3	0.9312
WEEK 72	9	13.42 (2.67)	12.92 (3.14)	14.1	5.6, 16.0	-0.50 (4.47)	0.5	-10.4, 5.1	0.7462
Low Dose	5	13.41 (2.53)	14.13 (1.79)	14.3	12.3, 16.0	0.72 (0.92)	0.5	0.0, 2.2	0.1553
High Dose	4	13.42 (3.25)	11.40 (4.07)	12.8	5.6, 14.3	-2.02 (6.83)	-1.4	-10.4, 5.1	0.5954
WEEK 84	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Geographic region:NORTH AMERICA (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia (Cont.)									
WEEK 96	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								
Geographic region:EUROPE AND AUSTRALIA									
Average Daily Normalized 'Off' Time									
BASELINE	46		2.64 (3.19)	1.2	0.0, 11.5				
Low Dose	22		2.46 (3.05)	1.3	0.0, 10.9				
High Dose	24		2.79 (3.36)	1.1	0.0, 11.5				
WEEK 12	37	2.78 (3.38)	2.81 (3.18)	1.9	0.0, 10.9	0.04 (2.85)	0.0	-8.2, 10.9	0.9368
Low Dose	19	2.29 (3.19)	1.83 (2.10)	1.5	0.0, 7.3	-0.46 (2.32)	0.0	-8.2, 1.9	0.3964
High Dose	18	3.29 (3.60)	3.85 (3.82)	3.6	0.0, 10.9	0.56 (3.31)	0.0	-6.4, 10.9	0.4797
WEEK 24	33	2.44 (2.62)	3.18 (4.10)	1.7	0.0, 16.0	0.73 (3.26)	0.0	-5.7, 13.3	0.2055
Low Dose	17	2.43 (2.60)	2.81 (4.43)	1.2	0.0, 16.0	0.38 (3.94)	0.0	-5.7, 13.3	0.6947
High Dose	16	2.45 (2.73)	3.56 (3.83)	2.3	0.0, 13.4	1.11 (2.43)	0.3	-3.1, 5.2	0.0878

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Geographic region:EUROPE AND AUSTRALIA (Cont.)									
Average Daily Normalized 'Off' Time (Cont.)									
WEEK 36	20	2.43 (2.82)	2.46 (3.17)	1.4	0.0, 12.1	0.03 (1.99)	0.0	-3.9, 5.6	0.9437
Low Dose	13	2.25 (2.58)	2.59 (3.69)	1.2	0.0, 12.1	0.34 (1.67)	0.0	-1.1, 5.6	0.4772
High Dose	7	2.76 (3.41)	2.22 (2.11)	1.6	0.0, 4.9	-0.54 (2.52)	0.0	-3.9, 3.6	0.5916
WEEK 48	28	2.33 (2.65)	3.42 (4.40)	1.2	0.0, 14.3	1.09 (2.61)	0.0	-2.3, 7.4	0.0353*
Low Dose	12	2.17 (2.67)	2.53 (3.75)	0.2	0.0, 10.1	0.36 (2.50)	0.0	-2.3, 7.4	0.6290
High Dose	16	2.45 (2.73)	4.09 (4.84)	1.2	0.0, 14.3	1.64 (2.63)	0.5	-1.0, 6.6	0.0246*
WEEK 60	14	3.21 (3.10)	3.67 (3.33)	3.0	0.0, 10.4	0.46 (1.64)	0.0	-2.0, 3.9	0.3151
Low Dose	7	3.09 (3.10)	3.15 (3.98)	1.2	0.0, 10.4	0.07 (1.76)	-0.2	-1.2, 3.9	0.9252
High Dose	7	3.34 (3.33)	4.19 (2.75)	3.1	0.0, 7.1	0.85 (1.53)	1.0	-2.0, 2.4	0.1926
WEEK 72	1	0.00 (N/A)	0.80 (N/A)	0.8	0.8, 0.8	0.80 (N/A)	0.8	0.8, 0.8	
Low Dose	1	0.00 (N/A)	0.80 (N/A)	0.8	0.8, 0.8	0.80 (N/A)	0.8	0.8, 0.8	
High Dose	0								

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Geographic region:EUROPE AND AUSTRALIA (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia									
BASELINE	46		10.68 (5.08)	12.8	0.0, 16.0				
Low Dose	22		10.89 (5.16)	12.8	0.0, 16.0				
High Dose	24		10.49 (5.11)	12.8	0.4, 16.0				
WEEK 12	37	10.86 (5.18)	11.58 (4.60)	12.7	0.0, 16.0	0.72 (3.73)	0.0	-10.9, 14.2	0.2462
Low Dose	19	10.81 (5.56)	11.93 (4.90)	13.6	0.0, 16.0	1.12 (3.84)	0.0	-1.4, 14.2	0.2212
High Dose	18	10.91 (4.90)	11.21 (4.37)	11.7	3.6, 16.0	0.31 (3.67)	0.0	-10.9, 6.2	0.7269
WEEK 24	33	10.81 (4.83)	10.49 (5.08)	11.3	0.0, 16.0	-0.32 (4.37)	0.0	-13.3, 14.2	0.6806
Low Dose	17	10.94 (4.96)	10.52 (5.82)	13.5	0.0, 16.0	-0.42 (5.32)	0.0	-13.3, 14.2	0.7465
High Dose	16	10.66 (4.85)	10.46 (4.34)	10.7	2.6, 16.0	-0.20 (3.24)	-0.3	-6.3, 5.5	0.8078
WEEK 36	20	11.67 (4.29)	12.08 (4.18)	13.0	3.4, 16.0	0.42 (3.73)	0.0	-5.9, 14.2	0.6219
Low Dose	13	12.11 (4.14)	12.73 (4.29)	14.8	3.4, 16.0	0.61 (4.50)	0.0	-5.9, 14.2	0.6320
High Dose	7	10.84 (4.77)	10.89 (4.01)	11.9	6.4, 16.0	0.06 (1.86)	0.2	-3.6, 2.4	0.9376

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Geographic region:EUROPE AND AUSTRALIA (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia (Cont.)									
WEEK 48	28	10.13 (5.21)	10.01 (5.07)	9.7	0.0, 16.0	-0.12 (4.28)	0.0	-8.0, 13.7	0.8810
Low Dose	12	10.72 (5.33)	10.74 (4.90)	10.4	1.1, 16.0	0.02 (5.54)	0.3	-8.0, 13.7	0.9914
High Dose	16	9.69 (5.25)	9.46 (5.29)	9.3	0.0, 16.0	-0.23 (3.22)	-0.0	-6.6, 5.3	0.7822
WEEK 60	14	9.80 (4.84)	10.75 (4.22)	9.4	4.3, 16.0	0.95 (4.49)	0.1	-4.7, 13.9	0.4411
Low Dose	7	10.18 (4.80)	10.97 (4.81)	9.5	4.5, 16.0	0.78 (6.11)	-0.9	-4.7, 13.9	0.7463
High Dose	7	9.41 (5.22)	10.54 (3.90)	9.2	4.3, 16.0	1.13 (2.51)	1.0	-2.0, 5.8	0.2806
WEEK 72	1	16.00 (N/A)	15.20 (N/A)	15.2	15.2, 15.2	-0.80 (N/A)	-0.8	-0.8, -0.8	
Low Dose	1	16.00 (N/A)	15.20 (N/A)	15.2	15.2, 15.2	-0.80 (N/A)	-0.8	-0.8, -0.8	
High Dose	0								
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia									
BASELINE	46		2.06 (4.04)	0.1	0.0, 16.0				
Low Dose	22		1.83 (4.11)	0.0	0.0, 16.0				
High Dose	24		2.27 (4.06)	0.4	0.0, 15.6				

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Geographic region:EUROPE AND AUSTRALIA (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia (Cont.)									
WEEK 12	37	1.64 (3.64)	1.14 (2.42)	0.0	0.0, 11.6	-0.49 (3.73)	0.0	-11.6, 11.6	0.4290
Low Dose	19	1.96 (4.39)	1.63 (3.21)	0.0	0.0, 11.6	-0.33 (4.75)	0.0	-11.6, 11.6	0.7685
High Dose	18	1.30 (2.71)	0.63 (0.99)	0.0	0.0, 2.8	-0.67 (2.35)	0.0	-8.8, 1.8	0.2464
WEEK 24	33	2.34 (3.97)	1.87 (3.43)	0.0	0.0, 16.0	-0.47 (3.37)	0.0	-11.6, 6.1	0.4246
Low Dose	17	2.37 (4.57)	2.16 (3.92)	0.3	0.0, 16.0	-0.20 (3.14)	0.0	-11.6, 3.3	0.7921
High Dose	16	2.32 (3.38)	1.56 (2.92)	0.0	0.0, 10.2	-0.76 (3.68)	-0.1	-10.7, 6.1	0.4207
WEEK 36	20	1.65 (3.17)	1.29 (2.17)	0.1	0.0, 8.1	-0.36 (2.80)	0.0	-11.6, 2.9	0.5714
Low Dose	13	1.41 (3.25)	0.69 (1.12)	0.0	0.0, 3.0	-0.73 (3.35)	0.0	-11.6, 1.8	0.4499
High Dose	7	2.08 (3.21)	2.40 (3.19)	0.5	0.0, 8.1	0.32 (1.24)	0.0	-1.0, 2.9	0.5229
WEEK 48	28	3.11 (4.86)	2.15 (3.70)	0.4	0.0, 14.9	-0.96 (3.77)	-0.3	-11.1, 8.0	0.1870
Low Dose	12	2.86 (5.31)	2.71 (4.66)	0.4	0.0, 14.9	-0.15 (4.29)	-0.1	-11.1, 8.0	0.9058
High Dose	16	3.30 (4.67)	1.72 (2.87)	0.4	0.0, 9.8	-1.57 (3.33)	-0.6	-9.7, 4.9	0.0782
WEEK 60	14	2.43 (3.97)	1.48 (2.00)	0.3	0.0, 5.8	-0.95 (3.68)	0.0	-11.3, 2.7	0.3532
Low Dose	7	2.35 (4.32)	1.85 (2.15)	1.1	0.0, 5.8	-0.50 (4.87)	0.9	-11.3, 2.7	0.7936
High Dose	7	2.51 (3.94)	1.12 (1.93)	0.0	0.0, 4.3	-1.39 (2.26)	-0.7	-6.4, 0.0	0.1555

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Geographic region:EUROPE AND AUSTRALIA (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia (Cont.)									
WEEK 72	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								
Average Daily Normalized 'On' Time With Troublesome Dyskinesia									
BASELINE	46		0.62 (2.08)	0.0	0.0, 13.5				
Low Dose	22		0.81 (2.91)	0.0	0.0, 13.5				
High Dose	24		0.45 (0.83)	0.0	0.0, 3.0				
WEEK 12	37	0.73 (2.30)	0.46 (1.94)	0.0	0.0, 11.0	-0.27 (3.03)	0.0	-13.5, 11.0	0.5931
Low Dose	19	0.94 (3.12)	0.62 (2.53)	0.0	0.0, 11.0	-0.33 (4.16)	0.0	-13.5, 11.0	0.7358
High Dose	18	0.51 (0.90)	0.30 (1.06)	0.0	0.0, 4.4	-0.21 (1.03)	0.0	-3.0, 2.2	0.4068
WEEK 24	33	0.41 (0.85)	0.46 (1.48)	0.0	0.0, 7.8	0.06 (1.42)	0.0	-3.0, 6.4	0.8203
Low Dose	17	0.26 (0.71)	0.51 (1.90)	0.0	0.0, 7.8	0.25 (1.72)	0.0	-2.7, 6.4	0.5624
High Dose	16	0.56 (0.97)	0.42 (0.90)	0.0	0.0, 2.4	-0.15 (1.02)	0.0	-3.0, 1.9	0.5748

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Geographic region:EUROPE AND AUSTRALIA (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia (Cont.)									
WEEK 36	20	0.26 (0.76)	0.17 (0.64)	0.0	0.0, 2.8	-0.09 (0.64)	0.0	-2.7, 0.6	0.5348
Low Dose	13	0.23 (0.74)	0.00 (0.00)	0.0	0.0, 0.0	-0.23 (0.74)	0.0	-2.7, 0.0	0.2885
High Dose	7	0.33 (0.86)	0.49 (1.06)	0.0	0.0, 2.8	0.16 (0.28)	0.0	0.0, 0.6	0.1725
WEEK 48	28	0.43 (0.89)	0.42 (1.29)	0.0	0.0, 6.2	-0.01 (1.48)	0.0	-3.0, 6.2	0.9844
Low Dose	12	0.25 (0.77)	0.02 (0.07)	0.0	0.0, 0.2	-0.23 (0.78)	0.0	-2.7, 0.2	0.3356
High Dose	16	0.56 (0.97)	0.72 (1.66)	0.0	0.0, 6.2	0.16 (1.85)	0.0	-3.0, 6.2	0.7340
WEEK 60	14	0.56 (0.97)	0.09 (0.29)	0.0	0.0, 1.1	-0.46 (0.87)	0.0	-2.7, 0.3	0.0666
Low Dose	7	0.38 (1.01)	0.04 (0.10)	0.0	0.0, 0.3	-0.34 (1.03)	0.0	-2.7, 0.3	0.4102
High Dose	7	0.74 (0.96)	0.15 (0.40)	0.0	0.0, 1.1	-0.59 (0.74)	0.0	-1.5, 0.0	0.0801
WEEK 72	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Geographic region:EUROPE AND AUSTRALIA (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia									
BASELINE	46		12.74 (3.67)	14.3	2.5, 16.0				
Low Dose	22		12.72 (3.80)	13.9	2.5, 16.0				
High Dose	24		12.76 (3.63)	14.7	4.5, 16.0				
WEEK 12	37	12.49 (3.93)	12.72 (3.55)	13.9	5.0, 16.0	0.23 (3.94)	0.0	-11.0, 11.6	0.7234
Low Dose	19	12.77 (4.04)	13.56 (2.90)	14.1	5.0, 16.0	0.79 (4.44)	0.0	-11.0, 11.6	0.4481
High Dose	18	12.20 (3.90)	11.84 (4.03)	12.4	5.1, 16.0	-0.36 (3.37)	0.0	-10.9, 6.4	0.6573
WEEK 24	33	13.15 (2.83)	12.36 (4.31)	14.1	0.0, 16.0	-0.79 (3.29)	0.0	-13.3, 5.7	0.1769
Low Dose	17	13.31 (2.65)	12.68 (4.84)	14.8	0.0, 16.0	-0.63 (4.01)	0.0	-13.3, 5.7	0.5272
High Dose	16	12.98 (3.09)	12.02 (3.79)	13.7	2.6, 16.0	-0.96 (2.42)	-0.7	-5.2, 3.3	0.1328
WEEK 36	20	13.31 (2.91)	13.37 (3.18)	14.4	3.9, 16.0	0.06 (2.04)	0.0	-5.6, 3.9	0.9000
Low Dose	13	13.53 (2.49)	13.41 (3.69)	14.8	3.9, 16.0	-0.11 (1.87)	0.0	-5.6, 2.7	0.8314
High Dose	7	12.92 (3.77)	13.29 (2.18)	11.9	11.1, 16.0	0.38 (2.46)	0.0	-3.6, 3.9	0.7003

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Geographic region:EUROPE AND AUSTRALIA (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia (Cont.)									
WEEK 48	28	13.24 (2.84)	12.16 (4.36)	14.1	1.7, 16.0	-1.09 (2.92)	0.0	-7.4, 2.7	0.0598
Low Dose	12	13.59 (2.57)	13.45 (3.74)	15.8	5.9, 16.0	-0.13 (2.66)	0.0	-7.4, 2.7	0.8664
High Dose	16	12.98 (3.09)	11.18 (4.64)	12.6	1.7, 16.0	-1.80 (2.98)	-0.5	-6.6, 1.9	0.0290*
WEEK 60	14	12.23 (3.13)	12.24 (3.41)	13.0	5.6, 16.0	0.01 (1.65)	0.0	-3.9, 2.7	0.9861
Low Dose	7	12.53 (2.81)	12.81 (3.96)	14.5	5.6, 16.0	0.28 (2.05)	1.0	-3.9, 2.7	0.7310
High Dose	7	11.93 (3.62)	11.66 (2.96)	12.9	7.8, 16.0	-0.26 (1.24)	-0.5	-2.0, 2.0	0.5954
WEEK 72	1	16.00 (N/A)	15.20 (N/A)	15.2	15.2, 15.2	-0.80 (N/A)	-0.8	-0.8, -0.8	
Low Dose	1	16.00 (N/A)	15.20 (N/A)	15.2	15.2, 15.2	-0.80 (N/A)	-0.8	-0.8, -0.8	
High Dose	0								
Geographic region:JAPAN									
Average Daily Normalized 'Off' Time									
BASELINE	11		4.73 (2.78)	5.3	0.0, 10.1				
Low Dose	7		5.12 (2.84)	5.3	2.3, 10.1				
High Dose	4		4.06 (2.96)	4.9	0.0, 6.4				

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Geographic region:JAPAN (Cont.)									
Average Daily Normalized 'Off' Time (Cont.)									
WEEK 12	11	4.73 (2.78)	5.09 (2.09)	5.5	2.1, 8.0	0.36 (2.52)	1.5	-4.2, 3.8	0.6468
Low Dose	7	5.12 (2.84)	5.22 (2.14)	5.8	2.5, 8.0	0.10 (2.91)	0.2	-4.2, 3.8	0.9284
High Dose	4	4.06 (2.96)	4.87 (2.31)	4.9	2.1, 7.6	0.81 (1.95)	1.6	-2.1, 2.1	0.4686
WEEK 24	9	4.70 (3.06)	5.46 (3.02)	4.3	2.5, 10.9	0.76 (3.36)	2.1	-6.1, 4.5	0.5157
Low Dose	6	4.96 (3.08)	5.46 (2.37)	4.8	2.5, 8.8	0.50 (3.34)	2.1	-6.1, 2.5	0.7286
High Dose	3	4.17 (3.62)	5.46 (4.74)	2.8	2.6, 10.9	1.29 (4.10)	2.6	-3.3, 4.5	0.6410
WEEK 36	5	4.32 (2.99)	3.65 (1.75)	3.6	1.2, 6.1	-0.67 (3.62)	-0.3	-5.5, 3.9	0.6997
Low Dose	2	4.55 (3.09)	2.41 (1.71)	2.4	1.2, 3.6	-2.15 (4.80)	-2.1	-5.5, 1.2	0.6410
High Dose	3	4.17 (3.62)	4.48 (1.45)	3.9	3.4, 6.1	0.31 (3.34)	-0.3	-2.7, 3.9	0.8866
WEEK 48	4	3.72 (3.09)	4.64 (1.95)	4.7	2.3, 6.9	0.92 (2.18)	0.4	-1.0, 4.0	0.4612
Low Dose	1	2.37 (N/A)	2.32 (N/A)	2.3	2.3, 2.3	-0.04 (N/A)	-0.0	-0.0, -0.0	
High Dose	3	4.17 (3.62)	5.41 (1.45)	5.3	4.0, 6.9	1.24 (2.56)	0.8	-1.0, 4.0	0.4888
WEEK 60	3	2.83 (3.09)	4.13 (0.61)	3.9	3.7, 4.8	1.30 (2.61)	1.3	-1.3, 3.9	0.4794
Low Dose	1	2.37 (N/A)	3.66 (N/A)	3.7	3.7, 3.7	1.30 (N/A)	1.3	1.3, 1.3	
High Dose	2	3.06 (4.33)	4.36 (0.64)	4.4	3.9, 4.8	1.30 (3.69)	1.3	-1.3, 3.9	0.7059

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Geographic region:JAPAN (Cont.)									
Average Daily Normalized 'Off' Time (Cont.)									
WEEK 72	2	6.26 (0.18)	9.47 (1.31)	9.5	8.5, 10.4	3.21 (1.49)	3.2	2.2, 4.3	0.2021
Low Dose	0								
High Dose	2	6.26 (0.18)	9.47 (1.31)	9.5	8.5, 10.4	3.21 (1.49)	3.2	2.2, 4.3	0.2021
WEEK 84	1	6.13 (N/A)	11.43 (N/A)	11.4	11.4, 11.4	5.30 (N/A)	5.3	5.3, 5.3	
Low Dose	0								
High Dose	1	6.13 (N/A)	11.43 (N/A)	11.4	11.4, 11.4	5.30 (N/A)	5.3	5.3, 5.3	
Average Daily Normalized 'On' Time Without Dyskinesia									
BASELINE	11		9.98 (3.15)	9.6	4.2, 16.0				
Low Dose	7		9.16 (2.90)	9.3	4.2, 13.0				
High Dose	4		11.41 (3.46)	10.8	8.1, 16.0				
WEEK 12	11	9.98 (3.15)	8.41 (4.26)	8.4	1.0, 13.9	-1.57 (3.70)	-1.5	-6.7, 4.2	0.1894
Low Dose	7	9.16 (2.90)	7.56 (4.61)	8.0	1.0, 13.5	-1.60 (4.00)	-1.5	-6.7, 4.2	0.3298
High Dose	4	11.41 (3.46)	9.90 (3.67)	10.1	5.6, 13.9	-1.51 (3.69)	-0.9	-6.4, 2.1	0.4720

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Geographic region:JAPAN (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia (Cont.)									
WEEK 24	9	9.86 (3.43)	8.23 (3.60)	8.2	1.0, 13.4	-1.63 (3.68)	-2.5	-5.9, 6.6	0.2195
Low Dose	6	9.18 (3.18)	7.67 (3.56)	8.2	1.0, 10.8	-1.52 (4.21)	-2.4	-5.9, 6.6	0.4184
High Dose	3	11.22 (4.21)	9.35 (4.16)	9.6	5.1, 13.4	-1.87 (3.12)	-2.6	-4.5, 1.6	0.4076
WEEK 36	5	9.97 (3.54)	9.26 (5.09)	9.9	1.3, 14.8	-0.71 (4.33)	0.2	-5.6, 5.5	0.7320
Low Dose	2	8.09 (1.66)	8.05 (9.55)	8.0	1.3, 14.8	-0.04 (7.89)	-0.0	-5.6, 5.5	0.9950
High Dose	3	11.22 (4.21)	10.06 (1.95)	9.9	8.2, 12.1	-1.16 (2.37)	0.2	-3.9, 0.3	0.4870
WEEK 48	4	10.14 (4.06)	7.34 (4.81)	7.8	1.8, 12.0	-2.80 (2.69)	-3.6	-5.1, 1.0	0.1286
Low Dose	1	6.92 (N/A)	1.81 (N/A)	1.8	1.8, 1.8	-5.11 (N/A)	-5.1	-5.1, -5.1	
High Dose	3	11.22 (4.21)	9.19 (3.77)	10.7	4.9, 12.0	-2.03 (2.70)	-3.1	-4.0, 1.0	0.3225
WEEK 60	3	10.32 (4.95)	7.08 (5.76)	8.4	0.8, 12.1	-3.25 (3.27)	-3.9	-6.1, 0.3	0.2275
Low Dose	1	6.92 (N/A)	0.78 (N/A)	0.8	0.8, 0.8	-6.13 (N/A)	-6.1	-6.1, -6.1	
High Dose	2	12.03 (5.62)	10.22 (2.64)	10.2	8.4, 12.1	-1.80 (2.98)	-1.8	-3.9, 0.3	0.5492
WEEK 72	2	8.83 (1.10)	5.81 (2.34)	5.8	4.2, 7.5	-3.03 (1.23)	-3.0	-3.9, -2.2	0.1783
Low Dose	0								
High Dose	2	8.83 (1.10)	5.81 (2.34)	5.8	4.2, 7.5	-3.03 (1.23)	-3.0	-3.9, -2.2	0.1783

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Geographic region:JAPAN (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia (Cont.)									
WEEK 84	1	8.05 (N/A)	4.57 (N/A)	4.6	4.6, 4.6	-3.48 (N/A)	-3.5	-3.5, -3.5	
Low Dose	0								
High Dose	1	8.05 (N/A)	4.57 (N/A)	4.6	4.6, 4.6	-3.48 (N/A)	-3.5	-3.5, -3.5	
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia									
BASELINE	11		1.26 (2.04)	0.3	0.0, 6.7				
Low Dose	7		1.69 (2.45)	0.6	0.0, 6.7				
High Dose	4		0.52 (0.88)	0.1	0.0, 1.8				
WEEK 12	11	1.26 (2.04)	2.10 (3.84)	0.0	0.0, 12.4	0.84 (2.56)	0.0	-2.7, 5.7	0.3033
Low Dose	7	1.69 (2.45)	2.60 (4.56)	0.0	0.0, 12.4	0.91 (2.66)	0.0	-2.7, 5.7	0.3991
High Dose	4	0.52 (0.88)	1.23 (2.46)	0.0	0.0, 4.9	0.71 (2.76)	0.0	-1.8, 4.6	0.6447
WEEK 24	9	1.44 (2.24)	2.29 (4.08)	0.0	0.0, 12.4	0.85 (1.94)	0.0	-0.5, 5.7	0.2260
Low Dose	6	1.86 (2.64)	2.84 (4.88)	0.6	0.0, 12.4	0.98 (2.35)	0.0	-0.5, 5.7	0.3553
High Dose	3	0.61 (1.05)	1.19 (2.07)	0.0	0.0, 3.6	0.59 (1.02)	0.0	0.0, 1.8	0.4226

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Geographic region:JAPAN (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia (Cont.)									
WEEK 36	5	1.71 (2.91)	3.09 (4.86)	0.0	0.0, 11.1	1.38 (2.00)	0.0	0.0, 4.4	0.1974
Low Dose	2	3.36 (4.75)	5.55 (7.85)	5.5	0.0, 11.1	2.19 (3.10)	2.2	0.0, 4.4	0.5000
High Dose	3	0.61 (1.05)	1.45 (2.52)	0.0	0.0, 4.4	0.85 (1.46)	0.0	0.0, 2.5	0.4226
WEEK 48	4	2.14 (3.17)	4.02 (5.60)	2.1	0.0, 11.9	1.88 (2.45)	1.2	0.0, 5.2	0.2223
Low Dose	1	6.72 (N/A)	11.87 (N/A)	11.9	11.9, 11.9	5.15 (N/A)	5.2	5.2, 5.2	
High Dose	3	0.61 (1.05)	1.40 (2.42)	0.0	0.0, 4.2	0.79 (1.37)	0.0	0.0, 2.4	0.4226
WEEK 60	3	2.85 (3.47)	4.79 (6.02)	2.8	0.0, 11.6	1.95 (2.55)	1.0	0.0, 4.8	0.3170
Low Dose	1	6.72 (N/A)	11.55 (N/A)	11.6	11.6, 11.6	4.83 (N/A)	4.8	4.8, 4.8	
High Dose	2	0.91 (1.29)	1.42 (2.00)	1.4	0.0, 2.8	0.50 (0.71)	0.5	0.0, 1.0	0.5000
WEEK 72	2	0.91 (1.29)	0.73 (1.03)	0.7	0.0, 1.5	-0.18 (0.26)	-0.2	-0.4, 0.0	0.5000
Low Dose	0								
High Dose	2	0.91 (1.29)	0.73 (1.03)	0.7	0.0, 1.5	-0.18 (0.26)	-0.2	-0.4, 0.0	0.5000
WEEK 84	1	1.82 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	-1.82 (N/A)	-1.8	-1.8, -1.8	
Low Dose	0								
High Dose	1	1.82 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	-1.82 (N/A)	-1.8	-1.8, -1.8	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Geographic region:JAPAN (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia									
BASELINE	11		0.02 (0.07)	0.0	0.0, 0.2				
Low Dose	7		0.03 (0.09)	0.0	0.0, 0.2				
High Dose	4		0.00 (0.00)	0.0	0.0, 0.0				
WEEK 12	11	0.02 (0.07)	0.39 (1.30)	0.0	0.0, 4.3	0.37 (1.23)	0.0	0.0, 4.1	0.3409
Low Dose	7	0.03 (0.09)	0.62 (1.63)	0.0	0.0, 4.3	0.59 (1.55)	0.0	0.0, 4.1	0.3559
High Dose	4	0.00 (0.00)	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
WEEK 24	9	0.00 (0.00)	0.02 (0.07)	0.0	0.0, 0.2	0.02 (0.07)	0.0	0.0, 0.2	0.3466
Low Dose	6	0.00 (0.00)	0.04 (0.09)	0.0	0.0, 0.2	0.04 (0.09)	0.0	0.0, 0.2	0.3632
High Dose	3	0.00 (0.00)	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
WEEK 36	5	0.00 (0.00)	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
Low Dose	2	0.00 (0.00)	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
High Dose	3	0.00 (0.00)	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Geographic region:JAPAN (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia (Cont.)									
WEEK 48	4	0.00 (0.00)	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	3	0.00 (0.00)	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
WEEK 60	3	0.00 (0.00)	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	2	0.00 (0.00)	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
WEEK 72	2	0.00 (0.00)	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
Low Dose	0								
High Dose	2	0.00 (0.00)	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
WEEK 84	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	0								
High Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Geographic region:JAPAN (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia									
BASELINE	11		11.24 (2.80)	10.7	5.9, 16.0				
Low Dose	7		10.85 (2.86)	10.7	5.9, 13.7				
High Dose	4		11.94 (2.96)	11.1	9.6, 16.0				
WEEK 12	11	11.24 (2.80)	10.51 (2.59)	10.5	5.8, 13.9	-0.73 (2.72)	-1.5	-3.8, 4.2	0.3931
Low Dose	7	10.85 (2.86)	10.16 (2.85)	9.9	5.8, 13.5	-0.69 (3.23)	-1.5	-3.8, 4.2	0.5929
High Dose	4	11.94 (2.96)	11.13 (2.31)	11.1	8.4, 13.9	-0.81 (1.95)	-1.6	-2.1, 2.1	0.4686
WEEK 24	9	11.30 (3.06)	10.52 (3.01)	11.4	5.1, 13.5	-0.79 (3.38)	-2.3	-4.5, 6.1	0.5040
Low Dose	6	11.04 (3.08)	10.51 (2.36)	11.1	7.2, 13.5	-0.54 (3.36)	-2.2	-2.5, 6.1	0.7114
High Dose	3	11.83 (3.62)	10.54 (4.74)	13.2	5.1, 13.4	-1.29 (4.10)	-2.6	-4.5, 3.3	0.6410
WEEK 36	5	11.68 (2.99)	12.35 (1.75)	12.4	9.9, 14.8	0.67 (3.62)	0.3	-3.9, 5.5	0.6997
Low Dose	2	11.45 (3.09)	13.59 (1.71)	13.6	12.4, 14.8	2.15 (4.80)	2.1	-1.2, 5.5	0.6410
High Dose	3	11.83 (3.62)	11.52 (1.45)	12.1	9.9, 12.6	-0.31 (3.34)	0.3	-3.9, 2.7	0.8866

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
Geographic region:JAPAN (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia (Cont.)									
WEEK 48	4	12.28 (3.09)	11.36 (1.95)	11.3	9.1, 13.7	-0.92 (2.18)	-0.4	-4.0, 1.0	0.4612
Low Dose	1	13.63 (N/A)	13.68 (N/A)	13.7	13.7, 13.7	0.04 (N/A)	0.0	0.0, 0.0	
High Dose	3	11.83 (3.62)	10.59 (1.45)	10.7	9.1, 12.0	-1.24 (2.56)	-0.8	-4.0, 1.0	0.4888
WEEK 60	3	13.17 (3.09)	11.87 (0.61)	12.1	11.2, 12.3	-1.30 (2.61)	-1.3	-3.9, 1.3	0.4794
Low Dose	1	13.63 (N/A)	12.34 (N/A)	12.3	12.3, 12.3	-1.30 (N/A)	-1.3	-1.3, -1.3	
High Dose	2	12.94 (4.33)	11.64 (0.64)	11.6	11.2, 12.1	-1.30 (3.69)	-1.3	-3.9, 1.3	0.7059
WEEK 72	2	9.74 (0.18)	6.53 (1.31)	6.5	5.6, 7.5	-3.21 (1.49)	-3.2	-4.3, -2.2	0.2021
Low Dose	0								
High Dose	2	9.74 (0.18)	6.53 (1.31)	6.5	5.6, 7.5	-3.21 (1.49)	-3.2	-4.3, -2.2	0.2021
WEEK 84	1	9.87 (N/A)	4.57 (N/A)	4.6	4.6, 4.6	-5.30 (N/A)	-5.3	-5.3, -5.3	
Low Dose	0								
High Dose	1	9.87 (N/A)	4.57 (N/A)	4.6	4.6, 4.6	-5.30 (N/A)	-5.3	-5.3, -5.3	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PD duration (time since diagnosis) category:<10 years									
Average Daily Normalized 'Off' Time									
BASELINE	56		2.91 (3.24)	1.8	0.0, 11.5				
Low Dose	25		3.42 (3.25)	2.6	0.0, 10.9				
High Dose	31		2.50 (3.23)	0.7	0.0, 11.5				
WEEK 12	47	3.12 (3.37)	3.09 (3.00)	2.3	0.0, 10.9	-0.03 (2.97)	0.0	-8.2, 10.9	0.9459
Low Dose	22	3.44 (3.41)	2.79 (2.51)	2.6	0.0, 8.0	-0.66 (2.71)	0.0	-8.2, 3.8	0.2679
High Dose	25	2.84 (3.38)	3.37 (3.41)	2.3	0.0, 10.9	0.52 (3.13)	0.0	-6.4, 10.9	0.4107
WEEK 24	45	2.68 (2.84)	2.94 (3.17)	2.4	0.0, 13.4	0.26 (2.81)	0.0	-6.1, 7.7	0.5346
Low Dose	21	3.49 (2.90)	2.42 (2.22)	2.4	0.0, 7.8	-1.07 (2.49)	-0.0	-6.1, 2.5	0.0630
High Dose	24	1.97 (2.64)	3.40 (3.80)	2.3	0.0, 13.4	1.43 (2.58)	0.3	-3.1, 7.7	0.0123*
WEEK 36	23	2.68 (2.69)	2.44 (2.41)	1.9	0.0, 7.7	-0.24 (1.27)	0.0	-3.9, 1.2	0.3691
Low Dose	13	2.51 (2.41)	2.65 (2.65)	1.9	0.0, 7.7	0.13 (0.73)	0.0	-1.1, 1.2	0.5219
High Dose	10	2.90 (3.15)	2.17 (2.17)	1.8	0.0, 6.1	-0.73 (1.65)	-0.1	-3.9, 1.2	0.1963

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
PD duration (time since diagnosis) category:<10 years (Cont.)									
Average Daily Normalized 'Off' Time (Cont.)									
WEEK 48	32	2.37 (2.61)	2.77 (3.78)	1.1	0.0, 14.3	0.39 (2.19)	0.0	-3.0, 6.6	0.3203
Low Dose	13	2.29 (2.42)	1.86 (2.31)	0.7	0.0, 6.0	-0.43 (1.20)	0.0	-3.0, 1.6	0.2226
High Dose	19	2.43 (2.80)	3.38 (4.48)	1.1	0.0, 14.3	0.95 (2.55)	0.0	-2.0, 6.6	0.1205
WEEK 60	20	2.71 (2.78)	2.90 (2.81)	2.4	0.0, 7.1	0.18 (1.41)	0.0	-3.0, 2.4	0.5671
Low Dose	14	2.43 (2.38)	2.38 (2.58)	1.8	0.0, 6.9	-0.05 (1.32)	-0.0	-3.0, 1.9	0.8997
High Dose	6	3.38 (3.73)	4.09 (3.18)	4.6	0.0, 7.1	0.72 (1.58)	1.0	-2.0, 2.4	0.3175
WEEK 72	10	2.34 (2.54)	2.45 (2.64)	1.8	0.0, 8.5	0.11 (1.81)	-0.2	-2.2, 3.9	0.8518
Low Dose	6	2.16 (2.50)	1.69 (1.66)	1.3	0.0, 3.7	-0.47 (1.03)	-0.2	-2.2, 0.8	0.3183
High Dose	4	2.61 (2.97)	3.58 (3.67)	2.9	0.0, 8.5	0.97 (2.52)	0.8	-1.7, 3.9	0.4965
WEEK 84	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								
WEEK 96	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PD duration (time since diagnosis) category:<10 years (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia									
BASELINE	56		10.14 (4.98)	10.9	0.0, 16.0				
Low Dose	25		10.25 (4.43)	11.0	1.5, 16.0				
High Dose	31		10.05 (5.46)	9.6	0.0, 16.0				
WEEK 12	47	10.23 (5.03)	10.96 (4.61)	11.7	0.0, 16.0	0.73 (3.88)	0.0	-10.9, 14.2	0.2056
Low Dose	22	10.04 (4.67)	11.31 (4.73)	12.8	1.0, 16.0	1.26 (4.13)	0.2	-5.9, 14.2	0.1655
High Dose	25	10.40 (5.42)	10.65 (4.57)	11.1	0.0, 16.0	0.25 (3.66)	0.0	-10.9, 9.0	0.7334
WEEK 24	45	10.34 (4.84)	10.68 (4.77)	10.7	0.0, 16.0	0.33 (4.53)	0.0	-9.6, 14.2	0.6249
Low Dose	21	10.37 (4.06)	11.15 (4.62)	10.7	1.0, 16.0	0.77 (4.39)	0.0	-5.9, 14.2	0.4293
High Dose	24	10.32 (5.52)	10.26 (4.96)	10.9	0.0, 16.0	-0.05 (4.71)	0.0	-9.6, 13.7	0.9564
WEEK 36	23	10.60 (4.70)	11.74 (4.22)	11.9	1.3, 16.0	1.14 (4.49)	0.0	-5.6, 14.2	0.2370
Low Dose	13	11.41 (4.30)	11.69 (4.65)	11.5	1.3, 16.0	0.28 (4.54)	-0.3	-5.6, 14.2	0.8275
High Dose	10	9.55 (5.23)	11.80 (3.83)	12.9	6.4, 16.0	2.25 (4.39)	0.6	-0.6, 14.0	0.1394

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
PD duration (time since diagnosis) category:<10 years (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia (Cont.)									
WEEK 48	32	10.02 (5.07)	11.12 (4.95)	10.7	0.0, 16.0	1.10 (4.79)	0.0	-6.6, 14.9	0.2028
Low Dose	13	11.10 (4.33)	12.30 (4.47)	15.3	1.8, 16.0	1.20 (4.90)	0.0	-5.1, 13.7	0.3948
High Dose	19	9.27 (5.50)	10.31 (5.21)	10.7	0.0, 16.0	1.03 (4.84)	0.0	-6.6, 14.9	0.3643
WEEK 60	20	9.92 (4.67)	10.77 (4.39)	10.2	0.8, 16.0	0.85 (4.20)	0.0	-6.1, 13.9	0.3744
Low Dose	14	11.16 (4.16)	11.27 (4.51)	10.6	0.8, 16.0	0.12 (4.68)	-0.7	-6.1, 13.9	0.9272
High Dose	6	7.03 (4.86)	9.61 (4.25)	9.2	4.3, 16.0	2.58 (2.27)	1.8	0.3, 6.3	0.0387*
WEEK 72	10	11.22 (4.89)	12.77 (2.70)	12.7	7.5, 16.0	1.55 (3.41)	0.2	-2.2, 9.8	0.1835
Low Dose	6	13.60 (2.96)	14.03 (1.84)	14.1	11.9, 16.0	0.42 (1.43)	0.0	-0.8, 3.2	0.5010
High Dose	4	7.64 (5.36)	10.88 (2.88)	11.0	7.5, 14.1	3.24 (5.00)	2.7	-2.2, 9.8	0.2854
WEEK 84	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								
WEEK 96	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PD duration (time since diagnosis) category:<10 years (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia									
BASELINE	56		2.34 (4.33)	0.0	0.0, 16.0				
Low Dose	25		1.50 (2.77)	0.0	0.0, 11.8				
High Dose	31		3.02 (5.21)	0.2	0.0, 16.0				
WEEK 12	47	2.04 (4.13)	1.79 (3.59)	0.0	0.0, 16.0	-0.26 (3.82)	0.0	-15.8, 11.6	0.6469
Low Dose	22	1.56 (2.90)	1.91 (3.77)	0.0	0.0, 12.4	0.35 (4.03)	0.0	-11.6, 11.6	0.6910
High Dose	25	2.47 (4.99)	1.68 (3.49)	0.0	0.0, 16.0	-0.79 (3.63)	0.0	-15.8, 4.6	0.2881
WEEK 24	45	2.54 (4.27)	1.89 (3.48)	0.0	0.0, 16.0	-0.64 (4.02)	0.0	-16.0, 6.2	0.2881
Low Dose	21	1.78 (2.94)	1.96 (3.13)	0.2	0.0, 12.4	0.17 (3.45)	0.0	-11.6, 6.2	0.8196
High Dose	24	3.19 (5.14)	1.84 (3.83)	0.0	0.0, 16.0	-1.36 (4.40)	0.0	-16.0, 4.5	0.1434
WEEK 36	23	2.50 (3.96)	1.60 (2.92)	0.0	0.0, 11.1	-0.90 (3.99)	0.0	-12.9, 4.4	0.2891
Low Dose	13	1.87 (3.56)	1.54 (3.08)	0.2	0.0, 11.1	-0.34 (3.62)	0.0	-11.6, 4.4	0.7427
High Dose	10	3.32 (4.49)	1.68 (2.85)	0.0	0.0, 8.1	-1.64 (4.50)	0.0	-12.9, 2.9	0.2798

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
PD duration (time since diagnosis) category:<10 years (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia (Cont.)									
WEEK 48	32	3.23 (4.80)	1.75 (3.06)	0.0	0.0, 11.9	-1.48 (4.29)	0.0	-12.9, 5.2	0.0598
Low Dose	13	2.14 (3.54)	1.74 (3.46)	0.0	0.0, 11.9	-0.40 (3.82)	0.0	-11.1, 5.2	0.7106
High Dose	19	3.97 (5.47)	1.75 (2.85)	0.0	0.0, 9.8	-2.22 (4.54)	0.0	-12.9, 4.9	0.0469*
WEEK 60	20	2.58 (4.34)	2.16 (3.06)	0.7	0.0, 11.6	-0.41 (4.11)	0.0	-11.3, 5.7	0.6577
Low Dose	14	1.99 (3.45)	2.29 (3.37)	0.7	0.0, 11.6	0.30 (4.06)	0.0	-11.3, 5.7	0.7899
High Dose	6	3.94 (6.11)	1.88 (2.40)	0.9	0.0, 5.8	-2.07 (4.07)	-0.8	-10.2, 1.1	0.2689
WEEK 72	10	1.82 (5.01)	0.56 (0.84)	0.0	0.0, 2.2	-1.26 (4.61)	0.0	-14.2, 1.4	0.4115
Low Dose	6	0.24 (0.59)	0.28 (0.50)	0.0	0.0, 1.2	0.04 (0.71)	0.0	-1.0, 1.2	0.8905
High Dose	4	4.19 (7.88)	0.98 (1.15)	0.9	0.0, 2.2	-3.20 (7.39)	0.0	-14.2, 1.4	0.4497
WEEK 84	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								
WEEK 96	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PD duration (time since diagnosis) category:<10 years (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia									
BASELINE	56		0.61 (2.07)	0.0	0.0, 13.5				
Low Dose	25		0.84 (2.78)	0.0	0.0, 13.5				
High Dose	31		0.43 (1.26)	0.0	0.0, 6.3				
WEEK 12	47	0.60 (2.09)	0.16 (0.72)	0.0	0.0, 4.4	-0.44 (2.10)	0.0	-13.5, 2.2	0.1578
Low Dose	22	0.95 (2.95)	0.00 (0.00)	0.0	0.0, 0.0	-0.95 (2.95)	0.0	-13.5, 0.0	0.1451
High Dose	25	0.29 (0.72)	0.30 (0.97)	0.0	0.0, 4.4	0.01 (0.60)	0.0	-1.3, 2.2	0.9224
WEEK 24	45	0.44 (1.21)	0.49 (1.61)	0.0	0.0, 7.8	0.05 (1.27)	0.0	-3.3, 6.4	0.7978
Low Dose	21	0.35 (0.94)	0.48 (1.71)	0.0	0.0, 7.8	0.12 (1.74)	0.0	-3.3, 6.4	0.7469
High Dose	24	0.52 (1.42)	0.50 (1.55)	0.0	0.0, 7.2	-0.02 (0.68)	0.0	-2.1, 1.9	0.9043
WEEK 36	23	0.22 (0.72)	0.22 (0.64)	0.0	0.0, 2.8	0.01 (0.66)	0.0	-2.7, 1.2	0.9610
Low Dose	13	0.21 (0.74)	0.13 (0.35)	0.0	0.0, 1.2	-0.08 (0.85)	0.0	-2.7, 1.2	0.7510
High Dose	10	0.23 (0.72)	0.34 (0.90)	0.0	0.0, 2.8	0.12 (0.24)	0.0	0.0, 0.6	0.1680

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
PD duration (time since diagnosis) category:<10 years (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia (Cont.)									
WEEK 48	32	0.38 (0.93)	0.37 (1.19)	0.0	0.0, 6.2	-0.01 (1.46)	0.0	-3.3, 6.2	0.9669
Low Dose	13	0.46 (1.13)	0.09 (0.21)	0.0	0.0, 0.7	-0.37 (1.19)	0.0	-3.3, 0.7	0.2859
High Dose	19	0.32 (0.80)	0.56 (1.52)	0.0	0.0, 6.2	0.23 (1.60)	0.0	-2.3, 6.2	0.5333
WEEK 60	20	0.79 (1.65)	0.17 (0.40)	0.0	0.0, 1.5	-0.62 (1.70)	0.0	-6.3, 1.5	0.1180
Low Dose	14	0.43 (1.09)	0.06 (0.17)	0.0	0.0, 0.6	-0.37 (1.13)	0.0	-3.3, 0.6	0.2470
High Dose	6	1.64 (2.44)	0.42 (0.66)	0.0	0.0, 1.5	-1.22 (2.66)	-0.6	-6.3, 1.5	0.3110
WEEK 72	10	0.63 (1.98)	0.22 (0.54)	0.0	0.0, 1.7	-0.41 (1.47)	0.0	-4.6, 0.5	0.4065
Low Dose	6	0.00 (0.00)	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
High Dose	4	1.56 (3.13)	0.55 (0.79)	0.3	0.0, 1.7	-1.01 (2.39)	0.0	-4.6, 0.5	0.4575
WEEK 84	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								
WEEK 96	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
PD duration (time since diagnosis) category:<10 years (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia									
BASELINE	56		12.48 (3.55)	13.4	2.5, 16.0				
Low Dose	25		11.75 (3.63)	13.0	2.5, 16.0				
High Dose	31		13.07 (3.44)	14.9	4.5, 16.0				
WEEK 12	47	12.28 (3.68)	12.75 (3.11)	13.7	5.1, 16.0	0.47 (3.48)	0.0	-10.9, 11.6	0.3610
Low Dose	22	11.60 (3.80)	13.21 (2.51)	13.4	8.0, 16.0	1.61 (3.50)	1.3	-3.8, 11.6	0.0428*
High Dose	25	12.87 (3.54)	12.33 (3.55)	13.7	5.1, 16.0	-0.54 (3.21)	0.0	-10.9, 6.4	0.4118
WEEK 24	45	12.88 (2.93)	12.57 (3.58)	13.6	2.6, 16.0	-0.31 (2.94)	0.0	-7.7, 6.1	0.4813
Low Dose	21	12.16 (2.78)	13.10 (2.87)	13.6	5.4, 16.0	0.95 (2.68)	0.0	-3.3, 6.1	0.1208
High Dose	24	13.51 (2.97)	12.10 (4.10)	13.7	2.6, 16.0	-1.41 (2.75)	-0.6	-7.7, 3.3	0.0193*
WEEK 36	23	13.10 (2.76)	13.34 (2.50)	14.0	8.3, 16.0	0.24 (1.42)	0.0	-2.3, 3.9	0.4349
Low Dose	13	13.28 (2.29)	13.23 (2.76)	14.1	8.3, 16.0	-0.06 (1.24)	0.0	-2.3, 2.7	0.8717
High Dose	10	12.87 (3.40)	13.48 (2.24)	14.0	9.9, 16.0	0.61 (1.61)	0.1	-1.2, 3.9	0.2570

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
PD duration (time since diagnosis) category:<10 years (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia (Cont.)									
WEEK 48	32	13.25 (2.69)	12.87 (3.85)	14.5	1.7, 16.0	-0.38 (2.66)	0.0	-6.6, 3.8	0.4243
Low Dose	13	13.25 (2.27)	14.04 (2.41)	15.3	9.7, 16.0	0.80 (1.74)	0.0	-2.3, 3.8	0.1238
High Dose	19	13.25 (3.00)	12.06 (4.47)	13.8	1.7, 16.0	-1.19 (2.92)	0.0	-6.6, 2.3	0.0928
WEEK 60	20	12.49 (2.92)	12.94 (2.89)	13.3	7.8, 16.0	0.44 (1.95)	0.0	-3.9, 5.3	0.3259
Low Dose	14	13.15 (2.22)	13.56 (2.58)	14.0	9.1, 16.0	0.41 (1.41)	0.0	-1.8, 3.0	0.2950
High Dose	6	10.98 (3.95)	11.49 (3.30)	10.7	7.8, 16.0	0.51 (3.05)	0.2	-3.9, 5.3	0.7003
WEEK 72	10	13.04 (2.79)	13.33 (2.55)	14.2	7.5, 16.0	0.30 (2.55)	0.2	-4.4, 5.1	0.7218
Low Dose	6	13.84 (2.50)	14.31 (1.66)	14.7	12.3, 16.0	0.47 (1.03)	0.2	-0.8, 2.2	0.3183
High Dose	4	11.83 (3.13)	11.87 (3.19)	12.8	7.5, 14.3	0.04 (4.19)	-0.2	-4.4, 5.1	0.9856
WEEK 84	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								
WEEK 96	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	16.00 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PD duration (time since diagnosis) category:>=10 years									
Average Daily Normalized 'Off' Time									
BASELINE	41		2.06 (2.47)	0.7	0.0, 8.1				
Low Dose	20		2.35 (2.36)	2.1	0.0, 6.7				
High Dose	21		1.79 (2.60)	0.5	0.0, 8.1				
WEEK 12	28	2.36 (2.70)	2.79 (2.56)	2.3	0.0, 8.0	0.44 (1.78)	0.3	-4.3, 4.2	0.2042
Low Dose	16	2.38 (2.56)	2.44 (2.17)	2.3	0.0, 7.3	0.05 (1.39)	0.0	-4.2, 1.8	0.8793
High Dose	12	2.32 (2.99)	3.26 (3.05)	2.9	0.0, 8.0	0.95 (2.15)	1.2	-4.3, 4.2	0.1552
WEEK 24	30	1.86 (2.26)	3.38 (4.17)	2.3	0.0, 16.0	1.51 (3.14)	0.1	-3.3, 13.3	0.0131*
Low Dose	15	2.37 (2.32)	4.36 (5.07)	2.5	0.0, 16.0	1.98 (3.95)	0.0	-2.3, 13.3	0.0721
High Dose	15	1.35 (2.15)	2.40 (2.87)	2.3	0.0, 7.7	1.05 (2.08)	0.9	-3.3, 5.2	0.0718
WEEK 36	16	1.68 (2.55)	2.21 (3.05)	1.4	0.0, 12.1	0.53 (2.55)	0.0	-5.5, 5.6	0.4198
Low Dose	8	2.43 (2.86)	2.64 (4.04)	1.6	0.0, 12.1	0.21 (3.01)	0.0	-5.5, 5.6	0.8498
High Dose	8	0.92 (2.12)	1.77 (1.80)	1.4	0.0, 4.1	0.85 (2.14)	0.5	-2.7, 3.9	0.3002

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
PD duration (time since diagnosis) category:>=10 years (Cont.)									
Average Daily Normalized 'Off' Time (Cont.)									
WEEK 48	20	1.44 (1.99)	2.88 (3.34)	1.4	0.0, 10.1	1.44 (2.30)	0.6	-1.4, 7.4	0.0116*
Low Dose	8	1.81 (2.21)	3.05 (4.18)	0.9	0.0, 10.1	1.24 (2.90)	0.0	-1.4, 7.4	0.2641
High Dose	12	1.19 (1.89)	2.76 (2.84)	2.0	0.0, 8.6	1.57 (1.95)	0.7	-0.3, 6.1	0.0175*
WEEK 60	9	2.15 (2.56)	3.35 (3.04)	3.0	0.0, 10.4	1.20 (1.93)	0.5	-1.3, 3.9	0.0987
Low Dose	2	4.58 (2.71)	6.19 (5.93)	6.2	2.0, 10.4	1.61 (3.22)	1.6	-0.7, 3.9	0.6082
High Dose	7	1.45 (2.23)	2.54 (1.74)	3.0	0.0, 4.8	1.09 (1.78)	0.5	-1.3, 3.9	0.1578
WEEK 72	2	3.06 (4.33)	7.92 (3.49)	7.9	5.5, 10.4	4.86 (0.84)	4.9	4.3, 5.5	0.0774
Low Dose	0								
High Dose	2	3.06 (4.33)	7.92 (3.49)	7.9	5.5, 10.4	4.86 (0.84)	4.9	4.3, 5.5	0.0774
WEEK 84	1	6.13 (N/A)	11.43 (N/A)	11.4	11.4, 11.4	5.30 (N/A)	5.3	5.3, 5.3	
Low Dose	0								
High Dose	1	6.13 (N/A)	11.43 (N/A)	11.4	11.4, 11.4	5.30 (N/A)	5.3	5.3, 5.3	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PD duration (time since diagnosis) category:>=10 years (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia									
BASELINE	41		11.37 (4.61)	13.3	0.0, 16.0				
Low Dose	20		11.54 (4.51)	12.8	0.0, 16.0				
High Dose	21		11.21 (4.82)	13.3	1.3, 16.0				
WEEK 12	28	11.39 (4.69)	10.61 (4.75)	11.8	0.0, 16.0	-0.77 (3.28)	-0.6	-9.6, 6.2	0.2222
Low Dose	16	12.17 (4.09)	11.01 (4.76)	12.8	0.0, 16.0	-1.16 (2.80)	-0.8	-6.7, 4.2	0.1192
High Dose	12	10.34 (5.38)	10.08 (4.89)	9.8	0.0, 16.0	-0.26 (3.89)	0.0	-9.6, 6.2	0.8202
WEEK 24	30	11.15 (4.80)	10.43 (4.81)	10.7	0.0, 16.0	-0.71 (4.37)	0.0	-13.3, 6.5	0.3800
Low Dose	15	11.02 (4.93)	9.61 (5.84)	11.8	0.0, 16.0	-1.41 (4.65)	-0.1	-13.3, 4.2	0.2600
High Dose	15	11.27 (4.84)	11.26 (3.52)	9.7	6.0, 16.0	-0.01 (4.11)	0.0	-9.2, 6.5	0.9900
WEEK 36	16	12.67 (4.04)	11.09 (5.50)	12.9	0.0, 16.0	-1.58 (3.83)	-0.2	-11.2, 5.5	0.1208
Low Dose	8	13.26 (2.76)	13.23 (4.23)	14.4	3.4, 16.0	-0.03 (3.15)	0.0	-5.9, 5.5	0.9822
High Dose	8	12.07 (5.16)	8.95 (6.04)	10.6	0.0, 16.0	-3.13 (4.01)	-2.5	-11.2, 0.8	0.0631

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PD duration (time since diagnosis) category:>=10 years (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia (Cont.)									
WEEK 48	20	11.24 (5.09)	10.76 (4.36)	12.2	1.1, 16.0	-0.48 (4.83)	-0.4	-9.4, 11.4	0.6598
Low Dose	8	10.38 (6.33)	9.75 (5.07)	10.2	1.1, 15.7	-0.63 (6.15)	-0.9	-8.0, 11.4	0.7794
High Dose	12	11.81 (4.29)	11.43 (3.90)	12.2	4.9, 16.0	-0.38 (4.02)	-0.4	-9.4, 5.3	0.7479
WEEK 60	9	10.68 (5.65)	11.01 (3.55)	12.1	4.5, 16.0	0.33 (4.18)	0.0	-4.7, 8.0	0.8209
Low Dose	2	5.29 (5.60)	6.92 (3.41)	6.9	4.5, 9.3	1.63 (9.01)	1.6	-4.7, 8.0	0.8404
High Dose	7	12.22 (4.99)	12.18 (2.79)	13.0	8.4, 16.0	-0.05 (3.00)	0.0	-3.9, 5.8	0.9682
WEEK 72	2	9.67 (2.29)	2.79 (1.93)	2.8	1.4, 4.2	-6.88 (4.22)	-6.9	-9.9, -3.9	0.2606
Low Dose	0								
High Dose	2	9.67 (2.29)	2.79 (1.93)	2.8	1.4, 4.2	-6.88 (4.22)	-6.9	-9.9, -3.9	0.2606
WEEK 84	1	8.05 (N/A)	4.57 (N/A)	4.6	4.6, 4.6	-3.48 (N/A)	-3.5	-3.5, -3.5	
Low Dose	0								
High Dose	1	8.05 (N/A)	4.57 (N/A)	4.6	4.6, 4.6	-3.48 (N/A)	-3.5	-3.5, -3.5	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PD duration (time since diagnosis) category:>=10 years (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia									
BASELINE	41		2.26 (3.93)	0.6	0.0, 16.0				
Low Dose	20		2.07 (4.32)	0.6	0.0, 16.0				
High Dose	21		2.44 (3.62)	0.7	0.0, 10.7				
WEEK 12	28	1.88 (3.81)	1.91 (3.55)	0.1	0.0, 16.0	0.03 (3.74)	0.0	-11.0, 7.4	0.9655
Low Dose	16	1.40 (3.92)	1.53 (2.54)	0.1	0.0, 8.7	0.14 (3.64)	0.0	-11.0, 7.4	0.8817
High Dose	12	2.52 (3.72)	2.41 (4.64)	0.5	0.0, 16.0	-0.11 (4.04)	0.0	-8.8, 6.7	0.9255
WEEK 24	30	2.62 (4.18)	1.91 (3.43)	0.0	0.0, 16.0	-0.71 (3.70)	0.0	-12.0, 6.1	0.3044
Low Dose	15	2.58 (4.91)	1.92 (4.20)	0.0	0.0, 16.0	-0.65 (3.61)	0.0	-12.0, 4.5	0.4944
High Dose	15	2.66 (3.46)	1.90 (2.59)	0.0	0.0, 6.1	-0.76 (3.92)	0.0	-10.7, 6.1	0.4653
WEEK 36	16	1.31 (2.50)	2.59 (5.27)	0.0	0.0, 16.0	1.29 (3.29)	0.0	-2.0, 11.2	0.1384
Low Dose	8	0.27 (0.48)	0.12 (0.23)	0.0	0.0, 0.5	-0.15 (0.57)	0.0	-1.4, 0.5	0.4864
High Dose	8	2.34 (3.28)	5.06 (6.74)	2.3	0.0, 16.0	2.72 (4.26)	1.3	-2.0, 11.2	0.1137

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PD duration (time since diagnosis) category:>=10 years (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia (Cont.)									
WEEK 48	20	3.04 (4.62)	2.16 (3.75)	0.6	0.0, 14.9	-0.88 (4.04)	-0.3	-10.3, 8.0	0.3416
Low Dose	8	3.77 (6.42)	3.20 (5.45)	0.5	0.0, 14.9	-0.57 (4.91)	-0.3	-10.3, 8.0	0.7500
High Dose	12	2.55 (3.15)	1.46 (2.03)	0.6	0.0, 5.5	-1.09 (3.58)	-0.4	-9.7, 4.0	0.3154
WEEK 60	9	3.00 (4.81)	1.56 (1.90)	1.1	0.0, 4.7	-1.44 (3.14)	0.0	-7.3, 1.0	0.2067
Low Dose	2	6.13 (8.31)	2.89 (2.52)	2.9	1.1, 4.7	-3.24 (5.79)	-3.2	-7.3, 0.9	0.5738
High Dose	7	2.10 (3.90)	1.18 (1.74)	0.0	0.0, 4.3	-0.92 (2.47)	0.0	-6.4, 1.0	0.3630
WEEK 72	2	3.26 (2.04)	2.81 (1.91)	2.8	1.5, 4.2	-0.46 (0.13)	-0.5	-0.5, -0.4	0.1220
Low Dose	0								
High Dose	2	3.26 (2.04)	2.81 (1.91)	2.8	1.5, 4.2	-0.46 (0.13)	-0.5	-0.5, -0.4	0.1220
WEEK 84	1	1.82 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	-1.82 (N/A)	-1.8	-1.8, -1.8	
Low Dose	0								
High Dose	1	1.82 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	-1.82 (N/A)	-1.8	-1.8, -1.8	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PD duration (time since diagnosis) category:>=10 years (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia									
BASELINE	41		0.31 (0.97)	0.0	0.0, 5.3				
Low Dose	20		0.04 (0.09)	0.0	0.0, 0.3				
High Dose	21		0.56 (1.32)	0.0	0.0, 5.3				
WEEK 12	28	0.38 (1.14)	0.69 (2.25)	0.0	0.0, 11.0	0.31 (2.61)	0.0	-5.3, 11.0	0.5400
Low Dose	16	0.05 (0.10)	1.02 (2.88)	0.0	0.0, 11.0	0.97 (2.88)	0.0	-0.3, 11.0	0.1987
High Dose	12	0.82 (1.67)	0.25 (0.86)	0.0	0.0, 3.0	-0.58 (1.99)	0.0	-5.3, 3.0	0.3386
WEEK 24	30	0.37 (1.12)	0.28 (0.88)	0.0	0.0, 4.3	-0.10 (1.41)	0.0	-5.3, 4.3	0.7139
Low Dose	15	0.04 (0.09)	0.12 (0.23)	0.0	0.0, 0.8	0.08 (0.23)	0.0	-0.3, 0.8	0.1990
High Dose	15	0.71 (1.54)	0.44 (1.22)	0.0	0.0, 4.3	-0.27 (2.01)	0.0	-5.3, 4.3	0.6074
WEEK 36	16	0.35 (1.33)	0.11 (0.45)	0.0	0.0, 1.8	-0.24 (1.43)	0.0	-5.3, 1.8	0.5166
Low Dose	8	0.04 (0.10)	0.00 (0.00)	0.0	0.0, 0.0	-0.04 (0.10)	0.0	-0.3, 0.0	0.3506
High Dose	8	0.67 (1.89)	0.23 (0.64)	0.0	0.0, 1.8	-0.44 (2.08)	0.0	-5.3, 1.8	0.5669

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
PD duration (time since diagnosis) category:>=10 years (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia (Cont.)									
WEEK 48	20	0.28 (0.75)	0.21 (0.61)	0.0	0.0, 2.3	-0.07 (0.90)	0.0	-3.0, 2.3	0.7176
Low Dose	8	0.04 (0.10)	0.00 (0.00)	0.0	0.0, 0.0	-0.04 (0.10)	0.0	-0.3, 0.0	0.3506
High Dose	12	0.45 (0.94)	0.35 (0.77)	0.0	0.0, 2.3	-0.10 (1.17)	0.0	-3.0, 2.3	0.7762
WEEK 60	9	0.17 (0.52)	0.08 (0.24)	0.0	0.0, 0.7	-0.09 (0.60)	0.0	-1.5, 0.7	0.6588
Low Dose	2	0.00 (0.00)	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
High Dose	7	0.22 (0.59)	0.10 (0.27)	0.0	0.0, 0.7	-0.12 (0.69)	0.0	-1.5, 0.7	0.6672
WEEK 72	2	0.00 (0.00)	2.48 (3.51)	2.5	0.0, 5.0	2.48 (3.51)	2.5	0.0, 5.0	0.5000
Low Dose	0								
High Dose	2	0.00 (0.00)	2.48 (3.51)	2.5	0.0, 5.0	2.48 (3.51)	2.5	0.0, 5.0	0.5000
WEEK 84	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	0								
High Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
PD duration (time since diagnosis) category:>=10 years (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia									
BASELINE	41		13.63 (2.59)	14.6	7.9, 16.0				
Low Dose	20		13.61 (2.38)	13.7	9.3, 16.0				
High Dose	21		13.65 (2.83)	15.2	7.9, 16.0				
WEEK 12	28	13.26 (2.83)	12.52 (3.13)	13.0	5.0, 16.0	-0.74 (3.01)	-0.6	-11.0, 5.3	0.2026
Low Dose	16	13.57 (2.59)	12.55 (3.34)	13.4	5.0, 16.0	-1.02 (3.15)	-0.6	-11.0, 4.2	0.2147
High Dose	12	12.86 (3.21)	12.49 (2.97)	12.1	8.0, 16.0	-0.37 (2.91)	-0.4	-4.2, 5.3	0.6653
WEEK 24	30	13.76 (2.40)	12.34 (4.12)	13.6	0.0, 16.0	-1.42 (3.27)	-0.2	-13.3, 3.3	0.0243*
Low Dose	15	13.59 (2.33)	11.53 (5.12)	13.5	0.0, 16.0	-2.06 (3.99)	-0.2	-13.3, 2.3	0.0651
High Dose	15	13.94 (2.54)	13.16 (2.73)	13.7	8.3, 16.0	-0.77 (2.30)	-0.9	-5.2, 3.3	0.2141
WEEK 36	16	13.97 (2.66)	13.68 (3.00)	14.3	3.9, 16.0	-0.29 (2.83)	0.0	-5.6, 5.5	0.6877
Low Dose	8	13.53 (2.85)	13.36 (4.04)	14.4	3.9, 16.0	-0.17 (3.01)	0.0	-5.6, 5.5	0.8752
High Dose	8	14.41 (2.57)	14.01 (1.65)	14.3	11.9, 16.0	-0.41 (2.84)	-0.6	-3.9, 4.3	0.6975

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
PD duration (time since diagnosis) category:>=10 years (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia (Cont.)									
WEEK 48	20	14.28 (2.21)	12.91 (3.33)	14.4	5.9, 16.0	-1.36 (2.60)	-0.5	-7.4, 1.9	0.0299*
Low Dose	8	14.16 (2.21)	12.95 (4.18)	15.1	5.9, 16.0	-1.21 (2.93)	0.0	-7.4, 1.7	0.2828
High Dose	12	14.36 (2.30)	12.89 (2.83)	13.7	7.4, 16.0	-1.47 (2.48)	-0.6	-6.1, 1.9	0.0650
WEEK 60	9	13.68 (2.49)	12.57 (2.97)	13.0	5.6, 16.0	-1.11 (1.84)	-0.7	-3.9, 1.3	0.1077
Low Dose	2	11.42 (2.71)	9.81 (5.93)	9.8	5.6, 14.0	-1.61 (3.22)	-1.6	-3.9, 0.7	0.6082
High Dose	7	14.32 (2.20)	13.36 (1.62)	13.0	11.2, 16.0	-0.97 (1.64)	-0.7	-3.9, 1.3	0.1686
WEEK 72	2	12.94 (4.33)	5.60 (0.01)	5.6	5.6, 5.6	-7.34 (4.35)	-7.3	-10.4, -4.3	0.2525
Low Dose	0								
High Dose	2	12.94 (4.33)	5.60 (0.01)	5.6	5.6, 5.6	-7.34 (4.35)	-7.3	-10.4, -4.3	0.2525
WEEK 84	1	9.87 (N/A)	4.57 (N/A)	4.6	4.6, 4.6	-5.30 (N/A)	-5.3	-5.3, -5.3	
Low Dose	0								
High Dose	1	9.87 (N/A)	4.57 (N/A)	4.6	4.6, 4.6	-5.30 (N/A)	-5.3	-5.3, -5.3	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

表21　パーキンソン病日誌に基づく，早朝覚醒時状態の分布（FAS）：M15-737試験

[redacted]20[redacted] 10:46 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.2__1.4

Distribution of Early Morning First Non-Sleep Symptom in PD Diary
(FAS)

	N	Off n (%)	On without Dyskinesia n (%)	On with Non-Troublesome Dyskinesia n (%)	On with Troublesome Dyskinesia n (%)	Total n (%)
BASELINE	97	19 (31.1)	38 (62.3)	3 (4.9)	1 (1.6)	61 (100)
Low Dose	45	14 (46.7)	14 (46.7)	1 (3.3)	1 (3.3)	30 (100)
High Dose	52	5 (16.1)	24 (77.4)	2 (6.5)	0	31 (100)
WEEK 12	78	19 (32.8)	33 (56.9)	4 (6.9)	2 (3.4)	58 (100)
Low Dose	40	11 (36.7)	16 (53.3)	1 (3.3)	2 (6.7)	30 (100)
High Dose	38	8 (28.6)	17 (60.7)	3 (10.7)	0	28 (100)
WEEK 24	81	15 (26.8)	39 (69.6)	2 (3.6)	0	56 (100)
Low Dose	37	8 (30.8)	17 (65.4)	1 (3.8)	0	26 (100)
High Dose	44	7 (23.3)	22 (73.3)	1 (3.3)	0	30 (100)
WEEK 36	43	4 (14.3)	21 (75.0)	2 (7.1)	1 (3.6)	28 (100)
Low Dose	23	2 (15.4)	11 (84.6)	0	0	13 (100)
High Dose	20	2 (13.3)	10 (66.7)	2 (13.3)	1 (6.7)	15 (100)
WEEK 48	57	8 (20.0)	29 (72.5)	3 (7.5)	0	40 (100)
Low Dose	24	2 (12.5)	12 (75.0)	2 (12.5)	0	16 (100)
High Dose	33	6 (25.0)	17 (70.8)	1 (4.2)	0	24 (100)
WEEK 60	32	1 (5.0)	19 (95.0)	0	0	20 (100)
Low Dose	16	1 (9.1)	10 (90.9)	0	0	11 (100)
High Dose	16	0	9 (100)	0	0	9 (100)
WEEK 72	14	3 (27.3)	7 (63.6)	1 (9.1)	0	11 (100)
Low Dose	6	0	5 (100)	0	0	5 (100)
High Dose	8	3 (50.0)	2 (33.3)	1 (16.7)	0	6 (100)
WEEK 84	2	1 (50.0)	1 (50.0)	0	0	2 (100)
Low Dose	1	0	1 (100)	0	0	1 (100)
High Dose	1	1 (100)	0	0	0	1 (100)

Program Source Code: [redacted]

TABLE 14.2 1.4

Distribution of Early Morning First Non-Sleep Symptom in PD Diary
(FAS)

	N	Off n (%)	On without Dyskinesia n (%)	On with Non-Troublesome Dyskinesia n (%)	On with Troublesome Dyskinesia n (%)	Total n (%)
WEEK 96	1	0	1 (100)	0	0	1 (100)
Low Dose	1	0	1 (100)	0	0	1 (100)
High Dose	0	0	0	0	0	0

Program Source Code: [redacted]

表22　パーキンソン病日誌に基づく，早朝覚醒時状態の分布（FAS，日本人部分集団）：M15-737試験

[redacted]20[redacted] 10:45 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.2__1.4.J

Distribution of Early Morning First Non-Sleep Symptom in PD Diary
(FAS - Japan Subjects)

	N	Off n (%)	On without Dyskinesia n (%)	On with Non-Troublesome Dyskinesia n (%)	On with Troublesome Dyskinesia n (%)	Total n (%)
BASELINE	11	6 (75.0)	2 (25.0)	0	0	8 (100)
Low Dose	7	4 (80.0)	1 (20.0)	0	0	5 (100)
High Dose	4	2 (66.7)	1 (33.3)	0	0	3 (100)
WEEK 12	11	5 (62.5)	3 (37.5)	0	0	8 (100)
Low Dose	7	3 (60.0)	2 (40.0)	0	0	5 (100)
High Dose	4	2 (66.7)	1 (33.3)	0	0	3 (100)
WEEK 24	9	4 (57.1)	3 (42.9)	0	0	7 (100)
Low Dose	6	2 (50.0)	2 (50.0)	0	0	4 (100)
High Dose	3	2 (66.7)	1 (33.3)	0	0	3 (100)
WEEK 36	5	1 (33.3)	2 (66.7)	0	0	3 (100)
Low Dose	2	1 (100)	0	0	0	1 (100)
High Dose	3	0	2 (100)	0	0	2 (100)
WEEK 48	4	0	1 (100)	0	0	1 (100)
Low Dose	1	0	0	0	0	0
High Dose	3	0	1 (100)	0	0	1 (100)
WEEK 60	3	0	1 (100)	0	0	1 (100)
Low Dose	1	0	0	0	0	0
High Dose	2	0	1 (100)	0	0	1 (100)
WEEK 72	2	1 (100)	0	0	0	1 (100)
Low Dose	0	0	0	0	0	0
High Dose	2	1 (100)	0	0	0	1 (100)
WEEK 84	1	1 (100)	0	0	0	1 (100)
Low Dose	0	0	0	0	0	0
High Dose	1	1 (100)	0	0	0	1 (100)

Program Source Code: [redacted]

表23　MDS-UPDRSスコア（FAS）：M15-737試験

[redacted]20[redacted] 10:45 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.2__2.1

Change from Baseline to Each Planned Visit in Parkinson's Disease Symptoms as Assessed
by The Movement Disorder Society-Unified Parkinson's Disease Rating Scale Score by Part and Total
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MDS-UPDRS Part I Score									
BASELINE	106		10.7 (5.93)	10.5	0, 27				
Low dose	48		10.4 (5.75)	10.0	0, 27				
High dose	58		10.9 (6.12)	11.0	2, 25				
WEEK 24	83	10.7 (5.98)	11.1 (6.41)	11.0	0, 27	0.4 (4.36)	1.0	-11, 12	0.4523
Low dose	36	11.0 (6.08)	11.4 (6.99)	12.0	0, 27	0.4 (4.50)	1.0	-8, 10	0.6331
High dose	47	10.5 (5.95)	10.9 (6.00)	10.0	1, 23	0.4 (4.30)	0.0	-11, 12	0.5670
WEEK 48	64	10.4 (6.09)	10.6 (5.62)	10.0	1, 28	0.2 (5.18)	0.5	-15, 13	0.7730
Low dose	26	11.0 (6.05)	10.0 (5.44)	8.5	3, 23	-1.0 (4.63)	0.0	-11, 8	0.2632
High dose	38	10.0 (6.17)	11.1 (5.77)	11.0	1, 28	1.0 (5.43)	1.0	-15, 13	0.2510
WEEK 72	12	10.5 (7.10)	12.2 (6.86)	11.0	3, 23	1.7 (3.77)	1.0	-5, 9	0.1543
Low dose	5	10.0 (7.58)	10.0 (7.52)	8.0	4, 23	0.0 (3.24)	0.0	-5, 4	>0.999
High dose	7	10.9 (7.34)	13.7 (6.47)	13.0	3, 22	2.9 (3.89)	1.0	-2, 9	0.1001
MDS-UPDRS Part II Score									
BASELINE	106		11.8 (7.04)	11.0	0, 29				
Low dose	48		11.4 (7.56)	10.0	0, 28				
High dose	58		12.1 (6.64)	12.0	1, 29				
WEEK 24	83	11.6 (7.12)	12.4 (7.85)	11.0	0, 38	0.9 (4.16)	0.0	-9, 15	0.0649
Low dose	36	11.5 (8.02)	12.1 (8.34)	10.5	0, 32	0.6 (4.45)	1.0	-9, 11	0.4154
High dose	47	11.6 (6.45)	12.6 (7.54)	12.0	2, 38	1.0 (3.97)	0.0	-7, 15	0.0785

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 2.1

Change from Baseline to Each Planned Visit in Parkinson's Disease Symptoms as Assessed by The Movement Disorder Society-Unified Parkinson's Disease Rating Scale Score by Part and Total (FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MDS-UPDRS Part II Score									
WEEK 48	64	10.9 (6.91)	12.7 (7.04)	13.0	0, 34	1.8 (5.53)	1.5	-13, 21	0.0123*
Low dose	26	11.1 (9.04)	11.3 (7.28)	10.0	1, 29	0.3 (5.45)	1.5	-13, 9	0.8033
High dose	38	10.8 (5.12)	13.6 (6.82)	13.0	0, 34	2.8 (5.41)	1.5	-5, 21	0.0028**
WEEK 72	12	10.3 (6.65)	15.1 (9.37)	14.5	3, 31	4.8 (6.12)	2.5	0, 20	0.0211*
Low dose	5	6.8 (4.44)	11.2 (8.53)	11.0	3, 24	4.4 (8.73)	1.0	0, 20	0.3230
High dose	7	12.9 (7.08)	17.9 (9.53)	18.0	4, 31	5.0 (4.20)	3.0	1, 11	0.0199*
MDS-UPDRS Part III Score									
BASELINE	106		23.6 (13.76)	22.0	1, 62				
Low dose	48		22.1 (13.51)	21.0	1, 58				
High dose	58		24.8 (13.97)	23.0	2, 62				
WEEK 24	79	22.7 (13.58)	24.3 (15.90)	24.0	0, 92	1.6 (9.23)	1.0	-21, 40	0.1333
Low dose	35	19.5 (11.73)	24.2 (15.37)	25.0	0, 65	4.7 (7.71)	3.0	-6, 26	0.0011**
High dose	44	25.2 (14.53)	24.3 (16.48)	23.5	0, 92	-0.9 (9.69)	-1.5	-21, 40	0.5516
WEEK 48	56	22.5 (13.68)	22.9 (13.27)	23.0	0, 59	0.4 (7.96)	0.0	-17, 16	0.7259
Low dose	22	21.5 (14.78)	24.1 (15.17)	25.0	0, 59	2.7 (9.20)	3.0	-17, 16	0.1862
High dose	34	23.2 (13.11)	22.1 (12.05)	23.0	2, 45	-1.1 (6.78)	-0.5	-16, 13	0.3435
WEEK 72	12	21.1 (18.60)	24.5 (17.10)	24.0	1, 55	3.4 (11.73)	2.1	-18, 30	0.3334
Low dose	5	15.8 (12.44)	25.0 (16.55)	23.0	1, 45	9.2 (13.33)	2.0	-2, 30	0.1976
High dose	7	24.9 (22.17)	24.2 (18.79)	25.0	4, 55	-0.7 (9.29)	2.1	-18, 8	0.8494

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 2.1

Change from Baseline to Each Planned Visit in Parkinson's Disease Symptoms as Assessed by The Movement Disorder Society-Unified Parkinson's Disease Rating Scale Score by Part and Total (FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MDS-UPDRS Part IV Score									
BASELINE	106		5.4 (4.04)	5.0	0, 21				
Low dose	48		5.2 (3.74)	5.0	0, 16				
High dose	58		5.6 (4.28)	5.0	0, 21				
WEEK 24	83	5.0 (3.74)	5.8 (4.09)	6.0	0, 18	0.8 (3.16)	0.0	-10, 14	0.0189*
Low dose	36	4.8 (4.02)	5.4 (3.98)	5.5	0, 14	0.6 (2.44)	0.0	-3, 10	0.1420
High dose	47	5.1 (3.54)	6.1 (4.19)	6.0	0, 18	1.0 (3.64)	0.0	-10, 14	0.0657
WEEK 48	63	4.6 (3.50)	5.4 (4.18)	5.0	0, 15	0.8 (3.34)	0.0	-11, 10	0.0641
Low dose	25	4.2 (3.54)	5.0 (4.58)	5.0	0, 15	0.8 (3.33)	0.0	-5, 10	0.2654
High dose	38	4.8 (3.50)	5.6 (3.94)	6.5	0, 14	0.8 (3.39)	1.0	-11, 7	0.1467
WEEK 72	12	4.0 (2.56)	5.7 (3.42)	6.0	0, 10	1.7 (2.90)	2.0	-5, 7	0.0721
Low dose	5	3.4 (3.44)	5.8 (4.15)	8.0	0, 10	2.4 (2.70)	2.0	0, 7	0.1180
High dose	7	4.4 (1.90)	5.6 (3.15)	6.0	0, 10	1.1 (3.13)	2.0	-5, 5	0.3716
MDS-UPDRS Total Score of Parts I-III									
BASELINE	106		46.1 (21.59)	45.0	6, 105				
Low dose	48		44.0 (21.55)	39.0	8, 94				
High dose	58		47.9 (21.65)	47.0	6, 105				
WEEK 24	79	44.9 (22.09)	47.6 (26.02)	46.0	1, 148	2.7 (13.05)	2.0	-24, 64	0.0687
Low dose	35	41.7 (21.73)	47.4 (25.83)	49.0	1, 114	5.7 (11.38)	6.0	-12, 39	0.0053**
High dose	44	47.5 (22.28)	47.8 (26.46)	46.0	7, 148	0.3 (13.90)	0.0	-24, 64	0.8840

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 2.1

Change from Baseline to Each Planned Visit in Parkinson's Disease Symptoms as Assessed
by The Movement Disorder Society-Unified Parkinson's Disease Rating Scale Score by Part and Total
(FAS)

Parameter Time Point Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
MDS-UPDRS Total Score of Parts I-III									
WEEK 48	57	43.6 (22.85)	46.5 (21.31)	43.0	11, 95	2.9 (15.27)	2.0	-29, 64	0.1558
Low dose	22	43.7 (26.15)	45.5 (23.17)	41.5	11, 88	1.7 (13.64)	2.5	-29, 22	0.5588
High dose	35	43.5 (20.91)	47.1 (20.39)	47.0	13, 95	3.7 (16.36)	2.0	-23, 64	0.1953
WEEK 72	12	41.9 (27.68)	51.8 (27.88)	57.0	11, 95	9.8 (17.28)	7.1	-15, 54	0.0740
Low dose	5	32.6 (22.28)	46.2 (26.61)	54.0	11, 78	13.6 (23.69)	4.0	-3, 54	0.2686
High dose	7	48.6 (30.82)	55.7 (30.14)	66.0	11, 95	7.2 (12.38)	9.0	-15, 24	0.1764

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

表24　MDS-UPDRSスコア（FAS，日本人部分集団）：M15-737試験

[redacted]20[redacted] 10:46 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.2__2.1.J

Change from Baseline to Each Planned Visit in Parkinson's Disease Symptoms as Assessed
by The Movement Disorder Society-Unified Parkinson's Disease Rating Scale Score by Part and Total
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MDS-UPDRS Part I Score									
BASELINE	11		7.1 (3.86)	6.0	0, 14				
Low dose	7		7.3 (4.50)	6.0	0, 14				
High dose	4		6.8 (2.99)	7.0	3, 10				
WEEK 24	7	7.6 (3.55)	9.4 (5.44)	7.0	5, 21	1.9 (3.34)	2.0	-4, 7	0.1914
Low dose	4	9.0 (3.83)	11.0 (6.88)	8.5	6, 21	2.0 (4.69)	2.5	-4, 7	0.4564
High dose	3	5.7 (2.52)	7.3 (2.52)	7.0	5, 10	1.7 (0.58)	2.0	1, 2	0.0377*
WEEK 48	4	5.8 (2.06)	7.3 (2.75)	7.5	4, 10	1.5 (1.29)	1.5	0, 3	0.1027
Low dose	1	6.0 (N/A)	6.0 (N/A)	6.0	6, 6	0.0 (N/A)	0.0	0, 0	
High dose	3	5.7 (2.52)	7.7 (3.21)	9.0	4, 10	2.0 (1.00)	2.0	1, 3	0.0742
WEEK 72	2	5.5 (3.54)	11.0 (2.83)	11.0	9, 13	5.5 (0.71)	5.5	5, 6	0.0577
Low dose	0								
High dose	2	5.5 (3.54)	11.0 (2.83)	11.0	9, 13	5.5 (0.71)	5.5	5, 6	0.0577
MDS-UPDRS Part II Score									
BASELINE	11		11.6 (7.20)	10.0	0, 22				
Low dose	7		11.0 (8.04)	10.0	0, 22				
High dose	4		12.8 (6.40)	12.5	6, 20				
WEEK 24	7	11.3 (5.94)	14.3 (8.71)	11.0	5, 32	3.0 (3.79)	2.0	-1, 10	0.0809
Low dose	4	12.0 (7.16)	16.5 (10.41)	12.0	10, 32	4.5 (4.43)	4.0	0, 10	0.1354
High dose	3	10.3 (5.13)	11.3 (6.51)	11.0	5, 18	1.0 (1.73)	2.0	-1, 2	0.4226

&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 2.1.J

Change from Baseline to Each Planned Visit in Parkinson's Disease Symptoms as Assessed
by The Movement Disorder Society-Unified Parkinson's Disease Rating Scale Score by Part and Total
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MDS-UPDRS Part II Score									
WEEK 48	4	9.0 (4.97)	11.5 (6.14)	11.5	4, 19	2.5 (3.70)	2.5	-2, 7	0.2691
Low dose	1	5.0 (N/A)	12.0 (N/A)	12.0	12, 12	7.0 (N/A)	7.0	7, 7	
High dose	3	10.3 (5.13)	11.3 (7.51)	11.0	4, 19	1.0 (2.65)	2.0	-2, 3	0.5799
WEEK 72	2	11.0 (7.07)	18.0 (12.73)	18.0	9, 27	7.0 (5.66)	7.0	3, 11	0.3305
Low dose	0								
High dose	2	11.0 (7.07)	18.0 (12.73)	18.0	9, 27	7.0 (5.66)	7.0	3, 11	0.3305
MDS-UPDRS Part III Score									
BASELINE	11		21.4 (14.65)	26.0	1, 47				
Low dose	7		19.3 (13.72)	26.0	1, 34				
High dose	4		25.0 (17.64)	23.5	6, 47				
WEEK 24	7	22.4 (15.94)	26.4 (18.60)	30.0	6, 52	4.0 (8.31)	2.0	-3, 22	0.2498
Low dose	4	18.5 (13.30)	26.3 (21.11)	22.5	8, 52	7.8 (9.60)	3.5	2, 22	0.2050
High dose	3	27.7 (20.60)	26.7 (19.22)	30.0	6, 44	-1.0 (1.73)	0.0	-3, 0	0.4226
WEEK 48	4	22.3 (20.01)	22.3 (18.71)	19.5	5, 45	0.0 (2.16)	-0.5	-2, 3	>0.999
Low dose	1	6.0 (N/A)	9.0 (N/A)	9.0	9, 9	3.0 (N/A)	3.0	3, 3	
High dose	3	27.7 (20.60)	26.7 (20.21)	30.0	5, 45	-1.0 (1.00)	-1.0	-2, 0	0.2254
WEEK 72	2	26.5 (28.99)	30.5 (34.65)	30.5	6, 55	4.0 (5.66)	4.0	0, 8	0.5000
Low dose	0								
High dose	2	26.5 (28.99)	30.5 (34.65)	30.5	6, 55	4.0 (5.66)	4.0	0, 8	0.5000

&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 2.1.J

Change from Baseline to Each Planned Visit in Parkinson's Disease Symptoms as Assessed
by The Movement Disorder Society-Unified Parkinson's Disease Rating Scale Score by Part and Total
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MDS-UPDRS Part IV Score									
BASELINE	11		6.1 (2.43)	6.0	2, 10				
Low dose	7		6.1 (1.77)	6.0	3, 8				
High dose	4		6.0 (3.65)	6.0	2, 10				
WEEK 24	7	5.6 (2.57)	6.1 (3.08)	6.0	2, 11	0.6 (1.13)	0.0	0, 3	0.2308
Low dose	4	6.3 (2.36)	7.3 (2.99)	7.0	4, 11	1.0 (1.41)	0.5	0, 3	0.2522
High dose	3	4.7 (3.06)	4.7 (3.06)	4.0	2, 8	0.0 (0.00)	0.0	0, 0	
WEEK 48	4	5.5 (3.00)	6.0 (2.94)	6.0	3, 9	0.5 (0.58)	0.5	0, 1	0.1817
Low dose	1	8.0 (N/A)	8.0 (N/A)	8.0	8, 8	0.0 (N/A)	0.0	0, 0	
High dose	3	4.7 (3.06)	5.3 (3.21)	4.0	3, 9	0.7 (0.58)	1.0	0, 1	0.1835
WEEK 72	2	6.0 (2.83)	7.0 (1.41)	7.0	6, 8	1.0 (1.41)	1.0	0, 2	0.5000
Low dose	0								
High dose	2	6.0 (2.83)	7.0 (1.41)	7.0	6, 8	1.0 (1.41)	1.0	0, 2	0.5000
MDS-UPDRS Total Score of Parts I-III									
BASELINE	11		40.1 (18.71)	45.0	15, 71				
Low dose	7		37.6 (17.31)	32.0	17, 66				
High dose	4		44.5 (22.94)	46.0	15, 71				
WEEK 24	7	41.3 (22.84)	50.1 (30.37)	48.0	16, 105	8.9 (13.72)	3.0	1, 39	0.1384
Low dose	4	39.5 (22.58)	53.8 (35.75)	42.0	26, 105	14.3 (16.88)	8.5	1, 39	0.1899
High dose	3	43.7 (28.02)	45.3 (28.10)	48.0	16, 72	1.7 (1.15)	1.0	1, 3	0.1296

&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 2.1.J

Change from Baseline to Each Planned Visit in Parkinson's Disease Symptoms as Assessed
by The Movement Disorder Society-Unified Parkinson's Disease Rating Scale Score by Part and Total
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MDS-UPDRS Total Score of Parts I-III									
WEEK 48	4	37.0 (26.48)	41.0 (26.77)	38.5	13, 74	4.0 (4.97)	4.0	-2, 10	0.2056
Low dose	1	17.0 (N/A)	27.0 (N/A)	27.0	27, 27	10.0 (N/A)	10.0	10, 10	
High dose	3	43.7 (28.02)	45.7 (30.73)	50.0	13, 74	2.0 (3.61)	3.0	-2, 5	0.4380
WEEK 72	2	43.0 (39.60)	59.5 (50.20)	59.5	24, 95	16.5 (10.61)	16.5	9, 24	0.2716
Low dose	0								
High dose	2	43.0 (39.60)	59.5 (50.20)	59.5	24, 95	16.5 (10.61)	16.5	9, 24	0.2716

&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

表25　MDS-UPDRSスコア（Hoehn-Yahr 重症度分類，FAS）：M15-737試験

[redacted]20[redacted] 10:45 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.2__2.2

Change from Baseline to Each Planned Visit in Parkinson's Disease Symptoms as Assessed by
The Movement Disorder Society-Unified Parkinson's Disease Rating Scale Score Hoehn and Yahr Stage
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MDS-UPDRS Hoehn and Yahr Stage									
BASELINE	106		2.0 (0.56)	2.0	0, 4				
Low dose	48		2.0 (0.48)	2.0	0, 3				
High dose	58		2.1 (0.62)	2.0	0, 4				
WEEK 24	80	2.0 (0.55)	2.0 (0.83)	2.0	0, 5	0.0 (0.66)	0.0	-2, 2	0.7339
Low dose	35	1.9 (0.48)	2.1 (0.81)	2.0	0, 4	0.2 (0.63)	0.0	-1, 2	0.0700
High dose	45	2.0 (0.60)	1.9 (0.83)	2.0	0, 5	-0.1 (0.65)	0.0	-2, 2	0.2559
WEEK 48	58	1.9 (0.54)	2.1 (0.58)	2.0	0, 4	0.2 (0.45)	0.0	-1, 2	0.0113*
Low dose	23	2.0 (0.56)	2.1 (0.60)	2.0	0, 3	0.1 (0.34)	0.0	0, 1	0.0829
High dose	35	1.9 (0.54)	2.1 (0.58)	2.0	0, 4	0.2 (0.51)	0.0	-1, 2	0.0565
WEEK 72	12	1.8 (1.03)	2.2 (1.03)	2.0	0, 4	0.3 (0.65)	0.0	-1, 1	0.1039
Low dose	5	1.6 (0.89)	2.0 (1.22)	2.0	0, 3	0.4 (0.55)	0.0	0, 1	0.1778
High dose	7	2.0 (1.15)	2.3 (0.95)	2.0	1, 4	0.3 (0.76)	0.0	-1, 1	0.3559

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

表26　MDS-UPDRSスコア（Hoehn-Yahr 重症度分類，FAS，日本人部分集団）：M15-737試験

[redacted]20[redacted] 10:46 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 1

TABLE 14.2__2.2.J

Change from Baseline to Each Planned Visit in Parkinson's Disease Symptoms as Assessed by
The Movement Disorder Society-Unified Parkinson's Disease Rating Scale Score Hoehn and Yahr Stage
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
MDS-UPDRS Hoehn and Yahr Stage									
BASELINE	11		2.3 (0.47)	2.0	2, 3				
Low dose	7		2.3 (0.49)	2.0	2, 3				
High dose	4		2.3 (0.50)	2.0	2, 3				
WEEK 24	7	2.3 (0.49)	2.4 (0.79)	2.0	2, 4	0.1 (0.38)	0.0	0, 1	0.3559
Low dose	4	2.3 (0.50)	2.5 (1.00)	2.0	2, 4	0.3 (0.50)	0.0	0, 1	0.3910
High dose	3	2.3 (0.58)	2.3 (0.58)	2.0	2, 3	0.0 (0.00)	0.0	0, 0	
WEEK 48	4	2.3 (0.50)	2.3 (0.50)	2.0	2, 3	0.0 (0.00)	0.0	0, 0	
Low dose	1	2.0 (N/A)	2.0 (N/A)	2.0	2, 2	0.0 (N/A)	0.0	0, 0	
High dose	3	2.3 (0.58)	2.3 (0.58)	2.0	2, 3	0.0 (0.00)	0.0	0, 0	
WEEK 72	2	2.5 (0.71)	3.0 (1.41)	3.0	2, 4	0.5 (0.71)	0.5	0, 1	0.5000
Low dose	0								
High dose	2	2.5 (0.71)	3.0 (1.41)	3.0	2, 4	0.5 (0.71)	0.5	0, 1	0.5000

&: P-value is obtained from two-sided paired-sample t-test.

Program Source Code: [redacted]

表27　PDQ-39スコア（FAS）：M15-737試験

[redacted]20[redacted] 10:45 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.2__3

Change from Baseline to Each Planned Visit in Quality of Life as Assessed
by The PD Questionnaire-39 Items
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PDQ-Bodily Discomfort Domain Score									
BASELINE	106		28.9 (22.66)	25.0	0.0, 91.7				
Low dose	48		28.3 (21.79)	25.0	0.0, 75.0				
High dose	58		29.3 (23.53)	25.0	0.0, 91.7				
WEEK 24	83	28.8 (23.07)	30.9 (24.26)	25.0	0.0, 91.7	2.1 (17.36)	0.0	-41.7, 41.7	0.2716
Low dose	36	28.7 (22.66)	29.6 (24.43)	25.0	0.0, 83.3	0.9 (20.10)	0.0	-41.7, 41.7	0.7838
High dose	47	28.9 (23.62)	31.9 (24.35)	25.0	0.0, 91.7	3.0 (15.09)	0.0	-41.7, 41.7	0.1775
WEEK 48	64	28.6 (23.70)	31.9 (22.30)	25.0	0.0, 83.3	3.3 (18.88)	0.0	-41.7, 41.7	0.1726
Low dose	26	28.2 (22.74)	30.1 (19.01)	33.3	0.0, 66.7	1.9 (21.77)	0.0	-41.7, 41.7	0.6563
High dose	38	28.9 (24.64)	33.1 (24.47)	25.0	0.0, 83.3	4.2 (16.86)	4.2	-25.0, 41.7	0.1362
WEEK 72	12	30.6 (31.65)	39.6 (21.94)	37.5	8.3, 75.0	9.0 (20.86)	4.2	-16.7, 50.0	0.1619
Low dose	5	11.7 (12.64)	33.3 (13.18)	33.3	16.7, 50.0	21.7 (24.72)	33.3	-8.3, 50.0	0.1216
High dose	7	44.0 (34.93)	44.0 (26.66)	41.7	8.3, 75.0	0.0 (12.73)	0.0	-16.7, 16.7	>0.999
PDQ-Communication Domain Score									
BASELINE	106		26.9 (22.13)	25.0	0.0, 83.3				
Low dose	48		21.7 (21.18)	16.7	0.0, 75.0				
High dose	58		31.2 (22.16)	25.0	0.0, 83.3				
WEEK 24	83	26.4 (21.96)	25.3 (23.08)	16.7	0.0, 83.3	-1.1 (17.93)	0.0	-41.7, 50.0	0.5762
Low dose	36	22.9 (22.66)	19.7 (19.84)	12.5	0.0, 66.7	-3.2 (13.70)	0.0	-41.7, 33.3	0.1646
High dose	47	29.1 (21.27)	29.6 (24.62)	16.7	0.0, 83.3	0.5 (20.59)	0.0	-41.7, 50.0	0.8602

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 3

Change from Baseline to Each Planned Visit in Quality of Life as Assessed
by The PD Questionnaire-39 Items
(FAS)

Parameter Time Point Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
PDQ-Communication Domain Score									
WEEK 48	64	26.7 (21.11)	31.1 (25.73)	25.0	0.0, 100.0	4.4 (18.24)	0.0	-33.3, 58.3	0.0567
Low dose	26	22.4 (20.38)	23.1 (22.77)	12.5	0.0, 66.7	0.6 (12.46)	0.0	-25.0, 33.3	0.7951
High dose	38	29.6 (21.37)	36.6 (26.46)	37.5	0.0, 100.0	7.0 (21.09)	0.0	-33.3, 58.3	0.0474*
WEEK 72	12	27.1 (26.38)	31.9 (28.83)	25.0	0.0, 100.0	4.9 (12.03)	0.0	-8.3, 33.3	0.1891
Low dose	5	15.0 (14.91)	25.0 (18.63)	25.0	0.0, 50.0	10.0 (14.91)	0.0	0.0, 33.3	0.2080
High dose	7	35.7 (30.32)	36.9 (34.98)	25.0	0.0, 100.0	1.2 (8.91)	0.0	-8.3, 16.7	0.7358
PDQ-Social Support Domain Score									
BASELINE	94		14.3 (20.25)	4.2	0.0, 91.7				
Low dose	40		14.2 (20.52)	0.0	0.0, 75.0				
High dose	54		14.4 (20.25)	8.3	0.0, 91.7				
WEEK 24	72	12.4 (18.50)	13.4 (18.43)	8.3	0.0, 75.0	1.0 (18.66)	0.0	-58.3, 50.0	0.6371
Low dose	29	12.9 (20.24)	13.8 (18.93)	0.0	0.0, 58.3	0.9 (16.87)	0.0	-41.7, 50.0	0.7851
High dose	43	12.0 (17.47)	13.2 (18.30)	8.3	0.0, 75.0	1.2 (19.97)	0.0	-58.3, 50.0	0.7045
WEEK 48	58	13.5 (19.86)	12.4 (16.97)	8.3	0.0, 75.0	-1.1 (11.83)	0.0	-41.7, 25.0	0.4624
Low dose	23	15.9 (22.74)	12.7 (21.60)	0.0	0.0, 75.0	-3.3 (7.84)	0.0	-16.7, 16.7	0.0586
High dose	35	11.9 (17.88)	12.1 (13.46)	8.3	0.0, 41.7	0.2 (13.78)	0.0	-41.7, 25.0	0.9192
WEEK 72	11	7.6 (10.18)	8.3 (9.86)	8.3	0.0, 25.0	0.8 (8.70)	0.0	-16.7, 16.7	0.7787
Low dose	4	4.2 (8.33)	4.2 (8.33)	0.0	0.0, 16.7	0.0 (13.61)	0.0	-16.7, 16.7	>0.999
High dose	7	9.5 (11.21)	10.7 (10.45)	8.3	0.0, 25.0	1.2 (5.75)	0.0	-8.3, 8.3	0.6036

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 3

Change from Baseline to Each Planned Visit in Quality of Life as Assessed
by The PD Questionnaire-39 Items
(FAS)

Parameter Time Point Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
PDQ-Cognition Domain Score									
BASELINE	106		25.1 (18.44)	25.0	0.0, 81.3				
Low dose	48		23.4 (18.12)	18.8	0.0, 62.5				
High dose	58		26.5 (18.74)	25.0	0.0, 81.3				
WEEK 24	83	25.2 (18.70)	26.9 (21.71)	25.0	0.0, 87.5	1.7 (17.74)	0.0	-43.8, 68.8	0.3764
Low dose	36	22.6 (18.80)	25.2 (17.20)	25.0	0.0, 56.3	2.6 (12.88)	6.3	-37.5, 18.8	0.2334
High dose	47	27.1 (18.58)	28.2 (24.72)	18.8	0.0, 87.5	1.1 (20.82)	0.0	-43.8, 68.8	0.7278
WEEK 48	64	25.2 (18.60)	26.0 (17.30)	25.0	0.0, 75.0	0.8 (15.85)	0.0	-31.3, 31.3	0.6946
Low dose	26	25.0 (19.20)	26.2 (15.41)	25.0	0.0, 62.5	1.2 (16.58)	0.0	-31.3, 31.3	0.7148
High dose	38	25.3 (18.43)	25.8 (18.68)	21.9	0.0, 75.0	0.5 (15.54)	0.0	-31.3, 31.3	0.8459
WEEK 72	12	26.6 (22.16)	32.8 (16.88)	31.3	12.5, 68.8	6.3 (11.31)	6.3	-12.5, 31.3	0.0819
Low dose	5	22.5 (22.36)	28.8 (15.69)	31.3	12.5, 43.8	6.3 (17.12)	6.3	-12.5, 31.3	0.4601
High dose	7	29.5 (23.31)	35.7 (18.30)	31.3	12.5, 68.8	6.3 (6.25)	6.3	0.0, 12.5	0.0382*
PDQ-Stigma Domain Score									
BASELINE	106		15.9 (19.97)	6.3	0.0, 75.0				
Low dose	48		17.8 (19.89)	12.5	0.0, 75.0				
High dose	58		14.2 (20.07)	6.3	0.0, 75.0				
WEEK 24	83	13.0 (17.49)	13.8 (17.83)	6.3	0.0, 100.0	0.8 (13.40)	0.0	-43.8, 43.8	0.6100
Low dose	36	16.7 (18.18)	14.4 (15.15)	9.4	0.0, 50.0	-2.3 (12.69)	0.0	-43.8, 25.0	0.2933
High dose	47	10.2 (16.61)	13.3 (19.79)	0.0	0.0, 100.0	3.1 (13.60)	0.0	-25.0, 43.8	0.1299

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 3

Change from Baseline to Each Planned Visit in Quality of Life as Assessed
by The PD Questionnaire-39 Items
(FAS)

Parameter Time Point Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
PDQ-Stigma Domain Score									
WEEK 48	64	13.6 (18.38)	13.7 (17.78)	6.3	0.0, 87.5	0.1 (19.37)	0.0	-50.0, 68.8	0.9680
Low dose	26	17.3 (20.56)	11.5 (12.95)	6.3	0.0, 43.8	-5.8 (19.60)	0.0	-50.0, 18.8	0.1459
High dose	38	11.0 (16.53)	15.1 (20.48)	6.3	0.0, 87.5	4.1 (18.40)	0.0	-31.3, 68.8	0.1765
WEEK 72	12	12.5 (22.46)	22.9 (25.47)	21.9	0.0, 68.8	10.4 (24.76)	0.0	-31.3, 68.8	0.1730
Low dose	5	6.3 (13.98)	20.0 (30.43)	0.0	0.0, 68.8	13.8 (37.86)	0.0	-31.3, 68.8	0.4623
High dose	7	17.0 (27.17)	25.0 (23.66)	25.0	0.0, 68.8	8.0 (12.35)	0.0	-6.3, 25.0	0.1360
PDQ-Activities of Daily Living Domain Score									
BASELINE	106		28.9 (21.09)	25.0	0.0, 87.5				
Low dose	48		28.8 (23.06)	22.9	0.0, 87.5				
High dose	58		29.0 (19.51)	25.0	0.0, 87.5				
WEEK 24	83	28.6 (22.35)	31.0 (23.51)	25.0	0.0, 100.0	2.4 (16.13)	0.0	-29.2, 62.5	0.1863
Low dose	36	28.2 (24.30)	30.4 (24.09)	22.9	0.0, 83.3	2.2 (14.86)	2.1	-29.2, 45.8	0.3805
High dose	47	28.9 (21.00)	31.4 (23.31)	29.2	0.0, 100.0	2.5 (17.19)	0.0	-29.2, 62.5	0.3275
WEEK 48	64	29.4 (23.38)	31.2 (22.68)	25.0	0.0, 100.0	1.8 (16.01)	2.1	-33.3, 50.0	0.3657
Low dose	26	30.4 (26.48)	29.5 (22.64)	25.0	0.0, 75.0	-1.0 (14.54)	0.0	-33.3, 29.2	0.7389
High dose	38	28.6 (21.34)	32.3 (22.93)	25.0	0.0, 100.0	3.7 (16.86)	4.2	-29.2, 50.0	0.1810
WEEK 72	12	28.1 (28.54)	39.9 (29.65)	37.5	8.3, 100.0	11.8 (20.32)	10.4	-25.0, 54.2	0.0693
Low dose	5	10.0 (7.57)	25.0 (25.69)	8.3	8.3, 66.7	15.0 (22.55)	8.3	0.0, 54.2	0.2112
High dose	7	41.1 (31.41)	50.6 (29.21)	41.7	8.3, 100.0	9.5 (20.09)	12.5	-25.0, 33.3	0.2563

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 3

Change from Baseline to Each Planned Visit in Quality of Life as Assessed
by The PD Questionnaire-39 Items
(FAS)

Parameter Time Point Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
PDQ-Emotional Well-being Domain Score									
BASELINE	106		26.4 (20.04)	25.0	0.0, 79.2				
Low dose	48		25.9 (19.73)	25.0	0.0, 75.0				
High dose	58		26.9 (20.46)	25.0	0.0, 79.2				
WEEK 24	83	25.0 (19.92)	27.3 (19.85)	25.0	0.0, 75.0	2.3 (16.31)	0.0	-37.5, 45.8	0.2007
Low dose	36	26.2 (20.50)	28.2 (21.98)	25.0	0.0, 70.8	2.1 (14.76)	0.0	-20.8, 33.3	0.4027
High dose	47	24.1 (19.64)	26.6 (18.26)	25.0	0.0, 75.0	2.5 (17.56)	4.2	-37.5, 45.8	0.3376
WEEK 48	64	24.8 (20.24)	28.7 (20.70)	25.0	0.0, 79.2	3.9 (14.28)	2.1	-37.5, 45.8	0.0323*
Low dose	26	24.8 (20.09)	27.2 (22.34)	20.8	0.0, 79.2	2.4 (11.50)	2.1	-16.7, 25.0	0.2966
High dose	38	24.8 (20.62)	29.7 (19.74)	25.0	0.0, 79.2	4.9 (15.97)	2.1	-37.5, 45.8	0.0647
WEEK 72	12	27.4 (25.71)	30.2 (25.20)	22.9	0.0, 83.3	2.8 (12.97)	2.1	-16.7, 25.0	0.4739
Low dose	5	12.5 (16.40)	20.8 (24.47)	12.5	0.0, 62.5	8.3 (13.18)	8.3	-8.3, 25.0	0.2302
High dose	7	38.1 (26.73)	36.9 (25.28)	33.3	8.3, 83.3	-1.2 (12.20)	-4.2	-16.7, 20.8	0.8049
PDQ-Mobility Domain Score									
BASELINE	106		31.0 (24.09)	25.0	0.0, 100.0				
Low dose	48		31.3 (26.06)	25.0	0.0, 92.5				
High dose	58		30.7 (22.57)	27.5	0.0, 100.0				
WEEK 24	83	31.5 (24.94)	36.1 (27.09)	32.5	0.0, 100.0	4.6 (19.85)	0.0	-32.5, 70.0	0.0387*
Low dose	36	33.1 (26.97)	36.3 (27.33)	37.5	0.0, 90.0	3.2 (20.22)	0.0	-32.5, 50.0	0.3496
High dose	47	30.3 (23.48)	36.0 (27.20)	32.5	0.0, 100.0	5.6 (19.72)	0.0	-30.0, 70.0	0.0561

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 3

Change from Baseline to Each Planned Visit in Quality of Life as Assessed
by The PD Questionnaire-39 Items
(FAS)

Parameter Time Point Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
PDQ-Mobility Domain Score									
WEEK 48	64	30.7 (26.01)	35.9 (24.68)	35.0	0.0, 100.0	5.3 (19.30)	3.7	-50.0, 80.0	0.0325*
Low dose	26	31.0 (27.79)	34.5 (24.86)	32.5	0.0, 92.5	3.6 (19.85)	5.0	-50.0, 50.0	0.3695
High dose	38	30.5 (25.10)	36.9 (24.85)	35.0	0.0, 100.0	6.4 (19.09)	2.5	-17.5, 80.0	0.0443*
WEEK 72	12	33.3 (35.87)	44.2 (34.43)	40.0	0.0, 100.0	10.8 (18.32)	3.8	-12.5, 50.0	0.0651
Low dose	5	13.0 (13.16)	26.5 (23.22)	22.5	0.0, 60.0	13.5 (25.71)	0.0	-12.5, 50.0	0.3056
High dose	7	47.9 (40.66)	56.8 (36.99)	62.5	0.0, 100.0	8.9 (12.82)	7.5	-7.5, 30.0	0.1149
PDQ-Summary Index Total Score									
BASELINE	106		26.0 (16.29)	23.7	3.2, 76.9				
Low dose	48		25.5 (17.18)	22.1	3.2, 64.1				
High dose	58		26.4 (15.65)	24.0	3.2, 76.9				
WEEK 24	83	25.4 (16.73)	27.7 (16.73)	25.6	0.0, 76.3	2.3 (11.36)	0.6	-21.2, 35.9	0.0677
Low dose	36	25.8 (17.95)	27.2 (17.08)	24.0	0.0, 64.7	1.4 (10.59)	-0.6	-18.4, 22.4	0.4290
High dose	47	25.1 (15.93)	28.1 (16.63)	27.0	4.5, 76.3	3.0 (11.98)	1.3	-21.2, 35.9	0.0933
WEEK 48	64	25.4 (17.99)	28.3 (16.13)	27.6	1.3, 77.6	2.9 (11.91)	2.2	-27.6, 52.6	0.0595
Low dose	26	25.8 (19.50)	26.5 (15.74)	27.6	3.8, 56.4	0.7 (11.37)	0.6	-27.6, 23.0	0.7633
High dose	38	25.2 (17.15)	29.5 (16.49)	27.9	1.3, 77.6	4.3 (12.18)	2.9	-14.7, 52.6	0.0342*
WEEK 72	12	26.1 (24.06)	34.2 (22.11)	36.2	3.8, 75.6	8.1 (13.03)	1.0	-3.8, 38.2	0.0545
Low dose	5	12.1 (7.83)	24.2 (17.16)	23.7	3.8, 42.8	12.1 (18.46)	1.3	-3.8, 38.2	0.2160
High dose	7	36.1 (27.21)	41.3 (23.62)	44.2	4.5, 75.6	5.2 (7.82)	0.6	-1.9, 16.7	0.1278

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

表28　EQ-5D-5Lスコア（FAS）：M15-737試験

[redacted]20[redacted] 10:45 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.2__4

Change from Baseline to Each Planned Visit in Health-Related Quality of Life as Assessed
by EQ-5D-5L
(FAS)

Parameter Time Point Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
EQ-5D-5L Mobility									
BASELINE	106		1.9 (0.94)	2.0	1.0, 5.0				
Low dose	48		1.9 (0.99)	2.0	1.0, 4.0				
High dose	58		1.9 (0.90)	2.0	1.0, 5.0				
WEEK 24	78	2.0 (0.97)	2.1 (1.03)	2.0	1.0, 5.0	0.1 (1.05)	0.0	-3.0, 3.0	0.3918
Low dose	34	1.9 (1.01)	2.1 (1.07)	2.0	1.0, 5.0	0.2 (1.00)	0.0	-2.0, 3.0	0.3105
High dose	44	2.0 (0.94)	2.0 (1.01)	2.0	1.0, 4.0	0.0 (1.10)	0.0	-3.0, 2.0	0.7851
WEEK 48	53	1.9 (1.03)	2.1 (1.02)	2.0	1.0, 5.0	0.2 (0.82)	0.0	-2.0, 2.0	0.1850
Low dose	21	1.9 (1.09)	2.2 (1.09)	2.0	1.0, 4.0	0.3 (1.02)	0.0	-2.0, 2.0	0.1485
High dose	32	2.0 (1.00)	2.0 (0.98)	2.0	1.0, 5.0	0.0 (0.65)	0.0	-2.0, 2.0	0.7864
WEEK 72	11	2.2 (1.17)	2.7 (1.10)	3.0	1.0, 5.0	0.5 (0.93)	0.0	-1.0, 2.0	0.0816
Low dose	5	1.8 (0.45)	2.4 (1.14)	2.0	1.0, 4.0	0.6 (0.89)	0.0	0.0, 2.0	0.2080
High dose	6	2.5 (1.52)	3.0 (1.10)	3.0	2.0, 5.0	0.5 (1.05)	0.5	-1.0, 2.0	0.2956
EQ-5D-5L Self-care									
BASELINE	106		1.6 (0.77)	1.0	1.0, 4.0				
Low dose	48		1.6 (0.76)	1.5	1.0, 4.0				
High dose	58		1.6 (0.79)	1.0	1.0, 4.0				
WEEK 24	78	1.7 (0.83)	1.8 (0.80)	2.0	1.0, 4.0	0.1 (0.71)	0.0	-2.0, 2.0	0.1144
Low dose	34	1.8 (0.81)	1.9 (0.78)	2.0	1.0, 3.0	0.1 (0.60)	0.0	-1.0, 1.0	0.5715
High dose	44	1.6 (0.84)	1.8 (0.82)	2.0	1.0, 4.0	0.2 (0.79)	0.0	-2.0, 2.0	0.1321

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 4

Change from Baseline to Each Planned Visit in Health-Related Quality of Life as Assessed by EQ-5D-5L
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
EQ-5D-5L Self-care									
WEEK 48	53	1.7 (0.87)	1.8 (1.03)	2.0	1.0, 5.0	0.2 (0.79)	0.0	-2.0, 2.0	0.1723
Low dose	21	1.9 (0.91)	2.1 (1.09)	2.0	1.0, 5.0	0.2 (0.83)	0.0	-1.0, 2.0	0.2040
High dose	32	1.6 (0.84)	1.7 (0.97)	1.0	1.0, 5.0	0.1 (0.78)	0.0	-2.0, 2.0	0.5000
WEEK 72	11	1.8 (1.17)	2.4 (0.92)	2.0	1.0, 4.0	0.5 (0.82)	1.0	-1.0, 2.0	0.0519
Low dose	5	1.4 (0.55)	2.0 (1.00)	2.0	1.0, 3.0	0.6 (0.55)	1.0	0.0, 1.0	0.0705
High dose	6	2.2 (1.47)	2.7 (0.82)	2.5	2.0, 4.0	0.5 (1.05)	0.5	-1.0, 2.0	0.2956
EQ-5D-5L Usual Activities									
BASELINE	106		2.0 (0.89)	2.0	1.0, 5.0				
Low dose	48		2.0 (0.92)	2.0	1.0, 4.0				
High dose	58		2.1 (0.87)	2.0	1.0, 5.0				
WEEK 24	78	2.1 (0.94)	2.2 (0.94)	2.0	1.0, 4.0	0.1 (0.90)	0.0	-2.0, 2.0	0.2595
Low dose	34	2.1 (0.95)	2.1 (0.87)	2.0	1.0, 4.0	0.0 (0.83)	0.0	-2.0, 2.0	0.8384
High dose	44	2.1 (0.95)	2.3 (0.99)	2.0	1.0, 4.0	0.2 (0.95)	0.0	-2.0, 2.0	0.2096
WEEK 48	53	2.0 (1.02)	2.0 (0.90)	2.0	1.0, 4.0	0.0 (0.92)	0.0	-2.0, 2.0	0.7662
Low dose	21	2.0 (1.07)	2.2 (0.83)	2.0	1.0, 4.0	0.2 (0.87)	0.0	-2.0, 1.0	0.3293
High dose	32	2.0 (1.00)	1.9 (0.93)	2.0	1.0, 4.0	-0.1 (0.95)	0.0	-2.0, 2.0	0.7118
WEEK 72	11	2.0 (1.26)	2.7 (1.35)	3.0	1.0, 5.0	0.7 (1.42)	0.0	-1.0, 4.0	0.1204
Low dose	5	1.8 (0.84)	2.0 (1.00)	2.0	1.0, 3.0	0.2 (1.10)	0.0	-1.0, 2.0	0.7040
High dose	6	2.2 (1.60)	3.3 (1.37)	3.0	2.0, 5.0	1.2 (1.60)	0.5	0.0, 4.0	0.1345

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 4

Change from Baseline to Each Planned Visit in Health-Related Quality of Life as Assessed by EQ-5D-5L
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
EQ-5D-5L Pain/Discomfort									
BASELINE	106		1.9 (0.89)	2.0	1.0, 5.0				
Low dose	48		1.9 (0.94)	2.0	1.0, 5.0				
High dose	58		1.9 (0.86)	2.0	1.0, 4.0				
WEEK 24	78	1.9 (0.89)	2.0 (0.92)	2.0	1.0, 4.0	0.1 (0.78)	0.0	-2.0, 2.0	0.3103
Low dose	34	1.9 (0.93)	2.0 (0.94)	2.0	1.0, 4.0	0.2 (0.76)	0.0	-1.0, 2.0	0.1836
High dose	44	1.9 (0.87)	1.9 (0.91)	2.0	1.0, 4.0	0.0 (0.79)	0.0	-2.0, 2.0	0.8499
WEEK 48	53	1.8 (0.91)	2.1 (1.12)	2.0	1.0, 5.0	0.2 (0.87)	0.0	-2.0, 3.0	0.0464*
Low dose	21	1.8 (0.98)	2.3 (1.27)	2.0	1.0, 5.0	0.5 (0.93)	0.0	-1.0, 3.0	0.0291*
High dose	32	1.8 (0.88)	1.9 (1.01)	2.0	1.0, 4.0	0.1 (0.82)	0.0	-2.0, 1.0	0.5213
WEEK 72	11	2.0 (1.10)	2.2 (1.33)	2.0	1.0, 4.0	0.2 (1.54)	0.0	-3.0, 3.0	0.7031
Low dose	5	1.6 (0.55)	1.8 (1.30)	1.0	1.0, 4.0	0.2 (1.10)	0.0	-1.0, 2.0	0.7040
High dose	6	2.3 (1.37)	2.5 (1.38)	2.5	1.0, 4.0	0.2 (1.94)	0.0	-3.0, 3.0	0.8417
EQ-5D-5L Anxiety/Depression									
BASELINE	106		1.7 (0.69)	2.0	1.0, 4.0				
Low dose	48		1.7 (0.74)	2.0	1.0, 4.0				
High dose	58		1.8 (0.66)	2.0	1.0, 3.0				
WEEK 24	78	1.7 (0.71)	1.8 (0.90)	2.0	1.0, 4.0	0.1 (0.82)	0.0	-1.0, 3.0	0.2700
Low dose	34	1.7 (0.79)	1.9 (1.00)	2.0	1.0, 4.0	0.2 (0.87)	0.0	-1.0, 2.0	0.2450
High dose	44	1.7 (0.64)	1.7 (0.82)	2.0	1.0, 4.0	0.0 (0.78)	0.0	-1.0, 3.0	0.6996

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 4

Change from Baseline to Each Planned Visit in Health-Related Quality of Life as Assessed by EQ-5D-5L
(FAS)

Parameter Time Point Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
EQ-5D-5L Anxiety/Depression									
WEEK 48	53	1.5 (0.64)	1.7 (0.97)	1.0	1.0, 4.0	0.2 (0.83)	0.0	-2.0, 2.0	0.1405
Low dose	21	1.5 (0.51)	2.0 (1.07)	2.0	1.0, 4.0	0.5 (0.81)	0.0	-1.0, 2.0	0.0143*
High dose	32	1.6 (0.71)	1.6 (0.88)	1.0	1.0, 4.0	-0.0 (0.78)	0.0	-2.0, 2.0	0.8227
WEEK 72	11	1.5 (0.82)	2.1 (1.14)	2.0	1.0, 4.0	0.6 (1.21)	1.0	-2.0, 2.0	0.1107
Low dose	5	1.2 (0.45)	1.8 (1.10)	1.0	1.0, 3.0	0.6 (0.89)	0.0	0.0, 2.0	0.2080
High dose	6	1.7 (1.03)	2.3 (1.21)	2.5	1.0, 4.0	0.7 (1.51)	1.0	-2.0, 2.0	0.3276
EQ-5D-5L VAS									
BASELINE	106		73.0 (15.64)	75.0	30.0, 100.0				
Low dose	48		74.1 (14.08)	78.0	35.0, 96.0				
High dose	58		72.1 (16.90)	74.5	30.0, 100.0				
WEEK 24	78	73.7 (15.08)	74.3 (14.23)	75.0	31.0, 99.0	0.6 (14.88)	-0.5	-31.0, 45.0	0.7215
Low dose	34	74.4 (14.58)	71.7 (13.33)	70.5	48.0, 94.0	-2.7 (12.98)	-2.5	-31.0, 24.0	0.2279
High dose	44	73.1 (15.60)	76.3 (14.73)	79.0	31.0, 99.0	3.2 (15.85)	1.0	-30.0, 45.0	0.1901
WEEK 48	53	71.8 (16.16)	72.5 (14.09)	74.0	37.0, 96.0	0.7 (16.24)	-1.0	-34.0, 40.0	0.7429
Low dose	21	73.5 (16.06)	70.2 (16.18)	70.0	37.0, 90.0	-3.2 (16.73)	-2.0	-34.0, 37.0	0.3856
High dose	32	70.7 (16.38)	74.0 (12.57)	75.5	51.0, 96.0	3.3 (15.63)	-0.5	-29.0, 40.0	0.2354
WEEK 72	11	74.2 (18.70)	70.1 (19.95)	79.0	40.0, 96.0	-4.1 (22.73)	-1.0	-45.0, 42.0	0.5638
Low dose	5	83.8 (8.26)	80.8 (12.48)	81.0	67.0, 96.0	-3.0 (7.25)	-1.0	-13.0, 6.0	0.4069
High dose	6	66.2 (21.80)	61.2 (21.48)	62.0	40.0, 83.0	-5.0 (31.45)	-0.5	-45.0, 42.0	0.7130

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 4

Change from Baseline to Each Planned Visit in Health-Related Quality of Life as Assessed by EQ-5D-5L
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
EQ-5D-5L Summary Index - Based on USA									
BASELINE	106		0.765 (0.1402)	0.778	0.126, 1.000				
Low dose	48		0.765 (0.1416)	0.785	0.306, 1.000				
High dose	58		0.765 (0.1404)	0.756	0.126, 1.000				
WEEK 24	78	0.763 (0.1460)	0.739 (0.1580)	0.758	0.343, 1.000	-0.024 (0.1177)	-0.005	-0.480, 0.241	0.0770
Low dose	34	0.754 (0.1434)	0.723 (0.1693)	0.744	0.343, 1.000	-0.031 (0.1137)	0.000	-0.480, 0.161	0.1174
High dose	44	0.771 (0.1492)	0.752 (0.1494)	0.772	0.367, 1.000	-0.018 (0.1218)	-0.023	-0.347, 0.241	0.3287
WEEK 48	53	0.775 (0.1695)	0.735 (0.1970)	0.784	0.111, 1.000	-0.040 (0.1360)	-0.030	-0.520, 0.266	0.0372*
Low dose	21	0.762 (0.1651)	0.683 (0.2086)	0.738	0.228, 1.000	-0.079 (0.1586)	-0.033	-0.520, 0.192	0.0335*
High dose	32	0.783 (0.1744)	0.769 (0.1844)	0.794	0.111, 1.000	-0.014 (0.1144)	-0.016	-0.201, 0.266	0.4836
WEEK 72	11	0.741 (0.2546)	0.628 (0.2021)	0.647	0.276, 1.000	-0.113 (0.1884)	-0.065	-0.489, 0.150	0.0755
Low dose	5	0.822 (0.1056)	0.763 (0.1607)	0.738	0.561, 1.000	-0.059 (0.1010)	-0.065	-0.187, 0.073	0.2588
High dose	6	0.673 (0.3293)	0.516 (0.1663)	0.518	0.276, 0.738	-0.157 (0.2400)	-0.128	-0.489, 0.150	0.1700

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

表29　PDQ-39スコア（FAS，日本人部分集団）：M15-737試験

[redacted]20[redacted] 10:46 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.2__3.J

Change from Baseline to Each Planned Visit in Quality of Life as Assessed
by The PD Questionnaire-39 Items
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PDQ-Bodily Discomfort Domain Score									
BASELINE	11		24.2 (25.67)	16.7	0.0, 75.0				
Low dose	7		14.3 (17.16)	8.3	0.0, 41.7				
High dose	4		41.7 (31.18)	45.8	0.0, 75.0				
WEEK 24	7	29.8 (28.41)	29.8 (28.41)	25.0	0.0, 83.3	0.0 (25.46)	0.0	-41.7, 41.7	>0.999
Low dose	4	20.8 (19.84)	33.3 (35.36)	25.0	0.0, 83.3	12.5 (22.05)	8.3	-8.3, 41.7	0.3393
High dose	3	41.7 (38.19)	25.0 (22.05)	33.3	0.0, 41.7	-16.7 (22.05)	-8.3	-41.7, 0.0	0.3206
WEEK 48	4	31.3 (37.50)	33.3 (29.66)	29.2	8.3, 66.7	2.1 (7.98)	4.2	-8.3, 8.3	0.6376
Low dose	1	0.0 (N/A)	8.3 (N/A)	8.3	8.3, 8.3	8.3 (N/A)	8.3	8.3, 8.3	
High dose	3	41.7 (38.19)	41.7 (30.05)	50.0	8.3, 66.7	-0.0 (8.33)	0.0	-8.3, 8.3	>0.999
WEEK 72	2	37.5 (53.03)	37.5 (29.46)	37.5	16.7, 58.3	0.0 (23.57)	0.0	-16.7, 16.7	>0.999
Low dose	0								
High dose	2	37.5 (53.03)	37.5 (29.46)	37.5	16.7, 58.3	0.0 (23.57)	0.0	-16.7, 16.7	>0.999
PDQ-Communication Domain Score									
BASELINE	11		28.8 (29.43)	16.7	0.0, 83.3				
Low dose	7		26.2 (29.04)	16.7	0.0, 66.7				
High dose	4		33.3 (34.02)	20.8	8.3, 83.3				
WEEK 24	7	38.1 (33.28)	23.8 (23.29)	16.7	0.0, 66.7	-14.3 (15.00)	-8.3	-41.7, 0.0	0.0453*
Low dose	4	37.5 (34.36)	18.8 (18.48)	16.7	0.0, 41.7	-18.7 (18.48)	-16.7	-41.7, 0.0	0.1354
High dose	3	38.9 (39.38)	30.6 (31.55)	16.7	8.3, 66.7	-8.3 (8.33)	-8.3	-16.7, 0.0	0.2254

&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 3.J

Change from Baseline to Each Planned Visit in Quality of Life as Assessed
by The PD Questionnaire-39 Items
(FAS - Japan Subjects)

Parameter Time Point Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
PDQ-Communication Domain Score									
WEEK 48	4	29.2 (37.58)	27.1 (48.77)	4.2	0.0, 100.0	-2.1 (14.23)	-4.2	-16.7, 16.7	0.7888
Low dose	1	0.0 (N/A)	0.0 (N/A)	0.0	0.0, 0.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	3	38.9 (39.38)	36.1 (55.49)	8.3	0.0, 100.0	-2.8 (17.35)	-8.3	-16.7, 16.7	0.8075
WEEK 72	2	45.8 (53.03)	54.2 (64.82)	54.2	8.3, 100.0	8.3 (11.79)	8.3	0.0, 16.7	0.5000
Low dose	0								
High dose	2	45.8 (53.03)	54.2 (64.82)	54.2	8.3, 100.0	8.3 (11.79)	8.3	0.0, 16.7	0.5000
PDQ-Social Support Domain Score									
BASELINE	10		11.7 (11.92)	12.5	0.0, 33.3				
Low dose	6		11.1 (13.61)	8.3	0.0, 33.3				
High dose	4		12.5 (10.76)	12.5	0.0, 25.0				
WEEK 24	6	11.1 (10.09)	26.4 (25.50)	25.0	0.0, 66.7	15.3 (16.17)	12.5	0.0, 41.7	0.0686
Low dose	3	11.1 (9.62)	22.2 (20.97)	25.0	0.0, 41.7	11.1 (12.73)	8.3	0.0, 25.0	0.2697
High dose	3	11.1 (12.73)	30.6 (33.68)	25.0	0.0, 66.7	19.4 (20.97)	16.7	0.0, 41.7	0.2495
WEEK 48	4	8.3 (11.79)	8.3 (16.67)	0.0	0.0, 33.3	-0.0 (6.80)	0.0	-8.3, 8.3	>0.999
Low dose	1	0.0 (N/A)	0.0 (N/A)	0.0	0.0, 0.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	3	11.1 (12.73)	11.1 (19.25)	0.0	0.0, 33.3	-0.0 (8.33)	0.0	-8.3, 8.3	>0.999
WEEK 72	2	16.7 (11.79)	12.5 (17.68)	12.5	0.0, 25.0	-4.2 (5.89)	-4.2	-8.3, 0.0	0.5000
Low dose	0								
High dose	2	16.7 (11.79)	12.5 (17.68)	12.5	0.0, 25.0	-4.2 (5.89)	-4.2	-8.3, 0.0	0.5000

&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 3.J

Change from Baseline to Each Planned Visit in Quality of Life as Assessed
by The PD Questionnaire-39 Items
(FAS - Japan Subjects)

Parameter Time Point Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	Change from Baseline P-Value &
PDQ-Cognition Domain Score									
BASELINE	11		25.0 (14.79)	25.0	0.0, 50.0				
Low dose	7		19.6 (11.65)	18.8	0.0, 37.5				
High dose	4		34.4 (16.54)	37.5	12.5, 50.0				
WEEK 24	7	25.9 (15.06)	34.8 (14.82)	31.3	18.8, 62.5	8.9 (9.45)	12.5	-6.3, 18.8	0.0465*
Low dose	4	18.8 (5.10)	28.1 (8.07)	28.1	18.8, 37.5	9.4 (8.07)	9.4	0.0, 18.8	0.1027
High dose	3	35.4 (20.09)	43.8 (18.75)	43.8	25.0, 62.5	8.3 (13.01)	12.5	-6.3, 18.8	0.3828
WEEK 48	4	29.7 (20.01)	26.6 (12.88)	25.0	12.5, 43.8	-3.1 (15.73)	0.0	-25.0, 12.5	0.7177
Low dose	1	12.5 (N/A)	25.0 (N/A)	25.0	25.0, 25.0	12.5 (N/A)	12.5	12.5, 12.5	
High dose	3	35.4 (20.09)	27.1 (15.73)	25.0	12.5, 43.8	-8.3 (14.43)	0.0	-25.0, 0.0	0.4226
WEEK 72	2	31.3 (26.52)	37.5 (17.68)	37.5	25.0, 50.0	6.3 (8.84)	6.3	0.0, 12.5	0.5000
Low dose	0								
High dose	2	31.3 (26.52)	37.5 (17.68)	37.5	25.0, 50.0	6.3 (8.84)	6.3	0.0, 12.5	0.5000
PDQ-Stigma Domain Score									
BASELINE	11		17.6 (21.44)	12.5	0.0, 75.0				
Low dose	7		13.4 (11.65)	18.8	0.0, 31.3				
High dose	4		25.0 (33.85)	12.5	0.0, 75.0				
WEEK 24	7	20.5 (26.45)	26.8 (33.80)	12.5	6.3, 100.0	6.3 (14.88)	0.0	-12.5, 25.0	0.3089
Low dose	4	14.1 (13.86)	14.1 (11.83)	9.4	6.3, 31.3	0.0 (10.21)	0.0	-12.5, 12.5	>0.999
High dose	3	29.2 (40.18)	43.8 (49.61)	25.0	6.3, 100.0	14.6 (18.04)	25.0	-6.3, 25.0	0.2965

&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 3.J

Change from Baseline to Each Planned Visit in Quality of Life as Assessed
by The PD Questionnaire-39 Items
(FAS - Japan Subjects)

Parameter Time Point Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
PDQ-Stigma Domain Score									
WEEK 48	4	21.9 (35.90)	29.7 (38.65)	12.5	6.3, 87.5	7.8 (5.98)	9.4	0.0, 12.5	0.0796
Low dose	1	0.0 (N/A)	12.5 (N/A)	12.5	12.5, 12.5	12.5 (N/A)	12.5	12.5, 12.5	
High dose	3	29.2 (40.18)	35.4 (45.21)	12.5	6.3, 87.5	6.3 (6.25)	6.3	0.0, 12.5	0.2254
WEEK 72	2	37.5 (53.03)	43.8 (35.36)	43.8	18.8, 68.8	6.3 (17.68)	6.3	-6.3, 18.8	0.7048
Low dose	0								
High dose	2	37.5 (53.03)	43.8 (35.36)	43.8	18.8, 68.8	6.3 (17.68)	6.3	-6.3, 18.8	0.7048
PDQ-Activities of Daily Living Domain Score									
BASELINE	11		37.9 (25.98)	41.7	0.0, 87.5				
Low dose	7		32.7 (21.57)	41.7	0.0, 54.2				
High dose	4		46.9 (33.91)	45.8	8.3, 87.5				
WEEK 24	7	41.1 (28.71)	50.6 (23.87)	58.3	12.5, 75.0	9.5 (13.76)	12.5	-12.5, 29.2	0.1168
Low dose	4	33.3 (19.84)	52.1 (20.83)	54.2	25.0, 75.0	18.8 (7.98)	16.7	12.5, 29.2	0.0182*
High dose	3	51.4 (40.04)	48.6 (32.36)	58.3	12.5, 75.0	-2.8 (8.67)	0.0	-12.5, 4.2	0.6349
WEEK 48	4	39.6 (40.33)	45.8 (42.08)	35.4	12.5, 100.0	6.3 (5.38)	6.3	0.0, 12.5	0.1027
Low dose	1	4.2 (N/A)	12.5 (N/A)	12.5	12.5, 12.5	8.3 (N/A)	8.3	8.3, 8.3	
High dose	3	51.4 (40.04)	56.9 (43.77)	58.3	12.5, 100.0	5.6 (6.36)	4.2	0.0, 12.5	0.2697
WEEK 72	2	47.9 (55.98)	70.8 (41.25)	70.8	41.7, 100.0	22.9 (14.73)	22.9	12.5, 33.3	0.2716
Low dose	0								
High dose	2	47.9 (55.98)	70.8 (41.25)	70.8	41.7, 100.0	22.9 (14.73)	22.9	12.5, 33.3	0.2716

&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 3.J

Change from Baseline to Each Planned Visit in Quality of Life as Assessed
by The PD Questionnaire-39 Items
(FAS - Japan Subjects)

Parameter Time Point Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
PDQ-Emotional Well-being Domain Score									
BASELINE	11		29.5 (24.40)	25.0	0.0, 75.0				
Low dose	7		25.6 (25.28)	25.0	0.0, 75.0				
High dose	4		36.5 (24.62)	31.3	12.5, 70.8				
WEEK 24	7	35.1 (28.14)	40.5 (21.07)	29.2	16.7, 75.0	5.4 (17.30)	4.2	-16.7, 25.0	0.4439
Low dose	4	33.3 (31.18)	40.6 (16.09)	39.6	25.0, 58.3	7.3 (21.07)	10.4	-16.7, 25.0	0.5387
High dose	3	37.5 (30.05)	40.3 (30.71)	29.2	16.7, 75.0	2.8 (14.63)	4.2	-12.5, 16.7	0.7735
WEEK 48	4	28.1 (30.88)	35.4 (22.95)	33.3	12.5, 62.5	7.3 (10.96)	10.4	-8.3, 16.7	0.2754
Low dose	1	0.0 (N/A)	12.5 (N/A)	12.5	12.5, 12.5	12.5 (N/A)	12.5	12.5, 12.5	
High dose	3	37.5 (30.05)	43.1 (20.97)	45.8	20.8, 62.5	5.6 (12.73)	8.3	-8.3, 16.7	0.5286
WEEK 72	2	41.7 (41.25)	43.8 (14.73)	43.8	33.3, 54.2	2.1 (26.52)	2.1	-16.7, 20.8	0.9296
Low dose	0								
High dose	2	41.7 (41.25)	43.8 (14.73)	43.8	33.3, 54.2	2.1 (26.52)	2.1	-16.7, 20.8	0.9296
PDQ-Mobility Domain Score									
BASELINE	11		39.8 (31.45)	42.5	0.0, 100.0				
Low dose	7		37.5 (28.47)	42.5	0.0, 75.0				
High dose	4		43.8 (40.54)	35.0	5.0, 100.0				
WEEK 24	7	43.9 (35.64)	50.7 (31.74)	47.5	5.0, 100.0	6.8 (21.49)	0.0	-27.5, 42.5	0.4355
Low dose	4	40.0 (31.09)	47.5 (30.07)	57.5	5.0, 70.0	7.5 (29.23)	7.5	-27.5, 42.5	0.6432
High dose	3	49.2 (47.85)	55.0 (40.23)	42.5	22.5, 100.0	5.8 (10.10)	0.0	0.0, 17.5	0.4226

&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 3.J

Change from Baseline to Each Planned Visit in Quality of Life as Assessed
by The PD Questionnaire-39 Items
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PDQ-Mobility Domain Score									
WEEK 48	4	38.1 (44.88)	43.8 (40.13)	31.3	12.5, 100.0	5.6 (5.54)	5.0	0.0, 12.5	0.1354
Low dose	1	5.0 (N/A)	12.5 (N/A)	12.5	12.5, 12.5	7.5 (N/A)	7.5	7.5, 7.5	
High dose	3	49.2 (47.85)	54.2 (42.01)	45.0	17.5, 100.0	5.0 (6.61)	2.5	0.0, 12.5	0.3206
WEEK 72	2	52.5 (67.18)	61.3 (54.80)	61.3	22.5, 100.0	8.8 (12.37)	8.8	0.0, 17.5	0.5000
Low dose	0								
High dose	2	52.5 (67.18)	61.3 (54.80)	61.3	22.5, 100.0	8.8 (12.37)	8.8	0.0, 17.5	0.5000
PDQ-Summary Index Total Score									
BASELINE	11		29.9 (21.41)	27.6	3.2, 76.9				
Low dose	7		25.9 (16.83)	27.6	3.2, 44.9				
High dose	4		36.9 (29.33)	31.7	7.1, 76.9				
WEEK 24	7	33.8 (24.93)	39.4 (21.20)	35.9	12.2, 76.3	5.6 (9.27)	3.8	-5.1, 21.1	0.1630
Low dose	4	29.2 (18.83)	36.4 (17.22)	42.3	12.2, 48.7	7.2 (10.93)	6.4	-5.1, 21.1	0.2799
High dose	3	40.0 (35.11)	43.4 (29.36)	34.0	19.9, 76.3	3.4 (8.17)	-0.6	-1.9, 12.8	0.5438
WEEK 48	4	30.8 (34.05)	34.8 (31.04)	25.0	11.5, 77.6	4.0 (3.45)	3.5	0.6, 8.3	0.1027
Low dose	1	3.2 (N/A)	11.5 (N/A)	11.5	11.5, 11.5	8.3 (N/A)	8.3	8.3, 8.3	
High dose	3	40.0 (35.11)	42.5 (32.94)	37.8	12.2, 77.6	2.6 (2.31)	1.9	0.6, 5.1	0.1946
WEEK 72	2	42.0 (49.41)	49.7 (36.72)	49.7	23.7, 75.6	7.7 (12.69)	7.7	-1.3, 16.7	0.5489
Low dose	0								
High dose	2	42.0 (49.41)	49.7 (36.72)	49.7	23.7, 75.6	7.7 (12.69)	7.7	-1.3, 16.7	0.5489

&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

表30　EQ-5D-5Lスコア（FAS，日本人部分集団）：M15-737試験

[redacted]20[redacted] 10:46 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.2__4.J

Change from Baseline to Each Planned Visit in Health-Related Quality of Life as Assessed
by EQ-5D-5L
(FAS - Japan Subjects)

Parameter Time Point Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
EQ-5D-5L Mobility									
BASELINE	11		2.1 (1.30)	2.0	1.0, 5.0				
Low dose	7		2.0 (1.00)	2.0	1.0, 3.0				
High dose	4		2.3 (1.89)	1.5	1.0, 5.0				
WEEK 24	7	2.3 (1.50)	2.3 (1.38)	2.0	1.0, 4.0	0.0 (1.29)	0.0	-2.0, 2.0	>0.999
Low dose	4	2.0 (1.15)	1.8 (0.96)	1.5	1.0, 3.0	-0.3 (1.26)	0.0	-2.0, 1.0	0.7177
High dose	3	2.7 (2.08)	3.0 (1.73)	4.0	1.0, 4.0	0.3 (1.53)	0.0	-1.0, 2.0	0.7418
WEEK 48	4	2.3 (1.89)	2.5 (1.73)	2.0	1.0, 5.0	0.3 (0.50)	0.0	0.0, 1.0	0.3910
Low dose	1	1.0 (N/A)	2.0 (N/A)	2.0	2.0, 2.0	1.0 (N/A)	1.0	1.0, 1.0	
High dose	3	2.7 (2.08)	2.7 (2.08)	2.0	1.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 72	2	3.0 (2.83)	3.5 (2.12)	3.5	2.0, 5.0	0.5 (0.71)	0.5	0.0, 1.0	0.5000
Low dose	0								
High dose	2	3.0 (2.83)	3.5 (2.12)	3.5	2.0, 5.0	0.5 (0.71)	0.5	0.0, 1.0	0.5000
EQ-5D-5L Self-care									
BASELINE	11		2.0 (1.00)	2.0	1.0, 4.0				
Low dose	7		1.7 (0.76)	2.0	1.0, 3.0				
High dose	4		2.5 (1.29)	2.5	1.0, 4.0				
WEEK 24	7	2.1 (1.07)	2.3 (1.11)	2.0	1.0, 4.0	0.1 (1.21)	0.0	-2.0, 2.0	0.7663
Low dose	4	2.0 (0.82)	2.3 (0.96)	2.5	1.0, 3.0	0.3 (0.50)	0.0	0.0, 1.0	0.3910
High dose	3	2.3 (1.53)	2.3 (1.53)	2.0	1.0, 4.0	0.0 (2.00)	0.0	-2.0, 2.0	>0.999

&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 4.J

Change from Baseline to Each Planned Visit in Health-Related Quality of Life as Assessed by EQ-5D-5L
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
EQ-5D-5L Self-care									
WEEK 48	4	2.0 (1.41)	3.0 (1.83)	3.0	1.0, 5.0	1.0 (0.82)	1.0	0.0, 2.0	0.0917
Low dose	1	1.0 (N/A)	2.0 (N/A)	2.0	2.0, 2.0	1.0 (N/A)	1.0	1.0, 1.0	
High dose	3	2.3 (1.53)	3.3 (2.08)	4.0	1.0, 5.0	1.0 (1.00)	1.0	0.0, 2.0	0.2254
WEEK 72	2	2.5 (2.12)	3.0 (1.41)	3.0	2.0, 4.0	0.5 (0.71)	0.5	0.0, 1.0	0.5000
Low dose	0								
High dose	2	2.5 (2.12)	3.0 (1.41)	3.0	2.0, 4.0	0.5 (0.71)	0.5	0.0, 1.0	0.5000
EQ-5D-5L Usual Activities									
BASELINE	11		2.3 (1.19)	2.0	1.0, 5.0				
Low dose	7		2.1 (0.90)	2.0	1.0, 3.0				
High dose	4		2.5 (1.73)	2.0	1.0, 5.0				
WEEK 24	7	2.3 (1.38)	2.4 (1.13)	3.0	1.0, 4.0	0.1 (0.69)	0.0	-1.0, 1.0	0.6036
Low dose	4	2.0 (0.82)	2.3 (0.96)	2.5	1.0, 3.0	0.3 (0.50)	0.0	0.0, 1.0	0.3910
High dose	3	2.7 (2.08)	2.7 (1.53)	3.0	1.0, 4.0	0.0 (1.00)	0.0	-1.0, 1.0	>0.999
WEEK 48	4	2.3 (1.89)	2.8 (1.50)	3.0	1.0, 4.0	0.5 (1.29)	0.5	-1.0, 2.0	0.4950
Low dose	1	1.0 (N/A)	1.0 (N/A)	1.0	1.0, 1.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	3	2.7 (2.08)	3.3 (1.15)	4.0	2.0, 4.0	0.7 (1.53)	1.0	-1.0, 2.0	0.5286
WEEK 72	2	3.0 (2.83)	4.0 (1.41)	4.0	3.0, 5.0	1.0 (1.41)	1.0	0.0, 2.0	0.5000
Low dose	0								
High dose	2	3.0 (2.83)	4.0 (1.41)	4.0	3.0, 5.0	1.0 (1.41)	1.0	0.0, 2.0	0.5000

&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 4.J

Change from Baseline to Each Planned Visit in Health-Related Quality of Life as Assessed by EQ-5D-5L
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
EQ-5D-5L Pain/Discomfort									
BASELINE	11		2.1 (0.94)	2.0	1.0, 4.0				
Low dose	7		2.0 (0.82)	2.0	1.0, 3.0				
High dose	4		2.3 (1.26)	2.0	1.0, 4.0				
WEEK 24	7	2.1 (1.07)	2.1 (1.07)	2.0	1.0, 4.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	4	2.0 (0.82)	2.0 (0.82)	2.0	1.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	2.3 (1.53)	2.3 (1.53)	2.0	1.0, 4.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 48	4	2.0 (1.41)	2.3 (1.50)	2.0	1.0, 4.0	0.3 (0.50)	0.0	0.0, 1.0	0.3910
Low dose	1	1.0 (N/A)	1.0 (N/A)	1.0	1.0, 1.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	3	2.3 (1.53)	2.7 (1.53)	3.0	1.0, 4.0	0.3 (0.58)	0.0	0.0, 1.0	0.4226
WEEK 72	2	2.5 (2.12)	2.5 (2.12)	2.5	1.0, 4.0	0.0 (4.24)	0.0	-3.0, 3.0	>0.999
Low dose	0								
High dose	2	2.5 (2.12)	2.5 (2.12)	2.5	1.0, 4.0	0.0 (4.24)	0.0	-3.0, 3.0	>0.999
EQ-5D-5L Anxiety/Depression									
BASELINE	11		1.6 (0.81)	1.0	1.0, 3.0				
Low dose	7		1.4 (0.79)	1.0	1.0, 3.0				
High dose	4		2.0 (0.82)	2.0	1.0, 3.0				
WEEK 24	7	1.9 (0.90)	2.3 (1.11)	2.0	1.0, 4.0	0.4 (0.53)	0.0	0.0, 1.0	0.0781
Low dose	4	1.8 (0.96)	2.3 (0.96)	2.5	1.0, 3.0	0.5 (0.58)	0.5	0.0, 1.0	0.1817
High dose	3	2.0 (1.00)	2.3 (1.53)	2.0	1.0, 4.0	0.3 (0.58)	0.0	0.0, 1.0	0.4226

&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 4.J

Change from Baseline to Each Planned Visit in Health-Related Quality of Life as Assessed by EQ-5D-5L
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
EQ-5D-5L Anxiety/Depression									
WEEK 48	4	1.8 (0.96)	1.3 (0.50)	1.0	1.0, 2.0	-0.5 (1.00)	0.0	-2.0, 0.0	0.3910
Low dose	1	1.0 (N/A)	1.0 (N/A)	1.0	1.0, 1.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	3	2.0 (1.00)	1.3 (0.58)	1.0	1.0, 2.0	-0.7 (1.15)	0.0	-2.0, 0.0	0.4226
WEEK 72	2	2.0 (1.41)	2.0 (1.41)	2.0	1.0, 3.0	0.0 (2.83)	0.0	-2.0, 2.0	>0.999
Low dose	0								
High dose	2	2.0 (1.41)	2.0 (1.41)	2.0	1.0, 3.0	0.0 (2.83)	0.0	-2.0, 2.0	>0.999
EQ-5D-5L VAS									
BASELINE	11		74.1 (19.74)	80.0	40.0, 96.0				
Low dose	7		80.6 (12.75)	80.0	60.0, 96.0				
High dose	4		62.8 (26.53)	60.5	40.0, 90.0				
WEEK 24	7	71.4 (24.62)	70.0 (18.49)	69.0	45.0, 96.0	-1.4 (16.54)	5.0	-27.0, 15.0	0.8268
Low dose	4	82.5 (16.60)	73.5 (12.61)	72.0	60.0, 90.0	-9.0 (18.67)	-12.0	-27.0, 15.0	0.4062
High dose	3	56.7 (28.87)	65.3 (27.02)	55.0	45.0, 96.0	8.7 (5.51)	6.0	5.0, 15.0	0.1124
WEEK 48	4	66.0 (30.07)	73.0 (9.02)	76.0	60.0, 80.0	7.0 (27.78)	2.0	-16.0, 40.0	0.6490
Low dose	1	94.0 (N/A)	78.0 (N/A)	78.0	78.0, 78.0	-16.0 (N/A)	-16.0	-16.0, -16.0	
High dose	3	56.7 (28.87)	71.3 (10.26)	74.0	60.0, 80.0	14.7 (28.38)	20.0	-16.0, 40.0	0.4652
WEEK 72	2	65.0 (35.36)	42.5 (3.54)	42.5	40.0, 45.0	-22.5 (31.82)	-22.5	-45.0, 0.0	0.5000
Low dose	0								
High dose	2	65.0 (35.36)	42.5 (3.54)	42.5	40.0, 45.0	-22.5 (31.82)	-22.5	-45.0, 0.0	0.5000

&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 4.J

Change from Baseline to Each Planned Visit in Health-Related Quality of Life as Assessed by EQ-5D-5L
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
EQ-5D-5L Summary Index - Based on USA									
BASELINE	11		0.734 (0.2475)	0.729	0.126, 1.000				
Low dose	7		0.793 (0.1553)	0.778	0.597, 1.000				
High dose	4		0.631 (0.3656)	0.698	0.126, 1.000				
WEEK 24	7	0.692 (0.2965)	0.699 (0.2321)	0.662	0.367, 1.000	0.007 (0.1208)	0.000	-0.120, 0.241	0.8832
Low dose	4	0.760 (0.1764)	0.742 (0.1780)	0.686	0.597, 1.000	-0.018 (0.0685)	0.000	-0.116, 0.044	0.6358
High dose	3	0.601 (0.4420)	0.642 (0.3247)	0.558	0.367, 1.000	0.040 (0.1838)	0.000	-0.120, 0.241	0.7405
WEEK 48	4	0.701 (0.4123)	0.588 (0.3542)	0.676	0.111, 0.888	-0.114 (0.0709)	-0.131	-0.177, -0.015	0.0492*
Low dose	1	1.000 (N/A)	0.823 (N/A)	0.823	0.823, 0.823	-0.177 (N/A)	-0.177	-0.177, -0.177	
High dose	3	0.601 (0.4420)	0.509 (0.3888)	0.528	0.111, 0.888	-0.092 (0.0696)	-0.112	-0.150, -0.015	0.1484
WEEK 72	2	0.563 (0.6180)	0.394 (0.1662)	0.394	0.276, 0.511	-0.170 (0.4518)	-0.170	-0.489, 0.150	0.6895
Low dose	0								
High dose	2	0.563 (0.6180)	0.394 (0.1662)	0.394	0.276, 0.511	-0.170 (0.4518)	-0.170	-0.489, 0.150	0.6895

&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

表31　MMSEスコア（FAS）：M15-737試験

TABLE 14.2__5

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Attention/Calculation									
BASELINE	104		4.2 (1.18)	5.0	0.0, 5.0				
Low dose	48		4.3 (1.05)	5.0	1.0, 5.0				
High dose	56		4.1 (1.29)	5.0	0.0, 5.0				
WEEK 24	74	4.3 (1.08)	4.4 (1.14)	5.0	1.0, 5.0	0.1 (1.24)	0.0	-4.0, 3.0	0.5743
Low dose	33	4.4 (0.93)	4.5 (1.00)	5.0	1.0, 5.0	0.1 (1.26)	0.0	-2.0, 3.0	0.6811
High dose	41	4.2 (1.19)	4.3 (1.25)	5.0	1.0, 5.0	0.1 (1.23)	0.0	-4.0, 3.0	0.7059
WEEK 48	55	4.1 (1.34)	4.3 (1.22)	5.0	0.0, 5.0	0.3 (1.32)	0.0	-4.0, 4.0	0.1592
Low dose	22	4.3 (1.09)	4.5 (0.80)	5.0	3.0, 5.0	0.2 (1.05)	0.0	-1.0, 3.0	0.4270
High dose	33	3.9 (1.47)	4.2 (1.42)	5.0	0.0, 5.0	0.3 (1.49)	0.0	-4.0, 4.0	0.2511
WEEK 72	11	4.3 (1.19)	4.5 (1.21)	5.0	1.0, 5.0	0.3 (1.49)	0.0	-3.0, 3.0	0.5572
Low dose	4	4.8 (0.50)	4.0 (2.00)	5.0	1.0, 5.0	-0.8 (1.50)	0.0	-3.0, 0.0	0.3910
High dose	7	4.0 (1.41)	4.9 (0.38)	5.0	4.0, 5.0	0.9 (1.21)	0.0	0.0, 3.0	0.1112
POST-BASELINE MINIMUM	79	4.2 (1.21)	4.1 (1.36)	5.0	0.0, 5.0	-0.0 (1.34)	0.0	-4.0, 3.0	0.8024
Low dose	34	4.3 (1.00)	4.2 (1.17)	5.0	1.0, 5.0	-0.1 (1.29)	0.0	-3.0, 3.0	0.6921
High dose	45	4.1 (1.35)	4.1 (1.49)	5.0	0.0, 5.0	0.0 (1.40)	0.0	-4.0, 3.0	>0.999
POST-BASELINE MAXIMUM	80	4.2 (1.22)	4.5 (1.10)	5.0	0.0, 5.0	0.3 (1.31)	0.0	-4.0, 4.0	0.0293*
Low dose	34	4.3 (1.00)	4.6 (0.96)	5.0	1.0, 5.0	0.3 (1.24)	0.0	-2.0, 3.0	0.1773
High dose	46	4.0 (1.37)	4.4 (1.20)	5.0	0.0, 5.0	0.3 (1.37)	0.0	-4.0, 4.0	0.0919

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 5

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Comprehension									
BASELINE	104		3.0 (0.14)	3.0	2.0, 3.0				
Low dose	48		3.0 (0.14)	3.0	2.0, 3.0				
High dose	56		3.0 (0.13)	3.0	2.0, 3.0				
WEEK 24	75	3.0 (0.16)	2.9 (0.36)	3.0	0.0, 3.0	-0.0 (0.40)	0.0	-3.0, 1.0	0.5672
Low dose	33	3.0 (0.17)	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.17)	0.0	0.0, 1.0	0.3248
High dose	42	3.0 (0.15)	2.9 (0.48)	3.0	0.0, 3.0	-0.1 (0.51)	0.0	-3.0, 1.0	0.3720
WEEK 48	55	3.0 (0.13)	2.9 (0.46)	3.0	0.0, 3.0	-0.1 (0.48)	0.0	-3.0, 1.0	0.1676
Low dose	22	3.0 (0.00)	2.9 (0.29)	3.0	2.0, 3.0	-0.1 (0.29)	0.0	-1.0, 0.0	0.1621
High dose	33	3.0 (0.17)	2.9 (0.55)	3.0	0.0, 3.0	-0.1 (0.58)	0.0	-3.0, 1.0	0.3738
WEEK 72	11	3.0 (0.00)	2.7 (0.47)	3.0	2.0, 3.0	-0.3 (0.47)	0.0	-1.0, 0.0	0.0816
Low dose	4	3.0 (0.00)	2.8 (0.50)	3.0	2.0, 3.0	-0.3 (0.50)	0.0	-1.0, 0.0	0.3910
High dose	7	3.0 (0.00)	2.7 (0.49)	3.0	2.0, 3.0	-0.3 (0.49)	0.0	-1.0, 0.0	0.1723
POST-BASELINE MINIMUM	80	3.0 (0.16)	2.9 (0.53)	3.0	0.0, 3.0	-0.1 (0.56)	0.0	-3.0, 1.0	0.0492*
Low dose	34	3.0 (0.17)	2.9 (0.29)	3.0	2.0, 3.0	-0.1 (0.34)	0.0	-1.0, 1.0	0.3246
High dose	46	3.0 (0.15)	2.8 (0.65)	3.0	0.0, 3.0	-0.2 (0.68)	0.0	-3.0, 1.0	0.0882
POST-BASELINE MAXIMUM	80	3.0 (0.16)	3.0 (0.34)	3.0	0.0, 3.0	-0.0 (0.37)	0.0	-3.0, 1.0	0.7651
Low dose	34	3.0 (0.17)	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.17)	0.0	0.0, 1.0	0.3246
High dose	46	3.0 (0.15)	2.9 (0.44)	3.0	0.0, 3.0	-0.0 (0.47)	0.0	-3.0, 1.0	0.5330

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 5

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS)

Parameter Time Point Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
MMSE - Drawing									
BASELINE	104		0.9 (0.30)	1.0	0.0, 1.0				
Low dose	48		1.0 (0.14)	1.0	0.0, 1.0				
High dose	56		0.8 (0.37)	1.0	0.0, 1.0				
WEEK 24	75	0.9 (0.25)	0.9 (0.33)	1.0	0.0, 1.0	-0.1 (0.36)	0.0	-1.0, 1.0	0.2080
Low dose	33	1.0 (0.00)	0.8 (0.36)	1.0	0.0, 1.0	-0.2 (0.36)	0.0	-1.0, 0.0	0.0229*
High dose	42	0.9 (0.33)	0.9 (0.30)	1.0	0.0, 1.0	0.0 (0.35)	0.0	-1.0, 1.0	0.6602
WEEK 48	55	0.9 (0.36)	0.9 (0.34)	1.0	0.0, 1.0	0.0 (0.41)	0.0	-1.0, 1.0	0.7422
Low dose	22	1.0 (0.21)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.21)	0.0	0.0, 1.0	0.3287
High dose	33	0.8 (0.42)	0.8 (0.42)	1.0	0.0, 1.0	0.0 (0.50)	0.0	-1.0, 1.0	>0.999
WEEK 72	11	0.8 (0.40)	0.8 (0.40)	1.0	0.0, 1.0	0.0 (0.45)	0.0	-1.0, 1.0	>0.999
Low dose	4	1.0 (0.00)	0.8 (0.50)	1.0	0.0, 1.0	-0.3 (0.50)	0.0	-1.0, 0.0	0.3910
High dose	7	0.7 (0.49)	0.9 (0.38)	1.0	0.0, 1.0	0.1 (0.38)	0.0	0.0, 1.0	0.3559
POST-BASELINE MINIMUM	80	0.9 (0.30)	0.8 (0.41)	1.0	0.0, 1.0	-0.1 (0.42)	0.0	-1.0, 1.0	0.0192*
Low dose	34	1.0 (0.17)	0.8 (0.39)	1.0	0.0, 1.0	-0.1 (0.44)	0.0	-1.0, 1.0	0.0575
High dose	46	0.8 (0.36)	0.8 (0.43)	1.0	0.0, 1.0	-0.1 (0.41)	0.0	-1.0, 1.0	0.1596
POST-BASELINE MAXIMUM	80	0.9 (0.30)	1.0 (0.22)	1.0	0.0, 1.0	0.1 (0.31)	0.0	-1.0, 1.0	0.1586
Low dose	34	1.0 (0.17)	1.0 (0.17)	1.0	0.0, 1.0	0.0 (0.25)	0.0	-1.0, 1.0	>0.999
High dose	46	0.8 (0.36)	0.9 (0.25)	1.0	0.0, 1.0	0.1 (0.35)	0.0	-1.0, 1.0	0.1030

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 5

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Naming									
BASELINE	104		2.0 (0.00)	2.0	2.0, 2.0				
Low dose	48		2.0 (0.00)	2.0	2.0, 2.0				
High dose	56		2.0 (0.00)	2.0	2.0, 2.0				
WEEK 24	75	2.0 (0.00)	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	33	2.0 (0.00)	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	42	2.0 (0.00)	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 48	55	2.0 (0.00)	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	22	2.0 (0.00)	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	33	2.0 (0.00)	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 72	11	2.0 (0.00)	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	4	2.0 (0.00)	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	7	2.0 (0.00)	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MINIMUM	80	2.0 (0.00)	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	34	2.0 (0.00)	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	46	2.0 (0.00)	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MAXIMUM	80	2.0 (0.00)	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	34	2.0 (0.00)	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	46	2.0 (0.00)	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 5

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Orientation to Place									
BASELINE	104		4.9 (0.46)	5.0	2.0, 5.0				
Low dose	48		4.9 (0.45)	5.0	2.0, 5.0				
High dose	56		4.8 (0.46)	5.0	3.0, 5.0				
WEEK 24	75	4.9 (0.39)	4.8 (0.65)	5.0	1.0, 5.0	-0.1 (0.51)	0.0	-3.0, 1.0	0.0734
Low dose	33	4.9 (0.55)	4.8 (0.74)	5.0	1.0, 5.0	-0.1 (0.29)	0.0	-1.0, 0.0	0.0831
High dose	42	5.0 (0.22)	4.8 (0.58)	5.0	2.0, 5.0	-0.1 (0.63)	0.0	-3.0, 1.0	0.2295
WEEK 48	55	4.9 (0.33)	4.9 (0.46)	5.0	2.0, 5.0	-0.0 (0.33)	0.0	-1.0, 1.0	0.4192
Low dose	22	5.0 (0.21)	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.21)	0.0	0.0, 1.0	0.3287
High dose	33	4.9 (0.38)	4.8 (0.58)	5.0	2.0, 5.0	-0.1 (0.38)	0.0	-1.0, 1.0	0.1837
WEEK 72	11	4.9 (0.30)	4.8 (0.40)	5.0	4.0, 5.0	-0.1 (0.54)	0.0	-1.0, 1.0	0.5884
Low dose	4	5.0 (0.00)	4.8 (0.50)	5.0	4.0, 5.0	-0.3 (0.50)	0.0	-1.0, 0.0	0.3910
High dose	7	4.9 (0.38)	4.9 (0.38)	5.0	4.0, 5.0	0.0 (0.58)	0.0	-1.0, 1.0	>0.999
POST-BASELINE MINIMUM	80	4.9 (0.44)	4.7 (0.72)	5.0	1.0, 5.0	-0.2 (0.54)	0.0	-3.0, 1.0	0.0085**
Low dose	34	4.9 (0.54)	4.8 (0.74)	5.0	1.0, 5.0	-0.1 (0.33)	0.0	-1.0, 0.0	0.0437*
High dose	46	4.9 (0.35)	4.7 (0.72)	5.0	2.0, 5.0	-0.2 (0.65)	0.0	-3.0, 1.0	0.0484*
POST-BASELINE MAXIMUM	80	4.9 (0.44)	4.9 (0.61)	5.0	1.0, 5.0	-0.0 (0.37)	0.0	-2.0, 1.0	0.3690
Low dose	34	4.9 (0.54)	4.9 (0.69)	5.0	1.0, 5.0	0.0 (0.25)	0.0	-1.0, 1.0	>0.999
High dose	46	4.9 (0.35)	4.8 (0.56)	5.0	2.0, 5.0	-0.1 (0.44)	0.0	-2.0, 1.0	0.3227

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 5

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Orientation to Time									
BASELINE	104		4.8 (0.63)	5.0	2.0, 5.0				
Low dose	48		4.8 (0.66)	5.0	2.0, 5.0				
High dose	56		4.8 (0.61)	5.0	2.0, 5.0				
WEEK 24	75	4.8 (0.60)	4.7 (0.84)	5.0	0.0, 5.0	-0.1 (0.70)	0.0	-4.0, 1.0	0.1400
Low dose	33	4.7 (0.77)	4.7 (0.81)	5.0	1.0, 5.0	0.0 (0.50)	0.0	-1.0, 1.0	>0.999
High dose	42	4.9 (0.42)	4.6 (0.88)	5.0	0.0, 5.0	-0.2 (0.81)	0.0	-4.0, 1.0	0.0950
WEEK 48	55	4.8 (0.55)	4.6 (0.93)	5.0	1.0, 5.0	-0.2 (0.75)	0.0	-4.0, 1.0	0.0769
Low dose	22	4.7 (0.70)	4.8 (0.87)	5.0	1.0, 5.0	0.0 (0.49)	0.0	-1.0, 1.0	0.6652
High dose	33	4.9 (0.42)	4.5 (0.97)	5.0	1.0, 5.0	-0.3 (0.85)	0.0	-4.0, 0.0	0.0320*
WEEK 72	11	4.7 (0.90)	4.8 (0.40)	5.0	4.0, 5.0	0.1 (1.04)	0.0	-1.0, 3.0	0.7787
Low dose	4	4.3 (1.50)	5.0 (0.00)	5.0	5.0, 5.0	0.8 (1.50)	0.0	0.0, 3.0	0.3910
High dose	7	5.0 (0.00)	4.7 (0.49)	5.0	4.0, 5.0	-0.3 (0.49)	0.0	-1.0, 0.0	0.1723
POST-BASELINE MINIMUM	80	4.8 (0.59)	4.5 (1.04)	5.0	0.0, 5.0	-0.3 (0.82)	0.0	-4.0, 1.0	0.0015**
Low dose	34	4.7 (0.76)	4.6 (0.99)	5.0	1.0, 5.0	-0.1 (0.51)	0.0	-1.0, 1.0	0.3246
High dose	46	4.8 (0.42)	4.4 (1.08)	5.0	0.0, 5.0	-0.5 (0.96)	0.0	-4.0, 1.0	0.0023**
POST-BASELINE MAXIMUM	80	4.8 (0.59)	4.7 (0.84)	5.0	0.0, 5.0	-0.1 (0.77)	0.0	-4.0, 3.0	0.4693
Low dose	34	4.7 (0.76)	4.8 (0.72)	5.0	1.0, 5.0	0.1 (0.69)	0.0	-1.0, 3.0	0.3246
High dose	46	4.8 (0.42)	4.7 (0.92)	5.0	0.0, 5.0	-0.2 (0.81)	0.0	-4.0, 1.0	0.1067

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 5

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS)

Parameter Time Point Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
MMSE - Reading									
BASELINE	104		1.0 (0.14)	1.0	0.0, 1.0				
Low dose	48		1.0 (0.00)	1.0	1.0, 1.0				
High dose	56		1.0 (0.19)	1.0	0.0, 1.0				
WEEK 24	75	1.0 (0.12)	1.0 (0.16)	1.0	0.0, 1.0	-0.0 (0.12)	0.0	-1.0, 0.0	0.3206
Low dose	33	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	42	1.0 (0.15)	1.0 (0.22)	1.0	0.0, 1.0	-0.0 (0.15)	0.0	-1.0, 0.0	0.3232
WEEK 48	55	1.0 (0.19)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.19)	0.0	0.0, 1.0	0.1592
Low dose	22	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	33	0.9 (0.24)	1.0 (0.00)	1.0	1.0, 1.0	0.1 (0.24)	0.0	0.0, 1.0	0.1605
WEEK 72	11	0.8 (0.40)	1.0 (0.00)	1.0	1.0, 1.0	0.2 (0.40)	0.0	0.0, 1.0	0.1669
Low dose	4	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	7	0.7 (0.49)	1.0 (0.00)	1.0	1.0, 1.0	0.3 (0.49)	0.0	0.0, 1.0	0.1723
POST-BASELINE MINIMUM	80	1.0 (0.16)	1.0 (0.16)	1.0	0.0, 1.0	0.0 (0.16)	0.0	-1.0, 1.0	>0.999
Low dose	34	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	46	1.0 (0.21)	1.0 (0.21)	1.0	0.0, 1.0	0.0 (0.21)	0.0	-1.0, 1.0	>0.999
POST-BASELINE MAXIMUM	80	1.0 (0.16)	1.0 (0.11)	1.0	0.0, 1.0	0.0 (0.19)	0.0	-1.0, 1.0	0.5670
Low dose	34	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	46	1.0 (0.21)	1.0 (0.15)	1.0	0.0, 1.0	0.0 (0.26)	0.0	-1.0, 1.0	0.5694

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 5

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS)

Parameter Time Point Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
MMSE - Recall									
BASELINE	104		2.7 (0.57)	3.0	0.0, 3.0				
Low dose	48		2.6 (0.57)	3.0	1.0, 3.0				
High dose	56		2.8 (0.55)	3.0	0.0, 3.0				
WEEK 24	75	2.7 (0.61)	2.8 (0.43)	3.0	1.0, 3.0	0.1 (0.56)	0.0	-1.0, 2.0	0.1028
Low dose	33	2.6 (0.61)	2.7 (0.52)	3.0	1.0, 3.0	0.2 (0.57)	0.0	-1.0, 2.0	0.1338
High dose	42	2.8 (0.61)	2.9 (0.35)	3.0	2.0, 3.0	0.1 (0.56)	0.0	-1.0, 2.0	0.4119
WEEK 48	55	2.7 (0.52)	2.8 (0.49)	3.0	1.0, 3.0	0.1 (0.59)	0.0	-2.0, 1.0	0.4963
Low dose	22	2.6 (0.58)	2.8 (0.53)	3.0	1.0, 3.0	0.1 (0.71)	0.0	-2.0, 1.0	0.3780
High dose	33	2.8 (0.46)	2.8 (0.46)	3.0	1.0, 3.0	0.0 (0.50)	0.0	-1.0, 1.0	>0.999
WEEK 72	11	2.8 (0.60)	2.5 (0.69)	3.0	1.0, 3.0	-0.3 (0.47)	0.0	-1.0, 0.0	0.0816
Low dose	4	3.0 (0.00)	2.8 (0.50)	3.0	2.0, 3.0	-0.3 (0.50)	0.0	-1.0, 0.0	0.3910
High dose	7	2.7 (0.76)	2.4 (0.79)	3.0	1.0, 3.0	-0.3 (0.49)	0.0	-1.0, 0.0	0.1723
POST-BASELINE MINIMUM	80	2.7 (0.60)	2.7 (0.56)	3.0	1.0, 3.0	0.0 (0.60)	0.0	-2.0, 2.0	>0.999
Low dose	34	2.6 (0.61)	2.6 (0.60)	3.0	1.0, 3.0	0.1 (0.69)	0.0	-2.0, 2.0	0.6243
High dose	46	2.8 (0.59)	2.7 (0.53)	3.0	1.0, 3.0	-0.0 (0.51)	0.0	-1.0, 2.0	0.5694
POST-BASELINE MAXIMUM	80	2.7 (0.60)	2.8 (0.49)	3.0	1.0, 3.0	0.1 (0.63)	0.0	-2.0, 2.0	0.1586
Low dose	34	2.6 (0.61)	2.7 (0.57)	3.0	1.0, 3.0	0.1 (0.70)	0.0	-2.0, 2.0	0.2306
High dose	46	2.8 (0.59)	2.8 (0.42)	3.0	1.0, 3.0	0.1 (0.57)	0.0	-1.0, 2.0	0.4446

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 5

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS)

Parameter Time Point Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
MMSE - Registration									
BASELINE	104		3.0 (0.10)	3.0	2.0, 3.0				
Low dose	48		3.0 (0.00)	3.0	3.0, 3.0				
High dose	56		3.0 (0.13)	3.0	2.0, 3.0				
WEEK 24	75	3.0 (0.00)	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	33	3.0 (0.00)	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	42	3.0 (0.00)	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 48	55	3.0 (0.13)	3.0 (0.19)	3.0	2.0, 3.0	-0.0 (0.13)	0.0	-1.0, 0.0	0.3218
Low dose	22	3.0 (0.00)	3.0 (0.21)	3.0	2.0, 3.0	-0.0 (0.21)	0.0	-1.0, 0.0	0.3287
High dose	33	3.0 (0.17)	3.0 (0.17)	3.0	2.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 72	11	3.0 (0.00)	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	4	3.0 (0.00)	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	7	3.0 (0.00)	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MINIMUM	80	3.0 (0.11)	3.0 (0.16)	3.0	2.0, 3.0	-0.0 (0.11)	0.0	-1.0, 0.0	0.3204
Low dose	34	3.0 (0.00)	3.0 (0.17)	3.0	2.0, 3.0	-0.0 (0.17)	0.0	-1.0, 0.0	0.3246
High dose	46	3.0 (0.15)	3.0 (0.15)	3.0	2.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MAXIMUM	80	3.0 (0.11)	3.0 (0.11)	3.0	2.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	34	3.0 (0.00)	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	46	3.0 (0.15)	3.0 (0.15)	3.0	2.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 5

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS)

Parameter Time Point Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
MMSE - Repetition									
BASELINE	104		0.9 (0.27)	1.0	0.0, 1.0				
Low dose	48		0.9 (0.24)	1.0	0.0, 1.0				
High dose	56		0.9 (0.29)	1.0	0.0, 1.0				
WEEK 24	75	0.9 (0.23)	0.9 (0.23)	1.0	0.0, 1.0	0.0 (0.23)	0.0	-1.0, 1.0	>0.999
Low dose	33	1.0 (0.17)	1.0 (0.17)	1.0	0.0, 1.0	0.0 (0.25)	0.0	-1.0, 1.0	>0.999
High dose	42	0.9 (0.26)	0.9 (0.26)	1.0	0.0, 1.0	0.0 (0.22)	0.0	-1.0, 1.0	>0.999
WEEK 48	55	0.9 (0.26)	0.9 (0.23)	1.0	0.0, 1.0	0.0 (0.23)	0.0	-1.0, 1.0	0.5685
Low dose	22	1.0 (0.21)	1.0 (0.21)	1.0	0.0, 1.0	0.0 (0.31)	0.0	-1.0, 1.0	>0.999
High dose	33	0.9 (0.29)	0.9 (0.24)	1.0	0.0, 1.0	0.0 (0.17)	0.0	0.0, 1.0	0.3248
WEEK 72	11	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	4	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	7	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MINIMUM	80	0.9 (0.24)	0.9 (0.27)	1.0	0.0, 1.0	-0.0 (0.25)	0.0	-1.0, 1.0	0.6576
Low dose	34	1.0 (0.17)	0.9 (0.24)	1.0	0.0, 1.0	-0.0 (0.30)	0.0	-1.0, 1.0	0.5715
High dose	46	0.9 (0.28)	0.9 (0.28)	1.0	0.0, 1.0	0.0 (0.21)	0.0	-1.0, 1.0	>0.999
POST-BASELINE MAXIMUM	80	0.9 (0.24)	1.0 (0.16)	1.0	0.0, 1.0	0.0 (0.19)	0.0	0.0, 1.0	0.0832
Low dose	34	1.0 (0.17)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.17)	0.0	0.0, 1.0	0.3246
High dose	46	0.9 (0.28)	1.0 (0.21)	1.0	0.0, 1.0	0.0 (0.21)	0.0	0.0, 1.0	0.1596

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 5

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Total									
BASELINE	104		28.3 (2.10)	29.0	18.0, 30.0				
Low dose	48		28.5 (1.89)	29.0	21.0, 30.0				
High dose	56		28.2 (2.27)	29.0	18.0, 30.0				
WEEK 24	75	28.5 (1.92)	28.4 (2.97)	29.0	12.0, 30.0	-0.1 (2.25)	0.0	-13.0, 4.0	0.6461
Low dose	33	28.5 (2.05)	28.5 (2.69)	29.0	15.0, 30.0	0.0 (2.00)	0.0	-6.0, 4.0	>0.999
High dose	42	28.5 (1.84)	28.3 (3.20)	30.0	12.0, 30.0	-0.2 (2.45)	0.0	-13.0, 3.0	0.5747
WEEK 48	55	28.2 (2.27)	28.2 (3.08)	29.0	14.0, 30.0	0.0 (2.24)	0.0	-12.0, 4.0	>0.999
Low dose	22	28.5 (1.71)	28.8 (1.71)	29.0	23.0, 30.0	0.3 (1.28)	0.0	-3.0, 3.0	0.3287
High dose	33	28.0 (2.57)	27.8 (3.70)	29.0	14.0, 30.0	-0.2 (2.71)	0.0	-12.0, 4.0	0.7024
WEEK 72	11	28.4 (1.86)	28.2 (2.71)	29.0	22.0, 30.0	-0.2 (2.27)	0.0	-4.0, 4.0	0.7961
Low dose	4	29.0 (2.00)	28.0 (4.00)	30.0	22.0, 30.0	-1.0 (2.00)	0.0	-4.0, 0.0	0.3910
High dose	7	28.0 (1.83)	28.3 (2.06)	29.0	24.0, 30.0	0.3 (2.43)	0.0	-3.0, 4.0	0.7663
POST-BASELINE MINIMUM	80	28.3 (2.22)	27.7 (3.61)	29.0	12.0, 30.0	-0.6 (2.54)	0.0	-13.0, 4.0	0.0564
Low dose	34	28.4 (2.06)	28.1 (2.88)	29.0	15.0, 30.0	-0.2 (1.95)	0.0	-6.0, 4.0	0.4877
High dose	46	28.2 (2.36)	27.4 (4.06)	29.0	12.0, 30.0	-0.8 (2.90)	0.0	-13.0, 3.0	0.0736
POST-BASELINE MAXIMUM	80	28.3 (2.22)	28.5 (3.26)	30.0	12.0, 30.0	0.2 (2.28)	0.0	-13.0, 4.0	0.5258
Low dose	34	28.4 (2.06)	28.7 (2.68)	30.0	15.0, 30.0	0.3 (1.85)	0.0	-6.0, 4.0	0.3163
High dose	46	28.2 (2.36)	28.3 (3.64)	30.0	12.0, 30.0	0.0 (2.56)	0.0	-13.0, 4.0	0.9090

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 5

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS)

Parameter Time Point Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	Change from Baseline P-Value &
MMSE - Writing									
BASELINE	104		1.0 (0.14)	1.0	0.0, 1.0				
Low dose	48		1.0 (0.00)	1.0	1.0, 1.0				
High dose	56		1.0 (0.19)	1.0	0.0, 1.0				
WEEK 24	75	1.0 (0.12)	1.0 (0.20)	1.0	0.0, 1.0	-0.0 (0.16)	0.0	-1.0, 0.0	0.1587
Low dose	33	1.0 (0.00)	1.0 (0.17)	1.0	0.0, 1.0	-0.0 (0.17)	0.0	-1.0, 0.0	0.3248
High dose	42	1.0 (0.15)	1.0 (0.22)	1.0	0.0, 1.0	-0.0 (0.15)	0.0	-1.0, 0.0	0.3232
WEEK 48	55	1.0 (0.19)	0.9 (0.29)	1.0	0.0, 1.0	-0.1 (0.23)	0.0	-1.0, 0.0	0.0832
Low dose	22	1.0 (0.00)	1.0 (0.21)	1.0	0.0, 1.0	-0.0 (0.21)	0.0	-1.0, 0.0	0.3287
High dose	33	0.9 (0.24)	0.9 (0.33)	1.0	0.0, 1.0	-0.1 (0.24)	0.0	-1.0, 0.0	0.1605
WEEK 72	11	1.0 (0.00)	0.9 (0.30)	1.0	0.0, 1.0	-0.1 (0.30)	0.0	-1.0, 0.0	0.3409
Low dose	4	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	7	1.0 (0.00)	0.9 (0.38)	1.0	0.0, 1.0	-0.1 (0.38)	0.0	-1.0, 0.0	0.3559
POST-BASELINE MINIMUM	80	1.0 (0.16)	0.9 (0.28)	1.0	0.0, 1.0	-0.1 (0.24)	0.0	-1.0, 0.0	0.0244*
Low dose	34	1.0 (0.00)	0.9 (0.24)	1.0	0.0, 1.0	-0.1 (0.24)	0.0	-1.0, 0.0	0.1604
High dose	46	1.0 (0.21)	0.9 (0.31)	1.0	0.0, 1.0	-0.1 (0.25)	0.0	-1.0, 0.0	0.0832
POST-BASELINE MAXIMUM	80	1.0 (0.16)	0.9 (0.24)	1.0	0.0, 1.0	-0.0 (0.19)	0.0	-1.0, 0.0	0.0832
Low dose	34	1.0 (0.00)	1.0 (0.17)	1.0	0.0, 1.0	-0.0 (0.17)	0.0	-1.0, 0.0	0.3246
High dose	46	1.0 (0.21)	0.9 (0.28)	1.0	0.0, 1.0	-0.0 (0.21)	0.0	-1.0, 0.0	0.1596

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

表32　MMSEスコア（FAS，日本人部分集団）：M15-737試験

[redacted]20[redacted] 10:46 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.2__5.J

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Attention/Calculation									
BASELINE	11		4.5 (0.82)	5.0	3.0, 5.0				
Low dose	7		4.3 (0.95)	5.0	3.0, 5.0				
High dose	4		5.0 (0.00)	5.0	5.0, 5.0				
WEEK 24	7	4.7 (0.76)	4.4 (1.51)	5.0	1.0, 5.0	-0.3 (0.76)	0.0	-2.0, 0.0	0.3559
Low dose	4	4.5 (1.00)	4.0 (2.00)	5.0	1.0, 5.0	-0.5 (1.00)	0.0	-2.0, 0.0	0.3910
High dose	3	5.0 (0.00)	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 48	4	5.0 (0.00)	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	1	5.0 (N/A)	5.0 (N/A)	5.0	5.0, 5.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	3	5.0 (0.00)	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 72	2	5.0 (0.00)	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	0								
High dose	2	5.0 (0.00)	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MINIMUM	7	4.7 (0.76)	4.4 (1.51)	5.0	1.0, 5.0	-0.3 (0.76)	0.0	-2.0, 0.0	0.3559
Low dose	4	4.5 (1.00)	4.0 (2.00)	5.0	1.0, 5.0	-0.5 (1.00)	0.0	-2.0, 0.0	0.3910
High dose	3	5.0 (0.00)	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MAXIMUM	7	4.7 (0.76)	4.4 (1.51)	5.0	1.0, 5.0	-0.3 (0.76)	0.0	-2.0, 0.0	0.3559
Low dose	4	4.5 (1.00)	4.0 (2.00)	5.0	1.0, 5.0	-0.5 (1.00)	0.0	-2.0, 0.0	0.3910
High dose	3	5.0 (0.00)	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	

&: P-value is obtained from two-sided paired-sample t-test.

Program Source Code: [redacted]

TABLE 14.2 5.J

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Comprehension									
BASELINE	11		3.0 (0.00)	3.0	3.0, 3.0				
Low dose	7		3.0 (0.00)	3.0	3.0, 3.0				
High dose	4		3.0 (0.00)	3.0	3.0, 3.0				
WEEK 24	7	3.0 (0.00)	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	4	3.0 (0.00)	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	3.0 (0.00)	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 48	4	3.0 (0.00)	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	1	3.0 (N/A)	3.0 (N/A)	3.0	3.0, 3.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	3	3.0 (0.00)	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 72	2	3.0 (0.00)	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	0								
High dose	2	3.0 (0.00)	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MINIMUM	7	3.0 (0.00)	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	4	3.0 (0.00)	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	3.0 (0.00)	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MAXIMUM	7	3.0 (0.00)	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	4	3.0 (0.00)	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	3.0 (0.00)	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	

&: P-value is obtained from two-sided paired-sample t-test.

Program Source Code: [redacted]

TABLE 14.2 5.J

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Drawing									
BASELINE	11		1.0 (0.00)	1.0	1.0, 1.0				
Low dose	7		1.0 (0.00)	1.0	1.0, 1.0				
High dose	4		1.0 (0.00)	1.0	1.0, 1.0				
WEEK 24	7	1.0 (0.00)	0.9 (0.38)	1.0	0.0, 1.0	-0.1 (0.38)	0.0	-1.0, 0.0	0.3559
Low dose	4	1.0 (0.00)	0.8 (0.50)	1.0	0.0, 1.0	-0.3 (0.50)	0.0	-1.0, 0.0	0.3910
High dose	3	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 48	4	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	1	1.0 (N/A)	1.0 (N/A)	1.0	1.0, 1.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	3	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 72	2	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	0								
High dose	2	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MINIMUM	7	1.0 (0.00)	0.9 (0.38)	1.0	0.0, 1.0	-0.1 (0.38)	0.0	-1.0, 0.0	0.3559
Low dose	4	1.0 (0.00)	0.8 (0.50)	1.0	0.0, 1.0	-0.3 (0.50)	0.0	-1.0, 0.0	0.3910
High dose	3	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MAXIMUM	7	1.0 (0.00)	0.9 (0.38)	1.0	0.0, 1.0	-0.1 (0.38)	0.0	-1.0, 0.0	0.3559
Low dose	4	1.0 (0.00)	0.8 (0.50)	1.0	0.0, 1.0	-0.3 (0.50)	0.0	-1.0, 0.0	0.3910
High dose	3	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	

&: P-value is obtained from two-sided paired-sample t-test.

Program Source Code: [redacted]

TABLE 14.2 5.J

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Naming									
BASELINE	11		2.0 (0.00)	2.0	2.0, 2.0				
Low dose	7		2.0 (0.00)	2.0	2.0, 2.0				
High dose	4		2.0 (0.00)	2.0	2.0, 2.0				
WEEK 24	7	2.0 (0.00)	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	4	2.0 (0.00)	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	2.0 (0.00)	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 48	4	2.0 (0.00)	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	1	2.0 (N/A)	2.0 (N/A)	2.0	2.0, 2.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	3	2.0 (0.00)	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 72	2	2.0 (0.00)	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	0								
High dose	2	2.0 (0.00)	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MINIMUM	7	2.0 (0.00)	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	4	2.0 (0.00)	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	2.0 (0.00)	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MAXIMUM	7	2.0 (0.00)	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	4	2.0 (0.00)	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	2.0 (0.00)	2.0 (0.00)	2.0	2.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	

&: P-value is obtained from two-sided paired-sample t-test.

Program Source Code: [redacted]

TABLE 14.2 5.J

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Orientation to Place									
BASELINE	11		4.6 (0.92)	5.0	2.0, 5.0				
Low dose	7		4.6 (1.13)	5.0	2.0, 5.0				
High dose	4		4.8 (0.50)	5.0	4.0, 5.0				
WEEK 24	7	4.6 (1.13)	4.4 (1.51)	5.0	1.0, 5.0	-0.1 (0.38)	0.0	-1.0, 0.0	0.3559
Low dose	4	4.3 (1.50)	4.0 (2.00)	5.0	1.0, 5.0	-0.3 (0.50)	0.0	-1.0, 0.0	0.3910
High dose	3	5.0 (0.00)	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 48	4	5.0 (0.00)	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	1	5.0 (N/A)	5.0 (N/A)	5.0	5.0, 5.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	3	5.0 (0.00)	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 72	2	5.0 (0.00)	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	0								
High dose	2	5.0 (0.00)	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MINIMUM	7	4.6 (1.13)	4.4 (1.51)	5.0	1.0, 5.0	-0.1 (0.38)	0.0	-1.0, 0.0	0.3559
Low dose	4	4.3 (1.50)	4.0 (2.00)	5.0	1.0, 5.0	-0.3 (0.50)	0.0	-1.0, 0.0	0.3910
High dose	3	5.0 (0.00)	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MAXIMUM	7	4.6 (1.13)	4.4 (1.51)	5.0	1.0, 5.0	-0.1 (0.38)	0.0	-1.0, 0.0	0.3559
Low dose	4	4.3 (1.50)	4.0 (2.00)	5.0	1.0, 5.0	-0.3 (0.50)	0.0	-1.0, 0.0	0.3910
High dose	3	5.0 (0.00)	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	

&: P-value is obtained from two-sided paired-sample t-test.

Program Source Code: [redacted]

TABLE 14.2 5.J

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Orientation to Time									
BASELINE	11		4.5 (1.21)	5.0	2.0, 5.0				
Low dose	7		4.6 (1.13)	5.0	2.0, 5.0				
High dose	4		4.3 (1.50)	5.0	2.0, 5.0				
WEEK 24	7	4.6 (1.13)	4.3 (1.50)	5.0	1.0, 5.0	-0.3 (0.49)	0.0	-1.0, 0.0	0.1723
Low dose	4	4.3 (1.50)	3.8 (1.89)	4.5	1.0, 5.0	-0.5 (0.58)	-0.5	-1.0, 0.0	0.1817
High dose	3	5.0 (0.00)	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 48	4	5.0 (0.00)	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	1	5.0 (N/A)	5.0 (N/A)	5.0	5.0, 5.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	3	5.0 (0.00)	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 72	2	5.0 (0.00)	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	0								
High dose	2	5.0 (0.00)	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MINIMUM	7	4.6 (1.13)	4.3 (1.50)	5.0	1.0, 5.0	-0.3 (0.49)	0.0	-1.0, 0.0	0.1723
Low dose	4	4.3 (1.50)	3.8 (1.89)	4.5	1.0, 5.0	-0.5 (0.58)	-0.5	-1.0, 0.0	0.1817
High dose	3	5.0 (0.00)	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MAXIMUM	7	4.6 (1.13)	4.3 (1.50)	5.0	1.0, 5.0	-0.3 (0.49)	0.0	-1.0, 0.0	0.1723
Low dose	4	4.3 (1.50)	3.8 (1.89)	4.5	1.0, 5.0	-0.5 (0.58)	-0.5	-1.0, 0.0	0.1817
High dose	3	5.0 (0.00)	5.0 (0.00)	5.0	5.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	

&: P-value is obtained from two-sided paired-sample t-test.

Program Source Code: [redacted]

TABLE 14.2 5.J

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Reading									
BASELINE	11		1.0 (0.00)	1.0	1.0, 1.0				
Low dose	7		1.0 (0.00)	1.0	1.0, 1.0				
High dose	4		1.0 (0.00)	1.0	1.0, 1.0				
WEEK 24	7	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	4	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 48	4	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	1	1.0 (N/A)	1.0 (N/A)	1.0	1.0, 1.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	3	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 72	2	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	0								
High dose	2	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MINIMUM	7	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	4	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MAXIMUM	7	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	4	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	

&: P-value is obtained from two-sided paired-sample t-test.

Program Source Code: [redacted]

TABLE 14.2 5.J

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Recall									
BASELINE	11		2.5 (0.69)	3.0	1.0, 3.0				
Low dose	7		2.7 (0.49)	3.0	2.0, 3.0				
High dose	4		2.3 (0.96)	2.5	1.0, 3.0				
WEEK 24	7	2.6 (0.79)	2.6 (0.79)	3.0	1.0, 3.0	0.0 (1.00)	0.0	-1.0, 2.0	>0.999
Low dose	4	2.8 (0.50)	2.3 (0.96)	2.5	1.0, 3.0	-0.5 (0.58)	-0.5	-1.0, 0.0	0.1817
High dose	3	2.3 (1.15)	3.0 (0.00)	3.0	3.0, 3.0	0.7 (1.15)	0.0	0.0, 2.0	0.4226
WEEK 48	4	2.5 (1.00)	2.8 (0.50)	3.0	2.0, 3.0	0.3 (0.50)	0.0	0.0, 1.0	0.3910
Low dose	1	3.0 (N/A)	3.0 (N/A)	3.0	3.0, 3.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	3	2.3 (1.15)	2.7 (0.58)	3.0	2.0, 3.0	0.3 (0.58)	0.0	0.0, 1.0	0.4226
WEEK 72	2	2.0 (1.41)	2.0 (1.41)	2.0	1.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	0								
High dose	2	2.0 (1.41)	2.0 (1.41)	2.0	1.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MINIMUM	7	2.6 (0.79)	2.3 (0.95)	3.0	1.0, 3.0	-0.3 (0.49)	0.0	-1.0, 0.0	0.1723
Low dose	4	2.8 (0.50)	2.3 (0.96)	2.5	1.0, 3.0	-0.5 (0.58)	-0.5	-1.0, 0.0	0.1817
High dose	3	2.3 (1.15)	2.3 (1.15)	3.0	1.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MAXIMUM	7	2.6 (0.79)	2.6 (0.79)	3.0	1.0, 3.0	0.0 (1.00)	0.0	-1.0, 2.0	>0.999
Low dose	4	2.8 (0.50)	2.3 (0.96)	2.5	1.0, 3.0	-0.5 (0.58)	-0.5	-1.0, 0.0	0.1817
High dose	3	2.3 (1.15)	3.0 (0.00)	3.0	3.0, 3.0	0.7 (1.15)	0.0	0.0, 2.0	0.4226

&: P-value is obtained from two-sided paired-sample t-test.

Program Source Code: [redacted]

TABLE 14.2 5.J

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Registration									
BASELINE	11		3.0 (0.00)	3.0	3.0, 3.0				
Low dose	7		3.0 (0.00)	3.0	3.0, 3.0				
High dose	4		3.0 (0.00)	3.0	3.0, 3.0				
WEEK 24	7	3.0 (0.00)	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	4	3.0 (0.00)	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	3.0 (0.00)	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 48	4	3.0 (0.00)	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	1	3.0 (N/A)	3.0 (N/A)	3.0	3.0, 3.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	3	3.0 (0.00)	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 72	2	3.0 (0.00)	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	0								
High dose	2	3.0 (0.00)	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MINIMUM	7	3.0 (0.00)	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	4	3.0 (0.00)	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	3.0 (0.00)	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MAXIMUM	7	3.0 (0.00)	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	4	3.0 (0.00)	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	3.0 (0.00)	3.0 (0.00)	3.0	3.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	

&: P-value is obtained from two-sided paired-sample t-test.

Program Source Code: [redacted]

TABLE 14.2 5.J

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Repetition									
BASELINE	11		1.0 (0.00)	1.0	1.0, 1.0				
Low dose	7		1.0 (0.00)	1.0	1.0, 1.0				
High dose	4		1.0 (0.00)	1.0	1.0, 1.0				
WEEK 24	7	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	4	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 48	4	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	1	1.0 (N/A)	1.0 (N/A)	1.0	1.0, 1.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	3	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 72	2	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	0								
High dose	2	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MINIMUM	7	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	4	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MAXIMUM	7	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	4	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	

&: P-value is obtained from two-sided paired-sample t-test.

Program Source Code: [redacted]

TABLE 14.2 5.J

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Total									
BASELINE	11		28.2 (2.86)	30.0	21.0, 30.0				
Low dose	7		28.1 (3.29)	30.0	21.0, 30.0				
High dose	4		28.3 (2.36)	29.0	25.0, 30.0				
WEEK 24	7	28.4 (3.36)	27.6 (5.59)	30.0	15.0, 30.0	-0.9 (2.54)	0.0	-6.0, 2.0	0.4072
Low dose	4	27.8 (4.50)	25.8 (7.23)	29.0	15.0, 30.0	-2.0 (2.83)	-1.0	-6.0, 0.0	0.2522
High dose	3	29.3 (1.15)	30.0 (0.00)	30.0	30.0, 30.0	0.7 (1.15)	0.0	0.0, 2.0	0.4226
WEEK 48	4	29.5 (1.00)	29.8 (0.50)	30.0	29.0, 30.0	0.3 (0.50)	0.0	0.0, 1.0	0.3910
Low dose	1	30.0 (N/A)	30.0 (N/A)	30.0	30.0, 30.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	3	29.3 (1.15)	29.7 (0.58)	30.0	29.0, 30.0	0.3 (0.58)	0.0	0.0, 1.0	0.4226
WEEK 72	2	29.0 (1.41)	29.0 (1.41)	29.0	28.0, 30.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	0								
High dose	2	29.0 (1.41)	29.0 (1.41)	29.0	28.0, 30.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MINIMUM	7	28.4 (3.36)	27.3 (5.50)	30.0	15.0, 30.0	-1.1 (2.27)	0.0	-6.0, 0.0	0.2308
Low dose	4	27.8 (4.50)	25.8 (7.23)	29.0	15.0, 30.0	-2.0 (2.83)	-1.0	-6.0, 0.0	0.2522
High dose	3	29.3 (1.15)	29.3 (1.15)	30.0	28.0, 30.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MAXIMUM	7	28.4 (3.36)	27.6 (5.59)	30.0	15.0, 30.0	-0.9 (2.54)	0.0	-6.0, 2.0	0.4072
Low dose	4	27.8 (4.50)	25.8 (7.23)	29.0	15.0, 30.0	-2.0 (2.83)	-1.0	-6.0, 0.0	0.2522
High dose	3	29.3 (1.15)	30.0 (0.00)	30.0	30.0, 30.0	0.7 (1.15)	0.0	0.0, 2.0	0.4226

&: P-value is obtained from two-sided paired-sample t-test.

Program Source Code: [redacted]

TABLE 14.2 5.J

Change from Baseline to Each Planned Visit
in Mini-Mental State Examination (MMSE) Total Score
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MMSE - Writing									
BASELINE	11		1.0 (0.00)	1.0	1.0, 1.0				
Low dose	7		1.0 (0.00)	1.0	1.0, 1.0				
High dose	4		1.0 (0.00)	1.0	1.0, 1.0				
WEEK 24	7	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	4	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 48	4	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	1	1.0 (N/A)	1.0 (N/A)	1.0	1.0, 1.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	3	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 72	2	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	0								
High dose	2	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MINIMUM	7	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	4	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
POST-BASELINE MAXIMUM	7	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	4	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	

&: P-value is obtained from two-sided paired-sample t-test.

Program Source Code: [redacted]

表33　有害事象の概要（安全性解析対象集団）：M15-737試験

[redacted]20[redacted] 10:47 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.3__1.1

Overview of Treatment-Emergent Adverse Events and All Deaths
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=55) n (%)	High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Subjects with:			
Any TEAE	39 (70.9)	49 (80.3)	88 (75.9)
Any severe TEAE	10 (18.2)	10 (16.4)	20 (17.2)
Any TEAE that is considered associated with study drug$	27 (49.1)	33 (54.1)	60 (51.7)
Any TEAE that is considered associated with product complaint$	21 (38.2)	22 (36.1)	43 (37.1)
ABBV-951	6 (10.9)	10 (16.4)	16 (13.8)
Infusion pump	3 (5.5)	3 (4.9)	6 (5.2)
Vial adapter	0	0	0
Syringes	0	1 (1.6)	1 (0.9)
[redacted] infusion set (total)	5 (9.1)	4 (6.6)	9 (7.8)
[redacted] infusion set 6 mm	1 (1.8)	3 (4.9)	4 (3.4)
[redacted] infusion set 9 mm	4 (7.3)	1 (1.6)	5 (4.3)
Neria guard infusion set (total)	10 (18.2)	11 (18.0)	21 (18.1)
Neria guard infusion set 6 mm	7 (12.7)	4 (6.6)	11 (9.5)
Neria guard infusion set 9 mm	3 (5.5)	8 (13.1)	11 (9.5)
Any TEAE that is considered associated with loading dose$	0	0	0
Any TEAE that is considered associated with rescue dose$	0	2 (3.3)	2 (1.7)
Any TEAE that is considered associated with COVID-19 infection	1 (1.8)	6 (9.8)	7 (6.0)
Any TEAE leading to prematurely discontinuation of study drug	3 (5.5)	4 (6.6)	7 (6.0)
Any TEAE leading to death (fatal TEAE)	1 (1.8)	2 (3.3)	3 (2.6)
Any serious TEAE	14 (25.5)	12 (19.7)	26 (22.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
$ As assessed by investigator.

Program Source Code: [redacted]

TABLE 14.3 1.1

Overview of Treatment-Emergent Adverse Events and All Deaths
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=55) n (%)	High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Any SAE that is considered associated with infusion pump$	4 (7.3)	2 (3.3)	6 (5.2)
Possible	2 (3.6)	0	2 (1.7)
Probable	0	1 (1.6)	1 (0.9)
Causal relationship	2 (3.6)	1 (1.6)	3 (2.6)
Any SAE that is considered associated with neria guards infusion set$	2 (3.6)	2 (3.3)	4 (3.4)
Possible	0	1 (1.6)	1 (0.9)
Probable	2 (3.6)	0	2 (1.7)
Causal relationship	0	1 (1.6)	1 (0.9)
Any SAE that is considered associated with product complaint$	6 (10.9)	4 (6.6)	10 (8.6)
ABBV-951	2 (3.6)	3 (4.9)	5 (4.3)
Infusion pump	2 (3.6)	1 (1.6)	3 (2.6)
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	0	0	0
[redacted] infusion set 6 mm	0	0	0
[redacted] infusion set 9 mm	0	0	0
Neria guard infusion set (total)	3 (5.5)	1 (1.6)	4 (3.4)
Neria guard infusion set 6 mm	2 (3.6)	0	2 (1.7)
Neria guard infusion set 9 mm	1 (1.8)	1 (1.6)	2 (1.7)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
$ As assessed by investigator.

Program Source Code: [redacted]

TABLE 14.3 1.1

Overview of Treatment-Emergent Adverse Events and All Deaths
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=55) n (%)	High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Any AE (non-SAE) that is considered associated with infusion pump$&	2 (3.6)	3 (4.9)	5 (4.3)
Possible	2 (3.6)	2 (3.3)	4 (3.4)
Probable	0	0	0
Causal relationship	0	1 (1.6)	1 (0.9)
Any AE (non-SAE) that is considered associated with [redacted] infusion set$&	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any AE (non-SAE) that is considered associated with neria guards infusion set$&	8 (14.5)	7 (11.5)	15 (12.9)
Possible	3 (5.5)	3 (4.9)	6 (5.2)
Probable	3 (5.5)	3 (4.9)	6 (5.2)
Causal relationship	3 (5.5)	4 (6.6)	7 (6.0)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
$ As assessed by investigator.
& For subjects with AE onset date later than [redacted], 20[redacted].

Program Source Code: [redacted]

TABLE 14.3 1.1

Overview of Treatment-Emergent Adverse Events and All Deaths
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=55) n (%)	High Dose (N=61) n (%)	All Subjects (N=116) n (%)
All deaths#	1 (1.8)	2 (3.3)	3 (2.6)
All TE-deaths	1 (1.8)	2 (3.3)	3 (2.6)
Deaths related to COVID-19 infection	0	0	0
AESI: polyneuropathy (narrow)	0	0	0
AESI: weight loss	1 (1.8)	5 (8.2)	6 (5.2)
AESI: hallucinations/psychosis	8 (14.5)	8 (13.1)	16 (13.8)
AESI: somnolence	0	0	0
AESI: infusion site related infections	11 (20.0)	11 (18.0)	22 (19.0)
AESI: infusion site related non infection reactions	18 (32.7)	21 (34.4)	39 (33.6)
AESI: falls and associated injuries	8 (14.5)	15 (24.6)	23 (19.8)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Includes non treatment-emergent deaths.

Program Source Code: [redacted]

表34　すべての有害事象（安全性解析対象集団）：M15-737試験

[redacted]20[redacted] 10:48 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Any adverse event	39 (70.9)	49 (80.3)	88 (75.9)
心臓障害	3 (5.5)	1 (1.6)	4 (3.4)
急性心筋梗塞	1 (1.8)	0	1 (0.9)
徐脈	1 (1.8)	0	1 (0.9)
左脚ブロック	0	1 (1.6)	1 (0.9)
洞性頻脈	1 (1.8)	0	1 (0.9)
耳および迷路障害	0	2 (3.3)	2 (1.7)
回転性めまい	0	2 (3.3)	2 (1.7)
眼障害	1 (1.8)	3 (4.9)	4 (3.4)
眼瞼痙攣	0	1 (1.6)	1 (0.9)
眼の異物感	0	1 (1.6)	1 (0.9)
黄斑症	1 (1.8)	0	1 (0.9)
眼部不快感	0	1 (1.6)	1 (0.9)
眼充血	0	2 (3.3)	2 (1.7)
霧視	0	1 (1.6)	1 (0.9)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
胃腸障害	7 (12.7)	7 (11.5)	14 (12.1)
腹部不快感	0	1 (1.6)	1 (0.9)
腹部膨満	0	1 (1.6)	1 (0.9)
腹痛	0	1 (1.6)	1 (0.9)
便秘	3 (5.5)	2 (3.3)	5 (4.3)
出血性腸憩室	0	1 (1.6)	1 (0.9)
嚥下障害	1 (1.8)	2 (3.3)	3 (2.6)
胃潰瘍	1 (1.8)	0	1 (0.9)
胃食道逆流性疾患	1 (1.8)	0	1 (0.9)
悪心	2 (3.6)	2 (3.3)	4 (3.4)
吐き戻し	0	1 (1.6)	1 (0.9)
流涎過多	0	1 (1.6)	1 (0.9)
嘔吐	1 (1.8)	0	1 (0.9)
一般・全身障害および投与部位の状態	21 (38.2)	21 (34.4)	42 (36.2)
投与部位内出血	0	1 (1.6)	1 (0.9)
投与部位漏出	1 (1.8)	0	1 (0.9)
カテーテル留置部位内出血	1 (1.8)	2 (3.3)	3 (2.6)
カテーテル留置部位紅斑	1 (1.8)	0	1 (0.9)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
一般・全身障害および投与部位の状態 (Cont.)			
カテーテル留置部位漏出	0	1 (1.6)	1 (0.9)
カテーテル留置部位炎症	0	1 (1.6)	1 (0.9)
カテーテル留置部位疼痛	1 (1.8)	0	1 (0.9)
カテーテル留置部位腫脹	1 (1.8)	0	1 (0.9)
薬効欠如	1 (1.8)	0	1 (0.9)
薬物相互作用	1 (1.8)	0	1 (0.9)
疲労	3 (5.5)	0	3 (2.6)
注入部位内出血	2 (3.6)	3 (4.9)	5 (4.3)
注入部位皮膚炎	1 (1.8)	0	1 (0.9)
注入部位変色	0	1 (1.6)	1 (0.9)
注入部位紅斑	11 (20.0)	8 (13.1)	19 (16.4)
注入部位血管外漏出	0	2 (3.3)	2 (1.7)
注入部位血腫	1 (1.8)	1 (1.6)	2 (1.7)
注入部位硬結	1 (1.8)	2 (3.3)	3 (2.6)
注入部位炎症	0	1 (1.6)	1 (0.9)
注入部位刺激感	2 (3.6)	0	2 (1.7)
注入部位腫瘤	1 (1.8)	0	1 (0.9)
注入部位結節	2 (3.6)	3 (4.9)	5 (4.3)
注入部位浮腫	1 (1.8)	1 (1.6)	2 (1.7)
注入部位疼痛	1 (1.8)	1 (1.6)	2 (1.7)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
一般・全身障害および投与部位の状態 (Cont.)			
注入部位丘疹	1 (1.8)	3 (4.9)	4 (3.4)
注入部位異常感覚	0	1 (1.6)	1 (0.9)
注入部位発疹	0	1 (1.6)	1 (0.9)
注入部位反応	0	1 (1.6)	1 (0.9)
注入部位痂皮	0	1 (1.6)	1 (0.9)
注入部位腫脹	1 (1.8)	1 (1.6)	2 (1.7)
注入部位熱感	1 (1.8)	0	1 (0.9)
注射部位内出血	1 (1.8)	1 (1.6)	2 (1.7)
注射部位紅斑	1 (1.8)	2 (3.3)	3 (2.6)
注射部位硬結	0	1 (1.6)	1 (0.9)
注射部位炎症	0	1 (1.6)	1 (0.9)
注射部位結節	1 (1.8)	0	1 (0.9)
注射部位浮腫	0	1 (1.6)	1 (0.9)
末梢性浮腫	1 (1.8)	0	1 (0.9)
穿刺部位紅斑	1 (1.8)	0	1 (0.9)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	Dose Category High Dose (N=61) n (%)	All Subjects (N=116) n (%)
感染症および寄生虫症	15 (27.3)	19 (31.1)	34 (29.3)
ダニ皮膚炎	0	1 (1.6)	1 (0.9)
無症候性COVID-19	0	2 (3.3)	2 (1.7)
COVID-19	1 (1.8)	4 (6.6)	5 (4.3)
膀胱炎	1 (1.8)	0	1 (0.9)
大腸菌性尿路感染	0	1 (1.6)	1 (0.9)
胃腸炎	1 (1.8)	1 (1.6)	2 (1.7)
ヘリコバクター性胃炎	1 (1.8)	0	1 (0.9)
ヘリコバクター感染	1 (1.8)	0	1 (0.9)
帯状疱疹	0	1 (1.6)	1 (0.9)
注入部位膿瘍	3 (5.5)	0	3 (2.6)
注入部位蜂巣炎	6 (10.9)	10 (16.4)	16 (13.8)
注入部位感染	3 (5.5)	0	3 (2.6)
注射部位蜂巣炎	0	1 (1.6)	1 (0.9)
注射部位感染	0	1 (1.6)	1 (0.9)
上咽頭炎	1 (1.8)	1 (1.6)	2 (1.7)
口腔カンジダ症	0	1 (1.6)	1 (0.9)
RSウイルス感染	1 (1.8)	0	1 (0.9)
敗血症	0	1 (1.6)	1 (0.9)
副鼻腔炎	0	1 (1.6)	1 (0.9)
上気道感染	1 (1.8)	0	1 (0.9)
尿路感染	1 (1.8)	4 (6.6)	5 (4.3)
尿路性敗血症	0	1 (1.6)	1 (0.9)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
傷害、中毒および処置合併症	8 (14.5)	13 (21.3)	21 (18.1)
節足動物咬傷	0	1 (1.6)	1 (0.9)
節足動物刺傷	1 (1.8)	0	1 (0.9)
挫傷	0	1 (1.6)	1 (0.9)
顔面骨骨折	0	1 (1.6)	1 (0.9)
転倒	5 (9.1)	9 (14.8)	14 (12.1)
大腿骨頚部骨折	0	1 (1.6)	1 (0.9)
大腿骨骨折	1 (1.8)	0	1 (0.9)
転位骨折	0	1 (1.6)	1 (0.9)
手骨折	1 (1.8)	2 (3.3)	3 (2.6)
股関節部骨折	1 (1.8)	1 (1.6)	2 (1.7)
上腕骨骨折	1 (1.8)	1 (1.6)	2 (1.7)
靭帯捻挫	0	1 (1.6)	1 (0.9)
四肢損傷	0	1 (1.6)	1 (0.9)
肉離れ	1 (1.8)	0	1 (0.9)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
傷害、中毒および処置合併症 (Cont.)			
開放骨折	0	1 (1.6)	1 (0.9)
処置による疼痛	0	1 (1.6)	1 (0.9)
肩甲骨骨折	0	1 (1.6)	1 (0.9)
外傷性頭蓋内出血	0	1 (1.6)	1 (0.9)
臨床検査	6 (10.9)	7 (11.5)	13 (11.2)
血中葉酸減少	0	2 (3.3)	2 (1.7)
血中ホモシステイン増加	2 (3.6)	0	2 (1.7)
血中ナトリウム減少	1 (1.8)	0	1 (0.9)
ヘモグロビン減少	0	1 (1.6)	1 (0.9)
リンパ球数減少	1 (1.8)	0	1 (0.9)
プロトロンビン時間延長	0	1 (1.6)	1 (0.9)
ビタミンB12減少	1 (1.8)	1 (1.6)	2 (1.7)
ビタミンB6減少	2 (3.6)	0	2 (1.7)
ビタミンB6増加	1 (1.8)	0	1 (0.9)
ビタミンD減少	0	1 (1.6)	1 (0.9)
体重減少	0	3 (4.9)	3 (2.6)
代謝および栄養障害	4 (7.3)	5 (8.2)	9 (7.8)
食欲減退	0	1 (1.6)	1 (0.9)
高ナトリウム血症	0	1 (1.6)	1 (0.9)
低カリウム血症	1 (1.8)	1 (1.6)	2 (1.7)
低マグネシウム血症	1 (1.8)	1 (1.6)	2 (1.7)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
代謝および栄養障害 (Cont.)			
鉄欠乏	1 (1.8)	1 (1.6)	2 (1.7)
ビタミンB群欠乏	1 (1.8)	0	1 (0.9)
ビタミンB12欠乏	1 (1.8)	3 (4.9)	4 (3.4)
ビタミンB6欠乏	1 (1.8)	0	1 (0.9)
筋骨格系および結合組織障害	10 (18.2)	7 (11.5)	17 (14.7)
関節痛	0	1 (1.6)	1 (0.9)
背部痛	1 (1.8)	2 (3.3)	3 (2.6)
滑液包炎	1 (1.8)	0	1 (0.9)
出血性関節症	0	1 (1.6)	1 (0.9)
椎間板変性症	0	1 (1.6)	1 (0.9)
腰部脊柱管狭窄症	1 (1.8)	0	1 (0.9)
筋力低下	0	2 (3.3)	2 (1.7)
筋骨格系胸痛	1 (1.8)	0	1 (0.9)
筋骨格硬直	0	1 (1.6)	1 (0.9)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
筋骨格系および結合組織障害 (Cont.)			
変形性関節症	3 (5.5)	0	3 (2.6)
骨粗鬆症	2 (3.6)	0	2 (1.7)
四肢痛	2 (3.6)	0	2 (1.7)
肩回旋筋腱板症候群	2 (3.6)	0	2 (1.7)
変形性脊椎症	1 (1.8)	0	1 (0.9)
腱鞘炎	1 (1.8)	0	1 (0.9)
斜頚	1 (1.8)	0	1 (0.9)
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 (1.6)	1 (0.9)
ケラトアカントーマ	0	1 (1.6)	1 (0.9)
神経系障害	11 (20.0)	16 (26.2)	27 (23.3)
健忘	1 (1.8)	0	1 (0.9)
平衡障害	0	1 (1.6)	1 (0.9)
運動緩慢	1 (1.8)	0	1 (0.9)
認知障害	1 (1.8)	2 (3.3)	3 (2.6)
注意力障害	0	1 (1.6)	1 (0.9)
浮動性めまい	1 (1.8)	1 (1.6)	2 (1.7)
薬物離脱性頭痛	0	1 (1.6)	1 (0.9)
ジスキネジア	1 (1.8)	0	1 (0.9)
ジストニア	0	1 (1.6)	1 (0.9)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
神経系障害 (Cont.)			
伸展性足底反応	1 (1.8)	0	1 (0.9)
すくみ現象	3 (5.5)	0	3 (2.6)
頭蓋内出血	1 (1.8)	0	1 (0.9)
頭部不快感	0	2 (3.3)	2 (1.7)
頭痛	1 (1.8)	1 (1.6)	2 (1.7)
感覚鈍麻	1 (1.8)	1 (1.6)	2 (1.7)
反射減弱	1 (1.8)	1 (1.6)	2 (1.7)
記憶障害	0	2 (3.3)	2 (1.7)
オンオフ現象	2 (3.6)	5 (8.2)	7 (6.0)
錯感覚	1 (1.8)	1 (1.6)	2 (1.7)
パーキンソン病	2 (3.6)	5 (8.2)	7 (6.0)
精神運動亢進	0	1 (1.6)	1 (0.9)
呼吸器ジスキネジア	1 (1.8)	0	1 (0.9)
痙攣発作	0	1 (1.6)	1 (0.9)
失神	0	2 (3.3)	2 (1.7)
一過性脳虚血発作	0	1 (1.6)	1 (0.9)
振戦	1 (1.8)	0	1 (0.9)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
精神障害	15 (27.3)	18 (29.5)	33 (28.4)
異常な夢	0	1 (1.6)	1 (0.9)
適応障害	0	1 (1.6)	1 (0.9)
攻撃性	0	1 (1.6)	1 (0.9)
激越	0	1 (1.6)	1 (0.9)
不安	4 (7.3)	4 (6.6)	8 (6.9)
歯ぎしり	1 (1.8)	0	1 (0.9)
錯乱状態	0	1 (1.6)	1 (0.9)
譫妄	0	2 (3.3)	2 (1.7)
妄想	1 (1.8)	1 (1.6)	2 (1.7)
抑うつ気分	1 (1.8)	0	1 (0.9)
うつ病	2 (3.6)	1 (1.6)	3 (2.6)
自傷性皮膚症	0	1 (1.6)	1 (0.9)
失見当識	1 (1.8)	0	1 (0.9)
ギャンブル障害	1 (1.8)	0	1 (0.9)
幻覚	4 (7.3)	5 (8.2)	9 (7.8)
幻嗅	1 (1.8)	0	1 (0.9)
幻視	1 (1.8)	1 (1.6)	2 (1.7)
軽躁	1 (1.8)	0	1 (0.9)
錯覚	1 (1.8)	1 (1.6)	2 (1.7)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
精神障害 (Cont.)			
衝動制御障害	0	1 (1.6)	1 (0.9)
衝動行為	1 (1.8)	0	1 (0.9)
不眠症	1 (1.8)	1 (1.6)	2 (1.7)
消極的思考	1 (1.8)	0	1 (0.9)
パニック発作	1 (1.8)	1 (1.6)	2 (1.7)
妄想症	1 (1.8)	0	1 (0.9)
精神病性障害	1 (1.8)	1 (1.6)	2 (1.7)
レム睡眠行動障害	1 (1.8)	0	1 (0.9)
睡眠障害	0	1 (1.6)	1 (0.9)
腎および尿路障害	3 (5.5)	4 (6.6)	7 (6.0)
急性腎障害	0	1 (1.6)	1 (0.9)
膀胱痙縮	1 (1.8)	0	1 (0.9)
血尿	0	1 (1.6)	1 (0.9)
水腎症	0	1 (1.6)	1 (0.9)
水尿管症	0	1 (1.6)	1 (0.9)
緊張性膀胱	1 (1.8)	0	1 (0.9)
腎結石症	0	1 (1.6)	1 (0.9)
蛋白尿	0	1 (1.6)	1 (0.9)
尿失禁	1 (1.8)	0	1 (0.9)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	Dose Category High Dose (N=61) n (%)	All Subjects (N=116) n (%)
生殖系および乳房障害	2 (3.6)	3 (4.9)	5 (4.3)
良性前立腺肥大症	1 (1.8)	0	1 (0.9)
膀胱瘤	0	1 (1.6)	1 (0.9)
勃起不全	0	1 (1.6)	1 (0.9)
生殖器萎縮	0	1 (1.6)	1 (0.9)
腟脱	0	1 (1.6)	1 (0.9)
外陰腟乾燥	1 (1.8)	0	1 (0.9)
呼吸器、胸郭および縦隔障害	2 (3.6)	1 (1.6)	3 (2.6)
窒息	1 (1.8)	0	1 (0.9)
誤嚥	1 (1.8)	0	1 (0.9)
呼吸困難	1 (1.8)	0	1 (0.9)
痰貯留	0	1 (1.6)	1 (0.9)
皮膚および皮下組織障害	4 (7.3)	1 (1.6)	5 (4.3)
光線角化症	1 (1.8)	0	1 (0.9)
脱毛症	1 (1.8)	0	1 (0.9)
湿疹	1 (1.8)	1 (1.6)	2 (1.7)
発疹	1 (1.8)	0	1 (0.9)
蕁麻疹	1 (1.8)	0	1 (0.9)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
血管障害	3 (5.5)	6 (9.8)	9 (7.8)
血腫	1 (1.8)	0	1 (0.9)
高血圧	0	1 (1.6)	1 (0.9)
低血圧	1 (1.8)	1 (1.6)	2 (1.7)
起立性高血圧	0	1 (1.6)	1 (0.9)
起立性低血圧	1 (1.8)	2 (3.3)	3 (2.6)
表在性血栓性静脈炎	0	1 (1.6)	1 (0.9)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

表35　治験薬との因果関係別の有害事象（安全性解析対象集団）：M15-737試験

[redacted]20[redacted] 10:48 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.3__1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	Dose Category High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Any adverse event	39 (70.9)	49 (80.3)	88 (75.9)
No reasonable possibility	12 (21.8)	16 (26.2)	28 (24.1)
Reasonable possibility	27 (49.1)	33 (54.1)	60 (51.7)
心臓障害	3 (5.5)	1 (1.6)	4 (3.4)
No reasonable possibility	3 (5.5)	1 (1.6)	4 (3.4)
急性心筋梗塞	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
徐脈	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
左脚ブロック	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
心臓障害 (Cont.)			
洞性頻脈	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
耳および迷路障害	0	2 (3.3)	2 (1.7)
No reasonable possibility	0	2 (3.3)	2 (1.7)
回転性めまい	0	2 (3.3)	2 (1.7)
No reasonable possibility	0	2 (3.3)	2 (1.7)
眼障害	1 (1.8)	3 (4.9)	4 (3.4)
No reasonable possibility	1 (1.8)	2 (3.3)	3 (2.6)
Reasonable possibility	0	1 (1.6)	1 (0.9)
眼瞼痙攣	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
眼障害 (Cont.)			
眼の異物感	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
黄斑症	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
眼部不快感	0	1 (1.6)	1 (0.9)
Reasonable possibility	0	1 (1.6)	1 (0.9)
眼充血	0	2 (3.3)	2 (1.7)
No reasonable possibility	0	2 (3.3)	2 (1.7)
霧視	0	1 (1.6)	1 (0.9)
Reasonable possibility	0	1 (1.6)	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
胃腸障害	7 (12.7)	7 (11.5)	14 (12.1)
No reasonable possibility	7 (12.7)	4 (6.6)	11 (9.5)
Reasonable possibility	0	3 (4.9)	3 (2.6)
腹部不快感	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
腹部膨満	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
腹痛	0	1 (1.6)	1 (0.9)
Reasonable possibility	0	1 (1.6)	1 (0.9)
便秘	3 (5.5)	2 (3.3)	5 (4.3)
No reasonable possibility	3 (5.5)	1 (1.6)	4 (3.4)
Reasonable possibility	0	1 (1.6)	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
胃腸障害 (Cont.)			
出血性腸憩室	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
嚥下障害	1 (1.8)	2 (3.3)	3 (2.6)
No reasonable possibility	1 (1.8)	2 (3.3)	3 (2.6)
胃潰瘍	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
胃食道逆流性疾患	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
悪心	2 (3.6)	2 (3.3)	4 (3.4)
No reasonable possibility	2 (3.6)	1 (1.6)	3 (2.6)
Reasonable possibility	0	1 (1.6)	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
胃腸障害 (Cont.)			
吐き戻し	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
流涎過多	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
嘔吐	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
一般・全身障害および投与部位の状態	21 (38.2)	21 (34.4)	42 (36.2)
No reasonable possibility	4 (7.3)	1 (1.6)	5 (4.3)
Reasonable possibility	17 (30.9)	20 (32.8)	37 (31.9)
投与部位内出血	0	1 (1.6)	1 (0.9)
Reasonable possibility	0	1 (1.6)	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
一般・全身障害および投与部位の状態 (Cont.)			
投与部位漏出	1 (1.8)	0	1 (0.9)
Reasonable possibility	1 (1.8)	0	1 (0.9)
カテーテル留置部位内出血	1 (1.8)	2 (3.3)	3 (2.6)
Reasonable possibility	1 (1.8)	2 (3.3)	3 (2.6)
カテーテル留置部位紅斑	1 (1.8)	0	1 (0.9)
Reasonable possibility	1 (1.8)	0	1 (0.9)
カテーテル留置部位漏出	0	1 (1.6)	1 (0.9)
Reasonable possibility	0	1 (1.6)	1 (0.9)
カテーテル留置部位炎症	0	1 (1.6)	1 (0.9)
Reasonable possibility	0	1 (1.6)	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
一般・全身障害および投与部位の状態 (Cont.)			
カテーテル留置部位疼痛	1 (1.8)	0	1 (0.9)
Reasonable possibility	1 (1.8)	0	1 (0.9)
カテーテル留置部位腫脹	1 (1.8)	0	1 (0.9)
Reasonable possibility	1 (1.8)	0	1 (0.9)
薬効欠如	1 (1.8)	0	1 (0.9)
Reasonable possibility	1 (1.8)	0	1 (0.9)
薬物相互作用	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
疲労	3 (5.5)	0	3 (2.6)
No reasonable possibility	3 (5.5)	0	3 (2.6)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
一般・全身障害および投与部位の状態 (Cont.)			
注入部位内出血	2 (3.6)	3 (4.9)	5 (4.3)
Reasonable possibility	2 (3.6)	3 (4.9)	5 (4.3)
注入部位皮膚炎	1 (1.8)	0	1 (0.9)
Reasonable possibility	1 (1.8)	0	1 (0.9)
注入部位変色	0	1 (1.6)	1 (0.9)
Reasonable possibility	0	1 (1.6)	1 (0.9)
注入部位紅斑	11 (20.0)	8 (13.1)	19 (16.4)
No reasonable possibility	2 (3.6)	1 (1.6)	3 (2.6)
Reasonable possibility	9 (16.4)	7 (11.5)	16 (13.8)
注入部位血管外漏出	0	2 (3.3)	2 (1.7)
Reasonable possibility	0	2 (3.3)	2 (1.7)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
一般・全身障害および投与部位の状態 (Cont.)			
注入部位血腫	1 (1.8)	1 (1.6)	2 (1.7)
Reasonable possibility	1 (1.8)	1 (1.6)	2 (1.7)
注入部位硬結	1 (1.8)	2 (3.3)	3 (2.6)
Reasonable possibility	1 (1.8)	2 (3.3)	3 (2.6)
注入部位炎症	0	1 (1.6)	1 (0.9)
Reasonable possibility	0	1 (1.6)	1 (0.9)
注入部位刺激感	2 (3.6)	0	2 (1.7)
Reasonable possibility	2 (3.6)	0	2 (1.7)
注入部位腫瘤	1 (1.8)	0	1 (0.9)
Reasonable possibility	1 (1.8)	0	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
一般・全身障害および投与部位の状態 (Cont.)			
注入部位結節	2 (3.6)	3 (4.9)	5 (4.3)
Reasonable possibility	2 (3.6)	3 (4.9)	5 (4.3)
注入部位浮腫	1 (1.8)	1 (1.6)	2 (1.7)
Reasonable possibility	1 (1.8)	1 (1.6)	2 (1.7)
注入部位疼痛	1 (1.8)	1 (1.6)	2 (1.7)
Reasonable possibility	1 (1.8)	1 (1.6)	2 (1.7)
注入部位丘疹	1 (1.8)	3 (4.9)	4 (3.4)
Reasonable possibility	1 (1.8)	3 (4.9)	4 (3.4)
注入部位異常感覚	0	1 (1.6)	1 (0.9)
Reasonable possibility	0	1 (1.6)	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
一般・全身障害および投与部位の状態 (Cont.)			
注入部位発疹	0	1 (1.6)	1 (0.9)
Reasonable possibility	0	1 (1.6)	1 (0.9)
注入部位反応	0	1 (1.6)	1 (0.9)
Reasonable possibility	0	1 (1.6)	1 (0.9)
注入部位痂皮	0	1 (1.6)	1 (0.9)
Reasonable possibility	0	1 (1.6)	1 (0.9)
注入部位腫脹	1 (1.8)	1 (1.6)	2 (1.7)
Reasonable possibility	1 (1.8)	1 (1.6)	2 (1.7)
注入部位熱感	1 (1.8)	0	1 (0.9)
Reasonable possibility	1 (1.8)	0	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
一般・全身障害および投与部位の状態 (Cont.)			
注射部位内出血	1 (1.8)	1 (1.6)	2 (1.7)
Reasonable possibility	1 (1.8)	1 (1.6)	2 (1.7)
注射部位紅斑	1 (1.8)	2 (3.3)	3 (2.6)
Reasonable possibility	1 (1.8)	2 (3.3)	3 (2.6)
注射部位硬結	0	1 (1.6)	1 (0.9)
Reasonable possibility	0	1 (1.6)	1 (0.9)
注射部位炎症	0	1 (1.6)	1 (0.9)
Reasonable possibility	0	1 (1.6)	1 (0.9)
注射部位結節	1 (1.8)	0	1 (0.9)
Reasonable possibility	1 (1.8)	0	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
一般・全身障害および投与部位の状態 (Cont.)			
注射部位浮腫	0	1 (1.6)	1 (0.9)
Reasonable possibility	0	1 (1.6)	1 (0.9)
末梢性浮腫	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
穿刺部位紅斑	1 (1.8)	0	1 (0.9)
Reasonable possibility	1 (1.8)	0	1 (0.9)
感染症および寄生虫症	15 (27.3)	19 (31.1)	34 (29.3)
No reasonable possibility	6 (10.9)	8 (13.1)	14 (12.1)
Reasonable possibility	9 (16.4)	11 (18.0)	20 (17.2)
ダニ皮膚炎	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
感染症および寄生虫症 (Cont.)			
無症候性COVID-19	0	2 (3.3)	2 (1.7)
No reasonable possibility	0	2 (3.3)	2 (1.7)
COVID-19	1 (1.8)	4 (6.6)	5 (4.3)
No reasonable possibility	1 (1.8)	4 (6.6)	5 (4.3)
膀胱炎	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
大腸菌性尿路感染	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
胃腸炎	1 (1.8)	1 (1.6)	2 (1.7)
No reasonable possibility	1 (1.8)	1 (1.6)	2 (1.7)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
感染症および寄生虫症 (Cont.)			
ヘリコバクター性胃炎	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
ヘリコバクター感染	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
帯状疱疹	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
注入部位膿瘍	3 (5.5)	0	3 (2.6)
Reasonable possibility	3 (5.5)	0	3 (2.6)
注入部位蜂巣炎	6 (10.9)	10 (16.4)	16 (13.8)
No reasonable possibility	1 (1.8)	0	1 (0.9)
Reasonable possibility	5 (9.1)	10 (16.4)	15 (12.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
感染症および寄生虫症 (Cont.)			
注入部位感染	3 (5.5)	0	3 (2.6)
No reasonable possibility	1 (1.8)	0	1 (0.9)
Reasonable possibility	2 (3.6)	0	2 (1.7)
注射部位蜂巣炎	0	1 (1.6)	1 (0.9)
Reasonable possibility	0	1 (1.6)	1 (0.9)
注射部位感染	0	1 (1.6)	1 (0.9)
Reasonable possibility	0	1 (1.6)	1 (0.9)
上咽頭炎	1 (1.8)	1 (1.6)	2 (1.7)
No reasonable possibility	1 (1.8)	1 (1.6)	2 (1.7)
口腔カンジダ症	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
感染症および寄生虫症 (Cont.)			
RSウイルス感染	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
敗血症	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
副鼻腔炎	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
上気道感染	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
尿路感染	1 (1.8)	4 (6.6)	5 (4.3)
No reasonable possibility	1 (1.8)	4 (6.6)	5 (4.3)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
感染症および寄生虫症 (Cont.)			
尿路性敗血症	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
傷害、中毒および処置合併症	8 (14.5)	13 (21.3)	21 (18.1)
No reasonable possibility	8 (14.5)	11 (18.0)	19 (16.4)
Reasonable possibility	0	2 (3.3)	2 (1.7)
節足動物咬傷	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
節足動物刺傷	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
挫傷	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
傷害、中毒および処置合併症 (Cont.)			
顔面骨骨折	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
転倒	5 (9.1)	9 (14.8)	14 (12.1)
No reasonable possibility	5 (9.1)	8 (13.1)	13 (11.2)
Reasonable possibility	0	1 (1.6)	1 (0.9)
大腿骨頚部骨折	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
大腿骨骨折	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
転位骨折	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	Dose Category High Dose (N=61) n (%)	All Subjects (N=116) n (%)
傷害、中毒および処置合併症 (Cont.)			
手骨折	1 (1.8)	2 (3.3)	3 (2.6)
No reasonable possibility	1 (1.8)	2 (3.3)	3 (2.6)
股関節部骨折	1 (1.8)	1 (1.6)	2 (1.7)
No reasonable possibility	1 (1.8)	1 (1.6)	2 (1.7)
上腕骨骨折	1 (1.8)	1 (1.6)	2 (1.7)
No reasonable possibility	1 (1.8)	1 (1.6)	2 (1.7)
靭帯捻挫	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
四肢損傷	0	1 (1.6)	1 (0.9)
Reasonable possibility	0	1 (1.6)	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
傷害、中毒および処置合併症 (Cont.)			
肉離れ	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
開放骨折	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
処置による疼痛	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
肩甲骨骨折	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
外傷性頭蓋内出血	0	1 (1.6)	1 (0.9)
Reasonable possibility	0	1 (1.6)	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
臨床検査	6 (10.9)	7 (11.5)	13 (11.2)
No reasonable possibility	3 (5.5)	4 (6.6)	7 (6.0)
Reasonable possibility	3 (5.5)	3 (4.9)	6 (5.2)
血中葉酸減少	0	2 (3.3)	2 (1.7)
No reasonable possibility	0	1 (1.6)	1 (0.9)
Reasonable possibility	0	1 (1.6)	1 (0.9)
血中ホモシステイン増加	2 (3.6)	0	2 (1.7)
Reasonable possibility	2 (3.6)	0	2 (1.7)
血中ナトリウム減少	1 (1.8)	0	1 (0.9)
Reasonable possibility	1 (1.8)	0	1 (0.9)
ヘモグロビン減少	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
臨床検査 (Cont.)			
リンパ球数減少	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
プロトロンビン時間延長	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
ビタミンB12減少	1 (1.8)	1 (1.6)	2 (1.7)
No reasonable possibility	0	1 (1.6)	1 (0.9)
Reasonable possibility	1 (1.8)	0	1 (0.9)
ビタミンB6減少	2 (3.6)	0	2 (1.7)
No reasonable possibility	1 (1.8)	0	1 (0.9)
Reasonable possibility	1 (1.8)	0	1 (0.9)
ビタミンB6増加	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
臨床検査 (Cont.)			
ビタミンD減少	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
体重減少	0	3 (4.9)	3 (2.6)
No reasonable possibility	0	1 (1.6)	1 (0.9)
Reasonable possibility	0	2 (3.3)	2 (1.7)
代謝および栄養障害	4 (7.3)	5 (8.2)	9 (7.8)
No reasonable possibility	2 (3.6)	2 (3.3)	4 (3.4)
Reasonable possibility	2 (3.6)	3 (4.9)	5 (4.3)
食欲減退	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
高ナトリウム血症	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
代謝および栄養障害 (Cont.)			
低カリウム血症	1 (1.8)	1 (1.6)	2 (1.7)
No reasonable possibility	1 (1.8)	1 (1.6)	2 (1.7)
低マグネシウム血症	1 (1.8)	1 (1.6)	2 (1.7)
No reasonable possibility	1 (1.8)	1 (1.6)	2 (1.7)
鉄欠乏	1 (1.8)	1 (1.6)	2 (1.7)
No reasonable possibility	1 (1.8)	1 (1.6)	2 (1.7)
ビタミンB群欠乏	1 (1.8)	0	1 (0.9)
Reasonable possibility	1 (1.8)	0	1 (0.9)
ビタミンB12欠乏	1 (1.8)	3 (4.9)	4 (3.4)
No reasonable possibility	1 (1.8)	0	1 (0.9)
Reasonable possibility	0	3 (4.9)	3 (2.6)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
代謝および栄養障害 (Cont.)			
ビタミンB6欠乏	1 (1.8)	0	1 (0.9)
Reasonable possibility	1 (1.8)	0	1 (0.9)
筋骨格系および結合組織障害	10 (18.2)	7 (11.5)	17 (14.7)
No reasonable possibility	10 (18.2)	6 (9.8)	16 (13.8)
Reasonable possibility	0	1 (1.6)	1 (0.9)
関節痛	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
背部痛	1 (1.8)	2 (3.3)	3 (2.6)
No reasonable possibility	1 (1.8)	2 (3.3)	3 (2.6)
滑液包炎	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
筋骨格系および結合組織障害 (Cont.)			
出血性関節症	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
椎間板変性症	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
腰部脊柱管狭窄症	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
筋力低下	0	2 (3.3)	2 (1.7)
No reasonable possibility	0	2 (3.3)	2 (1.7)
筋骨格系胸痛	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
筋骨格系および結合組織障害 (Cont.)			
筋骨格硬直	0	1 (1.6)	1 (0.9)
Reasonable possibility	0	1 (1.6)	1 (0.9)
変形性関節症	3 (5.5)	0	3 (2.6)
No reasonable possibility	3 (5.5)	0	3 (2.6)
骨粗鬆症	2 (3.6)	0	2 (1.7)
No reasonable possibility	2 (3.6)	0	2 (1.7)
四肢痛	2 (3.6)	0	2 (1.7)
No reasonable possibility	2 (3.6)	0	2 (1.7)
肩回旋筋腱板症候群	2 (3.6)	0	2 (1.7)
No reasonable possibility	2 (3.6)	0	2 (1.7)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
筋骨格系および結合組織障害 (Cont.)			
変形性脊椎症	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
腱鞘炎	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
斜頚	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
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 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
ケラトアカントーマ	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
神経系障害	11 (20.0)	16 (26.2)	27 (23.3)
No reasonable possibility	6 (10.9)	8 (13.1)	14 (12.1)
Reasonable possibility	5 (9.1)	8 (13.1)	13 (11.2)
健忘	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
平衡障害	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
運動緩慢	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
認知障害	1 (1.8)	2 (3.3)	3 (2.6)
No reasonable possibility	1 (1.8)	1 (1.6)	2 (1.7)
Reasonable possibility	0	1 (1.6)	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
神経系障害 (Cont.)			
注意力障害	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
浮動性めまい	1 (1.8)	1 (1.6)	2 (1.7)
No reasonable possibility	0	1 (1.6)	1 (0.9)
Reasonable possibility	1 (1.8)	0	1 (0.9)
薬物離脱性頭痛	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
ジスキネジア	1 (1.8)	0	1 (0.9)
Reasonable possibility	1 (1.8)	0	1 (0.9)
ジストニア	0	1 (1.6)	1 (0.9)
Reasonable possibility	0	1 (1.6)	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
神経系障害 (Cont.)			
伸展性足底反応	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
すくみ現象	3 (5.5)	0	3 (2.6)
No reasonable possibility	3 (5.5)	0	3 (2.6)
頭蓋内出血	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
頭部不快感	0	2 (3.3)	2 (1.7)
Reasonable possibility	0	2 (3.3)	2 (1.7)
頭痛	1 (1.8)	1 (1.6)	2 (1.7)
No reasonable possibility	1 (1.8)	1 (1.6)	2 (1.7)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
神経系障害 (Cont.)			
感覚鈍麻	1 (1.8)	1 (1.6)	2 (1.7)
No reasonable possibility	1 (1.8)	1 (1.6)	2 (1.7)
反射減弱	1 (1.8)	1 (1.6)	2 (1.7)
No reasonable possibility	1 (1.8)	1 (1.6)	2 (1.7)
記憶障害	0	2 (3.3)	2 (1.7)
No reasonable possibility	0	2 (3.3)	2 (1.7)
オンオフ現象	2 (3.6)	5 (8.2)	7 (6.0)
Reasonable possibility	2 (3.6)	5 (8.2)	7 (6.0)
錯感覚	1 (1.8)	1 (1.6)	2 (1.7)
No reasonable possibility	0	1 (1.6)	1 (0.9)
Reasonable possibility	1 (1.8)	0	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
神経系障害 (Cont.)			
パーキンソン病	2 (3.6)	5 (8.2)	7 (6.0)
No reasonable possibility	1 (1.8)	2 (3.3)	3 (2.6)
Reasonable possibility	1 (1.8)	3 (4.9)	4 (3.4)
精神運動亢進	0	1 (1.6)	1 (0.9)
Reasonable possibility	0	1 (1.6)	1 (0.9)
呼吸器ジスキネジア	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
痙攣発作	0	1 (1.6)	1 (0.9)
Reasonable possibility	0	1 (1.6)	1 (0.9)
失神	0	2 (3.3)	2 (1.7)
No reasonable possibility	0	1 (1.6)	1 (0.9)
Reasonable possibility	0	1 (1.6)	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
神経系障害 (Cont.)			
一過性脳虚血発作	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
振戦	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
精神障害	15 (27.3)	18 (29.5)	33 (28.4)
No reasonable possibility	6 (10.9)	8 (13.1)	14 (12.1)
Reasonable possibility	9 (16.4)	10 (16.4)	19 (16.4)
異常な夢	0	1 (1.6)	1 (0.9)
Reasonable possibility	0	1 (1.6)	1 (0.9)
適応障害	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
精神障害 (Cont.)			
攻撃性	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
激越	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
不安	4 (7.3)	4 (6.6)	8 (6.9)
No reasonable possibility	3 (5.5)	3 (4.9)	6 (5.2)
Reasonable possibility	1 (1.8)	1 (1.6)	2 (1.7)
歯ぎしり	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
錯乱状態	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
精神障害 (Cont.)			
譫妄	0	2 (3.3)	2 (1.7)
No reasonable possibility	0	1 (1.6)	1 (0.9)
Reasonable possibility	0	1 (1.6)	1 (0.9)
妄想	1 (1.8)	1 (1.6)	2 (1.7)
No reasonable possibility	1 (1.8)	0	1 (0.9)
Reasonable possibility	0	1 (1.6)	1 (0.9)
抑うつ気分	1 (1.8)	0	1 (0.9)
Reasonable possibility	1 (1.8)	0	1 (0.9)
うつ病	2 (3.6)	1 (1.6)	3 (2.6)
No reasonable possibility	2 (3.6)	1 (1.6)	3 (2.6)
自傷性皮膚症	0	1 (1.6)	1 (0.9)
Reasonable possibility	0	1 (1.6)	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
精神障害 (Cont.)			
失見当識	1 (1.8)	0	1 (0.9)
Reasonable possibility	1 (1.8)	0	1 (0.9)
ギャンブル障害	1 (1.8)	0	1 (0.9)
Reasonable possibility	1 (1.8)	0	1 (0.9)
幻覚	4 (7.3)	5 (8.2)	9 (7.8)
No reasonable possibility	1 (1.8)	3 (4.9)	4 (3.4)
Reasonable possibility	3 (5.5)	2 (3.3)	5 (4.3)
幻嗅	1 (1.8)	0	1 (0.9)
Reasonable possibility	1 (1.8)	0	1 (0.9)
幻視	1 (1.8)	1 (1.6)	2 (1.7)
Reasonable possibility	1 (1.8)	1 (1.6)	2 (1.7)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
精神障害 (Cont.)			
軽躁	1 (1.8)	0	1 (0.9)
Reasonable possibility	1 (1.8)	0	1 (0.9)
錯覚	1 (1.8)	1 (1.6)	2 (1.7)
Reasonable possibility	1 (1.8)	1 (1.6)	2 (1.7)
衝動制御障害	0	1 (1.6)	1 (0.9)
Reasonable possibility	0	1 (1.6)	1 (0.9)
衝動行為	1 (1.8)	0	1 (0.9)
Reasonable possibility	1 (1.8)	0	1 (0.9)
不眠症	1 (1.8)	1 (1.6)	2 (1.7)
No reasonable possibility	1 (1.8)	1 (1.6)	2 (1.7)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
精神障害 (Cont.)			
消極的思考	1 (1.8)	0	1 (0.9)
Reasonable possibility	1 (1.8)	0	1 (0.9)
パニック発作	1 (1.8)	1 (1.6)	2 (1.7)
No reasonable possibility	1 (1.8)	0	1 (0.9)
Reasonable possibility	0	1 (1.6)	1 (0.9)
妄想症	1 (1.8)	0	1 (0.9)
Reasonable possibility	1 (1.8)	0	1 (0.9)
精神病性障害	1 (1.8)	1 (1.6)	2 (1.7)
Reasonable possibility	1 (1.8)	1 (1.6)	2 (1.7)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
精神障害 (Cont.)			
レム睡眠行動障害	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
睡眠障害	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
腎および尿路障害	3 (5.5)	4 (6.6)	7 (6.0)
No reasonable possibility	3 (5.5)	4 (6.6)	7 (6.0)
急性腎障害	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
膀胱痙縮	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
腎および尿路障害 (Cont.)			
血尿	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
水腎症	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
水尿管症	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
緊張性膀胱	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
腎結石症	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
腎および尿路障害 (Cont.)			
蛋白尿	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
尿失禁	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
生殖系および乳房障害	2 (3.6)	3 (4.9)	5 (4.3)
No reasonable possibility	2 (3.6)	3 (4.9)	5 (4.3)
良性前立腺肥大症	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
膀胱癌	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
生殖系および乳房障害 (Cont.)			
勃起不全	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
生殖器萎縮	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
腟脱	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
外陰腟乾燥	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
呼吸器、胸郭および縦隔障害	2 (3.6)	1 (1.6)	3 (2.6)
No reasonable possibility	2 (3.6)	1 (1.6)	3 (2.6)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)			
窒息	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
誤嚥	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
呼吸困難	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
痰貯留	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
皮膚および皮下組織障害	4 (7.3)	1 (1.6)	5 (4.3)
No reasonable possibility	3 (5.5)	1 (1.6)	4 (3.4)
Reasonable possibility	1 (1.8)	0	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
皮膚および皮下組織障害 (Cont.)			
光線角化症	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
脱毛症	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
湿疹	1 (1.8)	1 (1.6)	2 (1.7)
No reasonable possibility	0	1 (1.6)	1 (0.9)
Reasonable possibility	1 (1.8)	0	1 (0.9)
発疹	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
蕁麻疹	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	Dose Category High Dose (N=61) n (%)	All Subjects (N=116) n (%)
血管障害	3 (5.5)	6 (9.8)	9 (7.8)
No reasonable possibility	3 (5.5)	4 (6.6)	7 (6.0)
Reasonable possibility	0	2 (3.3)	2 (1.7)
血腫	1 (1.8)	0	1 (0.9)
No reasonable possibility	1 (1.8)	0	1 (0.9)
高血圧	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)
低血圧	1 (1.8)	1 (1.6)	2 (1.7)
No reasonable possibility	1 (1.8)	1 (1.6)	2 (1.7)
起立性高血圧	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)

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.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
血管障害 (Cont.)			
起立性低血圧	1 (1.8)	2 (3.3)	3 (2.6)
No reasonable possibility	1 (1.8)	0	1 (0.9)
Reasonable possibility	0	2 (3.3)	2 (1.7)
表在性血栓性静脈炎	0	1 (1.6)	1 (0.9)
No reasonable possibility	0	1 (1.6)	1 (0.9)

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.

Program Source Code: [redacted]

表36　死亡した被験者一覧：M15-737試験

[redacted]20[redacted] 10:47 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.3__2.1

Listing of All Deaths
(All Screened Subjects)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 HIGH DOSE								
[redacted]# Age: 8[redacted] Sex: Male Race: WHITE Weight: 5[redacted].[redacted] kg								
	TRT	1 TO 174	174	174	R: END STAGE PARKINSON DISEASE S: 神経系障害 P: パーキンソン病 L: End stage Parkinson's disease	E: 174 L: 1 Day	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DRUG WITHDRAWN O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED	S: Yes, Death of subject R: NOT RELATED O: CARDIO RESPIRATORY FAILURE A: NO REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.1

Listing of All Deaths
(All Screened Subjects)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted]# Age: 7[redacted] Sex: Female Race: ASIAN Weight: 4[redacted].[redacted] kg								
	TRT	1 TO 243	243	243	R: DUE TO ASPIRATION S: 呼吸器、胸郭および縦隔障害 P: 誤嚥 L: Aspiration	E: 243 L: 1 Day	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DRUG WITHDRAWN O: NONE	S: Yes, Death of subject R: NOT RELATED O: ASPIRATION ACCIDENTALLY A: NO REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.1

Listing of All Deaths
(All Screened Subjects)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	Day	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE									
[redacted]# Age: 7[redacted] Sex: Female Race: ASIAN Weight: 4[redacted].[redacted] kg									
	TRT	1 TO 243	243	243		R: SUFFOCATION S: 呼吸器、胸郭および縦隔障害 P: 窒息 L: Suffocation	E: 243 L: 1 Day	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DRUG WITHDRAWN O: NONE	S: Yes, Death of subject R: NOT RELATED O: ASPIRATION ACCIDENTALLY A: NO REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.1

Listing of All Deaths
(All Screened Subjects)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 HIGH DOSE [redacted]# Age: 7[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg								
	TRT	1 TO 234	232	232	R: END STAGE PARKINSON'S DISEASE S: 神経系障害 P: パーキンソン病 L: End stage Parkinson's disease	E: 234 L: 3 Days	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DRUG WITHDRAWN O: MULTIPLE: (CONCOMITANT MEDICATION OR THERAPY DISCONTINUED; Other: SUBJECT WAS PLACED ON HOSPICE AND DIED AT HOME ON [redacted] 20[redacted]; CONCOMITANT MEDICATION OR THERAPY STARTED)	S: Yes, Death of subject R: NOT RELATED O: PROGRESSION OF HER PARKINSON'S TO DEATH A: NO REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

表37　重篤な有害事象（安全性解析対象集団）：M15-737試験

[redacted]20[redacted] 10:48 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.3__1.11.1

Subjects with Treatment-Emergent Serious Adverse Events
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Any adverse event	14 (25.5)	12 (19.7)	26 (22.4)
心臓障害	1 (1.8)	0	1 (0.9)
急性心筋梗塞	1 (1.8)	0	1 (0.9)
胃腸障害	0	2 (3.3)	2 (1.7)
出血性腸憩室	0	1 (1.6)	1 (0.9)
嚥下障害	0	1 (1.6)	1 (0.9)
感染症および寄生虫症	5 (9.1)	4 (6.6)	9 (7.8)
無症候性COVID-19	0	1 (1.6)	1 (0.9)
COVID-19	1 (1.8)	0	1 (0.9)
胃腸炎	0	1 (1.6)	1 (0.9)
注入部位膿瘍	1 (1.8)	0	1 (0.9)
注入部位蜂巣炎	3 (5.5)	2 (3.3)	5 (4.3)
敗血症	0	1 (1.6)	1 (0.9)
尿路感染	0	1 (1.6)	1 (0.9)
尿路性敗血症	0	1 (1.6)	1 (0.9)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.11.1

Subjects with Treatment-Emergent Serious Adverse Events
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
傷害、中毒および処置合併症	3 (5.5)	5 (8.2)	8 (6.9)
転倒	2 (3.6)	1 (1.6)	3 (2.6)
大腿骨頚部骨折	0	1 (1.6)	1 (0.9)
大腿骨骨折	1 (1.8)	0	1 (0.9)
転位骨折	0	1 (1.6)	1 (0.9)
股関節部骨折	1 (1.8)	1 (1.6)	2 (1.7)
上腕骨骨折	1 (1.8)	0	1 (0.9)
処置による疼痛	0	1 (1.6)	1 (0.9)
肩甲骨骨折	0	1 (1.6)	1 (0.9)
外傷性頭蓋内出血	0	1 (1.6)	1 (0.9)
臨床検査	0	1 (1.6)	1 (0.9)
ヘモグロビン減少	0	1 (1.6)	1 (0.9)
代謝および栄養障害	0	1 (1.6)	1 (0.9)
高ナトリウム血症	0	1 (1.6)	1 (0.9)
筋骨格系および結合組織障害	5 (9.1)	0	5 (4.3)
滑液包炎	1 (1.8)	0	1 (0.9)
筋骨格系胸痛	1 (1.8)	0	1 (0.9)
変形性関節症	2 (3.6)	0	2 (1.7)
四肢痛	1 (1.8)	0	1 (0.9)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.11.1

Subjects with Treatment-Emergent Serious Adverse Events
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
筋骨格系および結合組織障害 (Cont.)			
肩回旋筋腱板症候群	1 (1.8)	0	1 (0.9)
神経系障害	2 (3.6)	4 (6.6)	6 (5.2)
頭蓋内出血	1 (1.8)	0	1 (0.9)
パーキンソン病	1 (1.8)	2 (3.3)	3 (2.6)
痙攣発作	0	1 (1.6)	1 (0.9)
一過性脳虚血発作	0	1 (1.6)	1 (0.9)
精神障害	3 (5.5)	2 (3.3)	5 (4.3)
不安	1 (1.8)	0	1 (0.9)
譫妄	0	1 (1.6)	1 (0.9)
失見当識	1 (1.8)	0	1 (0.9)
幻覚	0	1 (1.6)	1 (0.9)
精神病性障害	1 (1.8)	1 (1.6)	2 (1.7)
腎および尿路障害	0	2 (3.3)	2 (1.7)
急性腎障害	0	1 (1.6)	1 (0.9)
腎結石症	0	1 (1.6)	1 (0.9)
生殖系および乳房障害	0	1 (1.6)	1 (0.9)
腟脱	0	1 (1.6)	1 (0.9)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.11.1

Subjects with Treatment-Emergent Serious Adverse Events
by Primary System Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
呼吸器、胸郭および縦隔障害	1 (1.8)	0	1 (0.9)
窒息	1 (1.8)	0	1 (0.9)
誤嚥	1 (1.8)	0	1 (0.9)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

表38　中止に至った有害事象（安全性解析対象集団）：M15-737試験

[redacted]20[redacted] 10:48 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.3__1.8.1

Subjects with Treatment-Emergent Adverse Events
Leading to Study Drug Premature Discontinuation (Withdrawn) by Primary System
Organ Class and Preferred Term
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Any adverse event	3 (5.5)	4 (6.6)	7 (6.0)
一般・全身障害および投与部位の状態	0	1 (1.6)	1 (0.9)
注入部位発疹	0	1 (1.6)	1 (0.9)
感染症および寄生虫症	2 (3.6)	1 (1.6)	3 (2.6)
注入部位膿瘍	1 (1.8)	0	1 (0.9)
注入部位蜂巣炎	1 (1.8)	1 (1.6)	2 (1.7)
神経系障害	0	2 (3.3)	2 (1.7)
パーキンソン病	0	2 (3.3)	2 (1.7)
呼吸器、胸郭および縦隔障害	1 (1.8)	0	1 (0.9)
窒息	1 (1.8)	0	1 (0.9)
誤嚥	1 (1.8)	0	1 (0.9)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

表39　有害事象の90日間ごとの初回発現割合の推移（安全性解析対象集団）：M15-737試験

[redacted]20[redacted] 10:04 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.3 1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=116) n/N_eval (%)	 Days 91 to 180 (N=112) n/N_eval (%)	 Days 181 to 270 (N=78) n/N_eval (%)	 Days 271 to 360 (N=69) n/N_eval (%)
Total (Any Dose)				
Any adverse event	57/116 (49.1)	15/56 (26.8)	11/23 (47.8)	2/11 (18.2)
心臓障害	0/116	0/112	1/78 (1.3)	1/68 (1.5)
急性心筋梗塞	0/116	0/112	0/78	0/69
徐脈	0/116	0/112	0/78	1/69 (1.4)
左脚ブロック	0/116	0/112	1/78 (1.3)	0/68
洞性頻脈	0/116	0/112	0/78	0/69
耳および迷路障害	0/116	1/112 (0.9)	0/77	0/68
回転性めまい	0/116	1/112 (0.9)	0/77	0/68
眼障害	0/116	2/112 (1.8)	1/76 (1.3)	1/66 (1.5)
眼瞼痙攣	0/116	1/112 (0.9)	0/77	0/68
眼の異物感	0/116	0/112	0/78	1/69 (1.4)
黄斑症	0/116	0/112	0/78	1/69 (1.4)
眼部不快感	0/116	0/112	1/78 (1.3)	0/68
眼充血	0/116	1/112 (0.9)	0/77	1/68 (1.5)
霧視	0/116	0/112	1/78 (1.3)	0/68
胃腸障害	9/116 (7.8)	1/103 (1.0)	1/71 (1.4)	2/63 (3.2)
腹部不快感	0/116	0/112	1/78 (1.3)	0/68
腹部膨満	1/116 (0.9)	0/111	0/77	0/68
腹痛	0/116	1/112 (0.9)	0/77	0/68
便秘	4/116 (3.4)	0/108	1/75 (1.3)	0/66

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Total (Any Dose)				
Any adverse event	2/8 (25.0)	1/3 (33.3)	0/0	88/116 (75.9)
心臓障害	2/63 (3.2)	0/30	0/5	4/116 (3.4)
急性心筋梗塞	1/64 (1.6)	0/32	0/5	1/116 (0.9)
徐脈	0/64	0/32	0/5	1/116 (0.9)
左脚ブロック	0/63	0/31	0/5	1/116 (0.9)
洞性頻脈	1/64 (1.6)	0/31	0/5	1/116 (0.9)
耳および迷路障害	1/63 (1.6)	0/30	0/5	2/116 (1.7)
回転性めまい	1/63 (1.6)	0/30	0/5	2/116 (1.7)
眼障害	0/60	0/30	0/5	4/116 (3.4)
眼瞼痙攣	0/63	0/31	0/5	1/116 (0.9)
眼の異物感	0/63	0/32	0/5	1/116 (0.9)
黄斑症	0/63	0/32	0/5	1/116 (0.9)
眼部不快感	0/63	0/32	0/5	1/116 (0.9)
眼充血	0/62	0/31	0/5	2/116 (1.7)
霧視	0/63	0/32	0/5	1/116 (0.9)
胃腸障害	0/57	0/30	1/5 (20.0)	14/116 (12.1)
腹部不快感	0/63	0/31	0/5	1/116 (0.9)
腹部膨満	0/63	0/32	0/5	1/116 (0.9)
腹痛	0/63	0/32	0/5	1/116 (0.9)
便秘	0/61	0/31	0/5	5/116 (4.3)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Total (Any Dose)				
胃腸障害 (Cont.)				
出血性腸憩室	1/116 (0.9)	0/111	0/77	0/69
嚥下障害	2/116 (1.7)	0/110	0/77	0/68
胃潰瘍	0/116	0/112	0/78	1/69 (1.4)
胃食道逆流性疾患	1/116 (0.9)	0/111	0/77	0/68
悪心	2/116 (1.7)	1/110 (0.9)	0/77	1/69 (1.4)
吐き戻し	1/116 (0.9)	0/111	0/78	0/69
流涎過多	0/116	0/112	1/78 (1.3)	0/68
嘔吐	1/116 (0.9)	0/111	0/77	0/69
一般・全身障害および投与部位の状態	23/116 (19.8)	12/89 (13.5)	1/53 (1.9)	5/46 (10.9)
投与部位内出血	1/116 (0.9)	0/111	0/78	0/69
投与部位漏出	0/116	1/112 (0.9)	0/77	0/68
カテーテル留置部位内出血	0/116	2/112 (1.8)	0/78	0/69
カテーテル留置部位紅斑	1/116 (0.9)	0/111	0/78	0/69
カテーテル留置部位漏出	0/116	1/112 (0.9)	0/78	0/69
カテーテル留置部位炎症	0/116	0/112	0/78	1/69 (1.4)
カテーテル留置部位疼痛	0/116	0/112	0/78	1/69 (1.4)
カテーテル留置部位腫脹	0/116	0/112	0/78	0/69
薬効欠如	1/116 (0.9)	0/111	0/77	0/68
薬物相互作用	0/116	0/112	0/78	1/69 (1.4)
疲労	1/116 (0.9)	0/111	0/78	2/69 (2.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Total (Any Dose)				
胃腸障害 (Cont.)				
出血性腸憩室	0/64	0/32	0/5	1/116 (0.9)
嚥下障害	0/63	0/32	1/5 (20.0)	3/116 (2.6)
胃潰瘍	0/63	0/31	0/5	1/116 (0.9)
胃食道逆流性疾患	0/63	0/32	0/5	1/116 (0.9)
悪心	0/64	0/32	0/5	4/116 (3.4)
吐き戻し	0/64	0/32	0/5	1/116 (0.9)
流涎過多	0/63	0/32	0/5	1/116 (0.9)
嘔吐	0/64	0/32	0/5	1/116 (0.9)
一般・全身障害および投与部位の状態	1/39 (2.6)	0/22	0/4	42/116 (36.2)
投与部位内出血	0/64	0/32	0/5	1/116 (0.9)
投与部位漏出	0/63	0/31	0/5	1/116 (0.9)
カテーテル留置部位内出血	1/64 (1.6)	0/32	0/5	3/116 (2.6)
カテーテル留置部位紅斑	0/64	0/32	0/5	1/116 (0.9)
カテーテル留置部位漏出	0/64	0/32	0/5	1/116 (0.9)
カテーテル留置部位炎症	0/63	0/32	0/5	1/116 (0.9)
カテーテル留置部位疼痛	0/63	0/32	0/5	1/116 (0.9)
カテーテル留置部位腫脹	1/64 (1.6)	0/32	0/5	1/116 (0.9)
薬効欠如	0/63	0/32	0/5	1/116 (0.9)
薬物相互作用	0/64	0/32	0/5	1/116 (0.9)
疲労	0/63	0/32	0/5	3/116 (2.6)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態(Cont.)				
注入部位内出血	3/116 (2.6)	1/109 (0.9)	1/74 (1.4)	0/65
注入部位皮膚炎	0/116	1/112 (0.9)	0/77	0/68
注入部位変色	0/116	1/112 (0.9)	0/77	0/68
注入部位紅斑	8/116 (6.9)	6/104 (5.8)	2/68 (2.9)	2/59 (3.4)
注入部位血管外漏出	0/116	1/112 (0.9)	0/77	0/68
注入部位血腫	1/116 (0.9)	1/111 (0.9)	0/77	0/68
注入部位硬結	1/116 (0.9)	1/111 (0.9)	0/77	1/68 (1.5)
注入部位炎症	0/116	1/112 (0.9)	0/77	0/68
注入部位刺激感	0/116	2/112 (1.8)	0/77	0/68
注入部位腫瘤	0/116	0/112	1/78 (1.3)	0/68
注入部位結節	3/116 (2.6)	0/109	0/76	2/68 (2.9)
注入部位浮腫	2/116 (1.7)	0/110	0/77	0/68
注入部位疼痛	1/116 (0.9)	0/111	0/77	0/68
注入部位丘疹	4/116 (3.4)	0/108	0/75	0/67
注入部位異常感覚	1/116 (0.9)	0/111	0/77	0/69
注入部位発疹	1/116 (0.9)	0/111	0/78	0/69
注入部位反応	0/116	1/112 (0.9)	0/77	0/68
注入部位痂皮	0/116	0/112	0/78	1/69 (1.4)
注入部位腫脹	1/116 (0.9)	0/111	0/77	1/69 (1.4)
注入部位熱感	1/116 (0.9)	0/111	0/78	0/69
注射部位内出血	0/116	1/112 (0.9)	1/77 (1.3)	0/67

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態(Cont.)				
注入部位内出血	0/60	0/31	0/5	5/116 (4.3)
注入部位皮膚炎	0/64	0/32	0/5	1/116 (0.9)
注入部位変色	0/63	0/32	0/5	1/116 (0.9)
注入部位紅斑	1/54 (1.9)	0/27	0/5	19/116 (16.4)
注入部位血管外漏出	1/63 (1.6)	0/31	0/4	2/116 (1.7)
注入部位血腫	0/63	0/31	0/5	2/116 (1.7)
注入部位硬結	0/62	0/31	0/5	3/116 (2.6)
注入部位炎症	0/63	0/32	0/5	1/116 (0.9)
注入部位刺激感	0/63	0/32	0/5	2/116 (1.7)
注入部位腫瘤	0/63	0/32	0/5	1/116 (0.9)
注入部位結節	0/61	0/32	0/5	5/116 (4.3)
注入部位浮腫	0/63	0/32	0/5	2/116 (1.7)
注入部位疼痛	1/63 (1.6)	0/31	0/4	2/116 (1.7)
注入部位丘疹	0/63	0/32	0/5	4/116 (3.4)
注入部位異常感覚	0/64	0/32	0/5	1/116 (0.9)
注入部位発疹	0/64	0/32	0/5	1/116 (0.9)
注入部位反応	0/63	0/32	0/5	1/116 (0.9)
注入部位痂皮	0/63	0/32	0/5	1/116 (0.9)
注入部位腫脹	0/64	0/32	0/5	2/116 (1.7)
注入部位熱感	0/64	0/32	0/5	1/116 (0.9)
注射部位内出血	0/62	0/32	0/5	2/116 (1.7)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態(Cont.)				
注射部位紅斑	2/116 (1.7)	1/110 (0.9)	0/76	0/67
注射部位硬結	1/116 (0.9)	0/111	0/77	0/68
注射部位炎症	1/116 (0.9)	0/111	0/77	0/68
注射部位結節	1/116 (0.9)	0/111	0/78	0/69
注射部位浮腫	1/116 (0.9)	0/111	0/78	0/69
末梢性浮腫	1/116 (0.9)	0/111	0/77	0/68
穿刺部位紅斑	0/116	1/112 (0.9)	0/77	0/68
感染症および寄生虫症	12/116 (10.3)	8/100 (8.0)	7/62 (11.3)	4/52 (7.7)
ダニ皮膚炎	0/116	0/112	0/78	1/69 (1.4)
無症候性COVID-19	1/116 (0.9)	1/111 (0.9)	0/78	0/69
COVID-19	0/116	1/112 (0.9)	0/78	2/69 (2.9)
膀胱炎	1/116 (0.9)	0/111	0/77	0/68
大腸菌性尿路感染	0/116	1/112 (0.9)	0/77	0/68
胃腸炎	1/116 (0.9)	0/111	1/77 (1.3)	0/67
ヘリコバクター性胃炎	1/116 (0.9)	0/111	0/77	0/68
ヘリコバクター感染	0/116	0/112	0/78	1/69 (1.4)
帯状疱疹	0/116	1/112 (0.9)	0/77	0/68
注入部位膿瘍	0/116	0/112	1/78 (1.3)	2/68 (2.9)
注入部位蜂巣炎	6/116 (5.2)	3/106 (2.8)	3/70 (4.3)	3/64 (4.7)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態(Cont.)				
注射部位紅斑	0/62	0/31	0/5	3/116 (2.6)
注射部位硬結	0/63	0/31	0/5	1/116 (0.9)
注射部位炎症	0/63	0/32	0/5	1/116 (0.9)
注射部位結節	0/64	0/32	0/5	1/116 (0.9)
注射部位浮腫	0/64	0/32	0/5	1/116 (0.9)
末梢性浮腫	0/63	0/32	0/5	1/116 (0.9)
穿刺部位紅斑	0/63	0/32	0/5	1/116 (0.9)
感染症および寄生虫症	3/44 (6.8)	0/22	0/3	34/116 (29.3)
ダニ皮膚炎	0/63	0/32	0/5	1/116 (0.9)
無症候性COVID-19	0/64	0/32	0/5	2/116 (1.7)
COVID-19	2/62 (3.2)	0/31	0/4	5/116 (4.3)
膀胱炎	0/63	0/32	0/5	1/116 (0.9)
大腸菌性尿路感染	0/63	0/32	0/5	1/116 (0.9)
胃腸炎	0/62	0/31	0/5	2/116 (1.7)
ヘリコバクター性胃炎	0/63	0/32	0/5	1/116 (0.9)
ヘリコバクター感染	0/63	0/31	0/5	1/116 (0.9)
帯状疱疹	0/63	0/32	0/5	1/116 (0.9)
注入部位膿瘍	0/61	0/30	0/5	3/116 (2.6)
注入部位蜂巣炎	1/57 (1.8)	0/27	0/4	16/116 (13.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Total (Any Dose)				
感染症および寄生虫症 (Cont.)				
注入部位感染	0/116	2/112 (1.8)	1/76 (1.3)	0/66
注射部位蜂巣炎	0/116	0/112	0/78	0/69
注射部位感染	0/116	0/112	1/78 (1.3)	0/68
上咽頭炎	0/116	0/112	2/78 (2.6)	0/67
口腔カンジダ症	0/116	1/112 (0.9)	0/78	0/69
RSウイルス感染	0/116	0/112	1/78 (1.3)	0/68
敗血症	0/116	1/112 (0.9)	0/78	0/69
副鼻腔炎	1/116 (0.9)	0/111	0/77	0/68
上気道感染	0/116	1/112 (0.9)	0/77	0/68
尿路感染	2/116 (1.7)	1/110 (0.9)	0/76	1/67 (1.5)
尿路性敗血症	1/116 (0.9)	0/111	0/78	0/69
傷害、中毒および処置合併症	10/116 (8.6)	8/103 (7.8)	3/64 (4.7)	0/53
節足動物咬傷	0/116	1/112 (0.9)	0/77	0/68
節足動物刺傷	0/116	1/112 (0.9)	0/77	0/68
挫傷	1/116 (0.9)	0/111	0/78	0/69
顔面骨骨折	1/116 (0.9)	0/111	0/77	0/69
転倒	7/116 (6.0)	4/106 (3.8)	3/69 (4.3)	0/58
大腿骨頚部骨折	0/116	0/112	0/78	1/69 (1.4)
大腿骨骨折	1/116 (0.9)	0/112	0/78	0/69
転位骨折	0/116	1/112 (0.9)	0/77	0/68

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Total (Any Dose)				
感染症および寄生虫症 (Cont.)				
注入部位感染	0/61	0/31	0/5	3/116 (2.6)
注射部位蜂巣炎	0/64	1/32 (3.1)	0/5	1/116 (0.9)
注射部位感染	0/63	0/32	0/5	1/116 (0.9)
上咽頭炎	0/62	0/31	0/5	2/116 (1.7)
口腔カンジダ症	0/64	0/32	0/5	1/116 (0.9)
RSウイルス感染	0/63	0/32	0/5	1/116 (0.9)
敗血症	0/64	0/32	0/5	1/116 (0.9)
副鼻腔炎	0/63	0/32	0/5	1/116 (0.9)
上気道感染	0/63	0/32	0/5	1/116 (0.9)
尿路感染	1/61 (1.6)	0/30	0/4	5/116 (4.3)
尿路性敗血症	0/64	0/32	0/5	1/116 (0.9)
傷害、中毒および処置合併症	0/49	0/24	0/5	21/116 (18.1)
節足動物咬傷	0/63	0/32	0/5	1/116 (0.9)
節足動物刺傷	0/63	0/31	0/5	1/116 (0.9)
挫傷	0/64	0/32	0/5	1/116 (0.9)
顔面骨骨折	0/64	0/32	0/5	1/116 (0.9)
転倒	0/53	0/26	0/5	14/116 (12.1)
大腿骨頚部骨折	0/63	0/32	0/5	1/116 (0.9)
大腿骨骨折	0/64	0/32	0/5	1/116 (0.9)
転位骨折	0/63	0/32	0/5	1/116 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Total (Any Dose)				
傷害、中毒および処置合併症(Cont.)				
手骨折	1/116 (0.9)	1/111 (0.9)	1/77 (1.3)	0/67
股関節部骨折	1/116 (0.9)	1/111 (0.9)	0/76	0/68
上腕骨骨折	1/116 (0.9)	0/111	0/77	1/69 (1.4)
靭帯捻挫	0/116	1/112 (0.9)	0/77	0/68
四肢損傷	0/116	1/112 (0.9)	0/77	0/68
肉離れ	1/116 (0.9)	0/111	0/77	0/68
開放骨折	1/116 (0.9)	0/111	0/78	0/69
処置による疼痛	0/116	1/112 (0.9)	0/77	0/68
肩甲骨骨折	1/116 (0.9)	0/111	0/77	0/68
外傷性頭蓋内出血	0/116	1/112 (0.9)	0/78	0/69
臨床検査	5/116 (4.3)	2/107 (1.9)	3/73 (4.1)	3/62 (4.8)
血中葉酸減少	1/116 (0.9)	1/111 (0.9)	0/77	0/68
血中ホモシステイン増加	2/116 (1.7)	0/110	0/77	0/68
血中ナトリウム減少	1/116 (0.9)	0/111	0/77	0/68
ヘモグロビン減少	0/116	1/112 (0.9)	0/78	0/69
リンパ球数減少	0/116	0/112	1/78 (1.3)	0/68
プロトロンビン時間延長	1/116 (0.9)	0/111	0/77	0/68
ビタミンB12減少	0/116	1/112 (0.9)	0/77	1/68 (1.5)
ビタミンB6減少	0/116	0/112	2/78 (2.6)	0/67
ビタミンB6増加	0/116	0/112	0/78	1/69 (1.4)
ビタミンD減少	0/116	0/112	0/78	1/69 (1.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Total (Any Dose)				
傷害、中毒および処置合併症(Cont.)				
手骨折	0/62	0/30	0/5	3/116 (2.6)
股関節部骨折	0/63	0/31	0/5	2/116 (1.7)
上腕骨骨折	0/63	0/32	0/5	2/116 (1.7)
靭帯捻挫	0/63	0/32	0/5	1/116 (0.9)
四肢損傷	0/64	0/32	0/5	1/116 (0.9)
肉離れ	0/63	0/32	0/5	1/116 (0.9)
開放骨折	0/64	0/32	0/5	1/116 (0.9)
処置による疼痛	0/63	0/31	0/5	1/116 (0.9)
肩甲骨骨折	0/63	0/31	0/5	1/116 (0.9)
外傷性頭蓋内出血	0/64	0/32	0/5	1/116 (0.9)
臨床検査	0/55	0/31	0/5	13/116 (11.2)
血中葉酸減少	0/63	0/32	0/5	2/116 (1.7)
血中ホモシステイン増加	0/63	0/32	0/5	2/116 (1.7)
血中ナトリウム減少	0/63	0/32	0/5	1/116 (0.9)
ヘモグロビン減少	0/64	0/32	0/5	1/116 (0.9)
リンパ球数減少	0/64	0/32	0/5	1/116 (0.9)
プロトロンビン時間延長	0/63	0/32	0/5	1/116 (0.9)
ビタミンB12減少	0/62	0/32	0/5	2/116 (1.7)
ビタミンB6減少	0/62	0/32	0/5	2/116 (1.7)
ビタミンB6増加	0/63	0/32	0/5	1/116 (0.9)
ビタミンD減少	0/63	0/32	0/5	1/116 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Total (Any Dose)				
臨床検査 (Cont.)				
体重減少	1/116 (0.9)	1/111 (0.9)	1/76 (1.3)	0/67
代謝および栄養障害	3/116 (2.6)	2/109 (1.8)	3/74 (4.1)	1/62 (1.6)
食欲減退	1/116 (0.9)	0/111	0/78	0/69
高ナトリウム血症	0/116	1/112 (0.9)	0/78	0/69
低カリウム血症	1/116 (0.9)	0/111	0/78	0/69
低マグネシウム血症	1/116 (0.9)	0/111	0/78	0/69
鉄欠乏	0/116	2/112 (1.8)	0/76	0/67
ビタミンB群欠乏	1/116 (0.9)	0/111	0/77	0/68
ビタミンB12欠乏	1/116 (0.9)	0/111	3/77 (3.9)	0/65
ビタミンB6欠乏	0/116	0/112	0/78	1/69 (1.4)
筋骨格系および結合組織障害	4/116 (3.4)	6/108 (5.6)	3/70 (4.3)	2/61 (3.3)
関節痛	0/116	1/112 (0.9)	0/78	0/69
背部痛	0/116	1/112 (0.9)	1/77 (1.3)	1/67 (1.5)
滑液包炎	1/116 (0.9)	0/111	0/77	0/68
出血性関節症	0/116	1/112 (0.9)	0/77	0/68
椎間板変性症	0/116	0/112	1/78 (1.3)	0/68
腰部脊柱管狭窄症	0/116	0/112	1/78 (1.3)	0/68
筋力低下	0/116	1/112 (0.9)	0/77	0/68
筋骨格系胸痛	1/116 (0.9)	0/111	0/78	0/69
筋骨格硬直	0/116	1/112 (0.9)	0/77	0/68

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Total (Any Dose)				
臨床検査 (Cont.)				
体重減少	0/62	0/31	0/5	3/116 (2.6)
代謝および栄養障害	0/56	0/27	0/5	9/116 (7.8)
食欲減退	0/64	0/32	0/5	1/116 (0.9)
高ナトリウム血症	0/64	0/32	0/5	1/116 (0.9)
低カリウム血症	1/64 (1.6)	0/31	0/5	2/116 (1.7)
低マグネシウム血症	1/64 (1.6)	0/31	0/5	2/116 (1.7)
鉄欠乏	0/62	0/31	0/5	2/116 (1.7)
ビタミンB群欠乏	0/63	0/32	0/5	1/116 (0.9)
ビタミンB12欠乏	0/60	0/28	0/5	4/116 (3.4)
ビタミンB6欠乏	0/63	0/32	0/5	1/116 (0.9)
筋骨格系および結合組織障害	1/54 (1.9)	0/27	1/4 (25.0)	17/116 (14.7)
関節痛	0/64	0/32	0/5	1/116 (0.9)
背部痛	0/61	0/30	0/5	3/116 (2.6)
滑液包炎	0/63	0/32	0/5	1/116 (0.9)
出血性関節症	0/63	0/32	0/5	1/116 (0.9)
椎間板変性症	0/63	0/31	0/5	1/116 (0.9)
腰部脊柱管狭窄症	0/63	0/31	0/5	1/116 (0.9)
筋力低下	0/63	0/32	1/5 (20.0)	2/116 (1.7)
筋骨格系胸痛	0/64	0/32	0/5	1/116 (0.9)
筋骨格硬直	0/63	0/32	0/5	1/116 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Total (Any Dose)				
筋骨格系および結合組織障害(Cont.)				
変形性関節症	1/116 (0.9)	1/111 (0.9)	0/76	1/68 (1.5)
骨粗鬆症	1/116 (0.9)	0/111	0/77	1/68 (1.5)
四肢痛	1/116 (0.9)	0/111	0/78	1/69 (1.4)
肩回旋筋腱板症候群	0/116	0/112	0/78	0/69
変形性脊椎症	0/116	0/112	1/78 (1.3)	0/69
腱鞘炎	1/116 (0.9)	0/111	0/77	0/69
斜頚	0/116	1/112 (0.9)	0/77	0/69
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）	0/116	0/112	1/78 (1.3)	0/68
ケラトアカントーマ	0/116	0/112	1/78 (1.3)	0/68
神経系障害	12/116 (10.3)	5/100 (5.0)	4/65 (6.2)	3/55 (5.5)
健忘	1/116 (0.9)	0/111	0/77	0/69
平衡障害	1/116 (0.9)	0/111	0/77	0/68
運動緩慢	0/116	0/112	0/78	0/69
認知障害	2/116 (1.7)	0/110	0/76	1/67 (1.5)
注意力障害	1/116 (0.9)	0/111	0/77	0/68
浮動性めまい	1/116 (0.9)	0/111	0/78	0/69
薬物離脱性頭痛	0/116	1/112 (0.9)	0/78	0/69
ジスキネジア	0/116	0/112	0/78	1/69 (1.4)
ジストニア	1/116 (0.9)	0/111	0/77	0/68

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Total (Any Dose)				
筋骨格系および結合組織障害(Cont.)				
変形性関節症	0/62	0/31	0/4	3/116 (2.6)
骨粗鬆症	0/62	0/32	0/5	2/116 (1.7)
四肢痛	0/63	0/32	0/5	2/116 (1.7)
肩回旋筋腱板症候群	1/64 (1.6)	1/32 (3.1)	0/4	2/116 (1.7)
変形性脊椎症	0/64	0/32	0/5	1/116 (0.9)
腱鞘炎	0/64	0/32	0/5	1/116 (0.9)
斜頚	0/64	0/32	0/5	1/116 (0.9)
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）	0/63	0/32	0/5	1/116 (0.9)
ケラトアカントーマ	0/63	0/32	0/5	1/116 (0.9)
神経系障害	1/48 (2.1)	2/26 (7.7)	0/4	27/116 (23.3)
健忘	0/64	0/32	0/5	1/116 (0.9)
平衡障害	0/63	0/32	0/5	1/116 (0.9)
運動緩慢	1/64 (1.6)	0/32	0/5	1/116 (0.9)
認知障害	0/61	0/32	0/5	3/116 (2.6)
注意力障害	0/63	0/32	0/5	1/116 (0.9)
浮動性めまい	1/64 (1.6)	0/31	0/5	2/116 (1.7)
薬物離脱性頭痛	0/64	0/32	0/5	1/116 (0.9)
ジスキネジア	0/64	0/32	0/5	1/116 (0.9)
ジストニア	0/63	0/32	0/5	1/116 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Total (Any Dose)				
神経系障害 (Cont.)				
伸展性足底反応	0/116	1/112 (0.9)	0/77	0/68
すくみ現象	0/116	2/112 (1.8)	0/76	1/67 (1.5)
頭蓋内出血	0/116	0/112	1/78 (1.3)	0/68
頭部不快感	1/116 (0.9)	0/111	1/78 (1.3)	0/68
頭痛	0/116	1/112 (0.9)	0/78	0/69
感覚鈍麻	0/116	0/112	1/78 (1.3)	0/68
反射減弱	1/116 (0.9)	1/111 (0.9)	0/76	0/68
記憶障害	1/116 (0.9)	0/111	0/77	0/68
オンオフ現象	2/116 (1.7)	4/110 (3.6)	1/74 (1.4)	0/65
錯感覚	1/116 (0.9)	0/111	0/78	0/69
パーキンソン病	2/116 (1.7)	3/110 (2.7)	1/75 (1.3)	1/67 (1.5)
精神運動亢進	0/116	0/112	1/78 (1.3)	0/68
呼吸器ジスキネジア	0/116	0/112	0/78	0/69
痙攣発作	0/116	1/112 (0.9)	0/78	0/69
失神	1/116 (0.9)	1/111 (0.9)	0/76	0/67
一過性脳虚血発作	1/116 (0.9)	0/111	0/77	0/68
振戦	0/116	1/112 (0.9)	0/77	0/68
精神障害	13/116 (11.2)	10/99 (10.1)	8/60 (13.3)	2/46 (4.3)
異常な夢	0/116	1/112 (0.9)	0/78	0/69
適応障害	0/116	1/112 (0.9)	0/77	0/68
攻撃性	1/116 (0.9)	0/111	0/77	0/69
激越	1/116 (0.9)	0/111	0/77	0/68

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Total (Any Dose)				
神経系障害 (Cont.)				
伸展性足底反応	0/63	0/31	0/5	1/116 (0.9)
すくみ現象	0/61	0/32	0/5	3/116 (2.6)
頭蓋内出血	0/63	0/32	0/5	1/116 (0.9)
頭部不快感	0/63	0/32	0/5	2/116 (1.7)
頭痛	1/64 (1.6)	0/31	0/5	2/116 (1.7)
感覚鈍麻	0/63	1/31 (3.2)	0/5	2/116 (1.7)
反射減弱	0/63	0/32	0/5	2/116 (1.7)
記憶障害	0/63	1/32 (3.1)	0/4	2/116 (1.7)
オンオフ現象	0/60	0/31	0/5	7/116 (6.0)
錯感覚	0/64	1/32 (3.1)	0/5	2/116 (1.7)
パーキンソン病	0/61	0/32	0/5	7/116 (6.0)
精神運動亢進	0/63	0/31	0/5	1/116 (0.9)
呼吸器ジスキネジア	0/64	1/32 (3.1)	0/5	1/116 (0.9)
痙攣発作	0/64	0/32	0/5	1/116 (0.9)
失神	0/62	0/31	0/5	2/116 (1.7)
一過性脳虚血発作	0/63	0/32	0/5	1/116 (0.9)
振戦	0/63	0/32	0/5	1/116 (0.9)
精神障害	0/41	0/23	0/4	33/116 (28.4)
異常な夢	0/64	0/32	0/5	1/116 (0.9)
適応障害	0/63	0/32	0/5	1/116 (0.9)
攻撃性	0/64	0/32	0/5	1/116 (0.9)
激越	0/63	0/31	0/5	1/116 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Total (Any Dose)				
精神障害 (Cont.)				
不安	1/116 (0.9)	2/111 (1.8)	3/75 (4.0)	2/64 (3.1)
歯ぎしり	1/116 (0.9)	0/111	0/77	0/68
錯乱状態	0/116	0/112	1/78 (1.3)	0/68
譫妄	1/116 (0.9)	1/111 (0.9)	0/77	0/69
妄想	0/116	1/112 (0.9)	1/78 (1.3)	0/68
抑うつ気分	0/116	0/112	1/78 (1.3)	0/68
うつ病	2/116 (1.7)	1/110 (0.9)	0/75	0/66
自傷性皮膚症	0/116	1/112 (0.9)	0/77	0/68
失見当識	0/116	0/112	0/78	0/69
ギャンブル障害	1/116 (0.9)	0/111	0/77	0/68
幻覚	4/116 (3.4)	2/108 (1.9)	2/72 (2.8)	1/62 (1.6)
幻嗅	0/116	1/112 (0.9)	0/77	0/68
幻視	0/116	1/112 (0.9)	0/77	1/68 (1.5)
軽躁	1/116 (0.9)	0/111	0/78	0/69
錯覚	0/116	0/112	2/78 (2.6)	0/67
衝動制御障害	0/116	1/112 (0.9)	0/77	0/68
衝動行為	0/116	1/112 (0.9)	0/77	0/68
不眠症	0/116	1/112 (0.9)	1/78 (1.3)	0/68
消極的思考	0/116	0/112	1/78 (1.3)	0/68
パニック発作	0/116	1/112 (0.9)	0/77	1/68 (1.5)
妄想症	0/116	0/112	1/78 (1.3)	0/68
精神病性障害	0/116	2/112 (1.8)	0/76	0/67

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Total (Any Dose)				
精神障害 (Cont.)				
不安	0/57	0/28	0/4	8/116 (6.9)
歯ぎしり	0/63	0/31	0/5	1/116 (0.9)
錯乱状態	0/63	0/31	0/5	1/116 (0.9)
譫妄	0/64	0/32	0/5	2/116 (1.7)
妄想	0/63	0/31	0/5	2/116 (1.7)
抑うつ気分	0/63	0/32	0/5	1/116 (0.9)
うつ病	0/61	0/32	0/5	3/116 (2.6)
自傷性皮膚症	0/64	0/32	0/5	1/116 (0.9)
失見当識	1/64 (1.6)	0/32	0/5	1/116 (0.9)
ギャンブル障害	0/64	0/32	0/5	1/116 (0.9)
幻覚	0/56	0/29	0/4	9/116 (7.8)
幻嗅	0/63	0/32	0/5	1/116 (0.9)
幻視	0/62	0/30	0/5	2/116 (1.7)
軽躁	0/64	0/32	0/5	1/116 (0.9)
錯覚	0/62	0/32	0/5	2/116 (1.7)
衝動制御障害	0/63	0/32	0/5	1/116 (0.9)
衝動行為	0/63	0/32	0/5	1/116 (0.9)
不眠症	0/63	0/32	0/5	2/116 (1.7)
消極的思考	0/63	0/32	0/5	1/116 (0.9)
パニック発作	0/62	0/32	0/5	2/116 (1.7)
妄想症	0/63	0/32	0/5	1/116 (0.9)
精神病性障害	0/62	0/32	0/5	2/116 (1.7)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Total (Any Dose)				
精神障害 (Cont.)				
レム睡眠行動障害	1/116 (0.9)	0/111	0/77	0/68
睡眠障害	1/116 (0.9)	0/111	0/78	0/69
腎および尿路障害	2/116 (1.7)	1/110 (0.9)	0/76	1/67 (1.5)
急性腎障害	1/116 (0.9)	0/111	0/78	0/69
膀胱痙縮	1/116 (0.9)	0/111	0/77	0/68
血尿	0/116	1/112 (0.9)	0/77	0/68
水腎症	1/116 (0.9)	0/111	0/78	0/69
水尿管症	1/116 (0.9)	0/111	0/78	0/69
緊張性膀胱	0/116	0/112	0/78	0/69
腎結石症	0/116	0/112	0/78	0/69
蛋白尿	0/116	0/112	0/78	1/69 (1.4)
尿失禁	0/116	0/112	0/78	0/69
生殖系および乳房障害	3/116 (2.6)	1/109 (0.9)	0/75	0/66
良性前立腺肥大症	1/116 (0.9)	0/111	0/77	0/68
膀胱瘤	0/116	0/112	0/78	0/69
勃起不全	1/116 (0.9)	0/111	0/77	0/68
生殖器萎縮	0/116	0/112	0/78	0/69
膣脱	0/116	1/112 (0.9)	0/78	0/69

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Total (Any Dose)				
精神障害 (Cont.)				
レム睡眠行動障害	0/63	0/32	0/5	1/116 (0.9)
睡眠障害	0/64	0/32	0/5	1/116 (0.9)
腎および尿路障害	3/61 (4.9)	0/28	0/5	7/116 (6.0)
急性腎障害	0/64	0/32	0/5	1/116 (0.9)
膀胱痙縮	0/63	0/31	0/5	1/116 (0.9)
血尿	0/63	0/31	0/5	1/116 (0.9)
水腎症	0/64	0/32	0/5	1/116 (0.9)
水尿管症	0/64	0/32	0/5	1/116 (0.9)
緊張性膀胱	1/64 (1.6)	0/32	0/5	1/116 (0.9)
腎結石症	1/64 (1.6)	0/31	0/5	1/116 (0.9)
蛋白尿	0/63	0/32	0/5	1/116 (0.9)
尿失禁	1/64 (1.6)	0/31	0/5	1/116 (0.9)
生殖系および乳房障害	1/61 (1.6)	0/31	0/5	5/116 (4.3)
良性前立腺肥大症	0/63	0/32	0/5	1/116 (0.9)
膀胱瘤	1/64 (1.6)	0/31	0/5	1/116 (0.9)
勃起不全	0/63	0/32	0/5	1/116 (0.9)
生殖器萎縮	1/64 (1.6)	0/31	0/5	1/116 (0.9)
腟脱	0/64	0/32	0/5	1/116 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Total (Any Dose)				
生殖系および乳房障害(Cont.)				
外陰腟乾燥	1/116 (0.9)	0/111	0/77	0/68
呼吸器、胸郭および縦隔障害	0/116	0/112	1/78 (1.3)	1/68 (1.5)
窒息	0/116	0/112	1/78 (1.3)	0/68
誤嚥	0/116	0/112	1/78 (1.3)	0/68
呼吸困難	0/116	0/112	0/78	1/69 (1.4)
痰貯留	0/116	0/112	0/78	0/69
皮膚および皮下組織障害	0/116	2/112 (1.8)	1/76 (1.3)	2/66 (3.0)
光線角化症	0/116	0/112	1/78 (1.3)	0/68
脱毛症	0/116	1/112 (0.9)	0/77	0/68
湿疹	0/116	1/112 (0.9)	0/77	1/68 (1.5)
発疹	0/116	1/112 (0.9)	0/77	0/68
蕁麻疹	0/116	0/112	0/78	1/69 (1.4)
血管障害	3/116 (2.6)	4/109 (3.7)	1/72 (1.4)	1/62 (1.6)
血腫	0/116	1/112 (0.9)	0/77	0/68
高血圧	0/116	1/112 (0.9)	0/77	0/68
低血圧	1/116 (0.9)	0/111	0/77	1/68 (1.5)
起立性高血圧	1/116 (0.9)	0/111	0/77	0/68

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Total (Any Dose)				
生殖系および乳房障害(Cont.)				
外陰腟乾燥	0/63	0/32	0/5	1/116 (0.9)
呼吸器、胸郭および縦隔障害	1/63 (1.6)	0/30	0/5	3/116 (2.6)
窒息	0/64	0/32	0/5	1/116 (0.9)
誤嚥	0/64	0/32	0/5	1/116 (0.9)
呼吸困難	0/63	0/31	0/5	1/116 (0.9)
痰貯留	1/64 (1.6)	0/31	0/5	1/116 (0.9)
皮膚および皮下組織障害	0/59	0/29	0/5	5/116 (4.3)
光線角化症	0/63	0/31	0/5	1/116 (0.9)
脱毛症	0/63	0/32	0/5	1/116 (0.9)
湿疹	0/62	0/31	0/5	2/116 (1.7)
発疹	0/63	0/32	0/5	1/116 (0.9)
蕁麻疹	0/63	0/31	0/5	1/116 (0.9)
血管障害	0/57	0/30	0/4	9/116 (7.8)
血腫	0/63	0/32	0/5	1/116 (0.9)
高血圧	0/63	0/32	0/5	1/116 (0.9)
低血圧	0/63	0/32	0/5	2/116 (1.7)
起立性高血圧	0/63	0/32	0/5	1/116 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Total (Any Dose)				
血管障害 (Cont.)				
起立性低血圧	1/116 (0.9)	2/111 (1.8)	0/76	0/67
表在性血栓性静脈炎	0/116	0/112	1/78 (1.3)	0/68

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Total (Any Dose)				
血管障害 (Cont.)				
起立性低血圧	0/62	0/31	0/5	3/116 (2.6)
表在性血栓性静脈炎	0/63	0/31	0/4	1/116 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Low Dose				
Any adverse event	28/55 (50.9)	6/24 (25.0)	5/8 (62.5)	0/3
心臓障害	0/55	0/51	0/33	1/30 (3.3)
急性心筋梗塞	0/55	0/51	0/33	0/30
徐脈	0/55	0/51	0/33	1/30 (3.3)
洞性頻脈	0/55	0/51	0/33	0/30
眼障害	0/55	0/51	0/33	1/30 (3.3)
黄斑症	0/55	0/51	0/33	1/30 (3.3)
胃腸障害	5/55 (9.1)	0/46	0/29	2/27 (7.4)
便秘	2/55 (3.6)	0/49	1/32 (3.1)	0/28
嚥下障害	1/55 (1.8)	0/50	0/32	0/29
胃潰瘍	0/55	0/51	0/33	1/30 (3.3)
胃食道逆流性疾患	1/55 (1.8)	0/50	0/32	0/29
悪心	1/55 (1.8)	0/50	0/32	1/30 (3.3)
嘔吐	1/55 (1.8)	0/50	0/32	0/30
一般・全身障害および投与部位の状態	11/55 (20.0)	6/40 (15.0)	1/21 (4.8)	3/18 (16.7)
投与部位漏出	0/55	1/51 (2.0)	0/32	0/29
カテーテル留置部位内出血	0/55	0/51	0/33	0/30
カテーテル留置部位紅斑	1/55 (1.8)	0/50	0/33	0/30
カテーテル留置部位疼痛	0/55	0/51	0/33	1/30 (3.3)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Low Dose				
Any adverse event	0/2	0/1	0/0	39/55 (70.9)
心臓障害	2/26 (7.7)	0/11	0/1	3/55 (5.5)
急性心筋梗塞	1/26 (3.8)	0/12	0/1	1/55 (1.8)
徐脈	0/26	0/12	0/1	1/55 (1.8)
洞性頻脈	1/26 (3.8)	0/11	0/1	1/55 (1.8)
眼障害	0/25	0/12	0/1	1/55 (1.8)
黄斑症	0/25	0/12	0/1	1/55 (1.8)
胃腸障害	0/22	0/11	0/1	7/55 (12.7)
便秘	0/24	0/12	0/1	3/55 (5.5)
嚥下障害	0/25	0/12	0/1	1/55 (1.8)
胃潰瘍	0/25	0/11	0/1	1/55 (1.8)
胃食道逆流性疾患	0/25	0/12	0/1	1/55 (1.8)
悪心	0/26	0/12	0/1	2/55 (3.6)
嘔吐	0/26	0/12	0/1	1/55 (1.8)
一般・全身障害および投与部位の状態	0/13	0/7	0/1	21/55 (38.2)
投与部位漏出	0/25	0/11	0/1	1/55 (1.8)
カテーテル留置部位内出血	1/26 (3.8)	0/12	0/1	1/55 (1.8)
カテーテル留置部位紅斑	0/26	0/12	0/1	1/55 (1.8)
カテーテル留置部位疼痛	0/25	0/12	0/1	1/55 (1.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Low Dose				
一般・全身障害および投与部位の状態(Cont.)				
カテーテル留置部位腫脹	0/55	0/51	0/33	0/30
薬効欠如	1/55 (1.8)	0/50	0/32	0/29
薬物相互作用	0/55	0/51	0/33	1/30 (3.3)
疲労	1/55 (1.8)	0/50	0/33	2/30 (6.7)
注入部位内出血	1/55 (1.8)	0/50	1/32 (3.1)	0/28
注入部位皮膚炎	0/55	1/51 (2.0)	0/32	0/29
注入部位紅斑	3/55 (5.5)	4/48 (8.3)	2/29 (6.9)	2/25 (8.0)
注入部位血腫	0/55	1/51 (2.0)	0/32	0/29
注入部位硬結	1/55 (1.8)	0/50	0/33	0/30
注入部位刺激感	0/55	2/51 (3.9)	0/32	0/29
注入部位腫瘤	0/55	0/51	1/33 (3.0)	0/29
注入部位結節	1/55 (1.8)	0/50	0/33	1/30 (3.3)
注入部位浮腫	1/55 (1.8)	0/50	0/32	0/29
注入部位疼痛	1/55 (1.8)	0/50	0/32	0/29
注入部位丘疹	1/55 (1.8)	0/50	0/32	0/29
注入部位腫脹	0/55	0/51	0/33	1/30 (3.3)
注入部位熱感	1/55 (1.8)	0/50	0/33	0/30
注射部位内出血	0/55	1/51 (2.0)	0/32	0/29
注射部位紅斑	1/55 (1.8)	0/50	0/32	0/29
注射部位結節	1/55 (1.8)	0/50	0/33	0/30
末梢性浮腫	1/55 (1.8)	0/50	0/32	0/29

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Low Dose				
一般・全身障害および投与部位の状態(Cont.)				
カテーテル留置部位腫脹	1/26 (3.8)	0/12	0/1	1/55 (1.8)
薬効欠如	0/25	0/12	0/1	1/55 (1.8)
薬物相互作用	0/26	0/12	0/1	1/55 (1.8)
疲労	0/25	0/12	0/1	3/55 (5.5)
注入部位内出血	0/24	0/11	0/1	2/55 (3.6)
注入部位皮膚炎	0/26	0/12	0/1	1/55 (1.8)
注入部位紅斑	0/20	0/9	0/1	11/55 (20.0)
注入部位血腫	0/25	0/11	0/1	1/55 (1.8)
注入部位硬結	0/26	0/12	0/1	1/55 (1.8)
注入部位刺激感	0/25	0/12	0/1	2/55 (3.6)
注入部位腫瘤	0/25	0/12	0/1	1/55 (1.8)
注入部位結節	0/25	0/12	0/1	2/55 (3.6)
注入部位浮腫	0/25	0/12	0/1	1/55 (1.8)
注入部位疼痛	0/25	0/12	0/1	1/55 (1.8)
注入部位丘疹	0/25	0/12	0/1	1/55 (1.8)
注入部位腫脹	0/26	0/12	0/1	1/55 (1.8)
注入部位熱感	0/26	0/12	0/1	1/55 (1.8)
注射部位内出血	0/25	0/12	0/1	1/55 (1.8)
注射部位紅斑	0/25	0/12	0/1	1/55 (1.8)
注射部位結節	0/26	0/12	0/1	1/55 (1.8)
末梢性浮腫	0/25	0/12	0/1	1/55 (1.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Low Dose				
一般・全身障害および投与部位の状態(Cont.)				
穿刺部位紅斑	0/55	1/51 (2.0)	0/32	0/29
感染症および寄生虫症	4/55 (7.3)	4/47 (8.5)	4/26 (15.4)	3/21 (14.3)
COVID-19	0/55	1/51 (2.0)	0/33	0/30
膀胱炎	1/55 (1.8)	0/50	0/32	0/29
胃腸炎	1/55 (1.8)	0/50	0/32	0/29
ヘリコバクター性胃炎	1/55 (1.8)	0/50	0/32	0/29
ヘリコバクター感染	0/55	0/51	0/33	1/30 (3.3)
注入部位膿瘍	0/55	0/51	1/33 (3.0)	2/29 (6.9)
注入部位蜂巣炎	2/55 (3.6)	1/49 (2.0)	0/30	3/29 (10.3)
注入部位感染	0/55	2/51 (3.9)	1/31 (3.2)	0/27
上咽頭炎	0/55	0/51	1/33 (3.0)	0/29
RSウイルス感染	0/55	0/51	1/33 (3.0)	0/29
上気道感染	0/55	1/51 (2.0)	0/32	0/29
尿路感染	0/55	0/51	0/33	0/30
傷害、中毒および処置合併症	4/55 (7.3)	3/48 (6.3)	1/28 (3.6)	0/24
節足動物刺傷	0/55	1/51 (2.0)	0/32	0/29
転倒	2/55 (3.6)	2/50 (4.0)	1/30 (3.3)	0/26

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Low Dose				
一般・全身障害および投与部位の状態(Cont.)				
穿刺部位紅斑	0/25	0/12	0/1	1/55 (1.8)
感染症および寄生虫症	0/15	0/7	0/1	15/55 (27.3)
COVID-19	0/26	0/12	0/1	1/55 (1.8)
膀胱炎	0/25	0/12	0/1	1/55 (1.8)
胃腸炎	0/25	0/12	0/1	1/55 (1.8)
ヘリコバクター性胃炎	0/25	0/12	0/1	1/55 (1.8)
ヘリコバクター感染	0/25	0/11	0/1	1/55 (1.8)
注入部位膿瘍	0/23	0/10	0/1	3/55 (5.5)
注入部位蜂巣炎	0/23	0/10	0/1	6/55 (10.9)
注入部位感染	0/23	0/11	0/1	3/55 (5.5)
上咽頭炎	0/25	0/11	0/1	1/55 (1.8)
RSウイルス感染	0/25	0/12	0/1	1/55 (1.8)
上気道感染	0/25	0/12	0/1	1/55 (1.8)
尿路感染	1/26 (3.8)	0/11	0/1	1/55 (1.8)
傷害、中毒および処置合併症	0/20	0/9	0/1	8/55 (14.5)
節足動物刺傷	0/25	0/11	0/1	1/55 (1.8)
転倒	0/22	0/10	0/1	5/55 (9.1)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Low Dose				
傷害、中毒および処置合併症(Cont.)				
大腿骨骨折	1/55 (1.8)	0/51	0/33	0/30
手骨折	1/55 (1.8)	0/50	0/33	0/30
股関節部骨折	0/55	1/51 (2.0)	0/32	0/29
上腕骨骨折	0/55	0/51	0/33	1/30 (3.3)
肉離れ	1/55 (1.8)	0/50	0/32	0/29
臨床検査	3/55 (5.5)	0/48	2/31 (6.5)	1/26 (3.8)
血中ホモシステイン増加	2/55 (3.6)	0/49	0/32	0/29
血中ナトリウム減少	1/55 (1.8)	0/50	0/32	0/29
リンパ球数減少	0/55	0/51	1/33 (3.0)	0/29
ビタミンB12減少	0/55	1/51 (2.0)	0/32	0/29
ビタミンB6減少	0/55	0/51	2/33 (6.1)	0/28
ビタミンB6増加	0/55	0/51	0/33	1/30 (3.3)
代謝および栄養障害	1/55 (1.8)	1/50 (2.0)	1/31 (3.2)	1/27 (3.7)
低カリウム血症	0/55	0/51	0/33	0/30
低マグネシウム血症	0/55	0/51	0/33	0/30
鉄欠乏	0/55	1/51 (2.0)	0/32	0/29
ビタミンB群欠乏	1/55 (1.8)	0/50	0/32	0/29
ビタミンB12欠乏	0/55	0/51	1/33 (3.0)	0/29
ビタミンB6欠乏	0/55	0/51	0/33	1/30 (3.3)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Low Dose				
傷害、中毒および処置合併症(Cont.)				
大腿骨骨折	0/26	0/12	0/1	1/55 (1.8)
手骨折	0/26	0/12	0/1	1/55 (1.8)
股関節部骨折	0/25	0/11	0/1	1/55 (1.8)
上腕骨骨折	0/25	0/12	0/1	1/55 (1.8)
肉離れ	0/25	0/12	0/1	1/55 (1.8)
臨床検査	0/22	0/12	0/1	6/55 (10.9)
血中ホモシステイン増加	0/25	0/12	0/1	2/55 (3.6)
血中ナトリウム減少	0/25	0/12	0/1	1/55 (1.8)
リンパ球数減少	0/26	0/12	0/1	1/55 (1.8)
ビタミンB12減少	0/25	0/12	0/1	1/55 (1.8)
ビタミンB6減少	0/24	0/12	0/1	2/55 (3.6)
ビタミンB6増加	0/25	0/12	0/1	1/55 (1.8)
代謝および栄養障害	0/22	0/10	0/1	4/55 (7.3)
低カリウム血症	1/26 (3.8)	0/11	0/1	1/55 (1.8)
低マグネシウム血症	1/26 (3.8)	0/11	0/1	1/55 (1.8)
鉄欠乏	0/25	0/11	0/1	1/55 (1.8)
ビタミンB群欠乏	0/25	0/12	0/1	1/55 (1.8)
ビタミンB12欠乏	0/25	0/11	0/1	1/55 (1.8)
ビタミンB6欠乏	0/25	0/12	0/1	1/55 (1.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Low Dose				
筋骨格系および結合組織障害	4/55 (7.3)	2/47 (4.3)	1/28 (3.6)	2/27 (7.4)
背部痛	0/55	0/51	0/33	1/30 (3.3)
滑液包炎	1/55 (1.8)	0/50	0/32	0/29
腰部脊柱管狭窄症	0/55	0/51	1/33 (3.0)	0/29
筋骨格系胸痛	1/55 (1.8)	0/50	0/33	0/30
変形性関節症	1/55 (1.8)	1/50 (2.0)	0/31	1/29 (3.4)
骨粗鬆症	1/55 (1.8)	0/50	0/32	1/29 (3.4)
四肢痛	1/55 (1.8)	0/50	0/33	1/30 (3.3)
肩回旋筋腱板症候群	0/55	0/51	0/33	0/30
変形性脊椎症	0/55	0/51	1/33 (3.0)	0/30
腱鞘炎	1/55 (1.8)	0/50	0/32	0/30
斜頚	0/55	1/51 (2.0)	0/32	0/30
神経系障害	4/55 (7.3)	3/47 (6.4)	1/28 (3.6)	2/25 (8.0)
健忘	1/55 (1.8)	0/50	0/32	0/30
運動緩慢	0/55	0/51	0/33	0/30
認知障害	1/55 (1.8)	0/50	0/32	0/29
浮動性めまい	1/55 (1.8)	0/50	0/33	0/30
ジスキネジア	0/55	0/51	0/33	1/30 (3.3)
伸展性足底反応	0/55	1/51 (2.0)	0/32	0/29
すくみ現象	0/55	2/51 (3.9)	0/31	1/28 (3.6)
頭蓋内出血	0/55	0/51	1/33 (3.0)	0/29
頭痛	0/55	0/51	0/33	0/30

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Low Dose				
筋骨格系および結合組織障害	1/21 (4.8)	0/10	0/0	10/55 (18.2)
背部痛	0/25	0/12	0/1	1/55 (1.8)
滑液包炎	0/25	0/12	0/1	1/55 (1.8)
腰部脊柱管狭窄症	0/25	0/11	0/1	1/55 (1.8)
筋骨格系胸痛	0/26	0/12	0/1	1/55 (1.8)
変形性関節症	0/24	0/11	0/0	3/55 (5.5)
骨粗鬆症	0/24	0/12	0/1	2/55 (3.6)
四肢痛	0/25	0/12	0/1	2/55 (3.6)
肩回旋筋腱板症候群	1/26 (3.8)	1/12 (8.3)	0/0	2/55 (3.6)
変形性脊椎症	0/26	0/12	0/1	1/55 (1.8)
腱鞘炎	0/26	0/12	0/1	1/55 (1.8)
斜頸	0/26	0/12	0/1	1/55 (1.8)
神経系障害	0/20	1/11 (9.1)	0/1	11/55 (20.0)
健忘	0/26	0/12	0/1	1/55 (1.8)
運動緩慢	1/26 (3.8)	0/12	0/1	1/55 (1.8)
認知障害	0/25	0/12	0/1	1/55 (1.8)
浮動性めまい	0/26	0/12	0/1	1/55 (1.8)
ジスキネジア	0/26	0/12	0/1	1/55 (1.8)
伸展性足底反応	0/25	0/11	0/1	1/55 (1.8)
すくみ現象	0/23	0/12	0/1	3/55 (5.5)
頭蓋内出血	0/25	0/12	0/1	1/55 (1.8)
頭痛	1/26 (3.8)	0/11	0/1	1/55 (1.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Low Dose				
神経系障害 (Cont.)				
感覚鈍麻	0/55	0/51	0/33	0/30
反射減弱	1/55 (1.8)	0/50	0/32	0/30
オンオフ現象	0/55	1/51 (2.0)	1/32 (3.1)	0/29
錯感覚	1/55 (1.8)	0/50	0/33	0/30
パーキンソン病	0/55	1/51 (2.0)	0/32	1/29 (3.4)
呼吸器ジスキネジア	0/55	0/51	0/33	0/30
振戦	0/55	1/51 (2.0)	0/32	0/29
精神障害	7/55 (12.7)	7/44 (15.9)	1/22 (4.5)	0/20
不安	0/55	2/51 (3.9)	0/31	2/29 (6.9)
歯ぎしり	1/55 (1.8)	0/50	0/32	0/29
妄想	0/55	1/51 (2.0)	0/33	0/30
抑うつ気分	0/55	0/51	1/33 (3.0)	0/29
うつ病	1/55 (1.8)	1/50 (2.0)	0/31	0/28
失見当識	0/55	0/51	0/33	0/30
ギャンブル障害	1/55 (1.8)	0/50	0/32	0/29
幻覚	2/55 (3.6)	2/49 (4.1)	0/29	0/27
幻嗅	0/55	1/51 (2.0)	0/32	0/29
幻視	0/55	1/51 (2.0)	0/32	0/29
軽躁	1/55 (1.8)	0/50	0/33	0/30
錯覚	0/55	0/51	1/33 (3.0)	0/29
衝動行為	0/55	1/51 (2.0)	0/32	0/29
不眠症	0/55	1/51 (2.0)	0/33	0/30

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Low Dose				
神経系障害 (Cont.)				
感覚鈍麻	0/26	1/12 (8.3)	0/1	1/55 (1.8)
反射減弱	0/26	0/12	0/1	1/55 (1.8)
オンオフ現象	0/25	0/12	0/1	2/55 (3.6)
錯感覚	0/26	0/12	0/1	1/55 (1.8)
パーキンソン病	0/24	0/12	0/1	2/55 (3.6)
呼吸器ジスキネジア	0/26	1/12 (8.3)	0/1	1/55 (1.8)
振戦	0/25	0/12	0/1	1/55 (1.8)
精神障害	0/17	0/9	0/1	15/55 (27.3)
不安	0/23	0/10	0/1	4/55 (7.3)
歯ぎしり	0/25	0/11	0/1	1/55 (1.8)
妄想	0/26	0/12	0/1	1/55 (1.8)
抑うつ気分	0/25	0/12	0/1	1/55 (1.8)
うつ病	0/24	0/12	0/1	2/55 (3.6)
失見当識	1/26 (3.8)	0/12	0/1	1/55 (1.8)
ギャンブル障害	0/26	0/12	0/1	1/55 (1.8)
幻覚	0/23	0/11	0/1	4/55 (7.3)
幻嗅	0/25	0/12	0/1	1/55 (1.8)
幻視	0/25	0/11	0/1	1/55 (1.8)
軽躁	0/26	0/12	0/1	1/55 (1.8)
錯覚	0/25	0/12	0/1	1/55 (1.8)
衝動行為	0/25	0/12	0/1	1/55 (1.8)
不眠症	0/26	0/12	0/1	1/55 (1.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Low Dose				
精神障害 (Cont.)				
消極的思考	0/55	0/51	1/33 (3.0)	0/29
パニック発作	0/55	0/51	0/33	1/30 (3.3)
妄想症	0/55	0/51	1/33 (3.0)	0/29
精神病性障害	0/55	1/51 (2.0)	0/32	0/29
レム睡眠行動障害	1/55 (1.8)	0/50	0/32	0/29
腎および尿路障害	1/55 (1.8)	0/50	0/32	0/29
膀胱痙縮	1/55 (1.8)	0/50	0/32	0/29
緊張性膀胱	0/55	0/51	0/33	0/30
尿失禁	0/55	0/51	0/33	0/30
生殖系および乳房障害	2/55 (3.6)	0/49	0/31	0/28
良性前立腺肥大症	1/55 (1.8)	0/50	0/32	0/29
外陰膣乾燥	1/55 (1.8)	0/50	0/32	0/29
呼吸器、胸郭および縦隔障害	0/55	0/51	1/33 (3.0)	1/29 (3.4)
窒息	0/55	0/51	1/33 (3.0)	0/29
誤嚥	0/55	0/51	1/33 (3.0)	0/29
呼吸困難	0/55	0/51	0/33	1/30 (3.3)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Low Dose				
精神障害 (Cont.)				
消極的思考	0/25	0/12	0/1	1/55 (1.8)
パニック発作	0/25	0/12	0/1	1/55 (1.8)
妄想症	0/25	0/12	0/1	1/55 (1.8)
精神病性障害	0/25	0/12	0/1	1/55 (1.8)
レム睡眠行動障害	0/25	0/12	0/1	1/55 (1.8)
腎および尿路障害	2/25 (8.0)	0/10	0/1	3/55 (5.5)
膀胱痙縮	0/25	0/11	0/1	1/55 (1.8)
緊張性膀胱	1/26 (3.8)	0/12	0/1	1/55 (1.8)
尿失禁	1/26 (3.8)	0/11	0/1	1/55 (1.8)
生殖系および乳房障害	0/24	0/12	0/1	2/55 (3.6)
良性前立腺肥大症	0/25	0/12	0/1	1/55 (1.8)
外陰腟乾燥	0/25	0/12	0/1	1/55 (1.8)
呼吸器、胸郭および縦隔障害	0/25	0/11	0/1	2/55 (3.6)
窒息	0/26	0/12	0/1	1/55 (1.8)
誤嚥	0/26	0/12	0/1	1/55 (1.8)
呼吸困難	0/25	0/11	0/1	1/55 (1.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Low Dose				
皮膚および皮下組織障害	0/55	2/51 (3.9)	1/31 (3.2)	1/27 (3.7)
光線角化症	0/55	0/51	1/33 (3.0)	0/29
脱毛症	0/55	1/51 (2.0)	0/32	0/29
湿疹	0/55	1/51 (2.0)	0/32	0/29
発疹	0/55	1/51 (2.0)	0/32	0/29
蕁麻疹	0/55	0/51	0/33	1/30 (3.3)
血管障害	0/55	2/51 (3.9)	0/31	1/28 (3.6)
血腫	0/55	1/51 (2.0)	0/32	0/29
低血圧	0/55	0/51	0/33	1/30 (3.3)
起立性低血圧	0/55	1/51 (2.0)	0/32	0/29

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Low Dose				
皮膚および皮下組織障害	0/22	0/10	0/1	4/55 (7.3)
光線角化症	0/25	0/11	0/1	1/55 (1.8)
脱毛症	0/25	0/12	0/1	1/55 (1.8)
湿疹	0/25	0/12	0/1	1/55 (1.8)
発疹	0/25	0/12	0/1	1/55 (1.8)
蕁麻疹	0/25	0/11	0/1	1/55 (1.8)
血管障害	0/24	0/12	0/1	3/55 (5.5)
血腫	0/25	0/12	0/1	1/55 (1.8)
低血圧	0/26	0/12	0/1	1/55 (1.8)
起立性低血圧	0/25	0/12	0/1	1/55 (1.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
High Dose				
Any adverse event	29/61 (47.5)	9/32 (28.1)	6/15 (40.0)	2/8 (25.0)
心臓障害	0/61	0/61	1/45 (2.2)	0/38
左脚ブロック	0/61	0/61	1/45 (2.2)	0/38
耳および迷路障害	0/61	1/61 (1.6)	0/44	0/38
回転性めまい	0/61	1/61 (1.6)	0/44	0/38
眼障害	0/61	2/61 (3.3)	1/43 (2.3)	0/36
眼瞼痙攣	0/61	1/61 (1.6)	0/44	0/38
眼の異物感	0/61	0/61	0/45	1/39 (2.6)
眼部不快感	0/61	0/61	1/45 (2.2)	0/38
眼充血	0/61	1/61 (1.6)	0/44	1/38 (2.6)
霧視	0/61	0/61	1/45 (2.2)	0/38
胃腸障害	4/61 (6.6)	1/57 (1.8)	1/42 (2.4)	0/36
腹部不快感	0/61	0/61	1/45 (2.2)	0/38
腹部膨満	1/61 (1.6)	0/60	0/44	0/38
腹痛	0/61	1/61 (1.6)	0/44	0/38
便秘	2/61 (3.3)	0/59	0/43	0/38
出血性腸憩室	1/61 (1.6)	0/60	0/44	0/39
嚥下障害	1/61 (1.6)	0/60	0/45	0/39
悪心	1/61 (1.6)	1/60 (1.7)	0/45	0/39

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
High Dose				
Any adverse event	2/6 (33.3)	1/2 (50.0)	0/0	49/61 (80.3)
心臓障害	0/37	0/19	0/4	1/61 (1.6)
左脚ブロック	0/37	0/19	0/4	1/61 (1.6)
耳および迷路障害	1/37 (2.7)	0/18	0/4	2/61 (3.3)
回転性めまい	1/37 (2.7)	0/18	0/4	2/61 (3.3)
眼障害	0/35	0/18	0/4	3/61 (4.9)
眼瞼痙攣	0/37	0/19	0/4	1/61 (1.6)
眼の異物感	0/37	0/20	0/4	1/61 (1.6)
眼部不快感	0/37	0/20	0/4	1/61 (1.6)
眼充血	0/36	0/19	0/4	2/61 (3.3)
霧視	0/37	0/20	0/4	1/61 (1.6)
胃腸障害	0/35	0/19	1/4 (25.0)	7/61 (11.5)
腹部不快感	0/37	0/19	0/4	1/61 (1.6)
腹部膨満	0/37	0/20	0/4	1/61 (1.6)
腹痛	0/37	0/20	0/4	1/61 (1.6)
便秘	0/37	0/19	0/4	2/61 (3.3)
出血性腸憩室	0/38	0/20	0/4	1/61 (1.6)
嚥下障害	0/38	0/20	1/4 (25.0)	2/61 (3.3)
悪心	0/38	0/20	0/4	2/61 (3.3)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
High Dose				
胃腸障害 (Cont.)				
吐き戻し	1/61 (1.6)	0/60	0/45	0/39
流涎過多	0/61	0/61	1/45 (2.2)	0/38
一般・全身障害および投与部位の状態	12/61 (19.7)	6/49 (12.2)	0/32	2/28 (7.1)
投与部位内出血	1/61 (1.6)	0/60	0/45	0/39
カテーテル留置部位内出血	0/61	2/61 (3.3)	0/45	0/39
カテーテル留置部位漏出	0/61	1/61 (1.6)	0/45	0/39
カテーテル留置部位炎症	0/61	0/61	0/45	1/39 (2.6)
注入部位内出血	2/61 (3.3)	1/59 (1.7)	0/42	0/37
注入部位変色	0/61	1/61 (1.6)	0/44	0/38
注入部位紅斑	5/61 (8.2)	2/56 (3.6)	0/39	0/34
注入部位血管外漏出	0/61	1/61 (1.6)	0/44	0/38
注入部位血腫	1/61 (1.6)	0/60	0/45	0/39
注入部位硬結	0/61	1/61 (1.6)	0/44	1/38 (2.6)
注入部位炎症	0/61	1/61 (1.6)	0/44	0/38
注入部位結節	2/61 (3.3)	0/59	0/43	1/38 (2.6)
注入部位浮腫	1/61 (1.6)	0/60	0/45	0/39
注入部位疼痛	0/61	0/61	0/45	0/39
注入部位丘疹	3/61 (4.9)	0/58	0/43	0/38
注入部位異常感覚	1/61 (1.6)	0/60	0/44	0/39
注入部位発疹	1/61 (1.6)	0/60	0/45	0/39
注入部位反応	0/61	1/61 (1.6)	0/44	0/38

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
High Dose				
胃腸障害 (Cont.)				
吐き戻し	0/38	0/20	0/4	1/61 (1.6)
流涎過多	0/37	0/20	0/4	1/61 (1.6)
一般・全身障害および投与部位の状態	1/26 (3.8)	0/15	0/3	21/61 (34.4)
投与部位内出血	0/38	0/20	0/4	1/61 (1.6)
カテーテル留置部位内出血	0/38	0/20	0/4	2/61 (3.3)
カテーテル留置部位漏出	0/38	0/20	0/4	1/61 (1.6)
カテーテル留置部位炎症	0/37	0/20	0/4	1/61 (1.6)
注入部位内出血	0/36	0/20	0/4	3/61 (4.9)
注入部位変色	0/37	0/20	0/4	1/61 (1.6)
注入部位紅斑	1/34 (2.9)	0/18	0/4	8/61 (13.1)
注入部位血管外漏出	1/37 (2.7)	0/19	0/3	2/61 (3.3)
注入部位血腫	0/38	0/20	0/4	1/61 (1.6)
注入部位硬結	0/36	0/19	0/4	2/61 (3.3)
注入部位炎症	0/37	0/20	0/4	1/61 (1.6)
注入部位結節	0/36	0/20	0/4	3/61 (4.9)
注入部位浮腫	0/38	0/20	0/4	1/61 (1.6)
注入部位疼痛	1/38 (2.6)	0/19	0/3	1/61 (1.6)
注入部位丘疹	0/38	0/20	0/4	3/61 (4.9)
注入部位異常感覚	0/38	0/20	0/4	1/61 (1.6)
注入部位発疹	0/38	0/20	0/4	1/61 (1.6)
注入部位反応	0/37	0/20	0/4	1/61 (1.6)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
High Dose				
一般・全身障害および投与部位の状態(Cont.)				
注入部位痂皮	0/61	0/61	0/45	1/39 (2.6)
注入部位腫脹	1/61 (1.6)	0/60	0/44	0/39
注射部位内出血	0/61	0/61	1/45 (2.2)	0/38
注射部位紅斑	1/61 (1.6)	1/60 (1.7)	0/44	0/38
注射部位硬結	1/61 (1.6)	0/60	0/44	0/38
注射部位炎症	1/61 (1.6)	0/60	0/44	0/38
注射部位浮腫	1/61 (1.6)	0/60	0/45	0/39
感染症および寄生虫症	8/61 (13.1)	4/53 (7.5)	3/36 (8.3)	1/31 (3.2)
ダニ皮膚炎	0/61	0/61	0/45	1/39 (2.6)
無症候性COVID-19	1/61 (1.6)	1/60 (1.7)	0/45	0/39
COVID-19	0/61	0/61	0/45	2/39 (5.1)
大腸菌性尿路感染	0/61	1/61 (1.6)	0/44	0/38
胃腸炎	0/61	0/61	1/45 (2.2)	0/38
帯状疱疹	0/61	1/61 (1.6)	0/44	0/38
注入部位蜂巣炎	4/61 (6.6)	2/57 (3.5)	3/40 (7.5)	0/35
注射部位蜂巣炎	0/61	0/61	0/45	0/39
注射部位感染	0/61	0/61	1/45 (2.2)	0/38
上咽頭炎	0/61	0/61	1/45 (2.2)	0/38
口腔カンジダ症	0/61	1/61 (1.6)	0/45	0/39

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
High Dose				
一般・全身障害および投与部位の状態(Cont.)				
注入部位痂皮	0/37	0/20	0/4	1/61 (1.6)
注入部位腫脹	0/38	0/20	0/4	1/61 (1.6)
注射部位内出血	0/37	0/20	0/4	1/61 (1.6)
注射部位紅斑	0/37	0/19	0/4	2/61 (3.3)
注射部位硬結	0/37	0/19	0/4	1/61 (1.6)
注射部位炎症	0/37	0/20	0/4	1/61 (1.6)
注射部位浮腫	0/38	0/20	0/4	1/61 (1.6)
感染症および寄生虫症	3/29 (10.3)	0/15	0/2	19/61 (31.1)
ダニ皮膚炎	0/37	0/20	0/4	1/61 (1.6)
無症候性COVID-19	0/38	0/20	0/4	2/61 (3.3)
COVID-19	2/36 (5.6)	0/19	0/3	4/61 (6.6)
大腸菌性尿路感染	0/37	0/20	0/4	1/61 (1.6)
胃腸炎	0/37	0/19	0/4	1/61 (1.6)
帯状疱疹	0/37	0/20	0/4	1/61 (1.6)
注入部位蜂巣炎	1/34 (2.9)	0/17	0/3	10/61 (16.4)
注射部位蜂巣炎	0/38	1/20 (5.0)	0/4	1/61 (1.6)
注射部位感染	0/37	0/20	0/4	1/61 (1.6)
上咽頭炎	0/37	0/20	0/4	1/61 (1.6)
口腔カンジダ症	0/38	0/20	0/4	1/61 (1.6)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
High Dose				
感染症および寄生虫症 (Cont.)				
敗血症	0/61	1/61 (1.6)	0/45	0/39
副鼻腔炎	1/61 (1.6)	0/60	0/44	0/38
尿路感染	2/61 (3.3)	1/59 (1.7)	0/43	1/37 (2.7)
尿路性敗血症	1/61 (1.6)	0/60	0/45	0/39
傷害、中毒および処置合併症	6/61 (9.8)	5/55 (9.1)	2/36 (5.6)	0/29
節足動物咬傷	0/61	1/61 (1.6)	0/44	0/38
挫傷	1/61 (1.6)	0/60	0/45	0/39
顔面骨骨折	1/61 (1.6)	0/60	0/44	0/39
転倒	5/61 (8.2)	2/56 (3.6)	2/39 (5.1)	0/32
大腿骨頚部骨折	0/61	0/61	0/45	1/39 (2.6)
転位骨折	0/61	1/61 (1.6)	0/44	0/38
手骨折	0/61	1/61 (1.6)	1/44 (2.3)	0/37
股関節部骨折	1/61 (1.6)	0/60	0/44	0/39
上腕骨骨折	1/61 (1.6)	0/60	0/44	0/39
靭帯捻挫	0/61	1/61 (1.6)	0/44	0/38
四肢損傷	0/61	1/61 (1.6)	0/44	0/38
開放骨折	1/61 (1.6)	0/60	0/45	0/39
処置による疼痛	0/61	1/61 (1.6)	0/44	0/38
肩甲骨骨折	1/61 (1.6)	0/60	0/44	0/38
外傷性頭蓋内出血	0/61	1/61 (1.6)	0/45	0/39

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
High Dose				
感染症および寄生虫症 (Cont.)				
敗血症	0/38	0/20	0/4	1/61 (1.6)
副鼻腔炎	0/37	0/20	0/4	1/61 (1.6)
尿路感染	0/35	0/19	0/3	4/61 (6.6)
尿路性敗血症	0/38	0/20	0/4	1/61 (1.6)
傷害、中毒および処置合併症	0/29	0/15	0/4	13/61 (21.3)
節足動物咬傷	0/37	0/20	0/4	1/61 (1.6)
挫傷	0/38	0/20	0/4	1/61 (1.6)
顔面骨骨折	0/38	0/20	0/4	1/61 (1.6)
転倒	0/31	0/16	0/4	9/61 (14.8)
大腿骨頚部骨折	0/37	0/20	0/4	1/61 (1.6)
転位骨折	0/37	0/20	0/4	1/61 (1.6)
手骨折	0/36	0/18	0/4	2/61 (3.3)
股関節部骨折	0/38	0/20	0/4	1/61 (1.6)
上腕骨骨折	0/38	0/20	0/4	1/61 (1.6)
靭帯捻挫	0/37	0/20	0/4	1/61 (1.6)
四肢損傷	0/38	0/20	0/4	1/61 (1.6)
開放骨折	0/38	0/20	0/4	1/61 (1.6)
処置による疼痛	0/37	0/19	0/4	1/61 (1.6)
肩甲骨骨折	0/37	0/19	0/4	1/61 (1.6)
外傷性頭蓋内出血	0/38	0/20	0/4	1/61 (1.6)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
High Dose				
臨床検査	2/61 (3.3)	2/59 (3.4)	1/42 (2.4)	2/36 (5.6)
血中葉酸減少	1/61 (1.6)	1/60 (1.7)	0/44	0/38
ヘモグロビン減少	0/61	1/61 (1.6)	0/45	0/39
プロトロンビン時間延長	1/61 (1.6)	0/60	0/44	0/38
ビタミンB12減少	0/61	0/61	0/45	1/39 (2.6)
ビタミンD減少	0/61	0/61	0/45	1/39 (2.6)
体重減少	1/61 (1.6)	1/60 (1.7)	1/43 (2.3)	0/37
代謝および栄養障害	2/61 (3.3)	1/59 (1.7)	2/43 (4.7)	0/35
食欲減退	1/61 (1.6)	0/60	0/45	0/39
高ナトリウム血症	0/61	1/61 (1.6)	0/45	0/39
低カリウム血症	1/61 (1.6)	0/60	0/45	0/39
低マグネシウム血症	1/61 (1.6)	0/60	0/45	0/39
鉄欠乏	0/61	1/61 (1.6)	0/44	0/38
ビタミンB12欠乏	1/61 (1.6)	0/60	2/44 (4.5)	0/36
筋骨格系および結合組織障害	0/61	4/61 (6.6)	2/42 (4.8)	0/34
関節痛	0/61	1/61 (1.6)	0/45	0/39
背部痛	0/61	1/61 (1.6)	1/44 (2.3)	0/37
出血性関節症	0/61	1/61 (1.6)	0/44	0/38
椎間板変性症	0/61	0/61	1/45 (2.2)	0/38
筋力低下	0/61	1/61 (1.6)	0/44	0/38

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
High Dose				
臨床検査	0/33	0/19	0/4	7/61 (11.5)
血中葉酸減少	0/37	0/20	0/4	2/61 (3.3)
ヘモグロビン減少	0/38	0/20	0/4	1/61 (1.6)
プロトロンビン時間延長	0/37	0/20	0/4	1/61 (1.6)
ビタミンB12減少	0/37	0/20	0/4	1/61 (1.6)
ビタミンD減少	0/37	0/20	0/4	1/61 (1.6)
体重減少	0/36	0/19	0/4	3/61 (4.9)
代謝および栄養障害	0/34	0/17	0/4	5/61 (8.2)
食欲減退	0/38	0/20	0/4	1/61 (1.6)
高ナトリウム血症	0/38	0/20	0/4	1/61 (1.6)
低カリウム血症	0/38	0/20	0/4	1/61 (1.6)
低マグネシウム血症	0/38	0/20	0/4	1/61 (1.6)
鉄欠乏	0/37	0/20	0/4	1/61 (1.6)
ビタミンB12欠乏	0/35	0/17	0/4	3/61 (4.9)
筋骨格系および結合組織障害	0/33	0/17	1/4 (25.0)	7/61 (11.5)
関節痛	0/38	0/20	0/4	1/61 (1.6)
背部痛	0/36	0/18	0/4	2/61 (3.3)
出血性関節症	0/37	0/20	0/4	1/61 (1.6)
椎間板変性症	0/37	0/19	0/4	1/61 (1.6)
筋力低下	0/37	0/20	1/4 (25.0)	2/61 (3.3)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
High Dose				
筋骨格系および結合組織障害(Cont.)				
筋骨格硬直	0/61	1/61 (1.6)	0/44	0/38
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)	0/61	0/61	1/45 (2.2)	0/38
ケラトアカントーマ	0/61	0/61	1/45 (2.2)	0/38
神経系障害	8/61 (13.1)	2/53 (3.8)	3/37 (8.1)	1/30 (3.3)
平衡障害	1/61 (1.6)	0/60	0/44	0/38
認知障害	1/61 (1.6)	0/60	0/44	1/38 (2.6)
注意力障害	1/61 (1.6)	0/60	0/44	0/38
浮動性めまい	0/61	0/61	0/45	0/39
薬物離脱性頭痛	0/61	1/61 (1.6)	0/45	0/39
ジストニア	1/61 (1.6)	0/60	0/44	0/38
頭部不快感	1/61 (1.6)	0/60	1/45 (2.2)	0/38
頭痛	0/61	1/61 (1.6)	0/45	0/39
感覚鈍麻	0/61	0/61	1/45 (2.2)	0/38
反射減弱	0/61	1/61 (1.6)	0/44	0/38
記憶障害	1/61 (1.6)	0/60	0/44	0/38
オンオフ現象	2/61 (3.3)	3/59 (5.1)	0/42	0/36
錯感覚	0/61	0/61	0/45	0/39
パーキンソン病	2/61 (3.3)	2/59 (3.4)	1/43 (2.3)	0/38
精神運動亢進	0/61	0/61	1/45 (2.2)	0/38

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
High Dose				
筋骨格系および結合組織障害(Cont.)				
筋骨格硬直	0/37	0/20	0/4	1/61 (1.6)
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)	0/37	0/20	0/4	1/61 (1.6)
ケラトアカントーマ	0/37	0/20	0/4	1/61 (1.6)
神経系障害	1/28 (3.6)	1/15 (6.7)	0/3	16/61 (26.2)
平衡障害	0/37	0/20	0/4	1/61 (1.6)
認知障害	0/36	0/20	0/4	2/61 (3.3)
注意力障害	0/37	0/20	0/4	1/61 (1.6)
浮動性めまい	1/38 (2.6)	0/19	0/4	1/61 (1.6)
薬物離脱性頭痛	0/38	0/20	0/4	1/61 (1.6)
ジストニア	0/37	0/20	0/4	1/61 (1.6)
頭部不快感	0/37	0/20	0/4	2/61 (3.3)
頭痛	0/38	0/20	0/4	1/61 (1.6)
感覚鈍麻	0/37	0/19	0/4	1/61 (1.6)
反射減弱	0/37	0/20	0/4	1/61 (1.6)
記憶障害	0/37	1/20 (5.0)	0/3	2/61 (3.3)
オンオフ現象	0/35	0/19	0/4	5/61 (8.2)
錯感覚	0/38	1/20 (5.0)	0/4	1/61 (1.6)
パーキンソン病	0/37	0/20	0/4	5/61 (8.2)
精神運動亢進	0/37	0/19	0/4	1/61 (1.6)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
High Dose				
神経系障害 (Cont.)				
痙攣発作	0/61	1/61 (1.6)	0/45	0/39
失神	1/61 (1.6)	1/60 (1.7)	0/43	0/37
一過性脳虚血発作	1/61 (1.6)	0/60	0/44	0/38
精神障害	6/61 (9.8)	3/55 (5.5)	7/38 (18.4)	2/26 (7.7)
異常な夢	0/61	1/61 (1.6)	0/45	0/39
適応障害	0/61	1/61 (1.6)	0/44	0/38
攻撃性	1/61 (1.6)	0/60	0/44	0/39
激越	1/61 (1.6)	0/60	0/44	0/38
不安	1/61 (1.6)	0/60	3/44 (6.8)	0/35
錯乱状態	0/61	0/61	1/45 (2.2)	0/38
譫妄	1/61 (1.6)	1/60 (1.7)	0/44	0/39
妄想	0/61	0/61	1/45 (2.2)	0/38
うつ病	1/61 (1.6)	0/60	0/44	0/38
自傷性皮膚症	0/61	1/61 (1.6)	0/44	0/38
幻覚	2/61 (3.3)	0/59	2/43 (4.7)	1/35 (2.9)
幻視	0/61	0/61	0/45	1/39 (2.6)
錯覚	0/61	0/61	1/45 (2.2)	0/38
衝動制御障害	0/61	1/61 (1.6)	0/44	0/38
不眠症	0/61	0/61	1/45 (2.2)	0/38
パニック発作	0/61	1/61 (1.6)	0/44	0/38
精神病性障害	0/61	1/61 (1.6)	0/44	0/38

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
High Dose				
神経系障害 (Cont.)				
痙攣発作	0/38	0/20	0/4	1/61 (1.6)
失神	0/36	0/19	0/4	2/61 (3.3)
一過性脳虚血発作	0/37	0/20	0/4	1/61 (1.6)
精神障害	0/24	0/14	0/3	18/61 (29.5)
異常な夢	0/38	0/20	0/4	1/61 (1.6)
適応障害	0/37	0/20	0/4	1/61 (1.6)
攻撃性	0/38	0/20	0/4	1/61 (1.6)
激越	0/37	0/19	0/4	1/61 (1.6)
不安	0/34	0/18	0/3	4/61 (6.6)
錯乱状態	0/37	0/19	0/4	1/61 (1.6)
譫妄	0/38	0/20	0/4	2/61 (3.3)
妄想	0/37	0/19	0/4	1/61 (1.6)
うつ病	0/37	0/20	0/4	1/61 (1.6)
自傷性皮膚症	0/38	0/20	0/4	1/61 (1.6)
幻覚	0/33	0/18	0/3	5/61 (8.2)
幻視	0/37	0/19	0/4	1/61 (1.6)
錯覚	0/37	0/20	0/4	1/61 (1.6)
衝動制御障害	0/37	0/20	0/4	1/61 (1.6)
不眠症	0/37	0/20	0/4	1/61 (1.6)
パニック発作	0/37	0/20	0/4	1/61 (1.6)
精神病性障害	0/37	0/20	0/4	1/61 (1.6)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
High Dose				
精神障害 (Cont.)				
睡眠障害	1/61 (1.6)	0/60	0/45	0/39
腎および尿路障害	1/61 (1.6)	1/60 (1.7)	0/44	1/38 (2.6)
急性腎障害	1/61 (1.6)	0/60	0/45	0/39
血尿	0/61	1/61 (1.6)	0/44	0/38
水腎症	1/61 (1.6)	0/60	0/45	0/39
水尿管症	1/61 (1.6)	0/60	0/45	0/39
腎結石症	0/61	0/61	0/45	0/39
蛋白尿	0/61	0/61	0/45	1/39 (2.6)
生殖系および乳房障害	1/61 (1.6)	1/60 (1.7)	0/44	0/38
膀胱瘤	0/61	0/61	0/45	0/39
勃起不全	1/61 (1.6)	0/60	0/44	0/38
生殖器萎縮	0/61	0/61	0/45	0/39
腟脱	0/61	1/61 (1.6)	0/45	0/39
呼吸器、胸郭および縦隔障害	0/61	0/61	0/45	0/39
痰貯留	0/61	0/61	0/45	0/39

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
High Dose				
精神障害 (Cont.)				
睡眠障害	0/38	0/20	0/4	1/61 (1.6)
腎および尿路障害	1/36 (2.8)	0/18	0/4	4/61 (6.6)
急性腎障害	0/38	0/20	0/4	1/61 (1.6)
血尿	0/37	0/19	0/4	1/61 (1.6)
水腎症	0/38	0/20	0/4	1/61 (1.6)
水尿管症	0/38	0/20	0/4	1/61 (1.6)
腎結石症	1/38 (2.6)	0/19	0/4	1/61 (1.6)
蛋白尿	0/37	0/20	0/4	1/61 (1.6)
生殖系および乳房障害	1/37 (2.7)	0/19	0/4	3/61 (4.9)
膀胱瘤	1/38 (2.6)	0/19	0/4	1/61 (1.6)
勃起不全	0/37	0/20	0/4	1/61 (1.6)
生殖器萎縮	1/38 (2.6)	0/19	0/4	1/61 (1.6)
腟脱	0/38	0/20	0/4	1/61 (1.6)
呼吸器、胸郭および縦隔障害	1/38 (2.6)	0/19	0/4	1/61 (1.6)
痰貯留	1/38 (2.6)	0/19	0/4	1/61 (1.6)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
High Dose				
皮膚および皮下組織障害	0/61	0/61	0/45	1/39 (2.6)
湿疹	0/61	0/61	0/45	1/39 (2.6)
血管障害	3/61 (4.9)	2/58 (3.4)	1/41 (2.4)	0/34
高血圧	0/61	1/61 (1.6)	0/44	0/38
低血圧	1/61 (1.6)	0/60	0/44	0/38
起立性高血圧	1/61 (1.6)	0/60	0/44	0/38
起立性低血圧	1/61 (1.6)	1/60 (1.7)	0/44	0/38
表在性血栓性静脈炎	0/61	0/61	1/45 (2.2)	0/38

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1.J

Incidence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
High Dose				
皮膚および皮下組織障害	0/37	0/19	0/4	1/61 (1.6)
湿疹	0/37	0/19	0/4	1/61 (1.6)
血管障害	0/33	0/18	0/3	6/61 (9.8)
高血圧	0/37	0/20	0/4	1/61 (1.6)
低血圧	0/37	0/20	0/4	1/61 (1.6)
起立性高血圧	0/37	0/20	0/4	1/61 (1.6)
起立性低血圧	0/37	0/19	0/4	2/61 (3.3)
表在性血栓性静脈炎	0/37	0/19	0/3	1/61 (1.6)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

表40　有害事象の90日間ごとの有病割合の推移（安全性解析対象集団）：M15-737試験

[redacted]20[redacted] 10:04 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.3 1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=116) n/N_eval (%)	 Days 91 to 180 (N=112) n/N_eval (%)	 Days 181 to 270 (N=78) n/N_eval (%)	 Days 271 to 360 (N=69) n/N_eval (%)
Total (Any Dose)				
Any adverse event	57/116 (49.1)	65/112 (58.0)	57/78 (73.1)	52/69 (75.4)
心臓障害	0/116	0/112	1/78 (1.3)	2/69 (2.9)
急性心筋梗塞	0/116	0/112	0/78	0/69
徐脈	0/116	0/112	0/78	1/69 (1.4)
左脚ブロック	0/116	0/112	1/78 (1.3)	1/69 (1.4)
洞性頻脈	0/116	0/112	0/78	0/69
耳および迷路障害	0/116	1/112 (0.9)	0/78	0/69
回転性めまい	0/116	1/112 (0.9)	0/78	0/69
眼障害	0/116	2/112 (1.8)	2/78 (2.6)	3/69 (4.3)
眼瞼痙攣	0/116	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
眼の異物感	0/116	0/112	0/78	1/69 (1.4)
黄斑症	0/116	0/112	0/78	1/69 (1.4)
眼部不快感	0/116	0/112	1/78 (1.3)	1/69 (1.4)
眼充血	0/116	1/112 (0.9)	0/78	1/69 (1.4)
霧視	0/116	0/112	1/78 (1.3)	1/69 (1.4)
胃腸障害	9/116 (7.8)	9/112 (8.0)	6/78 (7.7)	7/69 (10.1)
腹部不快感	0/116	0/112	1/78 (1.3)	0/69
腹部膨満	1/116 (0.9)	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Total (Any Dose)				
Any adverse event	51/64 (79.7)	24/32 (75.0)	3/5 (60.0)	88/116 (75.9)
心臓障害	3/64 (4.7)	1/32 (3.1)	0/5	4/116 (3.4)
急性心筋梗塞	1/64 (1.6)	0/32	0/5	1/116 (0.9)
徐脈	0/64	0/32	0/5	1/116 (0.9)
左脚ブロック	1/64 (1.6)	1/32 (3.1)	0/5	1/116 (0.9)
洞性頻脈	1/64 (1.6)	0/32	0/5	1/116 (0.9)
耳および迷路障害	1/64 (1.6)	0/32	0/5	2/116 (1.7)
回転性めまい	1/64 (1.6)	0/32	0/5	2/116 (1.7)
眼障害	3/64 (4.7)	1/32 (3.1)	0/5	4/116 (3.4)
眼瞼痙攣	1/64 (1.6)	1/32 (3.1)	0/5	1/116 (0.9)
眼の異物感	1/64 (1.6)	0/32	0/5	1/116 (0.9)
黄斑症	1/64 (1.6)	0/32	0/5	1/116 (0.9)
眼部不快感	1/64 (1.6)	0/32	0/5	1/116 (0.9)
眼充血	1/64 (1.6)	0/32	0/5	2/116 (1.7)
霧視	1/64 (1.6)	0/32	0/5	1/116 (0.9)
胃腸障害	6/64 (9.4)	2/32 (6.3)	1/5 (20.0)	14/116 (12.1)
腹部不快感	0/64	0/32	0/5	1/116 (0.9)
腹部膨満	0/64	0/32	0/5	1/116 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Total (Any Dose)				
胃腸障害 (Cont.)				
腹痛	0/116	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
便秘	4/116 (3.4)	4/112 (3.6)	3/78 (3.8)	3/69 (4.3)
出血性腸憩室	1/116 (0.9)	1/112 (0.9)	0/78	0/69
嚥下障害	2/116 (1.7)	2/112 (1.8)	1/78 (1.3)	1/69 (1.4)
胃潰瘍	0/116	0/112	0/78	1/69 (1.4)
胃食道逆流性疾患	1/116 (0.9)	1/112 (0.9)	1/78 (1.3)	0/69
悪心	2/116 (1.7)	2/112 (1.8)	0/78	1/69 (1.4)
吐き戻し	1/116 (0.9)	1/112 (0.9)	0/78	0/69
流涎過多	0/116	0/112	1/78 (1.3)	1/69 (1.4)
嘔吐	1/116 (0.9)	0/112	0/78	0/69
一般・全身障害および投与部位の状態	23/116 (19.8)	30/112 (26.8)	19/78 (24.4)	20/69 (29.0)
投与部位内出血	1/116 (0.9)	1/112 (0.9)	0/78	0/69
投与部位漏出	0/116	1/112 (0.9)	1/78 (1.3)	0/69
カテーテル留置部位内出血	0/116	2/112 (1.8)	0/78	0/69
カテーテル留置部位紅斑	1/116 (0.9)	1/112 (0.9)	0/78	0/69
カテーテル留置部位漏出	0/116	1/112 (0.9)	0/78	0/69
カテーテル留置部位炎症	0/116	0/112	0/78	1/69 (1.4)
カテーテル留置部位疼痛	0/116	0/112	0/78	1/69 (1.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Total (Any Dose)				
胃腸障害 (Cont.)				
腹痛	1/64 (1.6)	0/32	0/5	1/116 (0.9)
便秘	3/64 (4.7)	1/32 (3.1)	0/5	5/116 (4.3)
出血性腸憩室	0/64	0/32	0/5	1/116 (0.9)
嚥下障害	1/64 (1.6)	0/32	1/5 (20.0)	3/116 (2.6)
胃潰瘍	1/64 (1.6)	1/32 (3.1)	0/5	1/116 (0.9)
胃食道逆流性疾患	0/64	0/32	0/5	1/116 (0.9)
悪心	0/64	0/32	0/5	4/116 (3.4)
吐き戻し	0/64	0/32	0/5	1/116 (0.9)
流涎過多	1/64 (1.6)	0/32	0/5	1/116 (0.9)
嘔吐	0/64	0/32	0/5	1/116 (0.9)
一般・全身障害および投与部位の状態	17/64 (26.6)	4/32 (12.5)	0/5	42/116 (36.2)
投与部位内出血	0/64	0/32	0/5	1/116 (0.9)
投与部位漏出	0/64	0/32	0/5	1/116 (0.9)
カテーテル留置部位内出血	1/64 (1.6)	0/32	0/5	3/116 (2.6)
カテーテル留置部位紅斑	0/64	0/32	0/5	1/116 (0.9)
カテーテル留置部位漏出	0/64	0/32	0/5	1/116 (0.9)
カテーテル留置部位炎症	0/64	0/32	0/5	1/116 (0.9)
カテーテル留置部位疼痛	0/64	0/32	0/5	1/116 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態 (Cont.)				
カテーテル留置部位腫脹	0/116	0/112	0/78	0/69
薬効欠如	1/116 (0.9)	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
薬物相互作用	0/116	0/112	0/78	1/69 (1.4)
疲労	1/116 (0.9)	1/112 (0.9)	0/78	2/69 (2.9)
注入部位内出血	3/116 (2.6)	2/112 (1.8)	3/78 (3.8)	2/69 (2.9)
注入部位皮膚炎	0/116	1/112 (0.9)	1/78 (1.3)	0/69
注入部位変色	0/116	1/112 (0.9)	0/78	0/69
注入部位紅斑	8/116 (6.9)	11/112 (9.8)	8/78 (10.3)	8/69 (11.6)
注入部位血管外漏出	0/116	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
注入部位血腫	1/116 (0.9)	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
注入部位硬結	1/116 (0.9)	2/112 (1.8)	1/78 (1.3)	2/69 (2.9)
注入部位炎症	0/116	1/112 (0.9)	0/78	0/69
注入部位刺激感	0/116	2/112 (1.8)	1/78 (1.3)	1/69 (1.4)
注入部位腫瘤	0/116	0/112	1/78 (1.3)	0/69
注入部位結節	3/116 (2.6)	2/112 (1.8)	1/78 (1.3)	3/69 (4.3)
注入部位浮腫	2/116 (1.7)	0/112	1/78 (1.3)	1/69 (1.4)
注入部位疼痛	1/116 (0.9)	0/112	0/78	0/69
注入部位丘疹	4/116 (3.4)	2/112 (1.8)	1/78 (1.3)	1/69 (1.4)
注入部位異常感覚	1/116 (0.9)	0/112	0/78	0/69

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態 (Cont.)				
カテーテル留置部位腫脹	1/64 (1.6)	0/32	0/5	1/116 (0.9)
薬効欠如	1/64 (1.6)	0/32	0/5	1/116 (0.9)
薬物相互作用	0/64	0/32	0/5	1/116 (0.9)
疲労	0/64	0/32	0/5	3/116 (2.6)
注入部位内出血	2/64 (3.1)	1/32 (3.1)	0/5	5/116 (4.3)
注入部位皮膚炎	0/64	0/32	0/5	1/116 (0.9)
注入部位変色	0/64	0/32	0/5	1/116 (0.9)
注入部位紅斑	6/64 (9.4)	2/32 (6.3)	0/5	19/116 (16.4)
注入部位血管外漏出	2/64 (3.1)	0/32	0/5	2/116 (1.7)
注入部位血腫	1/64 (1.6)	1/32 (3.1)	0/5	2/116 (1.7)
注入部位硬結	1/64 (1.6)	0/32	0/5	3/116 (2.6)
注入部位炎症	0/64	0/32	0/5	1/116 (0.9)
注入部位刺激感	1/64 (1.6)	0/32	0/5	2/116 (1.7)
注入部位腫瘤	0/64	0/32	0/5	1/116 (0.9)
注入部位結節	3/64 (4.7)	0/32	0/5	5/116 (4.3)
注入部位浮腫	0/64	0/32	0/5	2/116 (1.7)
注入部位疼痛	2/64 (3.1)	0/32	0/5	2/116 (1.7)
注入部位丘疹	1/64 (1.6)	0/32	0/5	4/116 (3.4)
注入部位異常感覚	0/64	0/32	0/5	1/116 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態 (Cont.)				
注入部位発疹	1/116 (0.9)	1/112 (0.9)	0/78	0/69
注入部位反応	0/116	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
注入部位痂皮	0/116	0/112	0/78	1/69 (1.4)
注入部位腫脹	1/116 (0.9)	0/112	0/78	1/69 (1.4)
注入部位熱感	1/116 (0.9)	1/112 (0.9)	0/78	0/69
注射部位内出血	0/116	1/112 (0.9)	2/78 (2.6)	2/69 (2.9)
注射部位紅斑	2/116 (1.7)	3/112 (2.7)	1/78 (1.3)	0/69
注射部位硬結	1/116 (0.9)	1/112 (0.9)	1/78 (1.3)	0/69
注射部位炎症	1/116 (0.9)	0/112	0/78	0/69
注射部位結節	1/116 (0.9)	1/112 (0.9)	0/78	0/69
注射部位浮腫	1/116 (0.9)	0/112	0/78	0/69
末梢性浮腫	1/116 (0.9)	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
穿刺部位紅斑	0/116	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
感染症および寄生虫症	12/116 (10.3)	15/112 (13.4)	16/78 (20.5)	15/69 (21.7)
ダニ皮膚炎	0/116	0/112	0/78	1/69 (1.4)
無症候性COVID-19	1/116 (0.9)	1/112 (0.9)	0/78	0/69
COVID-19	0/116	1/112 (0.9)	0/78	2/69 (2.9)
膀胱炎	1/116 (0.9)	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態 (Cont.)				
注入部位発疹	0/64	0/32	0/5	1/116 (0.9)
注入部位反応	1/64 (1.6)	0/32	0/5	1/116 (0.9)
注入部位痂皮	1/64 (1.6)	0/32	0/5	1/116 (0.9)
注入部位腫脹	0/64	0/32	0/5	2/116 (1.7)
注入部位熱感	0/64	0/32	0/5	1/116 (0.9)
注射部位内出血	2/64 (3.1)	0/32	0/5	2/116 (1.7)
注射部位紅斑	0/64	0/32	0/5	3/116 (2.6)
注射部位硬結	0/64	0/32	0/5	1/116 (0.9)
注射部位炎症	0/64	0/32	0/5	1/116 (0.9)
注射部位結節	0/64	0/32	0/5	1/116 (0.9)
注射部位浮腫	0/64	0/32	0/5	1/116 (0.9)
末梢性浮腫	1/64 (1.6)	0/32	0/5	1/116 (0.9)
穿刺部位紅斑	1/64 (1.6)	0/32	0/5	1/116 (0.9)
感染症および寄生虫症	13/64 (20.3)	6/32 (18.8)	0/5	34/116 (29.3)
ダニ皮膚炎	0/64	0/32	0/5	1/116 (0.9)
無症候性COVID-19	0/64	0/32	0/5	2/116 (1.7)
COVID-19	2/64 (3.1)	1/32 (3.1)	0/5	5/116 (4.3)
膀胱炎	0/64	0/32	0/5	1/116 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
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N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Total (Any Dose)				
感染症および寄生虫症 (Cont.)				
大腸菌性尿路感染	0/116	1/112 (0.9)	1/78 (1.3)	0/69
胃腸炎	1/116 (0.9)	0/112	2/78 (2.6)	0/69
ヘリコバクター性胃炎	1/116 (0.9)	1/112 (0.9)	1/78 (1.3)	0/69
ヘリコバクター感染	0/116	0/112	0/78	1/69 (1.4)
帯状疱疹	0/116	1/112 (0.9)	1/78 (1.3)	0/69
注入部位膿瘍	0/116	0/112	1/78 (1.3)	3/69 (4.3)
注入部位蜂巣炎	6/116 (5.2)	5/112 (4.5)	6/78 (7.7)	5/69 (7.2)
注入部位感染	0/116	2/112 (1.8)	1/78 (1.3)	2/69 (2.9)
注射部位蜂巣炎	0/116	0/112	0/78	0/69
注射部位感染	0/116	0/112	1/78 (1.3)	1/69 (1.4)
上咽頭炎	0/116	0/112	2/78 (2.6)	1/69 (1.4)
口腔カンジダ症	0/116	1/112 (0.9)	0/78	0/69
RSウイルス感染	0/116	0/112	1/78 (1.3)	1/69 (1.4)
敗血症	0/116	1/112 (0.9)	0/78	0/69
副鼻腔炎	1/116 (0.9)	0/112	0/78	0/69
上気道感染	0/116	1/112 (0.9)	0/78	0/69
尿路感染	2/116 (1.7)	3/112 (2.7)	1/78 (1.3)	2/69 (2.9)
尿路性敗血症	1/116 (0.9)	0/112	0/78	0/69

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N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2.J

Prevalence of Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Total (Any Dose)				
感染症および寄生虫症 (Cont.)				
大腸菌性尿路感染	0/64	0/32	0/5	1/116 (0.9)
胃腸炎	0/64	0/32	0/5	2/116 (1.7)
ヘリコバクター性胃炎	0/64	0/32	0/5	1/116 (0.9)
ヘリコバクター感染	1/64 (1.6)	1/32 (3.1)	0/5	1/116 (0.9)
帯状疱疹	0/64	0/32	0/5	1/116 (0.9)
注入部位膿瘍	2/64 (3.1)	0/32	0/5	3/116 (2.6)
注入部位蜂巣炎	6/64 (9.4)	3/32 (9.4)	0/5	16/116 (13.8)
注入部位感染	2/64 (3.1)	1/32 (3.1)	0/5	3/116 (2.6)
注射部位蜂巣炎	0/64	1/32 (3.1)	0/5	1/116 (0.9)
注射部位感染	0/64	0/32	0/5	1/116 (0.9)
上咽頭炎	0/64	0/32	0/5	2/116 (1.7)
口腔カンジダ症	0/64	0/32	0/5	1/116 (0.9)
RSウイルス感染	0/64	0/32	0/5	1/116 (0.9)
敗血症	0/64	0/32	0/5	1/116 (0.9)
副鼻腔炎	0/64	0/32	0/5	1/116 (0.9)
上気道感染	0/64	0/32	0/5	1/116 (0.9)
尿路感染	2/64 (3.1)	0/32	0/5	5/116 (4.3)
尿路性敗血症	0/64	0/32	0/5	1/116 (0.9)

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Program Source Code: [redacted]