TABLE 14.3__1.2

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
神経系障害	37 (33.3)	34 (35.8)	71 (34.5)
アカシジア	1 (0.9)	0	1 (0.5)
健忘	1 (0.9)	0	1 (0.5)
失語症	0	1 (1.1)	1 (0.5)
平衡障害	0	4 (4.2)	4 (1.9)
運動緩慢	0	1 (1.1)	1 (0.5)
手根管症候群	0	1 (1.1)	1 (0.5)
大脳萎縮	0	1 (1.1)	1 (0.5)
脳出血	0	1 (1.1)	1 (0.5)
脳圧排効果	0	1 (1.1)	1 (0.5)
脳血管発作	0	1 (1.1)	1 (0.5)
認知障害	2 (1.8)	2 (2.1)	4 (1.9)
振動覚低下	1 (0.9)	0	1 (0.5)
注意力障害	0	1 (1.1)	1 (0.5)
浮動性めまい	6 (5.4)	2 (2.1)	8 (3.9)
体位性めまい	3 (2.7)	0	3 (1.5)
構語障害	0	2 (2.1)	2 (1.0)
味覚不全	0	1 (1.1)	1 (0.5)
ジスキネジア	7 (6.3)	3 (3.2)	10 (4.9)
ジストニア	1 (0.9)	4 (4.2)	5 (2.4)

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__1.2

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
神経系障害 (Cont.)			
脳症	0	1 (1.1)	1 (0.5)
てんかん	0	1 (1.1)	1 (0.5)
伸展性足底反応	1 (0.9)	0	1 (0.5)
すくみ現象	1 (0.9)	0	1 (0.5)
全身性強直性間代性発作	0	1 (1.1)	1 (0.5)
頭痛	3 (2.7)	6 (6.3)	9 (4.4)
知覚過敏	0	1 (1.1)	1 (0.5)
感覚鈍麻	1 (0.9)	2 (2.1)	3 (1.5)
反射減弱	2 (1.8)	1 (1.1)	3 (1.5)
不規則睡眠覚醒リズム障害	1 (0.9)	0	1 (0.5)
嗜眠	1 (0.9)	1 (1.1)	2 (1.0)
意識消失	1 (0.9)	1 (1.1)	2 (1.0)
腰仙部神経根障害	0	1 (1.1)	1 (0.5)
記憶障害	0	2 (2.1)	2 (1.0)
代謝性脳症	1 (0.9)	0	1 (0.5)
神経痛	0	1 (1.1)	1 (0.5)
末梢性ニューロパチー	1 (0.9)	1 (1.1)	2 (1.0)
オンオフ現象	1 (0.9)	2 (2.1)	3 (1.5)
錯感覚	4 (3.6)	2 (2.1)	6 (2.9)
パーキンソン病	7 (6.3)	2 (2.1)	9 (4.4)

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__1.2

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
神経系障害 (Cont.)			
パーキンソニズム	0	2 (2.1)	2 (1.0)
末梢性感覚ニューロパチー	0	1 (1.1)	1 (0.5)
側反弓	1 (0.9)	2 (2.1)	3 (1.5)
多発ニューロパチー	0	2 (2.1)	2 (1.0)
失神寸前の状態	0	1 (1.1)	1 (0.5)
心因性発作	0	1 (1.1)	1 (0.5)
反射異常	0	1 (1.1)	1 (0.5)
坐骨神経痛	0	3 (3.2)	3 (1.5)
痙攣発作	0	1 (1.1)	1 (0.5)
感覚障害	0	1 (1.1)	1 (0.5)
感覚消失	0	1 (1.1)	1 (0.5)
睡眠時麻痺	1 (0.9)	0	1 (0.5)
傾眠	8 (7.2)	1 (1.1)	9 (4.4)
失神	0	3 (3.2)	3 (1.5)
振戦	1 (0.9)	0	1 (0.5)
製品の問題	2 (1.8)	0	2 (1.0)
医療機器送達システムの問題	1 (0.9)	0	1 (0.5)
医療機器位置異常	1 (0.9)	0	1 (0.5)
精神障害	38 (34.2)	42 (44.2)	80 (38.8)
感情不安定	0	1 (1.1)	1 (0.5)
激越	0	1 (1.1)	1 (0.5)
不安	10 (9.0)	12 (12.6)	22 (10.7)
不安障害	0	1 (1.1)	1 (0.5)

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__1.2

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
精神障害 (Cont.)			
無感情	1 (0.9)	0	1 (0.5)
強迫行為	0	1 (1.1)	1 (0.5)
強迫性性行動	1 (0.9)	0	1 (0.5)
錯乱状態	4 (3.6)	4 (4.2)	8 (3.9)
譫妄	0	2 (2.1)	2 (1.0)
妄想	7 (6.3)	1 (1.1)	8 (3.9)
寄生虫妄想	1 (0.9)	0	1 (0.5)
妄想性障害、詳細不明	0	1 (1.1)	1 (0.5)
抑うつ気分	2 (1.8)	1 (1.1)	3 (1.5)
うつ病	3 (2.7)	2 (2.1)	5 (2.4)
ドーパミン調節障害症候群	1 (0.9)	0	1 (0.5)
ディスフェミア	0	1 (1.1)	1 (0.5)
睡眠異常	1 (0.9)	0	1 (0.5)
情動障害	1 (0.9)	0	1 (0.5)
注射恐怖	0	1 (1.1)	1 (0.5)
幻覚	12 (10.8)	19 (20.0)	31 (15.0)
幻聴	3 (2.7)	2 (2.1)	5 (2.4)
幻嗅	0	1 (1.1)	1 (0.5)
幻視	6 (5.4)	4 (4.2)	10 (4.9)
混合性幻覚	1 (0.9)	0	1 (0.5)

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__1.2

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
精神障害 (Cont.)			
性欲過剰	1 (0.9)	0	1 (0.5)
錯覚	1 (0.9)	1 (1.1)	2 (1.0)
衝動制御障害	0	4 (4.2)	4 (1.9)
衝動行為	0	1 (1.1)	1 (0.5)
不眠症	2 (1.8)	6 (6.3)	8 (3.9)
易刺激性	0	1 (1.1)	1 (0.5)
躁病	0	1 (1.1)	1 (0.5)
気分動揺	0	1 (1.1)	1 (0.5)
悪夢	1 (0.9)	1 (1.1)	2 (1.0)
パニック発作	0	1 (1.1)	1 (0.5)
パニック反応	0	1 (1.1)	1 (0.5)
妄想症	2 (1.8)	0	2 (1.0)
睡眠の質低下	1 (0.9)	0	1 (0.5)
処置に対する不安	0	1 (1.1)	1 (0.5)
精神病性障害	3 (2.7)	2 (2.1)	5 (2.4)
精神病症状	1 (0.9)	0	1 (0.5)
レム睡眠行動障害	0	1 (1.1)	1 (0.5)
レム睡眠異常	1 (0.9)	0	1 (0.5)
睡眠障害	2 (1.8)	0	2 (1.0)
ねごと	1 (0.9)	0	1 (0.5)

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__1.2

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
精神障害 (Cont.)			
常同症	0	1 (1.1)	1 (0.5)
ストレス	0	1 (1.1)	1 (0.5)
自殺念慮	1 (0.9)	2 (2.1)	3 (1.5)
自殺企図	1 (0.9)	0	1 (0.5)
腎および尿路障害	7 (6.3)	7 (7.4)	14 (6.8)
膀胱痙縮	1 (0.9)	0	1 (0.5)
膀胱結石	1 (0.9)	0	1 (0.5)
尿路結石	1 (0.9)	0	1 (0.5)
排尿困難	0	1 (1.1)	1 (0.5)
緊張性膀胱	1 (0.9)	0	1 (0.5)
夜間頻尿	0	1 (1.1)	1 (0.5)
頻尿	1 (0.9)	0	1 (0.5)
多尿	0	1 (1.1)	1 (0.5)
腎機能障害	0	1 (1.1)	1 (0.5)
尿管結石症	0	1 (1.1)	1 (0.5)
切迫性尿失禁	1 (0.9)	0	1 (0.5)
尿失禁	1 (0.9)	2 (2.1)	3 (1.5)
尿閉	0	3 (3.2)	3 (1.5)
尿臭異常	0	1 (1.1)	1 (0.5)

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__1.2

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
生殖系および乳房障害	2 (1.8)	4 (4.2)	6 (2.9)
良性前立腺肥大症	1 (0.9)	0	1 (0.5)
勃起不全	1 (0.9)	0	1 (0.5)
骨盤痛	0	1 (1.1)	1 (0.5)
ペイロニー病	0	1 (1.1)	1 (0.5)
閉経後出血	0	1 (1.1)	1 (0.5)
前立腺腫大	0	1 (1.1)	1 (0.5)
腟脱	0	1 (1.1)	1 (0.5)
呼吸器、胸郭および縦隔障害	6 (5.4)	13 (13.7)	19 (9.2)
気管支拡張症	1 (0.9)	0	1 (0.5)
咳嗽	0	1 (1.1)	1 (0.5)
発声障害	0	2 (2.1)	2 (1.0)
呼吸困難	2 (1.8)	5 (5.3)	7 (3.4)

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__1.2

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
呼吸器、胸郭および縦隔障害 (Cont.)			
労作性呼吸困難	1 (0.9)	0	1 (0.5)
鼻出血	0	1 (1.1)	1 (0.5)
過換気	0	1 (1.1)	1 (0.5)
口腔咽頭痛	1 (0.9)	0	1 (0.5)
誤嚥性肺炎	0	1 (1.1)	1 (0.5)
湿性咳嗽	0	1 (1.1)	1 (0.5)
肺塞栓症	0	2 (2.1)	2 (1.0)
ラ音	0	1 (1.1)	1 (0.5)
呼吸窮迫	1 (0.9)	0	1 (0.5)
鼻漏	0	1 (1.1)	1 (0.5)
咽喉刺激感	0	1 (1.1)	1 (0.5)
皮膚および皮下組織障害	10 (9.0)	12 (12.6)	22 (10.7)
脱毛症	1 (0.9)	1 (1.1)	2 (1.0)
褥瘡性潰瘍	0	1 (1.1)	1 (0.5)
皮膚嚢腫	1 (0.9)	1 (1.1)	2 (1.0)
皮膚炎	0	1 (1.1)	1 (0.5)
接触皮膚炎	1 (0.9)	0	1 (0.5)
おむつ皮膚炎	1 (0.9)	0	1 (0.5)
薬疹	1 (0.9)	0	1 (0.5)
皮膚乾燥	1 (0.9)	0	1 (0.5)
紅斑	1 (0.9)	2 (2.1)	3 (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__1.2

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
皮膚および皮下組織障害 (Cont.)			
爪の障害	1 (0.9)	0	1 (0.5)
脂肪織炎	0	1 (1.1)	1 (0.5)
丘疹	0	2 (2.1)	2 (1.0)
口囲皮膚炎	0	1 (1.1)	1 (0.5)
そう痒症	2 (1.8)	2 (2.1)	4 (1.9)
乾癬	0	1 (1.1)	1 (0.5)
発疹	1 (0.9)	1 (1.1)	2 (1.0)
紅斑性皮疹	0	1 (1.1)	1 (0.5)
そう痒性皮疹	1 (0.9)	1 (1.1)	2 (1.0)
皮膚潰瘍	0	1 (1.1)	1 (0.5)
蕁麻疹	2 (1.8)	0	2 (1.0)
外科および内科処置	0	1 (1.1)	1 (0.5)
抜歯	0	1 (1.1)	1 (0.5)
血管障害	11 (9.9)	9 (9.5)	20 (9.7)
深部静脈血栓症	0	1 (1.1)	1 (0.5)
血腫	0	1 (1.1)	1 (0.5)
出血	0	1 (1.1)	1 (0.5)
高血圧	1 (0.9)	2 (2.1)	3 (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__1.2

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
血管障害 (Cont.)			
高血圧クリーゼ	1 (0.9)	0	1 (0.5)
低血圧	2 (1.8)	2 (2.1)	4 (1.9)
起立性高血圧	0	1 (1.1)	1 (0.5)
起立性低血圧	7 (6.3)	3 (3.2)	10 (4.9)

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

Program Source Code: [redacted]

表36　治験薬との因果関係別の有害事象（安全性解析対象集団）：M15-741試験

[redacted]20[redacted] 10:56 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - 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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period	N=132	N=112	N=244
Any adverse event	122 (92.4)	108 (96.4)	230 (94.3)
No reasonable possibility	4 (3.0)	2 (1.8)	6 (2.5)
Reasonable possibility	118 (89.4)	106 (94.6)	224 (91.8)
血液およびリンパ系障害	1 (0.8)	3 (2.7)	4 (1.6)
No reasonable possibility	1 (0.8)	3 (2.7)	4 (1.6)
大球性貧血	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
凝血異常	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
リンパ節症	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
血液およびリンパ系障害 (Cont.)			
縦隔リンパ節腫脹	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
心臓障害	5 (3.8)	8 (7.1)	13 (5.3)
No reasonable possibility	4 (3.0)	6 (5.4)	10 (4.1)
Reasonable possibility	1 (0.8)	2 (1.8)	3 (1.2)
急性心筋梗塞	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
狭心症	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
心房細動	0	2 (1.8)	2 (0.8)
No reasonable possibility	0	2 (1.8)	2 (0.8)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
心臓障害 (Cont.)			
徐脈	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
心停止	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
心肺停止	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
冠動脈疾患	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
冠動脈狭窄	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
心臓障害 (Cont.)			
期外収縮	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
左室肥大	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
心筋梗塞	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
動悸	0	2 (1.8)	2 (0.8)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
頻脈	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
耳および迷路障害	4 (3.0)	4 (3.6)	8 (3.3)
No reasonable possibility	2 (1.5)	2 (1.8)	4 (1.6)
Reasonable possibility	2 (1.5)	2 (1.8)	4 (1.6)
感音性難聴	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
乗物酔い	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
回転性めまい	3 (2.3)	2 (1.8)	5 (2.0)
No reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
Reasonable possibility	2 (1.5)	1 (0.9)	3 (1.2)
頭位性回転性めまい	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
眼障害	8 (6.1)	8 (7.1)	16 (6.6)
No reasonable possibility	8 (6.1)	7 (6.3)	15 (6.1)
Reasonable possibility	0	1 (0.9)	1 (0.4)
白内障	2 (1.5)	2 (1.8)	4 (1.6)
No reasonable possibility	2 (1.5)	2 (1.8)	4 (1.6)
複視	3 (2.3)	1 (0.9)	4 (1.6)
No reasonable possibility	3 (2.3)	1 (0.9)	4 (1.6)
ドライアイ	1 (0.8)	3 (2.7)	4 (1.6)
No reasonable possibility	1 (0.8)	3 (2.7)	4 (1.6)
緑内障	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
眼障害 (Cont.)			
眼窩周囲痛	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
眼窩周囲腫脹	0	2 (1.8)	2 (0.8)
No reasonable possibility	0	2 (1.8)	2 (0.8)
網膜裂孔	2 (1.5)	0	2 (0.8)
No reasonable possibility	2 (1.5)	0	2 (0.8)
霧視	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
視野欠損	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
胃腸障害	27 (20.5)	29 (25.9)	56 (23.0)
No reasonable possibility	17 (12.9)	14 (12.5)	31 (12.7)
Reasonable possibility	10 (7.6)	15 (13.4)	25 (10.2)
腹部膨満	1 (0.8)	3 (2.7)	4 (1.6)
No reasonable possibility	0	2 (1.8)	2 (0.8)
Reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
腹痛	2 (1.5)	1 (0.9)	3 (1.2)
No reasonable possibility	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
上腹部痛	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
アフタ性潰瘍	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
胃腸障害 (Cont.)			
呼気臭	2 (1.5)	1 (0.9)	3 (1.2)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	2 (1.5)	0	2 (0.8)
虚血性大腸炎	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
便秘	8 (6.1)	12 (10.7)	20 (8.2)
No reasonable possibility	8 (6.1)	9 (8.0)	17 (7.0)
Reasonable possibility	0	3 (2.7)	3 (1.2)
齲歯	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
下痢	6 (4.5)	3 (2.7)	9 (3.7)
No reasonable possibility	6 (4.5)	3 (2.7)	9 (3.7)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
胃腸障害 (Cont.)			
口内乾燥	3 (2.3)	5 (4.5)	8 (3.3)
No reasonable possibility	0	3 (2.7)	3 (1.2)
Reasonable possibility	3 (2.3)	2 (1.8)	5 (2.0)
消化不良	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
嚥下障害	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
糞塊	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
排便回数増加	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
胃腸障害 (Cont.)			
胃食道逆流性疾患	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
舌炎	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
舌痛	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
吐血	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
痔核	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
胃腸障害 (Cont.)			
裂孔ヘルニア	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
胃排出不全	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
単径ヘルニア	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
腸出血	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
過敏性腸症候群	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	1 (0.8)	0	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
胃腸障害 (Cont.)			
大腸ポリープ	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
口唇乾燥	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
メレナ	2 (1.5)	0	2 (0.8)
No reasonable possibility	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
口腔腫脹	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
悪心	8 (6.1)	11 (9.8)	19 (7.8)
No reasonable possibility	2 (1.5)	4 (3.6)	6 (2.5)
Reasonable possibility	6 (4.5)	7 (6.3)	13 (5.3)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
胃腸障害 (Cont.)			
口腔内不快感	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
口腔内痛	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
口の錯感覚	1 (0.8)	1 (0.9)	2 (0.8)
Reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
直腸出血	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
歯痛	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
胃腸障害 (Cont.)			
嘔吐	3 (2.3)	3 (2.7)	6 (2.5)
No reasonable possibility	1 (0.8)	2 (1.8)	3 (1.2)
Reasonable possibility	2 (1.5)	1 (0.9)	3 (1.2)
一般・全身障害および投与部位の状態	107 (81.1)	96 (85.7)	203 (83.2)
No reasonable possibility	6 (4.5)	1 (0.9)	7 (2.9)
Reasonable possibility	101 (76.5)	95 (84.8)	196 (80.3)
投与部位内出血	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
投与部位紅斑	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
投与部位漏出	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
無力症	3 (2.3)	0	3 (1.2)
No reasonable possibility	2 (1.5)	0	2 (0.8)
Reasonable possibility	1 (0.8)	0	1 (0.4)
カテーテル留置部位紅斑	1 (0.8)	1 (0.9)	2 (0.8)
Reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
カテーテル留置部位漏出	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
カテーテル留置部位出血	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
カテーテル留置部位炎症	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
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刺激感	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
カテーテル留置部位浮腫	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
カテーテル留置部位疼痛	0	2 (1.8)	2 (0.8)
Reasonable possibility	0	2 (1.8)	2 (0.8)
胸部不快感	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
胸痛	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
泣き	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
不快感	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
薬効欠如	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
薬剤離脱症候群	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
疲労	6 (4.5)	3 (2.7)	9 (3.7)
No reasonable possibility	2 (1.5)	0	2 (0.8)
Reasonable possibility	4 (3.0)	3 (2.7)	7 (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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
異常感	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
冷感	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
熱感	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
歩行障害	0	2 (1.8)	2 (0.8)
No reasonable possibility	0	2 (1.8)	2 (0.8)
歩行不能	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
低体温	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
インフルエンザ様疾患	1 (0.8)	2 (1.8)	3 (1.2)
No reasonable possibility	1 (0.8)	2 (1.8)	3 (1.2)
注入部位内出血	10 (7.6)	8 (7.1)	18 (7.4)
No reasonable possibility	2 (1.5)	1 (0.9)	3 (1.2)
Reasonable possibility	8 (6.1)	7 (6.3)	15 (6.1)
注入部位皮膚炎	2 (1.5)	2 (1.8)	4 (1.6)
Reasonable possibility	2 (1.5)	2 (1.8)	4 (1.6)
注入部位分泌物	1 (0.8)	1 (0.9)	2 (0.8)
Reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
注入部位変色	2 (1.5)	0	2 (0.8)
Reasonable possibility	2 (1.5)	0	2 (0.8)
注入部位不快感	3 (2.3)	1 (0.9)	4 (1.6)
Reasonable possibility	3 (2.3)	1 (0.9)	4 (1.6)
注入部位びらん	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	1 (0.8)	0	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
注入部位紅斑	65 (49.2)	61 (54.5)	126 (51.6)
No reasonable possibility	6 (4.5)	1 (0.9)	7 (2.9)
Reasonable possibility	59 (44.7)	60 (53.6)	119 (48.8)
注入部位皮膚剥脱	3 (2.3)	3 (2.7)	6 (2.5)
Reasonable possibility	3 (2.3)	3 (2.7)	6 (2.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
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	8 (6.1)	12 (10.7)	20 (8.2)
Reasonable possibility	8 (6.1)	12 (10.7)	20 (8.2)
注入部位血腫	10 (7.6)	8 (7.1)	18 (7.4)
No reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
Reasonable possibility	9 (6.8)	7 (6.3)	16 (6.6)
注入部位出血	4 (3.0)	5 (4.5)	9 (3.7)
No reasonable possibility	2 (1.5)	1 (0.9)	3 (1.2)
Reasonable possibility	2 (1.5)	4 (3.6)	6 (2.5)
注入部位硬結	7 (5.3)	3 (2.7)	10 (4.1)
Reasonable possibility	7 (5.3)	3 (2.7)	10 (4.1)
注入部位炎症	3 (2.3)	6 (5.4)	9 (3.7)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	3 (2.3)	5 (4.5)	8 (3.3)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
注入部位損傷	0	2 (1.8)	2 (0.8)
Reasonable possibility	0	2 (1.8)	2 (0.8)
注入部位刺激感	1 (0.8)	4 (3.6)	5 (2.0)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	1 (0.8)	3 (2.7)	4 (1.6)
注入部位腫瘤	5 (3.8)	3 (2.7)	8 (3.3)
Reasonable possibility	5 (3.8)	3 (2.7)	8 (3.3)
注入部位壊死	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
注入部位結節	35 (26.5)	34 (30.4)	69 (28.3)
Reasonable possibility	35 (26.5)	34 (30.4)	69 (28.3)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
注入部位浮腫	19 (14.4)	28 (25.0)	47 (19.3)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	19 (14.4)	27 (24.1)	46 (18.9)
注入部位疼痛	18 (13.6)	20 (17.9)	38 (15.6)
No reasonable possibility	2 (1.5)	2 (1.8)	4 (1.6)
Reasonable possibility	16 (12.1)	18 (16.1)	34 (13.9)
注入部位蒼白	3 (2.3)	2 (1.8)	5 (2.0)
No reasonable possibility	1 (0.8)	0	1 (0.4)
Reasonable possibility	2 (1.5)	2 (1.8)	4 (1.6)
注入部位丘疹	7 (5.3)	11 (9.8)	18 (7.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	7 (5.3)	10 (8.9)	17 (7.0)
注入部位異常感覚	0	2 (1.8)	2 (0.8)
Reasonable possibility	0	2 (1.8)	2 (0.8)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
注入部位そう痒感	5 (3.8)	2 (1.8)	7 (2.9)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	5 (3.8)	1 (0.9)	6 (2.5)
注入部位発疹	3 (2.3)	4 (3.6)	7 (2.9)
No reasonable possibility	0	2 (1.8)	2 (0.8)
Reasonable possibility	3 (2.3)	2 (1.8)	5 (2.0)
注入部位反応	13 (9.8)	17 (15.2)	30 (12.3)
Reasonable possibility	13 (9.8)	17 (15.2)	30 (12.3)
注入部位痂皮	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
注入部位腫脹	4 (3.0)	2 (1.8)	6 (2.5)
Reasonable possibility	4 (3.0)	2 (1.8)	6 (2.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
注入部位小水疱	0	2 (1.8)	2 (0.8)
Reasonable possibility	0	2 (1.8)	2 (0.8)
注入部位熱感	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
注射部位内出血	2 (1.5)	1 (0.9)	3 (1.2)
Reasonable possibility	2 (1.5)	1 (0.9)	3 (1.2)
注射部位変色	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
注射部位紅斑	6 (4.5)	8 (7.1)	14 (5.7)
Reasonable possibility	6 (4.5)	8 (7.1)	14 (5.7)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
注射部位漏出	1 (0.8)	1 (0.9)	2 (0.8)
Reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
注射部位血腫	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
注射部位出血	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
注射部位炎症	2 (1.5)	4 (3.6)	6 (2.5)
Reasonable possibility	2 (1.5)	4 (3.6)	6 (2.5)
注射部位結節	3 (2.3)	6 (5.4)	9 (3.7)
Reasonable possibility	3 (2.3)	6 (5.4)	9 (3.7)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
注射部位浮腫	2 (1.5)	3 (2.7)	5 (2.0)
Reasonable possibility	2 (1.5)	3 (2.7)	5 (2.0)
注射部位疼痛	2 (1.5)	6 (5.4)	8 (3.3)
No reasonable possibility	0	2 (1.8)	2 (0.8)
Reasonable possibility	2 (1.5)	4 (3.6)	6 (2.5)
注射部位丘疹	0	2 (1.8)	2 (0.8)
Reasonable possibility	0	2 (1.8)	2 (0.8)
注射部位反応	1 (0.8)	1 (0.9)	2 (0.8)
Reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
注射部位腫脹	2 (1.5)	2 (1.8)	4 (1.6)
Reasonable possibility	2 (1.5)	2 (1.8)	4 (1.6)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
注射部位蕁麻疹	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
滴下投与部位熱傷	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
滴下投与部位痛	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
限局性浮腫	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
適用部位からの吸収不良	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
倦怠感	1 (0.8)	2 (1.8)	3 (1.2)
No reasonable possibility	1 (0.8)	0	1 (0.4)
Reasonable possibility	0	2 (1.8)	2 (0.8)
医療機器使用部位刺激感	1 (0.8)	2 (1.8)	3 (1.2)
No reasonable possibility	1 (0.8)	2 (1.8)	3 (1.2)
医療機器使用部位そう痒感	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
医療機器使用部位発疹	0	2 (1.8)	2 (0.8)
No reasonable possibility	0	2 (1.8)	2 (0.8)
小結節	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
非心臓性胸痛	0	2 (1.8)	2 (0.8)
No reasonable possibility	0	2 (1.8)	2 (0.8)
末梢性浮腫	5 (3.8)	4 (3.6)	9 (3.7)
No reasonable possibility	4 (3.0)	3 (2.7)	7 (2.9)
Reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
疼痛	2 (1.5)	0	2 (0.8)
No reasonable possibility	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
末梢腫脹	0	4 (3.6)	4 (1.6)
No reasonable possibility	0	2 (1.8)	2 (0.8)
Reasonable possibility	0	2 (1.8)	2 (0.8)
穿刺部位内出血	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
穿刺部位紅斑	0	3 (2.7)	3 (1.2)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	2 (1.8)	2 (0.8)
穿刺部位出血	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
穿刺部位硬結	2 (1.5)	0	2 (0.8)
Reasonable possibility	2 (1.5)	0	2 (0.8)
穿刺部位浮腫	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
穿刺部位腫脹	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
発熱	2 (1.5)	2 (1.8)	4 (1.6)
No reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
Reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
口渇	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
血管穿刺部位硬結	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
肝胆道系障害	2 (1.5)	1 (0.9)	3 (1.2)
No reasonable possibility	2 (1.5)	1 (0.9)	3 (1.2)
肝嚢胞	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
肝胆道系障害 (Cont.)			
脂肪肝	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
門脈血栓症	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
感染症および寄生虫症	58 (43.9)	56 (50.0)	114 (46.7)
No reasonable possibility	17 (12.9)	16 (14.3)	33 (13.5)
Reasonable possibility	41 (31.1)	40 (35.7)	81 (33.2)
四肢膿瘍	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
無症候性COVID-19	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
感染症および寄生虫症 (Cont.)			
細菌性疾患キャリアー	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
ボレリア感染	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
ウイルス性気管支炎	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
COVID-19	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
COVID-19肺炎	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
感染症および寄生虫症 (Cont.)			
カテーテル留置部位感染	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
蜂巣炎	1 (0.8)	2 (1.8)	3 (1.2)
No reasonable possibility	1 (0.8)	2 (1.8)	3 (1.2)
結膜炎	2 (1.5)	0	2 (0.8)
No reasonable possibility	2 (1.5)	0	2 (0.8)
膀胱炎	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
爪の皮膚糸状菌症	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
感染症および寄生虫症 (Cont.)			
真菌感染	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
胃腸炎	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
歯肉炎	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
麦粒腫	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
感染性皮膚潰瘍	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
感染症および寄生虫症 (Cont.)			
インフルエンザ	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
注入部位膿瘍	14 (10.6)	13 (11.6)	27 (11.1)
No reasonable possibility	0	2 (1.8)	2 (0.8)
Reasonable possibility	14 (10.6)	11 (9.8)	25 (10.2)
注入部位蜂巣炎	29 (22.0)	27 (24.1)	56 (23.0)
No reasonable possibility	2 (1.5)	2 (1.8)	4 (1.6)
Reasonable possibility	27 (20.5)	25 (22.3)	52 (21.3)
注入部位感染	7 (5.3)	11 (9.8)	18 (7.4)
No reasonable possibility	2 (1.5)	1 (0.9)	3 (1.2)
Reasonable possibility	5 (3.8)	10 (8.9)	15 (6.1)
注入部位膿疱	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
感染症および寄生虫症 (Cont.)			
注射部位蜂巣炎	0	3 (2.7)	3 (1.2)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	2 (1.8)	2 (0.8)
リンパ管炎	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
上咽頭炎	5 (3.8)	5 (4.5)	10 (4.1)
No reasonable possibility	5 (3.8)	5 (4.5)	10 (4.1)
爪真菌症	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
耳下腺膿瘍	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
感染症および寄生虫症 (Cont.)			
肺炎	3 (2.3)	1 (0.9)	4 (1.6)
No reasonable possibility	3 (2.3)	1 (0.9)	4 (1.6)
術後膿瘍	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
シュードモナス感染	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
膿疱性皮疹	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
気道感染	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
感染症および寄生虫症 (Cont.)			
敗血症	3 (2.3)	0	3 (1.2)
No reasonable possibility	1 (0.8)	0	1 (0.4)
Reasonable possibility	2 (1.5)	0	2 (0.8)
敗血症性ショック	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
副鼻腔炎	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
ブドウ球菌感染	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
歯感染	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
感染症および寄生虫症 (Cont.)			
上気道感染	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
尿路感染	8 (6.1)	11 (9.8)	19 (7.8)
No reasonable possibility	8 (6.1)	11 (9.8)	19 (7.8)
水痘帯状疱疹ウイルス感染	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
傷害、中毒および処置合併症	21 (15.9)	27 (24.1)	48 (19.7)
No reasonable possibility	12 (9.1)	20 (17.9)	32 (13.1)
Reasonable possibility	9 (6.8)	7 (6.3)	16 (6.6)
足関節部骨折	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
傷害、中毒および処置合併症 (Cont.)			
節足動物咬傷	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
骨挫傷	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
脳挫傷	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
挫傷	2 (1.5)	6 (5.4)	8 (3.3)
No reasonable possibility	2 (1.5)	4 (3.6)	6 (2.5)
Reasonable possibility	0	2 (1.8)	2 (0.8)
医療機器設置の問題	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
傷害、中毒および処置合併症 (Cont.)			
医療機器による投与の欠落	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
期限切れの製品使用	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
眼挫傷	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
顔面損傷	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
顔面骨骨折	0	2 (1.8)	2 (0.8)
No reasonable possibility	0	2 (1.8)	2 (0.8)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
傷害、中毒および処置合併症 (Cont.)			
転倒	16 (12.1)	24 (21.4)	40 (16.4)
No reasonable possibility	11 (8.3)	19 (17.0)	30 (12.3)
Reasonable possibility	5 (3.8)	5 (4.5)	10 (4.1)
頭部損傷	2 (1.5)	3 (2.7)	5 (2.0)
No reasonable possibility	1 (0.8)	2 (1.8)	3 (1.2)
Reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
注入に伴う反応	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
関節脱臼	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
靭帯捻挫	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
傷害、中毒および処置合併症 (Cont.)			
腰椎骨折	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
過量投与	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
処置後挫傷	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
処置によるめまい	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
肋骨骨折	1 (0.8)	2 (1.8)	3 (1.2)
No reasonable possibility	1 (0.8)	2 (1.8)	3 (1.2)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
傷害、中毒および処置合併症 (Cont.)			
皮膚擦過傷	1 (0.8)	2 (1.8)	3 (1.2)
No reasonable possibility	1 (0.8)	2 (1.8)	3 (1.2)
皮膚損傷	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
皮膚裂傷	1 (0.8)	6 (5.4)	7 (2.9)
No reasonable possibility	1 (0.8)	6 (5.4)	7 (2.9)
ストレス骨折	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
硬膜下血腫	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
傷害、中毒および処置合併症 (Cont.)			
サンバーン	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
腱断裂	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
過少量投与	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
創傷	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
臨床検査	24 (18.2)	24 (21.4)	48 (19.7)
No reasonable possibility	13 (9.8)	8 (7.1)	21 (8.6)
Reasonable possibility	11 (8.3)	16 (14.3)	27 (11.1)

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

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
臨床検査 (Cont.)			
血中クレアチンホスホキナーゼ増加	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
血中クレアチニン減少	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
血中葉酸異常	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
血中葉酸減少	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
血中ホモシステイン増加	1 (0.8)	2 (1.8)	3 (1.2)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
臨床検査 (Cont.)			
血中リン減少	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
血圧上昇	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	1 (0.8)	0	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
起立血圧低下	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
血中ナトリウム減少	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
C-反応性蛋白増加	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
臨床検査 (Cont.)			
心雑音	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
握力低下	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
ヘモグロビン減少	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
リンパ球数減少	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
単球数増加	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
臨床検査 (Cont.)			
好中球数増加	0	2 (1.8)	2 (0.8)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
プロトロンビン時間延長	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
赤血球数減少	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
ビタミンB12減少	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	1 (0.8)	0	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
ビタミンB6減少	5 (3.8)	6 (5.4)	11 (4.5)
No reasonable possibility	1 (0.8)	4 (3.6)	5 (2.0)
Reasonable possibility	4 (3.0)	2 (1.8)	6 (2.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
臨床検査 (Cont.)			
ビタミンD減少	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
体重減少	10 (7.6)	14 (12.5)	24 (9.8)
No reasonable possibility	6 (4.5)	3 (2.7)	9 (3.7)
Reasonable possibility	4 (3.0)	11 (9.8)	15 (6.1)
体重増加	2 (1.5)	0	2 (0.8)
No reasonable possibility	2 (1.5)	0	2 (0.8)
白血球数増加	0	2 (1.8)	2 (0.8)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
代謝および栄養障害	11 (8.3)	19 (17.0)	30 (12.3)
No reasonable possibility	7 (5.3)	12 (10.7)	19 (7.8)
Reasonable possibility	4 (3.0)	7 (6.3)	11 (4.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
代謝および栄養障害 (Cont.)			
悪液質	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
食欲減退	3 (2.3)	3 (2.7)	6 (2.5)
No reasonable possibility	2 (1.5)	2 (1.8)	4 (1.6)
Reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
脱水	1 (0.8)	3 (2.7)	4 (1.6)
No reasonable possibility	1 (0.8)	3 (2.7)	4 (1.6)
糖尿病	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
水分過負荷	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
代謝および栄養障害 (Cont.)			
体液貯留	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	1 (0.8)	0	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
葉酸欠乏	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	1 (0.8)	0	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
耐糖能障害	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
高コレステロール血症	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
高血糖	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
代謝および栄養障害 (Cont.)			
高ホモシステイン血症	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
低カルシウム血症	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
低カリウム血症	0	3 (2.7)	3 (1.2)
No reasonable possibility	0	3 (2.7)	3 (1.2)
低ナトリウム血症	2 (1.5)	0	2 (0.8)
No reasonable possibility	2 (1.5)	0	2 (0.8)
栄養障害	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
代謝および栄養障害 (Cont.)			
ビタミンB群欠乏	1 (0.8)	1 (0.9)	2 (0.8)
Reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
ビタミンB12欠乏	0	2 (1.8)	2 (0.8)
Reasonable possibility	0	2 (1.8)	2 (0.8)
ビタミンB6欠乏	3 (2.3)	5 (4.5)	8 (3.3)
No reasonable possibility	1 (0.8)	2 (1.8)	3 (1.2)
Reasonable possibility	2 (1.5)	3 (2.7)	5 (2.0)
筋骨格系および結合組織障害	24 (18.2)	21 (18.8)	45 (18.4)
No reasonable possibility	17 (12.9)	18 (16.1)	35 (14.3)
Reasonable possibility	7 (5.3)	3 (2.7)	10 (4.1)
関節痛	3 (2.3)	5 (4.5)	8 (3.3)
No reasonable possibility	2 (1.5)	5 (4.5)	7 (2.9)
Reasonable possibility	1 (0.8)	0	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
筋骨格系および結合組織障害 (Cont.)			
反応性関節炎	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
背部痛	8 (6.1)	5 (4.5)	13 (5.3)
No reasonable possibility	7 (5.3)	5 (4.5)	12 (4.9)
Reasonable possibility	1 (0.8)	0	1 (0.4)
骨痛	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
滑液包炎	2 (1.5)	0	2 (0.8)
No reasonable possibility	2 (1.5)	0	2 (0.8)
外骨腫	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
筋骨格系および結合組織障害 (Cont.)			
椎間関節症候群	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
椎間板変性症	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
椎間板突出	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
関節滲出液	0	2 (1.8)	2 (0.8)
No reasonable possibility	0	2 (1.8)	2 (0.8)
関節腫脹	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
筋骨格系および結合組織障害 (Cont.)			
四肢不快感	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
筋萎縮	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
筋痙縮	2 (1.5)	3 (2.7)	5 (2.0)
No reasonable possibility	2 (1.5)	3 (2.7)	5 (2.0)
筋力低下	4 (3.0)	1 (0.9)	5 (2.0)
No reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
Reasonable possibility	3 (2.3)	0	3 (1.2)
筋骨格硬直	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
筋骨格系および結合組織障害 (Cont.)			
筋肉痛	2 (1.5)	1 (0.9)	3 (1.2)
No reasonable possibility	2 (1.5)	1 (0.9)	3 (1.2)
頚部痛	2 (1.5)	0	2 (0.8)
No reasonable possibility	2 (1.5)	0	2 (0.8)
骨炎	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
変形性関節症	1 (0.8)	4 (3.6)	5 (2.0)
No reasonable possibility	1 (0.8)	4 (3.6)	5 (2.0)
骨減少症	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
筋骨格系および結合組織障害 (Cont.)			
四肢痛	3 (2.3)	3 (2.7)	6 (2.5)
No reasonable possibility	2 (1.5)	2 (1.8)	4 (1.6)
Reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
関節周囲炎	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
姿勢異常	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
横紋筋融解症	2 (1.5)	0	2 (0.8)
No reasonable possibility	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
肩回旋筋腱板症候群	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
筋骨格系および結合組織障害 (Cont.)			
仙腸関節機能障害	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
変形性脊椎症	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
腱障害	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
腱炎	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
斜頚	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
筋骨格系および結合組織障害 (Cont.)			
弾発指	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	1 (0.8)	4 (3.6)	5 (2.0)
No reasonable possibility	1 (0.8)	4 (3.6)	5 (2.0)
基底細胞癌	0	2 (1.8)	2 (0.8)
No reasonable possibility	0	2 (1.8)	2 (0.8)
直腸腺癌	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
脂漏性角化症	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）(Cont.)			
皮膚有棘細胞癌	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
神経系障害	62 (47.0)	48 (42.9)	110 (45.1)
No reasonable possibility	17 (12.9)	17 (15.2)	34 (13.9)
Reasonable possibility	45 (34.1)	31 (27.7)	76 (31.1)
アカシジア	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
健忘	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
失語症	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
神経系障害 (Cont.)			
運動失調	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
平衡障害	0	4 (3.6)	4 (1.6)
No reasonable possibility	0	3 (2.7)	3 (1.2)
Reasonable possibility	0	1 (0.9)	1 (0.4)
運動緩慢	1 (0.8)	1 (0.9)	2 (0.8)
Reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
手根管症候群	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
大脳萎縮	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
神経系障害 (Cont.)			
脳出血	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
脳圧排効果	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
脳血管発作	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
認知障害	4 (3.0)	2 (1.8)	6 (2.5)
No reasonable possibility	3 (2.3)	2 (1.8)	5 (2.0)
Reasonable possibility	1 (0.8)	0	1 (0.4)
振動覚低下	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
神経系障害 (Cont.)			
注意力障害	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
浮動性めまい	15 (11.4)	10 (8.9)	25 (10.2)
No reasonable possibility	3 (2.3)	2 (1.8)	5 (2.0)
Reasonable possibility	12 (9.1)	8 (7.1)	20 (8.2)
体位性めまい	5 (3.8)	0	5 (2.0)
Reasonable possibility	5 (3.8)	0	5 (2.0)
構語障害	0	3 (2.7)	3 (1.2)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	2 (1.8)	2 (0.8)
味覚不全	2 (1.5)	1 (0.9)	3 (1.2)
Reasonable possibility	2 (1.5)	1 (0.9)	3 (1.2)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
神経系障害 (Cont.)			
ジスキネジア	12 (9.1)	6 (5.4)	18 (7.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
Reasonable possibility	11 (8.3)	6 (5.4)	17 (7.0)
起立障害	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
ジストニア	2 (1.5)	5 (4.5)	7 (2.9)
No reasonable possibility	1 (0.8)	3 (2.7)	4 (1.6)
Reasonable possibility	1 (0.8)	2 (1.8)	3 (1.2)
脳症	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
てんかん	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
神経系障害 (Cont.)			
本態性振戦	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
伸展性足底反応	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
すくみ現象	4 (3.0)	0	4 (1.6)
No reasonable possibility	1 (0.8)	0	1 (0.4)
Reasonable possibility	3 (2.3)	0	3 (1.2)
全身性強直性間代性発作	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
頭部不快感	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
神経系障害 (Cont.)			
頭痛	7 (5.3)	7 (6.3)	14 (5.7)
No reasonable possibility	3 (2.3)	5 (4.5)	8 (3.3)
Reasonable possibility	4 (3.0)	2 (1.8)	6 (2.5)
片側感覚消失	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
不全片麻痺	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
知覚過敏	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
感覚鈍麻	1 (0.8)	2 (1.8)	3 (1.2)
Reasonable possibility	1 (0.8)	2 (1.8)	3 (1.2)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
神経系障害 (Cont.)			
反射減弱	2 (1.5)	1 (0.9)	3 (1.2)
No reasonable possibility	2 (1.5)	1 (0.9)	3 (1.2)
不規則睡眠覚醒リズム障害	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
嗜眠	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
意識消失	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
腰仙部神経根障害	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
神経系障害 (Cont.)			
記憶障害	0	2 (1.8)	2 (0.8)
No reasonable possibility	0	2 (1.8)	2 (0.8)
代謝性脳症	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	1 (0.8)	0	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
神経痛	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
末梢性ニューロパチー	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
オンオフ現象	4 (3.0)	5 (4.5)	9 (3.7)
No reasonable possibility	2 (1.5)	1 (0.9)	3 (1.2)
Reasonable possibility	2 (1.5)	4 (3.6)	6 (2.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
神経系障害 (Cont.)			
錯感覚	4 (3.0)	3 (2.7)	7 (2.9)
No reasonable possibility	1 (0.8)	0	1 (0.4)
Reasonable possibility	3 (2.3)	3 (2.7)	6 (2.5)
パーキンソン病	12 (9.1)	5 (4.5)	17 (7.0)
No reasonable possibility	6 (4.5)	0	6 (2.5)
Reasonable possibility	6 (4.5)	5 (4.5)	11 (4.5)
パーキンソニズム	0	3 (2.7)	3 (1.2)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	2 (1.8)	2 (0.8)
末梢性感覚ニューロパチー	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
側反弓	1 (0.8)	2 (1.8)	3 (1.2)
No reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
Reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
神経系障害 (Cont.)			
多発ニューロパチー	0	2 (1.8)	2 (0.8)
Reasonable possibility	0	2 (1.8)	2 (0.8)
失神寸前の状態	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
心因性発作	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
精神運動亢進	1 (0.8)	1 (0.9)	2 (0.8)
Reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
反射異常	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
神経系障害 (Cont.)			
安静時振戦	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
坐骨神経痛	0	3 (2.7)	3 (1.2)
No reasonable possibility	0	2 (1.8)	2 (0.8)
Reasonable possibility	0	1 (0.9)	1 (0.4)
痙攣発作	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
感覚障害	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
感覚消失	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
神経系障害 (Cont.)			
睡眠時麻痺	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
傾眠	9 (6.8)	3 (2.7)	12 (4.9)
No reasonable possibility	4 (3.0)	0	4 (1.6)
Reasonable possibility	5 (3.8)	3 (2.7)	8 (3.3)
失神	0	3 (2.7)	3 (1.2)
No reasonable possibility	0	2 (1.8)	2 (0.8)
Reasonable possibility	0	1 (0.9)	1 (0.4)
振戦	1 (0.8)	2 (1.8)	3 (1.2)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
製品の問題	2 (1.5)	1 (0.9)	3 (1.2)
No reasonable possibility	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
製品の問題 (Cont.)			
医療機器送達システムの問題	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
医療機器位置異常	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
医療機器機能不良	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
精神障害	51 (38.6)	57 (50.9)	108 (44.3)
No reasonable possibility	9 (6.8)	19 (17.0)	28 (11.5)
Reasonable possibility	42 (31.8)	38 (33.9)	80 (32.8)
異常な夢	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
精神障害 (Cont.)			
感情不安定	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
激越	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
不安	11 (8.3)	18 (16.1)	29 (11.9)
No reasonable possibility	8 (6.1)	11 (9.8)	19 (7.8)
Reasonable possibility	3 (2.3)	7 (6.3)	10 (4.1)
不安障害	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
無感情	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
精神障害 (Cont.)			
歯ぎしり	2 (1.5)	0	2 (0.8)
No reasonable possibility	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
強迫行為	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
強迫性性行動	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
錯乱状態	4 (3.0)	5 (4.5)	9 (3.7)
No reasonable possibility	0	2 (1.8)	2 (0.8)
Reasonable possibility	4 (3.0)	3 (2.7)	7 (2.9)
譫妄	1 (0.8)	4 (3.6)	5 (2.0)
No reasonable possibility	1 (0.8)	2 (1.8)	3 (1.2)
Reasonable possibility	0	2 (1.8)	2 (0.8)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
精神障害 (Cont.)			
妄想	8 (6.1)	2 (1.8)	10 (4.1)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	8 (6.1)	1 (0.9)	9 (3.7)
寄生虫妄想	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
妄想性障害、詳細不明	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
抑うつ気分	2 (1.5)	2 (1.8)	4 (1.6)
No reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
Reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
うつ病	3 (2.3)	2 (1.8)	5 (2.0)
No reasonable possibility	3 (2.3)	1 (0.9)	4 (1.6)
Reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
精神障害 (Cont.)			
抑うつ症状	2 (1.5)	0	2 (0.8)
No reasonable possibility	2 (1.5)	0	2 (0.8)
ドーパミン調節障害症候群	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
ディスフェミア	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
睡眠異常	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
情動障害	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
精神障害 (Cont.)			
注射恐怖	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
幻覚	20 (15.2)	22 (19.6)	42 (17.2)
No reasonable possibility	1 (0.8)	4 (3.6)	5 (2.0)
Reasonable possibility	19 (14.4)	18 (16.1)	37 (15.2)
幻聴	3 (2.3)	3 (2.7)	6 (2.5)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	3 (2.3)	2 (1.8)	5 (2.0)
幻嗅	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
幻視	10 (7.6)	5 (4.5)	15 (6.1)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	10 (7.6)	4 (3.6)	14 (5.7)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
精神障害 (Cont.)			
混合性幻覚	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
性欲過剰	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
錯覚	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
衝動制御障害	0	4 (3.6)	4 (1.6)
No reasonable possibility	0	2 (1.8)	2 (0.8)
Reasonable possibility	0	2 (1.8)	2 (0.8)
衝動行為	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
精神障害 (Cont.)			
不眠症	9 (6.8)	9 (8.0)	18 (7.4)
No reasonable possibility	2 (1.5)	3 (2.7)	5 (2.0)
Reasonable possibility	7 (5.3)	6 (5.4)	13 (5.3)
易刺激性	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
嫉妬妄想	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
躁病	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
気分変化	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
精神障害 (Cont.)			
気分動揺	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
悪夢	1 (0.8)	1 (0.9)	2 (0.8)
Reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
強迫観念	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
パニック発作	0	3 (2.7)	3 (1.2)
Reasonable possibility	0	3 (2.7)	3 (1.2)
パニック反応	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
精神障害 (Cont.)			
妄想症	2 (1.5)	0	2 (0.8)
Reasonable possibility	2 (1.5)	0	2 (0.8)
睡眠の質低下	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
処置に対する不安	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
精神病性障害	4 (3.0)	2 (1.8)	6 (2.5)
Reasonable possibility	4 (3.0)	2 (1.8)	6 (2.5)
精神病症状	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
精神障害 (Cont.)			
レム睡眠行動障害	1 (0.8)	1 (0.9)	2 (0.8)
Reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
レム睡眠異常	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
睡眠障害	2 (1.5)	1 (0.9)	3 (1.2)
Reasonable possibility	2 (1.5)	1 (0.9)	3 (1.2)
ねごと	1 (0.8)	1 (0.9)	2 (0.8)
Reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
精神障害 (Cont.)			
常同症	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
ストレス	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
自殺念慮	1 (0.8)	2 (1.8)	3 (1.2)
No reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
Reasonable possibility	0	1 (0.9)	1 (0.4)
自殺企図	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
腎および尿路障害	13 (9.8)	7 (6.3)	20 (8.2)
No reasonable possibility	13 (9.8)	5 (4.5)	18 (7.4)
Reasonable possibility	0	2 (1.8)	2 (0.8)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
腎および尿路障害 (Cont.)			
膀胱痙縮	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
膀胱結石	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
尿路結石	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
排尿困難	1 (0.8)	2 (1.8)	3 (1.2)
No reasonable possibility	1 (0.8)	2 (1.8)	3 (1.2)
緊張性膀胱	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
腎および尿路障害 (Cont.)			
夜間頻尿	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
頻尿	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
多尿	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
腎機能障害	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
尿管結石症	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
腎および尿路障害 (Cont.)			
切迫性尿失禁	3 (2.3)	0	3 (1.2)
No reasonable possibility	3 (2.3)	0	3 (1.2)
尿失禁	3 (2.3)	2 (1.8)	5 (2.0)
No reasonable possibility	3 (2.3)	1 (0.9)	4 (1.6)
Reasonable possibility	0	1 (0.9)	1 (0.4)
尿閉	0	3 (2.7)	3 (1.2)
No reasonable possibility	0	3 (2.7)	3 (1.2)
尿路障害	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
尿異常	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
腎および尿路障害 (Cont.)			
尿臭異常	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
生殖系および乳房障害	2 (1.5)	5 (4.5)	7 (2.9)
No reasonable possibility	1 (0.8)	4 (3.6)	5 (2.0)
Reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
良性前立腺肥大症	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
勃起不全	1 (0.8)	1 (0.9)	2 (0.8)
Reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
骨盤痛	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
生殖系および乳房障害 (Cont.)			
ペイロニー病	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
閉経後出血	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
前立腺腫大	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
膣脱	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
呼吸器、胸郭および縦隔障害	7 (5.3)	19 (17.0)	26 (10.7)
No reasonable possibility	6 (4.5)	16 (14.3)	22 (9.0)
Reasonable possibility	1 (0.8)	3 (2.7)	4 (1.6)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
呼吸器、胸郭および縦隔障害 (Cont.)			
急性呼吸不全	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
気管支拡張症	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
咳嗽	1 (0.8)	2 (1.8)	3 (1.2)
No reasonable possibility	1 (0.8)	2 (1.8)	3 (1.2)
発声障害	0	2 (1.8)	2 (0.8)
No reasonable possibility	0	2 (1.8)	2 (0.8)
呼吸困難	2 (1.5)	6 (5.4)	8 (3.3)
No reasonable possibility	2 (1.5)	4 (3.6)	6 (2.5)
Reasonable possibility	0	2 (1.8)	2 (0.8)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
呼吸器、胸郭および縦隔障害 (Cont.)			
労作性呼吸困難	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
鼻出血	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
過換気	0	2 (1.8)	2 (0.8)
No reasonable possibility	0	2 (1.8)	2 (0.8)
口腔咽頭痛	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
誤嚥性肺炎	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
呼吸器、胸郭および縦隔障害 (Cont.)			
湿性咳嗽	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
肺塞栓症	0	2 (1.8)	2 (0.8)
No reasonable possibility	0	2 (1.8)	2 (0.8)
ラ音	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
呼吸窮迫	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
鼻痛	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
呼吸器、胸郭および縦隔障害 (Cont.)			
鼻漏	0	2 (1.8)	2 (0.8)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
咽喉刺激感	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
皮膚および皮下組織障害	14 (10.6)	16 (14.3)	30 (12.3)
No reasonable possibility	8 (6.1)	13 (11.6)	21 (8.6)
Reasonable possibility	6 (4.5)	3 (2.7)	9 (3.7)
脱毛症	2 (1.5)	1 (0.9)	3 (1.2)
Reasonable possibility	2 (1.5)	1 (0.9)	3 (1.2)
褥瘡性潰瘍	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
皮膚および皮下組織障害 (Cont.)			
皮膚嚢腫	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
皮膚炎	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
接触皮膚炎	2 (1.5)	0	2 (0.8)
No reasonable possibility	2 (1.5)	0	2 (0.8)
おむつ皮膚炎	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
薬疹	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
皮膚および皮下組織障害 (Cont.)			
皮膚乾燥	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
斑状出血	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
紅斑	1 (0.8)	3 (2.7)	4 (1.6)
No reasonable possibility	1 (0.8)	3 (2.7)	4 (1.6)
爪の障害	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
脂肪織炎	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
皮膚および皮下組織障害 (Cont.)			
丘疹	0	2 (1.8)	2 (0.8)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
口囲皮膚炎	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
光線過敏性反応	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
そう痒症	2 (1.5)	2 (1.8)	4 (1.6)
No reasonable possibility	1 (0.8)	2 (1.8)	3 (1.2)
Reasonable possibility	1 (0.8)	0	1 (0.4)
乾癬	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
皮膚および皮下組織障害 (Cont.)			
発疹	2 (1.5)	1 (0.9)	3 (1.2)
No reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
Reasonable possibility	1 (0.8)	0	1 (0.4)
紅斑性皮疹	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
そう痒性皮疹	2 (1.5)	1 (0.9)	3 (1.2)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	2 (1.5)	0	2 (0.8)
皮膚刺激	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
皮膚病変	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
皮膚および皮下組織障害 (Cont.)			
皮膚潰瘍	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
蕁麻疹	2 (1.5)	0	2 (0.8)
Reasonable possibility	2 (1.5)	0	2 (0.8)
社会環境	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
運動不能	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
外科および内科処置	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
外科および内科処置 (Cont.)			
抜歯	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
血管障害	12 (9.1)	15 (13.4)	27 (11.1)
No reasonable possibility	5 (3.8)	7 (6.3)	12 (4.9)
Reasonable possibility	7 (5.3)	8 (7.1)	15 (6.1)
深部静脈血栓症	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
血腫	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
出血	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
血管障害 (Cont.)			
ほてり	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
高血圧	3 (2.3)	3 (2.7)	6 (2.5)
No reasonable possibility	3 (2.3)	2 (1.8)	5 (2.0)
Reasonable possibility	0	1 (0.9)	1 (0.4)
高血圧クリーゼ	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
低血圧	2 (1.5)	4 (3.6)	6 (2.5)
No reasonable possibility	0	2 (1.8)	2 (0.8)
Reasonable possibility	2 (1.5)	2 (1.8)	4 (1.6)
不安定血圧	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
血管障害 (Cont.)			
起立性高血圧	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
起立性低血圧	7 (5.3)	6 (5.4)	13 (5.3)
No reasonable possibility	2 (1.5)	1 (0.9)	3 (1.2)
Reasonable possibility	5 (3.8)	5 (4.5)	10 (4.1)

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

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period	N=132	N=112	N=244
Any adverse event	106 (80.3)	97 (86.6)	203 (83.2)
No reasonable possibility	9 (6.8)	2 (1.8)	11 (4.5)
Reasonable possibility	97 (73.5)	95 (84.8)	192 (78.7)
心臓障害	0	2 (1.8)	2 (0.8)
Reasonable possibility	0	2 (1.8)	2 (0.8)
徐脈	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
動悸	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
耳および迷路障害	2 (1.5)	2 (1.8)	4 (1.6)
No reasonable possibility	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	2 (1.8)	3 (1.2)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
耳および迷路障害 (Cont.)			
乗物酔い	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
回転性めまい	2 (1.5)	1 (0.9)	3 (1.2)
No reasonable possibility	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
眼障害	2 (1.5)	2 (1.8)	4 (1.6)
No reasonable possibility	2 (1.5)	2 (1.8)	4 (1.6)
複視	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
眼窩周囲腫脹	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
眼障害 (Cont.)			
霧視	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
胃腸障害	13 (9.8)	15 (13.4)	28 (11.5)
No reasonable possibility	5 (3.8)	8 (7.1)	13 (5.3)
Reasonable possibility	8 (6.1)	7 (6.3)	15 (6.1)
腹部膨満	0	2 (1.8)	2 (0.8)
No reasonable possibility	0	2 (1.8)	2 (0.8)
腹痛	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
上腹部痛	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
胃腸障害 (Cont.)			
アフタ性潰瘍	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
呼気臭	2 (1.5)	0	2 (0.8)
Reasonable possibility	2 (1.5)	0	2 (0.8)
便秘	2 (1.5)	2 (1.8)	4 (1.6)
No reasonable possibility	2 (1.5)	1 (0.9)	3 (1.2)
Reasonable possibility	0	1 (0.9)	1 (0.4)
下痢	2 (1.5)	2 (1.8)	4 (1.6)
No reasonable possibility	2 (1.5)	2 (1.8)	4 (1.6)
口内乾燥	2 (1.5)	3 (2.7)	5 (2.0)
No reasonable possibility	0	2 (1.8)	2 (0.8)
Reasonable possibility	2 (1.5)	1 (0.9)	3 (1.2)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
胃腸障害 (Cont.)			
消化不良	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
胃食道逆流性疾患	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
痔核	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
過敏性腸症候群	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
悪心	5 (3.8)	5 (4.5)	10 (4.1)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	5 (3.8)	4 (3.6)	9 (3.7)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
胃腸障害 (Cont.)			
嘔吐	2 (1.5)	1 (0.9)	3 (1.2)
Reasonable possibility	2 (1.5)	1 (0.9)	3 (1.2)
一般・全身障害および投与部位の状態	91 (68.9)	82 (73.2)	173 (70.9)
No reasonable possibility	8 (6.1)	3 (2.7)	11 (4.5)
Reasonable possibility	83 (62.9)	79 (70.5)	162 (66.4)
投与部位紅斑	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
無力症	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
カテーテル留置部位紅斑	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
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炎症	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
カテーテル留置部位疼痛	0	2 (1.8)	2 (0.8)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
不快感	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
薬剤離脱症候群	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
疲労	3 (2.3)	2 (1.8)	5 (2.0)
No reasonable possibility	2 (1.5)	0	2 (0.8)
Reasonable possibility	1 (0.8)	2 (1.8)	3 (1.2)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
異常感	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
熱感	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
歩行障害	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
歩行不能	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
低体温	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
インフルエンザ様疾患	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
注入部位内出血	3 (2.3)	7 (6.3)	10 (4.1)
No reasonable possibility	2 (1.5)	2 (1.8)	4 (1.6)
Reasonable possibility	1 (0.8)	5 (4.5)	6 (2.5)
注入部位分泌物	1 (0.8)	1 (0.9)	2 (0.8)
Reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
注入部位変色	2 (1.5)	0	2 (0.8)
Reasonable possibility	2 (1.5)	0	2 (0.8)
注入部位不快感	2 (1.5)	1 (0.9)	3 (1.2)
Reasonable possibility	2 (1.5)	1 (0.9)	3 (1.2)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
注入部位びらん	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
注入部位紅斑	50 (37.9)	45 (40.2)	95 (38.9)
No reasonable possibility	4 (3.0)	0	4 (1.6)
Reasonable possibility	46 (34.8)	45 (40.2)	91 (37.3)
注入部位皮膚剥脱	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
注入部位血管外漏出	4 (3.0)	7 (6.3)	11 (4.5)
Reasonable possibility	4 (3.0)	7 (6.3)	11 (4.5)
注入部位血腫	4 (3.0)	4 (3.6)	8 (3.3)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	4 (3.0)	3 (2.7)	7 (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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
注入部位出血	0	3 (2.7)	3 (1.2)
Reasonable possibility	0	3 (2.7)	3 (1.2)
注入部位硬結	4 (3.0)	1 (0.9)	5 (2.0)
Reasonable possibility	4 (3.0)	1 (0.9)	5 (2.0)
注入部位炎症	1 (0.8)	3 (2.7)	4 (1.6)
Reasonable possibility	1 (0.8)	3 (2.7)	4 (1.6)
注入部位腫瘤	4 (3.0)	1 (0.9)	5 (2.0)
Reasonable possibility	4 (3.0)	1 (0.9)	5 (2.0)
注入部位壊死	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
注入部位結節	21 (15.9)	18 (16.1)	39 (16.0)
Reasonable possibility	21 (15.9)	18 (16.1)	39 (16.0)
注入部位浮腫	14 (10.6)	16 (14.3)	30 (12.3)
Reasonable possibility	14 (10.6)	16 (14.3)	30 (12.3)
注入部位疼痛	13 (9.8)	14 (12.5)	27 (11.1)
No reasonable possibility	1 (0.8)	2 (1.8)	3 (1.2)
Reasonable possibility	12 (9.1)	12 (10.7)	24 (9.8)
注入部位蒼白	2 (1.5)	1 (0.9)	3 (1.2)
No reasonable possibility	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
注入部位丘疹	1 (0.8)	4 (3.6)	5 (2.0)
Reasonable possibility	1 (0.8)	4 (3.6)	5 (2.0)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
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 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
注入部位そう痒感	2 (1.5)	1 (0.9)	3 (1.2)
Reasonable possibility	2 (1.5)	1 (0.9)	3 (1.2)
注入部位発疹	2 (1.5)	1 (0.9)	3 (1.2)
Reasonable possibility	2 (1.5)	1 (0.9)	3 (1.2)
注入部位反応	9 (6.8)	11 (9.8)	20 (8.2)
Reasonable possibility	9 (6.8)	11 (9.8)	20 (8.2)
注入部位腫脹	3 (2.3)	1 (0.9)	4 (1.6)
Reasonable possibility	3 (2.3)	1 (0.9)	4 (1.6)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
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 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
注射部位紅斑	5 (3.8)	5 (4.5)	10 (4.1)
Reasonable possibility	5 (3.8)	5 (4.5)	10 (4.1)
注射部位漏出	1 (0.8)	1 (0.9)	2 (0.8)
Reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
注射部位血腫	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
注射部位炎症	1 (0.8)	2 (1.8)	3 (1.2)
Reasonable possibility	1 (0.8)	2 (1.8)	3 (1.2)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
注射部位結節	1 (0.8)	2 (1.8)	3 (1.2)
Reasonable possibility	1 (0.8)	2 (1.8)	3 (1.2)
注射部位浮腫	2 (1.5)	2 (1.8)	4 (1.6)
Reasonable possibility	2 (1.5)	2 (1.8)	4 (1.6)
注射部位疼痛	2 (1.5)	4 (3.6)	6 (2.5)
No reasonable possibility	0	2 (1.8)	2 (0.8)
Reasonable possibility	2 (1.5)	2 (1.8)	4 (1.6)
注射部位反応	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
注射部位腫脹	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
滴下投与部位熱傷	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
限局性浮腫	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
適用部位からの吸収不良	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
倦怠感	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	1 (0.8)	0	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
医療機器使用部位刺激感	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
医療機器使用部位そう痒感	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
医療機器使用部位発疹	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
小結節	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
末梢性浮腫	1 (0.8)	3 (2.7)	4 (1.6)
No reasonable possibility	1 (0.8)	2 (1.8)	3 (1.2)
Reasonable possibility	0	1 (0.9)	1 (0.4)
末梢腫脹	0	2 (1.8)	2 (0.8)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
穿刺部位内出血	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
穿刺部位紅斑	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
穿刺部位出血	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
穿刺部位硬結	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
穿刺部位浮腫	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
穿刺部位腫脹	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
発熱	2 (1.5)	1 (0.9)	3 (1.2)
No reasonable possibility	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
口渇	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
肝胆道系障害	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
門脈血栓症	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
感染症および寄生虫症	17 (12.9)	27 (24.1)	44 (18.0)
No reasonable possibility	7 (5.3)	12 (10.7)	19 (7.8)
Reasonable possibility	10 (7.6)	15 (13.4)	25 (10.2)
ボレリア感染	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
膀胱炎	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
真菌感染	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
胃腸炎	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
感染症および寄生虫症 (Cont.)			
注入部位膿瘍	3 (2.3)	5 (4.5)	8 (3.3)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	3 (2.3)	4 (3.6)	7 (2.9)
注入部位蜂巣炎	10 (7.6)	13 (11.6)	23 (9.4)
No reasonable possibility	2 (1.5)	1 (0.9)	3 (1.2)
Reasonable possibility	8 (6.1)	12 (10.7)	20 (8.2)
注入部位感染	1 (0.8)	3 (2.7)	4 (1.6)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	1 (0.8)	2 (1.8)	3 (1.2)
注射部位蜂巣炎	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
上咽頭炎	0	3 (2.7)	3 (1.2)
No reasonable possibility	0	3 (2.7)	3 (1.2)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
感染症および寄生虫症 (Cont.)			
爪真菌症	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
肺炎	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
膿疱性皮疹	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
敗血症	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
敗血症性ショック	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
感染症および寄生虫症 (Cont.)			
尿路感染	3 (2.3)	3 (2.7)	6 (2.5)
No reasonable possibility	3 (2.3)	3 (2.7)	6 (2.5)
傷害、中毒および処置合併症	10 (7.6)	11 (9.8)	21 (8.6)
No reasonable possibility	5 (3.8)	8 (7.1)	13 (5.3)
Reasonable possibility	5 (3.8)	3 (2.7)	8 (3.3)
挫傷	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
医療機器設置の問題	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
医療機器による投与の欠落	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
傷害、中毒および処置合併症 (Cont.)			
顔面骨骨折	0	2 (1.8)	2 (0.8)
No reasonable possibility	0	2 (1.8)	2 (0.8)
転倒	7 (5.3)	9 (8.0)	16 (6.6)
No reasonable possibility	5 (3.8)	6 (5.4)	11 (4.5)
Reasonable possibility	2 (1.5)	3 (2.7)	5 (2.0)
頭部損傷	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
注入に伴う反応	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
腰椎骨折	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
傷害、中毒および処置合併症 (Cont.)			
処置後挫傷	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
処置によるめまい	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
肋骨骨折	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
皮膚擦過傷	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
皮膚裂傷	0	2 (1.8)	2 (0.8)
No reasonable possibility	0	2 (1.8)	2 (0.8)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
臨床検査	3 (2.3)	5 (4.5)	8 (3.3)
No reasonable possibility	3 (2.3)	2 (1.8)	5 (2.0)
Reasonable possibility	0	3 (2.7)	3 (1.2)
血圧上昇	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	1 (0.8)	0	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
起立血圧低下	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
リンパ球数減少	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
単球数増加	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
臨床検査 (Cont.)			
好中球数増加	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
ビタミンB12減少	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
ビタミンB6減少	0	2 (1.8)	2 (0.8)
No reasonable possibility	0	2 (1.8)	2 (0.8)
体重減少	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
白血球数増加	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
代謝および栄養障害	1 (0.8)	5 (4.5)	6 (2.5)
No reasonable possibility	0	4 (3.6)	4 (1.6)
Reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
食欲減退	1 (0.8)	1 (0.9)	2 (0.8)
Reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
脱水	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
耐糖能障害	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
高血糖	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
代謝および栄養障害 (Cont.)			
低カリウム血症	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
筋骨格系および結合組織障害	10 (7.6)	8 (7.1)	18 (7.4)
No reasonable possibility	6 (4.5)	6 (5.4)	12 (4.9)
Reasonable possibility	4 (3.0)	2 (1.8)	6 (2.5)
関節痛	2 (1.5)	2 (1.8)	4 (1.6)
No reasonable possibility	1 (0.8)	2 (1.8)	3 (1.2)
Reasonable possibility	1 (0.8)	0	1 (0.4)
反応性関節炎	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
背部痛	3 (2.3)	1 (0.9)	4 (1.6)
No reasonable possibility	2 (1.5)	1 (0.9)	3 (1.2)
Reasonable possibility	1 (0.8)	0	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
筋骨格系および結合組織障害 (Cont.)			
関節腫脹	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
筋力低下	2 (1.5)	0	2 (0.8)
No reasonable possibility	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
筋骨格硬直	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
筋肉痛	2 (1.5)	1 (0.9)	3 (1.2)
No reasonable possibility	2 (1.5)	1 (0.9)	3 (1.2)
四肢痛	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
筋骨格系および結合組織障害 (Cont.)			
姿勢異常	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
横紋筋融解症	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
仙腸関節機能障害	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
斜頚	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
神経系障害	36 (27.3)	26 (23.2)	62 (25.4)
No reasonable possibility	6 (4.5)	7 (6.3)	13 (5.3)
Reasonable possibility	30 (22.7)	19 (17.0)	49 (20.1)

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

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
神経系障害 (Cont.)			
運動失調	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
平衡障害	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
運動緩慢	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
認知障害	2 (1.5)	0	2 (0.8)
No reasonable possibility	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
浮動性めまい	10 (7.6)	8 (7.1)	18 (7.4)
No reasonable possibility	0	2 (1.8)	2 (0.8)
Reasonable possibility	10 (7.6)	6 (5.4)	16 (6.6)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
神経系障害 (Cont.)			
体位性めまい	3 (2.3)	0	3 (1.2)
Reasonable possibility	3 (2.3)	0	3 (1.2)
構語障害	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
味覚不全	2 (1.5)	0	2 (0.8)
Reasonable possibility	2 (1.5)	0	2 (0.8)
ジスキネジア	6 (4.5)	3 (2.7)	9 (3.7)
Reasonable possibility	6 (4.5)	3 (2.7)	9 (3.7)
起立障害	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
神経系障害 (Cont.)			
ジストニア	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
本態性振戦	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
すくみ現象	3 (2.3)	0	3 (1.2)
Reasonable possibility	3 (2.3)	0	3 (1.2)
頭部不快感	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
頭痛	4 (3.0)	2 (1.8)	6 (2.5)
No reasonable possibility	2 (1.5)	2 (1.8)	4 (1.6)
Reasonable possibility	2 (1.5)	0	2 (0.8)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
神経系障害 (Cont.)			
片側感覚消失	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
不全片麻痺	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
代謝性脳症	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
オンオフ現象	3 (2.3)	3 (2.7)	6 (2.5)
No reasonable possibility	1 (0.8)	0	1 (0.4)
Reasonable possibility	2 (1.5)	3 (2.7)	5 (2.0)
錯感覚	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
神経系障害 (Cont.)			
パーキンソン病	5 (3.8)	3 (2.7)	8 (3.3)
No reasonable possibility	2 (1.5)	0	2 (0.8)
Reasonable possibility	3 (2.3)	3 (2.7)	6 (2.5)
パーキンソニズム	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
精神運動亢進	1 (0.8)	1 (0.9)	2 (0.8)
Reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
安静時振戦	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
坐骨神経痛	0	2 (1.8)	2 (0.8)
No reasonable possibility	0	2 (1.8)	2 (0.8)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
神経系障害 (Cont.)			
傾眠	2 (1.5)	2 (1.8)	4 (1.6)
Reasonable possibility	2 (1.5)	2 (1.8)	4 (1.6)
振戦	0	2 (1.8)	2 (0.8)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
製品の問題	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
医療機器機能不良	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
精神障害	31 (23.5)	24 (21.4)	55 (22.5)
No reasonable possibility	6 (4.5)	9 (8.0)	15 (6.1)
Reasonable possibility	25 (18.9)	15 (13.4)	40 (16.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
精神障害 (Cont.)			
異常な夢	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
感情不安定	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
不安	2 (1.5)	8 (7.1)	10 (4.1)
No reasonable possibility	1 (0.8)	5 (4.5)	6 (2.5)
Reasonable possibility	1 (0.8)	3 (2.7)	4 (1.6)
歯ぎしり	2 (1.5)	0	2 (0.8)
No reasonable possibility	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
錯乱状態	1 (0.8)	1 (0.9)	2 (0.8)
Reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
精神障害 (Cont.)			
譫妄	1 (0.8)	2 (1.8)	3 (1.2)
No reasonable possibility	1 (0.8)	2 (1.8)	3 (1.2)
妄想	1 (0.8)	1 (0.9)	2 (0.8)
Reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
抑うつ気分	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	1 (0.8)	0	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
抑うつ症状	2 (1.5)	0	2 (0.8)
No reasonable possibility	2 (1.5)	0	2 (0.8)
睡眠異常	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
精神障害 (Cont.)			
情動障害	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
幻覚	13 (9.8)	5 (4.5)	18 (7.4)
No reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
Reasonable possibility	12 (9.1)	4 (3.6)	16 (6.6)
幻聴	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
幻視	4 (3.0)	1 (0.9)	5 (2.0)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	4 (3.0)	0	4 (1.6)
不眠症	7 (5.3)	3 (2.7)	10 (4.1)
No reasonable possibility	2 (1.5)	0	2 (0.8)
Reasonable possibility	5 (3.8)	3 (2.7)	8 (3.3)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
精神障害 (Cont.)			
易刺激性	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
嫉妬妄想	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
気分変化	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
強迫観念	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
パニック発作	0	3 (2.7)	3 (1.2)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	2 (1.8)	2 (0.8)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
精神障害 (Cont.)			
精神病性障害	2 (1.5)	0	2 (0.8)
Reasonable possibility	2 (1.5)	0	2 (0.8)
レム睡眠行動障害	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
睡眠障害	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
ねごと	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
腎および尿路障害	6 (4.5)	1 (0.9)	7 (2.9)
No reasonable possibility	6 (4.5)	1 (0.9)	7 (2.9)
排尿困難	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
切迫性尿失禁	2 (1.5)	0	2 (0.8)
No reasonable possibility	2 (1.5)	0	2 (0.8)
尿失禁	2 (1.5)	0	2 (0.8)
No reasonable possibility	2 (1.5)	0	2 (0.8)
尿路障害	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
腎および尿路障害 (Cont.)			
尿異常	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
生殖系および乳房障害	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
勃起不全	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
呼吸器、胸郭および縦隔障害	1 (0.8)	7 (6.3)	8 (3.3)
No reasonable possibility	1 (0.8)	6 (5.4)	7 (2.9)
Reasonable possibility	0	1 (0.9)	1 (0.4)
急性呼吸不全	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
呼吸器、胸郭および縦隔障害 (Cont.)			
咳嗽	1 (0.8)	1 (0.9)	2 (0.8)
No reasonable possibility	1 (0.8)	1 (0.9)	2 (0.8)
呼吸困難	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
過換気	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
口腔咽頭痛	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
鼻痛	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
呼吸器、胸郭および縦隔障害 (Cont.)			
鼻漏	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
皮膚および皮下組織障害	6 (4.5)	5 (4.5)	11 (4.5)
No reasonable possibility	4 (3.0)	5 (4.5)	9 (3.7)
Reasonable possibility	2 (1.5)	0	2 (0.8)
脱毛症	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
接触皮膚炎	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
皮膚乾燥	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
皮膚および皮下組織障害 (Cont.)			
斑状出血	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
紅斑	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
光線過敏性反応	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
発疹	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
そう痒性皮疹	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
皮膚および皮下組織障害 (Cont.)			
皮膚刺激	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
皮膚病変	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)
皮膚潰瘍	1 (0.8)	0	1 (0.4)
No reasonable possibility	1 (0.8)	0	1 (0.4)
社会環境	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)
運動不能	1 (0.8)	0	1 (0.4)
Reasonable possibility	1 (0.8)	0	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
血管障害	3 (2.3)	7 (6.3)	10 (4.1)
No reasonable possibility	2 (1.5)	2 (1.8)	4 (1.6)
Reasonable possibility	1 (0.8)	5 (4.5)	6 (2.5)
ほてり	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
高血圧	2 (1.5)	1 (0.9)	3 (1.2)
No reasonable possibility	2 (1.5)	1 (0.9)	3 (1.2)
低血圧	0	2 (1.8)	2 (0.8)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	0	1 (0.9)	1 (0.4)
不安定血圧	0	1 (0.9)	1 (0.4)
No reasonable possibility	0	1 (0.9)	1 (0.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
血管障害 (Cont.)			
起立性低血圧	1 (0.8)	4 (3.6)	5 (2.0)
No reasonable possibility	0	1 (0.9)	1 (0.4)
Reasonable possibility	1 (0.8)	3 (2.7)	4 (1.6)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period	N=111	N=95	N=206
Any adverse event	100 (90.1)	89 (93.7)	189 (91.7)
No reasonable possibility	10 (9.0)	5 (5.3)	15 (7.3)
Reasonable possibility	90 (81.1)	84 (88.4)	174 (84.5)
血液およびリンパ系障害	1 (0.9)	3 (3.2)	4 (1.9)
No reasonable possibility	1 (0.9)	3 (3.2)	4 (1.9)
大球性貧血	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
凝血異常	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
リンパ節症	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
血液およびリンパ系障害 (Cont.)			
縦隔リンパ節腫脹	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
心臓障害	5 (4.5)	6 (6.3)	11 (5.3)
No reasonable possibility	4 (3.6)	6 (6.3)	10 (4.9)
Reasonable possibility	1 (0.9)	0	1 (0.5)
急性心筋梗塞	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
狭心症	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
心房細動	0	2 (2.1)	2 (1.0)
No reasonable possibility	0	2 (2.1)	2 (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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
心臓障害 (Cont.)			
心停止	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
心肺停止	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
冠動脈疾患	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
冠動脈狭窄	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
期外収縮	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
心臓障害 (Cont.)			
左室肥大	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
心筋梗塞	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
動悸	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
頻脈	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
耳および迷路障害	2 (1.8)	2 (2.1)	4 (1.9)
No reasonable possibility	1 (0.9)	2 (2.1)	3 (1.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
耳および迷路障害 (Cont.)			
感音性難聴	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
回転性めまい	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
頭位性回転性めまい	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
眼障害	7 (6.3)	6 (6.3)	13 (6.3)
No reasonable possibility	7 (6.3)	5 (5.3)	12 (5.8)
Reasonable possibility	0	1 (1.1)	1 (0.5)
白内障	2 (1.8)	2 (2.1)	4 (1.9)
No reasonable possibility	2 (1.8)	2 (2.1)	4 (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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
眼障害 (Cont.)			
複視	2 (1.8)	0	2 (1.0)
No reasonable possibility	2 (1.8)	0	2 (1.0)
ドライアイ	1 (0.9)	3 (3.2)	4 (1.9)
No reasonable possibility	1 (0.9)	3 (3.2)	4 (1.9)
緑内障	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
眼窩周囲痛	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
眼窩周囲腫脹	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
眼障害 (Cont.)			
網膜裂孔	2 (1.8)	0	2 (1.0)
No reasonable possibility	2 (1.8)	0	2 (1.0)
視野欠損	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
胃腸障害	17 (15.3)	21 (22.1)	38 (18.4)
No reasonable possibility	14 (12.6)	12 (12.6)	26 (12.6)
Reasonable possibility	3 (2.7)	9 (9.5)	12 (5.8)
腹部膨満	1 (0.9)	2 (2.1)	3 (1.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
腹痛	1 (0.9)	1 (1.1)	2 (1.0)
Reasonable possibility	1 (0.9)	1 (1.1)	2 (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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
胃腸障害 (Cont.)			
上腹部痛	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
呼気臭	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
虚血性大腸炎	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
便秘	6 (5.4)	10 (10.5)	16 (7.8)
No reasonable possibility	6 (5.4)	8 (8.4)	14 (6.8)
Reasonable possibility	0	2 (2.1)	2 (1.0)
齲歯	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
胃腸障害 (Cont.)			
下痢	4 (3.6)	1 (1.1)	5 (2.4)
No reasonable possibility	4 (3.6)	1 (1.1)	5 (2.4)
口内乾燥	1 (0.9)	3 (3.2)	4 (1.9)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	1 (0.9)	2 (2.1)	3 (1.5)
嚥下障害	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
糞塊	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
排便回数増加	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
胃腸障害 (Cont.)			
胃食道逆流性疾患	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
舌炎	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
舌痛	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
吐血	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
裂孔ヘルニア	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
胃腸障害 (Cont.)			
胃排出不全	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
鼠径ヘルニア	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
腸出血	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
過敏性腸症候群	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
大腸ポリープ	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
胃腸障害 (Cont.)			
口唇乾燥	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
メレナ	2 (1.8)	0	2 (1.0)
No reasonable possibility	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
口腔腫脹	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
悪心	4 (3.6)	7 (7.4)	11 (5.3)
No reasonable possibility	2 (1.8)	4 (4.2)	6 (2.9)
Reasonable possibility	2 (1.8)	3 (3.2)	5 (2.4)
口腔内不快感	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
胃腸障害 (Cont.)			
口腔内痛	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
口の錯感覚	1 (0.9)	1 (1.1)	2 (1.0)
Reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
直腸出血	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
歯痛	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
嘔吐	1 (0.9)	2 (2.1)	3 (1.5)
No reasonable possibility	1 (0.9)	2 (2.1)	3 (1.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
一般・全身障害および投与部位の状態	66 (59.5)	72 (75.8)	138 (67.0)
No reasonable possibility	3 (2.7)	2 (2.1)	5 (2.4)
Reasonable possibility	63 (56.8)	70 (73.7)	133 (64.6)
投与部位内出血	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
投与部位漏出	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
無力症	2 (1.8)	0	2 (1.0)
No reasonable possibility	2 (1.8)	0	2 (1.0)
カテーテル留置部位紅斑	1 (0.9)	1 (1.1)	2 (1.0)
Reasonable possibility	1 (0.9)	1 (1.1)	2 (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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
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	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
カテーテル留置部位出血	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
カテーテル留置部位刺激感	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
カテーテル留置部位浮腫	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
カテーテル留置部位疼痛	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
一般・全身障害および投与部位の状態 (Cont.)			
胸部不快感	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
胸痛	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
泣き	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
薬効欠如	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
薬剤離脱症候群	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
一般・全身障害および投与部位の状態 (Cont.)			
疲労	3 (2.7)	1 (1.1)	4 (1.9)
Reasonable possibility	3 (2.7)	1 (1.1)	4 (1.9)
異常感	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
冷感	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
歩行障害	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
低体温	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
一般・全身障害および投与部位の状態 (Cont.)			
インフルエンザ様疾患	1 (0.9)	2 (2.1)	3 (1.5)
No reasonable possibility	1 (0.9)	2 (2.1)	3 (1.5)
注入部位内出血	7 (6.3)	2 (2.1)	9 (4.4)
Reasonable possibility	7 (6.3)	2 (2.1)	9 (4.4)
注入部位皮膚炎	2 (1.8)	2 (2.1)	4 (1.9)
Reasonable possibility	2 (1.8)	2 (2.1)	4 (1.9)
注入部位分泌物	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
注入部位不快感	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
一般・全身障害および投与部位の状態 (Cont.)			
注入部位びらん	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
注入部位紅斑	36 (32.4)	44 (46.3)	80 (38.8)
No reasonable possibility	4 (3.6)	1 (1.1)	5 (2.4)
Reasonable possibility	32 (28.8)	43 (45.3)	75 (36.4)
注入部位皮膚剥脱	3 (2.7)	2 (2.1)	5 (2.4)
Reasonable possibility	3 (2.7)	2 (2.1)	5 (2.4)
注入部位血管外漏出	5 (4.5)	6 (6.3)	11 (5.3)
Reasonable possibility	5 (4.5)	6 (6.3)	11 (5.3)
注入部位血腫	6 (5.4)	4 (4.2)	10 (4.9)
No reasonable possibility	1 (0.9)	0	1 (0.5)
Reasonable possibility	5 (4.5)	4 (4.2)	9 (4.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
一般・全身障害および投与部位の状態 (Cont.)			
注入部位出血	4 (3.6)	2 (2.1)	6 (2.9)
No reasonable possibility	2 (1.8)	1 (1.1)	3 (1.5)
Reasonable possibility	2 (1.8)	1 (1.1)	3 (1.5)
注入部位硬結	5 (4.5)	2 (2.1)	7 (3.4)
Reasonable possibility	5 (4.5)	2 (2.1)	7 (3.4)
注入部位炎症	2 (1.8)	6 (6.3)	8 (3.9)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	2 (1.8)	5 (5.3)	7 (3.4)
注入部位損傷	0	2 (2.1)	2 (1.0)
Reasonable possibility	0	2 (2.1)	2 (1.0)
注入部位刺激感	1 (0.9)	4 (4.2)	5 (2.4)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	1 (0.9)	3 (3.2)	4 (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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
一般・全身障害および投与部位の状態 (Cont.)			
注入部位腫瘤	1 (0.9)	2 (2.1)	3 (1.5)
Reasonable possibility	1 (0.9)	2 (2.1)	3 (1.5)
注入部位結節	20 (18.0)	25 (26.3)	45 (21.8)
Reasonable possibility	20 (18.0)	25 (26.3)	45 (21.8)
注入部位浮腫	8 (7.2)	18 (18.9)	26 (12.6)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	8 (7.2)	17 (17.9)	25 (12.1)
注入部位疼痛	8 (7.2)	11 (11.6)	19 (9.2)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
Reasonable possibility	7 (6.3)	10 (10.5)	17 (8.3)
注入部位蒼白	1 (0.9)	1 (1.1)	2 (1.0)
Reasonable possibility	1 (0.9)	1 (1.1)	2 (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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
一般・全身障害および投与部位の状態 (Cont.)			
注入部位丘疹	6 (5.4)	8 (8.4)	14 (6.8)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	6 (5.4)	7 (7.4)	13 (6.3)
注入部位異常感覚	0	2 (2.1)	2 (1.0)
Reasonable possibility	0	2 (2.1)	2 (1.0)
注入部位そう痒感	3 (2.7)	1 (1.1)	4 (1.9)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	3 (2.7)	0	3 (1.5)
注入部位発疹	1 (0.9)	3 (3.2)	4 (1.9)
No reasonable possibility	0	2 (2.1)	2 (1.0)
Reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
注入部位反応	8 (7.2)	11 (11.6)	19 (9.2)
Reasonable possibility	8 (7.2)	11 (11.6)	19 (9.2)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
一般・全身障害および投与部位の状態 (Cont.)			
注入部位痂皮	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
注入部位腫脹	2 (1.8)	1 (1.1)	3 (1.5)
Reasonable possibility	2 (1.8)	1 (1.1)	3 (1.5)
注入部位小水疱	0	2 (2.1)	2 (1.0)
Reasonable possibility	0	2 (2.1)	2 (1.0)
注入部位熱感	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
注射部位内出血	1 (0.9)	1 (1.1)	2 (1.0)
Reasonable possibility	1 (0.9)	1 (1.1)	2 (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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
一般・全身障害および投与部位の状態 (Cont.)			
注射部位変色	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
注射部位紅斑	5 (4.5)	5 (5.3)	10 (4.9)
Reasonable possibility	5 (4.5)	5 (5.3)	10 (4.9)
注射部位出血	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
注射部位炎症	2 (1.8)	4 (4.2)	6 (2.9)
Reasonable possibility	2 (1.8)	4 (4.2)	6 (2.9)
注射部位結節	3 (2.7)	5 (5.3)	8 (3.9)
Reasonable possibility	3 (2.7)	5 (5.3)	8 (3.9)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
一般・全身障害および投与部位の状態 (Cont.)			
注射部位浮腫	1 (0.9)	1 (1.1)	2 (1.0)
Reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
注射部位疼痛	0	2 (2.1)	2 (1.0)
Reasonable possibility	0	2 (2.1)	2 (1.0)
注射部位丘疹	0	2 (2.1)	2 (1.0)
Reasonable possibility	0	2 (2.1)	2 (1.0)
注射部位反応	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
注射部位腫脹	1 (0.9)	2 (2.1)	3 (1.5)
Reasonable possibility	1 (0.9)	2 (2.1)	3 (1.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
一般・全身障害および投与部位の状態 (Cont.)			
注射部位蕁麻疹	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
滴下投与部位痛	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
倦怠感	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
医療機器使用部位刺激感	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
医療機器使用部位発疹	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
一般・全身障害および投与部位の状態 (Cont.)			
非心臓性胸痛	0	2 (2.1)	2 (1.0)
No reasonable possibility	0	2 (2.1)	2 (1.0)
末梢性浮腫	4 (3.6)	1 (1.1)	5 (2.4)
No reasonable possibility	3 (2.7)	1 (1.1)	4 (1.9)
Reasonable possibility	1 (0.9)	0	1 (0.5)
疼痛	2 (1.8)	0	2 (1.0)
No reasonable possibility	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
末梢腫脹	0	3 (3.2)	3 (1.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	2 (2.1)	2 (1.0)
穿刺部位紅斑	0	2 (2.1)	2 (1.0)
Reasonable possibility	0	2 (2.1)	2 (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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
一般・全身障害および投与部位の状態 (Cont.)			
穿刺部位硬結	2 (1.8)	0	2 (1.0)
Reasonable possibility	2 (1.8)	0	2 (1.0)
発熱	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
血管穿刺部位硬結	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
肝胆道系障害	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
肝嚢胞	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
肝胆道系障害 (Cont.)			
脂肪肝	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
感染症および寄生虫症	46 (41.4)	45 (47.4)	91 (44.2)
No reasonable possibility	14 (12.6)	13 (13.7)	27 (13.1)
Reasonable possibility	32 (28.8)	32 (33.7)	64 (31.1)
四肢膿瘍	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
無症候性COVID-19	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
細菌性疾患キャリアー	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
感染症および寄生虫症 (Cont.)			
ウイルス性気管支炎	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
COVID-19	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
COVID-19肺炎	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
カテーテル留置部位感染	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
蜂巣炎	1 (0.9)	2 (2.1)	3 (1.5)
No reasonable possibility	1 (0.9)	2 (2.1)	3 (1.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
感染症および寄生虫症 (Cont.)			
結膜炎	2 (1.8)	0	2 (1.0)
No reasonable possibility	2 (1.8)	0	2 (1.0)
膀胱炎	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
爪の皮膚糸状菌症	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
歯肉炎	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
麦粒腫	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
感染症および寄生虫症 (Cont.)			
感染性皮膚潰瘍	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
インフルエンザ	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
注入部位膿瘍	11 (9.9)	9 (9.5)	20 (9.7)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	11 (9.9)	8 (8.4)	19 (9.2)
注入部位蜂巣炎	21 (18.9)	19 (20.0)	40 (19.4)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
Reasonable possibility	20 (18.0)	18 (18.9)	38 (18.4)
注入部位感染	6 (5.4)	9 (9.5)	15 (7.3)
No reasonable possibility	2 (1.8)	0	2 (1.0)
Reasonable possibility	4 (3.6)	9 (9.5)	13 (6.3)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
感染症および寄生虫症 (Cont.)			
注入部位膿疱	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
注射部位蜂巣炎	0	2 (2.1)	2 (1.0)
Reasonable possibility	0	2 (2.1)	2 (1.0)
リンパ管炎	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
上咽頭炎	5 (4.5)	2 (2.1)	7 (3.4)
No reasonable possibility	5 (4.5)	2 (2.1)	7 (3.4)
耳下腺膿瘍	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
感染症および寄生虫症 (Cont.)			
肺炎	2 (1.8)	1 (1.1)	3 (1.5)
No reasonable possibility	2 (1.8)	1 (1.1)	3 (1.5)
術後膿瘍	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
シュードモナス感染	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
気道感染	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
敗血症	2 (1.8)	0	2 (1.0)
Reasonable possibility	2 (1.8)	0	2 (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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
感染症および寄生虫症 (Cont.)			
副鼻腔炎	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
ブドウ球菌感染	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
歯感染	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
上気道感染	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
尿路感染	5 (4.5)	11 (11.6)	16 (7.8)
No reasonable possibility	5 (4.5)	11 (11.6)	16 (7.8)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
感染症および寄生虫症 (Cont.)			
水痘帯状疱疹ウイルス感染	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
傷害、中毒および処置合併症	13 (11.7)	21 (22.1)	34 (16.5)
No reasonable possibility	9 (8.1)	16 (16.8)	25 (12.1)
Reasonable possibility	4 (3.6)	5 (5.3)	9 (4.4)
足関節部骨折	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
節足動物咬傷	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
骨挫傷	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
傷害、中毒および処置合併症 (Cont.)			
脳挫傷	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
挫傷	1 (0.9)	6 (6.3)	7 (3.4)
No reasonable possibility	1 (0.9)	4 (4.2)	5 (2.4)
Reasonable possibility	0	2 (2.1)	2 (1.0)
期限切れの製品使用	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
眼挫傷	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
顔面損傷	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
傷害、中毒および処置合併症 (Cont.)			
転倒	11 (9.9)	18 (18.9)	29 (14.1)
No reasonable possibility	8 (7.2)	15 (15.8)	23 (11.2)
Reasonable possibility	3 (2.7)	3 (3.2)	6 (2.9)
頭部損傷	1 (0.9)	3 (3.2)	4 (1.9)
No reasonable possibility	0	2 (2.1)	2 (1.0)
Reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
関節脱臼	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
靭帯捻挫	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
過量投与	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
傷害、中毒および処置合併症 (Cont.)			
肋骨骨折	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
皮膚擦過傷	0	2 (2.1)	2 (1.0)
No reasonable possibility	0	2 (2.1)	2 (1.0)
皮膚損傷	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
皮膚裂傷	1 (0.9)	4 (4.2)	5 (2.4)
No reasonable possibility	1 (0.9)	4 (4.2)	5 (2.4)
ストレス骨折	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
傷害、中毒および処置合併症 (Cont.)			
硬膜下血腫	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
サンバーン	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
腱断裂	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
過少量投与	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
創傷	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
臨床検査	21 (18.9)	19 (20.0)	40 (19.4)
No reasonable possibility	10 (9.0)	6 (6.3)	16 (7.8)
Reasonable possibility	11 (9.9)	13 (13.7)	24 (11.7)
血中クレアチンホスホキナーゼ増加	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
血中クレアチニン減少	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
血中葉酸異常	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
血中葉酸減少	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
臨床検査 (Cont.)			
血中ホモシステイン増加	1 (0.9)	2 (2.1)	3 (1.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
血中リン減少	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
血中ナトリウム減少	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
C-反応性蛋白増加	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
心雑音	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
臨床検査 (Cont.)			
握力低下	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
ヘモグロビン減少	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
好中球数増加	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
プロトロンビン時間延長	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
赤血球数減少	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
臨床検査 (Cont.)			
ビタミンB12減少	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
ビタミンB6減少	5 (4.5)	4 (4.2)	9 (4.4)
No reasonable possibility	1 (0.9)	2 (2.1)	3 (1.5)
Reasonable possibility	4 (3.6)	2 (2.1)	6 (2.9)
ビタミンD減少	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
体重減少	10 (9.0)	13 (13.7)	23 (11.2)
No reasonable possibility	6 (5.4)	3 (3.2)	9 (4.4)
Reasonable possibility	4 (3.6)	10 (10.5)	14 (6.8)
体重増加	2 (1.8)	0	2 (1.0)
No reasonable possibility	2 (1.8)	0	2 (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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
臨床検査 (Cont.)			
白血球数増加	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
代謝および栄養障害	10 (9.0)	16 (16.8)	26 (12.6)
No reasonable possibility	7 (6.3)	10 (10.5)	17 (8.3)
Reasonable possibility	3 (2.7)	6 (6.3)	9 (4.4)
悪液質	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
食欲減退	2 (1.8)	2 (2.1)	4 (1.9)
No reasonable possibility	2 (1.8)	2 (2.1)	4 (1.9)
脱水	1 (0.9)	2 (2.1)	3 (1.5)
No reasonable possibility	1 (0.9)	2 (2.1)	3 (1.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
代謝および栄養障害 (Cont.)			
糖尿病	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
水分過負荷	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
体液貯留	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	1 (0.9)	0	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
葉酸欠乏	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	1 (0.9)	0	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
高コレステロール血症	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
代謝および栄養障害 (Cont.)			
高ホモシステイン血症	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
低カルシウム血症	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
低カリウム血症	0	2 (2.1)	2 (1.0)
No reasonable possibility	0	2 (2.1)	2 (1.0)
低ナトリウム血症	2 (1.8)	0	2 (1.0)
No reasonable possibility	2 (1.8)	0	2 (1.0)
栄養障害	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
代謝および栄養障害 (Cont.)			
ビタミンB群欠乏	1 (0.9)	1 (1.1)	2 (1.0)
Reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
ビタミンB12欠乏	0	2 (2.1)	2 (1.0)
Reasonable possibility	0	2 (2.1)	2 (1.0)
ビタミンB6欠乏	3 (2.7)	5 (5.3)	8 (3.9)
No reasonable possibility	1 (0.9)	2 (2.1)	3 (1.5)
Reasonable possibility	2 (1.8)	3 (3.2)	5 (2.4)
筋骨格系および結合組織障害	17 (15.3)	15 (15.8)	32 (15.5)
No reasonable possibility	14 (12.6)	13 (13.7)	27 (13.1)
Reasonable possibility	3 (2.7)	2 (2.1)	5 (2.4)
関節痛	1 (0.9)	3 (3.2)	4 (1.9)
No reasonable possibility	1 (0.9)	3 (3.2)	4 (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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
筋骨格系および結合組織障害 (Cont.)			
反応性関節炎	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
背部痛	5 (4.5)	4 (4.2)	9 (4.4)
No reasonable possibility	5 (4.5)	4 (4.2)	9 (4.4)
骨痛	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
滑液包炎	2 (1.8)	0	2 (1.0)
No reasonable possibility	2 (1.8)	0	2 (1.0)
外骨腫	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
筋骨格系および結合組織障害 (Cont.)			
椎間関節症候群	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
椎間板変性症	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
椎間板突出	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
関節滲出液	0	2 (2.1)	2 (1.0)
No reasonable possibility	0	2 (2.1)	2 (1.0)
四肢不快感	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
筋骨格系および結合組織障害 (Cont.)			
筋萎縮	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
筋痙縮	2 (1.8)	3 (3.2)	5 (2.4)
No reasonable possibility	2 (1.8)	3 (3.2)	5 (2.4)
筋力低下	2 (1.8)	1 (1.1)	3 (1.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	2 (1.8)	0	2 (1.0)
頚部痛	2 (1.8)	0	2 (1.0)
No reasonable possibility	2 (1.8)	0	2 (1.0)
骨炎	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
筋骨格系および結合組織障害 (Cont.)			
変形性関節症	1 (0.9)	4 (4.2)	5 (2.4)
No reasonable possibility	1 (0.9)	4 (4.2)	5 (2.4)
骨減少症	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
四肢痛	3 (2.7)	2 (2.1)	5 (2.4)
No reasonable possibility	2 (1.8)	2 (2.1)	4 (1.9)
Reasonable possibility	1 (0.9)	0	1 (0.5)
関節周囲炎	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
横紋筋融解症	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
筋骨格系および結合組織障害 (Cont.)			
肩回旋筋腱板症候群	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
変形性脊椎症	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
腱障害	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
腱炎	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
弾発指	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	1 (0.9)	4 (4.2)	5 (2.4)
No reasonable possibility	1 (0.9)	4 (4.2)	5 (2.4)
基底細胞癌	0	2 (2.1)	2 (1.0)
No reasonable possibility	0	2 (2.1)	2 (1.0)
直腸腺癌	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
脂漏性角化症	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
皮膚有棘細胞癌	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
神経系障害	37 (33.3)	34 (35.8)	71 (34.5)
No reasonable possibility	18 (16.2)	17 (17.9)	35 (17.0)
Reasonable possibility	19 (17.1)	17 (17.9)	36 (17.5)
アカシジア	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
健忘	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
失語症	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
平衡障害	0	4 (4.2)	4 (1.9)
No reasonable possibility	0	3 (3.2)	3 (1.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
神経系障害 (Cont.)			
運動緩慢	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
手根管症候群	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
大脳萎縮	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
脳出血	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
脳圧排効果	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
神経系障害 (Cont.)			
脳血管発作	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
認知障害	2 (1.8)	2 (2.1)	4 (1.9)
No reasonable possibility	2 (1.8)	2 (2.1)	4 (1.9)
振動覚低下	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
注意力障害	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
浮動性めまい	6 (5.4)	2 (2.1)	8 (3.9)
No reasonable possibility	3 (2.7)	0	3 (1.5)
Reasonable possibility	3 (2.7)	2 (2.1)	5 (2.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
神経系障害 (Cont.)			
体位性めまい	3 (2.7)	0	3 (1.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
Reasonable possibility	2 (1.8)	0	2 (1.0)
構語障害	0	2 (2.1)	2 (1.0)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
味覚不全	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
ジスキネジア	7 (6.3)	3 (3.2)	10 (4.9)
No reasonable possibility	1 (0.9)	0	1 (0.5)
Reasonable possibility	6 (5.4)	3 (3.2)	9 (4.4)
ジストニア	1 (0.9)	4 (4.2)	5 (2.4)
No reasonable possibility	0	2 (2.1)	2 (1.0)
Reasonable possibility	1 (0.9)	2 (2.1)	3 (1.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
神経系障害 (Cont.)			
脳症	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
てんかん	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
伸展性足底反応	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
すくみ現象	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
全身性強直性間代性発作	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
神経系障害 (Cont.)			
頭痛	3 (2.7)	6 (6.3)	9 (4.4)
No reasonable possibility	1 (0.9)	4 (4.2)	5 (2.4)
Reasonable possibility	2 (1.8)	2 (2.1)	4 (1.9)
知覚過敏	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
感覚鈍麻	1 (0.9)	2 (2.1)	3 (1.5)
Reasonable possibility	1 (0.9)	2 (2.1)	3 (1.5)
反射減弱	2 (1.8)	1 (1.1)	3 (1.5)
No reasonable possibility	2 (1.8)	1 (1.1)	3 (1.5)
不規則睡眠覚醒リズム障害	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
神経系障害 (Cont.)			
嗜眠	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
意識消失	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
腰仙部神経根障害	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
記憶障害	0	2 (2.1)	2 (1.0)
No reasonable possibility	0	2 (2.1)	2 (1.0)
代謝性脳症	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
神経系障害 (Cont.)			
神経痛	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
末梢性ニューロパチー	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
オンオフ現象	1 (0.9)	2 (2.1)	3 (1.5)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
Reasonable possibility	0	1 (1.1)	1 (0.5)
錯感覚	4 (3.6)	2 (2.1)	6 (2.9)
No reasonable possibility	1 (0.9)	0	1 (0.5)
Reasonable possibility	3 (2.7)	2 (2.1)	5 (2.4)
パーキンソン病	7 (6.3)	2 (2.1)	9 (4.4)
No reasonable possibility	4 (3.6)	0	4 (1.9)
Reasonable possibility	3 (2.7)	2 (2.1)	5 (2.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
神経系障害 (Cont.)			
パーキンソニズム	0	2 (2.1)	2 (1.0)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
末梢性感覚ニューロパチー	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
側反弓	1 (0.9)	2 (2.1)	3 (1.5)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
Reasonable possibility	0	1 (1.1)	1 (0.5)
多発ニューロパチー	0	2 (2.1)	2 (1.0)
Reasonable possibility	0	2 (2.1)	2 (1.0)
失神寸前の状態	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
神経系障害 (Cont.)			
心因性発作	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
反射異常	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
坐骨神経痛	0	3 (3.2)	3 (1.5)
No reasonable possibility	0	2 (2.1)	2 (1.0)
Reasonable possibility	0	1 (1.1)	1 (0.5)
痙攣発作	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
感覚障害	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
神経系障害 (Cont.)			
感覚消失	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
睡眠時麻痺	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
傾眠	8 (7.2)	1 (1.1)	9 (4.4)
No reasonable possibility	5 (4.5)	0	5 (2.4)
Reasonable possibility	3 (2.7)	1 (1.1)	4 (1.9)
失神	0	3 (3.2)	3 (1.5)
No reasonable possibility	0	2 (2.1)	2 (1.0)
Reasonable possibility	0	1 (1.1)	1 (0.5)
振戦	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
製品の問題	2 (1.8)	0	2 (1.0)
No reasonable possibility	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
医療機器送達システムの問題	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
医療機器位置異常	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
精神障害	38 (34.2)	42 (44.2)	80 (38.8)
No reasonable possibility	10 (9.0)	14 (14.7)	24 (11.7)
Reasonable possibility	28 (25.2)	28 (29.5)	56 (27.2)
感情不安定	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
精神障害 (Cont.)			
激越	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
不安	10 (9.0)	12 (12.6)	22 (10.7)
No reasonable possibility	8 (7.2)	7 (7.4)	15 (7.3)
Reasonable possibility	2 (1.8)	5 (5.3)	7 (3.4)
不安障害	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
無感情	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
強迫行為	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
精神障害 (Cont.)			
強迫性性行動	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
錯乱状態	4 (3.6)	4 (4.2)	8 (3.9)
No reasonable possibility	0	2 (2.1)	2 (1.0)
Reasonable possibility	4 (3.6)	2 (2.1)	6 (2.9)
譫妄	0	2 (2.1)	2 (1.0)
Reasonable possibility	0	2 (2.1)	2 (1.0)
妄想	7 (6.3)	1 (1.1)	8 (3.9)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	7 (6.3)	0	7 (3.4)
寄生虫妄想	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
精神障害 (Cont.)			
妄想性障害、詳細不明	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
抑うつ気分	2 (1.8)	1 (1.1)	3 (1.5)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
Reasonable possibility	1 (0.9)	0	1 (0.5)
うつ病	3 (2.7)	2 (2.1)	5 (2.4)
No reasonable possibility	3 (2.7)	1 (1.1)	4 (1.9)
Reasonable possibility	0	1 (1.1)	1 (0.5)
ドーパミン調節障害症候群	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
ディスフェミア	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
精神障害 (Cont.)			
睡眠異常	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
情動障害	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
注射恐怖	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
幻覚	12 (10.8)	19 (20.0)	31 (15.0)
No reasonable possibility	0	4 (4.2)	4 (1.9)
Reasonable possibility	12 (10.8)	15 (15.8)	27 (13.1)
幻聴	3 (2.7)	2 (2.1)	5 (2.4)
Reasonable possibility	3 (2.7)	2 (2.1)	5 (2.4)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
精神障害 (Cont.)			
幻嗅	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
幻視	6 (5.4)	4 (4.2)	10 (4.9)
Reasonable possibility	6 (5.4)	4 (4.2)	10 (4.9)
混合性幻覚	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
性欲過剰	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
錯覚	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
精神障害 (Cont.)			
衝動制御障害	0	4 (4.2)	4 (1.9)
No reasonable possibility	0	2 (2.1)	2 (1.0)
Reasonable possibility	0	2 (2.1)	2 (1.0)
衝動行為	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
不眠症	2 (1.8)	6 (6.3)	8 (3.9)
No reasonable possibility	0	3 (3.2)	3 (1.5)
Reasonable possibility	2 (1.8)	3 (3.2)	5 (2.4)
易刺激性	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
躁病	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
精神障害 (Cont.)			
気分動揺	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
悪夢	1 (0.9)	1 (1.1)	2 (1.0)
Reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
パニック発作	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
パニック反応	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
妄想症	2 (1.8)	0	2 (1.0)
Reasonable possibility	2 (1.8)	0	2 (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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
精神障害 (Cont.)			
睡眠の質低下	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
処置に対する不安	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
精神病性障害	3 (2.7)	2 (2.1)	5 (2.4)
Reasonable possibility	3 (2.7)	2 (2.1)	5 (2.4)
精神病症状	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
精神障害 (Cont.)			
レム睡眠行動障害	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
レム睡眠異常	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
睡眠障害	2 (1.8)	0	2 (1.0)
Reasonable possibility	2 (1.8)	0	2 (1.0)
ねごと	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
常同症	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
精神障害 (Cont.)			
ストレス	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
自殺念慮	1 (0.9)	2 (2.1)	3 (1.5)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
Reasonable possibility	0	1 (1.1)	1 (0.5)
自殺企図	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
腎および尿路障害	7 (6.3)	7 (7.4)	14 (6.8)
No reasonable possibility	7 (6.3)	5 (5.3)	12 (5.8)
Reasonable possibility	0	2 (2.1)	2 (1.0)
膀胱痙縮	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
腎および尿路障害 (Cont.)			
膀胱結石	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
尿路結石	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
排尿困難	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
緊張性膀胱	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
夜間頻尿	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
腎および尿路障害 (Cont.)			
頻尿	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
多尿	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
腎機能障害	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
尿管結石症	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
切迫性尿失禁	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
腎および尿路障害 (Cont.)			
尿失禁	1 (0.9)	2 (2.1)	3 (1.5)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
Reasonable possibility	0	1 (1.1)	1 (0.5)
尿閉	0	3 (3.2)	3 (1.5)
No reasonable possibility	0	3 (3.2)	3 (1.5)
尿臭異常	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
生殖系および乳房障害	2 (1.8)	4 (4.2)	6 (2.9)
No reasonable possibility	1 (0.9)	4 (4.2)	5 (2.4)
Reasonable possibility	1 (0.9)	0	1 (0.5)
良性前立腺肥大症	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
生殖系および乳房障害 (Cont.)			
勃起不全	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
骨盤痛	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
ペイロニー病	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
閉経後出血	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
前立腺腫大	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
生殖系および乳房障害 (Cont.)			
腟脱	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
呼吸器、胸郭および縦隔障害	6 (5.4)	13 (13.7)	19 (9.2)
No reasonable possibility	5 (4.5)	11 (11.6)	16 (7.8)
Reasonable possibility	1 (0.9)	2 (2.1)	3 (1.5)
気管支拡張症	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
咳嗽	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
発声障害	0	2 (2.1)	2 (1.0)
No reasonable possibility	0	2 (2.1)	2 (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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
呼吸器、胸郭および縦隔障害 (Cont.)			
呼吸困難	2 (1.8)	5 (5.3)	7 (3.4)
No reasonable possibility	2 (1.8)	3 (3.2)	5 (2.4)
Reasonable possibility	0	2 (2.1)	2 (1.0)
労作性呼吸困難	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
鼻出血	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
過換気	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
口腔咽頭痛	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
呼吸器、胸郭および縦隔障害 (Cont.)			
誤嚥性肺炎	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
湿性咳嗽	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
肺塞栓症	0	2 (2.1)	2 (1.0)
No reasonable possibility	0	2 (2.1)	2 (1.0)
ラ音	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
呼吸窮迫	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
呼吸器、胸郭および縦隔障害 (Cont.)			
鼻漏	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
咽喉刺激感	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
皮膚および皮下組織障害	10 (9.0)	12 (12.6)	22 (10.7)
No reasonable possibility	6 (5.4)	9 (9.5)	15 (7.3)
Reasonable possibility	4 (3.6)	3 (3.2)	7 (3.4)
脱毛症	1 (0.9)	1 (1.1)	2 (1.0)
Reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
褥瘡性潰瘍	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
皮膚および皮下組織障害 (Cont.)			
皮膚嚢腫	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
皮膚炎	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
接触皮膚炎	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
おむつ皮膚炎	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
薬疹	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
皮膚および皮下組織障害 (Cont.)			
皮膚乾燥	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
紅斑	1 (0.9)	2 (2.1)	3 (1.5)
No reasonable possibility	1 (0.9)	2 (2.1)	3 (1.5)
爪の障害	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
脂肪織炎	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
丘疹	0	2 (2.1)	2 (1.0)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
皮膚および皮下組織障害 (Cont.)			
口囲皮膚炎	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
そう痒症	2 (1.8)	2 (2.1)	4 (1.9)
No reasonable possibility	1 (0.9)	2 (2.1)	3 (1.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
乾癬	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
発疹	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
紅斑性皮疹	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
皮膚および皮下組織障害 (Cont.)			
そう痒性皮疹	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
皮膚潰瘍	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
蕁麻疹	2 (1.8)	0	2 (1.0)
Reasonable possibility	2 (1.8)	0	2 (1.0)
外科および内科処置	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
抜歯	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
血管障害	11 (9.9)	9 (9.5)	20 (9.7)
No reasonable possibility	5 (4.5)	6 (6.3)	11 (5.3)
Reasonable possibility	6 (5.4)	3 (3.2)	9 (4.4)
深部静脈血栓症	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
血腫	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
出血	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
高血圧	1 (0.9)	2 (2.1)	3 (1.5)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
Reasonable possibility	0	1 (1.1)	1 (0.5)

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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
血管障害 (Cont.)			
高血圧クリーゼ	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
低血圧	2 (1.8)	2 (2.1)	4 (1.9)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	2 (1.8)	1 (1.1)	3 (1.5)
起立性高血圧	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
起立性低血圧	7 (6.3)	3 (3.2)	10 (4.9)
No reasonable possibility	3 (2.7)	1 (1.1)	4 (1.9)
Reasonable possibility	4 (3.6)	2 (2.1)	6 (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]

表37　死亡した被験者一覧：M15-741試験

[redacted]20[redacted] 10:57 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - 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: 7[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg								
	FU	57 TO 63	119		R: MULTIPLE ORGAN FAILURE S: 一般・全身障害および投与部位の状態 P: 多臓器機能不全症候群 L: Multiple organ failure	E: 119 L: 1 Day	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: NONE	S: Yes, Death of subject R: UNLIKELY O: GENERAL IMPAIRMENT, PROGRESS IN PARKINSON'S DISEASE 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	Epoch Name	Epoch Interval	Rx Day of Onset	Reported Term / System Organ Class / MedDRA 24.0 Preferred Term / Lower Level Term	Rx Day Ended / Ongoing at the End of Study? / Length / Intermittent?	Severity / Relationship to ABBV-951 / Loading Dose Drug / Rescue Dose Drug / COVID-19 Infection / Action Taken with ABBV-951 / Action Taken with Rescue Dose Treatment / Other Actions Taken	Serious AE? / Relationship to Infusion Pump? / Other Cause of Event / 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 108	108	R: CARDIORESPIRATORY ARREST S: 心臓障害 P: 心肺停止 L: Cardio-respiratory arrest	E: 108 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: DETERIORATION OF THE GENERAL STATE OF HEALTH 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	Epoch 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: 6[redacted].[redacted] kg							
	FU	275 TO 37 Day	311	R: CAQUEXIA. S: 代謝および栄養障害 P: 悪液質 L: Cachexia	E: 322 L: 12 Days	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DRUG INTERRUPTED	S: Yes, Life threatening, Death of subject, Hospitalization or prolonged hospitalization, Other medically important serious event, Persistent or significant disability/incapacity R: NOT RELATED O: IT HAS BEEN IN THE CONTEXT OF URINARY INFECTION, 2 RESPIRATORY INFECTIONS AND PROLONGED BEDDING. 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	Epoch Name	Epoch Interval	Rx Day	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: 6[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg								
	TRT	1 TO 289	289	289	R: ACUTE LARGE RIGHT CEREBRAL SUBDURAL HEMATOMA S: 傷害、中毒および処置合併症 P: 硬膜下血腫 L: Acute subdural hematoma	E: 289 L: 1 Day	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DRUG WITHDRAWN	S: Yes, Life threatening, Death of subject R: NOT RELATED O: PATIENT DOES NOT HAVE GOOD MOBILITY DUE TO PARKINSON'S DISEASE AND GOT OUT OF BED WITHOUT ASSISTANCE 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	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: 6[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg									
	TRT	1 TO 289	289	289		R: CEREBRAL MARKED MASS EFFECT S: 神経系障害 P: 脳圧排効果 L: Cerebral mass effect	E: 289 L: 1 Day	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DRUG WITHDRAWN	S: Yes, Life threatening, Death of subject R: NOT RELATED O: PATIENT DOES NOT HAVE GOOD MOBILITY DUE TO PARKINSON'S DISEASE AND GOT OUT OF BED WITHOUT ASSISTANCE 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	Epoch Name	Epoch Interval	Rx Day	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: 6[redacted] Sex: Male Race: WHITE Weight: 10[redacted].[redacted] kg								
[redacted]	TRT	1 TO 117	117	117	R: CEREBRAL VASCULAR ACCIDENT S: 神経系障害 P: 脳血管発作 L: Cerebrovascular accident	E: 117 L: 1 Day	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DRUG WITHDRAWN O: NONE	S: Yes, Life threatening, Death of subject, Other medically important serious event, Persistent or significant disability/incapacity R: NOT RELATED O: MEDICAL HISTORY OF: CAD, INFERIOR MI [redacted]/[redacted]/20[redacted], INFRARENAL ABDOMINAL AORTIC ANEURYSM, BILATERAL LOWER LOBE CAP, EMPHYSEMA/COPD A: NO REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

表38　重篤な有害事象（安全性解析対象集団）：M15-741試験

[redacted]20[redacted] 10:56 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - CLINICAL/STATISTICAL

TABLE 14.3 1.11.1

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period	N=132	N=112	N=244
Any adverse event	33 (25.0)	30 (26.8)	63 (25.8)
心臓障害	1 (0.8)	2 (1.8)	3 (1.2)
急性心筋梗塞	1 (0.8)	0	1 (0.4)
心房細動	0	1 (0.9)	1 (0.4)
心停止	1 (0.8)	0	1 (0.4)
心肺停止	0	1 (0.9)	1 (0.4)
冠動脈疾患	1 (0.8)	1 (0.9)	2 (0.8)
眼障害	0	1 (0.9)	1 (0.4)
眼窩周囲痛	0	1 (0.9)	1 (0.4)
眼窩周囲腫脹	0	1 (0.9)	1 (0.4)
胃腸障害	1 (0.8)	0	1 (0.4)
虚血性大腸炎	1 (0.8)	0	1 (0.4)
腸出血	1 (0.8)	0	1 (0.4)

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__1.11.1

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態	3 (2.3)	3 (2.7)	6 (2.5)
無力症	1 (0.8)	0	1 (0.4)
胸部不快感	0	1 (0.9)	1 (0.4)
胸痛	1 (0.8)	0	1 (0.4)
低体温	1 (0.8)	0	1 (0.4)
注入部位血腫	0	1 (0.9)	1 (0.4)
注入部位損傷	0	1 (0.9)	1 (0.4)
感染症および寄生虫症	11 (8.3)	13 (11.6)	24 (9.8)
四肢膿瘍	0	1 (0.9)	1 (0.4)
COVID-19	1 (0.8)	0	1 (0.4)
蜂巣炎	0	1 (0.9)	1 (0.4)
注入部位膿瘍	5 (3.8)	3 (2.7)	8 (3.3)
注入部位蜂巣炎	4 (3.0)	6 (5.4)	10 (4.1)
注入部位感染	0	1 (0.9)	1 (0.4)
耳下腺膿瘍	0	1 (0.9)	1 (0.4)
肺炎	2 (1.5)	1 (0.9)	3 (1.2)
敗血症	3 (2.3)	0	3 (1.2)
敗血症性ショック	1 (0.8)	0	1 (0.4)
尿路感染	2 (1.5)	2 (1.8)	4 (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__1.11.1

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
傷害、中毒および処置合併症	1 (0.8)	2 (1.8)	3 (1.2)
顔面損傷	0	1 (0.9)	1 (0.4)
転倒	1 (0.8)	1 (0.9)	2 (0.8)
硬膜下血腫	0	1 (0.9)	1 (0.4)
臨床検査	1 (0.8)	0	1 (0.4)
血中ナトリウム減少	1 (0.8)	0	1 (0.4)
代謝および栄養障害	2 (1.5)	1 (0.9)	3 (1.2)
脱水	1 (0.8)	0	1 (0.4)
低カリウム血症	0	1 (0.9)	1 (0.4)
低ナトリウム血症	1 (0.8)	0	1 (0.4)
筋骨格系および結合組織障害	3 (2.3)	1 (0.9)	4 (1.6)
反応性関節炎	1 (0.8)	0	1 (0.4)
変形性関節症	0	1 (0.9)	1 (0.4)
横紋筋融解症	1 (0.8)	0	1 (0.4)
仙腸関節機能障害	1 (0.8)	0	1 (0.4)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	1 (0.8)	0	1 (0.4)
直腸腺癌	1 (0.8)	0	1 (0.4)

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__1.11.1

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
神経系障害	9 (6.8)	12 (10.7)	21 (8.6)
脳圧排効果	0	1 (0.9)	1 (0.4)
脳血管発作	0	1 (0.9)	1 (0.4)
認知障害	1 (0.8)	1 (0.9)	2 (0.8)
浮動性めまい	1 (0.8)	0	1 (0.4)
構語障害	0	1 (0.9)	1 (0.4)
ジストニア	0	2 (1.8)	2 (0.8)
全身性強直性間代性発作	0	1 (0.9)	1 (0.4)
片側感覚消失	0	1 (0.9)	1 (0.4)
不全片麻痺	0	1 (0.9)	1 (0.4)
意識消失	1 (0.8)	1 (0.9)	2 (0.8)
腰仙部神経根障害	0	1 (0.9)	1 (0.4)
オンオフ現象	1 (0.8)	0	1 (0.4)
錯感覚	0	1 (0.9)	1 (0.4)
パーキンソン病	5 (3.8)	1 (0.9)	6 (2.5)
パーキンソニズム	0	1 (0.9)	1 (0.4)
心因性発作	0	1 (0.9)	1 (0.4)
精神障害	12 (9.1)	6 (5.4)	18 (7.4)
不安	1 (0.8)	0	1 (0.4)
錯乱状態	0	1 (0.9)	1 (0.4)
譫妄	1 (0.8)	1 (0.9)	2 (0.8)
妄想	1 (0.8)	1 (0.9)	2 (0.8)

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__1.11.1

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
精神障害 (Cont.)			
妄想性障害、詳細不明	0	1 (0.9)	1 (0.4)
ドーパミン調節障害症候群	1 (0.8)	0	1 (0.4)
幻覚	6 (4.5)	1 (0.9)	7 (2.9)
精神病性障害	4 (3.0)	2 (1.8)	6 (2.5)
自殺企図	1 (0.8)	0	1 (0.4)
呼吸器、胸郭および縦隔障害	1 (0.8)	3 (2.7)	4 (1.6)
気管支拡張症	1 (0.8)	0	1 (0.4)
呼吸困難	0	1 (0.9)	1 (0.4)
過換気	0	1 (0.9)	1 (0.4)
肺塞栓症	0	1 (0.9)	1 (0.4)
血管障害	1 (0.8)	2 (1.8)	3 (1.2)
血腫	0	1 (0.9)	1 (0.4)
出血	0	1 (0.9)	1 (0.4)
起立性低血圧	1 (0.8)	0	1 (0.4)

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__1.11.1

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period	N=132	N=112	N=244
Any adverse event	11 (8.3)	6 (5.4)	17 (7.0)
一般・全身障害および投与部位の状態	1 (0.8)	0	1 (0.4)
低体温	1 (0.8)	0	1 (0.4)
感染症および寄生虫症	3 (2.3)	3 (2.7)	6 (2.5)
注入部位膿瘍	1 (0.8)	1 (0.9)	2 (0.8)
注入部位蜂巣炎	0	2 (1.8)	2 (0.8)
肺炎	1 (0.8)	1 (0.9)	2 (0.8)
敗血症	1 (0.8)	0	1 (0.4)
敗血症性ショック	1 (0.8)	0	1 (0.4)
尿路感染	1 (0.8)	0	1 (0.4)
傷害、中毒および処置合併症	1 (0.8)	0	1 (0.4)
転倒	1 (0.8)	0	1 (0.4)
代謝および栄養障害	0	1 (0.9)	1 (0.4)
低カリウム血症	0	1 (0.9)	1 (0.4)

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__1.11.1

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
筋骨格系および結合組織障害	2 (1.5)	0	2 (0.8)
横紋筋融解症	1 (0.8)	0	1 (0.4)
仙腸関節機能障害	1 (0.8)	0	1 (0.4)
神経系障害	5 (3.8)	3 (2.7)	8 (3.3)
認知障害	1 (0.8)	0	1 (0.4)
浮動性めまい	1 (0.8)	0	1 (0.4)
構語障害	0	1 (0.9)	1 (0.4)
片側感覚消失	0	1 (0.9)	1 (0.4)
不全片麻痺	0	1 (0.9)	1 (0.4)
錯感覚	0	1 (0.9)	1 (0.4)
パーキンソン病	3 (2.3)	1 (0.9)	4 (1.6)
精神障害	6 (4.5)	1 (0.9)	7 (2.9)
錯乱状態	0	1 (0.9)	1 (0.4)
譫妄	1 (0.8)	1 (0.9)	2 (0.8)
妄想	1 (0.8)	0	1 (0.4)
幻覚	4 (3.0)	0	4 (1.6)
精神病性障害	2 (1.5)	0	2 (0.8)

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__1.11.1

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
呼吸器、胸郭および縦隔障害	0	1 (0.9)	1 (0.4)
過換気	0	1 (0.9)	1 (0.4)

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__1.11.1

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period	N=111	N=95	N=206
Any adverse event	23 (20.7)	26 (27.4)	49 (23.8)
心臓障害	1 (0.9)	2 (2.1)	3 (1.5)
急性心筋梗塞	1 (0.9)	0	1 (0.5)
心房細動	0	1 (1.1)	1 (0.5)
心停止	1 (0.9)	0	1 (0.5)
心肺停止	0	1 (1.1)	1 (0.5)
冠動脈疾患	1 (0.9)	1 (1.1)	2 (1.0)
眼障害	0	1 (1.1)	1 (0.5)
眼窩周囲痛	0	1 (1.1)	1 (0.5)
眼窩周囲腫脹	0	1 (1.1)	1 (0.5)
胃腸障害	1 (0.9)	0	1 (0.5)
虚血性大腸炎	1 (0.9)	0	1 (0.5)
腸出血	1 (0.9)	0	1 (0.5)

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__1.11.1

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
一般・全身障害および投与部位の状態	2 (1.8)	3 (3.2)	5 (2.4)
無力症	1 (0.9)	0	1 (0.5)
胸部不快感	0	1 (1.1)	1 (0.5)
胸痛	1 (0.9)	0	1 (0.5)
注入部位血腫	0	1 (1.1)	1 (0.5)
注入部位損傷	0	1 (1.1)	1 (0.5)
感染症および寄生虫症	8 (7.2)	11 (11.6)	19 (9.2)
四肢膿瘍	0	1 (1.1)	1 (0.5)
COVID-19	1 (0.9)	0	1 (0.5)
蜂巣炎	0	1 (1.1)	1 (0.5)
注入部位膿瘍	4 (3.6)	2 (2.1)	6 (2.9)
注入部位蜂巣炎	4 (3.6)	4 (4.2)	8 (3.9)
注入部位感染	0	1 (1.1)	1 (0.5)
耳下腺膿瘍	0	1 (1.1)	1 (0.5)
肺炎	1 (0.9)	1 (1.1)	2 (1.0)
敗血症	2 (1.8)	0	2 (1.0)
尿路感染	1 (0.9)	2 (2.1)	3 (1.5)
傷害、中毒および処置合併症	0	2 (2.1)	2 (1.0)
顔面損傷	0	1 (1.1)	1 (0.5)
転倒	0	1 (1.1)	1 (0.5)
硬膜下血腫	0	1 (1.1)	1 (0.5)

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__1.11.1

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
臨床検査	1 (0.9)	0	1 (0.5)
血中ナトリウム減少	1 (0.9)	0	1 (0.5)
代謝および栄養障害	2 (1.8)	0	2 (1.0)
脱水	1 (0.9)	0	1 (0.5)
低ナトリウム血症	1 (0.9)	0	1 (0.5)
筋骨格系および結合組織障害	1 (0.9)	1 (1.1)	2 (1.0)
反応性関節炎	1 (0.9)	0	1 (0.5)
変形性関節症	0	1 (1.1)	1 (0.5)
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）	1 (0.9)	0	1 (0.5)
直腸腺癌	1 (0.9)	0	1 (0.5)
神経系障害	4 (3.6)	9 (9.5)	13 (6.3)
脳圧排効果	0	1 (1.1)	1 (0.5)
脳血管発作	0	1 (1.1)	1 (0.5)
認知障害	0	1 (1.1)	1 (0.5)
ジストニア	0	2 (2.1)	2 (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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
神経系障害 (Cont.)			
全身性強直性間代性発作	0	1 (1.1)	1 (0.5)
意識消失	1 (0.9)	1 (1.1)	2 (1.0)
腰仙部神経根障害	0	1 (1.1)	1 (0.5)
オンオフ現象	1 (0.9)	0	1 (0.5)
パーキンソン病	2 (1.8)	0	2 (1.0)
パーキンソニズム	0	1 (1.1)	1 (0.5)
心因性発作	0	1 (1.1)	1 (0.5)
精神障害	7 (6.3)	5 (5.3)	12 (5.8)
不安	1 (0.9)	0	1 (0.5)
妄想	0	1 (1.1)	1 (0.5)
妄想性障害、詳細不明	0	1 (1.1)	1 (0.5)
ドーパミン調節障害症候群	1 (0.9)	0	1 (0.5)
幻覚	2 (1.8)	1 (1.1)	3 (1.5)
精神病性障害	2 (1.8)	2 (2.1)	4 (1.9)
自殺企図	1 (0.9)	0	1 (0.5)
呼吸器、胸郭および縦隔障害	1 (0.9)	2 (2.1)	3 (1.5)
気管支拡張症	1 (0.9)	0	1 (0.5)
呼吸困難	0	1 (1.1)	1 (0.5)
肺塞栓症	0	1 (1.1)	1 (0.5)

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__1.11.1

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
血管障害	1 (0.9)	2 (2.1)	3 (1.5)
血腫	0	1 (1.1)	1 (0.5)
出血	0	1 (1.1)	1 (0.5)
起立性低血圧	1 (0.9)	0	1 (0.5)

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

Program Source Code: [redacted]

表39　中止に至った有害事象（安全性解析対象集団）：M15-741試験

[redacted]20[redacted] 10:56 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - 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 by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period	N=132	N=112	N=244
Any adverse event	33 (25.0)	30 (26.8)	63 (25.8)
心臓障害	1 (0.8)	1 (0.9)	2 (0.8)
心肺停止	0	1 (0.9)	1 (0.4)
頻脈	1 (0.8)	0	1 (0.4)
胃腸障害	1 (0.8)	0	1 (0.4)
舌炎	1 (0.8)	0	1 (0.4)
舌痛	1 (0.8)	0	1 (0.4)
口の錯感覚	1 (0.8)	0	1 (0.4)
一般・全身障害および投与部位の状態	14 (10.6)	7 (6.3)	21 (8.6)
不快感	1 (0.8)	0	1 (0.4)
注入部位紅斑	6 (4.5)	3 (2.7)	9 (3.7)
注入部位血管外漏出	0	1 (0.9)	1 (0.4)
注入部位硬結	1 (0.8)	0	1 (0.4)

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__1.8.1

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
注入部位腫瘤	1 (0.8)	0	1 (0.4)
注入部位結節	2 (1.5)	3 (2.7)	5 (2.0)
注入部位浮腫	2 (1.5)	2 (1.8)	4 (1.6)
注入部位疼痛	1 (0.8)	0	1 (0.4)
注入部位丘疹	0	1 (0.9)	1 (0.4)
注入部位発疹	1 (0.8)	0	1 (0.4)
注入部位反応	2 (1.5)	1 (0.9)	3 (1.2)
注射部位炎症	1 (0.8)	0	1 (0.4)
注射部位疼痛	0	1 (0.9)	1 (0.4)
穿刺部位腫脹	0	1 (0.9)	1 (0.4)
感染症および寄生虫症	5 (3.8)	8 (7.1)	13 (5.3)
注入部位膿瘍	1 (0.8)	2 (1.8)	3 (1.2)
注入部位蜂巣炎	4 (3.0)	5 (4.5)	9 (3.7)
注入部位感染	0	1 (0.9)	1 (0.4)
尿路感染	0	1 (0.9)	1 (0.4)
傷害、中毒および処置合併症	1 (0.8)	1 (0.9)	2 (0.8)
注入に伴う反応	1 (0.8)	0	1 (0.4)
硬膜下血腫	0	1 (0.9)	1 (0.4)

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__1.8.1

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
臨床検査	0	1 (0.9)	1 (0.4)
リンパ球数減少	0	1 (0.9)	1 (0.4)
単球数増加	0	1 (0.9)	1 (0.4)
好中球数増加	0	1 (0.9)	1 (0.4)
白血球数増加	0	1 (0.9)	1 (0.4)
代謝および栄養障害	0	1 (0.9)	1 (0.4)
低カリウム血症	0	1 (0.9)	1 (0.4)
筋骨格系および結合組織障害	2 (1.5)	0	2 (0.8)
筋力低下	1 (0.8)	0	1 (0.4)
横紋筋融解症	1 (0.8)	0	1 (0.4)
神経系障害	10 (7.6)	8 (7.1)	18 (7.4)
運動緩慢	1 (0.8)	0	1 (0.4)
脳圧排効果	0	1 (0.9)	1 (0.4)
脳血管発作	0	1 (0.9)	1 (0.4)
認知障害	0	1 (0.9)	1 (0.4)
ジスキネジア	5 (3.8)	0	5 (2.0)
すくみ現象	2 (1.5)	0	2 (0.8)
代謝性脳症	0	1 (0.9)	1 (0.4)
オンオフ現象	2 (1.5)	1 (0.9)	3 (1.2)
パーキンソン病	2 (1.5)	1 (0.9)	3 (1.2)
パーキンソニズム	0	2 (1.8)	2 (0.8)

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__1.8.1

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
精神障害	7 (5.3)	8 (7.1)	15 (6.1)
感情不安定	1 (0.8)	0	1 (0.4)
不安	1 (0.8)	1 (0.9)	2 (0.8)
錯乱状態	0	2 (1.8)	2 (0.8)
妄想	1 (0.8)	0	1 (0.4)
寄生虫妄想	1 (0.8)	0	1 (0.4)
注射恐怖	0	1 (0.9)	1 (0.4)
幻覚	5 (3.8)	5 (4.5)	10 (4.1)
幻視	2 (1.5)	0	2 (0.8)
処置に対する不安	0	1 (0.9)	1 (0.4)
精神病性障害	1 (0.8)	1 (0.9)	2 (0.8)
生殖系および乳房障害	0	1 (0.9)	1 (0.4)
勃起不全	0	1 (0.9)	1 (0.4)
呼吸器、胸郭および縦隔障害	1 (0.8)	1 (0.9)	2 (0.8)
過換気	0	1 (0.9)	1 (0.4)
呼吸窮迫	1 (0.8)	0	1 (0.4)

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__1.8.1

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
皮膚および皮下組織障害	1 (0.8)	0	1 (0.4)
蕁麻疹	1 (0.8)	0	1 (0.4)

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__1.8.1

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period	N=132	N=112	N=244
Any adverse event	17 (12.9)	10 (8.9)	27 (11.1)
一般・全身障害および投与部位の状態	8 (6.1)	2 (1.8)	10 (4.1)
不快感	1 (0.8)	0	1 (0.4)
注入部位紅斑	2 (1.5)	0	2 (0.8)
注入部位血管外漏出	0	1 (0.9)	1 (0.4)
注入部位腫瘤	1 (0.8)	0	1 (0.4)
注入部位結節	1 (0.8)	0	1 (0.4)
注入部位浮腫	1 (0.8)	0	1 (0.4)
注入部位発疹	1 (0.8)	0	1 (0.4)
注入部位反応	2 (1.5)	0	2 (0.8)
穿刺部位腫脹	0	1 (0.9)	1 (0.4)
感染症および寄生虫症	3 (2.3)	3 (2.7)	6 (2.5)
注入部位膿瘍	0	1 (0.9)	1 (0.4)
注入部位蜂巣炎	3 (2.3)	3 (2.7)	6 (2.5)
傷害、中毒および処置合併症	1 (0.8)	0	1 (0.4)
注入に伴う反応	1 (0.8)	0	1 (0.4)

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__1.8.1

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
臨床検査	0	1 (0.9)	1 (0.4)
リンパ球数減少	0	1 (0.9)	1 (0.4)
単球数増加	0	1 (0.9)	1 (0.4)
好中球数増加	0	1 (0.9)	1 (0.4)
白血球数増加	0	1 (0.9)	1 (0.4)
代謝および栄養障害	0	1 (0.9)	1 (0.4)
低カリウム血症	0	1 (0.9)	1 (0.4)
筋骨格系および結合組織障害	2 (1.5)	0	2 (0.8)
筋力低下	1 (0.8)	0	1 (0.4)
横紋筋融解症	1 (0.8)	0	1 (0.4)
神経系障害	7 (5.3)	4 (3.6)	11 (4.5)
運動緩慢	1 (0.8)	0	1 (0.4)
ジスキネジア	3 (2.3)	0	3 (1.2)
すくみ現象	2 (1.5)	0	2 (0.8)
代謝性脳症	0	1 (0.9)	1 (0.4)
オンオフ現象	1 (0.8)	1 (0.9)	2 (0.8)
パーキンソン病	2 (1.5)	1 (0.9)	3 (1.2)
パーキンソニズム	0	1 (0.9)	1 (0.4)

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__1.8.1

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
精神障害	3 (2.3)	2 (1.8)	5 (2.0)
感情不安定	1 (0.8)	0	1 (0.4)
不安	1 (0.8)	1 (0.9)	2 (0.8)
錯乱状態	0	1 (0.9)	1 (0.4)
幻覚	3 (2.3)	1 (0.9)	4 (1.6)
生殖系および乳房障害	0	1 (0.9)	1 (0.4)
勃起不全	0	1 (0.9)	1 (0.4)
呼吸器、胸郭および縦隔障害	0	1 (0.9)	1 (0.4)
過換気	0	1 (0.9)	1 (0.4)

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__1.8.1

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period	N=111	N=95	N=206
Any adverse event	17 (15.3)	20 (21.1)	37 (18.0)
心臓障害	1 (0.9)	1 (1.1)	2 (1.0)
心肺停止	0	1 (1.1)	1 (0.5)
頻脈	1 (0.9)	0	1 (0.5)
胃腸障害	1 (0.9)	0	1 (0.5)
舌炎	1 (0.9)	0	1 (0.5)
舌痛	1 (0.9)	0	1 (0.5)
口の錯感覚	1 (0.9)	0	1 (0.5)
一般・全身障害および投与部位の状態	6 (5.4)	5 (5.3)	11 (5.3)
注入部位紅斑	4 (3.6)	3 (3.2)	7 (3.4)
注入部位硬結	1 (0.9)	0	1 (0.5)
注入部位結節	1 (0.9)	3 (3.2)	4 (1.9)
注入部位浮腫	1 (0.9)	2 (2.1)	3 (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__1.8.1

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
一般・全身障害および投与部位の状態 (Cont.)			
注入部位疼痛	1 (0.9)	0	1 (0.5)
注入部位丘疹	0	1 (1.1)	1 (0.5)
注入部位反応	0	1 (1.1)	1 (0.5)
注射部位炎症	1 (0.9)	0	1 (0.5)
注射部位疼痛	0	1 (1.1)	1 (0.5)
感染症および寄生虫症	2 (1.8)	5 (5.3)	7 (3.4)
注入部位膿瘍	1 (0.9)	1 (1.1)	2 (1.0)
注入部位蜂巣炎	1 (0.9)	2 (2.1)	3 (1.5)
注入部位感染	0	1 (1.1)	1 (0.5)
尿路感染	0	1 (1.1)	1 (0.5)
傷害、中毒および処置合併症	0	1 (1.1)	1 (0.5)
硬膜下血腫	0	1 (1.1)	1 (0.5)
神経系障害	3 (2.7)	4 (4.2)	7 (3.4)
脳圧排効果	0	1 (1.1)	1 (0.5)
脳血管発作	0	1 (1.1)	1 (0.5)
認知障害	0	1 (1.1)	1 (0.5)
ジスキネジア	2 (1.8)	0	2 (1.0)
オンオフ現象	1 (0.9)	0	1 (0.5)
パーキンソニズム	0	1 (1.1)	1 (0.5)

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__1.8.1

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
精神障害	4 (3.6)	6 (6.3)	10 (4.9)
錯乱状態	0	1 (1.1)	1 (0.5)
妄想	1 (0.9)	0	1 (0.5)
寄生虫妄想	1 (0.9)	0	1 (0.5)
注射恐怖	0	1 (1.1)	1 (0.5)
幻覚	2 (1.8)	4 (4.2)	6 (2.9)
幻視	2 (1.8)	0	2 (1.0)
処置に対する不安	0	1 (1.1)	1 (0.5)
精神病性障害	1 (0.9)	1 (1.1)	2 (1.0)
呼吸器、胸郭および縦隔障害	1 (0.9)	0	1 (0.5)
呼吸窮迫	1 (0.9)	0	1 (0.5)
皮膚および皮下組織障害	1 (0.9)	0	1 (0.5)
蕁麻疹	1 (0.9)	0	1 (0.5)

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

Program Source Code: [redacted]

表40　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）：M15-741試験

[redacted]20[redacted] 10:56 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - CLINICAL/STATISTICAL

TABLE 14.3 1.16.1

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
Any adverse event	225/244 (92.2)	3/13 (23.1)	1/8 (12.5)	1/7 (14.3)
血液およびリンパ系障害	2/244 (0.8)	1/183 (0.5)	0/158	1/137 (0.7)
大球性貧血	0/244	0/184	0/160	1/139 (0.7)
凝血異常	1/244 (0.4)	0/184	0/160	0/139
リンパ節症	1/244 (0.4)	0/183	0/159	0/138
縦隔リンパ節腫脹	0/244	1/184 (0.5)	0/159	0/138
心臓障害	5/244 (2.0)	3/181 (1.7)	3/156 (1.9)	2/133 (1.5)
急性心筋梗塞	0/244	0/184	0/160	1/139 (0.7)
狭心症	0/244	1/184 (0.5)	0/159	0/138
心房細動	0/244	0/184	2/160 (1.3)	0/137
徐脈	1/244 (0.4)	0/183	0/159	0/138
心停止	0/244	0/184	0/160	1/139 (0.7)
心肺停止	0/244	1/184 (0.5)	0/160	0/139
冠動脈疾患	0/244	0/184	1/160 (0.6)	1/138 (0.7)
冠動脈狭窄	0/244	0/184	0/160	1/139 (0.7)
期外収縮	1/244 (0.4)	0/183	0/159	0/138
左室肥大	1/244 (0.4)	0/184	0/160	0/139
心筋梗塞	1/244 (0.4)	0/183	0/160	0/139
動悸	1/244 (0.4)	0/184	1/160 (0.6)	0/138
頻脈	0/244	1/184 (0.5)	0/159	0/139

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
Any adverse event	0/6	0/0	0/0	230/244 (94.3)
血液およびリンパ系障害	0/120	0/2	0/0	4/244 (1.6)
大球性貧血	0/122	0/2	0/0	1/244 (0.4)
凝血異常	0/123	0/2	0/0	1/244 (0.4)
リンパ節症	0/122	0/2	0/0	1/244 (0.4)
縦隔リンパ節腫脹	0/122	0/2	0/0	1/244 (0.4)
心臓障害	0/116	0/2	0/0	13/244 (5.3)
急性心筋梗塞	0/122	0/2	0/0	1/244 (0.4)
狭心症	0/122	0/2	0/0	1/244 (0.4)
心房細動	0/122	0/2	0/0	2/244 (0.8)
徐脈	0/122	0/2	0/0	1/244 (0.4)
心停止	0/122	0/2	0/0	1/244 (0.4)
心肺停止	0/123	0/2	0/0	1/244 (0.4)
冠動脈疾患	0/121	0/2	0/0	2/244 (0.8)
冠動脈狭窄	0/122	0/2	0/0	1/244 (0.4)
期外収縮	0/122	0/2	0/0	1/244 (0.4)
左室肥大	0/123	0/2	0/0	1/244 (0.4)
心筋梗塞	0/123	0/2	0/0	1/244 (0.4)
動悸	0/122	0/2	0/0	2/244 (0.8)
頻脈	0/123	0/2	0/0	1/244 (0.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
耳および迷路障害	6/244 (2.5)	1/179 (0.6)	1/155 (0.6)	0/134
感音性難聴	0/244	0/184	1/160 (0.6)	0/138
乗物酔い	1/244 (0.4)	0/183	0/159	0/138
回転性めまい	4/244 (1.6)	1/181 (0.6)	0/157	0/137
頭位性回転性めまい	1/244 (0.4)	0/183	0/159	0/138
眼障害	6/244 (2.5)	6/180 (3.3)	2/150 (1.3)	2/130 (1.5)
白内障	1/244 (0.4)	0/183	2/159 (1.3)	1/136 (0.7)
複視	4/244 (1.6)	0/182	0/158	0/137
ドライアイ	2/244 (0.8)	1/183 (0.5)	1/158 (0.6)	0/137
緑内障	0/244	1/184 (0.5)	0/159	1/138 (0.7)
眼窩周囲痛	0/244	1/184 (0.5)	0/159	0/138
眼窩周囲腫脹	1/244 (0.4)	1/183 (0.5)	0/158	0/138
網膜裂孔	0/244	2/184 (1.1)	0/158	0/137
霧視	1/244 (0.4)	0/184	0/160	0/139
視野欠損	0/244	1/184 (0.5)	0/159	0/139
胃腸障害	41/244 (16.8)	8/152 (5.3)	5/125 (4.0)	2/105 (1.9)
腹部膨満	3/244 (1.2)	1/181 (0.6)	0/156	0/137
腹痛	1/244 (0.4)	1/184 (0.5)	0/159	1/139 (0.7)
上腹部痛	1/244 (0.4)	1/184 (0.5)	0/159	0/138
アフタ性潰瘍	1/244 (0.4)	0/183	0/159	0/138
呼気臭	3/244 (1.2)	0/181	0/158	0/137
虚血性大腸炎	0/244	1/184 (0.5)	0/159	0/138

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
耳および迷路障害	0/119	0/2	0/0	8/244 (3.3)
感音性難聴	0/122	0/2	0/0	1/244 (0.4)
乗物酔い	0/122	0/2	0/0	1/244 (0.4)
回転性めまい	0/121	0/2	0/0	5/244 (2.0)
頭位性回転性めまい	0/123	0/2	0/0	1/244 (0.4)
眼障害	0/113	0/2	0/0	16/244 (6.6)
白内障	0/119	0/2	0/0	4/244 (1.6)
複視	0/122	0/2	0/0	4/244 (1.6)
ドライアイ	0/121	0/2	0/0	4/244 (1.6)
緑内障	0/121	0/2	0/0	2/244 (0.8)
眼窩周囲痛	0/122	0/2	0/0	1/244 (0.4)
眼窩周囲腫脹	0/122	0/2	0/0	2/244 (0.8)
網膜裂孔	0/121	0/2	0/0	2/244 (0.8)
霧視	0/123	0/2	0/0	1/244 (0.4)
視野欠損	0/123	0/2	0/0	1/244 (0.4)
胃腸障害	0/93	0/2	0/0	56/244 (23.0)
腹部膨満	0/121	0/2	0/0	4/244 (1.6)
腹痛	0/122	0/2	0/0	3/244 (1.2)
上腹部痛	0/123	0/2	0/0	2/244 (0.8)
アフタ性潰瘍	0/122	0/2	0/0	1/244 (0.4)
呼気臭	0/121	0/2	0/0	3/244 (1.2)
虚血性大腸炎	0/123	0/2	0/0	1/244 (0.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
胃腸障害 (Cont.)				
便秘	11/244 (4.5)	6/177 (3.4)	2/149 (1.3)	1/128 (0.8)
齲歯	0/244	0/184	1/160 (0.6)	0/139
下痢	5/244 (2.0)	2/180 (1.1)	2/154 (1.3)	0/134
口内乾燥	8/244 (3.3)	0/176	0/154	0/134
消化不良	1/244 (0.4)	0/183	0/159	0/138
嚥下障害	1/244 (0.4)	0/183	0/159	0/138
糞塊	1/244 (0.4)	0/184	0/160	0/139
排便回数増加	0/244	1/184 (0.5)	0/159	0/138
胃食道逆流性疾患	1/244 (0.4)	0/183	1/159 (0.6)	0/137
舌炎	0/244	1/184 (0.5)	0/159	0/139
舌痛	0/244	1/184 (0.5)	0/159	0/139
吐血	0/244	0/184	0/160	1/139 (0.7)
痔核	1/244 (0.4)	0/184	0/160	0/139
裂孔ヘルニア	0/244	0/184	0/160	1/139 (0.7)
胃排出不全	0/244	0/184	0/160	1/139 (0.7)
鼠径ヘルニア	0/244	1/184 (0.5)	0/159	0/138
腸出血	0/244	1/184 (0.5)	0/159	0/138
過敏性腸症候群	2/244 (0.8)	0/182	0/158	0/137
大腸ポリープ	0/244	0/184	0/160	1/139 (0.7)
口唇乾燥	0/244	1/184 (0.5)	0/159	0/138
メレナ	1/244 (0.4)	1/183 (0.5)	0/158	0/138
口腔腫脹	0/244	1/184 (0.5)	0/159	0/139
悪心	13/244 (5.3)	3/176 (1.7)	2/150 (1.3)	1/129 (0.8)

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
胃腸障害 (Cont.)				
便秘	0/113	0/2	0/0	20/244 (8.2)
齲歯	0/123	0/2	0/0	1/244 (0.4)
下痢	0/119	0/2	0/0	9/244 (3.7)
口内乾燥	0/119	0/2	0/0	8/244 (3.3)
消化不良	0/122	0/2	0/0	1/244 (0.4)
嚥下障害	0/123	0/2	0/0	1/244 (0.4)
糞塊	0/123	0/2	0/0	1/244 (0.4)
排便回数増加	0/123	0/2	0/0	1/244 (0.4)
胃食道逆流性疾患	0/121	0/2	0/0	2/244 (0.8)
舌炎	0/123	0/2	0/0	1/244 (0.4)
舌痛	0/123	0/2	0/0	1/244 (0.4)
吐血	0/122	0/2	0/0	1/244 (0.4)
痔核	0/123	0/2	0/0	1/244 (0.4)
裂孔ヘルニア	0/122	0/2	0/0	1/244 (0.4)
胃排出不全	0/122	0/2	0/0	1/244 (0.4)
鼠径ヘルニア	0/123	0/2	0/0	1/244 (0.4)
腸出血	0/123	0/2	0/0	1/244 (0.4)
過敏性腸症候群	0/121	0/2	0/0	2/244 (0.8)
大腸ポリープ	0/122	0/2	0/0	1/244 (0.4)
口唇乾燥	0/122	0/2	0/0	1/244 (0.4)
メレナ	0/122	0/2	0/0	2/244 (0.8)
口腔腫脹	0/123	0/2	0/0	1/244 (0.4)
悪心	0/112	0/2	0/0	19/244 (7.8)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
胃腸障害 (Cont.)				
口腔内不快感	0/244	1/184 (0.5)	0/159	0/139
口腔内痛	0/244	0/184	1/160 (0.6)	0/139
口の錯感覚	1/244 (0.4)	0/183	1/159 (0.6)	0/138
直腸出血	0/244	0/184	1/160 (0.6)	0/138
歯痛	1/244 (0.4)	0/183	0/159	0/138
嘔吐	4/244 (1.6)	1/182 (0.5)	1/157 (0.6)	0/135
一般・全身障害および投与部位の状態	195/244 (79.9)	3/34 (8.8)	5/26 (19.2)	0/18
投与部位内出血	0/244	0/184	0/160	1/139 (0.7)
投与部位紅斑	1/244 (0.4)	0/184	0/160	0/139
投与部位漏出	1/244 (0.4)	0/183	0/159	0/138
無力症	1/244 (0.4)	1/184 (0.5)	1/159 (0.6)	0/137
カテーテル留置部位紅斑	2/244 (0.8)	0/182	0/158	0/138
カテーテル留置部位漏出	0/244	0/184	1/160 (0.6)	0/138
カテーテル留置部位出血	1/244 (0.4)	0/183	0/159	0/138
カテーテル留置部位炎症	1/244 (0.4)	0/183	0/159	0/139
カテーテル留置部位刺激感	1/244 (0.4)	0/183	0/159	0/138
カテーテル留置部位浮腫	1/244 (0.4)	0/183	0/159	0/139
カテーテル留置部位疼痛	2/244 (0.8)	0/182	0/158	0/138
胸部不快感	0/244	1/184 (0.5)	0/159	0/138
胸痛	1/244 (0.4)	0/183	0/159	1/138 (0.7)
泣き	0/244	1/184 (0.5)	0/159	0/139

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
胃腸障害 (Cont.)				
口腔内不快感	0/123	0/2	0/0	1/244 (0.4)
口腔内痛	0/123	0/2	0/0	1/244 (0.4)
口の錯感覚	0/122	0/2	0/0	2/244 (0.8)
直腸出血	0/123	0/2	0/0	1/244 (0.4)
歯痛	0/122	0/2	0/0	1/244 (0.4)
嘔吐	0/120	0/2	0/0	6/244 (2.5)
一般・全身障害および投与部位の状態	0/16	0/1	0/0	203/244 (83.2)
投与部位内出血	0/122	0/2	0/0	1/244 (0.4)
投与部位紅斑	0/123	0/2	0/0	1/244 (0.4)
投与部位漏出	0/122	0/2	0/0	1/244 (0.4)
無力症	0/121	0/2	0/0	3/244 (1.2)
カテーテル留置部位紅斑	0/122	0/2	0/0	2/244 (0.8)
カテーテル留置部位漏出	0/122	0/2	0/0	1/244 (0.4)
カテーテル留置部位出血	0/122	0/2	0/0	1/244 (0.4)
カテーテル留置部位炎症	0/123	0/2	0/0	1/244 (0.4)
カテーテル留置部位刺激感	0/122	0/2	0/0	1/244 (0.4)
カテーテル留置部位浮腫	0/123	0/2	0/0	1/244 (0.4)
カテーテル留置部位疼痛	0/122	0/2	0/0	2/244 (0.8)
胸部不快感	0/122	0/2	0/0	1/244 (0.4)
胸痛	0/121	0/2	0/0	2/244 (0.8)
泣き	0/123	0/2	0/0	1/244 (0.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態 (Cont.)				
不快感	1/244 (0.4)	0/184	0/160	0/139
薬効欠如	0/244	1/184 (0.5)	0/159	0/138
薬剤離脱症候群	2/244 (0.8)	0/183	0/159	0/138
疲労	7/244 (2.9)	0/179	1/155 (0.6)	1/135 (0.7)
異常感	2/244 (0.8)	0/182	0/160	0/139
冷感	0/244	0/184	1/160 (0.6)	0/138
熱感	1/244 (0.4)	0/184	0/160	0/139
歩行障害	1/244 (0.4)	1/184 (0.5)	0/159	0/139
歩行不能	1/244 (0.4)	0/183	0/160	0/139
低体温	1/244 (0.4)	0/183	0/159	1/138 (0.7)
インフルエンザ様疾患	3/244 (1.2)	0/181	0/157	0/136
注入部位内出血	14/244 (5.7)	2/171 (1.2)	2/148 (1.4)	0/126
注入部位皮膚炎	1/244 (0.4)	1/183 (0.5)	0/158	2/138 (1.4)
注入部位分泌物	2/244 (0.8)	0/182	0/158	0/137
注入部位変色	2/244 (0.8)	0/182	0/158	0/137
注入部位不快感	3/244 (1.2)	1/181 (0.6)	0/156	0/136
注入部位びらん	2/244 (0.8)	0/182	0/159	0/138
注入部位紅斑	113/244 (46.3)	4/92 (4.3)	5/81 (6.2)	3/67 (4.5)
注入部位皮膚剥脱	3/244 (1.2)	0/182	1/159 (0.6)	2/137 (1.5)
注入部位血管外漏出	17/244 (7.0)	1/172 (0.6)	1/149 (0.7)	1/129 (0.8)
注入部位血腫	12/244 (4.9)	2/174 (1.1)	2/150 (1.3)	2/129 (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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態 (Cont.)				
不快感	0/123	0/2	0/0	1/244 (0.4)
薬効欠如	0/122	0/2	0/0	1/244 (0.4)
薬剤離脱症候群	0/122	0/2	0/0	2/244 (0.8)
疲労	0/119	0/2	0/0	9/244 (3.7)
異常感	0/123	0/2	0/0	2/244 (0.8)
冷感	0/122	0/2	0/0	1/244 (0.4)
熱感	0/123	0/2	0/0	1/244 (0.4)
歩行障害	0/123	0/2	0/0	2/244 (0.8)
歩行不能	0/123	0/2	0/0	1/244 (0.4)
低体温	0/121	0/2	0/0	2/244 (0.8)
インフルエンザ様疾患	0/120	0/2	0/0	3/244 (1.2)
注入部位内出血	0/110	0/1	0/0	18/244 (7.4)
注入部位皮膚炎	0/120	0/2	0/0	4/244 (1.6)
注入部位分泌物	0/121	0/2	0/0	2/244 (0.8)
注入部位変色	0/121	0/2	0/0	2/244 (0.8)
注入部位不快感	0/120	0/2	0/0	4/244 (1.6)
注入部位びらん	0/122	0/2	0/0	2/244 (0.8)
注入部位紅斑	1/57 (1.8)	0/2	0/0	126/244 (51.6)
注入部位皮膚剥脱	0/119	0/2	0/0	6/244 (2.5)
注入部位血管外漏出	0/114	0/2	0/0	20/244 (8.2)
注入部位血腫	0/113	0/2	0/0	18/244 (7.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態 (Cont.)				
注入部位出血	6/244 (2.5)	2/179 (1.1)	0/153	1/133 (0.8)
注入部位硬結	8/244 (3.3)	0/179	1/158 (0.6)	1/136 (0.7)
注入部位炎症	5/244 (2.0)	0/179	1/156 (0.6)	1/137 (0.7)
注入部位損傷	1/244 (0.4)	0/183	1/160 (0.6)	0/138
注入部位刺激感	3/244 (1.2)	1/181 (0.6)	1/156 (0.6)	0/135
注入部位腫瘤	8/244 (3.3)	0/178	0/155	0/136
注入部位壊死	1/244 (0.4)	0/183	0/159	0/139
注入部位結節	54/244 (22.1)	9/132 (6.8)	3/104 (2.9)	2/85 (2.4)
注入部位浮腫	36/244 (14.8)	5/161 (3.1)	2/134 (1.5)	3/116 (2.6)
注入部位疼痛	32/244 (13.1)	4/158 (2.5)	1/134 (0.7)	1/116 (0.9)
注入部位蒼白	4/244 (1.6)	1/181 (0.6)	0/157	0/136
注入部位丘疹	8/244 (3.3)	4/179 (2.2)	2/152 (1.3)	1/131 (0.8)
注入部位異常感覚	2/244 (0.8)	0/182	0/158	0/137
注入部位そう痒感	4/244 (1.6)	2/181 (1.1)	1/155 (0.6)	0/135
注入部位発疹	5/244 (2.0)	2/180 (1.1)	0/154	0/134
注入部位反応	22/244 (9.0)	4/170 (2.4)	2/146 (1.4)	2/126 (1.6)
注入部位痂皮	0/244	1/184 (0.5)	0/159	0/138
注入部位腫脹	6/244 (2.5)	0/179	0/157	0/137
注入部位小水疱	2/244 (0.8)	0/182	0/159	0/138
注入部位熱感	1/244 (0.4)	0/183	0/159	0/138
注射部位内出血	2/244 (0.8)	1/183 (0.5)	0/158	0/137

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態 (Cont.)				
注入部位出血	0/118	0/2	0/0	9/244 (3.7)
注入部位硬結	0/119	0/2	0/0	10/244 (4.1)
注入部位炎症	2/121 (1.7)	0/2	0/0	9/244 (3.7)
注入部位損傷	0/122	0/2	0/0	2/244 (0.8)
注入部位刺激感	0/120	0/2	0/0	5/244 (2.0)
注入部位腫瘤	0/120	0/2	0/0	8/244 (3.3)
注入部位壊死	0/123	0/2	0/0	1/244 (0.4)
注入部位結節	1/70 (1.4)	0/1	0/0	69/244 (28.3)
注入部位浮腫	1/99 (1.0)	0/2	0/0	47/244 (19.3)
注入部位疼痛	0/101	0/2	0/0	38/244 (15.6)
注入部位蒼白	0/120	0/2	0/0	5/244 (2.0)
注入部位丘疹	3/115 (2.6)	0/2	0/0	18/244 (7.4)
注入部位異常感覚	0/121	0/2	0/0	2/244 (0.8)
注入部位そう痒感	0/119	0/2	0/0	7/244 (2.9)
注入部位発疹	0/119	0/2	0/0	7/244 (2.9)
注入部位反応	0/108	0/2	0/0	30/244 (12.3)
注入部位痂皮	0/122	0/2	0/0	1/244 (0.4)
注入部位腫脹	0/121	0/2	0/0	6/244 (2.5)
注入部位小水疱	0/123	0/2	0/0	2/244 (0.8)
注入部位熱感	0/122	0/2	0/0	1/244 (0.4)
注射部位内出血	0/122	0/2	0/0	3/244 (1.2)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態 (Cont.)				
注射部位変色	0/244	1/184 (0.5)	0/159	0/138
注射部位紅斑	13/244 (5.3)	0/173	1/150 (0.7)	0/128
注射部位漏出	2/244 (0.8)	0/182	0/158	0/137
注射部位血腫	1/244 (0.4)	0/184	0/160	0/139
注射部位出血	0/244	1/184 (0.5)	0/159	0/138
注射部位炎症	4/244 (1.6)	1/181 (0.6)	1/156 (0.6)	0/134
注射部位結節	5/244 (2.0)	2/179 (1.1)	2/154 (1.3)	0/131
注射部位浮腫	4/244 (1.6)	0/180	0/157	0/136
注射部位疼痛	7/244 (2.9)	1/178 (0.6)	0/154	0/135
注射部位丘疹	1/244 (0.4)	1/184 (0.5)	0/160	0/139
注射部位反応	1/244 (0.4)	0/183	1/159 (0.6)	0/137
注射部位腫脹	2/244 (0.8)	1/183 (0.5)	1/158 (0.6)	0/136
注射部位蕁麻疹	1/244 (0.4)	0/184	0/160	0/139
滴下投与部位熱傷	1/244 (0.4)	0/183	0/159	0/138
滴下投与部位痛	0/244	1/184 (0.5)	0/160	0/139
限局性浮腫	1/244 (0.4)	0/183	0/159	0/138
適用部位からの吸収不良	1/244 (0.4)	0/183	0/159	0/138
倦怠感	2/244 (0.8)	0/184	1/160 (0.6)	0/138
医療機器使用部位刺激感	3/244 (1.2)	0/182	0/158	0/137
医療機器使用部位そう痒感	1/244 (0.4)	0/183	0/159	0/138

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態 (Cont.)				
注射部位変色	0/122	0/2	0/0	1/244 (0.4)
注射部位紅斑	0/114	0/2	0/0	14/244 (5.7)
注射部位漏出	0/122	0/2	0/0	2/244 (0.8)
注射部位血腫	0/123	0/2	0/0	1/244 (0.4)
注射部位出血	0/122	0/2	0/0	1/244 (0.4)
注射部位炎症	0/119	0/2	0/0	6/244 (2.5)
注射部位結節	0/116	0/2	0/0	9/244 (3.7)
注射部位浮腫	1/120 (0.8)	0/2	0/0	5/244 (2.0)
注射部位疼痛	0/119	0/2	0/0	8/244 (3.3)
注射部位丘疹	0/123	0/2	0/0	2/244 (0.8)
注射部位反応	0/121	0/2	0/0	2/244 (0.8)
注射部位腫脹	0/120	0/2	0/0	4/244 (1.6)
注射部位蕁麻疹	0/123	0/2	0/0	1/244 (0.4)
滴下投与部位熱傷	0/123	0/2	0/0	1/244 (0.4)
滴下投与部位痛	0/123	0/2	0/0	1/244 (0.4)
限局性浮腫	0/122	0/2	0/0	1/244 (0.4)
適用部位からの吸収不良	0/122	0/2	0/0	1/244 (0.4)
倦怠感	0/122	0/2	0/0	3/244 (1.2)
医療機器使用部位刺激感	0/121	0/2	0/0	3/244 (1.2)
医療機器使用部位そう痒感	0/122	0/2	0/0	1/244 (0.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態 (Cont.)				
医療機器使用部位発疹	2/244 (0.8)	0/182	0/158	0/137
小結節	1/244 (0.4)	0/184	0/160	0/139
非心臓性胸痛	2/244 (0.8)	0/183	0/159	0/138
末梢性浮腫	8/244 (3.3)	0/176	1/154 (0.6)	0/134
疼痛	0/244	1/184 (0.5)	0/159	1/139 (0.7)
末梢腫脹	3/244 (1.2)	0/182	0/158	1/137 (0.7)
穿刺部位内出血	1/244 (0.4)	0/184	0/160	0/139
穿刺部位紅斑	2/244 (0.8)	1/183 (0.5)	0/158	0/137
穿刺部位出血	1/244 (0.4)	0/183	0/159	0/139
穿刺部位硬結	2/244 (0.8)	0/183	0/159	0/138
穿刺部位浮腫	1/244 (0.4)	0/184	0/160	0/139
穿刺部位腫脹	1/244 (0.4)	0/184	0/160	0/139
発熱	3/244 (1.2)	1/183 (0.5)	0/158	0/137
口渇	1/244 (0.4)	0/183	0/159	0/138
血管穿刺部位硬結	1/244 (0.4)	0/184	0/160	0/139
肝胆道系障害	2/244 (0.8)	0/183	0/159	0/138
肝嚢胞	0/244	0/184	0/160	0/139
脂肪肝	1/244 (0.4)	0/183	0/159	0/138
門脈血栓症	1/244 (0.4)	0/184	0/160	0/139

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態 (Cont.)				
医療機器使用部位発疹	0/121	0/2	0/0	2/244 (0.8)
小結節	0/123	0/2	0/0	1/244 (0.4)
非心臓性胸痛	0/122	0/2	0/0	2/244 (0.8)
末梢性浮腫	0/118	0/2	0/0	9/244 (3.7)
疼痛	0/122	0/2	0/0	2/244 (0.8)
末梢腫脹	0/120	0/2	0/0	4/244 (1.6)
穿刺部位内出血	0/123	0/2	0/0	1/244 (0.4)
穿刺部位紅斑	0/121	0/2	0/0	3/244 (1.2)
穿刺部位出血	0/123	0/2	0/0	1/244 (0.4)
穿刺部位硬結	0/122	0/2	0/0	2/244 (0.8)
穿刺部位浮腫	0/123	0/2	0/0	1/244 (0.4)
穿刺部位腫脹	0/123	0/2	0/0	1/244 (0.4)
発熱	0/121	0/2	0/0	4/244 (1.6)
口渇	0/122	0/2	0/0	1/244 (0.4)
血管穿刺部位硬結	0/123	0/2	0/0	1/244 (0.4)
肝胆道系障害	1/122 (0.8)	0/1	0/0	3/244 (1.2)
肝嚢胞	1/123 (0.8)	0/1	0/0	1/244 (0.4)
脂肪肝	0/122	0/2	0/0	1/244 (0.4)
門脈血栓症	0/123	0/2	0/0	1/244 (0.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
感染症および寄生虫症	80/244 (32.8)	17/119 (14.3)	10/90 (11.1)	7/68 (10.3)
四肢膿瘍	0/244	0/184	1/160 (0.6)	0/138
無症候性COVID-19	0/244	0/184	1/160 (0.6)	0/138
細菌性疾患キャリアー	0/244	0/184	1/160 (0.6)	0/138
ボレリア感染	1/244 (0.4)	0/183	0/159	0/138
ウイルス性気管支炎	0/244	0/184	0/160	1/139 (0.7)
COVID-19	0/244	0/184	0/160	1/139 (0.7)
COVID-19肺炎	0/244	0/184	1/160 (0.6)	0/138
カテーテル留置部位感染	0/244	0/184	0/160	1/139 (0.7)
蜂巣炎	1/244 (0.4)	0/183	2/159 (1.3)	0/136
結膜炎	1/244 (0.4)	1/183 (0.5)	0/159	0/138
膀胱炎	1/244 (0.4)	0/184	1/160 (0.6)	0/138
爪の皮膚糸状菌症	0/244	1/184 (0.5)	0/159	0/138
真菌感染	1/244 (0.4)	0/184	0/160	0/139
胃腸炎	1/244 (0.4)	0/183	0/159	0/138
歯肉炎	1/244 (0.4)	0/183	0/159	0/138
麦粒腫	0/244	1/184 (0.5)	0/159	0/138
感染性皮膚潰瘍	1/244 (0.4)	0/183	0/159	0/138
インフルエンザ	0/244	0/184	0/160	1/139 (0.7)
注入部位膿瘍	18/244 (7.4)	4/172 (2.3)	3/148 (2.0)	2/129 (1.6)
注入部位蜂巣炎	40/244 (16.4)	5/152 (3.3)	6/132 (4.5)	5/107 (4.7)
注入部位感染	7/244 (2.9)	6/179 (3.4)	2/150 (1.3)	3/127 (2.4)
注入部位膿疱	1/244 (0.4)	0/183	0/160	0/139
注射部位蜂巣炎	2/244 (0.8)	1/182 (0.5)	0/157	0/136

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
感染症および寄生虫症	0/58	0/1	0/0	114/244 (46.7)
四肢膿瘍	0/123	0/2	0/0	1/244 (0.4)
無症候性COVID-19	0/122	0/2	0/0	1/244 (0.4)
細菌性疾患キャリアー	0/122	0/2	0/0	1/244 (0.4)
ボレリア感染	0/123	0/2	0/0	1/244 (0.4)
ウイルス性気管支炎	0/122	0/2	0/0	1/244 (0.4)
COVID-19	0/122	0/2	0/0	1/244 (0.4)
COVID-19肺炎	0/123	0/2	0/0	1/244 (0.4)
カテーテル留置部位感染	0/122	0/2	0/0	1/244 (0.4)
蜂巣炎	0/121	0/2	0/0	3/244 (1.2)
結膜炎	0/123	0/2	0/0	2/244 (0.8)
膀胱炎	0/123	0/2	0/0	2/244 (0.8)
爪の皮膚糸状菌症	0/122	0/2	0/0	1/244 (0.4)
真菌感染	0/123	0/2	0/0	1/244 (0.4)
胃腸炎	0/122	0/2	0/0	1/244 (0.4)
歯肉炎	0/122	0/2	0/0	1/244 (0.4)
麦粒腫	0/123	0/2	0/0	1/244 (0.4)
感染性皮膚潰瘍	0/122	0/2	0/0	1/244 (0.4)
インフルエンザ	0/122	0/2	0/0	1/244 (0.4)
注入部位膿瘍	0/116	0/2	0/0	27/244 (11.1)
注入部位蜂巣炎	0/87	0/1	0/0	56/244 (23.0)
注入部位感染	0/111	0/2	0/0	18/244 (7.4)
注入部位膿疱	0/123	0/2	0/0	1/244 (0.4)
注射部位蜂巣炎	0/120	0/2	0/0	3/244 (1.2)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
感染症および寄生虫症 (Cont.)				
リンパ管炎	0/244	0/184	1/160 (0.6)	0/138
上咽頭炎	5/244 (2.0)	3/179 (1.7)	0/152	2/133 (1.5)
爪真菌症	1/244 (0.4)	0/183	0/159	0/139
耳下腺膿瘍	0/244	0/184	1/160 (0.6)	0/138
肺炎	2/244 (0.8)	0/182	2/159 (1.3)	0/136
術後膿瘍	0/244	0/184	1/160 (0.6)	0/138
シュードモナス感染	1/244 (0.4)	0/183	0/159	0/139
膿疱性皮疹	1/244 (0.4)	0/184	0/160	0/139
気道感染	0/244	0/184	0/160	1/139 (0.7)
敗血症	2/244 (0.8)	0/182	0/159	1/138 (0.7)
敗血症性ショック	1/244 (0.4)	0/183	0/159	0/138
副鼻腔炎	1/244 (0.4)	0/183	0/159	0/139
ブドウ球菌感染	0/244	1/184 (0.5)	0/159	1/139 (0.7)
歯感染	1/244 (0.4)	0/183	0/159	1/139 (0.7)
上気道感染	1/244 (0.4)	0/183	0/159	0/138
尿路感染	10/244 (4.1)	5/175 (2.9)	3/148 (2.0)	1/126 (0.8)
水痘帯状疱疹ウイルス感染	0/244	1/184 (0.5)	0/159	0/138
傷害、中毒および処置合併症	29/244 (11.9)	9/161 (5.6)	6/131 (4.6)	4/111 (3.6)
足関節部骨折	1/244 (0.4)	0/183	0/159	0/138
節足動物咬傷	1/244 (0.4)	0/183	0/159	0/138
骨挫傷	0/244	1/184 (0.5)	0/159	1/139 (0.7)

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
感染症および寄生虫症 (Cont.)				
リンパ管炎	0/123	0/2	0/0	1/244 (0.4)
上咽頭炎	0/116	0/2	0/0	10/244 (4.1)
爪真菌症	0/123	0/2	0/0	1/244 (0.4)
耳下腺膿瘍	0/122	0/2	0/0	1/244 (0.4)
肺炎	0/121	0/2	0/0	4/244 (1.6)
術後膿瘍	0/122	0/2	0/0	1/244 (0.4)
シュードモナス感染	0/123	0/2	0/0	1/244 (0.4)
膿疱性皮疹	0/123	0/2	0/0	1/244 (0.4)
気道感染	0/123	0/2	0/0	1/244 (0.4)
敗血症	0/121	0/2	0/0	3/244 (1.2)
敗血症性ショック	0/122	0/2	0/0	1/244 (0.4)
副鼻腔炎	0/123	0/2	0/0	1/244 (0.4)
ブドウ球菌感染	0/122	0/2	0/0	2/244 (0.8)
歯感染	0/122	0/2	0/0	2/244 (0.8)
上気道感染	0/122	0/2	0/0	1/244 (0.4)
尿路感染	0/111	0/2	0/0	19/244 (7.8)
水痘帯状疱疹ウイルス感染	0/122	0/2	0/0	1/244 (0.4)
傷害、中毒および処置合併症	0/95	0/2	0/0	48/244 (19.7)
足関節部骨折	0/122	0/2	0/0	1/244 (0.4)
節足動物咬傷	0/123	0/2	0/0	1/244 (0.4)
骨挫傷	0/122	0/2	0/0	2/244 (0.8)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
傷害、中毒および処置合併症 (Cont.)				
脳挫傷	1/244 (0.4)	0/183	0/159	0/139
挫傷	3/244 (1.2)	4/181 (2.2)	1/154 (0.6)	0/133
医療機器設置の問題	1/244 (0.4)	0/183	0/159	0/138
医療機器による投与の欠落	1/244 (0.4)	0/184	0/160	0/139
期限切れの製品使用	1/244 (0.4)	0/183	0/160	0/139
眼挫傷	1/244 (0.4)	0/183	0/159	0/139
顔面損傷	0/244	1/184 (0.5)	0/159	0/138
顔面骨骨折	2/244 (0.8)	0/182	0/158	0/137
転倒	22/244 (9.0)	9/165 (5.5)	5/134 (3.7)	4/115 (3.5)
頭部損傷	1/244 (0.4)	2/183 (1.1)	2/158 (1.3)	0/135
注入に伴う反応	1/244 (0.4)	0/184	0/160	0/139
関節脱臼	0/244	1/184 (0.5)	0/159	0/139
靭帯捻挫	0/244	2/184 (1.1)	0/158	0/137
腰椎骨折	1/244 (0.4)	0/184	0/160	0/139
過量投与	0/244	0/184	1/160 (0.6)	0/138
処置後挫傷	1/244 (0.4)	0/183	0/159	0/138
処置によるめまい	1/244 (0.4)	0/184	0/160	0/139
肋骨骨折	1/244 (0.4)	1/183 (0.5)	0/158	1/137 (0.7)
皮膚擦過傷	1/244 (0.4)	1/183 (0.5)	1/158 (0.6)	0/137
皮膚損傷	1/244 (0.4)	0/183	0/159	0/139
皮膚裂傷	2/244 (0.8)	3/182 (1.6)	1/155 (0.6)	1/134 (0.7)
ストレス骨折	0/244	0/184	1/160 (0.6)	0/138

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
傷害、中毒および処置合併症 (Cont.)				
脳挫傷	0/123	0/2	0/0	1/244 (0.4)
挫傷	0/117	0/2	0/0	8/244 (3.3)
医療機器設置の問題	0/122	0/2	0/0	1/244 (0.4)
医療機器による投与の欠落	0/123	0/2	0/0	1/244 (0.4)
期限切れの製品使用	0/123	0/2	0/0	1/244 (0.4)
眼挫傷	0/123	0/2	0/0	1/244 (0.4)
顔面損傷	0/122	0/2	0/0	1/244 (0.4)
顔面骨骨折	0/121	0/2	0/0	2/244 (0.8)
転倒	0/99	0/2	0/0	40/244 (16.4)
頭部損傷	0/120	0/2	0/0	5/244 (2.0)
注入に伴う反応	0/123	0/2	0/0	1/244 (0.4)
関節脱臼	0/123	0/2	0/0	1/244 (0.4)
靭帯捻挫	0/121	0/2	0/0	2/244 (0.8)
腰椎骨折	0/123	0/2	0/0	1/244 (0.4)
過量投与	0/122	0/2	0/0	1/244 (0.4)
処置後挫傷	0/122	0/2	0/0	1/244 (0.4)
処置によるめまい	0/123	0/2	0/0	1/244 (0.4)
肋骨骨折	0/120	0/2	0/0	3/244 (1.2)
皮膚擦過傷	0/122	0/2	0/0	3/244 (1.2)
皮膚損傷	0/123	0/2	0/0	1/244 (0.4)
皮膚裂傷	0/117	0/2	0/0	7/244 (2.9)
ストレス骨折	0/122	0/2	0/0	1/244 (0.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
傷害、中毒および処置合併症 (Cont.)				
硬膜下血腫	0/244	0/184	0/160	1/139 (0.7)
サンバーン	1/244 (0.4)	0/183	0/159	0/138
腱断裂	0/244	1/184 (0.5)	0/159	1/139 (0.7)
過少量投与	0/244	0/184	1/160 (0.6)	0/138
創傷	0/244	0/184	0/160	1/139 (0.7)
臨床検査	31/244 (12.7)	6/158 (3.8)	7/131 (5.3)	2/109 (1.8)
血中クレアチンホスホキナーゼ増加	2/244 (0.8)	0/183	0/159	0/138
血中クレアチニン減少	1/244 (0.4)	0/183	0/159	0/138
血中葉酸異常	0/244	0/184	0/160	1/139 (0.7)
血中葉酸減少	1/244 (0.4)	0/183	0/159	0/138
血中ホモシステイン増加	1/244 (0.4)	0/183	1/159 (0.6)	0/137
血中リン減少	0/244	1/184 (0.5)	0/159	0/138
血圧上昇	2/244 (0.8)	0/183	0/159	0/139
起立血圧低下	1/244 (0.4)	0/183	0/159	0/138
血中ナトリウム減少	1/244 (0.4)	0/183	0/159	0/138
C-反応性蛋白増加	1/244 (0.4)	0/183	0/159	0/138
心雑音	0/244	0/184	1/160 (0.6)	0/138
握力低下	1/244 (0.4)	0/183	0/159	0/138
ヘモグロビン減少	1/244 (0.4)	0/183	0/160	1/139 (0.7)

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
傷害、中毒および処置合併症 (Cont.)				
硬膜下血腫	0/123	0/2	0/0	1/244 (0.4)
サンバーン	0/123	0/2	0/0	1/244 (0.4)
腱断裂	0/122	0/2	0/0	2/244 (0.8)
過少量投与	0/122	0/2	0/0	1/244 (0.4)
創傷	0/122	0/2	0/0	1/244 (0.4)
臨床検査	2/95 (2.1)	0/2	0/0	48/244 (19.7)
血中クレアチンホスホキナーゼ増加	0/122	0/2	0/0	2/244 (0.8)
血中クレアチニン減少	0/122	0/2	0/0	1/244 (0.4)
血中葉酸異常	0/122	0/2	0/0	1/244 (0.4)
血中葉酸減少	1/122 (0.8)	0/2	0/0	2/244 (0.8)
血中ホモシステイン増加	1/121 (0.8)	0/2	0/0	3/244 (1.2)
血中リン減少	0/122	0/2	0/0	1/244 (0.4)
血圧上昇	0/123	0/2	0/0	2/244 (0.8)
起立血圧低下	0/122	0/2	0/0	1/244 (0.4)
血中ナトリウム減少	0/122	0/2	0/0	1/244 (0.4)
C-反応性蛋白増加	0/122	0/2	0/0	1/244 (0.4)
心雑音	0/123	0/2	0/0	1/244 (0.4)
握力低下	0/122	0/2	0/0	1/244 (0.4)
ヘモグロビン減少	0/122	0/2	0/0	2/244 (0.8)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
臨床検査 (Cont.)				
リンパ球数減少	1/244 (0.4)	0/184	0/160	0/139
単球数増加	1/244 (0.4)	0/184	0/160	0/139
好中球数増加	2/244 (0.8)	0/183	0/159	0/138
プロトロンビン時間延長	0/244	0/184	0/160	0/139
赤血球数減少	1/244 (0.4)	0/183	0/159	0/138
ビタミンB12減少	1/244 (0.4)	0/184	1/160 (0.6)	0/138
ビタミンB6減少	9/244 (3.7)	0/175	2/151 (1.3)	0/130
ビタミンD減少	1/244 (0.4)	0/183	0/159	0/139
体重減少	13/244 (5.3)	4/172 (2.3)	5/147 (3.4)	2/124 (1.6)
体重増加	1/244 (0.4)	1/183 (0.5)	0/158	0/137
白血球数増加	2/244 (0.8)	0/183	0/159	0/138
代謝および栄養障害	16/244 (6.6)	5/171 (2.9)	6/144 (4.2)	3/119 (2.5)
悪液質	0/244	0/184	1/160 (0.6)	0/138
食欲減退	3/244 (1.2)	2/181 (1.1)	1/156 (0.6)	0/134
脱水	2/244 (0.8)	2/184 (1.1)	0/158	0/137
糖尿病	0/244	0/184	1/160 (0.6)	0/138
水分過負荷	1/244 (0.4)	0/183	0/160	0/139
体液貯留	1/244 (0.4)	0/183	0/159	1/138 (0.7)
葉酸欠乏	1/244 (0.4)	0/183	1/159 (0.6)	0/137
耐糖能障害	1/244 (0.4)	0/183	0/159	0/138
高コレステロール血症	0/244	1/184 (0.5)	0/159	0/138
高血糖	1/244 (0.4)	0/183	0/159	0/138

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
臨床検査 (Cont.)				
リンパ球数減少	0/123	0/2	0/0	1/244 (0.4)
単球数増加	0/123	0/2	0/0	1/244 (0.4)
好中球数増加	0/122	0/2	0/0	2/244 (0.8)
プロトロンビン時間延長	1/123 (0.8)	0/2	0/0	1/244 (0.4)
赤血球数減少	0/122	0/2	0/0	1/244 (0.4)
ビタミンB12減少	0/122	0/2	0/0	2/244 (0.8)
ビタミンB6減少	0/114	0/2	0/0	11/244 (4.5)
ビタミンD減少	0/123	0/2	0/0	1/244 (0.4)
体重減少	0/109	0/2	0/0	24/244 (9.8)
体重増加	0/121	0/2	0/0	2/244 (0.8)
白血球数増加	0/122	0/2	0/0	2/244 (0.8)
代謝および栄養障害	0/105	0/2	0/0	30/244 (12.3)
悪液質	0/122	0/2	0/0	1/244 (0.4)
食欲減退	0/119	0/2	0/0	6/244 (2.5)
脱水	0/121	0/2	0/0	4/244 (1.6)
糖尿病	0/123	0/2	0/0	1/244 (0.4)
水分過負荷	0/123	0/2	0/0	1/244 (0.4)
体液貯留	0/121	0/2	0/0	2/244 (0.8)
葉酸欠乏	0/122	0/2	0/0	2/244 (0.8)
耐糖能障害	0/122	0/2	0/0	1/244 (0.4)
高コレステロール血症	0/122	0/2	0/0	1/244 (0.4)
高血糖	0/122	0/2	0/0	1/244 (0.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
代謝および栄養障害 (Cont.)				
高ホモシステイン血症	0/244	0/184	1/160 (0.6)	0/138
低カルシウム血症	0/244	0/184	1/160 (0.6)	0/138
低カリウム血症	2/244 (0.8)	0/184	0/160	1/139 (0.7)
低ナトリウム血症	0/244	1/184 (0.5)	0/159	1/138 (0.7)
栄養障害	1/244 (0.4)	0/184	0/160	0/139
ビタミンB群欠乏	1/244 (0.4)	0/183	1/159 (0.6)	0/137
ビタミンB12欠乏	0/244	0/184	1/160 (0.6)	0/138
ビタミンB6欠乏	5/244 (2.0)	0/179	2/155 (1.3)	1/134 (0.7)
筋骨格系および結合組織障害	27/244 (11.1)	7/162 (4.3)	9/134 (6.7)	2/110 (1.8)
関節痛	4/244 (1.6)	1/181 (0.6)	2/156 (1.3)	1/134 (0.7)
反応性関節炎	1/244 (0.4)	0/183	1/159 (0.6)	0/137
背部痛	6/244 (2.5)	2/178 (1.1)	4/152 (2.6)	1/128 (0.8)
骨痛	0/244	0/184	1/160 (0.6)	0/138
滑液包炎	1/244 (0.4)	0/183	1/159 (0.6)	0/137
外骨腫	0/244	1/184 (0.5)	0/159	0/139
椎間関節症候群	0/244	1/184 (0.5)	0/159	0/139
椎間板変性症	0/244	1/184 (0.5)	0/159	0/138
椎間板突出	0/244	1/184 (0.5)	0/159	0/139
関節滲出液	0/244	1/184 (0.5)	0/159	0/139
関節腫脹	1/244 (0.4)	0/183	0/159	0/138

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
代謝および栄養障害 (Cont.)				
高ホモシステイン血症	0/122	0/2	0/0	1/244 (0.4)
低カルシウム血症	0/123	0/2	0/0	1/244 (0.4)
低カリウム血症	0/123	0/2	0/0	3/244 (1.2)
低ナトリウム血症	0/122	0/2	0/0	2/244 (0.8)
栄養障害	0/123	0/2	0/0	1/244 (0.4)
ビタミンB群欠乏	0/121	0/2	0/0	2/244 (0.8)
ビタミンB12欠乏	1/123 (0.8)	0/2	0/0	2/244 (0.8)
ビタミンB6欠乏	0/118	0/2	0/0	8/244 (3.3)
筋骨格系および結合組織障害	0/96	0/2	0/0	45/244 (18.4)
関節痛	0/119	0/2	0/0	8/244 (3.3)
反応性関節炎	0/122	0/2	0/0	2/244 (0.8)
背部痛	0/113	0/2	0/0	13/244 (5.3)
骨痛	0/122	0/2	0/0	1/244 (0.4)
滑液包炎	0/122	0/2	0/0	2/244 (0.8)
外骨腫	0/123	0/2	0/0	1/244 (0.4)
椎間関節症候群	0/123	0/2	0/0	1/244 (0.4)
椎間板変性症	0/122	0/2	0/0	1/244 (0.4)
椎間板突出	0/123	0/2	0/0	1/244 (0.4)
関節滲出液	1/123 (0.8)	0/2	0/0	2/244 (0.8)
関節腫脹	0/122	0/2	0/0	1/244 (0.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
筋骨格系および結合組織障害 (Cont.)				
四肢不快感	0/244	0/184	1/160 (0.6)	0/139
筋萎縮	0/244	1/184 (0.5)	0/159	0/139
筋痙縮	2/244 (0.8)	3/182 (1.6)	0/156	0/135
筋力低下	3/244 (1.2)	1/182 (0.5)	1/158 (0.6)	0/137
筋骨格硬直	1/244 (0.4)	0/184	0/160	0/139
筋肉痛	3/244 (1.2)	0/182	0/158	0/137
頚部痛	0/244	0/184	2/160 (1.3)	0/137
骨炎	1/244 (0.4)	0/184	0/160	0/139
変形性関節症	1/244 (0.4)	2/183 (1.1)	1/157 (0.6)	0/136
骨減少症	0/244	1/184 (0.5)	0/159	0/138
四肢痛	5/244 (2.0)	0/179	0/156	1/137 (0.7)
関節周囲炎	0/244	0/184	1/160 (0.6)	0/138
姿勢異常	1/244 (0.4)	0/183	0/159	0/139
横紋筋融解症	1/244 (0.4)	0/184	0/160	1/139 (0.7)
肩回旋筋腱板症候群	0/244	1/184 (0.5)	0/159	0/139
仙腸関節機能障害	1/244 (0.4)	0/183	0/159	0/138
変形性脊椎症	0/244	1/184 (0.5)	0/159	0/138
腱障害	0/244	1/184 (0.5)	0/159	0/139
腱炎	1/244 (0.4)	0/183	0/159	0/138
斜頚	1/244 (0.4)	0/183	0/159	0/138
弾発指	0/244	0/184	1/160 (0.6)	0/138

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
筋骨格系および結合組織障害 (Cont.)				
四肢不快感	0/123	0/2	0/0	1/244 (0.4)
筋萎縮	0/123	0/2	0/0	1/244 (0.4)
筋痙縮	0/120	0/2	0/0	5/244 (2.0)
筋力低下	0/121	0/2	0/0	5/244 (2.0)
筋骨格硬直	0/123	0/2	0/0	1/244 (0.4)
筋肉痛	0/121	0/2	0/0	3/244 (1.2)
頚部痛	0/121	0/2	0/0	2/244 (0.8)
骨炎	0/123	0/2	0/0	1/244 (0.4)
変形性関節症	1/120 (0.8)	0/2	0/0	5/244 (2.0)
骨減少症	0/122	0/2	0/0	1/244 (0.4)
四肢痛	0/120	0/2	0/0	6/244 (2.5)
関節周囲炎	0/122	0/2	0/0	1/244 (0.4)
姿勢異常	0/123	0/2	0/0	1/244 (0.4)
横紋筋融解症	0/122	0/2	0/0	2/244 (0.8)
肩回旋筋腱板症候群	0/123	0/2	0/0	1/244 (0.4)
仙腸関節機能障害	0/122	0/2	0/0	1/244 (0.4)
変形性脊椎症	0/122	0/2	0/0	1/244 (0.4)
腱障害	0/123	0/2	0/0	1/244 (0.4)
腱炎	0/122	0/2	0/0	1/244 (0.4)
斜頚	0/122	0/2	0/0	1/244 (0.4)
弾発指	0/122	0/2	0/0	1/244 (0.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) 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）	1/244 (0.4)	3/183 (1.6)	1/156 (0.6)	0/135
基底細胞癌	0/244	2/184 (1.1)	0/158	0/138
直腸腺癌	0/244	1/184 (0.5)	0/159	0/138
脂漏性角化症	0/244	0/184	1/160 (0.6)	0/138
皮膚有棘細胞癌	1/244 (0.4)	0/183	0/159	0/138
神経系障害	79/244 (32.4)	14/131 (10.7)	8/105 (7.6)	7/86 (8.1)
アカシジア	0/244	0/184	0/160	1/139 (0.7)
健忘	0/244	0/184	0/160	0/139
失語症	0/244	0/184	1/160 (0.6)	0/138
運動失調	1/244 (0.4)	0/183	0/159	0/138
平衡障害	1/244 (0.4)	0/183	1/159 (0.6)	1/138 (0.7)
運動緩慢	1/244 (0.4)	0/184	1/160 (0.6)	0/138
手根管症候群	0/244	0/184	1/160 (0.6)	0/138
大脳萎縮	0/244	0/184	0/160	1/139 (0.7)
脳出血	0/244	1/184 (0.5)	0/159	0/138
脳圧排効果	0/244	0/184	0/160	1/139 (0.7)
脳血管発作	0/244	1/184 (0.5)	0/160	0/139
認知障害	2/244 (0.8)	1/182 (0.5)	1/159 (0.6)	1/137 (0.7)
振動覚低下	0/244	1/184 (0.5)	0/159	0/138
注意力障害	1/244 (0.4)	0/183	0/160	0/139
浮動性めまい	23/244 (9.4)	2/165 (1.2)	0/141	0/125
体位性めまい	3/244 (1.2)	2/182 (1.1)	0/156	0/136

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) 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）	0/120	0/2	0/0	5/244 (2.0)
基底細胞癌	0/122	0/2	0/0	2/244 (0.8)
直腸腺癌	0/123	0/2	0/0	1/244 (0.4)
脂漏性角化症	0/122	0/2	0/0	1/244 (0.4)
皮膚有棘細胞癌	0/122	0/2	0/0	1/244 (0.4)
神経系障害	2/69 (2.9)	0/1	0/0	110/244 (45.1)
アカシジア	0/122	0/2	0/0	1/244 (0.4)
健忘	1/123 (0.8)	0/2	0/0	1/244 (0.4)
失語症	0/122	0/2	0/0	1/244 (0.4)
運動失調	0/123	0/2	0/0	1/244 (0.4)
平衡障害	1/121 (0.8)	0/2	0/0	4/244 (1.6)
運動緩慢	0/122	0/2	0/0	2/244 (0.8)
手根管症候群	0/122	0/2	0/0	1/244 (0.4)
大脳萎縮	0/122	0/2	0/0	1/244 (0.4)
脳出血	0/122	0/2	0/0	1/244 (0.4)
脳圧排効果	0/123	0/2	0/0	1/244 (0.4)
脳血管発作	0/123	0/2	0/0	1/244 (0.4)
認知障害	1/120 (0.8)	0/2	0/0	6/244 (2.5)
振動覚低下	0/122	0/2	0/0	1/244 (0.4)
注意力障害	0/123	0/2	0/0	1/244 (0.4)
浮動性めまい	0/109	0/2	0/0	25/244 (10.2)
体位性めまい	0/120	0/2	0/0	5/244 (2.0)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
神経系障害 (Cont.)				
構語障害	1/244 (0.4)	1/184 (0.5)	1/159 (0.6)	0/137
味覚不全	2/244 (0.8)	0/183	0/159	1/138 (0.7)
ジスキネジア	11/244 (4.5)	4/179 (2.2)	1/152 (0.7)	2/130 (1.5)
起立障害	1/244 (0.4)	0/183	0/160	0/139
ジストニア	4/244 (1.6)	2/181 (1.1)	0/155	1/135 (0.7)
脳症	1/244 (0.4)	0/184	0/160	0/139
てんかん	1/244 (0.4)	0/184	0/160	0/139
本態性振戦	1/244 (0.4)	0/183	0/159	0/139
伸展性足底反応	1/244 (0.4)	0/183	0/159	0/138
すくみ現象	4/244 (1.6)	0/182	0/159	0/138
全身性強直性間代性発作	0/244	0/184	0/160	1/139 (0.7)
頭部不快感	1/244 (0.4)	0/184	0/160	0/139
頭痛	9/244 (3.7)	3/176 (1.7)	1/151 (0.7)	1/131 (0.8)
片側感覚消失	1/244 (0.4)	0/183	0/159	0/139
不全片麻痺	1/244 (0.4)	0/183	0/159	0/139
知覚過敏	0/244	0/184	1/160 (0.6)	0/138
感覚鈍麻	0/244	0/184	3/160 (1.9)	0/136
反射減弱	0/244	1/184 (0.5)	1/159 (0.6)	0/137
不規則睡眠覚醒リズム障害	0/244	0/184	1/160 (0.6)	0/138
嗜眠	0/244	1/184 (0.5)	1/159 (0.6)	0/139
意識消失	0/244	2/184 (1.1)	0/159	0/138
腰仙部神経根障害	1/244 (0.4)	0/183	0/159	0/138

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
神経系障害 (Cont.)				
構語障害	0/122	0/2	0/0	3/244 (1.2)
味覚不全	0/121	0/2	0/0	3/244 (1.2)
ジスキネジア	0/113	0/2	0/0	18/244 (7.4)
起立障害	0/123	0/2	0/0	1/244 (0.4)
ジストニア	0/118	0/2	0/0	7/244 (2.9)
脳症	0/123	0/2	0/0	1/244 (0.4)
てんかん	0/123	0/2	0/0	1/244 (0.4)
本態性振戦	0/123	0/2	0/0	1/244 (0.4)
伸展性足底反応	0/122	0/2	0/0	1/244 (0.4)
すくみ現象	0/122	0/2	0/0	4/244 (1.6)
全身性強直性間代性発作	0/123	0/2	0/0	1/244 (0.4)
頭部不快感	0/123	0/2	0/0	1/244 (0.4)
頭痛	0/115	0/2	0/0	14/244 (5.7)
片側感覚消失	0/123	0/2	0/0	1/244 (0.4)
不全片麻痺	0/123	0/2	0/0	1/244 (0.4)
知覚過敏	0/122	0/2	0/0	1/244 (0.4)
感覚鈍麻	0/120	0/2	0/0	3/244 (1.2)
反射減弱	1/122 (0.8)	0/2	0/0	3/244 (1.2)
不規則睡眠覚醒リズム障害	0/122	0/2	0/0	1/244 (0.4)
嗜眠	0/123	0/2	0/0	2/244 (0.8)
意識消失	0/122	0/2	0/0	2/244 (0.8)
腰仙部神経根障害	0/122	0/2	0/0	1/244 (0.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
神経系障害 (Cont.)				
記憶障害	1/244 (0.4)	0/183	1/160 (0.6)	0/138
代謝性脳症	1/244 (0.4)	0/184	1/160 (0.6)	0/138
神経痛	0/244	1/184 (0.5)	0/159	0/138
末梢性ニューロパチー	1/244 (0.4)	0/183	0/159	1/139 (0.7)
オンオフ現象	8/244 (3.3)	0/180	1/157 (0.6)	0/135
錯感覚	4/244 (1.6)	1/183 (0.5)	0/158	2/137 (1.5)
パーキンソン病	11/244 (4.5)	4/178 (2.2)	2/151 (1.3)	0/130
パーキンソニズム	2/244 (0.8)	1/184 (0.5)	0/159	0/138
末梢性感覚ニューロパチー	0/244	1/184 (0.5)	0/159	0/138
側反弓	1/244 (0.4)	0/183	1/159 (0.6)	1/138 (0.7)
多発ニューロパチー	1/244 (0.4)	0/183	0/159	1/139 (0.7)
失神寸前の状態	0/244	1/184 (0.5)	0/159	0/139
心因性発作	1/244 (0.4)	0/183	0/159	0/138
精神運動亢進	2/244 (0.8)	0/183	0/160	0/139
反射異常	0/244	0/184	0/160	1/139 (0.7)
安静時振戦	1/244 (0.4)	0/183	0/159	0/139
坐骨神経痛	2/244 (0.8)	0/182	1/158 (0.6)	0/137
痙攣発作	0/244	1/184 (0.5)	0/159	0/138
感覚障害	1/244 (0.4)	0/183	0/159	0/138
感覚消失	0/244	1/184 (0.5)	0/159	0/138
睡眠時麻痺	0/244	1/184 (0.5)	0/159	0/138
傾眠	8/244 (3.3)	2/177 (1.1)	1/152 (0.7)	1/132 (0.8)
失神	0/244	1/184 (0.5)	0/159	1/138 (0.7)

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
神経系障害 (Cont.)				
記憶障害	0/122	0/2	0/0	2/244 (0.8)
代謝性脳症	0/122	0/2	0/0	2/244 (0.8)
神経痛	0/123	0/2	0/0	1/244 (0.4)
末梢性ニューロパチー	0/122	0/2	0/0	2/244 (0.8)
オンオフ現象	0/119	0/2	0/0	9/244 (3.7)
錯感覚	0/119	0/1	0/0	7/244 (2.9)
パーキンソン病	0/114	0/2	0/0	17/244 (7.0)
パーキンソニズム	0/122	0/2	0/0	3/244 (1.2)
末梢性感覚ニューロパチー	0/122	0/2	0/0	1/244 (0.4)
側反弓	0/121	0/2	0/0	3/244 (1.2)
多発ニューロパチー	0/122	0/2	0/0	2/244 (0.8)
失神寸前の状態	0/123	0/2	0/0	1/244 (0.4)
心因性発作	0/122	0/2	0/0	1/244 (0.4)
精神運動亢進	0/123	0/2	0/0	2/244 (0.8)
反射異常	0/122	0/2	0/0	1/244 (0.4)
安静時振戦	0/123	0/2	0/0	1/244 (0.4)
坐骨神経痛	0/122	0/2	0/0	3/244 (1.2)
痙攣発作	0/122	0/2	0/0	1/244 (0.4)
感覚障害	0/122	0/2	0/0	1/244 (0.4)
感覚消失	0/122	0/2	0/0	1/244 (0.4)
睡眠時麻痺	0/122	0/2	0/0	1/244 (0.4)
傾眠	0/115	0/2	0/0	12/244 (4.9)
失神	1/121 (0.8)	0/2	0/0	3/244 (1.2)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
神経系障害 (Cont.)				
振戦	2/244 (0.8)	1/182 (0.5)	0/157	0/137
製品の問題	3/244 (1.2)	0/182	0/159	0/138
医療機器送達システムの問題	1/244 (0.4)	0/183	0/160	0/139
医療機器位置異常	1/244 (0.4)	0/183	0/159	0/138
医療機器機能不良	1/244 (0.4)	0/184	0/160	0/139
精神障害	90/244 (36.9)	8/115 (7.0)	6/96 (6.3)	4/80 (5.0)
異常な夢	1/244 (0.4)	0/183	0/159	0/138
感情不安定	1/244 (0.4)	1/184 (0.5)	0/159	0/138
激越	1/244 (0.4)	0/184	0/160	0/139
不安	22/244 (9.0)	2/166 (1.2)	4/145 (2.8)	1/123 (0.8)
不安障害	0/244	0/184	0/160	1/139 (0.7)
無感情	0/244	1/184 (0.5)	0/159	0/139
歯ぎしり	2/244 (0.8)	0/182	0/159	0/138
強迫行為	1/244 (0.4)	0/183	0/159	0/138
強迫性性行動	0/244	0/184	1/160 (0.6)	0/138
錯乱状態	5/244 (2.0)	1/180 (0.6)	2/155 (1.3)	1/132 (0.8)
譫妄	4/244 (1.6)	1/181 (0.6)	0/157	0/137
妄想	7/244 (2.9)	1/178 (0.6)	2/154 (1.3)	0/134
寄生虫妄想	0/244	1/184 (0.5)	0/159	0/139
妄想性障害、詳細不明	1/244 (0.4)	0/183	0/159	0/139

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
神経系障害 (Cont.)				
振戦	0/121	0/2	0/0	3/244 (1.2)
製品の問題	0/122	0/2	0/0	3/244 (1.2)
医療機器送達システムの問題	0/123	0/2	0/0	1/244 (0.4)
医療機器位置異常	0/122	0/2	0/0	1/244 (0.4)
医療機器機能不良	0/123	0/2	0/0	1/244 (0.4)
精神障害	0/70	0/1	0/0	108/244 (44.3)
異常な夢	0/122	0/2	0/0	1/244 (0.4)
感情不安定	0/122	0/2	0/0	2/244 (0.8)
激越	0/123	0/2	0/0	1/244 (0.4)
不安	0/107	0/2	0/0	29/244 (11.9)
不安障害	0/122	0/2	0/0	1/244 (0.4)
無感情	0/123	0/2	0/0	1/244 (0.4)
歯ぎしり	0/122	0/2	0/0	2/244 (0.8)
強迫行為	0/122	0/2	0/0	1/244 (0.4)
強迫性性行動	0/122	0/2	0/0	1/244 (0.4)
錯乱状態	0/116	0/2	0/0	9/244 (3.7)
譫妄	0/122	0/2	0/0	5/244 (2.0)
妄想	0/119	0/2	0/0	10/244 (4.1)
寄生虫妄想	0/123	0/2	0/0	1/244 (0.4)
妄想性障害、詳細不明	0/123	0/2	0/0	1/244 (0.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
精神障害 (Cont.)				
抑うつ気分	2/244 (0.8)	1/182 (0.5)	0/157	1/137 (0.7)
うつ病	1/244 (0.4)	2/183 (1.1)	1/158 (0.6)	1/136 (0.7)
抑うつ症状	2/244 (0.8)	0/183	0/159	0/138
ドーパミン調節障害症候群	0/244	0/184	0/160	1/139 (0.7)
ディスフェミア	0/244	0/184	1/160 (0.6)	0/138
睡眠異常	1/244 (0.4)	0/183	0/159	0/138
情動障害	1/244 (0.4)	1/183 (0.5)	0/158	0/138
注射恐怖	0/244	1/184 (0.5)	0/160	0/139
幻覚	33/244 (13.5)	6/165 (3.6)	2/138 (1.4)	1/120 (0.8)
幻聴	2/244 (0.8)	3/182 (1.6)	0/155	1/137 (0.7)
幻嗅	1/244 (0.4)	0/183	0/160	0/139
幻視	10/244 (4.1)	3/175 (1.7)	2/150 (1.3)	0/130
混合性幻覚	1/244 (0.4)	0/183	0/159	0/138
性欲過剰	1/244 (0.4)	0/183	0/159	0/138
錯覚	1/244 (0.4)	0/183	1/159 (0.6)	0/137
衝動制御障害	2/244 (0.8)	1/182 (0.5)	0/158	1/139 (0.7)
衝動行為	0/244	0/184	0/160	1/139 (0.7)
不眠症	15/244 (6.1)	2/170 (1.2)	0/146	1/127 (0.8)
易刺激性	2/244 (0.8)	0/182	0/160	0/139
嫉妬妄想	1/244 (0.4)	0/183	0/159	0/138
躁病	1/244 (0.4)	0/183	0/159	0/139
気分変化	1/244 (0.4)	0/183	0/159	0/138
気分動揺	0/244	1/184 (0.5)	0/159	0/138

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
精神障害 (Cont.)				
抑うつ気分	0/121	0/2	0/0	4/244 (1.6)
うつ病	0/120	0/2	0/0	5/244 (2.0)
抑うつ症状	0/122	0/2	0/0	2/244 (0.8)
ドーパミン調節障害症候群	0/122	0/2	0/0	1/244 (0.4)
ディスフェミア	0/122	0/2	0/0	1/244 (0.4)
睡眠異常	0/122	0/2	0/0	1/244 (0.4)
情動障害	0/122	0/2	0/0	2/244 (0.8)
注射恐怖	0/123	0/2	0/0	1/244 (0.4)
幻覚	0/108	0/2	0/0	42/244 (17.2)
幻聴	0/120	0/2	0/0	6/244 (2.5)
幻嗅	0/123	0/2	0/0	1/244 (0.4)
幻視	0/115	0/2	0/0	15/244 (6.1)
混合性幻覚	0/122	0/2	0/0	1/244 (0.4)
性欲過剰	0/122	0/2	0/0	1/244 (0.4)
錯覚	0/123	0/2	0/0	2/244 (0.8)
衝動制御障害	0/122	0/2	0/0	4/244 (1.6)
衝動行為	0/122	0/2	0/0	1/244 (0.4)
不眠症	0/111	0/1	0/0	18/244 (7.4)
易刺激性	0/123	0/2	0/0	2/244 (0.8)
嫉妬妄想	0/122	0/2	0/0	1/244 (0.4)
躁病	0/123	0/2	0/0	1/244 (0.4)
気分変化	0/122	0/2	0/0	1/244 (0.4)
気分動揺	0/123	0/2	0/0	1/244 (0.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
精神障害 (Cont.)				
悪夢	1/244 (0.4)	1/184 (0.5)	0/159	0/139
強迫観念	1/244 (0.4)	0/183	0/160	0/139
パニック発作	3/244 (1.2)	0/182	0/158	0/137
パニック反応	0/244	0/184	1/160 (0.6)	0/138
妄想症	0/244	1/184 (0.5)	1/159 (0.6)	0/137
睡眠の質低下	0/244	1/184 (0.5)	0/159	0/139
処置に対する不安	0/244	1/184 (0.5)	0/160	0/139
精神病性障害	3/244 (1.2)	1/181 (0.6)	2/157 (1.3)	0/135
精神病症状	0/244	0/184	0/160	1/139 (0.7)
レム睡眠行動障害	2/244 (0.8)	0/183	0/159	0/138
レム睡眠異常	1/244 (0.4)	0/183	0/159	0/138
睡眠障害	2/244 (0.8)	1/182 (0.5)	0/157	0/137
ねごと	1/244 (0.4)	1/183 (0.5)	0/159	0/139
常同症	0/244	0/184	0/160	1/139 (0.7)
ストレス	1/244 (0.4)	0/183	0/159	0/138
自殺念慮	2/244 (0.8)	1/182 (0.5)	0/159	0/139
自殺企図	0/244	0/184	0/160	1/139 (0.7)
腎および尿路障害	11/244 (4.5)	3/174 (1.7)	4/149 (2.7)	2/127 (1.6)
膀胱痙縮	0/244	0/184	1/160 (0.6)	0/138
膀胱結石	0/244	1/184 (0.5)	0/160	0/139
尿路結石	0/244	0/184	1/160 (0.6)	0/138

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
精神障害 (Cont.)				
悪夢	0/123	0/2	0/0	2/244 (0.8)
強迫観念	0/123	0/2	0/0	1/244 (0.4)
パニック発作	0/121	0/2	0/0	3/244 (1.2)
パニック反応	0/122	0/2	0/0	1/244 (0.4)
妄想症	0/121	0/2	0/0	2/244 (0.8)
睡眠の質低下	0/123	0/2	0/0	1/244 (0.4)
処置に対する不安	0/123	0/2	0/0	1/244 (0.4)
精神病性障害	0/119	0/2	0/0	6/244 (2.5)
精神病症状	0/122	0/2	0/0	1/244 (0.4)
レム睡眠行動障害	0/122	0/2	0/0	2/244 (0.8)
レム睡眠異常	0/122	0/2	0/0	1/244 (0.4)
睡眠障害	0/121	0/2	0/0	3/244 (1.2)
ねごと	0/123	0/2	0/0	2/244 (0.8)
常同症	0/122	0/2	0/0	1/244 (0.4)
ストレス	0/123	0/2	0/0	1/244 (0.4)
自殺念慮	0/123	0/2	0/0	3/244 (1.2)
自殺企図	0/122	0/2	0/0	1/244 (0.4)
腎および尿路障害	0/112	0/2	0/0	20/244 (8.2)
膀胱痙縮	0/122	0/2	0/0	1/244 (0.4)
膀胱結石	0/123	0/2	0/0	1/244 (0.4)
尿路結石	0/123	0/2	0/0	1/244 (0.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
腎および尿路障害 (Cont.)				
排尿困難	2/244 (0.8)	0/182	0/158	1/137 (0.7)
緊張性膀胱	0/244	0/184	0/160	1/139 (0.7)
夜間頻尿	0/244	1/184 (0.5)	0/159	0/139
頻尿	1/244 (0.4)	0/183	0/159	0/138
多尿	1/244 (0.4)	0/183	0/159	0/138
腎機能障害	0/244	0/184	1/160 (0.6)	0/139
尿管結石症	1/244 (0.4)	0/184	0/160	0/139
切迫性尿失禁	3/244 (1.2)	0/181	0/158	0/137
尿失禁	2/244 (0.8)	1/182 (0.5)	1/157 (0.6)	1/136 (0.7)
尿閉	0/244	0/184	1/160 (0.6)	2/138 (1.4)
尿路障害	1/244 (0.4)	0/183	0/159	0/138
尿異常	1/244 (0.4)	0/183	0/159	0/138
尿臭異常	0/244	0/184	1/160 (0.6)	0/138
生殖系および乳房障害	3/244 (1.2)	3/182 (1.6)	1/155 (0.6)	0/133
良性前立腺肥大症	0/244	0/184	1/160 (0.6)	0/138
勃起不全	1/244 (0.4)	1/184 (0.5)	0/159	0/138
骨盤痛	0/244	1/184 (0.5)	0/159	0/138
ペイロニー病	1/244 (0.4)	0/183	0/159	0/138
閉経後出血	0/244	1/184 (0.5)	0/159	0/138
前立腺腫大	0/244	1/184 (0.5)	0/159	0/138

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
腎および尿路障害 (Cont.)				
排尿困難	0/121	0/2	0/0	3/244 (1.2)
緊張性膀胱	0/122	0/2	0/0	1/244 (0.4)
夜間頻尿	0/123	0/2	0/0	1/244 (0.4)
頻尿	0/123	0/2	0/0	1/244 (0.4)
多尿	0/122	0/2	0/0	1/244 (0.4)
腎機能障害	0/123	0/2	0/0	1/244 (0.4)
尿管結石症	0/123	0/2	0/0	1/244 (0.4)
切迫性尿失禁	0/121	0/2	0/0	3/244 (1.2)
尿失禁	0/119	0/2	0/0	5/244 (2.0)
尿閉	0/120	0/2	0/0	3/244 (1.2)
尿路障害	0/122	0/2	0/0	1/244 (0.4)
尿異常	0/122	0/2	0/0	1/244 (0.4)
尿臭異常	0/122	0/2	0/0	1/244 (0.4)
生殖系および乳房障害	0/118	0/2	0/0	7/244 (2.9)
良性前立腺肥大症	0/123	0/2	0/0	1/244 (0.4)
勃起不全	0/122	0/2	0/0	2/244 (0.8)
骨盤痛	0/122	0/2	0/0	1/244 (0.4)
ペイロニー病	0/122	0/2	0/0	1/244 (0.4)
閉経後出血	0/122	0/2	0/0	1/244 (0.4)
前立腺腫大	0/122	0/2	0/0	1/244 (0.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
生殖系および乳房障害 (Cont.)				
膣脱	1/244 (0.4)	0/183	0/159	0/138
呼吸器、胸郭および縦隔障害	15/244 (6.1)	6/172 (3.5)	2/145 (1.4)	2/125 (1.6)
急性呼吸不全	1/244 (0.4)	0/183	0/160	0/139
気管支拡張症	0/244	0/184	1/160 (0.6)	0/138
咳嗽	3/244 (1.2)	0/182	0/159	0/138
発声障害	1/244 (0.4)	0/183	1/159 (0.6)	0/137
呼吸困難	5/244 (2.0)	2/179 (1.1)	0/154	0/135
労作性呼吸困難	0/244	1/184 (0.5)	0/159	0/138
鼻出血	0/244	0/184	1/160 (0.6)	0/138
過換気	2/244 (0.8)	0/183	0/159	0/138
口腔咽頭痛	1/244 (0.4)	1/183 (0.5)	0/158	0/137
誤嚥性肺炎	0/244	0/184	0/160	1/139 (0.7)
湿性咳嗽	0/244	0/184	1/160 (0.6)	0/138
肺塞栓症	1/244 (0.4)	0/184	0/160	1/139 (0.7)
ラ音	0/244	1/184 (0.5)	0/159	0/138
呼吸窮迫	0/244	1/184 (0.5)	0/159	0/139
鼻痛	1/244 (0.4)	0/183	0/159	0/138
鼻漏	2/244 (0.8)	0/182	0/158	0/137
咽喉刺激感	1/244 (0.4)	0/183	0/160	0/139

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
生殖系および乳房障害 (Cont.)				
膣脱	0/122	0/2	0/0	1/244 (0.4)
呼吸器、胸郭および縦隔障害	1/110 (0.9)	0/2	0/0	26/244 (10.7)
急性呼吸不全	0/123	0/2	0/0	1/244 (0.4)
気管支拡張症	0/122	0/2	0/0	1/244 (0.4)
咳嗽	0/122	0/2	0/0	3/244 (1.2)
発声障害	0/121	0/2	0/0	2/244 (0.8)
呼吸困難	1/120 (0.8)	0/2	0/0	8/244 (3.3)
労作性呼吸困難	0/122	0/2	0/0	1/244 (0.4)
鼻出血	0/122	0/2	0/0	1/244 (0.4)
過換気	0/122	0/2	0/0	2/244 (0.8)
口腔咽頭痛	0/121	0/2	0/0	2/244 (0.8)
誤嚥性肺炎	0/123	0/2	0/0	1/244 (0.4)
湿性咳嗽	0/122	0/2	0/0	1/244 (0.4)
肺塞栓症	0/122	0/2	0/0	2/244 (0.8)
ラ音	0/123	0/2	0/0	1/244 (0.4)
呼吸窮迫	0/123	0/2	0/0	1/244 (0.4)
鼻痛	0/122	0/2	0/0	1/244 (0.4)
鼻漏	0/121	0/2	0/0	2/244 (0.8)
咽喉刺激感	0/123	0/2	0/0	1/244 (0.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
皮膚および皮下組織障害	22/244 (9.0)	2/165 (1.2)	3/142 (2.1)	3/120 (2.5)
脱毛症	1/244 (0.4)	1/183 (0.5)	0/158	1/137 (0.7)
褥瘡性潰瘍	1/244 (0.4)	0/183	0/159	0/138
皮膚嚢腫	1/244 (0.4)	0/183	0/160	1/139 (0.7)
皮膚炎	1/244 (0.4)	0/183	0/159	0/138
接触皮膚炎	1/244 (0.4)	0/183	0/159	1/138 (0.7)
おむつ皮膚炎	1/244 (0.4)	0/183	0/159	0/138
薬疹	1/244 (0.4)	0/183	0/159	0/138
皮膚乾燥	1/244 (0.4)	1/184 (0.5)	0/159	0/138
斑状出血	1/244 (0.4)	0/183	0/159	0/138
紅斑	4/244 (1.6)	0/180	0/158	0/137
爪の障害	0/244	0/184	1/160 (0.6)	0/138
脂肪織炎	0/244	0/184	1/160 (0.6)	0/138
丘疹	2/244 (0.8)	0/182	0/158	0/138
口囲皮膚炎	0/244	0/184	0/160	1/139 (0.7)
光線過敏性反応	1/244 (0.4)	0/183	0/159	0/139
そう痒症	1/244 (0.4)	0/183	2/159 (1.3)	1/136 (0.7)
乾癬	0/244	1/184 (0.5)	0/159	0/139
発疹	2/244 (0.8)	0/182	1/158 (0.6)	0/136
紅斑性皮疹	1/244 (0.4)	0/183	0/159	0/138
そう痒性皮疹	2/244 (0.8)	0/183	1/159 (0.6)	0/137
皮膚刺激	1/244 (0.4)	0/184	0/160	0/139
皮膚病変	1/244 (0.4)	0/183	0/159	0/139

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
皮膚および皮下組織障害	0/103	0/1	0/0	30/244 (12.3)
脱毛症	0/121	0/1	0/0	3/244 (1.2)
褥瘡性潰瘍	0/122	0/2	0/0	1/244 (0.4)
皮膚嚢腫	0/122	0/2	0/0	2/244 (0.8)
皮膚炎	0/122	0/2	0/0	1/244 (0.4)
接触皮膚炎	0/121	0/2	0/0	2/244 (0.8)
おむつ皮膚炎	0/122	0/2	0/0	1/244 (0.4)
薬疹	0/122	0/2	0/0	1/244 (0.4)
皮膚乾燥	0/122	0/2	0/0	2/244 (0.8)
斑状出血	0/122	0/2	0/0	1/244 (0.4)
紅斑	0/121	0/2	0/0	4/244 (1.6)
爪の障害	0/122	0/2	0/0	1/244 (0.4)
脂肪織炎	0/122	0/2	0/0	1/244 (0.4)
丘疹	0/122	0/2	0/0	2/244 (0.8)
口囲皮膚炎	0/123	0/2	0/0	1/244 (0.4)
光線過敏性反応	0/123	0/2	0/0	1/244 (0.4)
そう痒症	0/119	0/2	0/0	4/244 (1.6)
乾癬	0/123	0/2	0/0	1/244 (0.4)
発疹	0/121	0/2	0/0	3/244 (1.2)
紅斑性皮疹	0/122	0/2	0/0	1/244 (0.4)
そう痒性皮疹	0/121	0/2	0/0	3/244 (1.2)
皮膚刺激	0/123	0/2	0/0	1/244 (0.4)
皮膚病変	0/123	0/2	0/0	1/244 (0.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
皮膚および皮下組織障害 (Cont.)				
皮膚潰瘍	2/244 (0.8)	0/182	0/158	0/137
蕁麻疹	0/244	1/184 (0.5)	1/159 (0.6)	0/137
社会環境	1/244 (0.4)	0/183	0/160	0/139
運動不能	1/244 (0.4)	0/183	0/160	0/139
外科および内科処置	0/244	1/184 (0.5)	0/159	0/138
抜歯	0/244	1/184 (0.5)	0/159	0/138
血管障害	13/244 (5.3)	3/175 (1.7)	5/148 (3.4)	3/124 (2.4)
深部静脈血栓症	1/244 (0.4)	0/184	0/160	0/139
血腫	0/244	0/184	0/160	1/139 (0.7)
出血	0/244	1/184 (0.5)	0/159	0/138
ほてり	1/244 (0.4)	0/184	0/160	0/139
高血圧	4/244 (1.6)	0/181	1/157 (0.6)	1/135 (0.7)
高血圧クリーゼ	1/244 (0.4)	0/184	0/160	0/139
低血圧	3/244 (1.2)	0/181	1/157 (0.6)	1/135 (0.7)
不安定血圧	1/244 (0.4)	0/184	0/160	0/139
起立性高血圧	0/244	0/184	0/160	0/139
起立性低血圧	5/244 (2.0)	2/179 (1.1)	3/153 (2.0)	2/131 (1.5)

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
皮膚および皮下組織障害 (Cont.)				
皮膚潰瘍	0/121	0/2	0/0	2/244 (0.8)
蕁麻疹	0/122	0/2	0/0	2/244 (0.8)
社会環境	0/123	0/2	0/0	1/244 (0.4)
運動不能	0/123	0/2	0/0	1/244 (0.4)
外科および内科処置	0/122	0/2	0/0	1/244 (0.4)
抜歯	0/122	0/2	0/0	1/244 (0.4)
血管障害	3/106 (2.8)	0/1	0/0	27/244 (11.1)
深部静脈血栓症	0/123	0/2	0/0	1/244 (0.4)
血腫	0/122	0/2	0/0	1/244 (0.4)
出血	0/122	0/2	0/0	1/244 (0.4)
ほてり	0/123	0/2	0/0	1/244 (0.4)
高血圧	0/119	0/2	0/0	6/244 (2.5)
高血圧クリーゼ	0/123	0/2	0/0	1/244 (0.4)
低血圧	1/118 (0.8)	0/2	0/0	6/244 (2.5)
不安定血圧	0/123	0/2	0/0	1/244 (0.4)
起立性高血圧	1/123 (0.8)	0/2	0/0	1/244 (0.4)
起立性低血圧	1/113 (0.9)	0/1	0/0	13/244 (5.3)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Low Dose				
Any adverse event	120/132 (90.9)	2/8 (25.0)	0/4	0/4
血液およびリンパ系障害	1/132 (0.8)	0/98	0/86	0/75
リンパ節症	1/132 (0.8)	0/98	0/86	0/75
心臓障害	1/132 (0.8)	2/98 (2.0)	0/85	2/75 (2.7)
急性心筋梗塞	0/132	0/99	0/87	1/76 (1.3)
狭心症	0/132	1/99 (1.0)	0/86	0/75
心停止	0/132	0/99	0/87	1/76 (1.3)
冠動脈疾患	0/132	0/99	0/87	1/76 (1.3)
冠動脈狭窄	0/132	0/99	0/87	1/76 (1.3)
心筋梗塞	1/132 (0.8)	0/98	0/87	0/76
頻脈	0/132	1/99 (1.0)	0/86	0/76
耳および迷路障害	2/132 (1.5)	1/97 (1.0)	1/85 (1.2)	0/74
感音性難聴	0/132	0/99	1/87 (1.1)	0/75
回転性めまい	2/132 (1.5)	1/97 (1.0)	0/85	0/75
眼障害	3/132 (2.3)	2/97 (2.1)	1/83 (1.2)	2/71 (2.8)
白内障	0/132	0/99	1/87 (1.1)	1/75 (1.3)
複視	3/132 (2.3)	0/97	0/85	0/74
ドライアイ	1/132 (0.8)	0/99	0/87	0/76
緑内障	0/132	0/99	0/87	1/76 (1.3)
網膜裂孔	0/132	2/99 (2.0)	0/85	0/74

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Low Dose				
Any adverse event	0/4	0/0	0/0	122/132 (92.4)
血液およびリンパ系障害	0/67	0/2	0/0	1/132 (0.8)
リンパ節症	0/67	0/2	0/0	1/132 (0.8)
心臓障害	0/65	0/2	0/0	5/132 (3.8)
急性心筋梗塞	0/67	0/2	0/0	1/132 (0.8)
狭心症	0/67	0/2	0/0	1/132 (0.8)
心停止	0/67	0/2	0/0	1/132 (0.8)
冠動脈疾患	0/67	0/2	0/0	1/132 (0.8)
冠動脈狭窄	0/67	0/2	0/0	1/132 (0.8)
心筋梗塞	0/68	0/2	0/0	1/132 (0.8)
頻脈	0/68	0/2	0/0	1/132 (0.8)
耳および迷路障害	0/66	0/2	0/0	4/132 (3.0)
感音性難聴	0/67	0/2	0/0	1/132 (0.8)
回転性めまい	0/67	0/2	0/0	3/132 (2.3)
眼障害	0/62	0/2	0/0	8/132 (6.1)
白内障	0/66	0/2	0/0	2/132 (1.5)
複視	0/67	0/2	0/0	3/132 (2.3)
ドライアイ	0/68	0/2	0/0	1/132 (0.8)
緑内障	0/67	0/2	0/0	1/132 (0.8)
網膜裂孔	0/66	0/2	0/0	2/132 (1.5)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Low Dose				
眼障害 (Cont.)				
霧視	1/132 (0.8)	0/99	0/87	0/76
胃腸障害	18/132 (13.6)	7/84 (8.3)	2/67 (3.0)	0/58
腹部膨満	0/132	1/99 (1.0)	0/86	0/76
腹痛	1/132 (0.8)	1/99 (1.0)	0/86	0/76
上腹部痛	0/132	1/99 (1.0)	0/86	0/75
アフタ性潰瘍	1/132 (0.8)	0/98	0/86	0/75
呼気臭	2/132 (1.5)	0/97	0/85	0/74
虚血性大腸炎	0/132	1/99 (1.0)	0/86	0/75
便秘	5/132 (3.8)	2/96 (2.1)	1/83 (1.2)	0/72
齲歯	0/132	0/99	1/87 (1.1)	0/76
下痢	3/132 (2.3)	2/97 (2.1)	1/83 (1.2)	0/73
口内乾燥	3/132 (2.3)	0/96	0/84	0/74
消化不良	1/132 (0.8)	0/98	0/86	0/75
胃食道逆流性疾患	0/132	0/99	1/87 (1.1)	0/75
舌炎	0/132	1/99 (1.0)	0/86	0/76
舌痛	0/132	1/99 (1.0)	0/86	0/76
吐血	0/132	0/99	0/87	1/76 (1.3)
痔核	1/132 (0.8)	0/99	0/87	0/76
裂孔ヘルニア	0/132	0/99	0/87	1/76 (1.3)
胃排出不全	0/132	0/99	0/87	1/76 (1.3)
鼠径ヘルニア	0/132	1/99 (1.0)	0/86	0/75
腸出血	0/132	1/99 (1.0)	0/86	0/75

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Low Dose				
眼障害 (Cont.)				
霧視	0/68	0/2	0/0	1/132 (0.8)
胃腸障害	0/53	0/2	0/0	27/132 (20.5)
腹部膨満	0/68	0/2	0/0	1/132 (0.8)
腹痛	0/68	0/2	0/0	2/132 (1.5)
上腹部痛	0/68	0/2	0/0	1/132 (0.8)
アフタ性潰瘍	0/67	0/2	0/0	1/132 (0.8)
呼気臭	0/66	0/2	0/0	2/132 (1.5)
虚血性大腸炎	0/68	0/2	0/0	1/132 (0.8)
便秘	0/64	0/2	0/0	8/132 (6.1)
齲歯	0/68	0/2	0/0	1/132 (0.8)
下痢	0/66	0/2	0/0	6/132 (4.5)
口内乾燥	0/66	0/2	0/0	3/132 (2.3)
消化不良	0/67	0/2	0/0	1/132 (0.8)
胃食道逆流性疾患	0/67	0/2	0/0	1/132 (0.8)
舌炎	0/68	0/2	0/0	1/132 (0.8)
舌痛	0/68	0/2	0/0	1/132 (0.8)
吐血	0/67	0/2	0/0	1/132 (0.8)
痔核	0/68	0/2	0/0	1/132 (0.8)
裂孔ヘルニア	0/67	0/2	0/0	1/132 (0.8)
胃排出不全	0/67	0/2	0/0	1/132 (0.8)
鼠径ヘルニア	0/68	0/2	0/0	1/132 (0.8)
腸出血	0/68	0/2	0/0	1/132 (0.8)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Low Dose				
胃腸障害 (Cont.)				
過敏性腸症候群	1/132 (0.8)	0/98	0/86	0/75
口唇乾燥	0/132	1/99 (1.0)	0/86	0/75
メレナ	1/132 (0.8)	1/98 (1.0)	0/85	0/75
口腔腫脹	0/132	1/99 (1.0)	0/86	0/76
悪心	5/132 (3.8)	3/94 (3.2)	0/80	0/71
口腔内不快感	0/132	1/99 (1.0)	0/86	0/76
口腔内痛	0/132	0/99	1/87 (1.1)	0/76
口の錯感覚	0/132	0/99	1/87 (1.1)	0/76
嘔吐	2/132 (1.5)	1/97 (1.0)	0/84	0/73
一般・全身障害および投与部位の状態	103/132 (78.0)	0/21	4/18 (22.2)	0/13
投与部位紅斑	1/132 (0.8)	0/99	0/87	0/76
無力症	1/132 (0.8)	1/99 (1.0)	1/86 (1.2)	0/74
カテーテル留置部位紅斑	1/132 (0.8)	0/98	0/86	0/75
カテーテル留置部位漏出	0/132	0/99	1/87 (1.1)	0/75
胸痛	0/132	0/99	0/87	1/76 (1.3)
泣き	0/132	1/99 (1.0)	0/86	0/76
不快感	1/132 (0.8)	0/99	0/87	0/76
薬剤離脱症候群	1/132 (0.8)	0/99	0/87	0/76
疲労	4/132 (3.0)	0/96	1/84 (1.2)	1/74 (1.4)
異常感	1/132 (0.8)	0/98	0/87	0/76
熱感	1/132 (0.8)	0/99	0/87	0/76

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Low Dose				
胃腸障害 (Cont.)				
過敏性腸症候群	0/67	0/2	0/0	1/132 (0.8)
口唇乾燥	0/67	0/2	0/0	1/132 (0.8)
メレナ	0/67	0/2	0/0	2/132 (1.5)
口腔腫脹	0/68	0/2	0/0	1/132 (0.8)
悪心	0/63	0/2	0/0	8/132 (6.1)
口腔内不快感	0/68	0/2	0/0	1/132 (0.8)
口腔内痛	0/68	0/2	0/0	1/132 (0.8)
口の錯感覚	0/68	0/2	0/0	1/132 (0.8)
嘔吐	0/65	0/2	0/0	3/132 (2.3)
一般・全身障害および投与部位の状態	0/11	0/1	0/0	107/132 (81.1)
投与部位紅斑	0/68	0/2	0/0	1/132 (0.8)
無力症	0/66	0/2	0/0	3/132 (2.3)
カテーテル留置部位紅斑	0/67	0/2	0/0	1/132 (0.8)
カテーテル留置部位漏出	0/67	0/2	0/0	1/132 (0.8)
胸痛	0/67	0/2	0/0	1/132 (0.8)
泣き	0/68	0/2	0/0	1/132 (0.8)
不快感	0/68	0/2	0/0	1/132 (0.8)
薬剤離脱症候群	0/68	0/2	0/0	1/132 (0.8)
疲労	0/65	0/2	0/0	6/132 (4.5)
異常感	0/68	0/2	0/0	1/132 (0.8)
熱感	0/68	0/2	0/0	1/132 (0.8)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Low Dose				
一般・全身障害および投与部位の状態 (Cont.)				
歩行不能	1/132 (0.8)	0/98	0/87	0/76
低体温	1/132 (0.8)	0/98	0/86	0/75
インフルエンザ様疾患	1/132 (0.8)	0/98	0/86	0/75
注入部位内出血	7/132 (5.3)	2/93 (2.2)	1/82 (1.2)	0/71
注入部位皮膚炎	1/132 (0.8)	0/98	0/86	1/75 (1.3)
注入部位分泌物	1/132 (0.8)	0/98	0/86	0/75
注入部位変色	2/132 (1.5)	0/97	0/85	0/74
注入部位不快感	2/132 (1.5)	1/97 (1.0)	0/84	0/74
注入部位びらん	1/132 (0.8)	0/98	0/86	0/75
注入部位紅斑	60/132 (45.5)	0/50	3/46 (6.5)	1/39 (2.6)
注入部位皮膚剥脱	2/132 (1.5)	0/97	1/86 (1.2)	0/74
注入部位血管外漏出	6/132 (4.5)	1/94 (1.1)	1/82 (1.2)	0/71
注入部位血腫	5/132 (3.8)	1/95 (1.1)	2/83 (2.4)	2/71 (2.8)
注入部位出血	3/132 (2.3)	1/96 (1.0)	0/83	0/73
注入部位硬結	6/132 (4.5)	0/95	0/86	1/75 (1.3)
注入部位炎症	2/132 (1.5)	0/97	1/85 (1.2)	0/75
注入部位刺激感	0/132	0/99	1/87 (1.1)	0/75
注入部位腫瘤	5/132 (3.8)	0/96	0/85	0/76
注入部位結節	29/132 (22.0)	1/72 (1.4)	3/61 (4.9)	1/48 (2.1)
注入部位浮腫	16/132 (12.1)	1/88 (1.1)	2/76 (2.6)	0/65
注入部位疼痛	14/132 (10.6)	2/89 (2.2)	1/77 (1.3)	1/66 (1.5)

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Low Dose				
一般・全身障害および投与部位の状態 (Cont.)				
歩行不能	0/68	0/2	0/0	1/132 (0.8)
低体温	0/67	0/2	0/0	1/132 (0.8)
インフルエンザ様疾患	0/67	0/2	0/0	1/132 (0.8)
注入部位内出血	0/63	0/1	0/0	10/132 (7.6)
注入部位皮膚炎	0/66	0/2	0/0	2/132 (1.5)
注入部位分泌物	0/67	0/2	0/0	1/132 (0.8)
注入部位変色	0/66	0/2	0/0	2/132 (1.5)
注入部位不快感	0/66	0/2	0/0	3/132 (2.3)
注入部位びらん	0/67	0/2	0/0	1/132 (0.8)
注入部位紅斑	1/35 (2.9)	0/2	0/0	65/132 (49.2)
注入部位皮膚剥脱	0/66	0/2	0/0	3/132 (2.3)
注入部位血管外漏出	0/64	0/2	0/0	8/132 (6.1)
注入部位血腫	0/62	0/2	0/0	10/132 (7.6)
注入部位出血	0/65	0/2	0/0	4/132 (3.0)
注入部位硬結	0/66	0/2	0/0	7/132 (5.3)
注入部位炎症	0/68	0/2	0/0	3/132 (2.3)
注入部位刺激感	0/67	0/2	0/0	1/132 (0.8)
注入部位腫瘤	0/68	0/2	0/0	5/132 (3.8)
注入部位結節	1/39 (2.6)	0/1	0/0	35/132 (26.5)
注入部位浮腫	0/58	0/2	0/0	19/132 (14.4)
注入部位疼痛	0/57	0/2	0/0	18/132 (13.6)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Low Dose				
一般・全身障害および投与部位の状態 (Cont.)				
注入部位蒼白	2/132 (1.5)	1/98 (1.0)	0/86	0/75
注入部位丘疹	2/132 (1.5)	2/98 (2.0)	1/84 (1.2)	0/73
注入部位そう痒感	3/132 (2.3)	1/97 (1.0)	1/84 (1.2)	0/74
注入部位発疹	2/132 (1.5)	1/98 (1.0)	0/85	0/75
注入部位反応	9/132 (6.8)	3/93 (3.2)	1/80 (1.3)	0/69
注入部位腫脹	4/132 (3.0)	0/96	0/85	0/75
注射部位内出血	2/132 (1.5)	0/98	0/86	0/75
注射部位変色	0/132	1/99 (1.0)	0/86	0/75
注射部位紅斑	6/132 (4.5)	0/94	0/82	0/71
注射部位漏出	1/132 (0.8)	0/98	0/86	0/75
注射部位炎症	2/132 (1.5)	0/98	0/86	0/75
注射部位結節	1/132 (0.8)	2/98 (2.0)	0/84	0/73
注射部位浮腫	2/132 (1.5)	0/97	0/86	0/75
注射部位疼痛	2/132 (1.5)	0/97	0/85	0/75
注射部位反応	0/132	0/99	1/87 (1.1)	0/75
注射部位腫脹	1/132 (0.8)	0/99	1/87 (1.1)	0/75
倦怠感	1/132 (0.8)	0/99	0/87	0/76
医療機器使用部位刺激感	1/132 (0.8)	0/98	0/86	0/75
医療機器使用部位そう痒感	1/132 (0.8)	0/98	0/86	0/75
小結節	1/132 (0.8)	0/99	0/87	0/76
末梢性浮腫	4/132 (3.0)	0/95	1/84 (1.2)	0/74

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Low Dose				
一般・全身障害および投与部位の状態 (Cont.)				
注入部位蒼白	0/67	0/2	0/0	3/132 (2.3)
注入部位丘疹	2/65 (3.1)	0/2	0/0	7/132 (5.3)
注入部位そう痒感	0/66	0/2	0/0	5/132 (3.8)
注入部位発疹	0/67	0/2	0/0	3/132 (2.3)
注入部位反応	0/61	0/2	0/0	13/132 (9.8)
注入部位腫脹	0/67	0/2	0/0	4/132 (3.0)
注射部位内出血	0/67	0/2	0/0	2/132 (1.5)
注射部位変色	0/67	0/2	0/0	1/132 (0.8)
注射部位紅斑	0/63	0/2	0/0	6/132 (4.5)
注射部位漏出	0/67	0/2	0/0	1/132 (0.8)
注射部位炎症	0/68	0/2	0/0	2/132 (1.5)
注射部位結節	0/65	0/2	0/0	3/132 (2.3)
注射部位浮腫	0/67	0/2	0/0	2/132 (1.5)
注射部位疼痛	0/67	0/2	0/0	2/132 (1.5)
注射部位反応	0/67	0/2	0/0	1/132 (0.8)
注射部位腫脹	0/67	0/2	0/0	2/132 (1.5)
倦怠感	0/68	0/2	0/0	1/132 (0.8)
医療機器使用部位刺激感	0/67	0/2	0/0	1/132 (0.8)
医療機器使用部位そう痒感	0/67	0/2	0/0	1/132 (0.8)
小結節	0/68	0/2	0/0	1/132 (0.8)
末梢性浮腫	0/66	0/2	0/0	5/132 (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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Low Dose				
一般・全身障害および投与部位の状態 (Cont.)				
疼痛	0/132	1/99 (1.0)	0/86	1/76 (1.3)
穿刺部位内出血	1/132 (0.8)	0/99	0/87	0/76
穿刺部位出血	1/132 (0.8)	0/98	0/86	0/76
穿刺部位硬結	2/132 (1.5)	0/98	0/86	0/75
発熱	2/132 (1.5)	0/98	0/86	0/75
口渇	1/132 (0.8)	0/98	0/86	0/75
血管穿刺部位硬結	1/132 (0.8)	0/99	0/87	0/76
肝胆道系障害	1/132 (0.8)	0/99	0/87	0/76
肝嚢胞	0/132	0/99	0/87	0/76
門脈血栓症	1/132 (0.8)	0/99	0/87	0/76
感染症および寄生虫症	37/132 (28.0)	12/69 (17.4)	5/52 (9.6)	4/39 (10.3)
ボレリア感染	1/132 (0.8)	0/98	0/86	0/75
COVID-19	0/132	0/99	0/87	1/76 (1.3)
COVID-19肺炎	0/132	0/99	1/87 (1.1)	0/75
カテーテル留置部位感染	0/132	0/99	0/87	1/76 (1.3)
蜂巣炎	1/132 (0.8)	0/98	0/86	0/75
結膜炎	1/132 (0.8)	1/98 (1.0)	0/86	0/75
膀胱炎	0/132	0/99	1/87 (1.1)	0/75
真菌感染	1/132 (0.8)	0/99	0/87	0/76

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Low Dose				
一般・全身障害および投与部位の状態 (Cont.)				
疼痛	0/67	0/2	0/0	2/132 (1.5)
穿刺部位内出血	0/68	0/2	0/0	1/132 (0.8)
穿刺部位出血	0/68	0/2	0/0	1/132 (0.8)
穿刺部位硬結	0/67	0/2	0/0	2/132 (1.5)
発熱	0/67	0/2	0/0	2/132 (1.5)
口渇	0/67	0/2	0/0	1/132 (0.8)
血管穿刺部位硬結	0/68	0/2	0/0	1/132 (0.8)
肝胆道系障害	1/68 (1.5)	0/1	0/0	2/132 (1.5)
肝嚢胞	1/68 (1.5)	0/1	0/0	1/132 (0.8)
門脈血栓症	0/68	0/2	0/0	1/132 (0.8)
感染症および寄生虫症	0/35	0/1	0/0	58/132 (43.9)
ボレリア感染	0/68	0/2	0/0	1/132 (0.8)
COVID-19	0/67	0/2	0/0	1/132 (0.8)
COVID-19肺炎	0/68	0/2	0/0	1/132 (0.8)
カテーテル留置部位感染	0/67	0/2	0/0	1/132 (0.8)
蜂巣炎	0/67	0/2	0/0	1/132 (0.8)
結膜炎	0/68	0/2	0/0	2/132 (1.5)
膀胱炎	0/68	0/2	0/0	1/132 (0.8)
真菌感染	0/68	0/2	0/0	1/132 (0.8)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Low Dose				
感染症および寄生虫症 (Cont.)				
歯肉炎	1/132 (0.8)	0/98	0/86	0/75
麦粒腫	0/132	1/99 (1.0)	0/86	0/75
注入部位膿瘍	9/132 (6.8)	1/93 (1.1)	2/82 (2.4)	2/70 (2.9)
注入部位蜂巣炎	19/132 (14.4)	5/84 (6.0)	3/71 (4.2)	2/57 (3.5)
注入部位感染	1/132 (0.8)	3/98 (3.1)	1/84 (1.2)	2/72 (2.8)
上咽頭炎	1/132 (0.8)	2/98 (2.0)	0/84	2/74 (2.7)
肺炎	1/132 (0.8)	0/98	2/86 (2.3)	0/73
術後膿瘍	0/132	0/99	1/87 (1.1)	0/75
膿疱性皮疹	1/132 (0.8)	0/99	0/87	0/76
敗血症	2/132 (1.5)	0/97	0/86	1/75 (1.3)
敗血症性ショック	1/132 (0.8)	0/98	0/86	0/75
副鼻腔炎	1/132 (0.8)	0/98	0/86	0/76
ブドウ球菌感染	0/132	0/99	0/87	1/76 (1.3)
歯感染	1/132 (0.8)	0/98	0/86	0/76
上気道感染	1/132 (0.8)	0/98	0/86	0/75
尿路感染	4/132 (3.0)	2/95 (2.1)	1/83 (1.2)	1/71 (1.4)
水痘帯状疱疹ウイルス感染	0/132	1/99 (1.0)	0/86	0/75
傷害、中毒および処置合併症	13/132 (9.8)	5/89 (5.6)	2/74 (2.7)	1/64 (1.6)
骨挫傷	0/132	0/99	0/87	1/76 (1.3)
脳挫傷	1/132 (0.8)	0/98	0/86	0/76
挫傷	1/132 (0.8)	1/98 (1.0)	0/85	0/74

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Low Dose				
感染症および寄生虫症 (Cont.)				
歯肉炎	0/67	0/2	0/0	1/132 (0.8)
麦粒腫	0/68	0/2	0/0	1/132 (0.8)
注入部位膿瘍	0/65	0/2	0/0	14/132 (10.6)
注入部位蜂巣炎	0/47	0/1	0/0	29/132 (22.0)
注入部位感染	0/63	0/2	0/0	7/132 (5.3)
上咽頭炎	0/65	0/2	0/0	5/132 (3.8)
肺炎	0/66	0/2	0/0	3/132 (2.3)
術後膿瘍	0/67	0/2	0/0	1/132 (0.8)
膿疱性皮疹	0/68	0/2	0/0	1/132 (0.8)
敗血症	0/66	0/2	0/0	3/132 (2.3)
敗血症性ショック	0/67	0/2	0/0	1/132 (0.8)
副鼻腔炎	0/68	0/2	0/0	1/132 (0.8)
ブドウ球菌感染	0/67	0/2	0/0	1/132 (0.8)
歯感染	0/68	0/2	0/0	1/132 (0.8)
上気道感染	0/67	0/2	0/0	1/132 (0.8)
尿路感染	0/63	0/2	0/0	8/132 (6.1)
水痘帯状疱疹ウイルス感染	0/67	0/2	0/0	1/132 (0.8)
傷害、中毒および処置合併症	0/55	0/2	0/0	21/132 (15.9)
骨挫傷	0/67	0/2	0/0	1/132 (0.8)
脳挫傷	0/68	0/2	0/0	1/132 (0.8)
挫傷	0/66	0/2	0/0	2/132 (1.5)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Low Dose				
傷害、中毒および処置合併症 (Cont.)				
医療機器設置の問題	1/132 (0.8)	0/98	0/86	0/75
医療機器による投与の欠落	1/132 (0.8)	0/99	0/87	0/76
期限切れの製品使用	1/132 (0.8)	0/98	0/87	0/76
転倒	9/132 (6.8)	5/92 (5.4)	1/76 (1.3)	1/67 (1.5)
頭部損傷	1/132 (0.8)	1/98 (1.0)	0/86	0/75
注入に伴う反応	1/132 (0.8)	0/99	0/87	0/76
靭帯捻挫	0/132	1/99 (1.0)	0/86	0/75
処置後挫傷	1/132 (0.8)	0/98	0/86	0/75
肋骨骨折	0/132	1/99 (1.0)	0/86	0/75
皮膚擦過傷	1/132 (0.8)	0/98	0/86	0/75
皮膚損傷	1/132 (0.8)	0/98	0/86	0/76
皮膚裂傷	0/132	1/99 (1.0)	0/86	0/75
ストレス骨折	0/132	0/99	1/87 (1.1)	0/75
腱断裂	0/132	0/99	0/87	1/76 (1.3)
創傷	0/132	0/99	0/87	1/76 (1.3)
臨床検査	15/132 (11.4)	2/87 (2.3)	4/74 (5.4)	2/62 (3.2)
血中クレアチンホスホキナーゼ増加	1/132 (0.8)	0/99	0/87	0/76
血中葉酸減少	1/132 (0.8)	0/98	0/86	0/75
血中ホモシステイン増加	0/132	0/99	0/87	0/76
血圧上昇	1/132 (0.8)	0/98	0/86	0/76

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Low Dose				
傷害、中毒および処置合併症 (Cont.)				
医療機器設置の問題	0/67	0/2	0/0	1/132 (0.8)
医療機器による投与の欠落	0/68	0/2	0/0	1/132 (0.8)
期限切れの製品使用	0/68	0/2	0/0	1/132 (0.8)
転倒	0/58	0/2	0/0	16/132 (12.1)
頭部損傷	0/67	0/2	0/0	2/132 (1.5)
注入に伴う反応	0/68	0/2	0/0	1/132 (0.8)
靭帯捻挫	0/67	0/2	0/0	1/132 (0.8)
処置後挫傷	0/67	0/2	0/0	1/132 (0.8)
肋骨骨折	0/67	0/2	0/0	1/132 (0.8)
皮膚擦過傷	0/67	0/2	0/0	1/132 (0.8)
皮膚損傷	0/68	0/2	0/0	1/132 (0.8)
皮膚裂傷	0/67	0/2	0/0	1/132 (0.8)
ストレス骨折	0/67	0/2	0/0	1/132 (0.8)
腱断裂	0/67	0/2	0/0	1/132 (0.8)
創傷	0/67	0/2	0/0	1/132 (0.8)
臨床検査	1/53 (1.9)	0/2	0/0	24/132 (18.2)
血中クレアチンホスホキナーゼ増加	0/68	0/2	0/0	1/132 (0.8)
血中葉酸減少	0/67	0/2	0/0	1/132 (0.8)
血中ホモシステイン増加	1/68 (1.5)	0/2	0/0	1/132 (0.8)
血圧上昇	0/68	0/2	0/0	1/132 (0.8)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Low Dose				
臨床検査 (Cont.)				
起立血圧低下	1/132 (0.8)	0/98	0/86	0/75
血中ナトリウム減少	1/132 (0.8)	0/98	0/86	0/75
心雑音	0/132	0/99	1/87 (1.1)	0/75
握力低下	1/132 (0.8)	0/98	0/86	0/75
ヘモグロビン減少	1/132 (0.8)	0/98	0/87	0/76
ビタミンB12減少	1/132 (0.8)	0/99	0/87	0/76
ビタミンB6減少	4/132 (3.0)	0/95	1/83 (1.2)	0/72
体重減少	4/132 (3.0)	1/96 (1.0)	3/84 (3.6)	2/71 (2.8)
体重増加	1/132 (0.8)	1/98 (1.0)	0/85	0/74
代謝および栄養障害	4/132 (3.0)	3/95 (3.2)	2/80 (2.5)	2/67 (3.0)
悪液質	0/132	0/99	1/87 (1.1)	0/75
食欲減退	1/132 (0.8)	1/98 (1.0)	1/85 (1.2)	0/73
脱水	0/132	1/99 (1.0)	0/86	0/75
体液貯留	1/132 (0.8)	0/98	0/86	0/75
葉酸欠乏	0/132	0/99	1/87 (1.1)	0/75
低ナトリウム血症	0/132	1/99 (1.0)	0/86	1/75 (1.3)
ビタミンB群欠乏	1/132 (0.8)	0/98	0/86	0/75
ビタミンB6欠乏	1/132 (0.8)	0/98	1/86 (1.2)	1/74 (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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Low Dose				
臨床検査 (Cont.)				
起立血圧低下	0/67	0/2	0/0	1/132 (0.8)
血中ナトリウム減少	0/67	0/2	0/0	1/132 (0.8)
心雑音	0/68	0/2	0/0	1/132 (0.8)
握力低下	0/67	0/2	0/0	1/132 (0.8)
ヘモグロビン減少	0/68	0/2	0/0	1/132 (0.8)
ビタミンB12減少	0/68	0/2	0/0	1/132 (0.8)
ビタミンB6減少	0/64	0/2	0/0	5/132 (3.8)
体重減少	0/61	0/2	0/0	10/132 (7.6)
体重増加	0/66	0/2	0/0	2/132 (1.5)
代謝および栄養障害	0/58	0/2	0/0	11/132 (8.3)
悪液質	0/67	0/2	0/0	1/132 (0.8)
食欲減退	0/65	0/2	0/0	3/132 (2.3)
脱水	0/67	0/2	0/0	1/132 (0.8)
体液貯留	0/67	0/2	0/0	1/132 (0.8)
葉酸欠乏	0/67	0/2	0/0	1/132 (0.8)
低ナトリウム血症	0/67	0/2	0/0	2/132 (1.5)
ビタミンB群欠乏	0/67	0/2	0/0	1/132 (0.8)
ビタミンB6欠乏	0/65	0/2	0/0	3/132 (2.3)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Low Dose				
筋骨格系および結合組織障害	14/132 (10.6)	4/88 (4.5)	4/74 (5.4)	2/62 (3.2)
関節痛	2/132 (1.5)	0/98	1/86 (1.2)	0/74
反応性関節炎	0/132	0/99	1/87 (1.1)	0/75
背部痛	4/132 (3.0)	1/95 (1.1)	2/82 (2.4)	1/70 (1.4)
滑液包炎	1/132 (0.8)	0/98	1/86 (1.2)	0/74
椎間板変性症	0/132	1/99 (1.0)	0/86	0/75
筋痙縮	0/132	2/99 (2.0)	0/85	0/74
筋力低下	3/132 (2.3)	1/97 (1.0)	0/85	0/75
筋肉痛	2/132 (1.5)	0/97	0/85	0/74
頚部痛	0/132	0/99	2/87 (2.3)	0/74
変形性関節症	1/132 (0.8)	0/98	0/86	0/75
骨減少症	0/132	1/99 (1.0)	0/86	0/75
四肢痛	2/132 (1.5)	0/97	0/86	1/76 (1.3)
横紋筋融解症	1/132 (0.8)	0/99	0/87	1/76 (1.3)
仙腸関節機能障害	1/132 (0.8)	0/98	0/86	0/75
変形性脊椎症	0/132	1/99 (1.0)	0/86	0/75
腱炎	1/132 (0.8)	0/98	0/86	0/75
弾発指	0/132	0/99	1/87 (1.1)	0/75
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）	0/132	1/99 (1.0)	0/86	0/75
直腸腺癌	0/132	1/99 (1.0)	0/86	0/75

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Low Dose				
筋骨格系および結合組織障害	0/53	0/2	0/0	24/132 (18.2)
関節痛	0/66	0/2	0/0	3/132 (2.3)
反応性関節炎	0/68	0/2	0/0	1/132 (0.8)
背部痛	0/61	0/2	0/0	8/132 (6.1)
滑液包炎	0/67	0/2	0/0	2/132 (1.5)
椎間板変性症	0/67	0/2	0/0	1/132 (0.8)
筋痙縮	0/66	0/2	0/0	2/132 (1.5)
筋力低下	0/67	0/2	0/0	4/132 (3.0)
筋肉痛	0/66	0/2	0/0	2/132 (1.5)
頚部痛	0/66	0/2	0/0	2/132 (1.5)
変形性関節症	0/67	0/2	0/0	1/132 (0.8)
骨減少症	0/67	0/2	0/0	1/132 (0.8)
四肢痛	0/67	0/2	0/0	3/132 (2.3)
横紋筋融解症	0/67	0/2	0/0	2/132 (1.5)
仙腸関節機能障害	0/67	0/2	0/0	1/132 (0.8)
変形性脊椎症	0/67	0/2	0/0	1/132 (0.8)
腱炎	0/67	0/2	0/0	1/132 (0.8)
弾発指	0/67	0/2	0/0	1/132 (0.8)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0/68	0/2	0/0	1/132 (0.8)
直腸腺癌	0/68	0/2	0/0	1/132 (0.8)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Low Dose				
神経系障害	47/132 (35.6)	7/69 (10.1)	4/57 (7.0)	3/46 (6.5)
アカシジア	0/132	0/99	0/87	1/76 (1.3)
健忘	0/132	0/99	0/87	0/76
運動失調	1/132 (0.8)	0/98	0/86	0/75
運動緩慢	1/132 (0.8)	0/99	0/87	0/76
認知障害	2/132 (1.5)	0/97	0/86	1/75 (1.3)
振動覚低下	0/132	1/99 (1.0)	0/86	0/75
浮動性めまい	13/132 (9.8)	2/90 (2.2)	0/78	0/70
体位性めまい	3/132 (2.3)	2/97 (2.1)	0/83	0/73
味覚不全	2/132 (1.5)	0/98	0/86	0/75
ジスキネジア	8/132 (6.1)	3/96 (3.1)	0/82	1/71 (1.4)
起立障害	1/132 (0.8)	0/98	0/87	0/76
ジストニア	2/132 (1.5)	0/97	0/85	0/75
伸展性足底反応	1/132 (0.8)	0/98	0/86	0/75
すくみ現象	4/132 (3.0)	0/97	0/86	0/75
頭部不快感	1/132 (0.8)	0/99	0/87	0/76
頭痛	5/132 (3.8)	1/95 (1.1)	1/84 (1.2)	0/74
感覚鈍麻	0/132	0/99	1/87 (1.1)	0/75
反射減弱	0/132	0/99	1/87 (1.1)	0/75
不規則睡眠覚醒リズム障害	0/132	0/99	1/87 (1.1)	0/75
嗜眠	0/132	1/99 (1.0)	0/86	0/76
意識消失	0/132	1/99 (1.0)	0/87	0/76
代謝性脳症	0/132	0/99	1/87 (1.1)	0/75

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Low Dose				
神経系障害	1/37 (2.7)	0/1	0/0	62/132 (47.0)
アカシジア	0/67	0/2	0/0	1/132 (0.8)
健忘	1/68 (1.5)	0/2	0/0	1/132 (0.8)
運動失調	0/68	0/2	0/0	1/132 (0.8)
運動緩慢	0/68	0/2	0/0	1/132 (0.8)
認知障害	1/66 (1.5)	0/2	0/0	4/132 (3.0)
振動覚低下	0/67	0/2	0/0	1/132 (0.8)
浮動性めまい	0/62	0/2	0/0	15/132 (11.4)
体位性めまい	0/65	0/2	0/0	5/132 (3.8)
味覚不全	0/67	0/2	0/0	2/132 (1.5)
ジスキネジア	0/63	0/2	0/0	12/132 (9.1)
起立障害	0/68	0/2	0/0	1/132 (0.8)
ジストニア	0/67	0/2	0/0	2/132 (1.5)
伸展性足底反応	0/67	0/2	0/0	1/132 (0.8)
すくみ現象	0/67	0/2	0/0	4/132 (3.0)
頭部不快感	0/68	0/2	0/0	1/132 (0.8)
頭痛	0/66	0/2	0/0	7/132 (5.3)
感覚鈍麻	0/67	0/2	0/0	1/132 (0.8)
反射減弱	1/67 (1.5)	0/2	0/0	2/132 (1.5)
不規則睡眠覚醒リズム障害	0/67	0/2	0/0	1/132 (0.8)
嗜眠	0/68	0/2	0/0	1/132 (0.8)
意識消失	0/68	0/2	0/0	1/132 (0.8)
代謝性脳症	0/67	0/2	0/0	1/132 (0.8)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Low Dose				
神経系障害 (Cont.)				
末梢性ニューロパチー	0/132	0/99	0/87	1/76 (1.3)
オンオフ現象	4/132 (3.0)	0/98	0/86	0/75
錯感覚	2/132 (1.5)	1/99 (1.0)	0/86	1/75 (1.3)
パーキンソン病	8/132 (6.1)	3/94 (3.2)	1/80 (1.3)	0/70
側反弓	0/132	0/99	0/87	1/76 (1.3)
精神運動亢進	1/132 (0.8)	0/99	0/87	0/76
睡眠時麻痺	0/132	1/99 (1.0)	0/86	0/75
傾眠	6/132 (4.5)	2/93 (2.2)	0/80	1/71 (1.4)
振戦	0/132	1/99 (1.0)	0/86	0/76
製品の問題	2/132 (1.5)	0/97	0/86	0/75
医療機器送達システムの問題	1/132 (0.8)	0/98	0/87	0/76
医療機器位置異常	1/132 (0.8)	0/98	0/86	0/75
精神障害	45/132 (34.1)	2/64 (3.1)	3/55 (5.5)	1/45 (2.2)
感情不安定	1/132 (0.8)	0/99	0/87	0/76
不安	7/132 (5.3)	2/93 (2.2)	1/82 (1.2)	1/71 (1.4)
無感情	0/132	1/99 (1.0)	0/86	0/76
歯ぎしり	2/132 (1.5)	0/97	0/86	0/75
強迫性性行動	0/132	0/99	1/87 (1.1)	0/75
錯乱状態	4/132 (3.0)	0/95	0/83	0/72
譫妄	1/132 (0.8)	0/98	0/86	0/75
妄想	6/132 (4.5)	0/94	2/83 (2.4)	0/71

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Low Dose				
神経系障害 (Cont.)				
末梢性ニューロパチー	0/67	0/2	0/0	1/132 (0.8)
オンオフ現象	0/67	0/2	0/0	4/132 (3.0)
錯感覚	0/66	0/1	0/0	4/132 (3.0)
パーキンソン病	0/62	0/2	0/0	12/132 (9.1)
側反弓	0/67	0/2	0/0	1/132 (0.8)
精神運動亢進	0/68	0/2	0/0	1/132 (0.8)
睡眠時麻痺	0/67	0/2	0/0	1/132 (0.8)
傾眠	0/62	0/2	0/0	9/132 (6.8)
振戦	0/68	0/2	0/0	1/132 (0.8)
製品の問題	0/67	0/2	0/0	2/132 (1.5)
医療機器送達システムの問題	0/68	0/2	0/0	1/132 (0.8)
医療機器位置異常	0/67	0/2	0/0	1/132 (0.8)
精神障害	0/41	0/1	0/0	51/132 (38.6)
感情不安定	0/68	0/2	0/0	1/132 (0.8)
不安	0/63	0/2	0/0	11/132 (8.3)
無感情	0/68	0/2	0/0	1/132 (0.8)
歯ぎしり	0/67	0/2	0/0	2/132 (1.5)
強迫性性行動	0/67	0/2	0/0	1/132 (0.8)
錯乱状態	0/64	0/2	0/0	4/132 (3.0)
譫妄	0/67	0/2	0/0	1/132 (0.8)
妄想	0/64	0/2	0/0	8/132 (6.1)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Low Dose				
精神障害 (Cont.)				
寄生虫妄想	0/132	1/99 (1.0)	0/86	0/76
抑うつ気分	1/132 (0.8)	1/98 (1.0)	0/85	0/75
うつ病	1/132 (0.8)	1/98 (1.0)	1/86 (1.2)	0/74
抑うつ症状	2/132 (1.5)	0/98	0/86	0/75
ドーパミン調節障害症候群	0/132	0/99	0/87	1/76 (1.3)
睡眠異常	1/132 (0.8)	0/98	0/86	0/75
情動障害	0/132	1/99 (1.0)	0/86	0/76
幻覚	17/132 (12.9)	1/88 (1.1)	1/77 (1.3)	1/66 (1.5)
幻聴	1/132 (0.8)	1/98 (1.0)	0/85	1/74 (1.4)
幻視	6/132 (4.5)	2/94 (2.1)	2/81 (2.5)	0/70
混合性幻覚	1/132 (0.8)	0/98	0/86	0/75
性欲過剰	1/132 (0.8)	0/98	0/86	0/75
錯覚	1/132 (0.8)	0/98	0/86	0/75
不眠症	9/132 (6.8)	0/91	0/80	0/70
易刺激性	1/132 (0.8)	0/98	0/87	0/76
嫉妬妄想	1/132 (0.8)	0/98	0/86	0/75
気分変化	1/132 (0.8)	0/98	0/86	0/75
悪夢	0/132	1/99 (1.0)	0/86	0/76
強迫観念	1/132 (0.8)	0/98	0/87	0/76
妄想症	0/132	1/99 (1.0)	1/86 (1.2)	0/74
睡眠の質低下	0/132	1/99 (1.0)	0/86	0/76
精神病性障害	3/132 (2.3)	0/96	1/85 (1.2)	0/73
精神病症状	0/132	0/99	0/87	1/76 (1.3)

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Low Dose				
精神障害 (Cont.)				
寄生虫妄想	0/68	0/2	0/0	1/132 (0.8)
抑うつ気分	0/67	0/2	0/0	2/132 (1.5)
うつ病	0/67	0/2	0/0	3/132 (2.3)
抑うつ症状	0/67	0/2	0/0	2/132 (1.5)
ドーパミン調節障害症候群	0/67	0/2	0/0	1/132 (0.8)
睡眠異常	0/67	0/2	0/0	1/132 (0.8)
情動障害	0/68	0/2	0/0	1/132 (0.8)
幻覚	0/59	0/2	0/0	20/132 (15.2)
幻聴	0/65	0/2	0/0	3/132 (2.3)
幻視	0/63	0/2	0/0	10/132 (7.6)
混合性幻覚	0/67	0/2	0/0	1/132 (0.8)
性欲過剰	0/67	0/2	0/0	1/132 (0.8)
錯覚	0/68	0/2	0/0	1/132 (0.8)
不眠症	0/62	0/1	0/0	9/132 (6.8)
易刺激性	0/68	0/2	0/0	1/132 (0.8)
嫉妬妄想	0/67	0/2	0/0	1/132 (0.8)
気分変化	0/67	0/2	0/0	1/132 (0.8)
悪夢	0/68	0/2	0/0	1/132 (0.8)
強迫観念	0/68	0/2	0/0	1/132 (0.8)
妄想症	0/66	0/2	0/0	2/132 (1.5)
睡眠の質低下	0/68	0/2	0/0	1/132 (0.8)
精神病性障害	0/65	0/2	0/0	4/132 (3.0)
精神病症状	0/67	0/2	0/0	1/132 (0.8)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Low Dose				
精神障害 (Cont.)				
レム睡眠行動障害	1/132 (0.8)	0/99	0/87	0/76
レム睡眠異常	1/132 (0.8)	0/98	0/86	0/75
睡眠障害	1/132 (0.8)	1/98 (1.0)	0/85	0/75
ねごと	0/132	1/99 (1.0)	0/86	0/76
自殺念慮	0/132	1/99 (1.0)	0/87	0/76
自殺企図	0/132	0/99	0/87	1/76 (1.3)
腎および尿路障害	8/132 (6.1)	2/91 (2.2)	2/79 (2.5)	1/67 (1.5)
膀胱痙縮	0/132	0/99	1/87 (1.1)	0/75
膀胱結石	0/132	1/99 (1.0)	0/87	0/76
尿路結石	0/132	0/99	1/87 (1.1)	0/75
排尿困難	1/132 (0.8)	0/98	0/86	0/75
緊張性膀胱	0/132	0/99	0/87	1/76 (1.3)
頻尿	1/132 (0.8)	0/98	0/86	0/75
切迫性尿失禁	3/132 (2.3)	0/96	0/85	0/74
尿失禁	2/132 (1.5)	1/97 (1.0)	0/84	0/74
尿路障害	1/132 (0.8)	0/98	0/86	0/75
生殖系および乳房障害	0/132	1/99 (1.0)	1/86 (1.2)	0/74
良性前立腺肥大症	0/132	0/99	1/87 (1.1)	0/75

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Low Dose				
精神障害 (Cont.)				
レム睡眠行動障害	0/68	0/2	0/0	1/132 (0.8)
レム睡眠異常	0/67	0/2	0/0	1/132 (0.8)
睡眠障害	0/67	0/2	0/0	2/132 (1.5)
ねごと	0/68	0/2	0/0	1/132 (0.8)
自殺念慮	0/68	0/2	0/0	1/132 (0.8)
自殺企図	0/67	0/2	0/0	1/132 (0.8)
腎および尿路障害	0/61	0/2	0/0	13/132 (9.8)
膀胱痙縮	0/67	0/2	0/0	1/132 (0.8)
膀胱結石	0/68	0/2	0/0	1/132 (0.8)
尿路結石	0/68	0/2	0/0	1/132 (0.8)
排尿困難	0/68	0/2	0/0	1/132 (0.8)
緊張性膀胱	0/67	0/2	0/0	1/132 (0.8)
頻尿	0/68	0/2	0/0	1/132 (0.8)
切迫性尿失禁	0/66	0/2	0/0	3/132 (2.3)
尿失禁	0/66	0/2	0/0	3/132 (2.3)
尿路障害	0/67	0/2	0/0	1/132 (0.8)
生殖系および乳房障害	0/67	0/2	0/0	2/132 (1.5)
良性前立腺肥大症	0/68	0/2	0/0	1/132 (0.8)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Low Dose				
生殖系および乳房障害 (Cont.)				
勃起不全	0/132	1/99 (1.0)	0/86	0/75
呼吸器、胸郭および縦隔障害	2/132 (1.5)	3/98 (3.1)	1/83 (1.2)	0/73
気管支拡張症	0/132	0/99	1/87 (1.1)	0/75
咳嗽	1/132 (0.8)	0/99	0/87	0/76
呼吸困難	1/132 (0.8)	0/98	0/86	0/76
労作性呼吸困難	0/132	1/99 (1.0)	0/86	0/75
口腔咽頭痛	0/132	1/99 (1.0)	0/86	0/75
呼吸窮迫	0/132	1/99 (1.0)	0/86	0/76
皮膚および皮下組織障害	10/132 (7.6)	2/90 (2.2)	1/77 (1.3)	1/65 (1.5)
脱毛症	1/132 (0.8)	1/98 (1.0)	0/85	0/74
皮膚嚢腫	1/132 (0.8)	0/98	0/87	0/76
接触皮膚炎	1/132 (0.8)	0/98	0/86	1/75 (1.3)
おむつ皮膚炎	1/132 (0.8)	0/98	0/86	0/75
薬疹	1/132 (0.8)	0/98	0/86	0/75
皮膚乾燥	0/132	1/99 (1.0)	0/86	0/75
斑状出血	1/132 (0.8)	0/98	0/86	0/75
紅斑	1/132 (0.8)	0/98	0/86	0/75
爪の障害	0/132	0/99	1/87 (1.1)	0/75

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Low Dose				
生殖系および乳房障害 (Cont.)				
勃起不全	0/67	0/2	0/0	1/132 (0.8)
呼吸器、胸郭および縦隔障害	1/65 (1.5)	0/2	0/0	7/132 (5.3)
気管支拡張症	0/67	0/2	0/0	1/132 (0.8)
咳嗽	0/68	0/2	0/0	1/132 (0.8)
呼吸困難	1/68 (1.5)	0/2	0/0	2/132 (1.5)
労作性呼吸困難	0/67	0/2	0/0	1/132 (0.8)
口腔咽頭痛	0/67	0/2	0/0	1/132 (0.8)
呼吸窮迫	0/68	0/2	0/0	1/132 (0.8)
皮膚および皮下組織障害	0/57	0/1	0/0	14/132 (10.6)
脱毛症	0/66	0/1	0/0	2/132 (1.5)
皮膚嚢腫	0/68	0/2	0/0	1/132 (0.8)
接触皮膚炎	0/66	0/2	0/0	2/132 (1.5)
おむつ皮膚炎	0/67	0/2	0/0	1/132 (0.8)
薬疹	0/67	0/2	0/0	1/132 (0.8)
皮膚乾燥	0/67	0/2	0/0	1/132 (0.8)
斑状出血	0/67	0/2	0/0	1/132 (0.8)
紅斑	0/67	0/2	0/0	1/132 (0.8)
爪の障害	0/67	0/2	0/0	1/132 (0.8)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Low Dose				
皮膚および皮下組織障害 (Cont.)				
そう痒症	0/132	0/99	1/87 (1.1)	1/75 (1.3)
発疹	1/132 (0.8)	0/98	1/86 (1.2)	0/74
そう痒性皮疹	1/132 (0.8)	0/99	1/87 (1.1)	0/75
皮膚潰瘍	1/132 (0.8)	0/98	0/86	0/75
蕁麻疹	0/132	1/99 (1.0)	1/86 (1.2)	0/74
社会環境	1/132 (0.8)	0/98	0/87	0/76
運動不能	1/132 (0.8)	0/98	0/87	0/76
血管障害	5/132 (3.8)	1/95 (1.1)	3/82 (3.7)	2/69 (2.9)
高血圧	2/132 (1.5)	0/97	1/85 (1.2)	0/73
高血圧クリーゼ	1/132 (0.8)	0/99	0/87	0/76
低血圧	1/132 (0.8)	0/98	0/86	1/75 (1.3)
起立性低血圧	1/132 (0.8)	1/98 (1.0)	2/85 (2.4)	2/73 (2.7)

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Low Dose				
皮膚および皮下組織障害 (Cont.)				
そう痒症	0/66	0/2	0/0	2/132 (1.5)
発疹	0/67	0/2	0/0	2/132 (1.5)
そう痒性皮疹	0/67	0/2	0/0	2/132 (1.5)
皮膚潰瘍	0/67	0/2	0/0	1/132 (0.8)
蕁麻疹	0/67	0/2	0/0	2/132 (1.5)
社会環境	0/68	0/2	0/0	1/132 (0.8)
運動不能	0/68	0/2	0/0	1/132 (0.8)
血管障害	1/60 (1.7)	0/1	0/0	12/132 (9.1)
高血圧	0/66	0/2	0/0	3/132 (2.3)
高血圧クリーゼ	0/68	0/2	0/0	1/132 (0.8)
低血圧	0/66	0/2	0/0	2/132 (1.5)
起立性低血圧	1/63 (1.6)	0/1	0/0	7/132 (5.3)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
Any adverse event	105/112 (93.8)	1/5 (20.0)	1/4 (25.0)	1/3 (33.3)
血液およびリンパ系障害	1/112 (0.9)	1/85 (1.2)	0/72	1/62 (1.6)
大球性貧血	0/112	0/85	0/73	1/63 (1.6)
凝血異常	1/112 (0.9)	0/85	0/73	0/63
縦隔リンパ節腫脹	0/112	1/85 (1.2)	0/72	0/62
心臓障害	4/112 (3.6)	1/83 (1.2)	3/71 (4.2)	0/58
心房細動	0/112	0/85	2/73 (2.7)	0/61
徐脈	1/112 (0.9)	0/84	0/72	0/62
心肺停止	0/112	1/85 (1.2)	0/73	0/63
冠動脈疾患	0/112	0/85	1/73 (1.4)	0/62
期外収縮	1/112 (0.9)	0/84	0/72	0/62
左室肥大	1/112 (0.9)	0/85	0/73	0/63
動悸	1/112 (0.9)	0/85	1/73 (1.4)	0/62
耳および迷路障害	4/112 (3.6)	0/82	0/70	0/60
乗物酔い	1/112 (0.9)	0/84	0/72	0/62
回転性めまい	2/112 (1.8)	0/84	0/72	0/62
頭位性回転性めまい	1/112 (0.9)	0/84	0/72	0/62
眼障害	3/112 (2.7)	4/83 (4.8)	1/67 (1.5)	0/59
白内障	1/112 (0.9)	0/84	1/72 (1.4)	0/61
複視	1/112 (0.9)	0/85	0/73	0/63

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
Any adverse event	0/2	0/0	0/0	108/112 (96.4)
血液およびリンパ系障害	0/53	0/0	0/0	3/112 (2.7)
大球性貧血	0/54	0/0	0/0	1/112 (0.9)
凝血異常	0/55	0/0	0/0	1/112 (0.9)
縦隔リンパ節腫脹	0/54	0/0	0/0	1/112 (0.9)
心臓障害	0/51	0/0	0/0	8/112 (7.1)
心房細動	0/54	0/0	0/0	2/112 (1.8)
徐脈	0/54	0/0	0/0	1/112 (0.9)
心肺停止	0/55	0/0	0/0	1/112 (0.9)
冠動脈疾患	0/54	0/0	0/0	1/112 (0.9)
期外収縮	0/54	0/0	0/0	1/112 (0.9)
左室肥大	0/55	0/0	0/0	1/112 (0.9)
動悸	0/54	0/0	0/0	2/112 (1.8)
耳および迷路障害	0/53	0/0	0/0	4/112 (3.6)
乗物酔い	0/54	0/0	0/0	1/112 (0.9)
回転性めまい	0/54	0/0	0/0	2/112 (1.8)
頭位性回転性めまい	0/55	0/0	0/0	1/112 (0.9)
眼障害	0/51	0/0	0/0	8/112 (7.1)
白内障	0/53	0/0	0/0	2/112 (1.8)
複視	0/55	0/0	0/0	1/112 (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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
眼障害 (Cont.)				
ドライアイ	1/112 (0.9)	1/84 (1.2)	1/71 (1.4)	0/61
緑内障	0/112	1/85 (1.2)	0/72	0/62
眼窩周囲痛	0/112	1/85 (1.2)	0/72	0/62
眼窩周囲腫脹	1/112 (0.9)	1/84 (1.2)	0/71	0/62
視野欠損	0/112	1/85 (1.2)	0/72	0/63
胃腸障害	23/112 (20.5)	1/68 (1.5)	3/58 (5.2)	2/47 (4.3)
腹部膨満	3/112 (2.7)	0/82	0/70	0/61
腹痛	0/112	0/85	0/73	1/63 (1.6)
上腹部痛	1/112 (0.9)	0/85	0/73	0/63
呼気臭	1/112 (0.9)	0/84	0/73	0/63
便秘	6/112 (5.4)	4/81 (4.9)	1/66 (1.5)	1/56 (1.8)
下痢	2/112 (1.8)	0/83	1/71 (1.4)	0/61
口内乾燥	5/112 (4.5)	0/80	0/70	0/60
嚥下障害	1/112 (0.9)	0/84	0/72	0/62
糞塊	1/112 (0.9)	0/85	0/73	0/63
排便回数増加	0/112	1/85 (1.2)	0/72	0/62
胃食道逆流性疾患	1/112 (0.9)	0/84	0/72	0/62
過敏性腸症候群	1/112 (0.9)	0/84	0/72	0/62
大腸ポリープ	0/112	0/85	0/73	1/63 (1.6)
悪心	8/112 (7.1)	0/82	2/70 (2.9)	1/58 (1.7)
口の錯感覚	1/112 (0.9)	0/84	0/72	0/62
直腸出血	0/112	0/85	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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
眼障害 (Cont.)				
ドライアイ	0/53	0/0	0/0	3/112 (2.7)
緑内障	0/54	0/0	0/0	1/112 (0.9)
眼窩周囲痛	0/54	0/0	0/0	1/112 (0.9)
眼窩周囲腫脹	0/54	0/0	0/0	2/112 (1.8)
視野欠損	0/55	0/0	0/0	1/112 (0.9)
胃腸障害	0/40	0/0	0/0	29/112 (25.9)
腹部膨満	0/53	0/0	0/0	3/112 (2.7)
腹痛	0/54	0/0	0/0	1/112 (0.9)
上腹部痛	0/55	0/0	0/0	1/112 (0.9)
呼気臭	0/55	0/0	0/0	1/112 (0.9)
便秘	0/49	0/0	0/0	12/112 (10.7)
下痢	0/53	0/0	0/0	3/112 (2.7)
口内乾燥	0/53	0/0	0/0	5/112 (4.5)
嚥下障害	0/55	0/0	0/0	1/112 (0.9)
糞塊	0/55	0/0	0/0	1/112 (0.9)
排便回数増加	0/55	0/0	0/0	1/112 (0.9)
胃食道逆流性疾患	0/54	0/0	0/0	1/112 (0.9)
過敏性腸症候群	0/54	0/0	0/0	1/112 (0.9)
大腸ポリープ	0/54	0/0	0/0	1/112 (0.9)
悪心	0/49	0/0	0/0	11/112 (9.8)
口の錯感覚	0/54	0/0	0/0	1/112 (0.9)
直腸出血	0/55	0/0	0/0	1/112 (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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
胃腸障害 (Cont.)				
歯痛	1/112 (0.9)	0/84	0/72	0/62
嘔吐	2/112 (1.8)	0/85	1/73 (1.4)	0/62
一般・全身障害および投与部位の状態	92/112 (82.1)	3/13 (23.1)	1/8 (12.5)	0/5
投与部位内出血	0/112	0/85	0/73	1/63 (1.6)
投与部位漏出	1/112 (0.9)	0/84	0/72	0/62
カテーテル留置部位紅斑	1/112 (0.9)	0/84	0/72	0/63
カテーテル留置部位出血	1/112 (0.9)	0/84	0/72	0/62
カテーテル留置部位炎症	1/112 (0.9)	0/84	0/72	0/63
カテーテル留置部位刺激感	1/112 (0.9)	0/84	0/72	0/62
カテーテル留置部位浮腫	1/112 (0.9)	0/84	0/72	0/63
カテーテル留置部位疼痛	2/112 (1.8)	0/83	0/71	0/62
胸部不快感	0/112	1/85 (1.2)	0/72	0/62
胸痛	1/112 (0.9)	0/84	0/72	0/62
薬効欠如	0/112	1/85 (1.2)	0/72	0/62
薬剤離脱症候群	1/112 (0.9)	0/84	0/72	0/62
疲労	3/112 (2.7)	0/83	0/71	0/61
異常感	1/112 (0.9)	0/84	0/73	0/63
冷感	0/112	0/85	1/73 (1.4)	0/62
歩行障害	1/112 (0.9)	1/85 (1.2)	0/72	0/63
低体温	0/112	0/85	0/73	1/63 (1.6)
インフルエンザ様疾患	2/112 (1.8)	0/83	0/71	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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
胃腸障害 (Cont.)				
歯痛	0/54	0/0	0/0	1/112 (0.9)
嘔吐	0/55	0/0	0/0	3/112 (2.7)
一般・全身障害および投与部位の状態	0/5	0/0	0/0	96/112 (85.7)
投与部位内出血	0/54	0/0	0/0	1/112 (0.9)
投与部位漏出	0/54	0/0	0/0	1/112 (0.9)
カテーテル留置部位紅斑	0/55	0/0	0/0	1/112 (0.9)
カテーテル留置部位出血	0/54	0/0	0/0	1/112 (0.9)
カテーテル留置部位炎症	0/55	0/0	0/0	1/112 (0.9)
カテーテル留置部位刺激感	0/54	0/0	0/0	1/112 (0.9)
カテーテル留置部位浮腫	0/55	0/0	0/0	1/112 (0.9)
カテーテル留置部位疼痛	0/54	0/0	0/0	2/112 (1.8)
胸部不快感	0/54	0/0	0/0	1/112 (0.9)
胸痛	0/54	0/0	0/0	1/112 (0.9)
薬効欠如	0/54	0/0	0/0	1/112 (0.9)
薬剤離脱症候群	0/54	0/0	0/0	1/112 (0.9)
疲労	0/54	0/0	0/0	3/112 (2.7)
異常感	0/55	0/0	0/0	1/112 (0.9)
冷感	0/54	0/0	0/0	1/112 (0.9)
歩行障害	0/55	0/0	0/0	2/112 (1.8)
低体温	0/54	0/0	0/0	1/112 (0.9)
インフルエンザ様疾患	0/53	0/0	0/0	2/112 (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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
一般・全身障害および投与部位の状態 (Cont.)				
注入部位内出血	7/112 (6.3)	0/78	1/66 (1.5)	0/55
注入部位皮膚炎	0/112	1/85 (1.2)	0/72	1/63 (1.6)
注入部位分泌物	1/112 (0.9)	0/84	0/72	0/62
注入部位不快感	1/112 (0.9)	0/84	0/72	0/62
注入部位びらん	1/112 (0.9)	0/84	0/73	0/63
注入部位紅斑	53/112 (47.3)	4/42 (9.5)	2/35 (5.7)	2/28 (7.1)
注入部位皮膚剥脱	1/112 (0.9)	0/85	0/73	2/63 (3.2)
注入部位血管外漏出	11/112 (9.8)	0/78	0/67	1/58 (1.7)
注入部位血腫	7/112 (6.3)	1/79 (1.3)	0/67	0/58
注入部位出血	3/112 (2.7)	1/83 (1.2)	0/70	1/60 (1.7)
注入部位硬結	2/112 (1.8)	0/84	1/72 (1.4)	0/61
注入部位炎症	3/112 (2.7)	0/82	0/71	1/62 (1.6)
注入部位損傷	1/112 (0.9)	0/84	1/73 (1.4)	0/62
注入部位刺激感	3/112 (2.7)	1/82 (1.2)	0/69	0/60
注入部位腫瘤	3/112 (2.7)	0/82	0/70	0/60
注入部位壊死	1/112 (0.9)	0/84	0/72	0/63
注入部位結節	25/112 (22.3)	8/60 (13.3)	0/43	1/37 (2.7)
注入部位浮腫	20/112 (17.9)	4/73 (5.5)	0/58	3/51 (5.9)
注入部位疼痛	18/112 (16.1)	2/69 (2.9)	0/57	0/50
注入部位蒼白	2/112 (1.8)	0/83	0/71	0/61
注入部位丘疹	6/112 (5.4)	2/81 (2.5)	1/68 (1.5)	1/58 (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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
一般・全身障害および投与部位の状態 (Cont.)				
注入部位内出血	0/47	0/0	0/0	8/112 (7.1)
注入部位皮膚炎	0/54	0/0	0/0	2/112 (1.8)
注入部位分泌物	0/54	0/0	0/0	1/112 (0.9)
注入部位不快感	0/54	0/0	0/0	1/112 (0.9)
注入部位びらん	0/55	0/0	0/0	1/112 (0.9)
注入部位紅斑	0/22	0/0	0/0	61/112 (54.5)
注入部位皮膚剥脱	0/53	0/0	0/0	3/112 (2.7)
注入部位血管外漏出	0/50	0/0	0/0	12/112 (10.7)
注入部位血腫	0/51	0/0	0/0	8/112 (7.1)
注入部位出血	0/53	0/0	0/0	5/112 (4.5)
注入部位硬結	0/53	0/0	0/0	3/112 (2.7)
注入部位炎症	2/53 (3.8)	0/0	0/0	6/112 (5.4)
注入部位損傷	0/54	0/0	0/0	2/112 (1.8)
注入部位刺激感	0/53	0/0	0/0	4/112 (3.6)
注入部位腫瘤	0/52	0/0	0/0	3/112 (2.7)
注入部位壊死	0/55	0/0	0/0	1/112 (0.9)
注入部位結節	0/31	0/0	0/0	34/112 (30.4)
注入部位浮腫	1/41 (2.4)	0/0	0/0	28/112 (25.0)
注入部位疼痛	0/44	0/0	0/0	20/112 (17.9)
注入部位蒼白	0/53	0/0	0/0	2/112 (1.8)
注入部位丘疹	1/50 (2.0)	0/0	0/0	11/112 (9.8)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
一般・全身障害および投与部位の状態 (Cont.)				
注入部位異常感覚	2/112 (1.8)	0/83	0/71	0/61
注入部位そう痒感	1/112 (0.9)	1/84 (1.2)	0/71	0/61
注入部位発疹	3/112 (2.7)	1/82 (1.2)	0/69	0/59
注入部位反応	13/112 (11.6)	1/77 (1.3)	1/66 (1.5)	2/57 (3.5)
注入部位痂皮	0/112	1/85 (1.2)	0/72	0/62
注入部位腫脹	2/112 (1.8)	0/83	0/72	0/62
注入部位小水疱	2/112 (1.8)	0/83	0/72	0/62
注入部位熱感	1/112 (0.9)	0/84	0/72	0/62
注射部位内出血	0/112	1/85 (1.2)	0/72	0/62
注射部位紅斑	7/112 (6.3)	0/79	1/68 (1.5)	0/57
注射部位漏出	1/112 (0.9)	0/84	0/72	0/62
注射部位血腫	1/112 (0.9)	0/85	0/73	0/63
注射部位出血	0/112	1/85 (1.2)	0/72	0/62
注射部位炎症	2/112 (1.8)	1/83 (1.2)	1/70 (1.4)	0/59
注射部位結節	4/112 (3.6)	0/81	2/70 (2.9)	0/58
注射部位浮腫	2/112 (1.8)	0/83	0/71	0/61
注射部位疼痛	5/112 (4.5)	1/81 (1.2)	0/69	0/60
注射部位丘疹	1/112 (0.9)	1/85 (1.2)	0/73	0/63
注射部位反応	1/112 (0.9)	0/84	0/72	0/62
注射部位腫脹	1/112 (0.9)	1/84 (1.2)	0/71	0/61
注射部位蕁麻疹	1/112 (0.9)	0/85	0/73	0/63

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
一般・全身障害および投与部位の状態 (Cont.)				
注入部位異常感覚	0/53	0/0	0/0	2/112 (1.8)
注入部位そう痒感	0/53	0/0	0/0	2/112 (1.8)
注入部位発疹	0/52	0/0	0/0	4/112 (3.6)
注入部位反応	0/47	0/0	0/0	17/112 (15.2)
注入部位痂皮	0/54	0/0	0/0	1/112 (0.9)
注入部位腫脹	0/54	0/0	0/0	2/112 (1.8)
注入部位小水疱	0/55	0/0	0/0	2/112 (1.8)
注入部位熱感	0/54	0/0	0/0	1/112 (0.9)
注射部位内出血	0/55	0/0	0/0	1/112 (0.9)
注射部位紅斑	0/51	0/0	0/0	8/112 (7.1)
注射部位漏出	0/55	0/0	0/0	1/112 (0.9)
注射部位血腫	0/55	0/0	0/0	1/112 (0.9)
注射部位出血	0/54	0/0	0/0	1/112 (0.9)
注射部位炎症	0/51	0/0	0/0	4/112 (3.6)
注射部位結節	0/51	0/0	0/0	6/112 (5.4)
注射部位浮腫	1/53 (1.9)	0/0	0/0	3/112 (2.7)
注射部位疼痛	0/52	0/0	0/0	6/112 (5.4)
注射部位丘疹	0/55	0/0	0/0	2/112 (1.8)
注射部位反応	0/54	0/0	0/0	1/112 (0.9)
注射部位腫脹	0/53	0/0	0/0	2/112 (1.8)
注射部位蕁麻疹	0/55	0/0	0/0	1/112 (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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
一般・全身障害および投与部位の状態 (Cont.)				
滴下投与部位熱傷	1/112 (0.9)	0/84	0/72	0/62
滴下投与部位痛	0/112	1/85 (1.2)	0/73	0/63
限局性浮腫	1/112 (0.9)	0/84	0/72	0/62
適用部位からの吸収不良	1/112 (0.9)	0/84	0/72	0/62
倦怠感	1/112 (0.9)	0/85	1/73 (1.4)	0/62
医療機器使用部位刺激感	2/112 (1.8)	0/84	0/72	0/62
医療機器使用部位発疹	2/112 (1.8)	0/83	0/71	0/61
非心臓性胸痛	2/112 (1.8)	0/84	0/72	0/62
末梢性浮腫	4/112 (3.6)	0/81	0/70	0/60
末梢腫脹	3/112 (2.7)	0/83	0/71	1/61 (1.6)
穿刺部位紅斑	2/112 (1.8)	1/84 (1.2)	0/71	0/61
穿刺部位浮腫	1/112 (0.9)	0/85	0/73	0/63
穿刺部位腫脹	1/112 (0.9)	0/85	0/73	0/63
発熱	1/112 (0.9)	1/85 (1.2)	0/72	0/62
肝胆道系障害	1/112 (0.9)	0/84	0/72	0/62
脂肪肝	1/112 (0.9)	0/84	0/72	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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
一般・全身障害および投与部位の状態 (Cont.)				
滴下投与部位熱傷	0/55	0/0	0/0	1/112 (0.9)
滴下投与部位痛	0/55	0/0	0/0	1/112 (0.9)
限局性浮腫	0/54	0/0	0/0	1/112 (0.9)
適用部位からの吸収不良	0/54	0/0	0/0	1/112 (0.9)
倦怠感	0/54	0/0	0/0	2/112 (1.8)
医療機器使用部位刺激感	0/54	0/0	0/0	2/112 (1.8)
医療機器使用部位発疹	0/53	0/0	0/0	2/112 (1.8)
非心臓性胸痛	0/54	0/0	0/0	2/112 (1.8)
末梢性浮腫	0/52	0/0	0/0	4/112 (3.6)
末梢腫脹	0/52	0/0	0/0	4/112 (3.6)
穿刺部位紅斑	0/53	0/0	0/0	3/112 (2.7)
穿刺部位浮腫	0/55	0/0	0/0	1/112 (0.9)
穿刺部位腫脹	0/55	0/0	0/0	1/112 (0.9)
発熱	0/54	0/0	0/0	2/112 (1.8)
肝胆道系障害	0/54	0/0	0/0	1/112 (0.9)
脂肪肝	0/54	0/0	0/0	1/112 (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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
感染症および寄生虫症	43/112 (38.4)	5/50 (10.0)	5/38 (13.2)	3/29 (10.3)
四肢膿瘍	0/112	0/85	1/73 (1.4)	0/62
無症候性COVID-19	0/112	0/85	1/73 (1.4)	0/62
細菌性疾患キャリアー	0/112	0/85	1/73 (1.4)	0/62
ウイルス性気管支炎	0/112	0/85	0/73	1/63 (1.6)
蜂巣炎	0/112	0/85	2/73 (2.7)	0/61
膀胱炎	1/112 (0.9)	0/85	0/73	0/63
爪の皮膚糸状菌症	0/112	1/85 (1.2)	0/72	0/62
胃腸炎	1/112 (0.9)	0/84	0/72	0/62
感染性皮膚潰瘍	1/112 (0.9)	0/84	0/72	0/62
インフルエンザ	0/112	0/85	0/73	1/63 (1.6)
注入部位膿瘍	9/112 (8.0)	3/79 (3.8)	1/66 (1.5)	0/59
注入部位蜂巣炎	21/112 (18.8)	0/68	3/61 (4.9)	3/50 (6.0)
注入部位感染	6/112 (5.4)	3/81 (3.7)	1/66 (1.5)	1/55 (1.8)
注入部位膿疱	1/112 (0.9)	0/84	0/73	0/63
注射部位蜂巣炎	2/112 (1.8)	1/83 (1.2)	0/70	0/60
リンパ管炎	0/112	0/85	1/73 (1.4)	0/62
上咽頭炎	4/112 (3.6)	1/81 (1.2)	0/68	0/59
爪真菌症	1/112 (0.9)	0/84	0/72	0/63
耳下腺膿瘍	0/112	0/85	1/73 (1.4)	0/62
肺炎	1/112 (0.9)	0/84	0/73	0/63
シュードモナス感染	1/112 (0.9)	0/84	0/72	0/63
気道感染	0/112	0/85	0/73	1/63 (1.6)
ブドウ球菌感染	0/112	1/85 (1.2)	0/72	0/63

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
感染症および寄生虫症	0/23	0/0	0/0	56/112 (50.0)
四肢膿瘍	0/55	0/0	0/0	1/112 (0.9)
無症候性COVID-19	0/54	0/0	0/0	1/112 (0.9)
細菌性疾患キャリアー	0/54	0/0	0/0	1/112 (0.9)
ウイルス性気管支炎	0/54	0/0	0/0	1/112 (0.9)
蜂巣炎	0/54	0/0	0/0	2/112 (1.8)
膀胱炎	0/55	0/0	0/0	1/112 (0.9)
爪の皮膚糸状菌症	0/54	0/0	0/0	1/112 (0.9)
胃腸炎	0/54	0/0	0/0	1/112 (0.9)
感染性皮膚潰瘍	0/54	0/0	0/0	1/112 (0.9)
インフルエンザ	0/54	0/0	0/0	1/112 (0.9)
注入部位膿瘍	0/51	0/0	0/0	13/112 (11.6)
注入部位蜂巣炎	0/40	0/0	0/0	27/112 (24.1)
注入部位感染	0/48	0/0	0/0	11/112 (9.8)
注入部位膿疱	0/55	0/0	0/0	1/112 (0.9)
注射部位蜂巣炎	0/52	0/0	0/0	3/112 (2.7)
リンパ管炎	0/55	0/0	0/0	1/112 (0.9)
上咽頭炎	0/51	0/0	0/0	5/112 (4.5)
爪真菌症	0/55	0/0	0/0	1/112 (0.9)
耳下腺膿瘍	0/54	0/0	0/0	1/112 (0.9)
肺炎	0/55	0/0	0/0	1/112 (0.9)
シュードモナス感染	0/55	0/0	0/0	1/112 (0.9)
気道感染	0/55	0/0	0/0	1/112 (0.9)
ブドウ球菌感染	0/55	0/0	0/0	1/112 (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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
感染症および寄生虫症 (Cont.)				
歯感染	0/112	0/85	0/73	1/63 (1.6)
尿路感染	6/112 (5.4)	3/80 (3.8)	2/65 (3.1)	0/55
傷害、中毒および処置合併症	16/112 (14.3)	4/72 (5.6)	4/57 (7.0)	3/47 (6.4)
足関節部骨折	1/112 (0.9)	0/84	0/72	0/62
節足動物咬傷	1/112 (0.9)	0/84	0/72	0/62
骨挫傷	0/112	1/85 (1.2)	0/72	0/63
挫傷	2/112 (1.8)	3/83 (3.6)	1/69 (1.4)	0/59
眼挫傷	1/112 (0.9)	0/84	0/72	0/63
顔面損傷	0/112	1/85 (1.2)	0/72	0/62
顔面骨骨折	2/112 (1.8)	0/83	0/71	0/61
転倒	13/112 (11.6)	4/73 (5.5)	4/58 (6.9)	3/48 (6.3)
頭部損傷	0/112	1/85 (1.2)	2/72 (2.8)	0/60
関節脱臼	0/112	1/85 (1.2)	0/72	0/63
靭帯捻挫	0/112	1/85 (1.2)	0/72	0/62
腰椎骨折	1/112 (0.9)	0/85	0/73	0/63
過量投与	0/112	0/85	1/73 (1.4)	0/62
処置によるめまい	1/112 (0.9)	0/85	0/73	0/63
肋骨骨折	1/112 (0.9)	0/84	0/72	1/62 (1.6)
皮膚擦過傷	0/112	1/85 (1.2)	1/72 (1.4)	0/62
皮膚裂傷	2/112 (1.8)	2/83 (2.4)	1/69 (1.4)	1/59 (1.7)
硬膜下血腫	0/112	0/85	0/73	1/63 (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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
感染症および寄生虫症 (Cont.)				
歯感染	0/54	0/0	0/0	1/112 (0.9)
尿路感染	0/48	0/0	0/0	11/112 (9.8)
傷害、中毒および処置合併症	0/40	0/0	0/0	27/112 (24.1)
足関節部骨折	0/54	0/0	0/0	1/112 (0.9)
節足動物咬傷	0/55	0/0	0/0	1/112 (0.9)
骨挫傷	0/55	0/0	0/0	1/112 (0.9)
挫傷	0/51	0/0	0/0	6/112 (5.4)
眼挫傷	0/55	0/0	0/0	1/112 (0.9)
顔面損傷	0/54	0/0	0/0	1/112 (0.9)
顔面骨骨折	0/53	0/0	0/0	2/112 (1.8)
転倒	0/41	0/0	0/0	24/112 (21.4)
頭部損傷	0/53	0/0	0/0	3/112 (2.7)
関節脱臼	0/55	0/0	0/0	1/112 (0.9)
靭帯捻挫	0/54	0/0	0/0	1/112 (0.9)
腰椎骨折	0/55	0/0	0/0	1/112 (0.9)
過量投与	0/54	0/0	0/0	1/112 (0.9)
処置によるめまい	0/55	0/0	0/0	1/112 (0.9)
肋骨骨折	0/53	0/0	0/0	2/112 (1.8)
皮膚擦過傷	0/55	0/0	0/0	2/112 (1.8)
皮膚裂傷	0/50	0/0	0/0	6/112 (5.4)
硬膜下血腫	0/55	0/0	0/0	1/112 (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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
傷害、中毒および処置合併症 (Cont.)				
サンバーン	1/112 (0.9)	0/84	0/72	0/62
腱断裂	0/112	1/85 (1.2)	0/72	0/63
過少量投与	0/112	0/85	1/73 (1.4)	0/62
臨床検査	16/112 (14.3)	4/71 (5.6)	3/57 (5.3)	0/47
血中クレアチンホスホキナーゼ増加	1/112 (0.9)	0/84	0/72	0/62
血中クレアチニン減少	1/112 (0.9)	0/84	0/72	0/62
血中葉酸異常	0/112	0/85	0/73	1/63 (1.6)
血中葉酸減少	0/112	0/85	0/73	0/63
血中ホモシステイン増加	1/112 (0.9)	0/84	1/72 (1.4)	0/61
血中リン減少	0/112	1/85 (1.2)	0/72	0/62
血圧上昇	1/112 (0.9)	0/85	0/73	0/63
C-反応性蛋白増加	1/112 (0.9)	0/84	0/72	0/62
ヘモグロビン減少	0/112	0/85	0/73	1/63 (1.6)
リンパ球数減少	1/112 (0.9)	0/85	0/73	0/63
単球数増加	1/112 (0.9)	0/85	0/73	0/63
好中球数増加	2/112 (1.8)	0/84	0/72	0/62
プロトロンビン時間延長	0/112	0/85	0/73	0/63
赤血球数減少	1/112 (0.9)	0/84	0/72	0/62
ビタミンB12減少	0/112	0/85	1/73 (1.4)	0/62
ビタミンB6減少	5/112 (4.5)	0/80	1/68 (1.5)	0/58

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
傷害、中毒および処置合併症 (Cont.)				
サンバーン	0/55	0/0	0/0	1/112 (0.9)
腱断裂	0/55	0/0	0/0	1/112 (0.9)
過少量投与	0/54	0/0	0/0	1/112 (0.9)
臨床検査	1/42 (2.4)	0/0	0/0	24/112 (21.4)
血中クレアチンホスホキナーゼ増加	0/54	0/0	0/0	1/112 (0.9)
血中クレアチニン減少	0/54	0/0	0/0	1/112 (0.9)
血中葉酸異常	0/54	0/0	0/0	1/112 (0.9)
血中葉酸減少	1/55 (1.8)	0/0	0/0	1/112 (0.9)
血中ホモシステイン増加	0/53	0/0	0/0	2/112 (1.8)
血中リン減少	0/54	0/0	0/0	1/112 (0.9)
血圧上昇	0/55	0/0	0/0	1/112 (0.9)
C-反応性蛋白増加	0/54	0/0	0/0	1/112 (0.9)
ヘモグロビン減少	0/54	0/0	0/0	1/112 (0.9)
リンパ球数減少	0/55	0/0	0/0	1/112 (0.9)
単球数増加	0/55	0/0	0/0	1/112 (0.9)
好中球数増加	0/54	0/0	0/0	2/112 (1.8)
プロトロンビン時間延長	1/55 (1.8)	0/0	0/0	1/112 (0.9)
赤血球数減少	0/54	0/0	0/0	1/112 (0.9)
ビタミンB12減少	0/54	0/0	0/0	1/112 (0.9)
ビタミンB6減少	0/50	0/0	0/0	6/112 (5.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
臨床検査 (Cont.)				
ビタミンD減少	1/112 (0.9)	0/84	0/72	0/63
体重減少	9/112 (8.0)	3/76 (3.9)	2/63 (3.2)	0/53
白血球数増加	2/112 (1.8)	0/84	0/72	0/62
代謝および栄養障害	12/112 (10.7)	2/76 (2.6)	4/64 (6.3)	1/52 (1.9)
食欲減退	2/112 (1.8)	1/83 (1.2)	0/71	0/61
脱水	2/112 (1.8)	1/85 (1.2)	0/72	0/62
糖尿病	0/112	0/85	1/73 (1.4)	0/62
水分過負荷	1/112 (0.9)	0/84	0/73	0/63
体液貯留	0/112	0/85	0/73	1/63 (1.6)
葉酸欠乏	1/112 (0.9)	0/84	0/72	0/62
耐糖能障害	1/112 (0.9)	0/84	0/72	0/62
高コレステロール血症	0/112	1/85 (1.2)	0/72	0/62
高血糖	1/112 (0.9)	0/84	0/72	0/62
高ホモシステイン血症	0/112	0/85	1/73 (1.4)	0/62
低カルシウム血症	0/112	0/85	1/73 (1.4)	0/62
低カリウム血症	2/112 (1.8)	0/85	0/73	1/63 (1.6)
栄養障害	1/112 (0.9)	0/85	0/73	0/63
ビタミンB群欠乏	0/112	0/85	1/73 (1.4)	0/62
ビタミンB12欠乏	0/112	0/85	1/73 (1.4)	0/62
ビタミンB6欠乏	4/112 (3.6)	0/81	1/69 (1.4)	0/60

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
臨床検査 (Cont.)				
ビタミンD減少	0/55	0/0	0/0	1/112 (0.9)
体重減少	0/48	0/0	0/0	14/112 (12.5)
白血球数増加	0/54	0/0	0/0	2/112 (1.8)
代謝および栄養障害	0/47	0/0	0/0	19/112 (17.0)
食欲減退	0/54	0/0	0/0	3/112 (2.7)
脱水	0/54	0/0	0/0	3/112 (2.7)
糖尿病	0/55	0/0	0/0	1/112 (0.9)
水分過負荷	0/55	0/0	0/0	1/112 (0.9)
体液貯留	0/54	0/0	0/0	1/112 (0.9)
葉酸欠乏	0/55	0/0	0/0	1/112 (0.9)
耐糖能障害	0/54	0/0	0/0	1/112 (0.9)
高コレステロール血症	0/54	0/0	0/0	1/112 (0.9)
高血糖	0/54	0/0	0/0	1/112 (0.9)
高ホモシステイン血症	0/54	0/0	0/0	1/112 (0.9)
低カルシウム血症	0/55	0/0	0/0	1/112 (0.9)
低カリウム血症	0/55	0/0	0/0	3/112 (2.7)
栄養障害	0/55	0/0	0/0	1/112 (0.9)
ビタミンB群欠乏	0/54	0/0	0/0	1/112 (0.9)
ビタミンB12欠乏	1/55 (1.8)	0/0	0/0	2/112 (1.8)
ビタミンB6欠乏	0/53	0/0	0/0	5/112 (4.5)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
筋骨格系および結合組織障害	13/112 (11.6)	3/74 (4.1)	5/60 (8.3)	0/48
関節痛	2/112 (1.8)	1/83 (1.2)	1/70 (1.4)	1/60 (1.7)
反応性関節炎	1/112 (0.9)	0/84	0/72	0/62
背部痛	2/112 (1.8)	1/83 (1.2)	2/70 (2.9)	0/58
骨痛	0/112	0/85	1/73 (1.4)	0/62
外骨腫	0/112	1/85 (1.2)	0/72	0/63
椎間関節症候群	0/112	1/85 (1.2)	0/72	0/63
椎間板突出	0/112	1/85 (1.2)	0/72	0/63
関節滲出液	0/112	1/85 (1.2)	0/72	0/63
関節腫脹	1/112 (0.9)	0/84	0/72	0/62
四肢不快感	0/112	0/85	1/73 (1.4)	0/63
筋萎縮	0/112	1/85 (1.2)	0/72	0/63
筋痙縮	2/112 (1.8)	1/83 (1.2)	0/71	0/61
筋力低下	0/112	0/85	1/73 (1.4)	0/62
筋骨格硬直	1/112 (0.9)	0/85	0/73	0/63
筋肉痛	1/112 (0.9)	0/85	0/73	0/63
骨炎	1/112 (0.9)	0/85	0/73	0/63
変形性関節症	0/112	2/85 (2.4)	1/71 (1.4)	0/61
四肢痛	3/112 (2.7)	0/82	0/70	0/61
関節周囲炎	0/112	0/85	1/73 (1.4)	0/62
姿勢異常	1/112 (0.9)	0/84	0/72	0/63
肩回旋筋腱板症候群	0/112	1/85 (1.2)	0/72	0/63
腱障害	0/112	1/85 (1.2)	0/72	0/63

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
筋骨格系および結合組織障害	0/43	0/0	0/0	21/112 (18.8)
関節痛	0/53	0/0	0/0	5/112 (4.5)
反応性関節炎	0/54	0/0	0/0	1/112 (0.9)
背部痛	0/52	0/0	0/0	5/112 (4.5)
骨痛	0/54	0/0	0/0	1/112 (0.9)
外骨腫	0/55	0/0	0/0	1/112 (0.9)
椎間関節症候群	0/55	0/0	0/0	1/112 (0.9)
椎間板突出	0/55	0/0	0/0	1/112 (0.9)
関節滲出液	1/55 (1.8)	0/0	0/0	2/112 (1.8)
関節腫脹	0/54	0/0	0/0	1/112 (0.9)
四肢不快感	0/55	0/0	0/0	1/112 (0.9)
筋萎縮	0/55	0/0	0/0	1/112 (0.9)
筋痙縮	0/54	0/0	0/0	3/112 (2.7)
筋力低下	0/54	0/0	0/0	1/112 (0.9)
筋骨格硬直	0/55	0/0	0/0	1/112 (0.9)
筋肉痛	0/55	0/0	0/0	1/112 (0.9)
骨炎	0/55	0/0	0/0	1/112 (0.9)
変形性関節症	1/53 (1.9)	0/0	0/0	4/112 (3.6)
四肢痛	0/53	0/0	0/0	3/112 (2.7)
関節周囲炎	0/54	0/0	0/0	1/112 (0.9)
姿勢異常	0/55	0/0	0/0	1/112 (0.9)
肩回旋筋腱板症候群	0/55	0/0	0/0	1/112 (0.9)
腱障害	0/55	0/0	0/0	1/112 (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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
筋骨格系および結合組織障害 (Cont.)				
斜頚	1/112 (0.9)	0/84	0/72	0/62
良性、悪性および詳細不明の新生物 (嚢胞およびポリープを含む)	1/112 (0.9)	2/84 (2.4)	1/70 (1.4)	0/60
基底細胞癌	0/112	2/85 (2.4)	0/71	0/62
脂漏性角化症	0/112	0/85	1/73 (1.4)	0/62
皮膚有棘細胞癌	1/112 (0.9)	0/84	0/72	0/62
神経系障害	32/112 (28.6)	7/62 (11.3)	4/48 (8.3)	4/40 (10.0)
失語症	0/112	0/85	1/73 (1.4)	0/62
平衡障害	1/112 (0.9)	0/84	1/72 (1.4)	1/62 (1.6)
運動緩慢	0/112	0/85	1/73 (1.4)	0/62
手根管症候群	0/112	0/85	1/73 (1.4)	0/62
大脳萎縮	0/112	0/85	0/73	1/63 (1.6)
脳出血	0/112	1/85 (1.2)	0/72	0/62
脳圧排効果	0/112	0/85	0/73	1/63 (1.6)
脳血管発作	0/112	1/85 (1.2)	0/73	0/63
認知障害	0/112	1/85 (1.2)	1/73 (1.4)	0/62
注意力障害	1/112 (0.9)	0/84	0/73	0/63
浮動性めまい	10/112 (8.9)	0/75	0/63	0/55
構語障害	1/112 (0.9)	1/85 (1.2)	1/72 (1.4)	0/61
味覚不全	0/112	0/85	0/73	1/63 (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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
筋骨格系および結合組織障害 (Cont.)				
斜頚	0/54	0/0	0/0	1/112 (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)	0/52	0/0	0/0	4/112 (3.6)
基底細胞癌	0/54	0/0	0/0	2/112 (1.8)
脂漏性角化症	0/54	0/0	0/0	1/112 (0.9)
皮膚有棘細胞癌	0/54	0/0	0/0	1/112 (0.9)
神経系障害	1/32 (3.1)	0/0	0/0	48/112 (42.9)
失語症	0/54	0/0	0/0	1/112 (0.9)
平衡障害	1/53 (1.9)	0/0	0/0	4/112 (3.6)
運動緩慢	0/54	0/0	0/0	1/112 (0.9)
手根管症候群	0/54	0/0	0/0	1/112 (0.9)
大脳萎縮	0/54	0/0	0/0	1/112 (0.9)
脳出血	0/54	0/0	0/0	1/112 (0.9)
脳圧排効果	0/55	0/0	0/0	1/112 (0.9)
脳血管発作	0/55	0/0	0/0	1/112 (0.9)
認知障害	0/54	0/0	0/0	2/112 (1.8)
注意力障害	0/55	0/0	0/0	1/112 (0.9)
浮動性めまい	0/47	0/0	0/0	10/112 (8.9)
構語障害	0/54	0/0	0/0	3/112 (2.7)
味覚不全	0/54	0/0	0/0	1/112 (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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
神経系障害 (Cont.)				
ジスキネジア	3/112 (2.7)	1/83 (1.2)	1/70 (1.4)	1/59 (1.7)
ジストニア	2/112 (1.8)	2/84 (2.4)	0/70	1/60 (1.7)
脳症	1/112 (0.9)	0/85	0/73	0/63
てんかん	1/112 (0.9)	0/85	0/73	0/63
本態性振戦	1/112 (0.9)	0/84	0/72	0/63
全身性強直性間代性発作	0/112	0/85	0/73	1/63 (1.6)
頭痛	4/112 (3.6)	2/81 (2.5)	0/67	1/57 (1.8)
片側感覚消失	1/112 (0.9)	0/84	0/72	0/63
不全片麻痺	1/112 (0.9)	0/84	0/72	0/63
知覚過敏	0/112	0/85	1/73 (1.4)	0/62
感覚鈍麻	0/112	0/85	2/73 (2.7)	0/61
反射減弱	0/112	1/85 (1.2)	0/72	0/62
嗜眠	0/112	0/85	1/73 (1.4)	0/63
意識消失	0/112	1/85 (1.2)	0/72	0/62
腰仙部神経根障害	1/112 (0.9)	0/84	0/72	0/62
記憶障害	1/112 (0.9)	0/84	1/73 (1.4)	0/62
代謝性脳症	1/112 (0.9)	0/85	0/73	0/63
神経痛	0/112	1/85 (1.2)	0/72	0/62
末梢性ニューロパチー	1/112 (0.9)	0/84	0/72	0/63
オンオフ現象	4/112 (3.6)	0/82	1/71 (1.4)	0/60
錯感覚	2/112 (1.8)	0/84	0/72	1/62 (1.6)
パーキンソン病	3/112 (2.7)	1/84 (1.2)	1/71 (1.4)	0/60
パーキンソニズム	2/112 (1.8)	1/85 (1.2)	0/72	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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
神経系障害 (Cont.)				
ジスキネジア	0/50	0/0	0/0	6/112 (5.4)
ジストニア	0/51	0/0	0/0	5/112 (4.5)
脳症	0/55	0/0	0/0	1/112 (0.9)
てんかん	0/55	0/0	0/0	1/112 (0.9)
本態性振戦	0/55	0/0	0/0	1/112 (0.9)
全身性強直性間代性発作	0/55	0/0	0/0	1/112 (0.9)
頭痛	0/49	0/0	0/0	7/112 (6.3)
片側感覚消失	0/55	0/0	0/0	1/112 (0.9)
不全片麻痺	0/55	0/0	0/0	1/112 (0.9)
知覚過敏	0/54	0/0	0/0	1/112 (0.9)
感覚鈍麻	0/53	0/0	0/0	2/112 (1.8)
反射減弱	0/55	0/0	0/0	1/112 (0.9)
嗜眠	0/55	0/0	0/0	1/112 (0.9)
意識消失	0/54	0/0	0/0	1/112 (0.9)
腰仙部神経根障害	0/54	0/0	0/0	1/112 (0.9)
記憶障害	0/54	0/0	0/0	2/112 (1.8)
代謝性脳症	0/55	0/0	0/0	1/112 (0.9)
神経痛	0/55	0/0	0/0	1/112 (0.9)
末梢性ニューロパチー	0/55	0/0	0/0	1/112 (0.9)
オンオフ現象	0/52	0/0	0/0	5/112 (4.5)
錯感覚	0/53	0/0	0/0	3/112 (2.7)
パーキンソン病	0/52	0/0	0/0	5/112 (4.5)
パーキンソニズム	0/54	0/0	0/0	3/112 (2.7)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
神経系障害 (Cont.)				
末梢性感覚ニューロパチー	0/112	1/85 (1.2)	0/72	0/62
側反弓	1/112 (0.9)	0/84	1/72 (1.4)	0/62
多発ニューロパチー	1/112 (0.9)	0/84	0/72	1/63 (1.6)
失神寸前の状態	0/112	1/85 (1.2)	0/72	0/63
心因性発作	1/112 (0.9)	0/84	0/72	0/62
精神運動亢進	1/112 (0.9)	0/84	0/73	0/63
反射異常	0/112	0/85	0/73	1/63 (1.6)
安静時振戦	1/112 (0.9)	0/84	0/72	0/63
坐骨神経痛	2/112 (1.8)	0/83	1/71 (1.4)	0/61
痙攣発作	0/112	1/85 (1.2)	0/72	0/62
感覚障害	1/112 (0.9)	0/84	0/72	0/62
感覚消失	0/112	1/85 (1.2)	0/72	0/62
傾眠	2/112 (1.8)	0/84	1/72 (1.4)	0/61
失神	0/112	1/85 (1.2)	0/72	1/62 (1.6)
振戦	2/112 (1.8)	0/83	0/71	0/61
製品の問題	1/112 (0.9)	0/85	0/73	0/63
医療機器機能不良	1/112 (0.9)	0/85	0/73	0/63
精神障害	45/112 (40.2)	6/51 (11.8)	3/41 (7.3)	3/35 (8.6)
異常な夢	1/112 (0.9)	0/84	0/72	0/62
感情不安定	0/112	1/85 (1.2)	0/72	0/62
激越	1/112 (0.9)	0/85	0/73	0/63

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
神経系障害 (Cont.)				
末梢性感覚ニューロパチー	0/54	0/0	0/0	1/112 (0.9)
側反弓	0/54	0/0	0/0	2/112 (1.8)
多発ニューロパチー	0/54	0/0	0/0	2/112 (1.8)
失神寸前の状態	0/55	0/0	0/0	1/112 (0.9)
心因性発作	0/54	0/0	0/0	1/112 (0.9)
精神運動亢進	0/55	0/0	0/0	1/112 (0.9)
反射異常	0/54	0/0	0/0	1/112 (0.9)
安静時振戦	0/55	0/0	0/0	1/112 (0.9)
坐骨神経痛	0/54	0/0	0/0	3/112 (2.7)
痙攣発作	0/54	0/0	0/0	1/112 (0.9)
感覚障害	0/54	0/0	0/0	1/112 (0.9)
感覚消失	0/54	0/0	0/0	1/112 (0.9)
傾眠	0/53	0/0	0/0	3/112 (2.7)
失神	1/53 (1.9)	0/0	0/0	3/112 (2.7)
振戦	0/53	0/0	0/0	2/112 (1.8)
製品の問題	0/55	0/0	0/0	1/112 (0.9)
医療機器機能不良	0/55	0/0	0/0	1/112 (0.9)
精神障害	0/29	0/0	0/0	57/112 (50.9)
異常な夢	0/54	0/0	0/0	1/112 (0.9)
感情不安定	0/54	0/0	0/0	1/112 (0.9)
激越	0/55	0/0	0/0	1/112 (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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
精神障害 (Cont.)				
不安	15/112 (13.4)	0/73	3/63 (4.8)	0/52
不安障害	0/112	0/85	0/73	1/63 (1.6)
強迫行為	1/112 (0.9)	0/84	0/72	0/62
錯乱状態	1/112 (0.9)	1/85 (1.2)	2/72 (2.8)	1/60 (1.7)
譫妄	3/112 (2.7)	1/83 (1.2)	0/71	0/62
妄想	1/112 (0.9)	1/84 (1.2)	0/71	0/63
妄想性障害、詳細不明	1/112 (0.9)	0/84	0/72	0/63
抑うつ気分	1/112 (0.9)	0/84	0/72	1/62 (1.6)
うつ病	0/112	1/85 (1.2)	0/72	1/62 (1.6)
ディスフェミア	0/112	0/85	1/73 (1.4)	0/62
情動障害	1/112 (0.9)	0/84	0/72	0/62
注射恐怖	0/112	1/85 (1.2)	0/73	0/63
幻覚	16/112 (14.3)	5/77 (6.5)	1/61 (1.6)	0/54
幻聴	1/112 (0.9)	2/84 (2.4)	0/70	0/63
幻嗅	1/112 (0.9)	0/84	0/73	0/63
幻視	4/112 (3.6)	1/81 (1.2)	0/69	0/60
錯覚	0/112	0/85	1/73 (1.4)	0/62
衝動制御障害	2/112 (1.8)	1/83 (1.2)	0/71	1/63 (1.6)
衝動行為	0/112	0/85	0/73	1/63 (1.6)
不眠症	6/112 (5.4)	2/79 (2.5)	0/66	1/57 (1.8)
易刺激性	1/112 (0.9)	0/84	0/73	0/63
躁病	1/112 (0.9)	0/84	0/72	0/63

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
精神障害 (Cont.)				
不安	0/44	0/0	0/0	18/112 (16.1)
不安障害	0/54	0/0	0/0	1/112 (0.9)
強迫行為	0/54	0/0	0/0	1/112 (0.9)
錯乱状態	0/52	0/0	0/0	5/112 (4.5)
譫妄	0/55	0/0	0/0	4/112 (3.6)
妄想	0/55	0/0	0/0	2/112 (1.8)
妄想性障害、詳細不明	0/55	0/0	0/0	1/112 (0.9)
抑うつ気分	0/54	0/0	0/0	2/112 (1.8)
うつ病	0/53	0/0	0/0	2/112 (1.8)
ディスフェミア	0/54	0/0	0/0	1/112 (0.9)
情動障害	0/54	0/0	0/0	1/112 (0.9)
注射恐怖	0/55	0/0	0/0	1/112 (0.9)
幻覚	0/49	0/0	0/0	22/112 (19.6)
幻聴	0/55	0/0	0/0	3/112 (2.7)
幻嗅	0/55	0/0	0/0	1/112 (0.9)
幻視	0/52	0/0	0/0	5/112 (4.5)
錯覚	0/55	0/0	0/0	1/112 (0.9)
衝動制御障害	0/54	0/0	0/0	4/112 (3.6)
衝動行為	0/54	0/0	0/0	1/112 (0.9)
不眠症	0/49	0/0	0/0	9/112 (8.0)
易刺激性	0/55	0/0	0/0	1/112 (0.9)
躁病	0/55	0/0	0/0	1/112 (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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
精神障害 (Cont.)				
気分動揺	0/112	1/85 (1.2)	0/72	0/62
悪夢	1/112 (0.9)	0/85	0/73	0/63
パニック発作	3/112 (2.7)	0/83	0/71	0/61
パニック反応	0/112	0/85	1/73 (1.4)	0/62
処置に対する不安	0/112	1/85 (1.2)	0/73	0/63
精神病性障害	0/112	1/85 (1.2)	1/72 (1.4)	0/62
レム睡眠行動障害	1/112 (0.9)	0/84	0/72	0/62
睡眠障害	1/112 (0.9)	0/84	0/72	0/62
ねごと	1/112 (0.9)	0/84	0/73	0/63
常同症	0/112	0/85	0/73	1/63 (1.6)
ストレス	1/112 (0.9)	0/84	0/72	0/62
自殺念慮	2/112 (1.8)	0/83	0/72	0/63
腎および尿路障害	3/112 (2.7)	1/83 (1.2)	2/70 (2.9)	1/60 (1.7)
排尿困難	1/112 (0.9)	0/84	0/72	1/62 (1.6)
夜間頻尿	0/112	1/85 (1.2)	0/72	0/63
多尿	1/112 (0.9)	0/84	0/72	0/62
腎機能障害	0/112	0/85	1/73 (1.4)	0/63
尿管結石症	1/112 (0.9)	0/85	0/73	0/63
尿失禁	0/112	0/85	1/73 (1.4)	1/62 (1.6)
尿閉	0/112	0/85	1/73 (1.4)	2/62 (3.2)
尿異常	1/112 (0.9)	0/84	0/72	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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
精神障害 (Cont.)				
気分動揺	0/55	0/0	0/0	1/112 (0.9)
悪夢	0/55	0/0	0/0	1/112 (0.9)
パニック発作	0/53	0/0	0/0	3/112 (2.7)
パニック反応	0/54	0/0	0/0	1/112 (0.9)
処置に対する不安	0/55	0/0	0/0	1/112 (0.9)
精神病性障害	0/54	0/0	0/0	2/112 (1.8)
レム睡眠行動障害	0/54	0/0	0/0	1/112 (0.9)
睡眠障害	0/54	0/0	0/0	1/112 (0.9)
ねごと	0/55	0/0	0/0	1/112 (0.9)
常同症	0/54	0/0	0/0	1/112 (0.9)
ストレス	0/55	0/0	0/0	1/112 (0.9)
自殺念慮	0/55	0/0	0/0	2/112 (1.8)
腎および尿路障害	0/51	0/0	0/0	7/112 (6.3)
排尿困難	0/53	0/0	0/0	2/112 (1.8)
夜間頻尿	0/55	0/0	0/0	1/112 (0.9)
多尿	0/54	0/0	0/0	1/112 (0.9)
腎機能障害	0/55	0/0	0/0	1/112 (0.9)
尿管結石症	0/55	0/0	0/0	1/112 (0.9)
尿失禁	0/53	0/0	0/0	2/112 (1.8)
尿閉	0/52	0/0	0/0	3/112 (2.7)
尿異常	0/54	0/0	0/0	1/112 (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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
腎および尿路障害 (Cont.)				
尿臭異常	0/112	0/85	1/73 (1.4)	0/62
生殖系および乳房障害	3/112 (2.7)	2/83 (2.4)	0/69	0/59
勃起不全	1/112 (0.9)	0/85	0/73	0/63
骨盤痛	0/112	1/85 (1.2)	0/72	0/62
ペイロニー病	1/112 (0.9)	0/84	0/72	0/62
閉経後出血	0/112	1/85 (1.2)	0/72	0/62
前立腺腫大	0/112	1/85 (1.2)	0/72	0/62
腟脱	1/112 (0.9)	0/84	0/72	0/62
呼吸器、胸郭および縦隔障害	13/112 (11.6)	3/74 (4.1)	1/62 (1.6)	2/52 (3.8)
急性呼吸不全	1/112 (0.9)	0/84	0/73	0/63
咳嗽	2/112 (1.8)	0/83	0/72	0/62
発声障害	1/112 (0.9)	0/84	1/72 (1.4)	0/61
呼吸困難	4/112 (3.6)	2/81 (2.5)	0/68	0/59
鼻出血	0/112	0/85	1/73 (1.4)	0/62
過換気	2/112 (1.8)	0/84	0/72	0/62
口腔咽頭痛	1/112 (0.9)	0/84	0/72	0/62
誤嚥性肺炎	0/112	0/85	0/73	1/63 (1.6)
湿性咳嗽	0/112	0/85	1/73 (1.4)	0/62
肺塞栓症	1/112 (0.9)	0/85	0/73	1/63 (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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
腎および尿路障害 (Cont.)				
尿臭異常	0/54	0/0	0/0	1/112 (0.9)
生殖系および乳房障害	0/51	0/0	0/0	5/112 (4.5)
勃起不全	0/55	0/0	0/0	1/112 (0.9)
骨盤痛	0/54	0/0	0/0	1/112 (0.9)
ペイロニー病	0/54	0/0	0/0	1/112 (0.9)
閉経後出血	0/54	0/0	0/0	1/112 (0.9)
前立腺腫大	0/54	0/0	0/0	1/112 (0.9)
腟脱	0/54	0/0	0/0	1/112 (0.9)
呼吸器、胸郭および縦隔障害	0/45	0/0	0/0	19/112 (17.0)
急性呼吸不全	0/55	0/0	0/0	1/112 (0.9)
咳嗽	0/54	0/0	0/0	2/112 (1.8)
発声障害	0/53	0/0	0/0	2/112 (1.8)
呼吸困難	0/52	0/0	0/0	6/112 (5.4)
鼻出血	0/54	0/0	0/0	1/112 (0.9)
過換気	0/54	0/0	0/0	2/112 (1.8)
口腔咽頭痛	0/54	0/0	0/0	1/112 (0.9)
誤嚥性肺炎	0/55	0/0	0/0	1/112 (0.9)
湿性咳嗽	0/54	0/0	0/0	1/112 (0.9)
肺塞栓症	0/54	0/0	0/0	2/112 (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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
呼吸器、胸郭および縦隔障害 (Cont.)				
ラ音	0/112	1/85 (1.2)	0/72	0/62
鼻痛	1/112 (0.9)	0/84	0/72	0/62
鼻漏	2/112 (1.8)	0/83	0/71	0/61
咽喉刺激感	1/112 (0.9)	0/84	0/73	0/63
皮膚および皮下組織障害	12/112 (10.7)	0/75	2/65 (3.1)	2/55 (3.6)
脱毛症	0/112	0/85	0/73	1/63 (1.6)
褥瘡性潰瘍	1/112 (0.9)	0/84	0/72	0/62
皮膚嚢腫	0/112	0/85	0/73	1/63 (1.6)
皮膚炎	1/112 (0.9)	0/84	0/72	0/62
皮膚乾燥	1/112 (0.9)	0/85	0/73	0/63
紅斑	3/112 (2.7)	0/82	0/72	0/62
脂肪織炎	0/112	0/85	1/73 (1.4)	0/62
丘疹	2/112 (1.8)	0/83	0/71	0/62
口囲皮膚炎	0/112	0/85	0/73	1/63 (1.6)
光線過敏性反応	1/112 (0.9)	0/84	0/72	0/63
そう痒症	1/112 (0.9)	0/84	1/72 (1.4)	0/61
乾癬	0/112	1/85 (1.2)	0/72	0/63
発疹	1/112 (0.9)	0/84	0/72	0/62
紅斑性皮疹	1/112 (0.9)	0/84	0/72	0/62
そう痒性皮疹	1/112 (0.9)	0/84	0/72	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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
呼吸器、胸郭および縦隔障害 (Cont.)				
ラ音	0/55	0/0	0/0	1/112 (0.9)
鼻痛	0/54	0/0	0/0	1/112 (0.9)
鼻漏	0/53	0/0	0/0	2/112 (1.8)
咽喉刺激感	0/55	0/0	0/0	1/112 (0.9)
皮膚および皮下組織障害	0/46	0/0	0/0	16/112 (14.3)
脱毛症	0/55	0/0	0/0	1/112 (0.9)
褥瘡性潰瘍	0/54	0/0	0/0	1/112 (0.9)
皮膚嚢腫	0/54	0/0	0/0	1/112 (0.9)
皮膚炎	0/54	0/0	0/0	1/112 (0.9)
皮膚乾燥	0/55	0/0	0/0	1/112 (0.9)
紅斑	0/54	0/0	0/0	3/112 (2.7)
脂肪織炎	0/54	0/0	0/0	1/112 (0.9)
丘疹	0/54	0/0	0/0	2/112 (1.8)
口囲皮膚炎	0/55	0/0	0/0	1/112 (0.9)
光線過敏性反応	0/55	0/0	0/0	1/112 (0.9)
そう痒症	0/53	0/0	0/0	2/112 (1.8)
乾癬	0/55	0/0	0/0	1/112 (0.9)
発疹	0/54	0/0	0/0	1/112 (0.9)
紅斑性皮疹	0/54	0/0	0/0	1/112 (0.9)
そう痒性皮疹	0/54	0/0	0/0	1/112 (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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
皮膚および皮下組織障害 (Cont.)				
皮膚刺激	1/112 (0.9)	0/85	0/73	0/63
皮膚病変	1/112 (0.9)	0/84	0/72	0/63
皮膚潰瘍	1/112 (0.9)	0/84	0/72	0/62
外科および内科処置	0/112	1/85 (1.2)	0/72	0/62
抜歯	0/112	1/85 (1.2)	0/72	0/62
血管障害	8/112 (7.1)	2/80 (2.5)	2/66 (3.0)	1/55 (1.8)
深部静脈血栓症	1/112 (0.9)	0/85	0/73	0/63
血腫	0/112	0/85	0/73	1/63 (1.6)
出血	0/112	1/85 (1.2)	0/72	0/62
ほてり	1/112 (0.9)	0/85	0/73	0/63
高血圧	2/112 (1.8)	0/84	0/72	1/62 (1.6)
低血圧	2/112 (1.8)	0/83	1/71 (1.4)	0/60
不安定血圧	1/112 (0.9)	0/85	0/73	0/63
起立性高血圧	0/112	0/85	0/73	0/63
起立性低血圧	4/112 (3.6)	1/81 (1.2)	1/68 (1.5)	0/58

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
皮膚および皮下組織障害 (Cont.)				
皮膚刺激	0/55	0/0	0/0	1/112 (0.9)
皮膚病変	0/55	0/0	0/0	1/112 (0.9)
皮膚潰瘍	0/54	0/0	0/0	1/112 (0.9)
外科および内科処置	0/54	0/0	0/0	1/112 (0.9)
抜歯	0/54	0/0	0/0	1/112 (0.9)
血管障害	2/46 (4.3)	0/0	0/0	15/112 (13.4)
深部静脈血栓症	0/55	0/0	0/0	1/112 (0.9)
血腫	0/54	0/0	0/0	1/112 (0.9)
出血	0/54	0/0	0/0	1/112 (0.9)
ほてり	0/55	0/0	0/0	1/112 (0.9)
高血圧	0/53	0/0	0/0	3/112 (2.7)
低血圧	1/52 (1.9)	0/0	0/0	4/112 (3.6)
不安定血圧	0/55	0/0	0/0	1/112 (0.9)
起立性高血圧	1/55 (1.8)	0/0	0/0	1/112 (0.9)
起立性低血圧	0/50	0/0	0/0	6/112 (5.4)

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]

表41　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）：M15-741試験

TABLE 14.3 1.16.2

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
Any adverse event	225/244 (92.2)	159/184 (86.4)	139/160 (86.9)	120/139 (86.3)
血液およびリンパ系障害	2/244 (0.8)	2/184 (1.1)	2/160 (1.3)	2/139 (1.4)
大球性貧血	0/244	0/184	0/160	1/139 (0.7)
凝血異常	1/244 (0.4)	0/184	0/160	0/139
リンパ節症	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	0/139
縦隔リンパ節腫脹	0/244	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
心臓障害	5/244 (2.0)	5/184 (2.7)	5/160 (3.1)	6/139 (4.3)
急性心筋梗塞	0/244	0/184	0/160	1/139 (0.7)
狭心症	0/244	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
心房細動	0/244	0/184	2/160 (1.3)	2/139 (1.4)
徐脈	1/244 (0.4)	0/184	0/160	0/139
心停止	0/244	0/184	0/160	1/139 (0.7)
心肺停止	0/244	1/184 (0.5)	0/160	0/139
冠動脈疾患	0/244	0/184	1/160 (0.6)	2/139 (1.4)
冠動脈狭窄	0/244	0/184	0/160	1/139 (0.7)
期外収縮	1/244 (0.4)	1/184 (0.5)	0/160	0/139
左室肥大	1/244 (0.4)	0/184	0/160	0/139
心筋梗塞	1/244 (0.4)	1/184 (0.5)	0/160	0/139
動悸	1/244 (0.4)	0/184	1/160 (0.6)	1/139 (0.7)
頻脈	0/244	1/184 (0.5)	1/160 (0.6)	0/139

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
Any adverse event	96/123 (78.0)	2/2 (100)	0/0	230/244 (94.3)
血液およびリンパ系障害	2/123 (1.6)	0/2	0/0	4/244 (1.6)
大球性貧血	1/123 (0.8)	0/2	0/0	1/244 (0.4)
凝血異常	0/123	0/2	0/0	1/244 (0.4)
リンパ節症	0/123	0/2	0/0	1/244 (0.4)
縦隔リンパ節腫脹	1/123 (0.8)	0/2	0/0	1/244 (0.4)
心臓障害	4/123 (3.3)	0/2	0/0	13/244 (5.3)
急性心筋梗塞	0/123	0/2	0/0	1/244 (0.4)
狭心症	1/123 (0.8)	0/2	0/0	1/244 (0.4)
心房細動	1/123 (0.8)	0/2	0/0	2/244 (0.8)
徐脈	0/123	0/2	0/0	1/244 (0.4)
心停止	0/123	0/2	0/0	1/244 (0.4)
心肺停止	0/123	0/2	0/0	1/244 (0.4)
冠動脈疾患	2/123 (1.6)	0/2	0/0	2/244 (0.8)
冠動脈狭窄	0/123	0/2	0/0	1/244 (0.4)
期外収縮	0/123	0/2	0/0	1/244 (0.4)
左室肥大	0/123	0/2	0/0	1/244 (0.4)
心筋梗塞	0/123	0/2	0/0	1/244 (0.4)
動悸	1/123 (0.8)	0/2	0/0	2/244 (0.8)
頻脈	0/123	0/2	0/0	1/244 (0.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
耳および迷路障害	6/244 (2.5)	3/184 (1.6)	2/160 (1.3)	2/139 (1.4)
感音性難聴	0/244	0/184	1/160 (0.6)	1/139 (0.7)
乗物酔い	1/244 (0.4)	0/184	0/160	0/139
回転性めまい	4/244 (1.6)	2/184 (1.1)	1/160 (0.6)	1/139 (0.7)
頭位性回転性めまい	1/244 (0.4)	1/184 (0.5)	0/160	0/139
眼障害	6/244 (2.5)	9/184 (4.9)	9/160 (5.6)	7/139 (5.0)
白内障	1/244 (0.4)	1/184 (0.5)	3/160 (1.9)	3/139 (2.2)
複視	4/244 (1.6)	2/184 (1.1)	1/160 (0.6)	1/139 (0.7)
ドライアイ	2/244 (0.8)	2/184 (1.1)	3/160 (1.9)	2/139 (1.4)
緑内障	0/244	1/184 (0.5)	1/160 (0.6)	2/139 (1.4)
眼窩周囲痛	0/244	1/184 (0.5)	0/160	0/139
眼窩周囲腫脹	1/244 (0.4)	1/184 (0.5)	0/160	0/139
網膜裂孔	0/244	2/184 (1.1)	1/160 (0.6)	0/139
霧視	1/244 (0.4)	0/184	0/160	0/139
視野欠損	0/244	1/184 (0.5)	1/160 (0.6)	0/139
胃腸障害	41/244 (16.8)	27/184 (14.7)	28/160 (17.5)	20/139 (14.4)
腹部膨満	3/244 (1.2)	1/184 (0.5)	2/160 (1.3)	0/139
腹痛	1/244 (0.4)	1/184 (0.5)	0/160	1/139 (0.7)
上腹部痛	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
アフタ性潰瘍	1/244 (0.4)	0/184	0/160	0/139
呼気臭	3/244 (1.2)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
虚血性大腸炎	0/244	1/184 (0.5)	0/160	0/139

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
耳および迷路障害	2/123 (1.6)	0/2	0/0	8/244 (3.3)
感音性難聴	1/123 (0.8)	0/2	0/0	1/244 (0.4)
乗物酔い	0/123	0/2	0/0	1/244 (0.4)
回転性めまい	1/123 (0.8)	0/2	0/0	5/244 (2.0)
頭位性回転性めまい	0/123	0/2	0/0	1/244 (0.4)
眼障害	4/123 (3.3)	0/2	0/0	16/244 (6.6)
白内障	1/123 (0.8)	0/2	0/0	4/244 (1.6)
複視	1/123 (0.8)	0/2	0/0	4/244 (1.6)
ドライアイ	1/123 (0.8)	0/2	0/0	4/244 (1.6)
緑内障	2/123 (1.6)	0/2	0/0	2/244 (0.8)
眼窩周囲痛	0/123	0/2	0/0	1/244 (0.4)
眼窩周囲腫脹	0/123	0/2	0/0	2/244 (0.8)
網膜裂孔	0/123	0/2	0/0	2/244 (0.8)
霧視	0/123	0/2	0/0	1/244 (0.4)
視野欠損	0/123	0/2	0/0	1/244 (0.4)
胃腸障害	12/123 (9.8)	0/2	0/0	56/244 (23.0)
腹部膨満	0/123	0/2	0/0	4/244 (1.6)
腹痛	0/123	0/2	0/0	3/244 (1.2)
上腹部痛	0/123	0/2	0/0	2/244 (0.8)
アフタ性潰瘍	0/123	0/2	0/0	1/244 (0.4)
呼気臭	0/123	0/2	0/0	3/244 (1.2)
虚血性大腸炎	0/123	0/2	0/0	1/244 (0.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
胃腸障害 (Cont.)				
便秘	11/244 (4.5)	10/184 (5.4)	9/160 (5.6)	6/139 (4.3)
齲歯	0/244	0/184	1/160 (0.6)	0/139
下痢	5/244 (2.0)	2/184 (1.1)	3/160 (1.9)	0/139
口内乾燥	8/244 (3.3)	7/184 (3.8)	5/160 (3.1)	4/139 (2.9)
消化不良	1/244 (0.4)	0/184	0/160	0/139
嚥下障害	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
糞塊	1/244 (0.4)	0/184	0/160	0/139
排便回数増加	0/244	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
胃食道逆流性疾患	1/244 (0.4)	1/184 (0.5)	2/160 (1.3)	2/139 (1.4)
舌炎	0/244	1/184 (0.5)	1/160 (0.6)	0/139
舌痛	0/244	1/184 (0.5)	1/160 (0.6)	0/139
吐血	0/244	0/184	0/160	1/139 (0.7)
痔核	1/244 (0.4)	0/184	0/160	0/139
裂孔ヘルニア	0/244	0/184	0/160	1/139 (0.7)
胃排出不全	0/244	0/184	0/160	1/139 (0.7)
鼠径ヘルニア	0/244	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
腸出血	0/244	1/184 (0.5)	0/160	0/139
過敏性腸症候群	2/244 (0.8)	2/184 (1.1)	1/160 (0.6)	1/139 (0.7)
大腸ポリープ	0/244	0/184	0/160	1/139 (0.7)
口唇乾燥	0/244	1/184 (0.5)	0/160	0/139
メレナ	1/244 (0.4)	2/184 (1.1)	0/160	0/139
口腔腫脹	0/244	1/184 (0.5)	0/160	0/139
悪心	13/244 (5.3)	5/184 (2.7)	6/160 (3.8)	5/139 (3.6)

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
胃腸障害 (Cont.)				
便秘	5/123 (4.1)	0/2	0/0	20/244 (8.2)
齲歯	0/123	0/2	0/0	1/244 (0.4)
下痢	0/123	0/2	0/0	9/244 (3.7)
口内乾燥	2/123 (1.6)	0/2	0/0	8/244 (3.3)
消化不良	0/123	0/2	0/0	1/244 (0.4)
嚥下障害	0/123	0/2	0/0	1/244 (0.4)
糞塊	0/123	0/2	0/0	1/244 (0.4)
排便回数増加	0/123	0/2	0/0	1/244 (0.4)
胃食道逆流性疾患	2/123 (1.6)	0/2	0/0	2/244 (0.8)
舌炎	0/123	0/2	0/0	1/244 (0.4)
舌痛	0/123	0/2	0/0	1/244 (0.4)
吐血	0/123	0/2	0/0	1/244 (0.4)
痔核	0/123	0/2	0/0	1/244 (0.4)
裂孔ヘルニア	1/123 (0.8)	0/2	0/0	1/244 (0.4)
胃排出不全	1/123 (0.8)	0/2	0/0	1/244 (0.4)
鼠径ヘルニア	0/123	0/2	0/0	1/244 (0.4)
腸出血	0/123	0/2	0/0	1/244 (0.4)
過敏性腸症候群	1/123 (0.8)	0/2	0/0	2/244 (0.8)
大腸ポリープ	0/123	0/2	0/0	1/244 (0.4)
口唇乾燥	0/123	0/2	0/0	1/244 (0.4)
メレナ	0/123	0/2	0/0	2/244 (0.8)
口腔腫脹	0/123	0/2	0/0	1/244 (0.4)
悪心	3/123 (2.4)	0/2	0/0	19/244 (7.8)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
胃腸障害 (Cont.)				
口腔内不快感	0/244	1/184 (0.5)	1/160 (0.6)	0/139
口腔内痛	0/244	0/184	1/160 (0.6)	0/139
口の錯感覚	1/244 (0.4)	0/184	1/160 (0.6)	0/139
直腸出血	0/244	0/184	1/160 (0.6)	0/139
歯痛	1/244 (0.4)	0/184	0/160	0/139
嘔吐	4/244 (1.6)	1/184 (0.5)	1/160 (0.6)	2/139 (1.4)
一般・全身障害および投与部位の状態	195/244 (79.9)	129/184 (70.1)	102/160 (63.8)	84/139 (60.4)
投与部位内出血	0/244	0/184	0/160	1/139 (0.7)
投与部位紅斑	1/244 (0.4)	0/184	0/160	0/139
投与部位漏出	1/244 (0.4)	1/184 (0.5)	0/160	0/139
無力症	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	0/139
カテーテル留置部位紅斑	2/244 (0.8)	1/184 (0.5)	0/160	0/139
カテーテル留置部位漏出	0/244	0/184	1/160 (0.6)	0/139
カテーテル留置部位出血	1/244 (0.4)	0/184	0/160	0/139
カテーテル留置部位炎症	1/244 (0.4)	1/184 (0.5)	0/160	0/139
カテーテル留置部位刺激感	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	0/139
カテーテル留置部位浮腫	1/244 (0.4)	0/184	0/160	0/139
カテーテル留置部位疼痛	2/244 (0.8)	0/184	0/160	0/139
胸部不快感	0/244	1/184 (0.5)	0/160	0/139
胸痛	1/244 (0.4)	1/184 (0.5)	0/160	1/139 (0.7)
泣き	0/244	1/184 (0.5)	0/160	0/139

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
胃腸障害 (Cont.)				
口腔内不快感	0/123	0/2	0/0	1/244 (0.4)
口腔内痛	0/123	0/2	0/0	1/244 (0.4)
口の錯感覚	0/123	0/2	0/0	2/244 (0.8)
直腸出血	0/123	0/2	0/0	1/244 (0.4)
歯痛	0/123	0/2	0/0	1/244 (0.4)
嘔吐	0/123	0/2	0/0	6/244 (2.5)
一般・全身障害および投与部位の状態	68/123 (55.3)	0/2	0/0	203/244 (83.2)
投与部位内出血	1/123 (0.8)	0/2	0/0	1/244 (0.4)
投与部位紅斑	0/123	0/2	0/0	1/244 (0.4)
投与部位漏出	0/123	0/2	0/0	1/244 (0.4)
無力症	0/123	0/2	0/0	3/244 (1.2)
カテーテル留置部位紅斑	0/123	0/2	0/0	2/244 (0.8)
カテーテル留置部位漏出	0/123	0/2	0/0	1/244 (0.4)
カテーテル留置部位出血	0/123	0/2	0/0	1/244 (0.4)
カテーテル留置部位炎症	0/123	0/2	0/0	1/244 (0.4)
カテーテル留置部位刺激感	0/123	0/2	0/0	1/244 (0.4)
カテーテル留置部位浮腫	0/123	0/2	0/0	1/244 (0.4)
カテーテル留置部位疼痛	0/123	0/2	0/0	2/244 (0.8)
胸部不快感	0/123	0/2	0/0	1/244 (0.4)
胸痛	1/123 (0.8)	0/2	0/0	2/244 (0.8)
泣き	0/123	0/2	0/0	1/244 (0.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態 (Cont.)				
不快感	1/244 (0.4)	0/184	0/160	0/139
薬効欠如	0/244	1/184 (0.5)	0/160	0/139
薬剤離脱症候群	2/244 (0.8)	0/184	0/160	0/139
疲労	7/244 (2.9)	4/184 (2.2)	4/160 (2.5)	4/139 (2.9)
異常感	2/244 (0.8)	1/184 (0.5)	0/160	0/139
冷感	0/244	0/184	1/160 (0.6)	0/139
熱感	1/244 (0.4)	0/184	0/160	0/139
歩行障害	1/244 (0.4)	1/184 (0.5)	0/160	0/139
歩行不能	1/244 (0.4)	0/184	0/160	0/139
低体温	1/244 (0.4)	0/184	0/160	1/139 (0.7)
インフルエンザ様疾患	3/244 (1.2)	0/184	0/160	0/139
注入部位内出血	14/244 (5.7)	6/184 (3.3)	6/160 (3.8)	3/139 (2.2)
注入部位皮膚炎	1/244 (0.4)	2/184 (1.1)	1/160 (0.6)	3/139 (2.2)
注入部位分泌物	2/244 (0.8)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
注入部位変色	2/244 (0.8)	1/184 (0.5)	0/160	0/139
注入部位不快感	3/244 (1.2)	1/184 (0.5)	1/160 (0.6)	0/139
注入部位びらん	2/244 (0.8)	0/184	0/160	0/139
注入部位紅斑	113/244 (46.3)	58/184 (31.5)	39/160 (24.4)	32/139 (23.0)
注入部位皮膚剥脱	3/244 (1.2)	2/184 (1.1)	1/160 (0.6)	3/139 (2.2)
注入部位血管外漏出	17/244 (7.0)	9/184 (4.9)	5/160 (3.1)	3/139 (2.2)
注入部位血腫	12/244 (4.9)	5/184 (2.7)	4/160 (2.5)	3/139 (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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態 (Cont.)				
不快感	0/123	0/2	0/0	1/244 (0.4)
薬効欠如	0/123	0/2	0/0	1/244 (0.4)
薬剤離脱症候群	0/123	0/2	0/0	2/244 (0.8)
疲労	3/123 (2.4)	0/2	0/0	9/244 (3.7)
異常感	0/123	0/2	0/0	2/244 (0.8)
冷感	0/123	0/2	0/0	1/244 (0.4)
熱感	0/123	0/2	0/0	1/244 (0.4)
歩行障害	0/123	0/2	0/0	2/244 (0.8)
歩行不能	0/123	0/2	0/0	1/244 (0.4)
低体温	0/123	0/2	0/0	2/244 (0.8)
インフルエンザ様疾患	0/123	0/2	0/0	3/244 (1.2)
注入部位内出血	2/123 (1.6)	0/2	0/0	18/244 (7.4)
注入部位皮膚炎	2/123 (1.6)	0/2	0/0	4/244 (1.6)
注入部位分泌物	1/123 (0.8)	0/2	0/0	2/244 (0.8)
注入部位変色	0/123	0/2	0/0	2/244 (0.8)
注入部位不快感	0/123	0/2	0/0	4/244 (1.6)
注入部位びらん	0/123	0/2	0/0	2/244 (0.8)
注入部位紅斑	22/123 (17.9)	0/2	0/0	126/244 (51.6)
注入部位皮膚剥脱	3/123 (2.4)	0/2	0/0	6/244 (2.5)
注入部位血管外漏出	1/123 (0.8)	0/2	0/0	20/244 (8.2)
注入部位血腫	1/123 (0.8)	0/2	0/0	18/244 (7.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態 (Cont.)				
注入部位出血	6/244 (2.5)	3/184 (1.6)	1/160 (0.6)	2/139 (1.4)
注入部位硬結	8/244 (3.3)	5/184 (2.7)	3/160 (1.9)	4/139 (2.9)
注入部位炎症	5/244 (2.0)	4/184 (2.2)	2/160 (1.3)	2/139 (1.4)
注入部位損傷	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
注入部位刺激感	3/244 (1.2)	3/184 (1.6)	2/160 (1.3)	0/139
注入部位腫瘤	8/244 (3.3)	3/184 (1.6)	3/160 (1.9)	2/139 (1.4)
注入部位壊死	1/244 (0.4)	0/184	0/160	0/139
注入部位結節	54/244 (22.1)	53/184 (28.8)	45/160 (28.1)	43/139 (30.9)
注入部位浮腫	36/244 (14.8)	13/184 (7.1)	10/160 (6.3)	8/139 (5.8)
注入部位疼痛	32/244 (13.1)	20/184 (10.9)	15/160 (9.4)	12/139 (8.6)
注入部位蒼白	4/244 (1.6)	2/184 (1.1)	1/160 (0.6)	1/139 (0.7)
注入部位丘疹	8/244 (3.3)	6/184 (3.3)	3/160 (1.9)	3/139 (2.2)
注入部位異常感覚	2/244 (0.8)	0/184	1/160 (0.6)	0/139
注入部位そう痒感	4/244 (1.6)	2/184 (1.1)	3/160 (1.9)	1/139 (0.7)
注入部位発疹	5/244 (2.0)	3/184 (1.6)	1/160 (0.6)	0/139
注入部位反応	22/244 (9.0)	11/184 (6.0)	7/160 (4.4)	9/139 (6.5)
注入部位痂皮	0/244	1/184 (0.5)	0/160	1/139 (0.7)
注入部位腫脹	6/244 (2.5)	1/184 (0.5)	2/160 (1.3)	0/139
注入部位小水疱	2/244 (0.8)	1/184 (0.5)	0/160	0/139
注入部位熱感	1/244 (0.4)	0/184	0/160	0/139
注射部位内出血	2/244 (0.8)	1/184 (0.5)	1/160 (0.6)	0/139

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態 (Cont.)				
注入部位出血	1/123 (0.8)	0/2	0/0	9/244 (3.7)
注入部位硬結	4/123 (3.3)	0/2	0/0	10/244 (4.1)
注入部位炎症	3/123 (2.4)	0/2	0/0	9/244 (3.7)
注入部位損傷	0/123	0/2	0/0	2/244 (0.8)
注入部位刺激感	0/123	0/2	0/0	5/244 (2.0)
注入部位腫瘤	2/123 (1.6)	0/2	0/0	8/244 (3.3)
注入部位壊死	0/123	0/2	0/0	1/244 (0.4)
注入部位結節	37/123 (30.1)	0/2	0/0	69/244 (28.3)
注入部位浮腫	7/123 (5.7)	0/2	0/0	47/244 (19.3)
注入部位疼痛	10/123 (8.1)	0/2	0/0	38/244 (15.6)
注入部位蒼白	1/123 (0.8)	0/2	0/0	5/244 (2.0)
注入部位丘疹	5/123 (4.1)	0/2	0/0	18/244 (7.4)
注入部位異常感覚	0/123	0/2	0/0	2/244 (0.8)
注入部位そう痒感	1/123 (0.8)	0/2	0/0	7/244 (2.9)
注入部位発疹	0/123	0/2	0/0	7/244 (2.9)
注入部位反応	8/123 (6.5)	0/2	0/0	30/244 (12.3)
注入部位痂皮	1/123 (0.8)	0/2	0/0	1/244 (0.4)
注入部位腫脹	0/123	0/2	0/0	6/244 (2.5)
注入部位小水疱	0/123	0/2	0/0	2/244 (0.8)
注入部位熱感	0/123	0/2	0/0	1/244 (0.4)
注射部位内出血	0/123	0/2	0/0	3/244 (1.2)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態 (Cont.)				
注射部位変色	0/244	1/184 (0.5)	0/160	0/139
注射部位紅斑	13/244 (5.3)	7/184 (3.8)	6/160 (3.8)	3/139 (2.2)
注射部位漏出	2/244 (0.8)	2/184 (1.1)	2/160 (1.3)	2/139 (1.4)
注射部位血腫	1/244 (0.4)	0/184	0/160	0/139
注射部位出血	0/244	1/184 (0.5)	0/160	0/139
注射部位炎症	4/244 (1.6)	4/184 (2.2)	2/160 (1.3)	1/139 (0.7)
注射部位結節	5/244 (2.0)	6/184 (3.3)	6/160 (3.8)	3/139 (2.2)
注射部位浮腫	4/244 (1.6)	1/184 (0.5)	1/160 (0.6)	2/139 (1.4)
注射部位疼痛	7/244 (2.9)	2/184 (1.1)	1/160 (0.6)	1/139 (0.7)
注射部位丘疹	1/244 (0.4)	1/184 (0.5)	0/160	0/139
注射部位反応	1/244 (0.4)	0/184	1/160 (0.6)	1/139 (0.7)
注射部位腫脹	2/244 (0.8)	2/184 (1.1)	2/160 (1.3)	1/139 (0.7)
注射部位蕁麻疹	1/244 (0.4)	0/184	0/160	0/139
滴下投与部位熱傷	1/244 (0.4)	0/184	0/160	0/139
滴下投与部位痛	0/244	1/184 (0.5)	0/160	0/139
限局性浮腫	1/244 (0.4)	0/184	0/160	0/139
適用部位からの吸収不良	1/244 (0.4)	0/184	0/160	0/139
倦怠感	2/244 (0.8)	0/184	1/160 (0.6)	0/139
医療機器使用部位刺激感	3/244 (1.2)	1/184 (0.5)	0/160	0/139
医療機器使用部位そう痒感	1/244 (0.4)	0/184	0/160	0/139

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態 (Cont.)				
注射部位変色	0/123	0/2	0/0	1/244 (0.4)
注射部位紅斑	1/123 (0.8)	0/2	0/0	14/244 (5.7)
注射部位漏出	1/123 (0.8)	0/2	0/0	2/244 (0.8)
注射部位血腫	0/123	0/2	0/0	1/244 (0.4)
注射部位出血	0/123	0/2	0/0	1/244 (0.4)
注射部位炎症	1/123 (0.8)	0/2	0/0	6/244 (2.5)
注射部位結節	2/123 (1.6)	0/2	0/0	9/244 (3.7)
注射部位浮腫	2/123 (1.6)	0/2	0/0	5/244 (2.0)
注射部位疼痛	1/123 (0.8)	0/2	0/0	8/244 (3.3)
注射部位丘疹	0/123	0/2	0/0	2/244 (0.8)
注射部位反応	1/123 (0.8)	0/2	0/0	2/244 (0.8)
注射部位腫脹	0/123	0/2	0/0	4/244 (1.6)
注射部位蕁麻疹	0/123	0/2	0/0	1/244 (0.4)
滴下投与部位熱傷	0/123	0/2	0/0	1/244 (0.4)
滴下投与部位痛	0/123	0/2	0/0	1/244 (0.4)
限局性浮腫	0/123	0/2	0/0	1/244 (0.4)
適用部位からの吸収不良	0/123	0/2	0/0	1/244 (0.4)
倦怠感	0/123	0/2	0/0	3/244 (1.2)
医療機器使用部位刺激感	0/123	0/2	0/0	3/244 (1.2)
医療機器使用部位そう痒感	0/123	0/2	0/0	1/244 (0.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態 (Cont.)				
医療機器使用部位発疹	2/244 (0.8)	0/184	0/160	0/139
小結節	1/244 (0.4)	0/184	0/160	0/139
非心臓性胸痛	2/244 (0.8)	0/184	0/160	0/139
末梢性浮腫	8/244 (3.3)	4/184 (2.2)	4/160 (2.5)	1/139 (0.7)
疼痛	0/244	1/184 (0.5)	0/160	1/139 (0.7)
末梢腫脹	3/244 (1.2)	1/184 (0.5)	1/160 (0.6)	2/139 (1.4)
穿刺部位内出血	1/244 (0.4)	0/184	0/160	0/139
穿刺部位紅斑	2/244 (0.8)	2/184 (1.1)	0/160	0/139
穿刺部位出血	1/244 (0.4)	0/184	0/160	0/139
穿刺部位硬結	2/244 (0.8)	1/184 (0.5)	0/160	0/139
穿刺部位浮腫	1/244 (0.4)	0/184	0/160	0/139
穿刺部位腫脹	1/244 (0.4)	0/184	0/160	0/139
発熱	3/244 (1.2)	1/184 (0.5)	1/160 (0.6)	0/139
口渇	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
血管穿刺部位硬結	1/244 (0.4)	0/184	0/160	0/139
肝胆道系障害	2/244 (0.8)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
肝嚢胞	0/244	0/184	0/160	0/139
脂肪肝	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
門脈血栓症	1/244 (0.4)	0/184	0/160	0/139

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態 (Cont.)				
医療機器使用部位発疹	0/123	0/2	0/0	2/244 (0.8)
小結節	0/123	0/2	0/0	1/244 (0.4)
非心臓性胸痛	0/123	0/2	0/0	2/244 (0.8)
末梢性浮腫	1/123 (0.8)	0/2	0/0	9/244 (3.7)
疼痛	0/123	0/2	0/0	2/244 (0.8)
末梢腫脹	2/123 (1.6)	0/2	0/0	4/244 (1.6)
穿刺部位内出血	0/123	0/2	0/0	1/244 (0.4)
穿刺部位紅斑	0/123	0/2	0/0	3/244 (1.2)
穿刺部位出血	0/123	0/2	0/0	1/244 (0.4)
穿刺部位硬結	0/123	0/2	0/0	2/244 (0.8)
穿刺部位浮腫	0/123	0/2	0/0	1/244 (0.4)
穿刺部位腫脹	0/123	0/2	0/0	1/244 (0.4)
発熱	0/123	0/2	0/0	4/244 (1.6)
口渇	1/123 (0.8)	0/2	0/0	1/244 (0.4)
血管穿刺部位硬結	0/123	0/2	0/0	1/244 (0.4)
肝胆道系障害	2/123 (1.6)	1/2 (50.0)	0/0	3/244 (1.2)
肝嚢胞	1/123 (0.8)	1/2 (50.0)	0/0	1/244 (0.4)
脂肪肝	1/123 (0.8)	0/2	0/0	1/244 (0.4)
門脈血栓症	0/123	0/2	0/0	1/244 (0.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
感染症および寄生虫症	80/244 (32.8)	46/184 (25.0)	37/160 (23.1)	35/139 (25.2)
四肢膿瘍	0/244	0/184	1/160 (0.6)	0/139
無症候性COVID-19	0/244	0/184	1/160 (0.6)	1/139 (0.7)
細菌性疾患キャリアー	0/244	0/184	1/160 (0.6)	1/139 (0.7)
ボレリア感染	1/244 (0.4)	0/184	0/160	0/139
ウイルス性気管支炎	0/244	0/184	0/160	1/139 (0.7)
COVID-19	0/244	0/184	0/160	1/139 (0.7)
COVID-19肺炎	0/244	0/184	1/160 (0.6)	0/139
カテーテル留置部位感染	0/244	0/184	0/160	1/139 (0.7)
蜂巣炎	1/244 (0.4)	0/184	2/160 (1.3)	0/139
結膜炎	1/244 (0.4)	2/184 (1.1)	0/160	0/139
膀胱炎	1/244 (0.4)	0/184	1/160 (0.6)	1/139 (0.7)
爪の皮膚糸状菌症	0/244	1/184 (0.5)	1/160 (0.6)	0/139
真菌感染	1/244 (0.4)	0/184	0/160	0/139
胃腸炎	1/244 (0.4)	0/184	0/160	0/139
歯肉炎	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	0/139
麦粒腫	0/244	1/184 (0.5)	0/160	0/139
感染性皮膚潰瘍	1/244 (0.4)	1/184 (0.5)	0/160	0/139
インフルエンザ	0/244	0/184	0/160	1/139 (0.7)
注入部位膿瘍	18/244 (7.4)	10/184 (5.4)	6/160 (3.8)	4/139 (2.9)
注入部位蜂巣炎	40/244 (16.4)	16/184 (8.7)	14/160 (8.8)	15/139 (10.8)
注入部位感染	7/244 (2.9)	8/184 (4.3)	3/160 (1.9)	5/139 (3.6)
注入部位膿疱	1/244 (0.4)	1/184 (0.5)	0/160	0/139
注射部位蜂巣炎	2/244 (0.8)	1/184 (0.5)	0/160	1/139 (0.7)

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
感染症および寄生虫症	13/123 (10.6)	0/2	0/0	114/244 (46.7)
四肢膿瘍	0/123	0/2	0/0	1/244 (0.4)
無症候性COVID-19	0/123	0/2	0/0	1/244 (0.4)
細菌性疾患キャリアー	1/123 (0.8)	0/2	0/0	1/244 (0.4)
ボレリア感染	0/123	0/2	0/0	1/244 (0.4)
ウイルス性気管支炎	0/123	0/2	0/0	1/244 (0.4)
COVID-19	0/123	0/2	0/0	1/244 (0.4)
COVID-19肺炎	0/123	0/2	0/0	1/244 (0.4)
カテーテル留置部位感染	1/123 (0.8)	0/2	0/0	1/244 (0.4)
蜂巣炎	0/123	0/2	0/0	3/244 (1.2)
結膜炎	0/123	0/2	0/0	2/244 (0.8)
膀胱炎	0/123	0/2	0/0	2/244 (0.8)
爪の皮膚糸状菌症	0/123	0/2	0/0	1/244 (0.4)
真菌感染	0/123	0/2	0/0	1/244 (0.4)
胃腸炎	0/123	0/2	0/0	1/244 (0.4)
歯肉炎	0/123	0/2	0/0	1/244 (0.4)
麦粒腫	0/123	0/2	0/0	1/244 (0.4)
感染性皮膚潰瘍	0/123	0/2	0/0	1/244 (0.4)
インフルエンザ	1/123 (0.8)	0/2	0/0	1/244 (0.4)
注入部位膿瘍	1/123 (0.8)	0/2	0/0	27/244 (11.1)
注入部位蜂巣炎	4/123 (3.3)	0/2	0/0	56/244 (23.0)
注入部位感染	2/123 (1.6)	0/2	0/0	18/244 (7.4)
注入部位膿疱	0/123	0/2	0/0	1/244 (0.4)
注射部位蜂巣炎	0/123	0/2	0/0	3/244 (1.2)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
感染症および寄生虫症 (Cont.)				
リンパ管炎	0/244	0/184	1/160 (0.6)	0/139
上咽頭炎	5/244 (2.0)	3/184 (1.6)	1/160 (0.6)	2/139 (1.4)
爪真菌症	1/244 (0.4)	0/184	0/160	0/139
耳下腺膿瘍	0/244	0/184	1/160 (0.6)	0/139
肺炎	2/244 (0.8)	1/184 (0.5)	2/160 (1.3)	1/139 (0.7)
術後膿瘍	0/244	0/184	1/160 (0.6)	0/139
シュードモナス感染	1/244 (0.4)	1/184 (0.5)	0/160	0/139
膿疱性皮疹	1/244 (0.4)	0/184	0/160	0/139
気道感染	0/244	0/184	0/160	1/139 (0.7)
敗血症	2/244 (0.8)	1/184 (0.5)	0/160	1/139 (0.7)
敗血症性ショック	1/244 (0.4)	0/184	0/160	0/139
副鼻腔炎	1/244 (0.4)	1/184 (0.5)	0/160	0/139
ブドウ球菌感染	0/244	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
歯感染	1/244 (0.4)	1/184 (0.5)	0/160	1/139 (0.7)
上気道感染	1/244 (0.4)	0/184	0/160	0/139
尿路感染	10/244 (4.1)	7/184 (3.8)	5/160 (3.1)	4/139 (2.9)
水痘帯状疱疹ウイルス感染	0/244	1/184 (0.5)	0/160	0/139
傷害、中毒および処置合併症	29/244 (11.9)	18/184 (9.8)	15/160 (9.4)	11/139 (7.9)
足関節部骨折	1/244 (0.4)	1/184 (0.5)	0/160	0/139
節足動物咬傷	1/244 (0.4)	0/184	0/160	0/139
骨挫傷	0/244	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
感染症および寄生虫症 (Cont.)				
リンパ管炎	0/123	0/2	0/0	1/244 (0.4)
上咽頭炎	1/123 (0.8)	0/2	0/0	10/244 (4.1)
爪真菌症	0/123	0/2	0/0	1/244 (0.4)
耳下腺膿瘍	0/123	0/2	0/0	1/244 (0.4)
肺炎	0/123	0/2	0/0	4/244 (1.6)
術後膿瘍	0/123	0/2	0/0	1/244 (0.4)
シュードモナス感染	0/123	0/2	0/0	1/244 (0.4)
膿疱性皮疹	0/123	0/2	0/0	1/244 (0.4)
気道感染	0/123	0/2	0/0	1/244 (0.4)
敗血症	0/123	0/2	0/0	3/244 (1.2)
敗血症性ショック	0/123	0/2	0/0	1/244 (0.4)
副鼻腔炎	0/123	0/2	0/0	1/244 (0.4)
ブドウ球菌感染	0/123	0/2	0/0	2/244 (0.8)
歯感染	0/123	0/2	0/0	2/244 (0.8)
上気道感染	0/123	0/2	0/0	1/244 (0.4)
尿路感染	2/123 (1.6)	0/2	0/0	19/244 (7.8)
水痘帯状疱疹ウイルス感染	0/123	0/2	0/0	1/244 (0.4)
傷害、中毒および処置合併症	6/123 (4.9)	0/2	0/0	48/244 (19.7)
足関節部骨折	0/123	0/2	0/0	1/244 (0.4)
節足動物咬傷	0/123	0/2	0/0	1/244 (0.4)
骨挫傷	1/123 (0.8)	0/2	0/0	2/244 (0.8)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
傷害、中毒および処置合併症 (Cont.)				
脳挫傷	1/244 (0.4)	0/184	0/160	0/139
挫傷	3/244 (1.2)	4/184 (2.2)	2/160 (1.3)	1/139 (0.7)
医療機器設置の問題	1/244 (0.4)	0/184	0/160	0/139
医療機器による投与の欠落	1/244 (0.4)	0/184	0/160	0/139
期限切れの製品使用	1/244 (0.4)	0/184	0/160	0/139
眼挫傷	1/244 (0.4)	0/184	0/160	0/139
顔面損傷	0/244	1/184 (0.5)	0/160	0/139
顔面骨骨折	2/244 (0.8)	0/184	0/160	0/139
転倒	22/244 (9.0)	14/184 (7.6)	10/160 (6.3)	7/139 (5.0)
頭部損傷	1/244 (0.4)	2/184 (1.1)	2/160 (1.3)	0/139
注入に伴う反応	1/244 (0.4)	0/184	0/160	0/139
関節脱臼	0/244	1/184 (0.5)	1/160 (0.6)	0/139
靭帯捻挫	0/244	2/184 (1.1)	0/160	0/139
腰椎骨折	1/244 (0.4)	0/184	0/160	0/139
過量投与	0/244	0/184	1/160 (0.6)	1/139 (0.7)
処置後挫傷	1/244 (0.4)	0/184	0/160	0/139
処置によるめまい	1/244 (0.4)	0/184	0/160	0/139
肋骨骨折	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
皮膚擦過傷	1/244 (0.4)	2/184 (1.1)	3/160 (1.9)	0/139
皮膚損傷	1/244 (0.4)	0/184	0/160	0/139
皮膚裂傷	2/244 (0.8)	3/184 (1.6)	1/160 (0.6)	2/139 (1.4)
ストレス骨折	0/244	0/184	1/160 (0.6)	1/139 (0.7)

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
傷害、中毒および処置合併症 (Cont.)				
脳挫傷	0/123	0/2	0/0	1/244 (0.4)
挫傷	2/123 (1.6)	0/2	0/0	8/244 (3.3)
医療機器設置の問題	0/123	0/2	0/0	1/244 (0.4)
医療機器による投与の欠落	0/123	0/2	0/0	1/244 (0.4)
期限切れの製品使用	0/123	0/2	0/0	1/244 (0.4)
眼挫傷	0/123	0/2	0/0	1/244 (0.4)
顔面損傷	0/123	0/2	0/0	1/244 (0.4)
顔面骨骨折	0/123	0/2	0/0	2/244 (0.8)
転倒	2/123 (1.6)	0/2	0/0	40/244 (16.4)
頭部損傷	0/123	0/2	0/0	5/244 (2.0)
注入に伴う反応	0/123	0/2	0/0	1/244 (0.4)
関節脱臼	0/123	0/2	0/0	1/244 (0.4)
靭帯捻挫	0/123	0/2	0/0	2/244 (0.8)
腰椎骨折	0/123	0/2	0/0	1/244 (0.4)
過量投与	0/123	0/2	0/0	1/244 (0.4)
処置後挫傷	0/123	0/2	0/0	1/244 (0.4)
処置によるめまい	0/123	0/2	0/0	1/244 (0.4)
肋骨骨折	1/123 (0.8)	0/2	0/0	3/244 (1.2)
皮膚擦過傷	0/123	0/2	0/0	3/244 (1.2)
皮膚損傷	0/123	0/2	0/0	1/244 (0.4)
皮膚裂傷	0/123	0/2	0/0	7/244 (2.9)
ストレス骨折	0/123	0/2	0/0	1/244 (0.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
傷害、中毒および処置合併症 (Cont.)				
硬膜下血腫	0/244	0/184	0/160	1/139 (0.7)
サンバーン	1/244 (0.4)	0/184	0/160	0/139
腱断裂	0/244	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
過少量投与	0/244	0/184	1/160 (0.6)	0/139
創傷	0/244	0/184	0/160	1/139 (0.7)
臨床検査	31/244 (12.7)	30/184 (16.3)	32/160 (20.0)	27/139 (19.4)
血中クレアチンホスホキナーゼ増加	2/244 (0.8)	0/184	0/160	0/139
血中クレアチニン減少	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
血中葉酸異常	0/244	0/184	0/160	1/139 (0.7)
血中葉酸減少	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
血中ホモシステイン増加	1/244 (0.4)	1/184 (0.5)	2/160 (1.3)	2/139 (1.4)
血中リン減少	0/244	1/184 (0.5)	0/160	0/139
血圧上昇	2/244 (0.8)	0/184	0/160	0/139
起立血圧低下	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
血中ナトリウム減少	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
C-反応性蛋白増加	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
心雑音	0/244	0/184	1/160 (0.6)	0/139
握力低下	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
ヘモグロビン減少	1/244 (0.4)	1/184 (0.5)	0/160	1/139 (0.7)

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
傷害、中毒および処置合併症 (Cont.)				
硬膜下血腫	0/123	0/2	0/0	1/244 (0.4)
サンバーン	0/123	0/2	0/0	1/244 (0.4)
腱断裂	1/123 (0.8)	0/2	0/0	2/244 (0.8)
過少量投与	0/123	0/2	0/0	1/244 (0.4)
創傷	1/123 (0.8)	0/2	0/0	1/244 (0.4)
臨床検査	23/123 (18.7)	0/2	0/0	48/244 (19.7)
血中クレアチンホスホキナーゼ増加	0/123	0/2	0/0	2/244 (0.8)
血中クレアチニン減少	1/123 (0.8)	0/2	0/0	1/244 (0.4)
血中葉酸異常	1/123 (0.8)	0/2	0/0	1/244 (0.4)
血中葉酸減少	2/123 (1.6)	0/2	0/0	2/244 (0.8)
血中ホモシステイン増加	3/123 (2.4)	0/2	0/0	3/244 (1.2)
血中リン減少	0/123	0/2	0/0	1/244 (0.4)
血圧上昇	0/123	0/2	0/0	2/244 (0.8)
起立血圧低下	1/123 (0.8)	0/2	0/0	1/244 (0.4)
血中ナトリウム減少	1/123 (0.8)	0/2	0/0	1/244 (0.4)
C-反応性蛋白増加	1/123 (0.8)	0/2	0/0	1/244 (0.4)
心雑音	0/123	0/2	0/0	1/244 (0.4)
握力低下	1/123 (0.8)	0/2	0/0	1/244 (0.4)
ヘモグロビン減少	0/123	0/2	0/0	2/244 (0.8)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
臨床検査 (Cont.)				
リンパ球数減少	1/244 (0.4)	0/184	0/160	0/139
単球数増加	1/244 (0.4)	0/184	0/160	0/139
好中球数増加	2/244 (0.8)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
プロトロンビン時間延長	0/244	0/184	0/160	0/139
赤血球数減少	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
ビタミンB12減少	1/244 (0.4)	0/184	1/160 (0.6)	1/139 (0.7)
ビタミンB6減少	9/244 (3.7)	9/184 (4.9)	10/160 (6.3)	9/139 (6.5)
ビタミンD減少	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	0/139
体重減少	13/244 (5.3)	16/184 (8.7)	17/160 (10.6)	14/139 (10.1)
体重増加	1/244 (0.4)	2/184 (1.1)	2/160 (1.3)	2/139 (1.4)
白血球数増加	2/244 (0.8)	0/184	0/160	0/139
代謝および栄養障害	16/244 (6.6)	15/184 (8.2)	16/160 (10.0)	13/139 (9.4)
悪液質	0/244	0/184	1/160 (0.6)	0/139
食欲減退	3/244 (1.2)	4/184 (2.2)	3/160 (1.9)	2/139 (1.4)
脱水	2/244 (0.8)	2/184 (1.1)	0/160	0/139
糖尿病	0/244	0/184	1/160 (0.6)	1/139 (0.7)
水分過負荷	1/244 (0.4)	0/184	0/160	0/139
体液貯留	1/244 (0.4)	0/184	0/160	1/139 (0.7)
葉酸欠乏	1/244 (0.4)	1/184 (0.5)	2/160 (1.3)	2/139 (1.4)
耐糖能障害	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
高コレステロール血症	0/244	1/184 (0.5)	0/160	0/139
高血糖	1/244 (0.4)	0/184	0/160	0/139

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
臨床検査 (Cont.)				
リンパ球数減少	0/123	0/2	0/0	1/244 (0.4)
単球数増加	0/123	0/2	0/0	1/244 (0.4)
好中球数増加	1/123 (0.8)	0/2	0/0	2/244 (0.8)
プロトロンビン時間延長	1/123 (0.8)	0/2	0/0	1/244 (0.4)
赤血球数減少	1/123 (0.8)	0/2	0/0	1/244 (0.4)
ビタミンB12減少	1/123 (0.8)	0/2	0/0	2/244 (0.8)
ビタミンB6減少	9/123 (7.3)	0/2	0/0	11/244 (4.5)
ビタミンD減少	0/123	0/2	0/0	1/244 (0.4)
体重減少	8/123 (6.5)	0/2	0/0	24/244 (9.8)
体重増加	2/123 (1.6)	0/2	0/0	2/244 (0.8)
白血球数増加	0/123	0/2	0/0	2/244 (0.8)
代謝および栄養障害	8/123 (6.5)	0/2	0/0	30/244 (12.3)
悪液質	0/123	0/2	0/0	1/244 (0.4)
食欲減退	1/123 (0.8)	0/2	0/0	6/244 (2.5)
脱水	0/123	0/2	0/0	4/244 (1.6)
糖尿病	0/123	0/2	0/0	1/244 (0.4)
水分過負荷	0/123	0/2	0/0	1/244 (0.4)
体液貯留	1/123 (0.8)	0/2	0/0	2/244 (0.8)
葉酸欠乏	0/123	0/2	0/0	2/244 (0.8)
耐糖能障害	1/123 (0.8)	0/2	0/0	1/244 (0.4)
高コレステロール血症	0/123	0/2	0/0	1/244 (0.4)
高血糖	0/123	0/2	0/0	1/244 (0.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
代謝および栄養障害 (Cont.)				
高ホモシステイン血症	0/244	0/184	1/160 (0.6)	0/139
低カルシウム血症	0/244	0/184	1/160 (0.6)	0/139
低カリウム血症	2/244 (0.8)	0/184	0/160	1/139 (0.7)
低ナトリウム血症	0/244	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
栄養障害	1/244 (0.4)	0/184	0/160	0/139
ビタミンB群欠乏	1/244 (0.4)	1/184 (0.5)	2/160 (1.3)	2/139 (1.4)
ビタミンB12欠乏	0/244	0/184	1/160 (0.6)	1/139 (0.7)
ビタミンB6欠乏	5/244 (2.0)	5/184 (2.7)	7/160 (4.4)	5/139 (3.6)
筋骨格系および結合組織障害	27/244 (11.1)	18/184 (9.8)	23/160 (14.4)	21/139 (15.1)
関節痛	4/244 (1.6)	3/184 (1.6)	4/160 (2.5)	4/139 (2.9)
反応性関節炎	1/244 (0.4)	0/184	1/160 (0.6)	1/139 (0.7)
背部痛	6/244 (2.5)	4/184 (2.2)	7/160 (4.4)	5/139 (3.6)
骨痛	0/244	0/184	1/160 (0.6)	0/139
滑液包炎	1/244 (0.4)	0/184	1/160 (0.6)	1/139 (0.7)
外骨腫	0/244	1/184 (0.5)	1/160 (0.6)	0/139
椎間関節症候群	0/244	1/184 (0.5)	1/160 (0.6)	0/139
椎間板変性症	0/244	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
椎間板突出	0/244	1/184 (0.5)	1/160 (0.6)	0/139
関節滲出液	0/244	1/184 (0.5)	1/160 (0.6)	0/139
関節腫脹	1/244 (0.4)	1/184 (0.5)	0/160	0/139

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
代謝および栄養障害 (Cont.)				
高ホモシステイン血症	0/123	0/2	0/0	1/244 (0.4)
低カルシウム血症	0/123	0/2	0/0	1/244 (0.4)
低カリウム血症	0/123	0/2	0/0	3/244 (1.2)
低ナトリウム血症	0/123	0/2	0/0	2/244 (0.8)
栄養障害	0/123	0/2	0/0	1/244 (0.4)
ビタミンB群欠乏	2/123 (1.6)	0/2	0/0	2/244 (0.8)
ビタミンB12欠乏	1/123 (0.8)	0/2	0/0	2/244 (0.8)
ビタミンB6欠乏	4/123 (3.3)	0/2	0/0	8/244 (3.3)
筋骨格系および結合組織障害	16/123 (13.0)	0/2	0/0	45/244 (18.4)
関節痛	2/123 (1.6)	0/2	0/0	8/244 (3.3)
反応性関節炎	0/123	0/2	0/0	2/244 (0.8)
背部痛	5/123 (4.1)	0/2	0/0	13/244 (5.3)
骨痛	0/123	0/2	0/0	1/244 (0.4)
滑液包炎	0/123	0/2	0/0	2/244 (0.8)
外骨腫	0/123	0/2	0/0	1/244 (0.4)
椎間関節症候群	0/123	0/2	0/0	1/244 (0.4)
椎間板変性症	1/123 (0.8)	0/2	0/0	1/244 (0.4)
椎間板突出	0/123	0/2	0/0	1/244 (0.4)
関節滲出液	1/123 (0.8)	0/2	0/0	2/244 (0.8)
関節腫脹	0/123	0/2	0/0	1/244 (0.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
筋骨格系および結合組織障害 (Cont.)				
四肢不快感	0/244	0/184	1/160 (0.6)	0/139
筋萎縮	0/244	1/184 (0.5)	1/160 (0.6)	0/139
筋痙縮	2/244 (0.8)	4/184 (2.2)	2/160 (1.3)	1/139 (0.7)
筋力低下	3/244 (1.2)	2/184 (1.1)	2/160 (1.3)	2/139 (1.4)
筋骨格硬直	1/244 (0.4)	0/184	0/160	0/139
筋肉痛	3/244 (1.2)	0/184	0/160	0/139
頚部痛	0/244	0/184	2/160 (1.3)	2/139 (1.4)
骨炎	1/244 (0.4)	0/184	0/160	0/139
変形性関節症	1/244 (0.4)	3/184 (1.6)	4/160 (2.5)	2/139 (1.4)
骨減少症	0/244	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
四肢痛	5/244 (2.0)	3/184 (1.6)	2/160 (1.3)	1/139 (0.7)
関節周囲炎	0/244	0/184	1/160 (0.6)	1/139 (0.7)
姿勢異常	1/244 (0.4)	0/184	0/160	0/139
横紋筋融解症	1/244 (0.4)	0/184	0/160	1/139 (0.7)
肩回旋筋腱板症候群	0/244	1/184 (0.5)	1/160 (0.6)	0/139
仙腸関節機能障害	1/244 (0.4)	0/184	0/160	0/139
変形性脊椎症	0/244	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
腱障害	0/244	1/184 (0.5)	1/160 (0.6)	0/139
腱炎	1/244 (0.4)	0/184	0/160	0/139
斜頚	1/244 (0.4)	0/184	0/160	0/139
弾発指	0/244	0/184	1/160 (0.6)	1/139 (0.7)

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
筋骨格系および結合組織障害 (Cont.)				
四肢不快感	0/123	0/2	0/0	1/244 (0.4)
筋萎縮	0/123	0/2	0/0	1/244 (0.4)
筋痙縮	0/123	0/2	0/0	5/244 (2.0)
筋力低下	1/123 (0.8)	0/2	0/0	5/244 (2.0)
筋骨格硬直	0/123	0/2	0/0	1/244 (0.4)
筋肉痛	0/123	0/2	0/0	3/244 (1.2)
頚部痛	2/123 (1.6)	0/2	0/0	2/244 (0.8)
骨炎	0/123	0/2	0/0	1/244 (0.4)
変形性関節症	3/123 (2.4)	0/2	0/0	5/244 (2.0)
骨減少症	1/123 (0.8)	0/2	0/0	1/244 (0.4)
四肢痛	1/123 (0.8)	0/2	0/0	6/244 (2.5)
関節周囲炎	1/123 (0.8)	0/2	0/0	1/244 (0.4)
姿勢異常	0/123	0/2	0/0	1/244 (0.4)
横紋筋融解症	0/123	0/2	0/0	2/244 (0.8)
肩回旋筋腱板症候群	0/123	0/2	0/0	1/244 (0.4)
仙腸関節機能障害	0/123	0/2	0/0	1/244 (0.4)
変形性脊椎症	1/123 (0.8)	0/2	0/0	1/244 (0.4)
腱障害	0/123	0/2	0/0	1/244 (0.4)
腱炎	0/123	0/2	0/0	1/244 (0.4)
斜頚	0/123	0/2	0/0	1/244 (0.4)
弾発指	1/123 (0.8)	0/2	0/0	1/244 (0.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) 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）	1/244 (0.4)	3/184 (1.6)	4/160 (2.5)	2/139 (1.4)
基底細胞癌	0/244	2/184 (1.1)	2/160 (1.3)	0/139
直腸腺癌	0/244	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
脂漏性角化症	0/244	0/184	1/160 (0.6)	1/139 (0.7)
皮膚有棘細胞癌	1/244 (0.4)	0/184	0/160	0/139
神経系障害	79/244 (32.4)	49/184 (26.6)	41/160 (25.6)	39/139 (28.1)
アカシジア	0/244	0/184	0/160	1/139 (0.7)
健忘	0/244	0/184	0/160	0/139
失語症	0/244	0/184	1/160 (0.6)	0/139
運動失調	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
平衡障害	1/244 (0.4)	0/184	2/160 (1.3)	2/139 (1.4)
運動緩慢	1/244 (0.4)	0/184	1/160 (0.6)	0/139
手根管症候群	0/244	0/184	1/160 (0.6)	1/139 (0.7)
大脳萎縮	0/244	0/184	0/160	1/139 (0.7)
脳出血	0/244	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
脳圧排効果	0/244	0/184	0/160	1/139 (0.7)
脳血管発作	0/244	1/184 (0.5)	0/160	0/139
認知障害	2/244 (0.8)	2/184 (1.1)	2/160 (1.3)	3/139 (2.2)
振動覚低下	0/244	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
注意力障害	1/244 (0.4)	1/184 (0.5)	0/160	0/139
浮動性めまい	23/244 (9.4)	10/184 (5.4)	6/160 (3.8)	5/139 (3.6)
体位性めまい	3/244 (1.2)	3/184 (1.6)	1/160 (0.6)	0/139

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) 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)	1/123 (0.8)	0/2	0/0	5/244 (2.0)
基底細胞癌	0/123	0/2	0/0	2/244 (0.8)
直腸腺癌	0/123	0/2	0/0	1/244 (0.4)
脂漏性角化症	1/123 (0.8)	0/2	0/0	1/244 (0.4)
皮膚有棘細胞癌	0/123	0/2	0/0	1/244 (0.4)
神経系障害	36/123 (29.3)	1/2 (50.0)	0/0	110/244 (45.1)
アカシジア	0/123	0/2	0/0	1/244 (0.4)
健忘	1/123 (0.8)	0/2	0/0	1/244 (0.4)
失語症	0/123	0/2	0/0	1/244 (0.4)
運動失調	0/123	0/2	0/0	1/244 (0.4)
平衡障害	3/123 (2.4)	0/2	0/0	4/244 (1.6)
運動緩慢	0/123	0/2	0/0	2/244 (0.8)
手根管症候群	1/123 (0.8)	0/2	0/0	1/244 (0.4)
大脳萎縮	1/123 (0.8)	0/2	0/0	1/244 (0.4)
脳出血	1/123 (0.8)	0/2	0/0	1/244 (0.4)
脳圧排効果	0/123	0/2	0/0	1/244 (0.4)
脳血管発作	0/123	0/2	0/0	1/244 (0.4)
認知障害	4/123 (3.3)	0/2	0/0	6/244 (2.5)
振動覚低下	0/123	0/2	0/0	1/244 (0.4)
注意力障害	0/123	0/2	0/0	1/244 (0.4)
浮動性めまい	5/123 (4.1)	0/2	0/0	25/244 (10.2)
体位性めまい	0/123	0/2	0/0	5/244 (2.0)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
神経系障害 (Cont.)				
構語障害	1/244 (0.4)	1/184 (0.5)	2/160 (1.3)	1/139 (0.7)
味覚不全	2/244 (0.8)	0/184	0/160	1/139 (0.7)
ジスキネジア	11/244 (4.5)	5/184 (2.7)	3/160 (1.9)	4/139 (2.9)
起立障害	1/244 (0.4)	0/184	0/160	0/139
ジストニア	4/244 (1.6)	4/184 (2.2)	4/160 (2.5)	4/139 (2.9)
脳症	1/244 (0.4)	0/184	0/160	0/139
てんかん	1/244 (0.4)	0/184	0/160	0/139
本態性振戦	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	0/139
伸展性足底反応	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
すくみ現象	4/244 (1.6)	2/184 (1.1)	0/160	0/139
全身性強直性間代性発作	0/244	0/184	0/160	1/139 (0.7)
頭部不快感	1/244 (0.4)	0/184	0/160	0/139
頭痛	9/244 (3.7)	5/184 (2.7)	5/160 (3.1)	4/139 (2.9)
片側感覚消失	1/244 (0.4)	0/184	0/160	0/139
不全片麻痺	1/244 (0.4)	0/184	0/160	0/139
知覚過敏	0/244	0/184	1/160 (0.6)	1/139 (0.7)
感覚鈍麻	0/244	0/184	3/160 (1.9)	2/139 (1.4)
反射減弱	0/244	1/184 (0.5)	2/160 (1.3)	2/139 (1.4)
不規則睡眠覚醒リズム障害	0/244	0/184	1/160 (0.6)	1/139 (0.7)
嗜眠	0/244	1/184 (0.5)	1/160 (0.6)	0/139
意識消失	0/244	2/184 (1.1)	0/160	0/139
腰仙部神経根障害	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
神経系障害 (Cont.)				
構語障害	0/123	0/2	0/0	3/244 (1.2)
味覚不全	1/123 (0.8)	0/2	0/0	3/244 (1.2)
ジスキネジア	2/123 (1.6)	0/2	0/0	18/244 (7.4)
起立障害	0/123	0/2	0/0	1/244 (0.4)
ジストニア	4/123 (3.3)	0/2	0/0	7/244 (2.9)
脳症	0/123	0/2	0/0	1/244 (0.4)
てんかん	0/123	0/2	0/0	1/244 (0.4)
本態性振戦	0/123	0/2	0/0	1/244 (0.4)
伸展性足底反応	1/123 (0.8)	0/2	0/0	1/244 (0.4)
すくみ現象	0/123	0/2	0/0	4/244 (1.6)
全身性強直性間代性発作	0/123	0/2	0/0	1/244 (0.4)
頭部不快感	0/123	0/2	0/0	1/244 (0.4)
頭痛	4/123 (3.3)	0/2	0/0	14/244 (5.7)
片側感覚消失	0/123	0/2	0/0	1/244 (0.4)
不全片麻痺	0/123	0/2	0/0	1/244 (0.4)
知覚過敏	1/123 (0.8)	0/2	0/0	1/244 (0.4)
感覚鈍麻	2/123 (1.6)	0/2	0/0	3/244 (1.2)
反射減弱	2/123 (1.6)	0/2	0/0	3/244 (1.2)
不規則睡眠覚醒リズム障害	1/123 (0.8)	0/2	0/0	1/244 (0.4)
嗜眠	0/123	0/2	0/0	2/244 (0.8)
意識消失	0/123	0/2	0/0	2/244 (0.8)
腰仙部神経根障害	0/123	0/2	0/0	1/244 (0.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
神経系障害 (Cont.)				
記憶障害	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
代謝性脳症	1/244 (0.4)	0/184	1/160 (0.6)	1/139 (0.7)
神経痛	0/244	1/184 (0.5)	0/160	0/139
末梢性ニューロパチー	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
オンオフ現象	8/244 (3.3)	2/184 (1.1)	2/160 (1.3)	1/139 (0.7)
錯感覚	4/244 (1.6)	1/184 (0.5)	0/160	2/139 (1.4)
パーキンソン病	11/244 (4.5)	8/184 (4.3)	5/160 (3.1)	2/139 (1.4)
パーキンソニズム	2/244 (0.8)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
末梢性感覚ニューロパチー	0/244	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
側反弓	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	2/139 (1.4)
多発ニューロパチー	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
失神寸前の状態	0/244	1/184 (0.5)	0/160	0/139
心因性発作	1/244 (0.4)	0/184	0/160	0/139
精神運動亢進	2/244 (0.8)	0/184	0/160	0/139
反射異常	0/244	0/184	0/160	1/139 (0.7)
安静時振戦	1/244 (0.4)	0/184	0/160	0/139
坐骨神経痛	2/244 (0.8)	2/184 (1.1)	2/160 (1.3)	1/139 (0.7)
痙攣発作	0/244	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
感覚障害	1/244 (0.4)	0/184	0/160	0/139
感覚消失	0/244	1/184 (0.5)	1/160 (0.6)	0/139
睡眠時麻痺	0/244	1/184 (0.5)	0/160	0/139
傾眠	8/244 (3.3)	7/184 (3.8)	4/160 (2.5)	3/139 (2.2)
失神	0/244	1/184 (0.5)	0/160	1/139 (0.7)

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
神経系障害 (Cont.)				
記憶障害	1/123 (0.8)	0/2	0/0	2/244 (0.8)
代謝性脳症	1/123 (0.8)	0/2	0/0	2/244 (0.8)
神経痛	0/123	0/2	0/0	1/244 (0.4)
末梢性ニューロパチー	1/123 (0.8)	0/2	0/0	2/244 (0.8)
オンオフ現象	1/123 (0.8)	0/2	0/0	9/244 (3.7)
錯感覚	2/123 (1.6)	1/2 (50.0)	0/0	7/244 (2.9)
パーキンソン病	2/123 (1.6)	0/2	0/0	17/244 (7.0)
パーキンソニズム	1/123 (0.8)	0/2	0/0	3/244 (1.2)
末梢性感覚ニューロパチー	1/123 (0.8)	0/2	0/0	1/244 (0.4)
側反弓	2/123 (1.6)	0/2	0/0	3/244 (1.2)
多発ニューロパチー	1/123 (0.8)	0/2	0/0	2/244 (0.8)
失神寸前の状態	0/123	0/2	0/0	1/244 (0.4)
心因性発作	0/123	0/2	0/0	1/244 (0.4)
精神運動亢進	0/123	0/2	0/0	2/244 (0.8)
反射異常	1/123 (0.8)	0/2	0/0	1/244 (0.4)
安静時振戦	0/123	0/2	0/0	1/244 (0.4)
坐骨神経痛	0/123	0/2	0/0	3/244 (1.2)
痙攣発作	1/123 (0.8)	0/2	0/0	1/244 (0.4)
感覚障害	0/123	0/2	0/0	1/244 (0.4)
感覚消失	0/123	0/2	0/0	1/244 (0.4)
睡眠時麻痺	0/123	0/2	0/0	1/244 (0.4)
傾眠	3/123 (2.4)	0/2	0/0	12/244 (4.9)
失神	1/123 (0.8)	0/2	0/0	3/244 (1.2)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
神経系障害 (Cont.)				
振戦	2/244 (0.8)	1/184 (0.5)	0/160	0/139
製品の問題	3/244 (1.2)	0/184	0/160	0/139
医療機器送達システムの問題	1/244 (0.4)	0/184	0/160	0/139
医療機器位置異常	1/244 (0.4)	0/184	0/160	0/139
医療機器機能不良	1/244 (0.4)	0/184	0/160	0/139
精神障害	90/244 (36.9)	61/184 (33.2)	53/160 (33.1)	47/139 (33.8)
異常な夢	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
感情不安定	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	0/139
激越	1/244 (0.4)	0/184	0/160	0/139
不安	22/244 (9.0)	14/184 (7.6)	15/160 (9.4)	14/139 (10.1)
不安障害	0/244	0/184	0/160	1/139 (0.7)
無感情	0/244	1/184 (0.5)	0/160	0/139
歯ぎしり	2/244 (0.8)	1/184 (0.5)	0/160	0/139
強迫行為	1/244 (0.4)	0/184	0/160	0/139
強迫性性行動	0/244	0/184	1/160 (0.6)	0/139
錯乱状態	5/244 (2.0)	3/184 (1.6)	4/160 (2.5)	3/139 (2.2)
譫妄	4/244 (1.6)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
妄想	7/244 (2.9)	5/184 (2.7)	3/160 (1.9)	2/139 (1.4)
寄生虫妄想	0/244	1/184 (0.5)	0/160	0/139
妄想性障害、詳細不明	1/244 (0.4)	1/184 (0.5)	0/160	0/139

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
神経系障害 (Cont.)				
振戦	0/123	0/2	0/0	3/244 (1.2)
製品の問題	0/123	0/2	0/0	3/244 (1.2)
医療機器送達システムの問題	0/123	0/2	0/0	1/244 (0.4)
医療機器位置異常	0/123	0/2	0/0	1/244 (0.4)
医療機器機能不良	0/123	0/2	0/0	1/244 (0.4)
精神障害	30/123 (24.4)	0/2	0/0	108/244 (44.3)
異常な夢	1/123 (0.8)	0/2	0/0	1/244 (0.4)
感情不安定	0/123	0/2	0/0	2/244 (0.8)
激越	0/123	0/2	0/0	1/244 (0.4)
不安	10/123 (8.1)	0/2	0/0	29/244 (11.9)
不安障害	1/123 (0.8)	0/2	0/0	1/244 (0.4)
無感情	0/123	0/2	0/0	1/244 (0.4)
歯ぎしり	0/123	0/2	0/0	2/244 (0.8)
強迫行為	0/123	0/2	0/0	1/244 (0.4)
強迫性性行動	0/123	0/2	0/0	1/244 (0.4)
錯乱状態	1/123 (0.8)	0/2	0/0	9/244 (3.7)
譫妄	0/123	0/2	0/0	5/244 (2.0)
妄想	1/123 (0.8)	0/2	0/0	10/244 (4.1)
寄生虫妄想	0/123	0/2	0/0	1/244 (0.4)
妄想性障害、詳細不明	0/123	0/2	0/0	1/244 (0.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
精神障害 (Cont.)				
抑うつ気分	2/244 (0.8)	3/184 (1.6)	3/160 (1.9)	3/139 (2.2)
うつ病	1/244 (0.4)	3/184 (1.6)	3/160 (1.9)	3/139 (2.2)
抑うつ症状	2/244 (0.8)	0/184	0/160	0/139
ドーパミン調節障害症候群	0/244	0/184	0/160	1/139 (0.7)
ディスフェミア	0/244	0/184	1/160 (0.6)	0/139
睡眠異常	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
情動障害	1/244 (0.4)	1/184 (0.5)	0/160	0/139
注射恐怖	0/244	1/184 (0.5)	0/160	0/139
幻覚	33/244 (13.5)	21/184 (11.4)	15/160 (9.4)	14/139 (10.1)
幻聴	2/244 (0.8)	4/184 (2.2)	3/160 (1.9)	2/139 (1.4)
幻嗅	1/244 (0.4)	0/184	0/160	0/139
幻視	10/244 (4.1)	7/184 (3.8)	7/160 (4.4)	5/139 (3.6)
混合性幻覚	1/244 (0.4)	0/184	0/160	0/139
性欲過剰	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
錯覚	1/244 (0.4)	1/184 (0.5)	2/160 (1.3)	2/139 (1.4)
衝動制御障害	2/244 (0.8)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
衝動行為	0/244	0/184	0/160	1/139 (0.7)
不眠症	15/244 (6.1)	9/184 (4.9)	5/160 (3.1)	5/139 (3.6)
易刺激性	2/244 (0.8)	2/184 (1.1)	0/160	0/139
嫉妬妄想	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	0/139
躁病	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	0/139
気分変化	1/244 (0.4)	0/184	0/160	0/139
気分動揺	0/244	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
精神障害 (Cont.)				
抑うつ気分	1/123 (0.8)	0/2	0/0	4/244 (1.6)
うつ病	1/123 (0.8)	0/2	0/0	5/244 (2.0)
抑うつ症状	0/123	0/2	0/0	2/244 (0.8)
ドーパミン調節障害症候群	0/123	0/2	0/0	1/244 (0.4)
ディスフェミア	0/123	0/2	0/0	1/244 (0.4)
睡眠異常	1/123 (0.8)	0/2	0/0	1/244 (0.4)
情動障害	0/123	0/2	0/0	2/244 (0.8)
注射恐怖	0/123	0/2	0/0	1/244 (0.4)
幻覚	8/123 (6.5)	0/2	0/0	42/244 (17.2)
幻聴	1/123 (0.8)	0/2	0/0	6/244 (2.5)
幻嗅	0/123	0/2	0/0	1/244 (0.4)
幻視	3/123 (2.4)	0/2	0/0	15/244 (6.1)
混合性幻覚	0/123	0/2	0/0	1/244 (0.4)
性欲過剰	0/123	0/2	0/0	1/244 (0.4)
錯覚	0/123	0/2	0/0	2/244 (0.8)
衝動制御障害	1/123 (0.8)	0/2	0/0	4/244 (1.6)
衝動行為	1/123 (0.8)	0/2	0/0	1/244 (0.4)
不眠症	5/123 (4.1)	0/2	0/0	18/244 (7.4)
易刺激性	0/123	0/2	0/0	2/244 (0.8)
嫉妬妄想	0/123	0/2	0/0	1/244 (0.4)
躁病	0/123	0/2	0/0	1/244 (0.4)
気分変化	0/123	0/2	0/0	1/244 (0.4)
気分動揺	0/123	0/2	0/0	1/244 (0.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
精神障害 (Cont.)				
悪夢	1/244 (0.4)	1/184 (0.5)	0/160	0/139
強迫観念	1/244 (0.4)	1/184 (0.5)	0/160	0/139
パニック発作	3/244 (1.2)	0/184	1/160 (0.6)	1/139 (0.7)
パニック反応	0/244	0/184	1/160 (0.6)	1/139 (0.7)
妄想症	0/244	1/184 (0.5)	2/160 (1.3)	2/139 (1.4)
睡眠の質低下	0/244	1/184 (0.5)	0/160	0/139
処置に対する不安	0/244	1/184 (0.5)	0/160	0/139
精神病性障害	3/244 (1.2)	2/184 (1.1)	3/160 (1.9)	2/139 (1.4)
精神病症状	0/244	0/184	0/160	1/139 (0.7)
レム睡眠行動障害	2/244 (0.8)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
レム睡眠異常	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
睡眠障害	2/244 (0.8)	2/184 (1.1)	1/160 (0.6)	1/139 (0.7)
ねごと	1/244 (0.4)	2/184 (1.1)	0/160	0/139
常同症	0/244	0/184	0/160	1/139 (0.7)
ストレス	1/244 (0.4)	0/184	0/160	0/139
自殺念慮	2/244 (0.8)	2/184 (1.1)	1/160 (0.6)	0/139
自殺企図	0/244	0/184	0/160	1/139 (0.7)
腎および尿路障害	11/244 (4.5)	8/184 (4.3)	11/160 (6.9)	11/139 (7.9)
膀胱痙縮	0/244	0/184	1/160 (0.6)	1/139 (0.7)
膀胱結石	0/244	1/184 (0.5)	0/160	0/139
尿路結石	0/244	0/184	1/160 (0.6)	1/139 (0.7)

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
精神障害 (Cont.)				
悪夢	0/123	0/2	0/0	2/244 (0.8)
強迫観念	0/123	0/2	0/0	1/244 (0.4)
パニック発作	1/123 (0.8)	0/2	0/0	3/244 (1.2)
パニック反応	0/123	0/2	0/0	1/244 (0.4)
妄想症	1/123 (0.8)	0/2	0/0	2/244 (0.8)
睡眠の質低下	0/123	0/2	0/0	1/244 (0.4)
処置に対する不安	0/123	0/2	0/0	1/244 (0.4)
精神病性障害	1/123 (0.8)	0/2	0/0	6/244 (2.5)
精神病症状	1/123 (0.8)	0/2	0/0	1/244 (0.4)
レム睡眠行動障害	1/123 (0.8)	0/2	0/0	2/244 (0.8)
レム睡眠異常	1/123 (0.8)	0/2	0/0	1/244 (0.4)
睡眠障害	1/123 (0.8)	0/2	0/0	3/244 (1.2)
ねごと	0/123	0/2	0/0	2/244 (0.8)
常同症	1/123 (0.8)	0/2	0/0	1/244 (0.4)
ストレス	0/123	0/2	0/0	1/244 (0.4)
自殺念慮	0/123	0/2	0/0	3/244 (1.2)
自殺企図	0/123	0/2	0/0	1/244 (0.4)
腎および尿路障害	6/123 (4.9)	0/2	0/0	20/244 (8.2)
膀胱痙縮	1/123 (0.8)	0/2	0/0	1/244 (0.4)
膀胱結石	0/123	0/2	0/0	1/244 (0.4)
尿路結石	0/123	0/2	0/0	1/244 (0.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
腎および尿路障害 (Cont.)				
排尿困難	2/244 (0.8)	0/184	0/160	1/139 (0.7)
緊張性膀胱	0/244	0/184	0/160	1/139 (0.7)
夜間頻尿	0/244	1/184 (0.5)	1/160 (0.6)	0/139
頻尿	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
多尿	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
腎機能障害	0/244	0/184	1/160 (0.6)	0/139
尿管結石症	1/244 (0.4)	0/184	0/160	0/139
切迫性尿失禁	3/244 (1.2)	3/184 (1.6)	2/160 (1.3)	2/139 (1.4)
尿失禁	2/244 (0.8)	1/184 (0.5)	2/160 (1.3)	2/139 (1.4)
尿閉	0/244	0/184	1/160 (0.6)	3/139 (2.2)
尿路障害	1/244 (0.4)	0/184	0/160	0/139
尿異常	1/244 (0.4)	0/184	0/160	0/139
尿臭異常	0/244	0/184	1/160 (0.6)	1/139 (0.7)
生殖系および乳房障害	3/244 (1.2)	5/184 (2.7)	5/160 (3.1)	5/139 (3.6)
良性前立腺肥大症	0/244	0/184	1/160 (0.6)	1/139 (0.7)
勃起不全	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
骨盤痛	0/244	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
ペイロニー病	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
閉経後出血	0/244	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
前立腺腫大	0/244	1/184 (0.5)	0/160	0/139

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
腎および尿路障害 (Cont.)				
排尿困難	1/123 (0.8)	0/2	0/0	3/244 (1.2)
緊張性膀胱	1/123 (0.8)	0/2	0/0	1/244 (0.4)
夜間頻尿	0/123	0/2	0/0	1/244 (0.4)
頻尿	0/123	0/2	0/0	1/244 (0.4)
多尿	1/123 (0.8)	0/2	0/0	1/244 (0.4)
腎機能障害	0/123	0/2	0/0	1/244 (0.4)
尿管結石症	0/123	0/2	0/0	1/244 (0.4)
切迫性尿失禁	1/123 (0.8)	0/2	0/0	3/244 (1.2)
尿失禁	0/123	0/2	0/0	5/244 (2.0)
尿閉	1/123 (0.8)	0/2	0/0	3/244 (1.2)
尿路障害	0/123	0/2	0/0	1/244 (0.4)
尿異常	0/123	0/2	0/0	1/244 (0.4)
尿臭異常	0/123	0/2	0/0	1/244 (0.4)
生殖系および乳房障害	4/123 (3.3)	0/2	0/0	7/244 (2.9)
良性前立腺肥大症	0/123	0/2	0/0	1/244 (0.4)
勃起不全	1/123 (0.8)	0/2	0/0	2/244 (0.8)
骨盤痛	1/123 (0.8)	0/2	0/0	1/244 (0.4)
ペイロニー病	1/123 (0.8)	0/2	0/0	1/244 (0.4)
閉経後出血	1/123 (0.8)	0/2	0/0	1/244 (0.4)
前立腺腫大	0/123	0/2	0/0	1/244 (0.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
生殖系および乳房障害 (Cont.)				
膣脱	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
呼吸器、胸郭および縦隔障害	15/244 (6.1)	8/184 (4.3)	8/160 (5.0)	5/139 (3.6)
急性呼吸不全	1/244 (0.4)	0/184	0/160	0/139
気管支拡張症	0/244	0/184	1/160 (0.6)	0/139
咳嗽	3/244 (1.2)	1/184 (0.5)	0/160	0/139
発声障害	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	0/139
呼吸困難	5/244 (2.0)	2/184 (1.1)	2/160 (1.3)	1/139 (0.7)
労作性呼吸困難	0/244	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
鼻出血	0/244	0/184	1/160 (0.6)	0/139
過換気	2/244 (0.8)	0/184	0/160	0/139
口腔咽頭痛	1/244 (0.4)	1/184 (0.5)	0/160	0/139
誤嚥性肺炎	0/244	0/184	0/160	1/139 (0.7)
湿性咳嗽	0/244	0/184	1/160 (0.6)	0/139
肺塞栓症	1/244 (0.4)	0/184	0/160	1/139 (0.7)
ラ音	0/244	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
呼吸窮迫	0/244	1/184 (0.5)	1/160 (0.6)	0/139
鼻痛	1/244 (0.4)	0/184	0/160	0/139
鼻漏	2/244 (0.8)	0/184	0/160	0/139
咽喉刺激感	1/244 (0.4)	0/184	0/160	0/139

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
生殖系および乳房障害 (Cont.)				
膣脱	1/123 (0.8)	0/2	0/0	1/244 (0.4)
呼吸器、胸郭および縦隔障害	3/123 (2.4)	0/2	0/0	26/244 (10.7)
急性呼吸不全	0/123	0/2	0/0	1/244 (0.4)
気管支拡張症	0/123	0/2	0/0	1/244 (0.4)
咳嗽	0/123	0/2	0/0	3/244 (1.2)
発声障害	0/123	0/2	0/0	2/244 (0.8)
呼吸困難	1/123 (0.8)	0/2	0/0	8/244 (3.3)
労作性呼吸困難	1/123 (0.8)	0/2	0/0	1/244 (0.4)
鼻出血	0/123	0/2	0/0	1/244 (0.4)
過換気	0/123	0/2	0/0	2/244 (0.8)
口腔咽頭痛	0/123	0/2	0/0	2/244 (0.8)
誤嚥性肺炎	0/123	0/2	0/0	1/244 (0.4)
湿性咳嗽	0/123	0/2	0/0	1/244 (0.4)
肺塞栓症	1/123 (0.8)	0/2	0/0	2/244 (0.8)
ラ音	0/123	0/2	0/0	1/244 (0.4)
呼吸窮迫	0/123	0/2	0/0	1/244 (0.4)
鼻痛	0/123	0/2	0/0	1/244 (0.4)
鼻漏	0/123	0/2	0/0	2/244 (0.8)
咽喉刺激感	0/123	0/2	0/0	1/244 (0.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
皮膚および皮下組織障害	22/244 (9.0)	13/184 (7.1)	11/160 (6.9)	12/139 (8.6)
脱毛症	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	2/139 (1.4)
褥瘡性潰瘍	1/244 (0.4)	1/184 (0.5)	0/160	0/139
皮膚嚢腫	1/244 (0.4)	1/184 (0.5)	0/160	1/139 (0.7)
皮膚炎	1/244 (0.4)	1/184 (0.5)	0/160	0/139
接触皮膚炎	1/244 (0.4)	0/184	0/160	1/139 (0.7)
おむつ皮膚炎	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
薬疹	1/244 (0.4)	1/184 (0.5)	0/160	0/139
皮膚乾燥	1/244 (0.4)	1/184 (0.5)	0/160	0/139
斑状出血	1/244 (0.4)	0/184	0/160	0/139
紅斑	4/244 (1.6)	0/184	0/160	0/139
爪の障害	0/244	0/184	1/160 (0.6)	1/139 (0.7)
脂肪織炎	0/244	0/184	1/160 (0.6)	1/139 (0.7)
丘疹	2/244 (0.8)	2/184 (1.1)	2/160 (1.3)	1/139 (0.7)
口囲皮膚炎	0/244	0/184	0/160	1/139 (0.7)
光線過敏性反応	1/244 (0.4)	0/184	0/160	0/139
そう痒症	1/244 (0.4)	1/184 (0.5)	3/160 (1.9)	3/139 (2.2)
乾癬	0/244	1/184 (0.5)	1/160 (0.6)	0/139
発疹	2/244 (0.8)	1/184 (0.5)	2/160 (1.3)	1/139 (0.7)
紅斑性皮疹	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	1/139 (0.7)
そう痒性皮疹	2/244 (0.8)	1/184 (0.5)	2/160 (1.3)	1/139 (0.7)
皮膚刺激	1/244 (0.4)	0/184	0/160	0/139
皮膚病変	1/244 (0.4)	1/184 (0.5)	1/160 (0.6)	0/139

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
皮膚および皮下組織障害	7/123 (5.7)	0/2	0/0	30/244 (12.3)
脱毛症	1/123 (0.8)	0/2	0/0	3/244 (1.2)
褥瘡性潰瘍	0/123	0/2	0/0	1/244 (0.4)
皮膚嚢腫	0/123	0/2	0/0	2/244 (0.8)
皮膚炎	0/123	0/2	0/0	1/244 (0.4)
接触皮膚炎	1/123 (0.8)	0/2	0/0	2/244 (0.8)
おむつ皮膚炎	1/123 (0.8)	0/2	0/0	1/244 (0.4)
薬疹	0/123	0/2	0/0	1/244 (0.4)
皮膚乾燥	0/123	0/2	0/0	2/244 (0.8)
斑状出血	0/123	0/2	0/0	1/244 (0.4)
紅斑	0/123	0/2	0/0	4/244 (1.6)
爪の障害	1/123 (0.8)	0/2	0/0	1/244 (0.4)
脂肪織炎	0/123	0/2	0/0	1/244 (0.4)
丘疹	1/123 (0.8)	0/2	0/0	2/244 (0.8)
口囲皮膚炎	0/123	0/2	0/0	1/244 (0.4)
光線過敏性反応	0/123	0/2	0/0	1/244 (0.4)
そう痒症	2/123 (1.6)	0/2	0/0	4/244 (1.6)
乾癬	0/123	0/2	0/0	1/244 (0.4)
発疹	1/123 (0.8)	0/2	0/0	3/244 (1.2)
紅斑性皮疹	1/123 (0.8)	0/2	0/0	1/244 (0.4)
そう痒性皮疹	1/123 (0.8)	0/2	0/0	3/244 (1.2)
皮膚刺激	0/123	0/2	0/0	1/244 (0.4)
皮膚病変	0/123	0/2	0/0	1/244 (0.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Total (Any Dose)				
皮膚および皮下組織障害 (Cont.)				
皮膚潰瘍	2/244 (0.8)	1/184 (0.5)	1/160 (0.6)	0/139
蕁麻疹	0/244	1/184 (0.5)	2/160 (1.3)	1/139 (0.7)
社会環境	1/244 (0.4)	1/184 (0.5)	0/160	0/139
運動不能	1/244 (0.4)	1/184 (0.5)	0/160	0/139
外科および内科処置	0/244	1/184 (0.5)	0/160	0/139
抜歯	0/244	1/184 (0.5)	0/160	0/139
血管障害	13/244 (5.3)	6/184 (3.3)	10/160 (6.3)	12/139 (8.6)
深部静脈血栓症	1/244 (0.4)	0/184	0/160	0/139
血腫	0/244	0/184	0/160	1/139 (0.7)
出血	0/244	1/184 (0.5)	0/160	0/139
ほてり	1/244 (0.4)	0/184	0/160	0/139
高血圧	4/244 (1.6)	0/184	1/160 (0.6)	2/139 (1.4)
高血圧クリーゼ	1/244 (0.4)	0/184	0/160	0/139
低血圧	3/244 (1.2)	1/184 (0.5)	2/160 (1.3)	2/139 (1.4)
不安定血圧	1/244 (0.4)	0/184	0/160	0/139
起立性高血圧	0/244	0/184	0/160	0/139
起立性低血圧	5/244 (2.0)	4/184 (2.2)	7/160 (4.4)	8/139 (5.8)

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Total (Any Dose)				
皮膚および皮下組織障害 (Cont.)				
皮膚潰瘍	0/123	0/2	0/0	2/244 (0.8)
蕁麻疹	0/123	0/2	0/0	2/244 (0.8)
社会環境	0/123	0/2	0/0	1/244 (0.4)
運動不能	0/123	0/2	0/0	1/244 (0.4)
外科および内科処置	0/123	0/2	0/0	1/244 (0.4)
抜歯	0/123	0/2	0/0	1/244 (0.4)
血管障害	13/123 (10.6)	1/2 (50.0)	0/0	27/244 (11.1)
深部静脈血栓症	0/123	0/2	0/0	1/244 (0.4)
血腫	0/123	0/2	0/0	1/244 (0.4)
出血	0/123	0/2	0/0	1/244 (0.4)
ほてり	0/123	0/2	0/0	1/244 (0.4)
高血圧	0/123	0/2	0/0	6/244 (2.5)
高血圧クリーゼ	0/123	0/2	0/0	1/244 (0.4)
低血圧	3/123 (2.4)	0/2	0/0	6/244 (2.5)
不安定血圧	0/123	0/2	0/0	1/244 (0.4)
起立性高血圧	1/123 (0.8)	0/2	0/0	1/244 (0.4)
起立性低血圧	9/123 (7.3)	1/2 (50.0)	0/0	13/244 (5.3)

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.
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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Low Dose				
Any adverse event	120/132 (90.9)	84/99 (84.8)	75/87 (86.2)	64/76 (84.2)
血液およびリンパ系障害	1/132 (0.8)	1/99 (1.0)	1/87 (1.1)	0/76
リンパ節症	1/132 (0.8)	1/99 (1.0)	1/87 (1.1)	0/76
心臓障害	1/132 (0.8)	3/99 (3.0)	2/87 (2.3)	3/76 (3.9)
急性心筋梗塞	0/132	0/99	0/87	1/76 (1.3)
狭心症	0/132	1/99 (1.0)	1/87 (1.1)	1/76 (1.3)
心停止	0/132	0/99	0/87	1/76 (1.3)
冠動脈疾患	0/132	0/99	0/87	1/76 (1.3)
冠動脈狭窄	0/132	0/99	0/87	1/76 (1.3)
心筋梗塞	1/132 (0.8)	1/99 (1.0)	0/87	0/76
頻脈	0/132	1/99 (1.0)	1/87 (1.1)	0/76
耳および迷路障害	2/132 (1.5)	1/99 (1.0)	1/87 (1.1)	1/76 (1.3)
感音性難聴	0/132	0/99	1/87 (1.1)	1/76 (1.3)
回転性めまい	2/132 (1.5)	1/99 (1.0)	0/87	0/76
眼障害	3/132 (2.3)	4/99 (4.0)	3/87 (3.4)	4/76 (5.3)
白内障	0/132	0/99	1/87 (1.1)	2/76 (2.6)
複視	3/132 (2.3)	2/99 (2.0)	1/87 (1.1)	1/76 (1.3)
ドライアイ	1/132 (0.8)	0/99	0/87	0/76
緑内障	0/132	0/99	0/87	1/76 (1.3)
網膜裂孔	0/132	2/99 (2.0)	1/87 (1.1)	0/76

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Low Dose				
Any adverse event	50/68 (73.5)	2/2 (100)	0/0	122/132 (92.4)
血液およびリンパ系障害	0/68	0/2	0/0	1/132 (0.8)
リンパ節症	0/68	0/2	0/0	1/132 (0.8)
心臓障害	2/68 (2.9)	0/2	0/0	5/132 (3.8)
急性心筋梗塞	0/68	0/2	0/0	1/132 (0.8)
狭心症	1/68 (1.5)	0/2	0/0	1/132 (0.8)
心停止	0/68	0/2	0/0	1/132 (0.8)
冠動脈疾患	1/68 (1.5)	0/2	0/0	1/132 (0.8)
冠動脈狭窄	0/68	0/2	0/0	1/132 (0.8)
心筋梗塞	0/68	0/2	0/0	1/132 (0.8)
頻脈	0/68	0/2	0/0	1/132 (0.8)
耳および迷路障害	1/68 (1.5)	0/2	0/0	4/132 (3.0)
感音性難聴	1/68 (1.5)	0/2	0/0	1/132 (0.8)
回転性めまい	0/68	0/2	0/0	3/132 (2.3)
眼障害	2/68 (2.9)	0/2	0/0	8/132 (6.1)
白内障	0/68	0/2	0/0	2/132 (1.5)
複視	1/68 (1.5)	0/2	0/0	3/132 (2.3)
ドライアイ	0/68	0/2	0/0	1/132 (0.8)
緑内障	1/68 (1.5)	0/2	0/0	1/132 (0.8)
網膜裂孔	0/68	0/2	0/0	2/132 (1.5)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Low Dose				
眼障害 (Cont.)				
霧視	1/132 (0.8)	0/99	0/87	0/76
胃腸障害	18/132 (13.6)	14/99 (14.1)	13/87 (14.9)	8/76 (10.5)
腹部膨満	0/132	1/99 (1.0)	1/87 (1.1)	0/76
腹痛	1/132 (0.8)	1/99 (1.0)	0/87	0/76
上腹部痛	0/132	1/99 (1.0)	1/87 (1.1)	1/76 (1.3)
アフタ性潰瘍	1/132 (0.8)	0/99	0/87	0/76
呼気臭	2/132 (1.5)	1/99 (1.0)	1/87 (1.1)	1/76 (1.3)
虚血性大腸炎	0/132	1/99 (1.0)	0/87	0/76
便秘	5/132 (3.8)	4/99 (4.0)	4/87 (4.6)	3/76 (3.9)
齲歯	0/132	0/99	1/87 (1.1)	0/76
下痢	3/132 (2.3)	2/99 (2.0)	2/87 (2.3)	0/76
口内乾燥	3/132 (2.3)	2/99 (2.0)	2/87 (2.3)	1/76 (1.3)
消化不良	1/132 (0.8)	0/99	0/87	0/76
胃食道逆流性疾患	0/132	0/99	1/87 (1.1)	1/76 (1.3)
舌炎	0/132	1/99 (1.0)	1/87 (1.1)	0/76
舌痛	0/132	1/99 (1.0)	1/87 (1.1)	0/76
吐血	0/132	0/99	0/87	1/76 (1.3)
痔核	1/132 (0.8)	0/99	0/87	0/76
裂孔ヘルニア	0/132	0/99	0/87	1/76 (1.3)
胃排出不全	0/132	0/99	0/87	1/76 (1.3)
鼠径ヘルニア	0/132	1/99 (1.0)	1/87 (1.1)	1/76 (1.3)
腸出血	0/132	1/99 (1.0)	0/87	0/76

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Low Dose				
眼障害 (Cont.)				
霧視	0/68	0/2	0/0	1/132 (0.8)
胃腸障害	5/68 (7.4)	0/2	0/0	27/132 (20.5)
腹部膨満	0/68	0/2	0/0	1/132 (0.8)
腹痛	0/68	0/2	0/0	2/132 (1.5)
上腹部痛	0/68	0/2	0/0	1/132 (0.8)
アフタ性潰瘍	0/68	0/2	0/0	1/132 (0.8)
呼気臭	0/68	0/2	0/0	2/132 (1.5)
虚血性大腸炎	0/68	0/2	0/0	1/132 (0.8)
便秘	3/68 (4.4)	0/2	0/0	8/132 (6.1)
齲歯	0/68	0/2	0/0	1/132 (0.8)
下痢	0/68	0/2	0/0	6/132 (4.5)
口内乾燥	0/68	0/2	0/0	3/132 (2.3)
消化不良	0/68	0/2	0/0	1/132 (0.8)
胃食道逆流性疾患	1/68 (1.5)	0/2	0/0	1/132 (0.8)
舌炎	0/68	0/2	0/0	1/132 (0.8)
舌痛	0/68	0/2	0/0	1/132 (0.8)
吐血	0/68	0/2	0/0	1/132 (0.8)
痔核	0/68	0/2	0/0	1/132 (0.8)
裂孔ヘルニア	1/68 (1.5)	0/2	0/0	1/132 (0.8)
胃排出不全	1/68 (1.5)	0/2	0/0	1/132 (0.8)
鼠径ヘルニア	0/68	0/2	0/0	1/132 (0.8)
腸出血	0/68	0/2	0/0	1/132 (0.8)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Low Dose				
胃腸障害 (Cont.)				
過敏性腸症候群	1/132 (0.8)	1/99 (1.0)	0/87	0/76
口唇乾燥	0/132	1/99 (1.0)	0/87	0/76
メレナ	1/132 (0.8)	2/99 (2.0)	0/87	0/76
口腔腫脹	0/132	1/99 (1.0)	0/87	0/76
悪心	5/132 (3.8)	4/99 (4.0)	2/87 (2.3)	2/76 (2.6)
口腔内不快感	0/132	1/99 (1.0)	1/87 (1.1)	0/76
口腔内痛	0/132	0/99	1/87 (1.1)	0/76
口の錯感覚	0/132	0/99	1/87 (1.1)	0/76
嘔吐	2/132 (1.5)	1/99 (1.0)	0/87	1/76 (1.3)
一般・全身障害および投与部位の状態	103/132 (78.0)	63/99 (63.6)	51/87 (58.6)	40/76 (52.6)
投与部位紅斑	1/132 (0.8)	0/99	0/87	0/76
無力症	1/132 (0.8)	1/99 (1.0)	1/87 (1.1)	0/76
カテーテル留置部位紅斑	1/132 (0.8)	1/99 (1.0)	0/87	0/76
カテーテル留置部位漏出	0/132	0/99	1/87 (1.1)	0/76
胸痛	0/132	0/99	0/87	1/76 (1.3)
泣き	0/132	1/99 (1.0)	0/87	0/76
不快感	1/132 (0.8)	0/99	0/87	0/76
薬剤離脱症候群	1/132 (0.8)	0/99	0/87	0/76
疲労	4/132 (3.0)	2/99 (2.0)	2/87 (2.3)	2/76 (2.6)
異常感	1/132 (0.8)	0/99	0/87	0/76
熱感	1/132 (0.8)	0/99	0/87	0/76

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Low Dose				
胃腸障害 (Cont.)				
過敏性腸症候群	0/68	0/2	0/0	1/132 (0.8)
口唇乾燥	0/68	0/2	0/0	1/132 (0.8)
メレナ	0/68	0/2	0/0	2/132 (1.5)
口腔腫脹	0/68	0/2	0/0	1/132 (0.8)
悪心	1/68 (1.5)	0/2	0/0	8/132 (6.1)
口腔内不快感	0/68	0/2	0/0	1/132 (0.8)
口腔内痛	0/68	0/2	0/0	1/132 (0.8)
口の錯感覚	0/68	0/2	0/0	1/132 (0.8)
嘔吐	0/68	0/2	0/0	3/132 (2.3)
一般・全身障害および投与部位の状態	34/68 (50.0)	0/2	0/0	107/132 (81.1)
投与部位紅斑	0/68	0/2	0/0	1/132 (0.8)
無力症	0/68	0/2	0/0	3/132 (2.3)
カテーテル留置部位紅斑	0/68	0/2	0/0	1/132 (0.8)
カテーテル留置部位漏出	0/68	0/2	0/0	1/132 (0.8)
胸痛	1/68 (1.5)	0/2	0/0	1/132 (0.8)
泣き	0/68	0/2	0/0	1/132 (0.8)
不快感	0/68	0/2	0/0	1/132 (0.8)
薬剤離脱症候群	0/68	0/2	0/0	1/132 (0.8)
疲労	2/68 (2.9)	0/2	0/0	6/132 (4.5)
異常感	0/68	0/2	0/0	1/132 (0.8)
熱感	0/68	0/2	0/0	1/132 (0.8)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Low Dose				
一般・全身障害および投与部位の状態 (Cont.)				
歩行不能	1/132 (0.8)	0/99	0/87	0/76
低体温	1/132 (0.8)	0/99	0/87	0/76
インフルエンザ様疾患	1/132 (0.8)	0/99	0/87	0/76
注入部位内出血	7/132 (5.3)	6/99 (6.1)	4/87 (4.6)	2/76 (2.6)
注入部位皮膚炎	1/132 (0.8)	1/99 (1.0)	0/87	2/76 (2.6)
注入部位分泌物	1/132 (0.8)	0/99	0/87	0/76
注入部位変色	2/132 (1.5)	1/99 (1.0)	0/87	0/76
注入部位不快感	2/132 (1.5)	1/99 (1.0)	1/87 (1.1)	0/76
注入部位びらん	1/132 (0.8)	0/99	0/87	0/76
注入部位紅斑	60/132 (45.5)	26/99 (26.3)	17/87 (19.5)	14/76 (18.4)
注入部位皮膚剥脱	2/132 (1.5)	2/99 (2.0)	1/87 (1.1)	1/76 (1.3)
注入部位血管外漏出	6/132 (4.5)	6/99 (6.1)	3/87 (3.4)	1/76 (1.3)
注入部位血腫	5/132 (3.8)	1/99 (1.0)	3/87 (3.4)	3/76 (3.9)
注入部位出血	3/132 (2.3)	2/99 (2.0)	1/87 (1.1)	1/76 (1.3)
注入部位硬結	6/132 (4.5)	4/99 (4.0)	1/87 (1.1)	2/76 (2.6)
注入部位炎症	2/132 (1.5)	1/99 (1.0)	1/87 (1.1)	1/76 (1.3)
注入部位刺激感	0/132	0/99	1/87 (1.1)	0/76
注入部位腫瘤	5/132 (3.8)	1/99 (1.0)	1/87 (1.1)	0/76
注入部位結節	29/132 (22.0)	25/99 (25.3)	22/87 (25.3)	20/76 (26.3)
注入部位浮腫	16/132 (12.1)	5/99 (5.1)	4/87 (4.6)	3/76 (3.9)
注入部位疼痛	14/132 (10.6)	9/99 (9.1)	6/87 (6.9)	5/76 (6.6)

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Low Dose				
一般・全身障害および投与部位の状態 (Cont.)				
歩行不能	0/68	0/2	0/0	1/132 (0.8)
低体温	0/68	0/2	0/0	1/132 (0.8)
インフルエンザ様疾患	0/68	0/2	0/0	1/132 (0.8)
注入部位内出血	2/68 (2.9)	0/2	0/0	10/132 (7.6)
注入部位皮膚炎	1/68 (1.5)	0/2	0/0	2/132 (1.5)
注入部位分泌物	0/68	0/2	0/0	1/132 (0.8)
注入部位変色	0/68	0/2	0/0	2/132 (1.5)
注入部位不快感	0/68	0/2	0/0	3/132 (2.3)
注入部位びらん	0/68	0/2	0/0	1/132 (0.8)
注入部位紅斑	13/68 (19.1)	0/2	0/0	65/132 (49.2)
注入部位皮膚剥脱	1/68 (1.5)	0/2	0/0	3/132 (2.3)
注入部位血管外漏出	1/68 (1.5)	0/2	0/0	8/132 (6.1)
注入部位血腫	1/68 (1.5)	0/2	0/0	10/132 (7.6)
注入部位出血	1/68 (1.5)	0/2	0/0	4/132 (3.0)
注入部位硬結	2/68 (2.9)	0/2	0/0	7/132 (5.3)
注入部位炎症	0/68	0/2	0/0	3/132 (2.3)
注入部位刺激感	0/68	0/2	0/0	1/132 (0.8)
注入部位腫瘤	0/68	0/2	0/0	5/132 (3.8)
注入部位結節	19/68 (27.9)	0/2	0/0	35/132 (26.5)
注入部位浮腫	3/68 (4.4)	0/2	0/0	19/132 (14.4)
注入部位疼痛	4/68 (5.9)	0/2	0/0	18/132 (13.6)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Low Dose				
一般・全身障害および投与部位の状態 (Cont.)				
注入部位蒼白	2/132 (1.5)	2/99 (2.0)	1/87 (1.1)	1/76 (1.3)
注入部位丘疹	2/132 (1.5)	3/99 (3.0)	1/87 (1.1)	1/76 (1.3)
注入部位そう痒感	3/132 (2.3)	1/99 (1.0)	2/87 (2.3)	0/76
注入部位発疹	2/132 (1.5)	1/99 (1.0)	1/87 (1.1)	0/76
注入部位反応	9/132 (6.8)	6/99 (6.1)	4/87 (4.6)	3/76 (3.9)
注入部位腫脹	4/132 (3.0)	1/99 (1.0)	1/87 (1.1)	0/76
注射部位内出血	2/132 (1.5)	0/99	0/87	0/76
注射部位変色	0/132	1/99 (1.0)	0/87	0/76
注射部位紅斑	6/132 (4.5)	5/99 (5.1)	3/87 (3.4)	0/76
注射部位漏出	1/132 (0.8)	1/99 (1.0)	1/87 (1.1)	1/76 (1.3)
注射部位炎症	2/132 (1.5)	1/99 (1.0)	0/87	0/76
注射部位結節	1/132 (0.8)	3/99 (3.0)	2/87 (2.3)	0/76
注射部位浮腫	2/132 (1.5)	0/99	0/87	1/76 (1.3)
注射部位疼痛	2/132 (1.5)	1/99 (1.0)	1/87 (1.1)	1/76 (1.3)
注射部位反応	0/132	0/99	1/87 (1.1)	1/76 (1.3)
注射部位腫脹	1/132 (0.8)	0/99	1/87 (1.1)	1/76 (1.3)
倦怠感	1/132 (0.8)	0/99	0/87	0/76
医療機器使用部位刺激感	1/132 (0.8)	1/99 (1.0)	0/87	0/76
医療機器使用部位そう痒感	1/132 (0.8)	0/99	0/87	0/76
小結節	1/132 (0.8)	0/99	0/87	0/76
末梢性浮腫	4/132 (3.0)	3/99 (3.0)	3/87 (3.4)	0/76

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Low Dose				
一般・全身障害および投与部位の状態 (Cont.)				
注入部位蒼白	1/68 (1.5)	0/2	0/0	3/132 (2.3)
注入部位丘疹	3/68 (4.4)	0/2	0/0	7/132 (5.3)
注入部位そう痒感	0/68	0/2	0/0	5/132 (3.8)
注入部位発疹	0/68	0/2	0/0	3/132 (2.3)
注入部位反応	3/68 (4.4)	0/2	0/0	13/132 (9.8)
注入部位腫脹	0/68	0/2	0/0	4/132 (3.0)
注射部位内出血	0/68	0/2	0/0	2/132 (1.5)
注射部位変色	0/68	0/2	0/0	1/132 (0.8)
注射部位紅斑	0/68	0/2	0/0	6/132 (4.5)
注射部位漏出	1/68 (1.5)	0/2	0/0	1/132 (0.8)
注射部位炎症	0/68	0/2	0/0	2/132 (1.5)
注射部位結節	0/68	0/2	0/0	3/132 (2.3)
注射部位浮腫	0/68	0/2	0/0	2/132 (1.5)
注射部位疼痛	1/68 (1.5)	0/2	0/0	2/132 (1.5)
注射部位反応	1/68 (1.5)	0/2	0/0	1/132 (0.8)
注射部位腫脹	0/68	0/2	0/0	2/132 (1.5)
倦怠感	0/68	0/2	0/0	1/132 (0.8)
医療機器使用部位刺激感	0/68	0/2	0/0	1/132 (0.8)
医療機器使用部位そう痒感	0/68	0/2	0/0	1/132 (0.8)
小結節	0/68	0/2	0/0	1/132 (0.8)
末梢性浮腫	0/68	0/2	0/0	5/132 (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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Low Dose				
一般・全身障害および投与部位の状態 (Cont.)				
疼痛	0/132	1/99 (1.0)	0/87	1/76 (1.3)
穿刺部位内出血	1/132 (0.8)	0/99	0/87	0/76
穿刺部位出血	1/132 (0.8)	0/99	0/87	0/76
穿刺部位硬結	2/132 (1.5)	1/99 (1.0)	0/87	0/76
発熱	2/132 (1.5)	0/99	0/87	0/76
口渇	1/132 (0.8)	1/99 (1.0)	1/87 (1.1)	1/76 (1.3)
血管穿刺部位硬結	1/132 (0.8)	0/99	0/87	0/76
肝胆道系障害	1/132 (0.8)	0/99	0/87	0/76
肝嚢胞	0/132	0/99	0/87	0/76
門脈血栓症	1/132 (0.8)	0/99	0/87	0/76
感染症および寄生虫症	37/132 (28.0)	23/99 (23.2)	17/87 (19.5)	18/76 (23.7)
ボレリア感染	1/132 (0.8)	0/99	0/87	0/76
COVID-19	0/132	0/99	0/87	1/76 (1.3)
COVID-19肺炎	0/132	0/99	1/87 (1.1)	0/76
カテーテル留置部位感染	0/132	0/99	0/87	1/76 (1.3)
蜂巣炎	1/132 (0.8)	0/99	0/87	0/76
結膜炎	1/132 (0.8)	2/99 (2.0)	0/87	0/76
膀胱炎	0/132	0/99	1/87 (1.1)	1/76 (1.3)
真菌感染	1/132 (0.8)	0/99	0/87	0/76

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Low Dose				
一般・全身障害および投与部位の状態 (Cont.)				
疼痛	0/68	0/2	0/0	2/132 (1.5)
穿刺部位内出血	0/68	0/2	0/0	1/132 (0.8)
穿刺部位出血	0/68	0/2	0/0	1/132 (0.8)
穿刺部位硬結	0/68	0/2	0/0	2/132 (1.5)
発熱	0/68	0/2	0/0	2/132 (1.5)
口渇	1/68 (1.5)	0/2	0/0	1/132 (0.8)
血管穿刺部位硬結	0/68	0/2	0/0	1/132 (0.8)
肝胆道系障害	1/68 (1.5)	1/2 (50.0)	0/0	2/132 (1.5)
肝嚢胞	1/68 (1.5)	1/2 (50.0)	0/0	1/132 (0.8)
門脈血栓症	0/68	0/2	0/0	1/132 (0.8)
感染症および寄生虫症	6/68 (8.8)	0/2	0/0	58/132 (43.9)
ボレリア感染	0/68	0/2	0/0	1/132 (0.8)
COVID-19	0/68	0/2	0/0	1/132 (0.8)
COVID-19肺炎	0/68	0/2	0/0	1/132 (0.8)
カテーテル留置部位感染	1/68 (1.5)	0/2	0/0	1/132 (0.8)
蜂巣炎	0/68	0/2	0/0	1/132 (0.8)
結膜炎	0/68	0/2	0/0	2/132 (1.5)
膀胱炎	0/68	0/2	0/0	1/132 (0.8)
真菌感染	0/68	0/2	0/0	1/132 (0.8)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Low Dose				
感染症および寄生虫症 (Cont.)				
歯肉炎	1/132 (0.8)	1/99 (1.0)	1/87 (1.1)	0/76
麦粒腫	0/132	1/99 (1.0)	0/87	0/76
注入部位膿瘍	9/132 (6.8)	3/99 (3.0)	2/87 (2.3)	3/76 (3.9)
注入部位蜂巣炎	19/132 (14.4)	10/99 (10.1)	7/87 (8.0)	8/76 (10.5)
注入部位感染	1/132 (0.8)	3/99 (3.0)	1/87 (1.1)	2/76 (2.6)
上咽頭炎	1/132 (0.8)	2/99 (2.0)	1/87 (1.1)	2/76 (2.6)
肺炎	1/132 (0.8)	0/99	2/87 (2.3)	1/76 (1.3)
術後膿瘍	0/132	0/99	1/87 (1.1)	0/76
膿疱性皮疹	1/132 (0.8)	0/99	0/87	0/76
敗血症	2/132 (1.5)	1/99 (1.0)	0/87	1/76 (1.3)
敗血症性ショック	1/132 (0.8)	0/99	0/87	0/76
副鼻腔炎	1/132 (0.8)	1/99 (1.0)	0/87	0/76
ブドウ球菌感染	0/132	0/99	0/87	1/76 (1.3)
歯感染	1/132 (0.8)	1/99 (1.0)	0/87	0/76
上気道感染	1/132 (0.8)	0/99	0/87	0/76
尿路感染	4/132 (3.0)	2/99 (2.0)	1/87 (1.1)	2/76 (2.6)
水痘帯状疱疹ウイルス感染	0/132	1/99 (1.0)	0/87	0/76
傷害、中毒および処置合併症	13/132 (9.8)	8/99 (8.1)	5/87 (5.7)	5/76 (6.6)
骨挫傷	0/132	0/99	0/87	1/76 (1.3)
脳挫傷	1/132 (0.8)	0/99	0/87	0/76
挫傷	1/132 (0.8)	1/99 (1.0)	0/87	1/76 (1.3)

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.
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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Low Dose				
感染症および寄生虫症 (Cont.)				
歯肉炎	0/68	0/2	0/0	1/132 (0.8)
麦粒腫	0/68	0/2	0/0	1/132 (0.8)
注入部位膿瘍	1/68 (1.5)	0/2	0/0	14/132 (10.6)
注入部位蜂巣炎	2/68 (2.9)	0/2	0/0	29/132 (22.0)
注入部位感染	0/68	0/2	0/0	7/132 (5.3)
上咽頭炎	1/68 (1.5)	0/2	0/0	5/132 (3.8)
肺炎	0/68	0/2	0/0	3/132 (2.3)
術後膿瘍	0/68	0/2	0/0	1/132 (0.8)
膿疱性皮疹	0/68	0/2	0/0	1/132 (0.8)
敗血症	0/68	0/2	0/0	3/132 (2.3)
敗血症性ショック	0/68	0/2	0/0	1/132 (0.8)
副鼻腔炎	0/68	0/2	0/0	1/132 (0.8)
ブドウ球菌感染	0/68	0/2	0/0	1/132 (0.8)
歯感染	0/68	0/2	0/0	1/132 (0.8)
上気道感染	0/68	0/2	0/0	1/132 (0.8)
尿路感染	1/68 (1.5)	0/2	0/0	8/132 (6.1)
水痘帯状疱疹ウイルス感染	0/68	0/2	0/0	1/132 (0.8)
傷害、中毒および処置合併症	4/68 (5.9)	0/2	0/0	21/132 (15.9)
骨挫傷	1/68 (1.5)	0/2	0/0	1/132 (0.8)
脳挫傷	0/68	0/2	0/0	1/132 (0.8)
挫傷	1/68 (1.5)	0/2	0/0	2/132 (1.5)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Low Dose				
傷害、中毒および処置合併症 (Cont.)				
医療機器設置の問題	1/132 (0.8)	0/99	0/87	0/76
医療機器による投与の欠落	1/132 (0.8)	0/99	0/87	0/76
期限切れの製品使用	1/132 (0.8)	0/99	0/87	0/76
転倒	9/132 (6.8)	8/99 (8.1)	3/87 (3.4)	3/76 (3.9)
頭部損傷	1/132 (0.8)	1/99 (1.0)	0/87	0/76
注入に伴う反応	1/132 (0.8)	0/99	0/87	0/76
靭帯捻挫	0/132	1/99 (1.0)	0/87	0/76
処置後挫傷	1/132 (0.8)	0/99	0/87	0/76
肋骨骨折	0/132	1/99 (1.0)	1/87 (1.1)	0/76
皮膚擦過傷	1/132 (0.8)	1/99 (1.0)	1/87 (1.1)	0/76
皮膚損傷	1/132 (0.8)	0/99	0/87	0/76
皮膚裂傷	0/132	1/99 (1.0)	0/87	0/76
ストレス骨折	0/132	0/99	1/87 (1.1)	1/76 (1.3)
腱断裂	0/132	0/99	0/87	1/76 (1.3)
創傷	0/132	0/99	0/87	1/76 (1.3)
臨床検査	15/132 (11.4)	13/99 (13.1)	15/87 (17.2)	13/76 (17.1)
血中クレアチンホスホキナーゼ増加	1/132 (0.8)	0/99	0/87	0/76
血中葉酸減少	1/132 (0.8)	1/99 (1.0)	1/87 (1.1)	1/76 (1.3)
血中ホモシステイン増加	0/132	0/99	0/87	0/76
血圧上昇	1/132 (0.8)	0/99	0/87	0/76

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Low Dose				
傷害、中毒および処置合併症 (Cont.)				
医療機器設置の問題	0/68	0/2	0/0	1/132 (0.8)
医療機器による投与の欠落	0/68	0/2	0/0	1/132 (0.8)
期限切れの製品使用	0/68	0/2	0/0	1/132 (0.8)
転倒	1/68 (1.5)	0/2	0/0	16/132 (12.1)
頭部損傷	0/68	0/2	0/0	2/132 (1.5)
注入に伴う反応	0/68	0/2	0/0	1/132 (0.8)
靭帯捻挫	0/68	0/2	0/0	1/132 (0.8)
処置後挫傷	0/68	0/2	0/0	1/132 (0.8)
肋骨骨折	0/68	0/2	0/0	1/132 (0.8)
皮膚擦過傷	0/68	0/2	0/0	1/132 (0.8)
皮膚損傷	0/68	0/2	0/0	1/132 (0.8)
皮膚裂傷	0/68	0/2	0/0	1/132 (0.8)
ストレス骨折	0/68	0/2	0/0	1/132 (0.8)
腱断裂	1/68 (1.5)	0/2	0/0	1/132 (0.8)
創傷	1/68 (1.5)	0/2	0/0	1/132 (0.8)
臨床検査	11/68 (16.2)	0/2	0/0	24/132 (18.2)
血中クレアチンホスホキナーゼ増加	0/68	0/2	0/0	1/132 (0.8)
血中葉酸減少	1/68 (1.5)	0/2	0/0	1/132 (0.8)
血中ホモシステイン増加	1/68 (1.5)	0/2	0/0	1/132 (0.8)
血圧上昇	0/68	0/2	0/0	1/132 (0.8)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Low Dose				
臨床検査 (Cont.)				
起立血圧低下	1/132 (0.8)	1/99 (1.0)	1/87 (1.1)	1/76 (1.3)
血中ナトリウム減少	1/132 (0.8)	1/99 (1.0)	1/87 (1.1)	1/76 (1.3)
心雑音	0/132	0/99	1/87 (1.1)	0/76
握力低下	1/132 (0.8)	1/99 (1.0)	1/87 (1.1)	1/76 (1.3)
ヘモグロビン減少	1/132 (0.8)	1/99 (1.0)	0/87	0/76
ビタミンB12減少	1/132 (0.8)	0/99	0/87	0/76
ビタミンB6減少	4/132 (3.0)	4/99 (4.0)	5/87 (5.7)	4/76 (5.3)
体重減少	4/132 (3.0)	4/99 (4.0)	5/87 (5.7)	5/76 (6.6)
体重増加	1/132 (0.8)	2/99 (2.0)	2/87 (2.3)	2/76 (2.6)
代謝および栄養障害	4/132 (3.0)	5/99 (5.1)	5/87 (5.7)	5/76 (6.6)
悪液質	0/132	0/99	1/87 (1.1)	0/76
食欲減退	1/132 (0.8)	1/99 (1.0)	1/87 (1.1)	0/76
脱水	0/132	1/99 (1.0)	0/87	0/76
体液貯留	1/132 (0.8)	0/99	0/87	0/76
葉酸欠乏	0/132	0/99	1/87 (1.1)	1/76 (1.3)
低ナトリウム血症	0/132	1/99 (1.0)	1/87 (1.1)	1/76 (1.3)
ビタミンB群欠乏	1/132 (0.8)	1/99 (1.0)	1/87 (1.1)	1/76 (1.3)
ビタミンB6欠乏	1/132 (0.8)	1/99 (1.0)	2/87 (2.3)	2/76 (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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Low Dose				
臨床検査 (Cont.)				
起立血圧低下	1/68 (1.5)	0/2	0/0	1/132 (0.8)
血中ナトリウム減少	1/68 (1.5)	0/2	0/0	1/132 (0.8)
心雑音	0/68	0/2	0/0	1/132 (0.8)
握力低下	1/68 (1.5)	0/2	0/0	1/132 (0.8)
ヘモグロビン減少	0/68	0/2	0/0	1/132 (0.8)
ビタミンB12減少	0/68	0/2	0/0	1/132 (0.8)
ビタミンB6減少	4/68 (5.9)	0/2	0/0	5/132 (3.8)
体重減少	2/68 (2.9)	0/2	0/0	10/132 (7.6)
体重増加	2/68 (2.9)	0/2	0/0	2/132 (1.5)
代謝および栄養障害	3/68 (4.4)	0/2	0/0	11/132 (8.3)
悪液質	0/68	0/2	0/0	1/132 (0.8)
食欲減退	0/68	0/2	0/0	3/132 (2.3)
脱水	0/68	0/2	0/0	1/132 (0.8)
体液貯留	0/68	0/2	0/0	1/132 (0.8)
葉酸欠乏	0/68	0/2	0/0	1/132 (0.8)
低ナトリウム血症	0/68	0/2	0/0	2/132 (1.5)
ビタミンB群欠乏	1/68 (1.5)	0/2	0/0	1/132 (0.8)
ビタミンB6欠乏	2/68 (2.9)	0/2	0/0	3/132 (2.3)

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.
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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Low Dose				
筋骨格系および結合組織障害	14/132 (10.6)	10/99 (10.1)	11/87 (12.6)	13/76 (17.1)
関節痛	2/132 (1.5)	0/99	1/87 (1.1)	1/76 (1.3)
反応性関節炎	0/132	0/99	1/87 (1.1)	1/76 (1.3)
背部痛	4/132 (3.0)	2/99 (2.0)	4/87 (4.6)	4/76 (5.3)
滑液包炎	1/132 (0.8)	0/99	1/87 (1.1)	1/76 (1.3)
椎間板変性症	0/132	1/99 (1.0)	1/87 (1.1)	1/76 (1.3)
筋痙縮	0/132	2/99 (2.0)	1/87 (1.1)	0/76
筋力低下	3/132 (2.3)	2/99 (2.0)	1/87 (1.1)	1/76 (1.3)
筋肉痛	2/132 (1.5)	0/99	0/87	0/76
頚部痛	0/132	0/99	2/87 (2.3)	2/76 (2.6)
変形性関節症	1/132 (0.8)	1/99 (1.0)	1/87 (1.1)	1/76 (1.3)
骨減少症	0/132	1/99 (1.0)	1/87 (1.1)	1/76 (1.3)
四肢痛	2/132 (1.5)	2/99 (2.0)	1/87 (1.1)	1/76 (1.3)
横紋筋融解症	1/132 (0.8)	0/99	0/87	1/76 (1.3)
仙腸関節機能障害	1/132 (0.8)	0/99	0/87	0/76
変形性脊椎症	0/132	1/99 (1.0)	1/87 (1.1)	1/76 (1.3)
腱炎	1/132 (0.8)	0/99	0/87	0/76
弾発指	0/132	0/99	1/87 (1.1)	1/76 (1.3)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0/132	1/99 (1.0)	1/87 (1.1)	1/76 (1.3)
直腸腺癌	0/132	1/99 (1.0)	1/87 (1.1)	1/76 (1.3)

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.
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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Low Dose				
筋骨格系および結合組織障害	11/68 (16.2)	0/2	0/0	24/132 (18.2)
関節痛	1/68 (1.5)	0/2	0/0	3/132 (2.3)
反応性関節炎	0/68	0/2	0/0	1/132 (0.8)
背部痛	4/68 (5.9)	0/2	0/0	8/132 (6.1)
滑液包炎	0/68	0/2	0/0	2/132 (1.5)
椎間板変性症	1/68 (1.5)	0/2	0/0	1/132 (0.8)
筋痙縮	0/68	0/2	0/0	2/132 (1.5)
筋力低下	1/68 (1.5)	0/2	0/0	4/132 (3.0)
筋肉痛	0/68	0/2	0/0	2/132 (1.5)
頚部痛	2/68 (2.9)	0/2	0/0	2/132 (1.5)
変形性関節症	1/68 (1.5)	0/2	0/0	1/132 (0.8)
骨減少症	1/68 (1.5)	0/2	0/0	1/132 (0.8)
四肢痛	1/68 (1.5)	0/2	0/0	3/132 (2.3)
横紋筋融解症	0/68	0/2	0/0	2/132 (1.5)
仙腸関節機能障害	0/68	0/2	0/0	1/132 (0.8)
変形性脊椎症	1/68 (1.5)	0/2	0/0	1/132 (0.8)
腱炎	0/68	0/2	0/0	1/132 (0.8)
弾発指	1/68 (1.5)	0/2	0/0	1/132 (0.8)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0/68	0/2	0/0	1/132 (0.8)
直腸腺癌	0/68	0/2	0/0	1/132 (0.8)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Low Dose				
神経系障害	47/132 (35.6)	27/99 (27.3)	18/87 (20.7)	19/76 (25.0)
アカシジア	0/132	0/99	0/87	1/76 (1.3)
健忘	0/132	0/99	0/87	0/76
運動失調	1/132 (0.8)	1/99 (1.0)	1/87 (1.1)	1/76 (1.3)
運動緩慢	1/132 (0.8)	0/99	0/87	0/76
認知障害	2/132 (1.5)	1/99 (1.0)	1/87 (1.1)	2/76 (2.6)
振動覚低下	0/132	1/99 (1.0)	1/87 (1.1)	1/76 (1.3)
浮動性めまい	13/132 (9.8)	5/99 (5.1)	3/87 (3.4)	3/76 (3.9)
体位性めまい	3/132 (2.3)	3/99 (3.0)	1/87 (1.1)	0/76
味覚不全	2/132 (1.5)	0/99	0/87	0/76
ジスキネジア	8/132 (6.1)	4/99 (4.0)	2/87 (2.3)	3/76 (3.9)
起立障害	1/132 (0.8)	0/99	0/87	0/76
ジストニア	2/132 (1.5)	1/99 (1.0)	1/87 (1.1)	0/76
伸展性足底反応	1/132 (0.8)	1/99 (1.0)	1/87 (1.1)	1/76 (1.3)
すくみ現象	4/132 (3.0)	2/99 (2.0)	0/87	0/76
頭部不快感	1/132 (0.8)	0/99	0/87	0/76
頭痛	5/132 (3.8)	3/99 (3.0)	3/87 (3.4)	1/76 (1.3)
感覚鈍麻	0/132	0/99	1/87 (1.1)	1/76 (1.3)
反射減弱	0/132	0/99	1/87 (1.1)	1/76 (1.3)
不規則睡眠覚醒リズム障害	0/132	0/99	1/87 (1.1)	1/76 (1.3)
嗜眠	0/132	1/99 (1.0)	0/87	0/76
意識消失	0/132	1/99 (1.0)	0/87	0/76
代謝性脳症	0/132	0/99	1/87 (1.1)	1/76 (1.3)

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.
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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Low Dose				
神経系障害	18/68 (26.5)	1/2 (50.0)	0/0	62/132 (47.0)
アカシジア	0/68	0/2	0/0	1/132 (0.8)
健忘	1/68 (1.5)	0/2	0/0	1/132 (0.8)
運動失調	0/68	0/2	0/0	1/132 (0.8)
運動緩慢	0/68	0/2	0/0	1/132 (0.8)
認知障害	3/68 (4.4)	0/2	0/0	4/132 (3.0)
振動覚低下	0/68	0/2	0/0	1/132 (0.8)
浮動性めまい	3/68 (4.4)	0/2	0/0	15/132 (11.4)
体位性めまい	0/68	0/2	0/0	5/132 (3.8)
味覚不全	0/68	0/2	0/0	2/132 (1.5)
ジスキネジア	1/68 (1.5)	0/2	0/0	12/132 (9.1)
起立障害	0/68	0/2	0/0	1/132 (0.8)
ジストニア	0/68	0/2	0/0	2/132 (1.5)
伸展性足底反応	1/68 (1.5)	0/2	0/0	1/132 (0.8)
すくみ現象	0/68	0/2	0/0	4/132 (3.0)
頭部不快感	0/68	0/2	0/0	1/132 (0.8)
頭痛	1/68 (1.5)	0/2	0/0	7/132 (5.3)
感覚鈍麻	1/68 (1.5)	0/2	0/0	1/132 (0.8)
反射減弱	2/68 (2.9)	0/2	0/0	2/132 (1.5)
不規則睡眠覚醒リズム障害	1/68 (1.5)	0/2	0/0	1/132 (0.8)
嗜眠	0/68	0/2	0/0	1/132 (0.8)
意識消失	0/68	0/2	0/0	1/132 (0.8)
代謝性脳症	1/68 (1.5)	0/2	0/0	1/132 (0.8)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Low Dose				
神経系障害 (Cont.)				
末梢性ニューロパチー	0/132	0/99	0/87	1/76 (1.3)
オンオフ現象	4/132 (3.0)	0/99	0/87	0/76
錯感覚	2/132 (1.5)	1/99 (1.0)	0/87	1/76 (1.3)
パーキンソン病	8/132 (6.1)	7/99 (7.1)	4/87 (4.6)	2/76 (2.6)
側反弓	0/132	0/99	0/87	1/76 (1.3)
精神運動亢進	1/132 (0.8)	0/99	0/87	0/76
睡眠時麻痺	0/132	1/99 (1.0)	0/87	0/76
傾眠	6/132 (4.5)	6/99 (6.1)	2/87 (2.3)	2/76 (2.6)
振戦	0/132	1/99 (1.0)	0/87	0/76
製品の問題	2/132 (1.5)	0/99	0/87	0/76
医療機器送達システムの問題	1/132 (0.8)	0/99	0/87	0/76
医療機器位置異常	1/132 (0.8)	0/99	0/87	0/76
精神障害	45/132 (34.1)	31/99 (31.3)	27/87 (31.0)	25/76 (32.9)
感情不安定	1/132 (0.8)	0/99	0/87	0/76
不安	7/132 (5.3)	6/99 (6.1)	5/87 (5.7)	6/76 (7.9)
無感情	0/132	1/99 (1.0)	0/87	0/76
歯ぎしり	2/132 (1.5)	1/99 (1.0)	0/87	0/76
強迫性性行動	0/132	0/99	1/87 (1.1)	0/76
錯乱状態	4/132 (3.0)	2/99 (2.0)	1/87 (1.1)	1/76 (1.3)
譫妄	1/132 (0.8)	0/99	0/87	0/76
妄想	6/132 (4.5)	4/99 (4.0)	3/87 (3.4)	2/76 (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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Low Dose				
神経系障害 (Cont.)				
末梢性ニューロパチー	1/68 (1.5)	0/2	0/0	1/132 (0.8)
オンオフ現象	0/68	0/2	0/0	4/132 (3.0)
錯感覚	1/68 (1.5)	1/2 (50.0)	0/0	4/132 (3.0)
パーキンソン病	2/68 (2.9)	0/2	0/0	12/132 (9.1)
側反弓	1/68 (1.5)	0/2	0/0	1/132 (0.8)
精神運動亢進	0/68	0/2	0/0	1/132 (0.8)
睡眠時麻痺	0/68	0/2	0/0	1/132 (0.8)
傾眠	2/68 (2.9)	0/2	0/0	9/132 (6.8)
振戦	0/68	0/2	0/0	1/132 (0.8)
製品の問題	0/68	0/2	0/0	2/132 (1.5)
医療機器送達システムの問題	0/68	0/2	0/0	1/132 (0.8)
医療機器位置異常	0/68	0/2	0/0	1/132 (0.8)
精神障害	14/68 (20.6)	0/2	0/0	51/132 (38.6)
感情不安定	0/68	0/2	0/0	1/132 (0.8)
不安	3/68 (4.4)	0/2	0/0	11/132 (8.3)
無感情	0/68	0/2	0/0	1/132 (0.8)
歯ぎしり	0/68	0/2	0/0	2/132 (1.5)
強迫性性行動	0/68	0/2	0/0	1/132 (0.8)
錯乱状態	1/68 (1.5)	0/2	0/0	4/132 (3.0)
譫妄	0/68	0/2	0/0	1/132 (0.8)
妄想	1/68 (1.5)	0/2	0/0	8/132 (6.1)

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.
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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Low Dose				
精神障害 (Cont.)				
寄生虫妄想	0/132	1/99 (1.0)	0/87	0/76
抑うつ気分	1/132 (0.8)	2/99 (2.0)	2/87 (2.3)	1/76 (1.3)
うつ病	1/132 (0.8)	2/99 (2.0)	2/87 (2.3)	2/76 (2.6)
抑うつ症状	2/132 (1.5)	0/99	0/87	0/76
ドーパミン調節障害症候群	0/132	0/99	0/87	1/76 (1.3)
睡眠異常	1/132 (0.8)	1/99 (1.0)	1/87 (1.1)	1/76 (1.3)
情動障害	0/132	1/99 (1.0)	0/87	0/76
幻覚	17/132 (12.9)	10/99 (10.1)	7/87 (8.0)	7/76 (9.2)
幻聴	1/132 (0.8)	1/99 (1.0)	1/87 (1.1)	2/76 (2.6)
幻視	6/132 (4.5)	5/99 (5.1)	5/87 (5.7)	4/76 (5.3)
混合性幻覚	1/132 (0.8)	0/99	0/87	0/76
性欲過剰	1/132 (0.8)	1/99 (1.0)	1/87 (1.1)	1/76 (1.3)
錯覚	1/132 (0.8)	1/99 (1.0)	1/87 (1.1)	1/76 (1.3)
不眠症	9/132 (6.8)	3/99 (3.0)	2/87 (2.3)	1/76 (1.3)
易刺激性	1/132 (0.8)	1/99 (1.0)	0/87	0/76
嫉妬妄想	1/132 (0.8)	1/99 (1.0)	1/87 (1.1)	0/76
気分変化	1/132 (0.8)	0/99	0/87	0/76
悪夢	0/132	1/99 (1.0)	0/87	0/76
強迫観念	1/132 (0.8)	1/99 (1.0)	0/87	0/76
妄想症	0/132	1/99 (1.0)	2/87 (2.3)	2/76 (2.6)
睡眠の質低下	0/132	1/99 (1.0)	0/87	0/76
精神病性障害	3/132 (2.3)	1/99 (1.0)	1/87 (1.1)	1/76 (1.3)
精神病症状	0/132	0/99	0/87	1/76 (1.3)

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.
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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Low Dose				
精神障害 (Cont.)				
寄生虫妄想	0/68	0/2	0/0	1/132 (0.8)
抑うつ気分	0/68	0/2	0/0	2/132 (1.5)
うつ病	1/68 (1.5)	0/2	0/0	3/132 (2.3)
抑うつ症状	0/68	0/2	0/0	2/132 (1.5)
ドーパミン調節障害症候群	0/68	0/2	0/0	1/132 (0.8)
睡眠異常	1/68 (1.5)	0/2	0/0	1/132 (0.8)
情動障害	0/68	0/2	0/0	1/132 (0.8)
幻覚	4/68 (5.9)	0/2	0/0	20/132 (15.2)
幻聴	1/68 (1.5)	0/2	0/0	3/132 (2.3)
幻視	3/68 (4.4)	0/2	0/0	10/132 (7.6)
混合性幻覚	0/68	0/2	0/0	1/132 (0.8)
性欲過剰	0/68	0/2	0/0	1/132 (0.8)
錯覚	0/68	0/2	0/0	1/132 (0.8)
不眠症	1/68 (1.5)	0/2	0/0	9/132 (6.8)
易刺激性	0/68	0/2	0/0	1/132 (0.8)
嫉妬妄想	0/68	0/2	0/0	1/132 (0.8)
気分変化	0/68	0/2	0/0	1/132 (0.8)
悪夢	0/68	0/2	0/0	1/132 (0.8)
強迫観念	0/68	0/2	0/0	1/132 (0.8)
妄想症	1/68 (1.5)	0/2	0/0	2/132 (1.5)
睡眠の質低下	0/68	0/2	0/0	1/132 (0.8)
精神病性障害	1/68 (1.5)	0/2	0/0	4/132 (3.0)
精神病症状	1/68 (1.5)	0/2	0/0	1/132 (0.8)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Low Dose				
精神障害 (Cont.)				
レム睡眠行動障害	1/132 (0.8)	0/99	0/87	0/76
レム睡眠異常	1/132 (0.8)	1/99 (1.0)	1/87 (1.1)	1/76 (1.3)
睡眠障害	1/132 (0.8)	2/99 (2.0)	1/87 (1.1)	1/76 (1.3)
ねごと	0/132	1/99 (1.0)	0/87	0/76
自殺念慮	0/132	1/99 (1.0)	0/87	0/76
自殺企図	0/132	0/99	0/87	1/76 (1.3)
腎および尿路障害	8/132 (6.1)	6/99 (6.1)	6/87 (6.9)	7/76 (9.2)
膀胱痙縮	0/132	0/99	1/87 (1.1)	1/76 (1.3)
膀胱結石	0/132	1/99 (1.0)	0/87	0/76
尿路結石	0/132	0/99	1/87 (1.1)	1/76 (1.3)
排尿困難	1/132 (0.8)	0/99	0/87	0/76
緊張性膀胱	0/132	0/99	0/87	1/76 (1.3)
頻尿	1/132 (0.8)	1/99 (1.0)	1/87 (1.1)	1/76 (1.3)
切迫性尿失禁	3/132 (2.3)	3/99 (3.0)	2/87 (2.3)	2/76 (2.6)
尿失禁	2/132 (1.5)	1/99 (1.0)	1/87 (1.1)	1/76 (1.3)
尿路障害	1/132 (0.8)	0/99	0/87	0/76
生殖系および乳房障害	0/132	1/99 (1.0)	2/87 (2.3)	2/76 (2.6)
良性前立腺肥大症	0/132	0/99	1/87 (1.1)	1/76 (1.3)

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.
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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Low Dose				
精神障害 (Cont.)				
レム睡眠行動障害	0/68	0/2	0/0	1/132 (0.8)
レム睡眠異常	1/68 (1.5)	0/2	0/0	1/132 (0.8)
睡眠障害	1/68 (1.5)	0/2	0/0	2/132 (1.5)
ねごと	0/68	0/2	0/0	1/132 (0.8)
自殺念慮	0/68	0/2	0/0	1/132 (0.8)
自殺企図	0/68	0/2	0/0	1/132 (0.8)
腎および尿路障害	3/68 (4.4)	0/2	0/0	13/132 (9.8)
膀胱痙縮	1/68 (1.5)	0/2	0/0	1/132 (0.8)
膀胱結石	0/68	0/2	0/0	1/132 (0.8)
尿路結石	0/68	0/2	0/0	1/132 (0.8)
排尿困難	0/68	0/2	0/0	1/132 (0.8)
緊張性膀胱	1/68 (1.5)	0/2	0/0	1/132 (0.8)
頻尿	0/68	0/2	0/0	1/132 (0.8)
切迫性尿失禁	1/68 (1.5)	0/2	0/0	3/132 (2.3)
尿失禁	0/68	0/2	0/0	3/132 (2.3)
尿路障害	0/68	0/2	0/0	1/132 (0.8)
生殖系および乳房障害	1/68 (1.5)	0/2	0/0	2/132 (1.5)
良性前立腺肥大症	0/68	0/2	0/0	1/132 (0.8)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Low Dose				
生殖系および乳房障害 (Cont.)				
勃起不全	0/132	1/99 (1.0)	1/87 (1.1)	1/76 (1.3)
呼吸器、胸郭および縦隔障害	2/132 (1.5)	3/99 (3.0)	3/87 (3.4)	1/76 (1.3)
気管支拡張症	0/132	0/99	1/87 (1.1)	0/76
咳嗽	1/132 (0.8)	0/99	0/87	0/76
呼吸困難	1/132 (0.8)	0/99	0/87	0/76
労作性呼吸困難	0/132	1/99 (1.0)	1/87 (1.1)	1/76 (1.3)
口腔咽頭痛	0/132	1/99 (1.0)	0/87	0/76
呼吸窮迫	0/132	1/99 (1.0)	1/87 (1.1)	0/76
皮膚および皮下組織障害	10/132 (7.6)	7/99 (7.1)	5/87 (5.7)	5/76 (6.6)
脱毛症	1/132 (0.8)	1/99 (1.0)	1/87 (1.1)	1/76 (1.3)
皮膚嚢腫	1/132 (0.8)	1/99 (1.0)	0/87	0/76
接触皮膚炎	1/132 (0.8)	0/99	0/87	1/76 (1.3)
おむつ皮膚炎	1/132 (0.8)	1/99 (1.0)	1/87 (1.1)	1/76 (1.3)
薬疹	1/132 (0.8)	1/99 (1.0)	0/87	0/76
皮膚乾燥	0/132	1/99 (1.0)	0/87	0/76
斑状出血	1/132 (0.8)	0/99	0/87	0/76
紅斑	1/132 (0.8)	0/99	0/87	0/76
爪の障害	0/132	0/99	1/87 (1.1)	1/76 (1.3)

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.
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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Low Dose				
生殖系および乳房障害 (Cont.)				
勃起不全	1/68 (1.5)	0/2	0/0	1/132 (0.8)
呼吸器、胸郭および縦隔障害	2/68 (2.9)	0/2	0/0	7/132 (5.3)
気管支拡張症	0/68	0/2	0/0	1/132 (0.8)
咳嗽	0/68	0/2	0/0	1/132 (0.8)
呼吸困難	1/68 (1.5)	0/2	0/0	2/132 (1.5)
労作性呼吸困難	1/68 (1.5)	0/2	0/0	1/132 (0.8)
口腔咽頭痛	0/68	0/2	0/0	1/132 (0.8)
呼吸窮迫	0/68	0/2	0/0	1/132 (0.8)
皮膚および皮下組織障害	3/68 (4.4)	0/2	0/0	14/132 (10.6)
脱毛症	1/68 (1.5)	0/2	0/0	2/132 (1.5)
皮膚嚢腫	0/68	0/2	0/0	1/132 (0.8)
接触皮膚炎	1/68 (1.5)	0/2	0/0	2/132 (1.5)
おむつ皮膚炎	1/68 (1.5)	0/2	0/0	1/132 (0.8)
薬疹	0/68	0/2	0/0	1/132 (0.8)
皮膚乾燥	0/68	0/2	0/0	1/132 (0.8)
斑状出血	0/68	0/2	0/0	1/132 (0.8)
紅斑	0/68	0/2	0/0	1/132 (0.8)
爪の障害	1/68 (1.5)	0/2	0/0	1/132 (0.8)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
Low Dose				
皮膚および皮下組織障害 (Cont.)				
そう痒症	0/132	0/99	1/87 (1.1)	1/76 (1.3)
発疹	1/132 (0.8)	0/99	1/87 (1.1)	0/76
そう痒性皮疹	1/132 (0.8)	0/99	1/87 (1.1)	0/76
皮膚潰瘍	1/132 (0.8)	1/99 (1.0)	1/87 (1.1)	0/76
蕁麻疹	0/132	1/99 (1.0)	2/87 (2.3)	1/76 (1.3)
社会環境	1/132 (0.8)	1/99 (1.0)	0/87	0/76
運動不能	1/132 (0.8)	1/99 (1.0)	0/87	0/76
血管障害	5/132 (3.8)	2/99 (2.0)	4/87 (4.6)	7/76 (9.2)
高血圧	2/132 (1.5)	0/99	1/87 (1.1)	1/76 (1.3)
高血圧クリーゼ	1/132 (0.8)	0/99	0/87	0/76
低血圧	1/132 (0.8)	0/99	0/87	1/76 (1.3)
起立性低血圧	1/132 (0.8)	2/99 (2.0)	3/87 (3.4)	5/76 (6.6)

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
Low Dose				
皮膚および皮下組織障害 (Cont.)				
そう痒症	0/68	0/2	0/0	2/132 (1.5)
発疹	0/68	0/2	0/0	2/132 (1.5)
そう痒性皮疹	0/68	0/2	0/0	2/132 (1.5)
皮膚潰瘍	0/68	0/2	0/0	1/132 (0.8)
蕁麻疹	0/68	0/2	0/0	2/132 (1.5)
社会環境	0/68	0/2	0/0	1/132 (0.8)
運動不能	0/68	0/2	0/0	1/132 (0.8)
血管障害	7/68 (10.3)	1/2 (50.0)	0/0	12/132 (9.1)
高血圧	0/68	0/2	0/0	3/132 (2.3)
高血圧クリーゼ	0/68	0/2	0/0	1/132 (0.8)
低血圧	1/68 (1.5)	0/2	0/0	2/132 (1.5)
起立性低血圧	6/68 (8.8)	1/2 (50.0)	0/0	7/132 (5.3)

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.
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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
Any adverse event	105/112 (93.8)	75/85 (88.2)	64/73 (87.7)	56/63 (88.9)
血液およびリンパ系障害	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	2/63 (3.2)
大球性貧血	0/112	0/85	0/73	1/63 (1.6)
凝血異常	1/112 (0.9)	0/85	0/73	0/63
縦隔リンパ節腫脹	0/112	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
心臓障害	4/112 (3.6)	2/85 (2.4)	3/73 (4.1)	3/63 (4.8)
心房細動	0/112	0/85	2/73 (2.7)	2/63 (3.2)
徐脈	1/112 (0.9)	0/85	0/73	0/63
心肺停止	0/112	1/85 (1.2)	0/73	0/63
冠動脈疾患	0/112	0/85	1/73 (1.4)	1/63 (1.6)
期外収縮	1/112 (0.9)	1/85 (1.2)	0/73	0/63
左室肥大	1/112 (0.9)	0/85	0/73	0/63
動悸	1/112 (0.9)	0/85	1/73 (1.4)	1/63 (1.6)
耳および迷路障害	4/112 (3.6)	2/85 (2.4)	1/73 (1.4)	1/63 (1.6)
乗物酔い	1/112 (0.9)	0/85	0/73	0/63
回転性めまい	2/112 (1.8)	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
頭位性回転性めまい	1/112 (0.9)	1/85 (1.2)	0/73	0/63
眼障害	3/112 (2.7)	5/85 (5.9)	6/73 (8.2)	3/63 (4.8)
白内障	1/112 (0.9)	1/85 (1.2)	2/73 (2.7)	1/63 (1.6)
複視	1/112 (0.9)	0/85	0/73	0/63

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
Any adverse event	46/55 (83.6)	0/0	0/0	108/112 (96.4)
血液およびリンパ系障害	2/55 (3.6)	0/0	0/0	3/112 (2.7)
大球性貧血	1/55 (1.8)	0/0	0/0	1/112 (0.9)
凝血異常	0/55	0/0	0/0	1/112 (0.9)
縦隔リンパ節腫脹	1/55 (1.8)	0/0	0/0	1/112 (0.9)
心臓障害	2/55 (3.6)	0/0	0/0	8/112 (7.1)
心房細動	1/55 (1.8)	0/0	0/0	2/112 (1.8)
徐脈	0/55	0/0	0/0	1/112 (0.9)
心肺停止	0/55	0/0	0/0	1/112 (0.9)
冠動脈疾患	1/55 (1.8)	0/0	0/0	1/112 (0.9)
期外収縮	0/55	0/0	0/0	1/112 (0.9)
左室肥大	0/55	0/0	0/0	1/112 (0.9)
動悸	1/55 (1.8)	0/0	0/0	2/112 (1.8)
耳および迷路障害	1/55 (1.8)	0/0	0/0	4/112 (3.6)
乗物酔い	0/55	0/0	0/0	1/112 (0.9)
回転性めまい	1/55 (1.8)	0/0	0/0	2/112 (1.8)
頭位性回転性めまい	0/55	0/0	0/0	1/112 (0.9)
眼障害	2/55 (3.6)	0/0	0/0	8/112 (7.1)
白内障	1/55 (1.8)	0/0	0/0	2/112 (1.8)
複視	0/55	0/0	0/0	1/112 (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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
眼障害 (Cont.)				
ドライアイ	1/112 (0.9)	2/85 (2.4)	3/73 (4.1)	2/63 (3.2)
緑内障	0/112	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
眼窩周囲痛	0/112	1/85 (1.2)	0/73	0/63
眼窩周囲腫脹	1/112 (0.9)	1/85 (1.2)	0/73	0/63
視野欠損	0/112	1/85 (1.2)	1/73 (1.4)	0/63
胃腸障害	23/112 (20.5)	13/85 (15.3)	15/73 (20.5)	12/63 (19.0)
腹部膨満	3/112 (2.7)	0/85	1/73 (1.4)	0/63
腹痛	0/112	0/85	0/73	1/63 (1.6)
上腹部痛	1/112 (0.9)	0/85	0/73	0/63
呼気臭	1/112 (0.9)	0/85	0/73	0/63
便秘	6/112 (5.4)	6/85 (7.1)	5/73 (6.8)	3/63 (4.8)
下痢	2/112 (1.8)	0/85	1/73 (1.4)	0/63
口内乾燥	5/112 (4.5)	5/85 (5.9)	3/73 (4.1)	3/63 (4.8)
嚥下障害	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
糞塊	1/112 (0.9)	0/85	0/73	0/63
排便回数増加	0/112	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
胃食道逆流性疾患	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
過敏性腸症候群	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
大腸ポリープ	0/112	0/85	0/73	1/63 (1.6)
悪心	8/112 (7.1)	1/85 (1.2)	4/73 (5.5)	3/63 (4.8)
口の錯感覚	1/112 (0.9)	0/85	0/73	0/63
直腸出血	0/112	0/85	1/73 (1.4)	0/63

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
眼障害 (Cont.)				
ドライアイ	1/55 (1.8)	0/0	0/0	3/112 (2.7)
緑内障	1/55 (1.8)	0/0	0/0	1/112 (0.9)
眼窩周囲痛	0/55	0/0	0/0	1/112 (0.9)
眼窩周囲腫脹	0/55	0/0	0/0	2/112 (1.8)
視野欠損	0/55	0/0	0/0	1/112 (0.9)
胃腸障害	7/55 (12.7)	0/0	0/0	29/112 (25.9)
腹部膨満	0/55	0/0	0/0	3/112 (2.7)
腹痛	0/55	0/0	0/0	1/112 (0.9)
上腹部痛	0/55	0/0	0/0	1/112 (0.9)
呼気臭	0/55	0/0	0/0	1/112 (0.9)
便秘	2/55 (3.6)	0/0	0/0	12/112 (10.7)
下痢	0/55	0/0	0/0	3/112 (2.7)
口内乾燥	2/55 (3.6)	0/0	0/0	5/112 (4.5)
嚥下障害	0/55	0/0	0/0	1/112 (0.9)
糞塊	0/55	0/0	0/0	1/112 (0.9)
排便回数増加	0/55	0/0	0/0	1/112 (0.9)
胃食道逆流性疾患	1/55 (1.8)	0/0	0/0	1/112 (0.9)
過敏性腸症候群	1/55 (1.8)	0/0	0/0	1/112 (0.9)
大腸ポリープ	0/55	0/0	0/0	1/112 (0.9)
悪心	2/55 (3.6)	0/0	0/0	11/112 (9.8)
口の錯感覚	0/55	0/0	0/0	1/112 (0.9)
直腸出血	0/55	0/0	0/0	1/112 (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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
胃腸障害 (Cont.)				
歯痛	1/112 (0.9)	0/85	0/73	0/63
嘔吐	2/112 (1.8)	0/85	1/73 (1.4)	1/63 (1.6)
一般・全身障害および投与部位の状態	92/112 (82.1)	66/85 (77.6)	51/73 (69.9)	44/63 (69.8)
投与部位内出血	0/112	0/85	0/73	1/63 (1.6)
投与部位漏出	1/112 (0.9)	1/85 (1.2)	0/73	0/63
カテーテル留置部位紅斑	1/112 (0.9)	0/85	0/73	0/63
カテーテル留置部位出血	1/112 (0.9)	0/85	0/73	0/63
カテーテル留置部位炎症	1/112 (0.9)	1/85 (1.2)	0/73	0/63
カテーテル留置部位刺激感	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	0/63
カテーテル留置部位浮腫	1/112 (0.9)	0/85	0/73	0/63
カテーテル留置部位疼痛	2/112 (1.8)	0/85	0/73	0/63
胸部不快感	0/112	1/85 (1.2)	0/73	0/63
胸痛	1/112 (0.9)	1/85 (1.2)	0/73	0/63
薬効欠如	0/112	1/85 (1.2)	0/73	0/63
薬剤離脱症候群	1/112 (0.9)	0/85	0/73	0/63
疲労	3/112 (2.7)	2/85 (2.4)	2/73 (2.7)	2/63 (3.2)
異常感	1/112 (0.9)	1/85 (1.2)	0/73	0/63
冷感	0/112	0/85	1/73 (1.4)	0/63
歩行障害	1/112 (0.9)	1/85 (1.2)	0/73	0/63
低体温	0/112	0/85	0/73	1/63 (1.6)
インフルエンザ様疾患	2/112 (1.8)	0/85	0/73	0/63

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
胃腸障害 (Cont.)				
歯痛	0/55	0/0	0/0	1/112 (0.9)
嘔吐	0/55	0/0	0/0	3/112 (2.7)
一般・全身障害および投与部位の状態	34/55 (61.8)	0/0	0/0	96/112 (85.7)
投与部位内出血	1/55 (1.8)	0/0	0/0	1/112 (0.9)
投与部位漏出	0/55	0/0	0/0	1/112 (0.9)
カテーテル留置部位紅斑	0/55	0/0	0/0	1/112 (0.9)
カテーテル留置部位出血	0/55	0/0	0/0	1/112 (0.9)
カテーテル留置部位炎症	0/55	0/0	0/0	1/112 (0.9)
カテーテル留置部位刺激感	0/55	0/0	0/0	1/112 (0.9)
カテーテル留置部位浮腫	0/55	0/0	0/0	1/112 (0.9)
カテーテル留置部位疼痛	0/55	0/0	0/0	2/112 (1.8)
胸部不快感	0/55	0/0	0/0	1/112 (0.9)
胸痛	0/55	0/0	0/0	1/112 (0.9)
薬効欠如	0/55	0/0	0/0	1/112 (0.9)
薬剤離脱症候群	0/55	0/0	0/0	1/112 (0.9)
疲労	1/55 (1.8)	0/0	0/0	3/112 (2.7)
異常感	0/55	0/0	0/0	1/112 (0.9)
冷感	0/55	0/0	0/0	1/112 (0.9)
歩行障害	0/55	0/0	0/0	2/112 (1.8)
低体温	0/55	0/0	0/0	1/112 (0.9)
インフルエンザ様疾患	0/55	0/0	0/0	2/112 (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.
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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
一般・全身障害および投与部位の状態 (Cont.)				
注入部位内出血	7/112 (6.3)	0/85	2/73 (2.7)	1/63 (1.6)
注入部位皮膚炎	0/112	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
注入部位分泌物	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
注入部位不快感	1/112 (0.9)	0/85	0/73	0/63
注入部位びらん	1/112 (0.9)	0/85	0/73	0/63
注入部位紅斑	53/112 (47.3)	32/85 (37.6)	22/73 (30.1)	18/63 (28.6)
注入部位皮膚剥脱	1/112 (0.9)	0/85	0/73	2/63 (3.2)
注入部位血管外漏出	11/112 (9.8)	3/85 (3.5)	2/73 (2.7)	2/63 (3.2)
注入部位血腫	7/112 (6.3)	4/85 (4.7)	1/73 (1.4)	0/63
注入部位出血	3/112 (2.7)	1/85 (1.2)	0/73	1/63 (1.6)
注入部位硬結	2/112 (1.8)	1/85 (1.2)	2/73 (2.7)	2/63 (3.2)
注入部位炎症	3/112 (2.7)	3/85 (3.5)	1/73 (1.4)	1/63 (1.6)
注入部位損傷	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
注入部位刺激感	3/112 (2.7)	3/85 (3.5)	1/73 (1.4)	0/63
注入部位腫瘤	3/112 (2.7)	2/85 (2.4)	2/73 (2.7)	2/63 (3.2)
注入部位壊死	1/112 (0.9)	0/85	0/73	0/63
注入部位結節	25/112 (22.3)	28/85 (32.9)	23/73 (31.5)	23/63 (36.5)
注入部位浮腫	20/112 (17.9)	8/85 (9.4)	6/73 (8.2)	5/63 (7.9)
注入部位疼痛	18/112 (16.1)	11/85 (12.9)	9/73 (12.3)	7/63 (11.1)
注入部位蒼白	2/112 (1.8)	0/85	0/73	0/63
注入部位丘疹	6/112 (5.4)	3/85 (3.5)	2/73 (2.7)	2/63 (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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
一般・全身障害および投与部位の状態 (Cont.)				
注入部位内出血	0/55	0/0	0/0	8/112 (7.1)
注入部位皮膚炎	1/55 (1.8)	0/0	0/0	2/112 (1.8)
注入部位分泌物	1/55 (1.8)	0/0	0/0	1/112 (0.9)
注入部位不快感	0/55	0/0	0/0	1/112 (0.9)
注入部位びらん	0/55	0/0	0/0	1/112 (0.9)
注入部位紅斑	9/55 (16.4)	0/0	0/0	61/112 (54.5)
注入部位皮膚剥脱	2/55 (3.6)	0/0	0/0	3/112 (2.7)
注入部位血管外漏出	0/55	0/0	0/0	12/112 (10.7)
注入部位血腫	0/55	0/0	0/0	8/112 (7.1)
注入部位出血	0/55	0/0	0/0	5/112 (4.5)
注入部位硬結	2/55 (3.6)	0/0	0/0	3/112 (2.7)
注入部位炎症	3/55 (5.5)	0/0	0/0	6/112 (5.4)
注入部位損傷	0/55	0/0	0/0	2/112 (1.8)
注入部位刺激感	0/55	0/0	0/0	4/112 (3.6)
注入部位腫瘤	2/55 (3.6)	0/0	0/0	3/112 (2.7)
注入部位壊死	0/55	0/0	0/0	1/112 (0.9)
注入部位結節	18/55 (32.7)	0/0	0/0	34/112 (30.4)
注入部位浮腫	4/55 (7.3)	0/0	0/0	28/112 (25.0)
注入部位疼痛	6/55 (10.9)	0/0	0/0	20/112 (17.9)
注入部位蒼白	0/55	0/0	0/0	2/112 (1.8)
注入部位丘疹	2/55 (3.6)	0/0	0/0	11/112 (9.8)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
一般・全身障害および投与部位の状態 (Cont.)				
注入部位異常感覚	2/112 (1.8)	0/85	1/73 (1.4)	0/63
注入部位そう痒感	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
注入部位発疹	3/112 (2.7)	2/85 (2.4)	0/73	0/63
注入部位反応	13/112 (11.6)	5/85 (5.9)	3/73 (4.1)	6/63 (9.5)
注入部位痂皮	0/112	1/85 (1.2)	0/73	1/63 (1.6)
注入部位腫脹	2/112 (1.8)	0/85	1/73 (1.4)	0/63
注入部位小水疱	2/112 (1.8)	1/85 (1.2)	0/73	0/63
注入部位熱感	1/112 (0.9)	0/85	0/73	0/63
注射部位内出血	0/112	1/85 (1.2)	1/73 (1.4)	0/63
注射部位紅斑	7/112 (6.3)	2/85 (2.4)	3/73 (4.1)	3/63 (4.8)
注射部位漏出	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
注射部位血腫	1/112 (0.9)	0/85	0/73	0/63
注射部位出血	0/112	1/85 (1.2)	0/73	0/63
注射部位炎症	2/112 (1.8)	3/85 (3.5)	2/73 (2.7)	1/63 (1.6)
注射部位結節	4/112 (3.6)	3/85 (3.5)	4/73 (5.5)	3/63 (4.8)
注射部位浮腫	2/112 (1.8)	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
注射部位疼痛	5/112 (4.5)	1/85 (1.2)	0/73	0/63
注射部位丘疹	1/112 (0.9)	1/85 (1.2)	0/73	0/63
注射部位反応	1/112 (0.9)	0/85	0/73	0/63
注射部位腫脹	1/112 (0.9)	2/85 (2.4)	1/73 (1.4)	0/63
注射部位蕁麻疹	1/112 (0.9)	0/85	0/73	0/63

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
一般・全身障害および投与部位の状態 (Cont.)				
注入部位異常感覚	0/55	0/0	0/0	2/112 (1.8)
注入部位そう痒感	1/55 (1.8)	0/0	0/0	2/112 (1.8)
注入部位発疹	0/55	0/0	0/0	4/112 (3.6)
注入部位反応	5/55 (9.1)	0/0	0/0	17/112 (15.2)
注入部位痂皮	1/55 (1.8)	0/0	0/0	1/112 (0.9)
注入部位腫脹	0/55	0/0	0/0	2/112 (1.8)
注入部位小水疱	0/55	0/0	0/0	2/112 (1.8)
注入部位熱感	0/55	0/0	0/0	1/112 (0.9)
注射部位内出血	0/55	0/0	0/0	1/112 (0.9)
注射部位紅斑	1/55 (1.8)	0/0	0/0	8/112 (7.1)
注射部位漏出	0/55	0/0	0/0	1/112 (0.9)
注射部位血腫	0/55	0/0	0/0	1/112 (0.9)
注射部位出血	0/55	0/0	0/0	1/112 (0.9)
注射部位炎症	1/55 (1.8)	0/0	0/0	4/112 (3.6)
注射部位結節	2/55 (3.6)	0/0	0/0	6/112 (5.4)
注射部位浮腫	2/55 (3.6)	0/0	0/0	3/112 (2.7)
注射部位疼痛	0/55	0/0	0/0	6/112 (5.4)
注射部位丘疹	0/55	0/0	0/0	2/112 (1.8)
注射部位反応	0/55	0/0	0/0	1/112 (0.9)
注射部位腫脹	0/55	0/0	0/0	2/112 (1.8)
注射部位蕁麻疹	0/55	0/0	0/0	1/112 (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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
一般・全身障害および投与部位の状態 (Cont.)				
滴下投与部位熱傷	1/112 (0.9)	0/85	0/73	0/63
滴下投与部位痛	0/112	1/85 (1.2)	0/73	0/63
限局性浮腫	1/112 (0.9)	0/85	0/73	0/63
適用部位からの吸収不良	1/112 (0.9)	0/85	0/73	0/63
倦怠感	1/112 (0.9)	0/85	1/73 (1.4)	0/63
医療機器使用部位刺激感	2/112 (1.8)	0/85	0/73	0/63
医療機器使用部位発疹	2/112 (1.8)	0/85	0/73	0/63
非心臓性胸痛	2/112 (1.8)	0/85	0/73	0/63
末梢性浮腫	4/112 (3.6)	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
末梢腫脹	3/112 (2.7)	1/85 (1.2)	1/73 (1.4)	2/63 (3.2)
穿刺部位紅斑	2/112 (1.8)	2/85 (2.4)	0/73	0/63
穿刺部位浮腫	1/112 (0.9)	0/85	0/73	0/63
穿刺部位腫脹	1/112 (0.9)	0/85	0/73	0/63
発熱	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	0/63
肝胆道系障害	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
脂肪肝	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	1/63 (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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
一般・全身障害および投与部位の状態 (Cont.)				
滴下投与部位熱傷	0/55	0/0	0/0	1/112 (0.9)
滴下投与部位痛	0/55	0/0	0/0	1/112 (0.9)
限局性浮腫	0/55	0/0	0/0	1/112 (0.9)
適用部位からの吸収不良	0/55	0/0	0/0	1/112 (0.9)
倦怠感	0/55	0/0	0/0	2/112 (1.8)
医療機器使用部位刺激感	0/55	0/0	0/0	2/112 (1.8)
医療機器使用部位発疹	0/55	0/0	0/0	2/112 (1.8)
非心臓性胸痛	0/55	0/0	0/0	2/112 (1.8)
末梢性浮腫	1/55 (1.8)	0/0	0/0	4/112 (3.6)
末梢腫脹	2/55 (3.6)	0/0	0/0	4/112 (3.6)
穿刺部位紅斑	0/55	0/0	0/0	3/112 (2.7)
穿刺部位浮腫	0/55	0/0	0/0	1/112 (0.9)
穿刺部位腫脹	0/55	0/0	0/0	1/112 (0.9)
発熱	0/55	0/0	0/0	2/112 (1.8)
肝胆道系障害	1/55 (1.8)	0/0	0/0	1/112 (0.9)
脂肪肝	1/55 (1.8)	0/0	0/0	1/112 (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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
感染症および寄生虫症	43/112 (38.4)	23/85 (27.1)	20/73 (27.4)	17/63 (27.0)
四肢膿瘍	0/112	0/85	1/73 (1.4)	0/63
無症候性COVID-19	0/112	0/85	1/73 (1.4)	1/63 (1.6)
細菌性疾患キャリアー	0/112	0/85	1/73 (1.4)	1/63 (1.6)
ウイルス性気管支炎	0/112	0/85	0/73	1/63 (1.6)
蜂巣炎	0/112	0/85	2/73 (2.7)	0/63
膀胱炎	1/112 (0.9)	0/85	0/73	0/63
爪の皮膚糸状菌症	0/112	1/85 (1.2)	1/73 (1.4)	0/63
胃腸炎	1/112 (0.9)	0/85	0/73	0/63
感染性皮膚潰瘍	1/112 (0.9)	1/85 (1.2)	0/73	0/63
インフルエンザ	0/112	0/85	0/73	1/63 (1.6)
注入部位膿瘍	9/112 (8.0)	7/85 (8.2)	4/73 (5.5)	1/63 (1.6)
注入部位蜂巣炎	21/112 (18.8)	6/85 (7.1)	7/73 (9.6)	7/63 (11.1)
注入部位感染	6/112 (5.4)	5/85 (5.9)	2/73 (2.7)	3/63 (4.8)
注入部位膿疱	1/112 (0.9)	1/85 (1.2)	0/73	0/63
注射部位蜂巣炎	2/112 (1.8)	1/85 (1.2)	0/73	1/63 (1.6)
リンパ管炎	0/112	0/85	1/73 (1.4)	0/63
上咽頭炎	4/112 (3.6)	1/85 (1.2)	0/73	0/63
爪真菌症	1/112 (0.9)	0/85	0/73	0/63
耳下腺膿瘍	0/112	0/85	1/73 (1.4)	0/63
肺炎	1/112 (0.9)	1/85 (1.2)	0/73	0/63
シュードモナス感染	1/112 (0.9)	1/85 (1.2)	0/73	0/63
気道感染	0/112	0/85	0/73	1/63 (1.6)
ブドウ球菌感染	0/112	1/85 (1.2)	1/73 (1.4)	0/63

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
感染症および寄生虫症	7/55 (12.7)	0/0	0/0	56/112 (50.0)
四肢膿瘍	0/55	0/0	0/0	1/112 (0.9)
無症候性COVID-19	0/55	0/0	0/0	1/112 (0.9)
細菌性疾患キャリアー	1/55 (1.8)	0/0	0/0	1/112 (0.9)
ウイルス性気管支炎	0/55	0/0	0/0	1/112 (0.9)
蜂巣炎	0/55	0/0	0/0	2/112 (1.8)
膀胱炎	0/55	0/0	0/0	1/112 (0.9)
爪の皮膚糸状菌症	0/55	0/0	0/0	1/112 (0.9)
胃腸炎	0/55	0/0	0/0	1/112 (0.9)
感染性皮膚潰瘍	0/55	0/0	0/0	1/112 (0.9)
インフルエンザ	1/55 (1.8)	0/0	0/0	1/112 (0.9)
注入部位膿瘍	0/55	0/0	0/0	13/112 (11.6)
注入部位蜂巣炎	2/55 (3.6)	0/0	0/0	27/112 (24.1)
注入部位感染	2/55 (3.6)	0/0	0/0	11/112 (9.8)
注入部位膿疱	0/55	0/0	0/0	1/112 (0.9)
注射部位蜂巣炎	0/55	0/0	0/0	3/112 (2.7)
リンパ管炎	0/55	0/0	0/0	1/112 (0.9)
上咽頭炎	0/55	0/0	0/0	5/112 (4.5)
爪真菌症	0/55	0/0	0/0	1/112 (0.9)
耳下腺膿瘍	0/55	0/0	0/0	1/112 (0.9)
肺炎	0/55	0/0	0/0	1/112 (0.9)
シュードモナス感染	0/55	0/0	0/0	1/112 (0.9)
気道感染	0/55	0/0	0/0	1/112 (0.9)
ブドウ球菌感染	0/55	0/0	0/0	1/112 (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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
感染症および寄生虫症 (Cont.)				
歯感染	0/112	0/85	0/73	1/63 (1.6)
尿路感染	6/112 (5.4)	5/85 (5.9)	4/73 (5.5)	2/63 (3.2)
傷害、中毒および処置合併症	16/112 (14.3)	10/85 (11.8)	10/73 (13.7)	6/63 (9.5)
足関節部骨折	1/112 (0.9)	1/85 (1.2)	0/73	0/63
節足動物咬傷	1/112 (0.9)	0/85	0/73	0/63
骨挫傷	0/112	1/85 (1.2)	1/73 (1.4)	0/63
挫傷	2/112 (1.8)	3/85 (3.5)	2/73 (2.7)	0/63
眼挫傷	1/112 (0.9)	0/85	0/73	0/63
顔面損傷	0/112	1/85 (1.2)	0/73	0/63
顔面骨骨折	2/112 (1.8)	0/85	0/73	0/63
転倒	13/112 (11.6)	6/85 (7.1)	7/73 (9.6)	4/63 (6.3)
頭部損傷	0/112	1/85 (1.2)	2/73 (2.7)	0/63
関節脱臼	0/112	1/85 (1.2)	1/73 (1.4)	0/63
靭帯捻挫	0/112	1/85 (1.2)	0/73	0/63
腰椎骨折	1/112 (0.9)	0/85	0/73	0/63
過量投与	0/112	0/85	1/73 (1.4)	1/63 (1.6)
処置によるめまい	1/112 (0.9)	0/85	0/73	0/63
肋骨骨折	1/112 (0.9)	0/85	0/73	1/63 (1.6)
皮膚擦過傷	0/112	1/85 (1.2)	2/73 (2.7)	0/63
皮膚裂傷	2/112 (1.8)	2/85 (2.4)	1/73 (1.4)	2/63 (3.2)
硬膜下血腫	0/112	0/85	0/73	1/63 (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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
感染症および寄生虫症 (Cont.)				
歯感染	0/55	0/0	0/0	1/112 (0.9)
尿路感染	1/55 (1.8)	0/0	0/0	11/112 (9.8)
傷害、中毒および処置合併症	2/55 (3.6)	0/0	0/0	27/112 (24.1)
足関節部骨折	0/55	0/0	0/0	1/112 (0.9)
節足動物咬傷	0/55	0/0	0/0	1/112 (0.9)
骨挫傷	0/55	0/0	0/0	1/112 (0.9)
挫傷	1/55 (1.8)	0/0	0/0	6/112 (5.4)
眼挫傷	0/55	0/0	0/0	1/112 (0.9)
顔面損傷	0/55	0/0	0/0	1/112 (0.9)
顔面骨骨折	0/55	0/0	0/0	2/112 (1.8)
転倒	1/55 (1.8)	0/0	0/0	24/112 (21.4)
頭部損傷	0/55	0/0	0/0	3/112 (2.7)
関節脱臼	0/55	0/0	0/0	1/112 (0.9)
靭帯捻挫	0/55	0/0	0/0	1/112 (0.9)
腰椎骨折	0/55	0/0	0/0	1/112 (0.9)
過量投与	0/55	0/0	0/0	1/112 (0.9)
処置によるめまい	0/55	0/0	0/0	1/112 (0.9)
肋骨骨折	1/55 (1.8)	0/0	0/0	2/112 (1.8)
皮膚擦過傷	0/55	0/0	0/0	2/112 (1.8)
皮膚裂傷	0/55	0/0	0/0	6/112 (5.4)
硬膜下血腫	0/55	0/0	0/0	1/112 (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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
傷害、中毒および処置合併症 (Cont.)				
サンバーン	1/112 (0.9)	0/85	0/73	0/63
腱断裂	0/112	1/85 (1.2)	1/73 (1.4)	0/63
過少量投与	0/112	0/85	1/73 (1.4)	0/63
臨床検査	16/112 (14.3)	17/85 (20.0)	17/73 (23.3)	14/63 (22.2)
血中クレアチンホスホキナーゼ増加	1/112 (0.9)	0/85	0/73	0/63
血中クレアチニン減少	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
血中葉酸異常	0/112	0/85	0/73	1/63 (1.6)
血中葉酸減少	0/112	0/85	0/73	0/63
血中ホモシステイン増加	1/112 (0.9)	1/85 (1.2)	2/73 (2.7)	2/63 (3.2)
血中リン減少	0/112	1/85 (1.2)	0/73	0/63
血圧上昇	1/112 (0.9)	0/85	0/73	0/63
C-反応性蛋白増加	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
ヘモグロビン減少	0/112	0/85	0/73	1/63 (1.6)
リンパ球数減少	1/112 (0.9)	0/85	0/73	0/63
単球数増加	1/112 (0.9)	0/85	0/73	0/63
好中球数増加	2/112 (1.8)	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
プロトロンビン時間延長	0/112	0/85	0/73	0/63
赤血球数減少	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
ビタミンB12減少	0/112	0/85	1/73 (1.4)	1/63 (1.6)
ビタミンB6減少	5/112 (4.5)	5/85 (5.9)	5/73 (6.8)	5/63 (7.9)

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
傷害、中毒および処置合併症 (Cont.)				
サンバーン	0/55	0/0	0/0	1/112 (0.9)
腱断裂	0/55	0/0	0/0	1/112 (0.9)
過少量投与	0/55	0/0	0/0	1/112 (0.9)
臨床検査	12/55 (21.8)	0/0	0/0	24/112 (21.4)
血中クレアチンホスホキナーゼ増加	0/55	0/0	0/0	1/112 (0.9)
血中クレアチニン減少	1/55 (1.8)	0/0	0/0	1/112 (0.9)
血中葉酸異常	1/55 (1.8)	0/0	0/0	1/112 (0.9)
血中葉酸減少	1/55 (1.8)	0/0	0/0	1/112 (0.9)
血中ホモシステイン増加	2/55 (3.6)	0/0	0/0	2/112 (1.8)
血中リン減少	0/55	0/0	0/0	1/112 (0.9)
血圧上昇	0/55	0/0	0/0	1/112 (0.9)
C-反応性蛋白増加	1/55 (1.8)	0/0	0/0	1/112 (0.9)
ヘモグロビン減少	0/55	0/0	0/0	1/112 (0.9)
リンパ球数減少	0/55	0/0	0/0	1/112 (0.9)
単球数増加	0/55	0/0	0/0	1/112 (0.9)
好中球数増加	1/55 (1.8)	0/0	0/0	2/112 (1.8)
プロトロンビン時間延長	1/55 (1.8)	0/0	0/0	1/112 (0.9)
赤血球数減少	1/55 (1.8)	0/0	0/0	1/112 (0.9)
ビタミンB12減少	1/55 (1.8)	0/0	0/0	1/112 (0.9)
ビタミンB6減少	5/55 (9.1)	0/0	0/0	6/112 (5.4)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
臨床検査 (Cont.)				
ビタミンD減少	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	0/63
体重減少	9/112 (8.0)	12/85 (14.1)	12/73 (16.4)	9/63 (14.3)
白血球数増加	2/112 (1.8)	0/85	0/73	0/63
代謝および栄養障害	12/112 (10.7)	10/85 (11.8)	11/73 (15.1)	8/63 (12.7)
食欲減退	2/112 (1.8)	3/85 (3.5)	2/73 (2.7)	2/63 (3.2)
脱水	2/112 (1.8)	1/85 (1.2)	0/73	0/63
糖尿病	0/112	0/85	1/73 (1.4)	1/63 (1.6)
水分過負荷	1/112 (0.9)	0/85	0/73	0/63
体液貯留	0/112	0/85	0/73	1/63 (1.6)
葉酸欠乏	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
耐糖能障害	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
高コレステロール血症	0/112	1/85 (1.2)	0/73	0/63
高血糖	1/112 (0.9)	0/85	0/73	0/63
高ホモシステイン血症	0/112	0/85	1/73 (1.4)	0/63
低カルシウム血症	0/112	0/85	1/73 (1.4)	0/63
低カリウム血症	2/112 (1.8)	0/85	0/73	1/63 (1.6)
栄養障害	1/112 (0.9)	0/85	0/73	0/63
ビタミンB群欠乏	0/112	0/85	1/73 (1.4)	1/63 (1.6)
ビタミンB12欠乏	0/112	0/85	1/73 (1.4)	1/63 (1.6)
ビタミンB6欠乏	4/112 (3.6)	4/85 (4.7)	5/73 (6.8)	3/63 (4.8)

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
臨床検査 (Cont.)				
ビタミンD減少	0/55	0/0	0/0	1/112 (0.9)
体重減少	6/55 (10.9)	0/0	0/0	14/112 (12.5)
白血球数増加	0/55	0/0	0/0	2/112 (1.8)
代謝および栄養障害	5/55 (9.1)	0/0	0/0	19/112 (17.0)
食欲減退	1/55 (1.8)	0/0	0/0	3/112 (2.7)
脱水	0/55	0/0	0/0	3/112 (2.7)
糖尿病	0/55	0/0	0/0	1/112 (0.9)
水分過負荷	0/55	0/0	0/0	1/112 (0.9)
体液貯留	1/55 (1.8)	0/0	0/0	1/112 (0.9)
葉酸欠乏	0/55	0/0	0/0	1/112 (0.9)
耐糖能障害	1/55 (1.8)	0/0	0/0	1/112 (0.9)
高コレステロール血症	0/55	0/0	0/0	1/112 (0.9)
高血糖	0/55	0/0	0/0	1/112 (0.9)
高ホモシステイン血症	0/55	0/0	0/0	1/112 (0.9)
低カルシウム血症	0/55	0/0	0/0	1/112 (0.9)
低カリウム血症	0/55	0/0	0/0	3/112 (2.7)
栄養障害	0/55	0/0	0/0	1/112 (0.9)
ビタミンB群欠乏	1/55 (1.8)	0/0	0/0	1/112 (0.9)
ビタミンB12欠乏	1/55 (1.8)	0/0	0/0	2/112 (1.8)
ビタミンB6欠乏	2/55 (3.6)	0/0	0/0	5/112 (4.5)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
筋骨格系および結合組織障害	13/112 (11.6)	8/85 (9.4)	12/73 (16.4)	8/63 (12.7)
関節痛	2/112 (1.8)	3/85 (3.5)	3/73 (4.1)	3/63 (4.8)
反応性関節炎	1/112 (0.9)	0/85	0/73	0/63
背部痛	2/112 (1.8)	2/85 (2.4)	3/73 (4.1)	1/63 (1.6)
骨痛	0/112	0/85	1/73 (1.4)	0/63
外骨腫	0/112	1/85 (1.2)	1/73 (1.4)	0/63
椎間関節症候群	0/112	1/85 (1.2)	1/73 (1.4)	0/63
椎間板突出	0/112	1/85 (1.2)	1/73 (1.4)	0/63
関節滲出液	0/112	1/85 (1.2)	1/73 (1.4)	0/63
関節腫脹	1/112 (0.9)	1/85 (1.2)	0/73	0/63
四肢不快感	0/112	0/85	1/73 (1.4)	0/63
筋萎縮	0/112	1/85 (1.2)	1/73 (1.4)	0/63
筋痙縮	2/112 (1.8)	2/85 (2.4)	1/73 (1.4)	1/63 (1.6)
筋力低下	0/112	0/85	1/73 (1.4)	1/63 (1.6)
筋骨格硬直	1/112 (0.9)	0/85	0/73	0/63
筋肉痛	1/112 (0.9)	0/85	0/73	0/63
骨炎	1/112 (0.9)	0/85	0/73	0/63
変形性関節症	0/112	2/85 (2.4)	3/73 (4.1)	1/63 (1.6)
四肢痛	3/112 (2.7)	1/85 (1.2)	1/73 (1.4)	0/63
関節周囲炎	0/112	0/85	1/73 (1.4)	1/63 (1.6)
姿勢異常	1/112 (0.9)	0/85	0/73	0/63
肩回旋筋腱板症候群	0/112	1/85 (1.2)	1/73 (1.4)	0/63
腱障害	0/112	1/85 (1.2)	1/73 (1.4)	0/63

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
筋骨格系および結合組織障害	5/55 (9.1)	0/0	0/0	21/112 (18.8)
関節痛	1/55 (1.8)	0/0	0/0	5/112 (4.5)
反応性関節炎	0/55	0/0	0/0	1/112 (0.9)
背部痛	1/55 (1.8)	0/0	0/0	5/112 (4.5)
骨痛	0/55	0/0	0/0	1/112 (0.9)
外骨腫	0/55	0/0	0/0	1/112 (0.9)
椎間関節症候群	0/55	0/0	0/0	1/112 (0.9)
椎間板突出	0/55	0/0	0/0	1/112 (0.9)
関節滲出液	1/55 (1.8)	0/0	0/0	2/112 (1.8)
関節腫脹	0/55	0/0	0/0	1/112 (0.9)
四肢不快感	0/55	0/0	0/0	1/112 (0.9)
筋萎縮	0/55	0/0	0/0	1/112 (0.9)
筋痙縮	0/55	0/0	0/0	3/112 (2.7)
筋力低下	0/55	0/0	0/0	1/112 (0.9)
筋骨格硬直	0/55	0/0	0/0	1/112 (0.9)
筋肉痛	0/55	0/0	0/0	1/112 (0.9)
骨炎	0/55	0/0	0/0	1/112 (0.9)
変形性関節症	2/55 (3.6)	0/0	0/0	4/112 (3.6)
四肢痛	0/55	0/0	0/0	3/112 (2.7)
関節周囲炎	1/55 (1.8)	0/0	0/0	1/112 (0.9)
姿勢異常	0/55	0/0	0/0	1/112 (0.9)
肩回旋筋腱板症候群	0/55	0/0	0/0	1/112 (0.9)
腱障害	0/55	0/0	0/0	1/112 (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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
筋骨格系および結合組織障害 (Cont.)				
斜頚	1/112 (0.9)	0/85	0/73	0/63
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	1/112 (0.9)	2/85 (2.4)	3/73 (4.1)	1/63 (1.6)
基底細胞癌	0/112	2/85 (2.4)	2/73 (2.7)	0/63
脂漏性角化症	0/112	0/85	1/73 (1.4)	1/63 (1.6)
皮膚有棘細胞癌	1/112 (0.9)	0/85	0/73	0/63
神経系障害	32/112 (28.6)	22/85 (25.9)	23/73 (31.5)	20/63 (31.7)
失語症	0/112	0/85	1/73 (1.4)	0/63
平衡障害	1/112 (0.9)	0/85	2/73 (2.7)	2/63 (3.2)
運動緩慢	0/112	0/85	1/73 (1.4)	0/63
手根管症候群	0/112	0/85	1/73 (1.4)	1/63 (1.6)
大脳萎縮	0/112	0/85	0/73	1/63 (1.6)
脳出血	0/112	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
脳圧排効果	0/112	0/85	0/73	1/63 (1.6)
脳血管発作	0/112	1/85 (1.2)	0/73	0/63
認知障害	0/112	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
注意力障害	1/112 (0.9)	1/85 (1.2)	0/73	0/63
浮動性めまい	10/112 (8.9)	5/85 (5.9)	3/73 (4.1)	2/63 (3.2)
構語障害	1/112 (0.9)	1/85 (1.2)	2/73 (2.7)	1/63 (1.6)
味覚不全	0/112	0/85	0/73	1/63 (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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
筋骨格系および結合組織障害 (Cont.)				
斜頚	0/55	0/0	0/0	1/112 (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）	1/55 (1.8)	0/0	0/0	4/112 (3.6)
基底細胞癌	0/55	0/0	0/0	2/112 (1.8)
脂漏性角化症	1/55 (1.8)	0/0	0/0	1/112 (0.9)
皮膚有棘細胞癌	0/55	0/0	0/0	1/112 (0.9)
神経系障害	18/55 (32.7)	0/0	0/0	48/112 (42.9)
失語症	0/55	0/0	0/0	1/112 (0.9)
平衡障害	3/55 (5.5)	0/0	0/0	4/112 (3.6)
運動緩慢	0/55	0/0	0/0	1/112 (0.9)
手根管症候群	1/55 (1.8)	0/0	0/0	1/112 (0.9)
大脳萎縮	1/55 (1.8)	0/0	0/0	1/112 (0.9)
脳出血	1/55 (1.8)	0/0	0/0	1/112 (0.9)
脳圧排効果	0/55	0/0	0/0	1/112 (0.9)
脳血管発作	0/55	0/0	0/0	1/112 (0.9)
認知障害	1/55 (1.8)	0/0	0/0	2/112 (1.8)
注意力障害	0/55	0/0	0/0	1/112 (0.9)
浮動性めまい	2/55 (3.6)	0/0	0/0	10/112 (8.9)
構語障害	0/55	0/0	0/0	3/112 (2.7)
味覚不全	1/55 (1.8)	0/0	0/0	1/112 (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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
神経系障害 (Cont.)				
ジスキネジア	3/112 (2.7)	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
ジストニア	2/112 (1.8)	3/85 (3.5)	3/73 (4.1)	4/63 (6.3)
脳症	1/112 (0.9)	0/85	0/73	0/63
てんかん	1/112 (0.9)	0/85	0/73	0/63
本態性振戦	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	0/63
全身性強直性間代性発作	0/112	0/85	0/73	1/63 (1.6)
頭痛	4/112 (3.6)	2/85 (2.4)	2/73 (2.7)	3/63 (4.8)
片側感覚消失	1/112 (0.9)	0/85	0/73	0/63
不全片麻痺	1/112 (0.9)	0/85	0/73	0/63
知覚過敏	0/112	0/85	1/73 (1.4)	1/63 (1.6)
感覚鈍麻	0/112	0/85	2/73 (2.7)	1/63 (1.6)
反射減弱	0/112	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
嗜眠	0/112	0/85	1/73 (1.4)	0/63
意識消失	0/112	1/85 (1.2)	0/73	0/63
腰仙部神経根障害	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
記憶障害	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
代謝性脳症	1/112 (0.9)	0/85	0/73	0/63
神経痛	0/112	1/85 (1.2)	0/73	0/63
末梢性ニューロパチー	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	0/63
オンオフ現象	4/112 (3.6)	2/85 (2.4)	2/73 (2.7)	1/63 (1.6)
錯感覚	2/112 (1.8)	0/85	0/73	1/63 (1.6)
パーキンソン病	3/112 (2.7)	1/85 (1.2)	1/73 (1.4)	0/63
パーキンソニズム	2/112 (1.8)	1/85 (1.2)	1/73 (1.4)	1/63 (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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
神経系障害 (Cont.)				
ジスキネジア	1/55 (1.8)	0/0	0/0	6/112 (5.4)
ジストニア	4/55 (7.3)	0/0	0/0	5/112 (4.5)
脳症	0/55	0/0	0/0	1/112 (0.9)
てんかん	0/55	0/0	0/0	1/112 (0.9)
本態性振戦	0/55	0/0	0/0	1/112 (0.9)
全身性強直性間代性発作	0/55	0/0	0/0	1/112 (0.9)
頭痛	3/55 (5.5)	0/0	0/0	7/112 (6.3)
片側感覚消失	0/55	0/0	0/0	1/112 (0.9)
不全片麻痺	0/55	0/0	0/0	1/112 (0.9)
知覚過敏	1/55 (1.8)	0/0	0/0	1/112 (0.9)
感覚鈍麻	1/55 (1.8)	0/0	0/0	2/112 (1.8)
反射減弱	0/55	0/0	0/0	1/112 (0.9)
嗜眠	0/55	0/0	0/0	1/112 (0.9)
意識消失	0/55	0/0	0/0	1/112 (0.9)
腰仙部神経根障害	0/55	0/0	0/0	1/112 (0.9)
記憶障害	1/55 (1.8)	0/0	0/0	2/112 (1.8)
代謝性脳症	0/55	0/0	0/0	1/112 (0.9)
神経痛	0/55	0/0	0/0	1/112 (0.9)
末梢性ニューロパチー	0/55	0/0	0/0	1/112 (0.9)
オンオフ現象	1/55 (1.8)	0/0	0/0	5/112 (4.5)
錯感覚	1/55 (1.8)	0/0	0/0	3/112 (2.7)
パーキンソン病	0/55	0/0	0/0	5/112 (4.5)
パーキンソニズム	1/55 (1.8)	0/0	0/0	3/112 (2.7)

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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
神経系障害 (Cont.)				
末梢性感覚ニューロパチー	0/112	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
側反弓	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
多発ニューロパチー	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
失神寸前の状態	0/112	1/85 (1.2)	0/73	0/63
心因性発作	1/112 (0.9)	0/85	0/73	0/63
精神運動亢進	1/112 (0.9)	0/85	0/73	0/63
反射異常	0/112	0/85	0/73	1/63 (1.6)
安静時振戦	1/112 (0.9)	0/85	0/73	0/63
坐骨神経痛	2/112 (1.8)	2/85 (2.4)	2/73 (2.7)	1/63 (1.6)
痙攣発作	0/112	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
感覚障害	1/112 (0.9)	0/85	0/73	0/63
感覚消失	0/112	1/85 (1.2)	1/73 (1.4)	0/63
傾眠	2/112 (1.8)	1/85 (1.2)	2/73 (2.7)	1/63 (1.6)
失神	0/112	1/85 (1.2)	0/73	1/63 (1.6)
振戦	2/112 (1.8)	0/85	0/73	0/63
製品の問題	1/112 (0.9)	0/85	0/73	0/63
医療機器機能不良	1/112 (0.9)	0/85	0/73	0/63
精神障害	45/112 (40.2)	30/85 (35.3)	26/73 (35.6)	22/63 (34.9)
異常な夢	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
感情不安定	0/112	1/85 (1.2)	1/73 (1.4)	0/63
激越	1/112 (0.9)	0/85	0/73	0/63

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
神経系障害 (Cont.)				
末梢性感覚ニューロパチー	1/55 (1.8)	0/0	0/0	1/112 (0.9)
側反弓	1/55 (1.8)	0/0	0/0	2/112 (1.8)
多発ニューロパチー	1/55 (1.8)	0/0	0/0	2/112 (1.8)
失神寸前の状態	0/55	0/0	0/0	1/112 (0.9)
心因性発作	0/55	0/0	0/0	1/112 (0.9)
精神運動亢進	0/55	0/0	0/0	1/112 (0.9)
反射異常	1/55 (1.8)	0/0	0/0	1/112 (0.9)
安静時振戦	0/55	0/0	0/0	1/112 (0.9)
坐骨神経痛	0/55	0/0	0/0	3/112 (2.7)
痙攣発作	1/55 (1.8)	0/0	0/0	1/112 (0.9)
感覚障害	0/55	0/0	0/0	1/112 (0.9)
感覚消失	0/55	0/0	0/0	1/112 (0.9)
傾眠	1/55 (1.8)	0/0	0/0	3/112 (2.7)
失神	1/55 (1.8)	0/0	0/0	3/112 (2.7)
振戦	0/55	0/0	0/0	2/112 (1.8)
製品の問題	0/55	0/0	0/0	1/112 (0.9)
医療機器機能不良	0/55	0/0	0/0	1/112 (0.9)
精神障害	16/55 (29.1)	0/0	0/0	57/112 (50.9)
異常な夢	1/55 (1.8)	0/0	0/0	1/112 (0.9)
感情不安定	0/55	0/0	0/0	1/112 (0.9)
激越	0/55	0/0	0/0	1/112 (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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
精神障害 (Cont.)				
不安	15/112 (13.4)	8/85 (9.4)	10/73 (13.7)	8/63 (12.7)
不安障害	0/112	0/85	0/73	1/63 (1.6)
強迫行為	1/112 (0.9)	0/85	0/73	0/63
錯乱状態	1/112 (0.9)	1/85 (1.2)	3/73 (4.1)	2/63 (3.2)
譫妄	3/112 (2.7)	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
妄想	1/112 (0.9)	1/85 (1.2)	0/73	0/63
妄想性障害、詳細不明	1/112 (0.9)	1/85 (1.2)	0/73	0/63
抑うつ気分	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	2/63 (3.2)
うつ病	0/112	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
ディスフェミア	0/112	0/85	1/73 (1.4)	0/63
情動障害	1/112 (0.9)	0/85	0/73	0/63
注射恐怖	0/112	1/85 (1.2)	0/73	0/63
幻覚	16/112 (14.3)	11/85 (12.9)	8/73 (11.0)	7/63 (11.1)
幻聴	1/112 (0.9)	3/85 (3.5)	2/73 (2.7)	0/63
幻嗅	1/112 (0.9)	0/85	0/73	0/63
幻視	4/112 (3.6)	2/85 (2.4)	2/73 (2.7)	1/63 (1.6)
錯覚	0/112	0/85	1/73 (1.4)	1/63 (1.6)
衝動制御障害	2/112 (1.8)	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
衝動行為	0/112	0/85	0/73	1/63 (1.6)
不眠症	6/112 (5.4)	6/85 (7.1)	3/73 (4.1)	4/63 (6.3)
易刺激性	1/112 (0.9)	1/85 (1.2)	0/73	0/63
躁病	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	0/63

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
精神障害 (Cont.)				
不安	7/55 (12.7)	0/0	0/0	18/112 (16.1)
不安障害	1/55 (1.8)	0/0	0/0	1/112 (0.9)
強迫行為	0/55	0/0	0/0	1/112 (0.9)
錯乱状態	0/55	0/0	0/0	5/112 (4.5)
譫妄	0/55	0/0	0/0	4/112 (3.6)
妄想	0/55	0/0	0/0	2/112 (1.8)
妄想性障害、詳細不明	0/55	0/0	0/0	1/112 (0.9)
抑うつ気分	1/55 (1.8)	0/0	0/0	2/112 (1.8)
うつ病	0/55	0/0	0/0	2/112 (1.8)
ディスフェミア	0/55	0/0	0/0	1/112 (0.9)
情動障害	0/55	0/0	0/0	1/112 (0.9)
注射恐怖	0/55	0/0	0/0	1/112 (0.9)
幻覚	4/55 (7.3)	0/0	0/0	22/112 (19.6)
幻聴	0/55	0/0	0/0	3/112 (2.7)
幻嗅	0/55	0/0	0/0	1/112 (0.9)
幻視	0/55	0/0	0/0	5/112 (4.5)
錯覚	0/55	0/0	0/0	1/112 (0.9)
衝動制御障害	1/55 (1.8)	0/0	0/0	4/112 (3.6)
衝動行為	1/55 (1.8)	0/0	0/0	1/112 (0.9)
不眠症	4/55 (7.3)	0/0	0/0	9/112 (8.0)
易刺激性	0/55	0/0	0/0	1/112 (0.9)
躁病	0/55	0/0	0/0	1/112 (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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
精神障害 (Cont.)				
気分動揺	0/112	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
悪夢	1/112 (0.9)	0/85	0/73	0/63
パニック発作	3/112 (2.7)	0/85	1/73 (1.4)	1/63 (1.6)
パニック反応	0/112	0/85	1/73 (1.4)	1/63 (1.6)
処置に対する不安	0/112	1/85 (1.2)	0/73	0/63
精神病性障害	0/112	1/85 (1.2)	2/73 (2.7)	1/63 (1.6)
レム睡眠行動障害	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
睡眠障害	1/112 (0.9)	0/85	0/73	0/63
ねごと	1/112 (0.9)	1/85 (1.2)	0/73	0/63
常同症	0/112	0/85	0/73	1/63 (1.6)
ストレス	1/112 (0.9)	0/85	0/73	0/63
自殺念慮	2/112 (1.8)	1/85 (1.2)	1/73 (1.4)	0/63
腎および尿路障害	3/112 (2.7)	2/85 (2.4)	5/73 (6.8)	4/63 (6.3)
排尿困難	1/112 (0.9)	0/85	0/73	1/63 (1.6)
夜間頻尿	0/112	1/85 (1.2)	1/73 (1.4)	0/63
多尿	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
腎機能障害	0/112	0/85	1/73 (1.4)	0/63
尿管結石症	1/112 (0.9)	0/85	0/73	0/63
尿失禁	0/112	0/85	1/73 (1.4)	1/63 (1.6)
尿閉	0/112	0/85	1/73 (1.4)	3/63 (4.8)
尿異常	1/112 (0.9)	0/85	0/73	0/63

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
精神障害 (Cont.)				
気分動揺	0/55	0/0	0/0	1/112 (0.9)
悪夢	0/55	0/0	0/0	1/112 (0.9)
パニック発作	1/55 (1.8)	0/0	0/0	3/112 (2.7)
パニック反応	0/55	0/0	0/0	1/112 (0.9)
処置に対する不安	0/55	0/0	0/0	1/112 (0.9)
精神病性障害	0/55	0/0	0/0	2/112 (1.8)
レム睡眠行動障害	1/55 (1.8)	0/0	0/0	1/112 (0.9)
睡眠障害	0/55	0/0	0/0	1/112 (0.9)
ねごと	0/55	0/0	0/0	1/112 (0.9)
常同症	1/55 (1.8)	0/0	0/0	1/112 (0.9)
ストレス	0/55	0/0	0/0	1/112 (0.9)
自殺念慮	0/55	0/0	0/0	2/112 (1.8)
腎および尿路障害	3/55 (5.5)	0/0	0/0	7/112 (6.3)
排尿困難	1/55 (1.8)	0/0	0/0	2/112 (1.8)
夜間頻尿	0/55	0/0	0/0	1/112 (0.9)
多尿	1/55 (1.8)	0/0	0/0	1/112 (0.9)
腎機能障害	0/55	0/0	0/0	1/112 (0.9)
尿管結石症	0/55	0/0	0/0	1/112 (0.9)
尿失禁	0/55	0/0	0/0	2/112 (1.8)
尿閉	1/55 (1.8)	0/0	0/0	3/112 (2.7)
尿異常	0/55	0/0	0/0	1/112 (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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
腎および尿路障害 (Cont.)				
尿臭異常	0/112	0/85	1/73 (1.4)	1/63 (1.6)
生殖系および乳房障害	3/112 (2.7)	4/85 (4.7)	3/73 (4.1)	3/63 (4.8)
勃起不全	1/112 (0.9)	0/85	0/73	0/63
骨盤痛	0/112	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
ペイロニー病	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
閉経後出血	0/112	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
前立腺腫大	0/112	1/85 (1.2)	0/73	0/63
膣脱	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
呼吸器、胸郭および縦隔障害	13/112 (11.6)	5/85 (5.9)	5/73 (6.8)	4/63 (6.3)
急性呼吸不全	1/112 (0.9)	0/85	0/73	0/63
咳嗽	2/112 (1.8)	1/85 (1.2)	0/73	0/63
発声障害	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	0/63
呼吸困難	4/112 (3.6)	2/85 (2.4)	2/73 (2.7)	1/63 (1.6)
鼻出血	0/112	0/85	1/73 (1.4)	0/63
過換気	2/112 (1.8)	0/85	0/73	0/63
口腔咽頭痛	1/112 (0.9)	0/85	0/73	0/63
誤嚥性肺炎	0/112	0/85	0/73	1/63 (1.6)
湿性咳嗽	0/112	0/85	1/73 (1.4)	0/63
肺塞栓症	1/112 (0.9)	0/85	0/73	1/63 (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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
腎および尿路障害 (Cont.)				
尿臭異常	0/55	0/0	0/0	1/112 (0.9)
生殖系および乳房障害	3/55 (5.5)	0/0	0/0	5/112 (4.5)
勃起不全	0/55	0/0	0/0	1/112 (0.9)
骨盤痛	1/55 (1.8)	0/0	0/0	1/112 (0.9)
ペイロニー病	1/55 (1.8)	0/0	0/0	1/112 (0.9)
閉経後出血	1/55 (1.8)	0/0	0/0	1/112 (0.9)
前立腺腫大	0/55	0/0	0/0	1/112 (0.9)
膣脱	1/55 (1.8)	0/0	0/0	1/112 (0.9)
呼吸器、胸郭および縦隔障害	1/55 (1.8)	0/0	0/0	19/112 (17.0)
急性呼吸不全	0/55	0/0	0/0	1/112 (0.9)
咳嗽	0/55	0/0	0/0	2/112 (1.8)
発声障害	0/55	0/0	0/0	2/112 (1.8)
呼吸困難	0/55	0/0	0/0	6/112 (5.4)
鼻出血	0/55	0/0	0/0	1/112 (0.9)
過換気	0/55	0/0	0/0	2/112 (1.8)
口腔咽頭痛	0/55	0/0	0/0	1/112 (0.9)
誤嚥性肺炎	0/55	0/0	0/0	1/112 (0.9)
湿性咳嗽	0/55	0/0	0/0	1/112 (0.9)
肺塞栓症	1/55 (1.8)	0/0	0/0	2/112 (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.
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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
呼吸器、胸郭および縦隔障害 (Cont.)				
ラ音	0/112	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
鼻痛	1/112 (0.9)	0/85	0/73	0/63
鼻漏	2/112 (1.8)	0/85	0/73	0/63
咽喉刺激感	1/112 (0.9)	0/85	0/73	0/63
皮膚および皮下組織障害	12/112 (10.7)	6/85 (7.1)	6/73 (8.2)	7/63 (11.1)
脱毛症	0/112	0/85	0/73	1/63 (1.6)
褥瘡性潰瘍	1/112 (0.9)	1/85 (1.2)	0/73	0/63
皮膚嚢腫	0/112	0/85	0/73	1/63 (1.6)
皮膚炎	1/112 (0.9)	1/85 (1.2)	0/73	0/63
皮膚乾燥	1/112 (0.9)	0/85	0/73	0/63
紅斑	3/112 (2.7)	0/85	0/73	0/63
脂肪織炎	0/112	0/85	1/73 (1.4)	1/63 (1.6)
丘疹	2/112 (1.8)	2/85 (2.4)	2/73 (2.7)	1/63 (1.6)
口囲皮膚炎	0/112	0/85	0/73	1/63 (1.6)
光線過敏性反応	1/112 (0.9)	0/85	0/73	0/63
そう痒症	1/112 (0.9)	1/85 (1.2)	2/73 (2.7)	2/63 (3.2)
乾癬	0/112	1/85 (1.2)	1/73 (1.4)	0/63
発疹	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
紅斑性皮疹	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	1/63 (1.6)
そう痒性皮疹	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	1/63 (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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
呼吸器、胸郭および縦隔障害 (Cont.)				
ラ音	0/55	0/0	0/0	1/112 (0.9)
鼻痛	0/55	0/0	0/0	1/112 (0.9)
鼻漏	0/55	0/0	0/0	2/112 (1.8)
咽喉刺激感	0/55	0/0	0/0	1/112 (0.9)
皮膚および皮下組織障害	4/55 (7.3)	0/0	0/0	16/112 (14.3)
脱毛症	0/55	0/0	0/0	1/112 (0.9)
褥瘡性潰瘍	0/55	0/0	0/0	1/112 (0.9)
皮膚嚢腫	0/55	0/0	0/0	1/112 (0.9)
皮膚炎	0/55	0/0	0/0	1/112 (0.9)
皮膚乾燥	0/55	0/0	0/0	1/112 (0.9)
紅斑	0/55	0/0	0/0	3/112 (2.7)
脂肪織炎	0/55	0/0	0/0	1/112 (0.9)
丘疹	1/55 (1.8)	0/0	0/0	2/112 (1.8)
口囲皮膚炎	0/55	0/0	0/0	1/112 (0.9)
光線過敏性反応	0/55	0/0	0/0	1/112 (0.9)
そう痒症	2/55 (3.6)	0/0	0/0	2/112 (1.8)
乾癬	0/55	0/0	0/0	1/112 (0.9)
発疹	1/55 (1.8)	0/0	0/0	1/112 (0.9)
紅斑性皮疹	1/55 (1.8)	0/0	0/0	1/112 (0.9)
そう痒性皮疹	1/55 (1.8)	0/0	0/0	1/112 (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

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=244) n/N eval (%)	 Days 91 to 180 (N=184) n/N eval (%)	 Days 181 to 270 (N=160) n/N eval (%)	 Days 271 to 360 (N=139) n/N eval (%)
High Dose				
皮膚および皮下組織障害 (Cont.)				
皮膚刺激	1/112 (0.9)	0/85	0/73	0/63
皮膚病変	1/112 (0.9)	1/85 (1.2)	1/73 (1.4)	0/63
皮膚潰瘍	1/112 (0.9)	0/85	0/73	0/63
外科および内科処置	0/112	1/85 (1.2)	0/73	0/63
抜歯	0/112	1/85 (1.2)	0/73	0/63
血管障害	8/112 (7.1)	4/85 (4.7)	6/73 (8.2)	5/63 (7.9)
深部静脈血栓症	1/112 (0.9)	0/85	0/73	0/63
血腫	0/112	0/85	0/73	1/63 (1.6)
出血	0/112	1/85 (1.2)	0/73	0/63
ほてり	1/112 (0.9)	0/85	0/73	0/63
高血圧	2/112 (1.8)	0/85	0/73	1/63 (1.6)
低血圧	2/112 (1.8)	1/85 (1.2)	2/73 (2.7)	1/63 (1.6)
不安定血圧	1/112 (0.9)	0/85	0/73	0/63
起立性高血圧	0/112	0/85	0/73	0/63
起立性低血圧	4/112 (3.6)	2/85 (2.4)	4/73 (5.5)	3/63 (4.8)

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

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=123) n/N eval (%)	 Days 451 to 540 (N=2) n/N eval (%)	 After Day 540 (N=0) n/N eval (%)	 At Any Time (N=244) n/N eval (%)
High Dose				
皮膚および皮下組織障害 (Cont.)				
皮膚刺激	0/55	0/0	0/0	1/112 (0.9)
皮膚病変	0/55	0/0	0/0	1/112 (0.9)
皮膚潰瘍	0/55	0/0	0/0	1/112 (0.9)
外科および内科処置	0/55	0/0	0/0	1/112 (0.9)
抜歯	0/55	0/0	0/0	1/112 (0.9)
血管障害	6/55 (10.9)	0/0	0/0	15/112 (13.4)
深部静脈血栓症	0/55	0/0	0/0	1/112 (0.9)
血腫	0/55	0/0	0/0	1/112 (0.9)
出血	0/55	0/0	0/0	1/112 (0.9)
ほてり	0/55	0/0	0/0	1/112 (0.9)
高血圧	0/55	0/0	0/0	3/112 (2.7)
低血圧	2/55 (3.6)	0/0	0/0	4/112 (3.6)
不安定血圧	0/55	0/0	0/0	1/112 (0.9)
起立性高血圧	1/55 (1.8)	0/0	0/0	1/112 (0.9)
起立性低血圧	3/55 (5.5)	0/0	0/0	6/112 (5.4)

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]

表42　有害事象の概要（安全性解析対象集団，日本人部分集団）：M15-741試験

[redacted]20[redacted] 10:57 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - CLINICAL/STATISTICAL

TABLE 14.3 1.1.J

Overview of Treatment-Emergent Adverse Events and All Deaths for Japan and Non-Japan Subjects by Time Interval
(Safety Analysis Set)

	Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Entire study period	N=22	N=5	N=27
Subjects with:			
Any TEAE	20 (90.9)	5 (100)	25 (92.6)
Any severe TEAE	3 (13.6)	1 (20.0)	4 (14.8)
Any TEAE that is considered associated with study drug$	20 (90.9)	5 (100)	25 (92.6)
Any TEAE that is considered associated with product complaint$	17 (77.3)	3 (60.0)	20 (74.1)
ABBV-951	10 (45.5)	2 (40.0)	12 (44.4)
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	7 (31.8)	3 (60.0)	10 (37.0)
[redacted] infusion set 6 mm	6 (27.3)	1 (20.0)	7 (25.9)
[redacted] infusion set 9 mm	1 (4.5)	3 (60.0)	4 (14.8)
Neria guard infusion set (total)	4 (18.2)	0	4 (14.8)
Neria guard infusion set 6 mm	1 (4.5)	0	1 (3.7)
Neria guard infusion set 9 mm	3 (13.6)	0	3 (11.1)
[redacted]	0	0	0
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	6 (27.3)	1 (20.0)	7 (25.9)
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	6 (27.3)	1 (20.0)	7 (25.9)

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 by Time Interval
(Safety Analysis Set)

	Non-Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Entire study period	N=110	N=107	N=217
Subjects with:			
Any TEAE	102 (92.7)	103 (96.3)	205 (94.5)
Any severe TEAE	24 (21.8)	35 (32.7)	59 (27.2)
Any TEAE that is considered associated with study drug$	98 (89.1)	101 (94.4)	199 (91.7)
Any TEAE that is considered associated with product complaint$	74 (67.3)	79 (73.8)	153 (70.5)
ABBV-951	42 (38.2)	42 (39.3)	84 (38.7)
Infusion pump	9 (8.2)	9 (8.4)	18 (8.3)
Vial adapter	0	1 (0.9)	1 (0.5)
Syringes	0	0	0
[redacted] infusion set (total)	44 (40.0)	38 (35.5)	82 (37.8)
[redacted] infusion set 6 mm	31 (28.2)	25 (23.4)	56 (25.8)
[redacted] infusion set 9 mm	24 (21.8)	21 (19.6)	45 (20.7)
Neria guard infusion set (total)	10 (9.1)	18 (16.8)	28 (12.9)
Neria guard infusion set 6 mm	7 (6.4)	9 (8.4)	16 (7.4)
Neria guard infusion set 9 mm	6 (5.5)	14 (13.1)	20 (9.2)
[redacted]	3 (2.7)	4 (3.7)	7 (3.2)
Any TEAE that is considered associated with loading dose$	2 (1.8)	5 (4.7)	7 (3.2)
Any TEAE that is considered associated with rescue dose$	4 (3.6)	8 (7.5)	12 (5.5)
Any TEAE that is considered associated with COVID-19 infection	2 (1.8)	1 (0.9)	3 (1.4)
Any TEAE leading to prematurely discontinuation of study drug	27 (24.5)	29 (27.1)	56 (25.8)
Any TEAE leading to death (fatal TEAE)	0	3 (2.8)	3 (1.4)
Any serious TEAE	27 (24.5)	29 (27.1)	56 (25.8)

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 by Time Interval
(Safety Analysis Set)

	Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	3 (13.6)	0	3 (11.1)
Possible	0	0	0
Probable	1 (4.5)	0	1 (3.7)
Causal relationship	2 (9.1)	0	2 (7.4)
Any 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 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
[redacted]	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 by Time Interval
(Safety Analysis Set)

	Non-Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	11 (10.0)	8 (7.5)	19 (8.8)
Possible	6 (5.5)	5 (4.7)	11 (5.1)
Probable	4 (3.6)	3 (2.8)	7 (3.2)
Causal relationship	5 (4.5)	2 (1.9)	7 (3.2)
Any SAE that is considered associated with [redacted] infusion set$	1 (0.9)	1 (0.9)	2 (0.9)
Possible	1 (0.9)	1 (0.9)	2 (0.9)
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with neria guards infusion set$	2 (1.8)	1 (0.9)	3 (1.4)
Possible	1 (0.9)	1 (0.9)	2 (0.9)
Probable	0	0	0
Causal relationship	1 (0.9)	0	1 (0.5)
Any SAE that is considered associated with product complaint$	11 (10.0)	9 (8.4)	20 (9.2)
ABBV-951	4 (3.6)	4 (3.7)	8 (3.7)
Infusion pump	2 (1.8)	2 (1.9)	4 (1.8)
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	3 (2.7)	2 (1.9)	5 (2.3)
[redacted] infusion set 6 mm	2 (1.8)	1 (0.9)	3 (1.4)
[redacted] infusion set 9 mm	1 (0.9)	1 (0.9)	2 (0.9)
Neria guard infusion set (total)	2 (1.8)	1 (0.9)	3 (1.4)
Neria guard infusion set 6 mm	2 (1.8)	1 (0.9)	3 (1.4)
Neria guard infusion set 9 mm	0	0	0
PKG wearable watch	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 by Time Interval
(Safety Analysis Set)

	Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any AE (non-SAE) that is considered associated with infusion pump$&	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any AE (non-SAE) that is considered associated with [redacted] infusion set$&	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$&	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	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.
& For subjects with AE onset date later than [redacted], 20[redacted].

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 by Time Interval
(Safety Analysis Set)

	Non-Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any AE (non-SAE) that is considered associated with infusion pump$&	0	2 (1.9)	2 (0.9)
Possible	0	2 (1.9)	2 (0.9)
Probable	0	0	0
Causal relationship	0	0	0
Any AE (non-SAE) that is considered associated with [redacted] infusion set$&	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$&	0	2 (1.9)	2 (0.9)
Possible	0	2 (1.9)	2 (0.9)
Probable	0	0	0
Causal relationship	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.
& For subjects with AE onset date later than [redacted], 20[redacted].

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 by Time Interval
(Safety Analysis Set)

	Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
All deaths#	0	0	0
All TE-deaths	0	0	0
Deaths related to COVID-19 infection	0	0	0
AESI: polyneuropathy (narrow)	0	0	0
AESI: weight loss	1 (4.5)	0	1 (3.7)
AESI: hallucinations/psychosis	10 (45.5)	2 (40.0)	12 (44.4)
AESI: somnolence	0	0	0
AESI: infusion site related infections	3 (13.6)	2 (40.0)	5 (18.5)
AESI: infusion site related non infection reactions	17 (77.3)	3 (60.0)	20 (74.1)
AESI: falls and associated injuries	8 (36.4)	3 (60.0)	11 (40.7)

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 by Time Interval
(Safety Analysis Set)

	Non-Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
All deaths#	0	5 (4.7)	5 (2.3)
All TE-deaths	0	3 (2.8)	3 (1.4)
Deaths related to COVID-19 infection	0	0	0
AESI: polyneuropathy (narrow)	2 (1.8)	6 (5.6)	8 (3.7)
AESI: weight loss	11 (10.0)	15 (14.0)	26 (12.0)
AESI: hallucinations/psychosis	22 (20.0)	27 (25.2)	49 (22.6)
AESI: somnolence	9 (8.2)	3 (2.8)	12 (5.5)
AESI: infusion site related infections	39 (35.5)	42 (39.3)	81 (37.3)
AESI: infusion site related non infection reactions	87 (79.1)	93 (86.9)	180 (82.9)
AESI: falls and associated injuries	28 (25.5)	34 (31.8)	62 (28.6)

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 by Time Interval
(Safety Analysis Set)

	Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Optimization period	N=22	N=5	N=27
Subjects with:			
Any TEAE	15 (68.2)	4 (80.0)	19 (70.4)
Any severe TEAE	3 (13.6)	0	3 (11.1)
Any TEAE that is considered associated with study drug$	15 (68.2)	4 (80.0)	19 (70.4)
Any TEAE that is considered associated with product complaint$	12 (54.5)	2 (40.0)	14 (51.9)
ABBV-951	7 (31.8)	0	7 (25.9)
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	5 (22.7)	2 (40.0)	7 (25.9)
[redacted] infusion set 6 mm	5 (22.7)	0	5 (18.5)
[redacted] infusion set 9 mm	0	2 (40.0)	2 (7.4)
Neria guard infusion set (total)	1 (4.5)	0	1 (3.7)
Neria guard infusion set 6 mm	0	0	0
Neria guard infusion set 9 mm	1 (4.5)	0	1 (3.7)
[redacted]	0	0	0
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	4 (18.2)	1 (20.0)	5 (18.5)
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	4 (18.2)	0	4 (14.8)

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 by Time Interval
(Safety Analysis Set)

	Non-Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Optimization period	N=110	N=107	N=217
Subjects with:			
Any TEAE	91 (82.7)	93 (86.9)	184 (84.8)
Any severe TEAE	8 (7.3)	10 (9.3)	18 (8.3)
Any TEAE that is considered associated with study drug$	82 (74.5)	91 (85.0)	173 (79.7)
Any TEAE that is considered associated with product complaint$	55 (50.0)	61 (57.0)	116 (53.5)
ABBV-951	31 (28.2)	32 (29.9)	63 (29.0)
Infusion pump	3 (2.7)	2 (1.9)	5 (2.3)
Vial adapter	0	1 (0.9)	1 (0.5)
Syringes	0	0	0
[redacted] infusion set (total)	32 (29.1)	29 (27.1)	61 (28.1)
[redacted] infusion set 6 mm	22 (20.0)	15 (14.0)	37 (17.1)
[redacted] infusion set 9 mm	15 (13.6)	15 (14.0)	30 (13.8)
Neria guard infusion set (total)	5 (4.5)	7 (6.5)	12 (5.5)
Neria guard infusion set 6 mm	3 (2.7)	5 (4.7)	8 (3.7)
Neria guard infusion set 9 mm	2 (1.8)	4 (3.7)	6 (2.8)
[redacted]	2 (1.8)	2 (1.9)	4 (1.8)
Any TEAE that is considered associated with loading dose$	2 (1.8)	3 (2.8)	5 (2.3)
Any TEAE that is considered associated with rescue dose$	2 (1.8)	2 (1.9)	4 (1.8)
Any TEAE that is considered associated with COVID-19 infection	0	0	0
Any TEAE leading to prematurely discontinuation of study drug	13 (11.8)	9 (8.4)	22 (10.1)
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	7 (6.4)	6 (5.6)	13 (6.0)

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 by Time Interval
(Safety Analysis Set)

	Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	2 (9.1)	0	2 (7.4)
Possible	0	0	0
Probable	0	0	0
Causal relationship	2 (9.1)	0	2 (7.4)
Any 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 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
[redacted]	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 by Time Interval
(Safety Analysis Set)

	Non-Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	4 (3.6)	2 (1.9)	6 (2.8)
Possible	3 (2.7)	1 (0.9)	4 (1.8)
Probable	0	1 (0.9)	1 (0.5)
Causal relationship	1 (0.9)	0	1 (0.5)
Any 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 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$	3 (2.7)	2 (1.9)	5 (2.3)
ABBV-951	2 (1.8)	0	2 (0.9)
Infusion pump	1 (0.9)	0	1 (0.5)
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	0	2 (1.9)	2 (0.9)
[redacted] infusion set 6 mm	0	1 (0.9)	1 (0.5)
[redacted] infusion set 9 mm	0	1 (0.9)	1 (0.5)
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
[redacted]	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 by Time Interval
(Safety Analysis Set)

	Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any AE (non-SAE) that is considered associated with infusion pump$&	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any AE (non-SAE) that is considered associated with [redacted] infusion set$&	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$&	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	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.
& For subjects with AE onset date later than [redacted], 20[redacted].

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 by Time Interval
(Safety Analysis Set)

	Non-Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any AE (non-SAE) that is considered associated with infusion pump$&	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any AE (non-SAE) that is considered associated with [redacted] infusion set$&	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$&	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	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.
& For subjects with AE onset date later than [redacted], 20[redacted].

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 by Time Interval
(Safety Analysis Set)

	Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
All deaths#	0	0	0
All TE-deaths	0	0	0
Deaths related to COVID-19 infection	0	0	0
AESI: polyneuropathy (narrow)	0	0	0
AESI: weight loss	0	0	0
AESI: hallucinations/psychosis	6 (27.3)	2 (40.0)	8 (29.6)
AESI: somnolence	0	0	0
AESI: infusion site related infections	0	0	0
AESI: infusion site related non infection reactions	12 (54.5)	2 (40.0)	14 (51.9)
AESI: falls and associated injuries	4 (18.2)	1 (20.0)	5 (18.5)

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 by Time Interval
(Safety Analysis Set)

	Non-Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
All deaths#	0	0	0
All TE-deaths	0	0	0
Deaths related to COVID-19 infection	0	0	0
AESI: polyneuropathy (narrow)	0	0	0
AESI: weight loss	1 (0.9)	1 (0.9)	2 (0.9)
AESI: hallucinations/psychosis	11 (10.0)	6 (5.6)	17 (7.8)
AESI: somnolence	2 (1.8)	2 (1.9)	4 (1.8)
AESI: infusion site related infections	11 (10.0)	18 (16.8)	29 (13.4)
AESI: infusion site related non infection reactions	76 (69.1)	80 (74.8)	156 (71.9)
AESI: falls and associated injuries	15 (13.6)	18 (16.8)	33 (15.2)

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 by Time Interval
(Safety Analysis Set)

	Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Maintenance period	N=17	N=3	N=20
Subjects with:			
Any TEAE	15 (88.2)	3 (100)	18 (90.0)
Any severe TEAE	0	1 (33.3)	1 (5.0)
Any TEAE that is considered associated with study drug$	15 (88.2)	2 (66.7)	17 (85.0)
Any TEAE that is considered associated with product complaint$	9 (52.9)	3 (100)	12 (60.0)
ABBV-951	6 (35.3)	2 (66.7)	8 (40.0)
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	2 (11.8)	2 (66.7)	4 (20.0)
[redacted] infusion set 6 mm	1 (5.9)	1 (33.3)	2 (10.0)
[redacted] infusion set 9 mm	1 (5.9)	1 (33.3)	2 (10.0)
Neria guard infusion set (total)	3 (17.6)	0	3 (15.0)
Neria guard infusion set 6 mm	1 (5.9)	0	1 (5.0)
Neria guard infusion set 9 mm	2 (11.8)	0	2 (10.0)
[redacted]	0	0	0
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	2 (11.8)	0	2 (10.0)
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	2 (11.8)	1 (33.3)	3 (15.0)

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 by Time Interval
(Safety Analysis Set)

	Non-Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Maintenance period	N=94	N=92	N=186
Subjects with:			
Any TEAE	85 (90.4)	86 (93.5)	171 (91.9)
Any severe TEAE	19 (20.2)	28 (30.4)	47 (25.3)
Any TEAE that is considered associated with study drug$	75 (79.8)	82 (89.1)	157 (84.4)
Any TEAE that is considered associated with product complaint$	56 (59.6)	61 (66.3)	117 (62.9)
ABBV-951	25 (26.6)	34 (37.0)	59 (31.7)
Infusion pump	6 (6.4)	7 (7.6)	13 (7.0)
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	31 (33.0)	27 (29.3)	58 (31.2)
[redacted] infusion set 6 mm	19 (20.2)	15 (16.3)	34 (18.3)
[redacted] infusion set 9 mm	17 (18.1)	16 (17.4)	33 (17.7)
Neria guard infusion set (total)	10 (10.6)	15 (16.3)	25 (13.4)
Neria guard infusion set 6 mm	5 (5.3)	7 (7.6)	12 (6.5)
Neria guard infusion set 9 mm	6 (6.4)	12 (13.0)	18 (9.7)
[redacted]	1 (1.1)	2 (2.2)	3 (1.6)
Any TEAE that is considered associated with loading dose$	0	2 (2.2)	2 (1.1)
Any TEAE that is considered associated with rescue dose$	2 (2.1)	6 (6.5)	8 (4.3)
Any TEAE that is considered associated with COVID-19 infection	2 (2.1)	1 (1.1)	3 (1.6)
Any TEAE leading to prematurely discontinuation of study drug	15 (16.0)	20 (21.7)	35 (18.8)
Any TEAE leading to death (fatal TEAE)	0	3 (3.3)	3 (1.6)
Any serious TEAE	21 (22.3)	25 (27.2)	46 (24.7)

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.J

Overview of Treatment-Emergent Adverse Events and All Deaths for Japan and Non-Japan Subjects by Time Interval
(Safety Analysis Set)

	Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	1 (5.9)	0	1 (5.0)
Possible	0	0	0
Probable	1 (5.9)	0	1 (5.0)
Causal relationship	0	0	0
Any 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 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
[redacted]	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 by Time Interval
(Safety Analysis Set)

	Non-Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	7 (7.4)	7 (7.6)	14 (7.5)
Possible	3 (3.2)	4 (4.3)	7 (3.8)
Probable	4 (4.3)	2 (2.2)	6 (3.2)
Causal relationship	4 (4.3)	2 (2.2)	6 (3.2)
Any SAE that is considered associated with [redacted] infusion set$	1 (1.1)	1 (1.1)	2 (1.1)
Possible	1 (1.1)	1 (1.1)	2 (1.1)
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with neria guards infusion set$	2 (2.1)	1 (1.1)	3 (1.6)
Possible	1 (1.1)	1 (1.1)	2 (1.1)
Probable	0	0	0
Causal relationship	1 (1.1)	0	1 (0.5)
Any SAE that is considered associated with product complaint$	8 (8.5)	7 (7.6)	15 (8.1)
ABBV-951	2 (2.1)	4 (4.3)	6 (3.2)
Infusion pump	1 (1.1)	2 (2.2)	3 (1.6)
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	3 (3.2)	0	3 (1.6)
[redacted] infusion set 6 mm	2 (2.1)	0	2 (1.1)
[redacted] infusion set 9 mm	1 (1.1)	0	1 (0.5)
Neria guard infusion set (total)	2 (2.1)	1 (1.1)	3 (1.6)
Neria guard infusion set 6 mm	2 (2.1)	1 (1.1)	3 (1.6)
Neria guard infusion set 9 mm	0	0	0
[redacted]	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 by Time Interval
(Safety Analysis Set)

	Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any AE (non-SAE) that is considered associated with infusion pump$&	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any AE (non-SAE) that is considered associated with [redacted] infusion set$&	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$&	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	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.
& For subjects with AE onset date later than [redacted], 20[redacted].

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 by Time Interval
(Safety Analysis Set)

	Non-Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any AE (non-SAE) that is considered associated with infusion pump$&	0	2 (2.2)	2 (1.1)
Possible	0	2 (2.2)	2 (1.1)
Probable	0	0	0
Causal relationship	0	0	0
Any AE (non-SAE) that is considered associated with [redacted] infusion set$&	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$&	0	2 (2.2)	2 (1.1)
Possible	0	2 (2.2)	2 (1.1)
Probable	0	0	0
Causal relationship	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.
& For subjects with AE onset date later than [redacted], 20[redacted].

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 by Time Interval
(Safety Analysis Set)

	Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
All deaths#	0	0	0
All TE-deaths	0	0	0
Deaths related to COVID-19 infection	0	0	0
AESI: polyneuropathy (narrow)	0	0	0
AESI: weight loss	1 (5.9)	0	1 (5.0)
AESI: hallucinations/psychosis	8 (47.1)	0	8 (40.0)
AESI: somnolence	0	0	0
AESI: infusion site related infections	3 (17.6)	2 (66.7)	5 (25.0)
AESI: infusion site related non infection reactions	10 (58.8)	3 (100)	13 (65.0)
AESI: falls and associated injuries	5 (29.4)	2 (66.7)	7 (35.0)

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 by Time Interval
(Safety Analysis Set)

	Non-Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
All deaths#	0	3 (3.3)	3 (1.6)
All TE-deaths	0	3 (3.3)	3 (1.6)
Deaths related to COVID-19 infection	0	0	0
AESI: polyneuropathy (narrow)	2 (2.1)	6 (6.5)	8 (4.3)
AESI: weight loss	10 (10.6)	14 (15.2)	24 (12.9)
AESI: hallucinations/psychosis	15 (16.0)	23 (25.0)	38 (20.4)
AESI: somnolence	8 (8.5)	1 (1.1)	9 (4.8)
AESI: infusion site related infections	31 (33.0)	32 (34.8)	63 (33.9)
AESI: infusion site related non infection reactions	54 (57.4)	68 (73.9)	122 (65.6)
AESI: falls and associated injuries	17 (18.1)	23 (25.0)	40 (21.5)

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43　すべての有害事象（安全性解析対象集団，日本人部分集団）：M15-741試験

[redacted]20[redacted] 10:57 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - CLINICAL/STATISTICAL

TABLE 14.3 1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period	N=22	N=5	N=27	N=110	N=107	N=217
Any adverse event	20 (90.9)	5 (100)	25 (92.6)	102 (92.7)	103 (96.3)	205 (94.5)
血液およびリンパ系障害	0	0	0	1 (0.9)	3 (2.8)	4 (1.8)
大球性貧血	0	0	0	0	1 (0.9)	1 (0.5)
凝血異常	0	0	0	0	1 (0.9)	1 (0.5)
リンパ節症	0	0	0	1 (0.9)	0	1 (0.5)
縦隔リンパ節腫脹	0	0	0	0	1 (0.9)	1 (0.5)
心臓障害	0	0	0	5 (4.5)	8 (7.5)	13 (6.0)
急性心筋梗塞	0	0	0	1 (0.9)	0	1 (0.5)
狭心症	0	0	0	1 (0.9)	0	1 (0.5)
心房細動	0	0	0	0	2 (1.9)	2 (0.9)
徐脈	0	0	0	0	1 (0.9)	1 (0.5)
心停止	0	0	0	1 (0.9)	0	1 (0.5)
心肺停止	0	0	0	0	1 (0.9)	1 (0.5)
冠動脈疾患	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
冠動脈狭窄	0	0	0	1 (0.9)	0	1 (0.5)
期外収縮	0	0	0	0	1 (0.9)	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
心臓障害 (Cont.)						
左室肥大	0	0	0	0	1 (0.9)	1 (0.5)
心筋梗塞	0	0	0	1 (0.9)	0	1 (0.5)
動悸	0	0	0	0	2 (1.9)	2 (0.9)
頻脈	0	0	0	1 (0.9)	0	1 (0.5)
耳および迷路障害	1 (4.5)	0	1 (3.7)	3 (2.7)	4 (3.7)	7 (3.2)
感音性難聴	1 (4.5)	0	1 (3.7)	0	0	0
乗物酔い	0	0	0	0	1 (0.9)	1 (0.5)
回転性めまい	0	0	0	3 (2.7)	2 (1.9)	5 (2.3)
頭位性回転性めまい	0	0	0	0	1 (0.9)	1 (0.5)
眼障害	1 (4.5)	1 (20.0)	2 (7.4)	7 (6.4)	7 (6.5)	14 (6.5)
白内障	1 (4.5)	1 (20.0)	2 (7.4)	1 (0.9)	1 (0.9)	2 (0.9)
複視	0	0	0	3 (2.7)	1 (0.9)	4 (1.8)
ドライアイ	0	1 (20.0)	1 (3.7)	1 (0.9)	2 (1.9)	3 (1.4)
緑内障	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
眼窩周囲痛	0	0	0	0	1 (0.9)	1 (0.5)
眼窩周囲腫脹	0	0	0	0	2 (1.9)	2 (0.9)
網膜裂孔	0	0	0	2 (1.8)	0	2 (0.9)
霧視	0	0	0	1 (0.9)	0	1 (0.5)
視野欠損	0	0	0	0	1 (0.9)	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
胃腸障害	6 (27.3)	1 (20.0)	7 (25.9)	21 (19.1)	28 (26.2)	49 (22.6)
腹部膨満	0	0	0	1 (0.9)	3 (2.8)	4 (1.8)
腹痛	0	0	0	2 (1.8)	1 (0.9)	3 (1.4)
上腹部痛	1 (4.5)	0	1 (3.7)	0	1 (0.9)	1 (0.5)
アフタ性潰瘍	0	0	0	1 (0.9)	0	1 (0.5)
呼気臭	0	0	0	2 (1.8)	1 (0.9)	3 (1.4)
虚血性大腸炎	0	0	0	1 (0.9)	0	1 (0.5)
便秘	2 (9.1)	0	2 (7.4)	6 (5.5)	12 (11.2)	18 (8.3)
齲歯	1 (4.5)	0	1 (3.7)	0	0	0
下痢	3 (13.6)	1 (20.0)	4 (14.8)	3 (2.7)	2 (1.9)	5 (2.3)
口内乾燥	0	0	0	3 (2.7)	5 (4.7)	8 (3.7)
消化不良	0	0	0	1 (0.9)	0	1 (0.5)
嚥下障害	0	0	0	0	1 (0.9)	1 (0.5)
糞塊	0	0	0	0	1 (0.9)	1 (0.5)
排便回数増加	0	0	0	0	1 (0.9)	1 (0.5)
胃食道逆流性疾患	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
舌炎	0	0	0	1 (0.9)	0	1 (0.5)
舌痛	0	0	0	1 (0.9)	0	1 (0.5)
吐血	0	0	0	1 (0.9)	0	1 (0.5)
痔核	0	0	0	1 (0.9)	0	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
胃腸障害 (Cont.)						
裂孔ヘルニア	0	0	0	1 (0.9)	0	1 (0.5)
胃排出不全	0	0	0	1 (0.9)	0	1 (0.5)
単径ヘルニア	0	0	0	1 (0.9)	0	1 (0.5)
腸出血	0	0	0	1 (0.9)	0	1 (0.5)
過敏性腸症候群	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
大腸ポリープ	0	0	0	0	1 (0.9)	1 (0.5)
口唇乾燥	1 (4.5)	0	1 (3.7)	0	0	0
メレナ	1 (4.5)	0	1 (3.7)	1 (0.9)	0	1 (0.5)
口腔腫脹	0	0	0	1 (0.9)	0	1 (0.5)
悪心	2 (9.1)	0	2 (7.4)	6 (5.5)	11 (10.3)	17 (7.8)
口腔内不快感	0	0	0	1 (0.9)	0	1 (0.5)
口腔内痛	0	0	0	1 (0.9)	0	1 (0.5)
口の錯感覚	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
直腸出血	0	0	0	0	1 (0.9)	1 (0.5)
歯痛	0	0	0	0	1 (0.9)	1 (0.5)
嘔吐	0	0	0	3 (2.7)	3 (2.8)	6 (2.8)
一般・全身障害および投与部位の状態	17 (77.3)	3 (60.0)	20 (74.1)	90 (81.8)	93 (86.9)	183 (84.3)
投与部位内出血	0	0	0	0	1 (0.9)	1 (0.5)
投与部位紅斑	1 (4.5)	0	1 (3.7)	0	0	0
投与部位漏出	0	0	0	0	1 (0.9)	1 (0.5)
無力症	0	0	0	3 (2.7)	0	3 (1.4)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
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紅斑	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
カテーテル留置部位漏出	0	0	0	1 (0.9)	0	1 (0.5)
カテーテル留置部位出血	0	0	0	0	1 (0.9)	1 (0.5)
カテーテル留置部位炎症	0	0	0	0	1 (0.9)	1 (0.5)
カテーテル留置部位刺激感	0	0	0	0	1 (0.9)	1 (0.5)
カテーテル留置部位浮腫	0	0	0	0	1 (0.9)	1 (0.5)
カテーテル留置部位疼痛	0	0	0	0	2 (1.9)	2 (0.9)
胸部不快感	0	0	0	0	1 (0.9)	1 (0.5)
胸痛	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
泣き	0	0	0	1 (0.9)	0	1 (0.5)
不快感	0	0	0	1 (0.9)	0	1 (0.5)
薬効欠如	0	0	0	0	1 (0.9)	1 (0.5)
薬剤離脱症候群	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
疲労	0	0	0	6 (5.5)	3 (2.8)	9 (4.1)
異常感	0	0	0	1 (0.9)	1 (0.9)	2 (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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
一般・全身障害および投与部位の状態 (Cont.)						
冷感	0	0	0	0	1 (0.9)	1 (0.5)
熱感	0	0	0	1 (0.9)	0	1 (0.5)
歩行障害	0	0	0	0	2 (1.9)	2 (0.9)
歩行不能	0	0	0	1 (0.9)	0	1 (0.5)
低体温	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
インフルエンザ様疾患	0	0	0	1 (0.9)	2 (1.9)	3 (1.4)
注入部位内出血	1 (4.5)	0	1 (3.7)	9 (8.2)	8 (7.5)	17 (7.8)
注入部位皮膚炎	2 (9.1)	0	2 (7.4)	0	2 (1.9)	2 (0.9)
注入部位分泌物	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
注入部位変色	0	0	0	2 (1.8)	0	2 (0.9)
注入部位不快感	0	0	0	3 (2.7)	1 (0.9)	4 (1.8)
注入部位びらん	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
注入部位紅斑	7 (31.8)	3 (60.0)	10 (37.0)	58 (52.7)	58 (54.2)	116 (53.5)
注入部位皮膚剥脱	0	0	0	3 (2.7)	3 (2.8)	6 (2.8)
注入部位血管外漏出	0	0	0	8 (7.3)	12 (11.2)	20 (9.2)
注入部位血腫	0	0	0	10 (9.1)	8 (7.5)	18 (8.3)
注入部位出血	0	0	0	4 (3.6)	5 (4.7)	9 (4.1)
注入部位硬結	4 (18.2)	1 (20.0)	5 (18.5)	3 (2.7)	2 (1.9)	5 (2.3)
注入部位炎症	0	0	0	3 (2.7)	6 (5.6)	9 (4.1)
注入部位損傷	0	0	0	0	2 (1.9)	2 (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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
一般・全身障害および投与部位の状態 (Cont.)						
注入部位刺激感	0	0	0	1 (0.9)	4 (3.7)	5 (2.3)
注入部位腫瘤	2 (9.1)	1 (20.0)	3 (11.1)	3 (2.7)	2 (1.9)	5 (2.3)
注入部位壊死	0	0	0	0	1 (0.9)	1 (0.5)
注入部位結節	0	0	0	35 (31.8)	34 (31.8)	69 (31.8)
注入部位浮腫	0	0	0	19 (17.3)	28 (26.2)	47 (21.7)
注入部位疼痛	1 (4.5)	0	1 (3.7)	17 (15.5)	20 (18.7)	37 (17.1)
注入部位蒼白	0	0	0	3 (2.7)	2 (1.9)	5 (2.3)
注入部位丘疹	0	0	0	7 (6.4)	11 (10.3)	18 (8.3)
注入部位異常感覚	0	0	0	0	2 (1.9)	2 (0.9)
注入部位そう痒感	0	0	0	5 (4.5)	2 (1.9)	7 (3.2)
注入部位発疹	1 (4.5)	1 (20.0)	2 (7.4)	2 (1.8)	3 (2.8)	5 (2.3)
注入部位反応	0	0	0	13 (11.8)	17 (15.9)	30 (13.8)
注入部位痂皮	0	0	0	0	1 (0.9)	1 (0.5)
注入部位腫脹	1 (4.5)	0	1 (3.7)	3 (2.7)	2 (1.9)	5 (2.3)
注入部位小水疱	0	0	0	0	2 (1.9)	2 (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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
一般・全身障害および投与部位の状態 (Cont.)						
注入部位熱感	0	0	0	0	1 (0.9)	1 (0.5)
注射部位内出血	0	0	0	2 (1.8)	1 (0.9)	3 (1.4)
注射部位変色	0	0	0	1 (0.9)	0	1 (0.5)
注射部位紅斑	1 (4.5)	0	1 (3.7)	5 (4.5)	8 (7.5)	13 (6.0)
注射部位漏出	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
注射部位血腫	0	0	0	0	1 (0.9)	1 (0.5)
注射部位出血	0	0	0	0	1 (0.9)	1 (0.5)
注射部位炎症	0	0	0	2 (1.8)	4 (3.7)	6 (2.8)
注射部位結節	0	0	0	3 (2.7)	6 (5.6)	9 (4.1)
注射部位浮腫	0	0	0	2 (1.8)	3 (2.8)	5 (2.3)
注射部位疼痛	0	0	0	2 (1.8)	6 (5.6)	8 (3.7)
注射部位丘疹	0	0	0	0	2 (1.9)	2 (0.9)
注射部位反応	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
注射部位腫脹	1 (4.5)	1 (20.0)	2 (7.4)	1 (0.9)	1 (0.9)	2 (0.9)
注射部位蕁麻疹	0	0	0	0	1 (0.9)	1 (0.5)
滴下投与部位熱傷	0	0	0	0	1 (0.9)	1 (0.5)
滴下投与部位痛	0	0	0	0	1 (0.9)	1 (0.5)
限局性浮腫	0	1 (20.0)	1 (3.7)	0	0	0
適用部位からの吸収不良	0	0	0	0	1 (0.9)	1 (0.5)
倦怠感	0	0	0	1 (0.9)	2 (1.9)	3 (1.4)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
一般・全身障害および投与部位の状態 (Cont.)						
医療機器使用部位刺激感	0	0	0	1 (0.9)	2 (1.9)	3 (1.4)
医療機器使用部位そう痒感	0	0	0	1 (0.9)	0	1 (0.5)
医療機器使用部位発疹	0	0	0	0	2 (1.9)	2 (0.9)
小結節	0	0	0	1 (0.9)	0	1 (0.5)
非心臓性胸痛	0	0	0	0	2 (1.9)	2 (0.9)
末梢性浮腫	1 (4.5)	1 (20.0)	2 (7.4)	4 (3.6)	3 (2.8)	7 (3.2)
疼痛	0	0	0	2 (1.8)	0	2 (0.9)
末梢腫脹	0	0	0	0	4 (3.7)	4 (1.8)
穿刺部位内出血	1 (4.5)	0	1 (3.7)	0	0	0
穿刺部位紅斑	0	0	0	0	3 (2.8)	3 (1.4)
穿刺部位出血	0	0	0	1 (0.9)	0	1 (0.5)
穿刺部位硬結	2 (9.1)	0	2 (7.4)	0	0	0
穿刺部位浮腫	0	0	0	0	1 (0.9)	1 (0.5)
穿刺部位腫脹	0	0	0	0	1 (0.9)	1 (0.5)
発熱	1 (4.5)	0	1 (3.7)	1 (0.9)	2 (1.9)	3 (1.4)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
一般・全身障害および投与部位の状態 (Cont.)						
口渇	1 (4.5)	0	1 (3.7)	0	0	0
血管穿刺部位硬結	1 (4.5)	0	1 (3.7)	0	0	0
肝胆道系障害	0	0	0	2 (1.8)	1 (0.9)	3 (1.4)
肝嚢胞	0	0	0	1 (0.9)	0	1 (0.5)
脂肪肝	0	0	0	0	1 (0.9)	1 (0.5)
門脈血栓症	0	0	0	1 (0.9)	0	1 (0.5)
感染症および寄生虫症	5 (22.7)	2 (40.0)	7 (25.9)	53 (48.2)	54 (50.5)	107 (49.3)
四肢膿瘍	0	0	0	0	1 (0.9)	1 (0.5)
無症候性COVID-19	0	0	0	0	1 (0.9)	1 (0.5)
細菌性疾患キャリアー	0	0	0	0	1 (0.9)	1 (0.5)
ボレリア感染	0	0	0	1 (0.9)	0	1 (0.5)
ウイルス性気管支炎	0	0	0	0	1 (0.9)	1 (0.5)
COVID-19	0	0	0	1 (0.9)	0	1 (0.5)
COVID-19肺炎	0	0	0	1 (0.9)	0	1 (0.5)
カテーテル留置部位感染	0	0	0	1 (0.9)	0	1 (0.5)
蜂巣炎	0	1 (20.0)	1 (3.7)	1 (0.9)	1 (0.9)	2 (0.9)
結膜炎	1 (4.5)	0	1 (3.7)	1 (0.9)	0	1 (0.5)
膀胱炎	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
爪の皮膚糸状菌症	0	1 (20.0)	1 (3.7)	0	0	0
真菌感染	0	0	0	1 (0.9)	0	1 (0.5)
胃腸炎	0	0	0	0	1 (0.9)	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
感染症および寄生虫症 (Cont.)						
歯肉炎	0	0	0	1 (0.9)	0	1 (0.5)
麦粒腫	1 (4.5)	0	1 (3.7)	0	0	0
感染性皮膚潰瘍	0	0	0	0	1 (0.9)	1 (0.5)
インフルエンザ	0	0	0	0	1 (0.9)	1 (0.5)
注入部位膿瘍	0	0	0	14 (12.7)	13 (12.1)	27 (12.4)
注入部位蜂巣炎	3 (13.6)	1 (20.0)	4 (14.8)	26 (23.6)	26 (24.3)	52 (24.0)
注入部位感染	0	0	0	7 (6.4)	11 (10.3)	18 (8.3)
注入部位膿疱	0	0	0	0	1 (0.9)	1 (0.5)
注射部位蜂巣炎	0	0	0	0	3 (2.8)	3 (1.4)
リンパ管炎	0	0	0	0	1 (0.9)	1 (0.5)
上咽頭炎	0	1 (20.0)	1 (3.7)	5 (4.5)	4 (3.7)	9 (4.1)
爪真菌症	0	0	0	0	1 (0.9)	1 (0.5)
耳下腺膿瘍	0	0	0	0	1 (0.9)	1 (0.5)
肺炎	0	0	0	3 (2.7)	1 (0.9)	4 (1.8)
術後膿瘍	1 (4.5)	0	1 (3.7)	0	0	0
シュードモナス感染	0	0	0	0	1 (0.9)	1 (0.5)
膿疱性皮疹	0	0	0	1 (0.9)	0	1 (0.5)
気道感染	0	0	0	0	1 (0.9)	1 (0.5)
敗血症	0	0	0	3 (2.7)	0	3 (1.4)
敗血症性ショック	0	0	0	1 (0.9)	0	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
感染症および寄生虫症 (Cont.)						
副鼻腔炎	0	0	0	1 (0.9)	0	1 (0.5)
ブドウ球菌感染	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
歯感染	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
上気道感染	0	0	0	1 (0.9)	0	1 (0.5)
尿路感染	0	0	0	8 (7.3)	11 (10.3)	19 (8.8)
水痘帯状疱疹ウイルス感染	0	0	0	1 (0.9)	0	1 (0.5)
傷害、中毒および処置合併症	6 (27.3)	2 (40.0)	8 (29.6)	15 (13.6)	25 (23.4)	40 (18.4)
足関節部骨折	0	0	0	0	1 (0.9)	1 (0.5)
節足動物咬傷	0	0	0	0	1 (0.9)	1 (0.5)
骨挫傷	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
脳挫傷	1 (4.5)	0	1 (3.7)	0	0	0
挫傷	1 (4.5)	0	1 (3.7)	1 (0.9)	6 (5.6)	7 (3.2)
医療機器設置の問題	0	0	0	1 (0.9)	0	1 (0.5)
医療機器による投与の欠落	0	0	0	1 (0.9)	0	1 (0.5)
期限切れの製品使用	0	0	0	1 (0.9)	0	1 (0.5)
眼挫傷	0	0	0	0	1 (0.9)	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
傷害、中毒および処置合併症 (Cont.)						
顔面損傷	0	0	0	0	1 (0.9)	1 (0.5)
顔面骨骨折	0	0	0	0	2 (1.9)	2 (0.9)
転倒	6 (27.3)	2 (40.0)	8 (29.6)	10 (9.1)	22 (20.6)	32 (14.7)
頭部損傷	1 (4.5)	0	1 (3.7)	1 (0.9)	3 (2.8)	4 (1.8)
注入に伴う反応	0	0	0	1 (0.9)	0	1 (0.5)
関節脱臼	0	0	0	0	1 (0.9)	1 (0.5)
靭帯捻挫	1 (4.5)	0	1 (3.7)	0	1 (0.9)	1 (0.5)
腰椎骨折	0	0	0	0	1 (0.9)	1 (0.5)
過量投与	0	0	0	0	1 (0.9)	1 (0.5)
処置後挫傷	0	0	0	1 (0.9)	0	1 (0.5)
処置によるめまい	0	0	0	0	1 (0.9)	1 (0.5)
肋骨骨折	1 (4.5)	1 (20.0)	2 (7.4)	0	1 (0.9)	1 (0.5)
皮膚擦過傷	0	0	0	1 (0.9)	2 (1.9)	3 (1.4)
皮膚損傷	1 (4.5)	0	1 (3.7)	0	0	0
皮膚裂傷	0	0	0	1 (0.9)	6 (5.6)	7 (3.2)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
傷害、中毒および処置合併症 (Cont.)						
ストレス骨折	0	0	0	1 (0.9)	0	1 (0.5)
硬膜下血腫	0	0	0	0	1 (0.9)	1 (0.5)
サンバーン	0	0	0	0	1 (0.9)	1 (0.5)
腱断裂	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
過少量投与	0	0	0	0	1 (0.9)	1 (0.5)
創傷	0	0	0	1 (0.9)	0	1 (0.5)
臨床検査	3 (13.6)	0	3 (11.1)	21 (19.1)	24 (22.4)	45 (20.7)
血中クレアチンホスホキナーゼ増加	1 (4.5)	0	1 (3.7)	0	1 (0.9)	1 (0.5)
血中クレアチニン減少	0	0	0	0	1 (0.9)	1 (0.5)
血中葉酸異常	0	0	0	0	1 (0.9)	1 (0.5)
血中葉酸減少	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
血中ホモシステイン増加	1 (4.5)	0	1 (3.7)	0	2 (1.9)	2 (0.9)
血中リン減少	0	0	0	0	1 (0.9)	1 (0.5)
血圧上昇	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
起立血圧低下	0	0	0	1 (0.9)	0	1 (0.5)
血中ナトリウム減少	0	0	0	1 (0.9)	0	1 (0.5)
C-反応性蛋白増加	0	0	0	0	1 (0.9)	1 (0.5)
心雑音	0	0	0	1 (0.9)	0	1 (0.5)
握力低下	0	0	0	1 (0.9)	0	1 (0.5)
ヘモグロビン減少	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
リンパ球数減少	0	0	0	0	1 (0.9)	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
臨床検査 (Cont.)						
単球数増加	0	0	0	0	1 (0.9)	1 (0.5)
好中球数増加	0	0	0	0	2 (1.9)	2 (0.9)
プロトロンビン時間延長	0	0	0	0	1 (0.9)	1 (0.5)
赤血球数減少	0	0	0	0	1 (0.9)	1 (0.5)
ビタミンB12減少	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
ビタミンB6減少	0	0	0	5 (4.5)	6 (5.6)	11 (5.1)
ビタミンD減少	0	0	0	0	1 (0.9)	1 (0.5)
体重減少	1 (4.5)	0	1 (3.7)	9 (8.2)	14 (13.1)	23 (10.6)
体重増加	0	0	0	2 (1.8)	0	2 (0.9)
白血球数増加	0	0	0	0	2 (1.9)	2 (0.9)
代謝および栄養障害	2 (9.1)	1 (20.0)	3 (11.1)	9 (8.2)	18 (16.8)	27 (12.4)
悪液質	0	0	0	1 (0.9)	0	1 (0.5)
食欲減退	0	0	0	3 (2.7)	3 (2.8)	6 (2.8)
脱水	0	0	0	1 (0.9)	3 (2.8)	4 (1.8)
糖尿病	0	0	0	0	1 (0.9)	1 (0.5)
水分過負荷	0	0	0	0	1 (0.9)	1 (0.5)
体液貯留	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
葉酸欠乏	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
耐糖能障害	0	0	0	0	1 (0.9)	1 (0.5)
高コレステロール血症	0	0	0	0	1 (0.9)	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
代謝および栄養障害 (Cont.)						
高血糖	0	0	0	0	1 (0.9)	1 (0.5)
高ホモシステイン血症	0	0	0	0	1 (0.9)	1 (0.5)
低カルシウム血症	0	0	0	0	1 (0.9)	1 (0.5)
低カリウム血症	0	0	0	0	3 (2.8)	3 (1.4)
低ナトリウム血症	1 (4.5)	0	1 (3.7)	1 (0.9)	0	1 (0.5)
栄養障害	0	0	0	0	1 (0.9)	1 (0.5)
ビタミンB群欠乏	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
ビタミンB12欠乏	0	1 (20.0)	1 (3.7)	0	1 (0.9)	1 (0.5)
ビタミンB6欠乏	1 (4.5)	1 (20.0)	2 (7.4)	2 (1.8)	4 (3.7)	6 (2.8)
筋骨格系および結合組織障害	5 (22.7)	1 (20.0)	6 (22.2)	19 (17.3)	20 (18.7)	39 (18.0)
関節痛	0	1 (20.0)	1 (3.7)	3 (2.7)	4 (3.7)	7 (3.2)
反応性関節炎	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
背部痛	1 (4.5)	0	1 (3.7)	7 (6.4)	5 (4.7)	12 (5.5)
骨痛	0	0	0	0	1 (0.9)	1 (0.5)
滑液包炎	0	0	0	2 (1.8)	0	2 (0.9)
外骨腫	0	0	0	0	1 (0.9)	1 (0.5)
椎間関節症候群	0	0	0	0	1 (0.9)	1 (0.5)
椎間板変性症	0	0	0	1 (0.9)	0	1 (0.5)
椎間板突出	0	0	0	0	1 (0.9)	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
筋骨格系および結合組織障害 (Cont.)						
関節滲出液	0	0	0	0	2 (1.9)	2 (0.9)
関節腫脹	0	0	0	0	1 (0.9)	1 (0.5)
四肢不快感	0	0	0	0	1 (0.9)	1 (0.5)
筋萎縮	0	0	0	0	1 (0.9)	1 (0.5)
筋痙縮	0	0	0	2 (1.8)	3 (2.8)	5 (2.3)
筋力低下	0	0	0	4 (3.6)	1 (0.9)	5 (2.3)
筋骨格硬直	0	0	0	0	1 (0.9)	1 (0.5)
筋肉痛	1 (4.5)	0	1 (3.7)	1 (0.9)	1 (0.9)	2 (0.9)
頚部痛	0	0	0	2 (1.8)	0	2 (0.9)
骨炎	0	0	0	0	1 (0.9)	1 (0.5)
変形性関節症	0	0	0	1 (0.9)	4 (3.7)	5 (2.3)
骨減少症	0	0	0	1 (0.9)	0	1 (0.5)
四肢痛	2 (9.1)	0	2 (7.4)	1 (0.9)	3 (2.8)	4 (1.8)
関節周囲炎	0	0	0	0	1 (0.9)	1 (0.5)
姿勢異常	0	0	0	0	1 (0.9)	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
筋骨格系および結合組織障害 (Cont.)						
横紋筋融解症	1 (4.5)	0	1 (3.7)	1 (0.9)	0	1 (0.5)
肩回旋筋腱板症候群	0	0	0	0	1 (0.9)	1 (0.5)
仙腸関節機能障害	0	0	0	1 (0.9)	0	1 (0.5)
変形性脊椎症	0	0	0	1 (0.9)	0	1 (0.5)
腱障害	0	0	0	0	1 (0.9)	1 (0.5)
腱炎	0	0	0	1 (0.9)	0	1 (0.5)
斜頚	0	0	0	0	1 (0.9)	1 (0.5)
弾発指	1 (4.5)	0	1 (3.7)	0	0	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	0	0	1 (0.9)	4 (3.7)	5 (2.3)
基底細胞癌	0	0	0	0	2 (1.9)	2 (0.9)
直腸腺癌	0	0	0	1 (0.9)	0	1 (0.5)
脂漏性角化症	0	0	0	0	1 (0.9)	1 (0.5)
皮膚有棘細胞癌	0	0	0	0	1 (0.9)	1 (0.5)
神経系障害	10 (45.5)	2 (40.0)	12 (44.4)	52 (47.3)	46 (43.0)	98 (45.2)
アカシジア	0	0	0	1 (0.9)	0	1 (0.5)
健忘	0	0	0	1 (0.9)	0	1 (0.5)
失語症	0	0	0	0	1 (0.9)	1 (0.5)
運動失調	1 (4.5)	0	1 (3.7)	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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
神経系障害 (Cont.)						
平衡障害	0	0	0	0	4 (3.7)	4 (1.8)
運動緩慢	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
手根管症候群	0	0	0	0	1 (0.9)	1 (0.5)
大脳萎縮	0	0	0	0	1 (0.9)	1 (0.5)
脳出血	0	0	0	0	1 (0.9)	1 (0.5)
脳圧排効果	0	0	0	0	1 (0.9)	1 (0.5)
脳血管発作	0	0	0	0	1 (0.9)	1 (0.5)
認知障害	0	0	0	4 (3.6)	2 (1.9)	6 (2.8)
振動覚低下	0	0	0	1 (0.9)	0	1 (0.5)
注意力障害	0	0	0	0	1 (0.9)	1 (0.5)
浮動性めまい	2 (9.1)	1 (20.0)	3 (11.1)	13 (11.8)	9 (8.4)	22 (10.1)
体位性めまい	0	0	0	5 (4.5)	0	5 (2.3)
構語障害	0	0	0	0	3 (2.8)	3 (1.4)
味覚不全	0	0	0	2 (1.8)	1 (0.9)	3 (1.4)
ジスキネジア	0	0	0	12 (10.9)	6 (5.6)	18 (8.3)
起立障害	0	0	0	1 (0.9)	0	1 (0.5)
ジストニア	0	0	0	2 (1.8)	5 (4.7)	7 (3.2)
脳症	0	0	0	0	1 (0.9)	1 (0.5)
てんかん	0	0	0	0	1 (0.9)	1 (0.5)
本態性振戦	0	0	0	0	1 (0.9)	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
神経系障害 (Cont.)						
伸展性足底反応	0	0	0	1 (0.9)	0	1 (0.5)
すくみ現象	0	0	0	4 (3.6)	0	4 (1.8)
全身性強直性間代性発作	0	0	0	0	1 (0.9)	1 (0.5)
頭部不快感	0	0	0	1 (0.9)	0	1 (0.5)
頭痛	2 (9.1)	0	2 (7.4)	5 (4.5)	7 (6.5)	12 (5.5)
片側感覚消失	0	0	0	0	1 (0.9)	1 (0.5)
不全片麻痺	0	0	0	0	1 (0.9)	1 (0.5)
知覚過敏	0	0	0	0	1 (0.9)	1 (0.5)
感覚鈍麻	0	0	0	1 (0.9)	2 (1.9)	3 (1.4)
反射減弱	0	0	0	2 (1.8)	1 (0.9)	3 (1.4)
不規則睡眠覚醒リズム障害	0	0	0	1 (0.9)	0	1 (0.5)
嗜眠	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
意識消失	1 (4.5)	0	1 (3.7)	0	1 (0.9)	1 (0.5)
腰仙部神経根障害	0	0	0	0	1 (0.9)	1 (0.5)
記憶障害	0	0	0	0	2 (1.9)	2 (0.9)
代謝性脳症	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
神経痛	0	0	0	0	1 (0.9)	1 (0.5)
末梢性ニューロパチー	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
オンオフ現象	0	0	0	4 (3.6)	5 (4.7)	9 (4.1)
錯感覚	0	0	0	4 (3.6)	3 (2.8)	7 (3.2)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
神経系障害 (Cont.)						
パーキンソン病	4 (18.2)	0	4 (14.8)	8 (7.3)	5 (4.7)	13 (6.0)
パーキンソニズム	0	1 (20.0)	1 (3.7)	0	2 (1.9)	2 (0.9)
末梢性感覚ニューロパチー	0	0	0	0	1 (0.9)	1 (0.5)
側反弓	1 (4.5)	0	1 (3.7)	0	2 (1.9)	2 (0.9)
多発ニューロパチー	0	0	0	0	2 (1.9)	2 (0.9)
失神寸前の状態	0	0	0	0	1 (0.9)	1 (0.5)
心因性発作	0	0	0	0	1 (0.9)	1 (0.5)
精神運動亢進	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
反射異常	0	0	0	0	1 (0.9)	1 (0.5)
安静時振戦	0	0	0	0	1 (0.9)	1 (0.5)
坐骨神経痛	0	0	0	0	3 (2.8)	3 (1.4)
痙攣発作	0	0	0	0	1 (0.9)	1 (0.5)
感覚障害	0	0	0	0	1 (0.9)	1 (0.5)
感覚消失	0	0	0	0	1 (0.9)	1 (0.5)
睡眠時麻痺	0	0	0	1 (0.9)	0	1 (0.5)
傾眠	0	0	0	9 (8.2)	3 (2.8)	12 (5.5)
失神	0	0	0	0	3 (2.8)	3 (1.4)
振戦	0	0	0	1 (0.9)	2 (1.9)	3 (1.4)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
製品の問題	0	0	0	2 (1.8)	1 (0.9)	3 (1.4)
医療機器送達システムの問題	0	0	0	1 (0.9)	0	1 (0.5)
医療機器位置異常	0	0	0	1 (0.9)	0	1 (0.5)
医療機器機能不良	0	0	0	0	1 (0.9)	1 (0.5)
精神障害	11 (50.0)	3 (60.0)	14 (51.9)	40 (36.4)	54 (50.5)	94 (43.3)
異常な夢	0	0	0	0	1 (0.9)	1 (0.5)
感情不安定	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
激越	0	0	0	0	1 (0.9)	1 (0.5)
不安	0	0	0	11 (10.0)	18 (16.8)	29 (13.4)
不安障害	0	1 (20.0)	1 (3.7)	0	0	0
無感情	0	0	0	1 (0.9)	0	1 (0.5)
歯ぎしり	0	0	0	2 (1.8)	0	2 (0.9)
強迫行為	0	0	0	0	1 (0.9)	1 (0.5)
強迫性性行動	0	0	0	1 (0.9)	0	1 (0.5)
錯乱状態	0	0	0	4 (3.6)	5 (4.7)	9 (4.1)
譫妄	0	0	0	1 (0.9)	4 (3.7)	5 (2.3)
妄想	5 (22.7)	0	5 (18.5)	3 (2.7)	2 (1.9)	5 (2.3)
寄生虫妄想	0	0	0	1 (0.9)	0	1 (0.5)
妄想性障害、詳細不明	0	0	0	0	1 (0.9)	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
精神障害 (Cont.)						
抑うつ気分	0	0	0	2 (1.8)	2 (1.9)	4 (1.8)
うつ病	0	1 (20.0)	1 (3.7)	3 (2.7)	1 (0.9)	4 (1.8)
抑うつ症状	1 (4.5)	0	1 (3.7)	1 (0.9)	0	1 (0.5)
ドーパミン調節障害症候群	0	0	0	1 (0.9)	0	1 (0.5)
ディスフェミア	0	0	0	0	1 (0.9)	1 (0.5)
睡眠異常	0	0	0	1 (0.9)	0	1 (0.5)
情動障害	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
注射恐怖	0	0	0	0	1 (0.9)	1 (0.5)
幻覚	8 (36.4)	1 (20.0)	9 (33.3)	12 (10.9)	21 (19.6)	33 (15.2)
幻聴	0	0	0	3 (2.7)	3 (2.8)	6 (2.8)
幻嗅	0	0	0	0	1 (0.9)	1 (0.5)
幻視	1 (4.5)	1 (20.0)	2 (7.4)	9 (8.2)	4 (3.7)	13 (6.0)
混合性幻覚	0	0	0	1 (0.9)	0	1 (0.5)
性欲過剰	0	0	0	1 (0.9)	0	1 (0.5)
錯覚	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
衝動制御障害	0	0	0	0	4 (3.7)	4 (1.8)
衝動行為	0	0	0	0	1 (0.9)	1 (0.5)
不眠症	1 (4.5)	0	1 (3.7)	8 (7.3)	9 (8.4)	17 (7.8)
易刺激性	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
嫉妬妄想	1 (4.5)	0	1 (3.7)	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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
精神障害 (Cont.)						
躁病	0	0	0	0	1 (0.9)	1 (0.5)
気分変化	0	0	0	1 (0.9)	0	1 (0.5)
気分動揺	0	0	0	0	1 (0.9)	1 (0.5)
悪夢	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
強迫観念	0	0	0	1 (0.9)	0	1 (0.5)
パニック発作	0	0	0	0	3 (2.8)	3 (1.4)
パニック反応	0	0	0	0	1 (0.9)	1 (0.5)
妄想症	0	0	0	2 (1.8)	0	2 (0.9)
睡眠の質低下	0	0	0	1 (0.9)	0	1 (0.5)
処置に対する不安	0	0	0	0	1 (0.9)	1 (0.5)
精神病性障害	0	0	0	4 (3.6)	2 (1.9)	6 (2.8)
精神病症状	0	0	0	1 (0.9)	0	1 (0.5)
レム睡眠行動障害	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
レム睡眠異常	1 (4.5)	0	1 (3.7)	0	0	0
睡眠障害	0	0	0	2 (1.8)	1 (0.9)	3 (1.4)
ねごと	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
常同症	0	0	0	0	1 (0.9)	1 (0.5)
ストレス	0	0	0	0	1 (0.9)	1 (0.5)
自殺念慮	0	0	0	1 (0.9)	2 (1.9)	3 (1.4)
自殺企図	0	0	0	1 (0.9)	0	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
腎および尿路障害	2 (9.1)	0	2 (7.4)	11 (10.0)	7 (6.5)	18 (8.3)
膀胱痙縮	0	0	0	1 (0.9)	0	1 (0.5)
膀胱結石	1 (4.5)	0	1 (3.7)	0	0	0
尿路結石	0	0	0	1 (0.9)	0	1 (0.5)
排尿困難	0	0	0	1 (0.9)	2 (1.9)	3 (1.4)
緊張性膀胱	0	0	0	1 (0.9)	0	1 (0.5)
夜間頻尿	0	0	0	0	1 (0.9)	1 (0.5)
頻尿	0	0	0	1 (0.9)	0	1 (0.5)
多尿	0	0	0	0	1 (0.9)	1 (0.5)
腎機能障害	0	0	0	0	1 (0.9)	1 (0.5)
尿管結石症	0	0	0	0	1 (0.9)	1 (0.5)
切迫性尿失禁	0	0	0	3 (2.7)	0	3 (1.4)
尿失禁	1 (4.5)	0	1 (3.7)	2 (1.8)	2 (1.9)	4 (1.8)
尿閉	0	0	0	0	3 (2.8)	3 (1.4)
尿路障害	0	0	0	1 (0.9)	0	1 (0.5)
尿異常	0	0	0	0	1 (0.9)	1 (0.5)
尿臭異常	0	0	0	0	1 (0.9)	1 (0.5)
生殖系および乳房障害	1 (4.5)	0	1 (3.7)	1 (0.9)	5 (4.7)	6 (2.8)
良性前立腺肥大症	1 (4.5)	0	1 (3.7)	0	0	0
勃起不全	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
骨盤痛	0	0	0	0	1 (0.9)	1 (0.5)
ペイロニー病	0	0	0	0	1 (0.9)	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
生殖系および乳房障害 (Cont.)						
閉経後出血	0	0	0	0	1 (0.9)	1 (0.5)
前立腺腫大	0	0	0	0	1 (0.9)	1 (0.5)
腟脱	0	0	0	0	1 (0.9)	1 (0.5)
呼吸器、胸郭および縦隔障害	0	0	0	7 (6.4)	19 (17.8)	26 (12.0)
急性呼吸不全	0	0	0	0	1 (0.9)	1 (0.5)
気管支拡張症	0	0	0	1 (0.9)	0	1 (0.5)
咳嗽	0	0	0	1 (0.9)	2 (1.9)	3 (1.4)
発声障害	0	0	0	0	2 (1.9)	2 (0.9)
呼吸困難	0	0	0	2 (1.8)	6 (5.6)	8 (3.7)
労作性呼吸困難	0	0	0	1 (0.9)	0	1 (0.5)
鼻出血	0	0	0	0	1 (0.9)	1 (0.5)
過換気	0	0	0	0	2 (1.9)	2 (0.9)
口腔咽頭痛	0	0	0	1 (0.9)	1 (0.9)	2 (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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
呼吸器、胸郭および縦隔障害 (Cont.)						
誤嚥性肺炎	0	0	0	0	1 (0.9)	1 (0.5)
湿性咳嗽	0	0	0	0	1 (0.9)	1 (0.5)
肺塞栓症	0	0	0	0	2 (1.9)	2 (0.9)
ラ音	0	0	0	0	1 (0.9)	1 (0.5)
呼吸窮迫	0	0	0	1 (0.9)	0	1 (0.5)
鼻痛	0	0	0	0	1 (0.9)	1 (0.5)
鼻漏	0	0	0	0	2 (1.9)	2 (0.9)
咽喉刺激感	0	0	0	0	1 (0.9)	1 (0.5)
皮膚および皮下組織障害	4 (18.2)	1 (20.0)	5 (18.5)	10 (9.1)	15 (14.0)	25 (11.5)
脱毛症	0	0	0	2 (1.8)	1 (0.9)	3 (1.4)
褥瘡性潰瘍	0	0	0	0	1 (0.9)	1 (0.5)
皮膚嚢腫	1 (4.5)	0	1 (3.7)	0	1 (0.9)	1 (0.5)
皮膚炎	0	0	0	0	1 (0.9)	1 (0.5)
接触皮膚炎	0	0	0	2 (1.8)	0	2 (0.9)
おむつ皮膚炎	1 (4.5)	0	1 (3.7)	0	0	0
薬疹	0	0	0	1 (0.9)	0	1 (0.5)
皮膚乾燥	1 (4.5)	0	1 (3.7)	0	1 (0.9)	1 (0.5)
斑状出血	0	0	0	1 (0.9)	0	1 (0.5)
紅斑	0	0	0	1 (0.9)	3 (2.8)	4 (1.8)
爪の障害	0	0	0	1 (0.9)	0	1 (0.5)
脂肪織炎	0	0	0	0	1 (0.9)	1 (0.5)
丘疹	0	0	0	0	2 (1.9)	2 (0.9)
口囲皮膚炎	0	0	0	0	1 (0.9)	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
皮膚および皮下組織障害 (Cont.)						
光線過敏性反応	0	0	0	0	1 (0.9)	1 (0.5)
そう痒症	0	1 (20.0)	1 (3.7)	2 (1.8)	1 (0.9)	3 (1.4)
乾癬	0	0	0	0	1 (0.9)	1 (0.5)
発疹	1 (4.5)	0	1 (3.7)	1 (0.9)	1 (0.9)	2 (0.9)
紅斑性皮疹	0	0	0	0	1 (0.9)	1 (0.5)
そう痒性皮疹	0	0	0	2 (1.8)	1 (0.9)	3 (1.4)
皮膚刺激	0	0	0	0	1 (0.9)	1 (0.5)
皮膚病変	0	0	0	0	1 (0.9)	1 (0.5)
皮膚潰瘍	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
蕁麻疹	1 (4.5)	0	1 (3.7)	1 (0.9)	0	1 (0.5)
社会環境	0	0	0	1 (0.9)	0	1 (0.5)
運動不能	0	0	0	1 (0.9)	0	1 (0.5)
外科および内科処置	0	1 (20.0)	1 (3.7)	0	0	0
抜歯	0	1 (20.0)	1 (3.7)	0	0	0
血管障害	0	0	0	12 (10.9)	15 (14.0)	27 (12.4)
深部静脈血栓症	0	0	0	0	1 (0.9)	1 (0.5)
血腫	0	0	0	0	1 (0.9)	1 (0.5)
出血	0	0	0	0	1 (0.9)	1 (0.5)
ほてり	0	0	0	0	1 (0.9)	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
血管障害 (Cont.)						
高血圧	0	0	0	3 (2.7)	3 (2.8)	6 (2.8)
高血圧クリーゼ	0	0	0	1 (0.9)	0	1 (0.5)
低血圧	0	0	0	2 (1.8)	4 (3.7)	6 (2.8)
不安定血圧	0	0	0	0	1 (0.9)	1 (0.5)
起立性高血圧	0	0	0	0	1 (0.9)	1 (0.5)
起立性低血圧	0	0	0	7 (6.4)	6 (5.6)	13 (6.0)

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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Optimization period	N=22	N=5	N=27	N=110	N=107	N=217
Any adverse event	15 (68.2)	4 (80.0)	19 (70.4)	91 (82.7)	93 (86.9)	184 (84.8)
心臓障害	0	0	0	0	2 (1.9)	2 (0.9)
徐脈	0	0	0	0	1 (0.9)	1 (0.5)
動悸	0	0	0	0	1 (0.9)	1 (0.5)
耳および迷路障害	0	0	0	2 (1.8)	2 (1.9)	4 (1.8)
乗物酔い	0	0	0	0	1 (0.9)	1 (0.5)
回転性めまい	0	0	0	2 (1.8)	1 (0.9)	3 (1.4)
眼障害	0	0	0	2 (1.8)	2 (1.9)	4 (1.8)
複視	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
眼窩周囲腫脹	0	0	0	0	1 (0.9)	1 (0.5)
霧視	0	0	0	1 (0.9)	0	1 (0.5)
胃腸障害	2 (9.1)	0	2 (7.4)	11 (10.0)	15 (14.0)	26 (12.0)
腹部膨満	0	0	0	0	2 (1.9)	2 (0.9)
腹痛	0	0	0	1 (0.9)	0	1 (0.5)
上腹部痛	0	0	0	0	1 (0.9)	1 (0.5)
アフタ性潰瘍	0	0	0	1 (0.9)	0	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
胃腸障害 (Cont.)						
呼気臭	0	0	0	2 (1.8)	0	2 (0.9)
便秘	0	0	0	2 (1.8)	2 (1.9)	4 (1.8)
下痢	1 (4.5)	0	1 (3.7)	1 (0.9)	2 (1.9)	3 (1.4)
口内乾燥	0	0	0	2 (1.8)	3 (2.8)	5 (2.3)
消化不良	0	0	0	1 (0.9)	0	1 (0.5)
胃食道逆流性疾患	0	0	0	0	1 (0.9)	1 (0.5)
痔核	0	0	0	1 (0.9)	0	1 (0.5)
過敏性腸症候群	0	0	0	0	1 (0.9)	1 (0.5)
悪心	1 (4.5)	0	1 (3.7)	4 (3.6)	5 (4.7)	9 (4.1)
嘔吐	0	0	0	2 (1.8)	1 (0.9)	3 (1.4)
一般・全身障害および投与部位の状態	12 (54.5)	2 (40.0)	14 (51.9)	79 (71.8)	80 (74.8)	159 (73.3)
投与部位紅斑	1 (4.5)	0	1 (3.7)	0	0	0
無力症	0	0	0	1 (0.9)	0	1 (0.5)
カテーテル留置部位紅斑	0	0	0	0	1 (0.9)	1 (0.5)
カテーテル留置部位炎症	0	0	0	0	1 (0.9)	1 (0.5)
カテーテル留置部位疼痛	0	0	0	0	2 (1.9)	2 (0.9)
不快感	0	0	0	1 (0.9)	0	1 (0.5)
薬剤離脱症候群	0	0	0	1 (0.9)	0	1 (0.5)
疲労	0	0	0	3 (2.7)	2 (1.9)	5 (2.3)
異常感	0	0	0	1 (0.9)	0	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
一般・全身障害および投与部位の状態 (Cont.)						
熱感	0	0	0	1 (0.9)	0	1 (0.5)
歩行障害	0	0	0	0	1 (0.9)	1 (0.5)
歩行不能	0	0	0	1 (0.9)	0	1 (0.5)
低体温	0	0	0	1 (0.9)	0	1 (0.5)
インフルエンザ様疾患	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
注入部位内出血	0	0	0	3 (2.7)	7 (6.5)	10 (4.6)
注入部位分泌物	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
注入部位変色	0	0	0	2 (1.8)	0	2 (0.9)
注入部位不快感	0	0	0	2 (1.8)	1 (0.9)	3 (1.4)
注入部位びらん	0	0	0	0	1 (0.9)	1 (0.5)
注入部位紅斑	5 (22.7)	2 (40.0)	7 (25.9)	45 (40.9)	43 (40.2)	88 (40.6)
注入部位皮膚剥脱	0	0	0	0	1 (0.9)	1 (0.5)
注入部位血管外漏出	0	0	0	4 (3.6)	7 (6.5)	11 (5.1)
注入部位血腫	0	0	0	4 (3.6)	4 (3.7)	8 (3.7)
注入部位出血	0	0	0	0	3 (2.8)	3 (1.4)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
一般・全身障害および投与部位の状態 (Cont.)						
注入部位硬結	3 (13.6)	0	3 (11.1)	1 (0.9)	1 (0.9)	2 (0.9)
注入部位炎症	0	0	0	1 (0.9)	3 (2.8)	4 (1.8)
注入部位腫瘤	2 (9.1)	0	2 (7.4)	2 (1.8)	1 (0.9)	3 (1.4)
注入部位壊死	0	0	0	0	1 (0.9)	1 (0.5)
注入部位結節	0	0	0	21 (19.1)	18 (16.8)	39 (18.0)
注入部位浮腫	0	0	0	14 (12.7)	16 (15.0)	30 (13.8)
注入部位疼痛	1 (4.5)	0	1 (3.7)	12 (10.9)	14 (13.1)	26 (12.0)
注入部位蒼白	0	0	0	2 (1.8)	1 (0.9)	3 (1.4)
注入部位丘疹	0	0	0	1 (0.9)	4 (3.7)	5 (2.3)
注入部位異常感覚	0	0	0	0	1 (0.9)	1 (0.5)
注入部位そう痒感	0	0	0	2 (1.8)	1 (0.9)	3 (1.4)
注入部位発疹	1 (4.5)	0	1 (3.7)	1 (0.9)	1 (0.9)	2 (0.9)
注入部位反応	0	0	0	9 (8.2)	11 (10.3)	20 (9.2)
注入部位腫脹	0	0	0	3 (2.7)	1 (0.9)	4 (1.8)
注射部位内出血	0	0	0	1 (0.9)	0	1 (0.5)
注射部位紅斑	1 (4.5)	0	1 (3.7)	4 (3.6)	5 (4.7)	9 (4.1)
注射部位漏出	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
注射部位血腫	0	0	0	0	1 (0.9)	1 (0.5)
注射部位炎症	0	0	0	1 (0.9)	2 (1.9)	3 (1.4)
注射部位結節	0	0	0	1 (0.9)	2 (1.9)	3 (1.4)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
一般・全身障害および投与部位の状態 (Cont.)						
注射部位浮腫	0	0	0	2 (1.8)	2 (1.9)	4 (1.8)
注射部位疼痛	0	0	0	2 (1.8)	4 (3.7)	6 (2.8)
注射部位反応	0	0	0	0	1 (0.9)	1 (0.5)
注射部位腫脹	0	0	0	1 (0.9)	0	1 (0.5)
滴下投与部位熱傷	0	0	0	0	1 (0.9)	1 (0.5)
限局性浮腫	0	1 (20.0)	1 (3.7)	0	0	0
適用部位からの吸収不良	0	0	0	0	1 (0.9)	1 (0.5)
倦怠感	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
医療機器使用部位刺激感	0	0	0	0	1 (0.9)	1 (0.5)
医療機器使用部位そう痒感	0	0	0	1 (0.9)	0	1 (0.5)
医療機器使用部位発疹	0	0	0	0	1 (0.9)	1 (0.5)
小結節	0	0	0	1 (0.9)	0	1 (0.5)
末梢性浮腫	0	1 (20.0)	1 (3.7)	1 (0.9)	2 (1.9)	3 (1.4)
末梢腫脹	0	0	0	0	2 (1.9)	2 (0.9)
穿刺部位内出血	1 (4.5)	0	1 (3.7)	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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
一般・全身障害および投与部位の状態 (Cont.)						
穿刺部位紅斑	0	0	0	0	1 (0.9)	1 (0.5)
穿刺部位出血	0	0	0	1 (0.9)	0	1 (0.5)
穿刺部位硬結	1 (4.5)	0	1 (3.7)	0	0	0
穿刺部位浮腫	0	0	0	0	1 (0.9)	1 (0.5)
穿刺部位腫脹	0	0	0	0	1 (0.9)	1 (0.5)
発熱	1 (4.5)	0	1 (3.7)	1 (0.9)	1 (0.9)	2 (0.9)
口渇	1 (4.5)	0	1 (3.7)	0	0	0
肝胆道系障害	0	0	0	1 (0.9)	0	1 (0.5)
門脈血栓症	0	0	0	1 (0.9)	0	1 (0.5)
感染症および寄生虫症	0	0	0	17 (15.5)	27 (25.2)	44 (20.3)
ボレリア感染	0	0	0	1 (0.9)	0	1 (0.5)
膀胱炎	0	0	0	0	1 (0.9)	1 (0.5)
真菌感染	0	0	0	1 (0.9)	0	1 (0.5)
胃腸炎	0	0	0	0	1 (0.9)	1 (0.5)
注入部位膿瘍	0	0	0	3 (2.7)	5 (4.7)	8 (3.7)
注入部位蜂巣炎	0	0	0	10 (9.1)	13 (12.1)	23 (10.6)
注入部位感染	0	0	0	1 (0.9)	3 (2.8)	4 (1.8)
注射部位蜂巣炎	0	0	0	0	1 (0.9)	1 (0.5)
上咽頭炎	0	0	0	0	3 (2.8)	3 (1.4)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
感染症および寄生虫症 (Cont.)						
爪真菌症	0	0	0	0	1 (0.9)	1 (0.5)
肺炎	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
膿疱性皮疹	0	0	0	1 (0.9)	0	1 (0.5)
敗血症	0	0	0	1 (0.9)	0	1 (0.5)
敗血症性ショック	0	0	0	1 (0.9)	0	1 (0.5)
尿路感染	0	0	0	3 (2.7)	3 (2.8)	6 (2.8)
傷害、中毒および処置合併症	2 (9.1)	1 (20.0)	3 (11.1)	8 (7.3)	10 (9.3)	18 (8.3)
挫傷	0	0	0	1 (0.9)	0	1 (0.5)
医療機器設置の問題	0	0	0	1 (0.9)	0	1 (0.5)
医療機器による投与の欠落	0	0	0	1 (0.9)	0	1 (0.5)
顔面骨骨折	0	0	0	0	2 (1.9)	2 (0.9)
転倒	2 (9.1)	1 (20.0)	3 (11.1)	5 (4.5)	8 (7.5)	13 (6.0)
頭部損傷	0	0	0	1 (0.9)	0	1 (0.5)
注入に伴う反応	0	0	0	1 (0.9)	0	1 (0.5)
腰椎骨折	0	0	0	0	1 (0.9)	1 (0.5)
処置後挫傷	0	0	0	1 (0.9)	0	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
傷害、中毒および処置合併症 (Cont.)						
処置によるめまい	0	0	0	0	1 (0.9)	1 (0.5)
肋骨骨折	0	0	0	0	1 (0.9)	1 (0.5)
皮膚擦過傷	0	0	0	1 (0.9)	0	1 (0.5)
皮膚裂傷	0	0	0	0	2 (1.9)	2 (0.9)
臨床検査	0	0	0	3 (2.7)	5 (4.7)	8 (3.7)
血圧上昇	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
起立血圧低下	0	0	0	1 (0.9)	0	1 (0.5)
リンパ球数減少	0	0	0	0	1 (0.9)	1 (0.5)
単球数増加	0	0	0	0	1 (0.9)	1 (0.5)
好中球数増加	0	0	0	0	1 (0.9)	1 (0.5)
ビタミンB12減少	0	0	0	1 (0.9)	0	1 (0.5)
ビタミンB6減少	0	0	0	0	2 (1.9)	2 (0.9)
体重減少	0	0	0	0	1 (0.9)	1 (0.5)
白血球数増加	0	0	0	0	1 (0.9)	1 (0.5)
代謝および栄養障害	0	0	0	1 (0.9)	5 (4.7)	6 (2.8)
食欲減退	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
脱水	0	0	0	0	1 (0.9)	1 (0.5)
耐糖能障害	0	0	0	0	1 (0.9)	1 (0.5)
高血糖	0	0	0	0	1 (0.9)	1 (0.5)
低カリウム血症	0	0	0	0	1 (0.9)	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
筋骨格系および結合組織障害	2 (9.1)	0	2 (7.4)	8 (7.3)	8 (7.5)	16 (7.4)
関節痛	0	0	0	2 (1.8)	2 (1.9)	4 (1.8)
反応性関節炎	0	0	0	0	1 (0.9)	1 (0.5)
背部痛	0	0	0	3 (2.7)	1 (0.9)	4 (1.8)
関節腫脹	0	0	0	0	1 (0.9)	1 (0.5)
筋力低下	0	0	0	2 (1.8)	0	2 (0.9)
筋骨格硬直	0	0	0	0	1 (0.9)	1 (0.5)
筋肉痛	1 (4.5)	0	1 (3.7)	1 (0.9)	1 (0.9)	2 (0.9)
四肢痛	0	0	0	0	1 (0.9)	1 (0.5)
姿勢異常	0	0	0	0	1 (0.9)	1 (0.5)
横紋筋融解症	1 (4.5)	0	1 (3.7)	0	0	0
仙腸関節機能障害	0	0	0	1 (0.9)	0	1 (0.5)
斜頚	0	0	0	0	1 (0.9)	1 (0.5)
神経系障害	6 (27.3)	1 (20.0)	7 (25.9)	30 (27.3)	25 (23.4)	55 (25.3)
運動失調	1 (4.5)	0	1 (3.7)	0	0	0
平衡障害	0	0	0	0	1 (0.9)	1 (0.5)
運動緩慢	0	0	0	1 (0.9)	0	1 (0.5)
認知障害	0	0	0	2 (1.8)	0	2 (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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
神経系障害 (Cont.)						
浮動性めまい	2 (9.1)	0	2 (7.4)	8 (7.3)	8 (7.5)	16 (7.4)
体位性めまい	0	0	0	3 (2.7)	0	3 (1.4)
構語障害	0	0	0	0	1 (0.9)	1 (0.5)
味覚不全	0	0	0	2 (1.8)	0	2 (0.9)
ジスキネジア	0	0	0	6 (5.5)	3 (2.8)	9 (4.1)
起立障害	0	0	0	1 (0.9)	0	1 (0.5)
ジストニア	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
本態性振戦	0	0	0	0	1 (0.9)	1 (0.5)
すくみ現象	0	0	0	3 (2.7)	0	3 (1.4)
頭部不快感	0	0	0	1 (0.9)	0	1 (0.5)
頭痛	1 (4.5)	0	1 (3.7)	3 (2.7)	2 (1.9)	5 (2.3)
片側感覚消失	0	0	0	0	1 (0.9)	1 (0.5)
不全片麻痺	0	0	0	0	1 (0.9)	1 (0.5)
代謝性脳症	0	0	0	0	1 (0.9)	1 (0.5)
オンオフ現象	0	0	0	3 (2.7)	3 (2.8)	6 (2.8)
錯感覚	0	0	0	0	1 (0.9)	1 (0.5)
パーキンソン病	2 (9.1)	0	2 (7.4)	3 (2.7)	3 (2.8)	6 (2.8)
パーキンソニズム	0	1 (20.0)	1 (3.7)	0	0	0
精神運動亢進	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
安静時振戦	0	0	0	0	1 (0.9)	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
神経系障害 (Cont.)						
坐骨神経痛	0	0	0	0	2 (1.9)	2 (0.9)
傾眠	0	0	0	2 (1.8)	2 (1.9)	4 (1.8)
振戦	0	0	0	0	2 (1.9)	2 (0.9)
製品の問題	0	0	0	0	1 (0.9)	1 (0.5)
医療機器機能不良	0	0	0	0	1 (0.9)	1 (0.5)
精神障害	7 (31.8)	2 (40.0)	9 (33.3)	24 (21.8)	22 (20.6)	46 (21.2)
異常な夢	0	0	0	0	1 (0.9)	1 (0.5)
感情不安定	0	0	0	1 (0.9)	0	1 (0.5)
不安	0	0	0	2 (1.8)	8 (7.5)	10 (4.6)
歯ぎしり	0	0	0	2 (1.8)	0	2 (0.9)
錯乱状態	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
譫妄	0	0	0	1 (0.9)	2 (1.9)	3 (1.4)
妄想	1 (4.5)	0	1 (3.7)	0	1 (0.9)	1 (0.5)
抑うつ気分	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
抑うつ症状	1 (4.5)	0	1 (3.7)	1 (0.9)	0	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
精神障害 (Cont.)						
睡眠異常	0	0	0	1 (0.9)	0	1 (0.5)
情動障害	0	0	0	0	1 (0.9)	1 (0.5)
幻覚	5 (22.7)	1 (20.0)	6 (22.2)	8 (7.3)	4 (3.7)	12 (5.5)
幻聴	0	0	0	0	1 (0.9)	1 (0.5)
幻視	0	1 (20.0)	1 (3.7)	4 (3.6)	0	4 (1.8)
不眠症	0	0	0	7 (6.4)	3 (2.8)	10 (4.6)
易刺激性	0	0	0	1 (0.9)	0	1 (0.5)
嫉妬妄想	1 (4.5)	0	1 (3.7)	0	0	0
気分変化	0	0	0	1 (0.9)	0	1 (0.5)
強迫観念	0	0	0	1 (0.9)	0	1 (0.5)
パニック発作	0	0	0	0	3 (2.8)	3 (1.4)
精神病性障害	0	0	0	2 (1.8)	0	2 (0.9)
レム睡眠行動障害	0	0	0	1 (0.9)	0	1 (0.5)
睡眠障害	0	0	0	0	1 (0.9)	1 (0.5)
ねごと	0	0	0	0	1 (0.9)	1 (0.5)
腎および尿路障害	1 (4.5)	0	1 (3.7)	5 (4.5)	1 (0.9)	6 (2.8)
排尿困難	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
切迫性尿失禁	0	0	0	2 (1.8)	0	2 (0.9)
尿失禁	1 (4.5)	0	1 (3.7)	1 (0.9)	0	1 (0.5)
尿路障害	0	0	0	1 (0.9)	0	1 (0.5)
尿異常	0	0	0	0	1 (0.9)	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
生殖系および乳房障害	0	0	0	0	1 (0.9)	1 (0.5)
勃起不全	0	0	0	0	1 (0.9)	1 (0.5)
呼吸器、胸郭および縦隔障害	0	0	0	1 (0.9)	7 (6.5)	8 (3.7)
急性呼吸不全	0	0	0	0	1 (0.9)	1 (0.5)
咳嗽	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
呼吸困難	0	0	0	0	1 (0.9)	1 (0.5)
過換気	0	0	0	0	1 (0.9)	1 (0.5)
口腔咽頭痛	0	0	0	0	1 (0.9)	1 (0.5)
鼻痛	0	0	0	0	1 (0.9)	1 (0.5)
鼻漏	0	0	0	0	1 (0.9)	1 (0.5)
皮膚および皮下組織障害	1 (4.5)	0	1 (3.7)	5 (4.5)	5 (4.7)	10 (4.6)
脱毛症	0	0	0	1 (0.9)	0	1 (0.5)
接触皮膚炎	0	0	0	1 (0.9)	0	1 (0.5)
皮膚乾燥	0	0	0	0	1 (0.9)	1 (0.5)
斑状出血	0	0	0	1 (0.9)	0	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
皮膚および皮下組織障害 (Cont.)						
紅斑	0	0	0	0	1 (0.9)	1 (0.5)
光線過敏性反応	0	0	0	0	1 (0.9)	1 (0.5)
発疹	1 (4.5)	0	1 (3.7)	0	0	0
そう痒性皮疹	0	0	0	1 (0.9)	0	1 (0.5)
皮膚刺激	0	0	0	0	1 (0.9)	1 (0.5)
皮膚病変	0	0	0	0	1 (0.9)	1 (0.5)
皮膚潰瘍	0	0	0	1 (0.9)	0	1 (0.5)
社会環境	0	0	0	1 (0.9)	0	1 (0.5)
運動不能	0	0	0	1 (0.9)	0	1 (0.5)
血管障害	0	0	0	3 (2.7)	7 (6.5)	10 (4.6)
ほてり	0	0	0	0	1 (0.9)	1 (0.5)
高血圧	0	0	0	2 (1.8)	1 (0.9)	3 (1.4)
低血圧	0	0	0	0	2 (1.9)	2 (0.9)
不安定血圧	0	0	0	0	1 (0.9)	1 (0.5)
起立性低血圧	0	0	0	1 (0.9)	4 (3.7)	5 (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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period	N=17	N=3	N=20	N=94	N=92	N=186
Any adverse event	15 (88.2)	3 (100)	18 (90.0)	85 (90.4)	86 (93.5)	171 (91.9)
血液およびリンパ系障害	0	0	0	1 (1.1)	3 (3.3)	4 (2.2)
大球性貧血	0	0	0	0	1 (1.1)	1 (0.5)
凝血異常	0	0	0	0	1 (1.1)	1 (0.5)
リンパ節症	0	0	0	1 (1.1)	0	1 (0.5)
縦隔リンパ節腫脹	0	0	0	0	1 (1.1)	1 (0.5)
心臓障害	0	0	0	5 (5.3)	6 (6.5)	11 (5.9)
急性心筋梗塞	0	0	0	1 (1.1)	0	1 (0.5)
狭心症	0	0	0	1 (1.1)	0	1 (0.5)
心房細動	0	0	0	0	2 (2.2)	2 (1.1)
心停止	0	0	0	1 (1.1)	0	1 (0.5)
心肺停止	0	0	0	0	1 (1.1)	1 (0.5)
冠動脈疾患	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
冠動脈狭窄	0	0	0	1 (1.1)	0	1 (0.5)
期外収縮	0	0	0	0	1 (1.1)	1 (0.5)
左室肥大	0	0	0	0	1 (1.1)	1 (0.5)
心筋梗塞	0	0	0	1 (1.1)	0	1 (0.5)
動悸	0	0	0	0	1 (1.1)	1 (0.5)
頻脈	0	0	0	1 (1.1)	0	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
耳および迷路障害	1 (5.9)	0	1 (5.0)	1 (1.1)	2 (2.2)	3 (1.6)
感音性難聴	1 (5.9)	0	1 (5.0)	0	0	0
回転性めまい	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
頭位性回転性めまい	0	0	0	0	1 (1.1)	1 (0.5)
眼障害	1 (5.9)	1 (33.3)	2 (10.0)	6 (6.4)	5 (5.4)	11 (5.9)
白内障	1 (5.9)	1 (33.3)	2 (10.0)	1 (1.1)	1 (1.1)	2 (1.1)
複視	0	0	0	2 (2.1)	0	2 (1.1)
ドライアイ	0	1 (33.3)	1 (5.0)	1 (1.1)	2 (2.2)	3 (1.6)
緑内障	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
眼窩周囲痛	0	0	0	0	1 (1.1)	1 (0.5)
眼窩周囲腫脹	0	0	0	0	1 (1.1)	1 (0.5)
網膜裂孔	0	0	0	2 (2.1)	0	2 (1.1)
視野欠損	0	0	0	0	1 (1.1)	1 (0.5)
胃腸障害	6 (35.3)	1 (33.3)	7 (35.0)	11 (11.7)	20 (21.7)	31 (16.7)
腹部膨満	0	0	0	1 (1.1)	2 (2.2)	3 (1.6)
腹痛	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
上腹部痛	1 (5.9)	0	1 (5.0)	0	0	0
呼気臭	0	0	0	0	1 (1.1)	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
胃腸障害 (Cont.)						
虚血性大腸炎	0	0	0	1 (1.1)	0	1 (0.5)
便秘	2 (11.8)	0	2 (10.0)	4 (4.3)	10 (10.9)	14 (7.5)
齲歯	1 (5.9)	0	1 (5.0)	0	0	0
下痢	2 (11.8)	1 (33.3)	3 (15.0)	2 (2.1)	0	2 (1.1)
口内乾燥	0	0	0	1 (1.1)	3 (3.3)	4 (2.2)
嚥下障害	0	0	0	0	1 (1.1)	1 (0.5)
糞塊	0	0	0	0	1 (1.1)	1 (0.5)
排便回数増加	0	0	0	0	1 (1.1)	1 (0.5)
胃食道逆流性疾患	0	0	0	1 (1.1)	0	1 (0.5)
舌炎	0	0	0	1 (1.1)	0	1 (0.5)
舌痛	0	0	0	1 (1.1)	0	1 (0.5)
吐血	0	0	0	1 (1.1)	0	1 (0.5)
裂孔ヘルニア	0	0	0	1 (1.1)	0	1 (0.5)
胃排出不全	0	0	0	1 (1.1)	0	1 (0.5)
単径ヘルニア	0	0	0	1 (1.1)	0	1 (0.5)
腸出血	0	0	0	1 (1.1)	0	1 (0.5)
過敏性腸症候群	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
大腸ポリープ	0	0	0	0	1 (1.1)	1 (0.5)
口唇乾燥	1 (5.9)	0	1 (5.0)	0	0	0
メレナ	1 (5.9)	0	1 (5.0)	1 (1.1)	0	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
胃腸障害 (Cont.)						
口腔腫脹	0	0	0	1 (1.1)	0	1 (0.5)
悪心	2 (11.8)	0	2 (10.0)	2 (2.1)	7 (7.6)	9 (4.8)
口腔内不快感	0	0	0	1 (1.1)	0	1 (0.5)
口腔内痛	0	0	0	1 (1.1)	0	1 (0.5)
口の錯感覚	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
直腸出血	0	0	0	0	1 (1.1)	1 (0.5)
歯痛	0	0	0	0	1 (1.1)	1 (0.5)
嘔吐	0	0	0	1 (1.1)	2 (2.2)	3 (1.6)
一般・全身障害および投与部位の状態	11 (64.7)	3 (100)	14 (70.0)	55 (58.5)	69 (75.0)	124 (66.7)
投与部位内出血	0	0	0	0	1 (1.1)	1 (0.5)
投与部位漏出	0	0	0	0	1 (1.1)	1 (0.5)
無力症	0	0	0	2 (2.1)	0	2 (1.1)
カテーテル留置部位紅斑	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
カテーテル留置部位漏出	0	0	0	1 (1.1)	0	1 (0.5)
カテーテル留置部位出血	0	0	0	0	1 (1.1)	1 (0.5)
カテーテル留置部位刺激感	0	0	0	0	1 (1.1)	1 (0.5)
カテーテル留置部位浮腫	0	0	0	0	1 (1.1)	1 (0.5)
カテーテル留置部位疼痛	0	0	0	0	1 (1.1)	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
一般・全身障害および投与部位の状態 (Cont.)						
胸部不快感	0	0	0	0	1 (1.1)	1 (0.5)
胸痛	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
泣き	0	0	0	1 (1.1)	0	1 (0.5)
薬効欠如	0	0	0	0	1 (1.1)	1 (0.5)
薬剤離脱症候群	0	0	0	0	1 (1.1)	1 (0.5)
疲労	0	0	0	3 (3.2)	1 (1.1)	4 (2.2)
異常感	0	0	0	0	1 (1.1)	1 (0.5)
冷感	0	0	0	0	1 (1.1)	1 (0.5)
歩行障害	0	0	0	0	1 (1.1)	1 (0.5)
低体温	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
インフルエンザ様疾患	0	0	0	1 (1.1)	2 (2.2)	3 (1.6)
注入部位内出血	1 (5.9)	0	1 (5.0)	6 (6.4)	2 (2.2)	8 (4.3)
注入部位皮膚炎	2 (11.8)	0	2 (10.0)	0	2 (2.2)	2 (1.1)
注入部位分泌物	0	0	0	0	1 (1.1)	1 (0.5)
注入部位不快感	0	0	0	1 (1.1)	0	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
一般・全身障害および投与部位の状態 (Cont.)						
注入部位びらん	0	0	0	1 (1.1)	0	1 (0.5)
注入部位紅斑	4 (23.5)	1 (33.3)	5 (25.0)	32 (34.0)	43 (46.7)	75 (40.3)
注入部位皮膚剥脱	0	0	0	3 (3.2)	2 (2.2)	5 (2.7)
注入部位血管外漏出	0	0	0	5 (5.3)	6 (6.5)	11 (5.9)
注入部位血腫	0	0	0	6 (6.4)	4 (4.3)	10 (5.4)
注入部位出血	0	0	0	4 (4.3)	2 (2.2)	6 (3.2)
注入部位硬結	3 (17.6)	1 (33.3)	4 (20.0)	2 (2.1)	1 (1.1)	3 (1.6)
注入部位炎症	0	0	0	2 (2.1)	6 (6.5)	8 (4.3)
注入部位損傷	0	0	0	0	2 (2.2)	2 (1.1)
注入部位刺激感	0	0	0	1 (1.1)	4 (4.3)	5 (2.7)
注入部位腫瘤	0	1 (33.3)	1 (5.0)	1 (1.1)	1 (1.1)	2 (1.1)
注入部位結節	0	0	0	20 (21.3)	25 (27.2)	45 (24.2)
注入部位浮腫	0	0	0	8 (8.5)	18 (19.6)	26 (14.0)
注入部位疼痛	0	0	0	8 (8.5)	11 (12.0)	19 (10.2)
注入部位蒼白	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
注入部位丘疹	0	0	0	6 (6.4)	8 (8.7)	14 (7.5)
注入部位異常感覚	0	0	0	0	2 (2.2)	2 (1.1)
注入部位そう痒感	0	0	0	3 (3.2)	1 (1.1)	4 (2.2)
注入部位発疹	0	1 (33.3)	1 (5.0)	1 (1.1)	2 (2.2)	3 (1.6)
注入部位反応	0	0	0	8 (8.5)	11 (12.0)	19 (10.2)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
一般・全身障害および投与部位の状態 (Cont.)						
注入部位痂皮	0	0	0	0	1 (1.1)	1 (0.5)
注入部位腫脹	1 (5.9)	0	1 (5.0)	1 (1.1)	1 (1.1)	2 (1.1)
注入部位小水疱	0	0	0	0	2 (2.2)	2 (1.1)
注入部位熱感	0	0	0	0	1 (1.1)	1 (0.5)
注射部位内出血	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
注射部位変色	0	0	0	1 (1.1)	0	1 (0.5)
注射部位紅斑	1 (5.9)	0	1 (5.0)	4 (4.3)	5 (5.4)	9 (4.8)
注射部位出血	0	0	0	0	1 (1.1)	1 (0.5)
注射部位炎症	0	0	0	2 (2.1)	4 (4.3)	6 (3.2)
注射部位結節	0	0	0	3 (3.2)	5 (5.4)	8 (4.3)
注射部位浮腫	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
注射部位疼痛	0	0	0	0	2 (2.2)	2 (1.1)
注射部位丘疹	0	0	0	0	2 (2.2)	2 (1.1)
注射部位反応	0	0	0	1 (1.1)	0	1 (0.5)
注射部位腫脹	1 (5.9)	1 (33.3)	2 (10.0)	0	1 (1.1)	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
一般・全身障害および投与部位の状態 (Cont.)						
注射部位蕁麻疹	0	0	0	0	1 (1.1)	1 (0.5)
滴下投与部位痛	0	0	0	0	1 (1.1)	1 (0.5)
倦怠感	0	0	0	0	1 (1.1)	1 (0.5)
医療機器使用部位刺激感	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
医療機器使用部位発疹	0	0	0	0	1 (1.1)	1 (0.5)
非心臓性胸痛	0	0	0	0	2 (2.2)	2 (1.1)
末梢性浮腫	1 (5.9)	0	1 (5.0)	3 (3.2)	1 (1.1)	4 (2.2)
疼痛	0	0	0	2 (2.1)	0	2 (1.1)
末梢腫脹	0	0	0	0	3 (3.3)	3 (1.6)
穿刺部位紅斑	0	0	0	0	2 (2.2)	2 (1.1)
穿刺部位硬結	2 (11.8)	0	2 (10.0)	0	0	0
発熱	0	0	0	0	1 (1.1)	1 (0.5)
血管穿刺部位硬結	1 (5.9)	0	1 (5.0)	0	0	0
肝胆道系障害	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
肝嚢胞	0	0	0	1 (1.1)	0	1 (0.5)
脂肪肝	0	0	0	0	1 (1.1)	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
感染症および寄生虫症	5 (29.4)	2 (66.7)	7 (35.0)	41 (43.6)	43 (46.7)	84 (45.2)
四肢膿瘍	0	0	0	0	1 (1.1)	1 (0.5)
無症候性COVID-19	0	0	0	0	1 (1.1)	1 (0.5)
細菌性疾患キャリアー	0	0	0	0	1 (1.1)	1 (0.5)
ウイルス性気管支炎	0	0	0	0	1 (1.1)	1 (0.5)
COVID-19	0	0	0	1 (1.1)	0	1 (0.5)
COVID-19肺炎	0	0	0	1 (1.1)	0	1 (0.5)
カテーテル留置部位感染	0	0	0	1 (1.1)	0	1 (0.5)
蜂巣炎	0	1 (33.3)	1 (5.0)	1 (1.1)	1 (1.1)	2 (1.1)
結膜炎	1 (5.9)	0	1 (5.0)	1 (1.1)	0	1 (0.5)
膀胱炎	0	0	0	1 (1.1)	0	1 (0.5)
爪の皮膚糸状菌症	0	1 (33.3)	1 (5.0)	0	0	0
歯肉炎	0	0	0	1 (1.1)	0	1 (0.5)
麦粒腫	1 (5.9)	0	1 (5.0)	0	0	0
感染性皮膚潰瘍	0	0	0	0	1 (1.1)	1 (0.5)
インフルエンザ	0	0	0	0	1 (1.1)	1 (0.5)
注入部位膿瘍	0	0	0	11 (11.7)	9 (9.8)	20 (10.8)
注入部位蜂巣炎	3 (17.6)	1 (33.3)	4 (20.0)	18 (19.1)	18 (19.6)	36 (19.4)
注入部位感染	0	0	0	6 (6.4)	9 (9.8)	15 (8.1)
注入部位膿疱	0	0	0	0	1 (1.1)	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
感染症および寄生虫症 (Cont.)						
注射部位蜂巣炎	0	0	0	0	2 (2.2)	2 (1.1)
リンパ管炎	0	0	0	0	1 (1.1)	1 (0.5)
上咽頭炎	0	1 (33.3)	1 (5.0)	5 (5.3)	1 (1.1)	6 (3.2)
耳下腺膿瘍	0	0	0	0	1 (1.1)	1 (0.5)
肺炎	0	0	0	2 (2.1)	1 (1.1)	3 (1.6)
術後膿瘍	1 (5.9)	0	1 (5.0)	0	0	0
シュードモナス感染	0	0	0	0	1 (1.1)	1 (0.5)
気道感染	0	0	0	0	1 (1.1)	1 (0.5)
敗血症	0	0	0	2 (2.1)	0	2 (1.1)
副鼻腔炎	0	0	0	1 (1.1)	0	1 (0.5)
ブドウ球菌感染	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
歯感染	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
上気道感染	0	0	0	1 (1.1)	0	1 (0.5)
尿路感染	0	0	0	5 (5.3)	11 (12.0)	16 (8.6)
水痘帯状疱疹ウイルス感染	0	0	0	1 (1.1)	0	1 (0.5)
傷害、中毒および処置合併症	5 (29.4)	1 (33.3)	6 (30.0)	8 (8.5)	20 (21.7)	28 (15.1)
足関節部骨折	0	0	0	0	1 (1.1)	1 (0.5)
節足動物咬傷	0	0	0	0	1 (1.1)	1 (0.5)
骨挫傷	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
脳挫傷	1 (5.9)	0	1 (5.0)	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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
傷害、中毒および処置合併症 (Cont.)						
挫傷	1 (5.9)	0	1 (5.0)	0	6 (6.5)	6 (3.2)
期限切れの製品使用	0	0	0	1 (1.1)	0	1 (0.5)
眼挫傷	0	0	0	0	1 (1.1)	1 (0.5)
顔面損傷	0	0	0	0	1 (1.1)	1 (0.5)
転倒	5 (29.4)	1 (33.3)	6 (30.0)	6 (6.4)	17 (18.5)	23 (12.4)
頭部損傷	1 (5.9)	0	1 (5.0)	0	3 (3.3)	3 (1.6)
関節脱臼	0	0	0	0	1 (1.1)	1 (0.5)
靭帯捻挫	1 (5.9)	0	1 (5.0)	0	1 (1.1)	1 (0.5)
過量投与	0	0	0	0	1 (1.1)	1 (0.5)
肋骨骨折	1 (5.9)	1 (33.3)	2 (10.0)	0	0	0
皮膚擦過傷	0	0	0	0	2 (2.2)	2 (1.1)
皮膚損傷	1 (5.9)	0	1 (5.0)	0	0	0
皮膚裂傷	0	0	0	1 (1.1)	4 (4.3)	5 (2.7)
ストレス骨折	0	0	0	1 (1.1)	0	1 (0.5)
硬膜下血腫	0	0	0	0	1 (1.1)	1 (0.5)
サンバーン	0	0	0	0	1 (1.1)	1 (0.5)
腱断裂	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
過少量投与	0	0	0	0	1 (1.1)	1 (0.5)
創傷	0	0	0	1 (1.1)	0	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
臨床検査	3 (17.6)	0	3 (15.0)	18 (19.1)	19 (20.7)	37 (19.9)
血中クレアチンホスホキナーゼ増加	1 (5.9)	0	1 (5.0)	0	1 (1.1)	1 (0.5)
血中クレアチニン減少	0	0	0	0	1 (1.1)	1 (0.5)
血中葉酸異常	0	0	0	0	1 (1.1)	1 (0.5)
血中葉酸減少	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
血中ホモシステイン増加	1 (5.9)	0	1 (5.0)	0	2 (2.2)	2 (1.1)
血中リン減少	0	0	0	0	1 (1.1)	1 (0.5)
血中ナトリウム減少	0	0	0	1 (1.1)	0	1 (0.5)
C-反応性蛋白増加	0	0	0	0	1 (1.1)	1 (0.5)
心雑音	0	0	0	1 (1.1)	0	1 (0.5)
握力低下	0	0	0	1 (1.1)	0	1 (0.5)
ヘモグロビン減少	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
好中球数増加	0	0	0	0	1 (1.1)	1 (0.5)
プロトロンビン時間延長	0	0	0	0	1 (1.1)	1 (0.5)
赤血球数減少	0	0	0	0	1 (1.1)	1 (0.5)
ビタミンB12減少	0	0	0	0	1 (1.1)	1 (0.5)
ビタミンB6減少	0	0	0	5 (5.3)	4 (4.3)	9 (4.8)
ビタミンD減少	0	0	0	0	1 (1.1)	1 (0.5)
体重減少	1 (5.9)	0	1 (5.0)	9 (9.6)	13 (14.1)	22 (11.8)
体重増加	0	0	0	2 (2.1)	0	2 (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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
臨床検査 (Cont.)						
白血球数増加	0	0	0	0	1 (1.1)	1 (0.5)
代謝および栄養障害	2 (11.8)	1 (33.3)	3 (15.0)	8 (8.5)	15 (16.3)	23 (12.4)
悪液質	0	0	0	1 (1.1)	0	1 (0.5)
食欲減退	0	0	0	2 (2.1)	2 (2.2)	4 (2.2)
脱水	0	0	0	1 (1.1)	2 (2.2)	3 (1.6)
糖尿病	0	0	0	0	1 (1.1)	1 (0.5)
水分過負荷	0	0	0	0	1 (1.1)	1 (0.5)
体液貯留	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
葉酸欠乏	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
高コレステロール血症	0	0	0	0	1 (1.1)	1 (0.5)
高ホモシステイン血症	0	0	0	0	1 (1.1)	1 (0.5)
低カルシウム血症	0	0	0	0	1 (1.1)	1 (0.5)
低カリウム血症	0	0	0	0	2 (2.2)	2 (1.1)
低ナトリウム血症	1 (5.9)	0	1 (5.0)	1 (1.1)	0	1 (0.5)
栄養障害	0	0	0	0	1 (1.1)	1 (0.5)
ビタミンB群欠乏	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
ビタミンB12欠乏	0	1 (33.3)	1 (5.0)	0	1 (1.1)	1 (0.5)
ビタミンB6欠乏	1 (5.9)	1 (33.3)	2 (10.0)	2 (2.1)	4 (4.3)	6 (3.2)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
筋骨格系および結合組織障害	4 (23.5)	1 (33.3)	5 (25.0)	13 (13.8)	14 (15.2)	27 (14.5)
関節痛	0	1 (33.3)	1 (5.0)	1 (1.1)	2 (2.2)	3 (1.6)
反応性関節炎	0	0	0	1 (1.1)	0	1 (0.5)
背部痛	1 (5.9)	0	1 (5.0)	4 (4.3)	4 (4.3)	8 (4.3)
骨痛	0	0	0	0	1 (1.1)	1 (0.5)
滑液包炎	0	0	0	2 (2.1)	0	2 (1.1)
外骨腫	0	0	0	0	1 (1.1)	1 (0.5)
椎間関節症候群	0	0	0	0	1 (1.1)	1 (0.5)
椎間板変性症	0	0	0	1 (1.1)	0	1 (0.5)
椎間板突出	0	0	0	0	1 (1.1)	1 (0.5)
関節滲出液	0	0	0	0	2 (2.2)	2 (1.1)
四肢不快感	0	0	0	0	1 (1.1)	1 (0.5)
筋萎縮	0	0	0	0	1 (1.1)	1 (0.5)
筋痙縮	0	0	0	2 (2.1)	3 (3.3)	5 (2.7)
筋力低下	0	0	0	2 (2.1)	1 (1.1)	3 (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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
筋骨格系および結合組織障害 (Cont.)						
頚部痛	0	0	0	2 (2.1)	0	2 (1.1)
骨炎	0	0	0	0	1 (1.1)	1 (0.5)
変形性関節症	0	0	0	1 (1.1)	4 (4.3)	5 (2.7)
骨減少症	0	0	0	1 (1.1)	0	1 (0.5)
四肢痛	2 (11.8)	0	2 (10.0)	1 (1.1)	2 (2.2)	3 (1.6)
関節周囲炎	0	0	0	0	1 (1.1)	1 (0.5)
横紋筋融解症	0	0	0	1 (1.1)	0	1 (0.5)
肩回旋筋腱板症候群	0	0	0	0	1 (1.1)	1 (0.5)
変形性脊椎症	0	0	0	1 (1.1)	0	1 (0.5)
腱障害	0	0	0	0	1 (1.1)	1 (0.5)
腱炎	0	0	0	1 (1.1)	0	1 (0.5)
弾発指	1 (5.9)	0	1 (5.0)	0	0	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	0	0	1 (1.1)	4 (4.3)	5 (2.7)
基底細胞癌	0	0	0	0	2 (2.2)	2 (1.1)
直腸腺癌	0	0	0	1 (1.1)	0	1 (0.5)
脂漏性角化症	0	0	0	0	1 (1.1)	1 (0.5)
皮膚有棘細胞癌	0	0	0	0	1 (1.1)	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
神経系障害	5 (29.4)	1 (33.3)	6 (30.0)	32 (34.0)	33 (35.9)	65 (34.9)
アカシジア	0	0	0	1 (1.1)	0	1 (0.5)
健忘	0	0	0	1 (1.1)	0	1 (0.5)
失語症	0	0	0	0	1 (1.1)	1 (0.5)
平衡障害	0	0	0	0	4 (4.3)	4 (2.2)
運動緩慢	0	0	0	0	1 (1.1)	1 (0.5)
手根管症候群	0	0	0	0	1 (1.1)	1 (0.5)
大脳萎縮	0	0	0	0	1 (1.1)	1 (0.5)
脳出血	0	0	0	0	1 (1.1)	1 (0.5)
脳圧排効果	0	0	0	0	1 (1.1)	1 (0.5)
脳血管発作	0	0	0	0	1 (1.1)	1 (0.5)
認知障害	0	0	0	2 (2.1)	2 (2.2)	4 (2.2)
振動覚低下	0	0	0	1 (1.1)	0	1 (0.5)
注意力障害	0	0	0	0	1 (1.1)	1 (0.5)
浮動性めまい	0	1 (33.3)	1 (5.0)	6 (6.4)	1 (1.1)	7 (3.8)
体位性めまい	0	0	0	3 (3.2)	0	3 (1.6)
構語障害	0	0	0	0	2 (2.2)	2 (1.1)
味覚不全	0	0	0	0	1 (1.1)	1 (0.5)
ジスキネジア	0	0	0	7 (7.4)	3 (3.3)	10 (5.4)
ジストニア	0	0	0	1 (1.1)	4 (4.3)	5 (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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
神経系障害 (Cont.)						
脳症	0	0	0	0	1 (1.1)	1 (0.5)
てんかん	0	0	0	0	1 (1.1)	1 (0.5)
伸展性足底反応	0	0	0	1 (1.1)	0	1 (0.5)
すくみ現象	0	0	0	1 (1.1)	0	1 (0.5)
全身性強直性間代性発作	0	0	0	0	1 (1.1)	1 (0.5)
頭痛	1 (5.9)	0	1 (5.0)	2 (2.1)	6 (6.5)	8 (4.3)
知覚過敏	0	0	0	0	1 (1.1)	1 (0.5)
感覚鈍麻	0	0	0	1 (1.1)	2 (2.2)	3 (1.6)
反射減弱	0	0	0	2 (2.1)	1 (1.1)	3 (1.6)
不規則睡眠覚醒リズム障害	0	0	0	1 (1.1)	0	1 (0.5)
嗜眠	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
意識消失	1 (5.9)	0	1 (5.0)	0	1 (1.1)	1 (0.5)
腰仙部神経根障害	0	0	0	0	1 (1.1)	1 (0.5)
記憶障害	0	0	0	0	2 (2.2)	2 (1.1)
代謝性脳症	0	0	0	1 (1.1)	0	1 (0.5)
神経痛	0	0	0	0	1 (1.1)	1 (0.5)
末梢性ニューロパチー	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
オンオフ現象	0	0	0	1 (1.1)	2 (2.2)	3 (1.6)
錯感覚	0	0	0	4 (4.3)	2 (2.2)	6 (3.2)
パーキンソン病	2 (11.8)	0	2 (10.0)	5 (5.3)	2 (2.2)	7 (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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
神経系障害 (Cont.)						
パーキンソニズム	0	0	0	0	2 (2.2)	2 (1.1)
末梢性感覚ニューロパチー	0	0	0	0	1 (1.1)	1 (0.5)
側反弓	1 (5.9)	0	1 (5.0)	0	2 (2.2)	2 (1.1)
多発ニューロパチー	0	0	0	0	2 (2.2)	2 (1.1)
失神寸前の状態	0	0	0	0	1 (1.1)	1 (0.5)
心因性発作	0	0	0	0	1 (1.1)	1 (0.5)
反射異常	0	0	0	0	1 (1.1)	1 (0.5)
坐骨神経痛	0	0	0	0	3 (3.3)	3 (1.6)
痙攣発作	0	0	0	0	1 (1.1)	1 (0.5)
感覚障害	0	0	0	0	1 (1.1)	1 (0.5)
感覚消失	0	0	0	0	1 (1.1)	1 (0.5)
睡眠時麻痺	0	0	0	1 (1.1)	0	1 (0.5)
傾眠	0	0	0	8 (8.5)	1 (1.1)	9 (4.8)
失神	0	0	0	0	3 (3.3)	3 (1.6)
振戦	0	0	0	1 (1.1)	0	1 (0.5)
製品の問題	0	0	0	2 (2.1)	0	2 (1.1)
医療機器送達システムの問題	0	0	0	1 (1.1)	0	1 (0.5)
医療機器位置異常	0	0	0	1 (1.1)	0	1 (0.5)
精神障害	8 (47.1)	1 (33.3)	9 (45.0)	30 (31.9)	41 (44.6)	71 (38.2)
感情不安定	0	0	0	0	1 (1.1)	1 (0.5)
激越	0	0	0	0	1 (1.1)	1 (0.5)
不安	0	0	0	10 (10.6)	12 (13.0)	22 (11.8)
不安障害	0	1 (33.3)	1 (5.0)	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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
精神障害 (Cont.)						
無感情	0	0	0	1 (1.1)	0	1 (0.5)
強迫行為	0	0	0	0	1 (1.1)	1 (0.5)
強迫性性行動	0	0	0	1 (1.1)	0	1 (0.5)
錯乱状態	0	0	0	4 (4.3)	4 (4.3)	8 (4.3)
譫妄	0	0	0	0	2 (2.2)	2 (1.1)
妄想	4 (23.5)	0	4 (20.0)	3 (3.2)	1 (1.1)	4 (2.2)
寄生虫妄想	0	0	0	1 (1.1)	0	1 (0.5)
妄想性障害、詳細不明	0	0	0	0	1 (1.1)	1 (0.5)
抑うつ気分	0	0	0	2 (2.1)	1 (1.1)	3 (1.6)
うつ病	0	1 (33.3)	1 (5.0)	3 (3.2)	1 (1.1)	4 (2.2)
ドーパミン調節障害症候群	0	0	0	1 (1.1)	0	1 (0.5)
ディスフェミア	0	0	0	0	1 (1.1)	1 (0.5)
睡眠異常	0	0	0	1 (1.1)	0	1 (0.5)
情動障害	0	0	0	1 (1.1)	0	1 (0.5)
注射恐怖	0	0	0	0	1 (1.1)	1 (0.5)
幻覚	5 (29.4)	0	5 (25.0)	7 (7.4)	19 (20.7)	26 (14.0)
幻聴	0	0	0	3 (3.2)	2 (2.2)	5 (2.7)
幻嗅	0	0	0	0	1 (1.1)	1 (0.5)
幻視	1 (5.9)	0	1 (5.0)	5 (5.3)	4 (4.3)	9 (4.8)
混合性幻覚	0	0	0	1 (1.1)	0	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
精神障害 (Cont.)						
性欲過剰	0	0	0	1 (1.1)	0	1 (0.5)
錯覚	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
衝動制御障害	0	0	0	0	4 (4.3)	4 (2.2)
衝動行為	0	0	0	0	1 (1.1)	1 (0.5)
不眠症	1 (5.9)	0	1 (5.0)	1 (1.1)	6 (6.5)	7 (3.8)
易刺激性	0	0	0	0	1 (1.1)	1 (0.5)
躁病	0	0	0	0	1 (1.1)	1 (0.5)
気分動揺	0	0	0	0	1 (1.1)	1 (0.5)
悪夢	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
パニック発作	0	0	0	0	1 (1.1)	1 (0.5)
パニック反応	0	0	0	0	1 (1.1)	1 (0.5)
妄想症	0	0	0	2 (2.1)	0	2 (1.1)
睡眠の質低下	0	0	0	1 (1.1)	0	1 (0.5)
処置に対する不安	0	0	0	0	1 (1.1)	1 (0.5)
精神病性障害	0	0	0	3 (3.2)	2 (2.2)	5 (2.7)
精神病症状	0	0	0	1 (1.1)	0	1 (0.5)
レム睡眠行動障害	0	0	0	0	1 (1.1)	1 (0.5)
レム睡眠異常	1 (5.9)	0	1 (5.0)	0	0	0
睡眠障害	0	0	0	2 (2.1)	0	2 (1.1)
ねごと	0	0	0	1 (1.1)	0	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
精神障害 (Cont.)						
常同症	0	0	0	0	1 (1.1)	1 (0.5)
ストレス	0	0	0	0	1 (1.1)	1 (0.5)
自殺念慮	0	0	0	1 (1.1)	2 (2.2)	3 (1.6)
自殺企図	0	0	0	1 (1.1)	0	1 (0.5)
腎および尿路障害	1 (5.9)	0	1 (5.0)	6 (6.4)	7 (7.6)	13 (7.0)
膀胱痙縮	0	0	0	1 (1.1)	0	1 (0.5)
膀胱結石	1 (5.9)	0	1 (5.0)	0	0	0
尿路結石	0	0	0	1 (1.1)	0	1 (0.5)
排尿困難	0	0	0	0	1 (1.1)	1 (0.5)
緊張性膀胱	0	0	0	1 (1.1)	0	1 (0.5)
夜間頻尿	0	0	0	0	1 (1.1)	1 (0.5)
頻尿	0	0	0	1 (1.1)	0	1 (0.5)
多尿	0	0	0	0	1 (1.1)	1 (0.5)
腎機能障害	0	0	0	0	1 (1.1)	1 (0.5)
尿管結石症	0	0	0	0	1 (1.1)	1 (0.5)
切迫性尿失禁	0	0	0	1 (1.1)	0	1 (0.5)
尿失禁	0	0	0	1 (1.1)	2 (2.2)	3 (1.6)
尿閉	0	0	0	0	3 (3.3)	3 (1.6)
尿臭異常	0	0	0	0	1 (1.1)	1 (0.5)

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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
生殖系および乳房障害	1 (5.9)	0	1 (5.0)	1 (1.1)	4 (4.3)	5 (2.7)
良性前立腺肥大症	1 (5.9)	0	1 (5.0)	0	0	0
勃起不全	0	0	0	1 (1.1)	0	1 (0.5)
骨盤痛	0	0	0	0	1 (1.1)	1 (0.5)
ペイロニー病	0	0	0	0	1 (1.1)	1 (0.5)
閉経後出血	0	0	0	0	1 (1.1)	1 (0.5)
前立腺腫大	0	0	0	0	1 (1.1)	1 (0.5)
腟脱	0	0	0	0	1 (1.1)	1 (0.5)
呼吸器、胸郭および縦隔障害	0	0	0	6 (6.4)	13 (14.1)	19 (10.2)
気管支拡張症	0	0	0	1 (1.1)	0	1 (0.5)
咳嗽	0	0	0	0	1 (1.1)	1 (0.5)
発声障害	0	0	0	0	2 (2.2)	2 (1.1)
呼吸困難	0	0	0	2 (2.1)	5 (5.4)	7 (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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
呼吸器、胸郭および縦隔障害 (Cont.)						
労作性呼吸困難	0	0	0	1 (1.1)	0	1 (0.5)
鼻出血	0	0	0	0	1 (1.1)	1 (0.5)
過換気	0	0	0	0	1 (1.1)	1 (0.5)
口腔咽頭痛	0	0	0	1 (1.1)	0	1 (0.5)
誤嚥性肺炎	0	0	0	0	1 (1.1)	1 (0.5)
湿性咳嗽	0	0	0	0	1 (1.1)	1 (0.5)
肺塞栓症	0	0	0	0	2 (2.2)	2 (1.1)
ラ音	0	0	0	0	1 (1.1)	1 (0.5)
呼吸窮迫	0	0	0	1 (1.1)	0	1 (0.5)
鼻漏	0	0	0	0	1 (1.1)	1 (0.5)
咽喉刺激感	0	0	0	0	1 (1.1)	1 (0.5)
皮膚および皮下組織障害	4 (23.5)	1 (33.3)	5 (25.0)	6 (6.4)	11 (12.0)	17 (9.1)
脱毛症	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
褥瘡性潰瘍	0	0	0	0	1 (1.1)	1 (0.5)
皮膚嚢腫	1 (5.9)	0	1 (5.0)	0	1 (1.1)	1 (0.5)
皮膚炎	0	0	0	0	1 (1.1)	1 (0.5)
接触皮膚炎	0	0	0	1 (1.1)	0	1 (0.5)
おむつ皮膚炎	1 (5.9)	0	1 (5.0)	0	0	0
薬疹	0	0	0	1 (1.1)	0	1 (0.5)
皮膚乾燥	1 (5.9)	0	1 (5.0)	0	0	0
紅斑	0	0	0	1 (1.1)	2 (2.2)	3 (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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
皮膚および皮下組織障害 (Cont.)						
爪の障害	0	0	0	1 (1.1)	0	1 (0.5)
脂肪織炎	0	0	0	0	1 (1.1)	1 (0.5)
丘疹	0	0	0	0	2 (2.2)	2 (1.1)
口囲皮膚炎	0	0	0	0	1 (1.1)	1 (0.5)
そう痒症	0	1 (33.3)	1 (5.0)	2 (2.1)	1 (1.1)	3 (1.6)
乾癬	0	0	0	0	1 (1.1)	1 (0.5)
発疹	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
紅斑性皮疹	0	0	0	0	1 (1.1)	1 (0.5)
そう痒性皮疹	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
皮膚潰瘍	0	0	0	0	1 (1.1)	1 (0.5)
蕁麻疹	1 (5.9)	0	1 (5.0)	1 (1.1)	0	1 (0.5)
外科および内科処置	0	1 (33.3)	1 (5.0)	0	0	0
抜歯	0	1 (33.3)	1 (5.0)	0	0	0
血管障害	0	0	0	11 (11.7)	9 (9.8)	20 (10.8)
深部静脈血栓症	0	0	0	0	1 (1.1)	1 (0.5)
血腫	0	0	0	0	1 (1.1)	1 (0.5)
出血	0	0	0	0	1 (1.1)	1 (0.5)
高血圧	0	0	0	1 (1.1)	2 (2.2)	3 (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__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
血管障害 (Cont.)						
高血圧クリーゼ	0	0	0	1 (1.1)	0	1 (0.5)
低血圧	0	0	0	2 (2.1)	2 (2.2)	4 (2.2)
起立性高血圧	0	0	0	0	1 (1.1)	1 (0.5)
起立性低血圧	0	0	0	7 (7.4)	3 (3.3)	10 (5.4)

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

Program Source Code: [redacted]

表44　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）：M15-741試験

[redacted]20[redacted] 10:57 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - 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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period	N=22	N=5	N=27
Any adverse event	20 (90.9)	5 (100)	25 (92.6)
Reasonable possibility	20 (90.9)	5 (100)	25 (92.6)
耳および迷路障害	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
感音性難聴	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
眼障害	1 (4.5)	1 (20.0)	2 (7.4)
No reasonable possibility	1 (4.5)	1 (20.0)	2 (7.4)
白内障	1 (4.5)	1 (20.0)	2 (7.4)
No reasonable possibility	1 (4.5)	1 (20.0)	2 (7.4)

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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
眼障害 (Cont.)			
ドライアイ	0	1 (20.0)	1 (3.7)
No reasonable possibility	0	1 (20.0)	1 (3.7)
胃腸障害	6 (27.3)	1 (20.0)	7 (25.9)
No reasonable possibility	5 (22.7)	1 (20.0)	6 (22.2)
Reasonable possibility	1 (4.5)	0	1 (3.7)
上腹部痛	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
便秘	2 (9.1)	0	2 (7.4)
No reasonable possibility	2 (9.1)	0	2 (7.4)
齲歯	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
胃腸障害 (Cont.)			
下痢	3 (13.6)	1 (20.0)	4 (14.8)
No reasonable possibility	3 (13.6)	1 (20.0)	4 (14.8)
口唇乾燥	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
メレナ	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
悪心	2 (9.1)	0	2 (7.4)
No reasonable possibility	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
一般・全身障害および投与部位の状態	17 (77.3)	3 (60.0)	20 (74.1)
No reasonable possibility	2 (9.1)	0	2 (7.4)
Reasonable possibility	15 (68.2)	3 (60.0)	18 (66.7)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
一般・全身障害および投与部位の状態 (Cont.)			
投与部位紅斑	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
注入部位内出血	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
注入部位皮膚炎	2 (9.1)	0	2 (7.4)
Reasonable possibility	2 (9.1)	0	2 (7.4)
注入部位紅斑	7 (31.8)	3 (60.0)	10 (37.0)
No reasonable possibility	1 (4.5)	0	1 (3.7)
Reasonable possibility	6 (27.3)	3 (60.0)	9 (33.3)
注入部位硬結	4 (18.2)	1 (20.0)	5 (18.5)
Reasonable possibility	4 (18.2)	1 (20.0)	5 (18.5)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
一般・全身障害および投与部位の状態 (Cont.)			
注入部位腫瘤	2 (9.1)	1 (20.0)	3 (11.1)
Reasonable possibility	2 (9.1)	1 (20.0)	3 (11.1)
注入部位疼痛	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
注入部位発疹	1 (4.5)	1 (20.0)	2 (7.4)
No reasonable possibility	0	1 (20.0)	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
注入部位腫脹	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
注射部位紅斑	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
一般・全身障害および投与部位の状態 (Cont.)			
注射部位腫脹	1 (4.5)	1 (20.0)	2 (7.4)
Reasonable possibility	1 (4.5)	1 (20.0)	2 (7.4)
限局性浮腫	0	1 (20.0)	1 (3.7)
Reasonable possibility	0	1 (20.0)	1 (3.7)
末梢性浮腫	1 (4.5)	1 (20.0)	2 (7.4)
No reasonable possibility	1 (4.5)	0	1 (3.7)
Reasonable possibility	0	1 (20.0)	1 (3.7)
穿刺部位内出血	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
穿刺部位硬結	2 (9.1)	0	2 (7.4)
Reasonable possibility	2 (9.1)	0	2 (7.4)

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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
一般・全身障害および投与部位の状態 (Cont.)			
発熱	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
口渇	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
血管穿刺部位硬結	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
感染症および寄生虫症	5 (22.7)	2 (40.0)	7 (25.9)
No reasonable possibility	2 (9.1)	1 (20.0)	3 (11.1)
Reasonable possibility	3 (13.6)	1 (20.0)	4 (14.8)
蜂巣炎	0	1 (20.0)	1 (3.7)
No reasonable possibility	0	1 (20.0)	1 (3.7)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
感染症および寄生虫症 (Cont.)			
結膜炎	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
爪の皮膚糸状菌症	0	1 (20.0)	1 (3.7)
No reasonable possibility	0	1 (20.0)	1 (3.7)
麦粒腫	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
注入部位蜂巣炎	3 (13.6)	1 (20.0)	4 (14.8)
Reasonable possibility	3 (13.6)	1 (20.0)	4 (14.8)
上咽頭炎	0	1 (20.0)	1 (3.7)
No reasonable possibility	0	1 (20.0)	1 (3.7)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
感染症および寄生虫症 (Cont.)			
術後膿瘍	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
傷害、中毒および処置合併症	6 (27.3)	2 (40.0)	8 (29.6)
No reasonable possibility	5 (22.7)	2 (40.0)	7 (25.9)
Reasonable possibility	1 (4.5)	0	1 (3.7)
脳挫傷	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
挫傷	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
転倒	6 (27.3)	2 (40.0)	8 (29.6)
No reasonable possibility	5 (22.7)	2 (40.0)	7 (25.9)
Reasonable possibility	1 (4.5)	0	1 (3.7)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
傷害、中毒および処置合併症 (Cont.)			
頭部損傷	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
靱帯捻挫	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
肋骨骨折	1 (4.5)	1 (20.0)	2 (7.4)
No reasonable possibility	1 (4.5)	1 (20.0)	2 (7.4)
皮膚損傷	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
臨床検査	3 (13.6)	0	3 (11.1)
No reasonable possibility	1 (4.5)	0	1 (3.7)
Reasonable possibility	2 (9.1)	0	2 (7.4)

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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
臨床検査 (Cont.)			
血中クレアチンホスホキナーゼ増加	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
血中ホモシステイン増加	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
体重減少	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
代謝および栄養障害	2 (9.1)	1 (20.0)	3 (11.1)
No reasonable possibility	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	1 (20.0)	2 (7.4)
低ナトリウム血症	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
代謝および栄養障害 (Cont.)			
ビタミンB12欠乏	0	1 (20.0)	1 (3.7)
Reasonable possibility	0	1 (20.0)	1 (3.7)
ビタミンB6欠乏	1 (4.5)	1 (20.0)	2 (7.4)
Reasonable possibility	1 (4.5)	1 (20.0)	2 (7.4)
筋骨格系および結合組織障害	5 (22.7)	1 (20.0)	6 (22.2)
No reasonable possibility	4 (18.2)	1 (20.0)	5 (18.5)
Reasonable possibility	1 (4.5)	0	1 (3.7)
関節痛	0	1 (20.0)	1 (3.7)
No reasonable possibility	0	1 (20.0)	1 (3.7)
背部痛	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
筋骨格系および結合組織障害 (Cont.)			
筋肉痛	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
四肢痛	2 (9.1)	0	2 (7.4)
No reasonable possibility	2 (9.1)	0	2 (7.4)
横紋筋融解症	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
弾発指	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
神経系障害	10 (45.5)	2 (40.0)	12 (44.4)
No reasonable possibility	4 (18.2)	0	4 (14.8)
Reasonable possibility	6 (27.3)	2 (40.0)	8 (29.6)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
神経系障害 (Cont.)			
運動失調	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
浮動性めまい	2 (9.1)	1 (20.0)	3 (11.1)
Reasonable possibility	2 (9.1)	1 (20.0)	3 (11.1)
頭痛	2 (9.1)	0	2 (7.4)
No reasonable possibility	2 (9.1)	0	2 (7.4)
意識消失	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
パーキンソン病	4 (18.2)	0	4 (14.8)
No reasonable possibility	2 (9.1)	0	2 (7.4)
Reasonable possibility	2 (9.1)	0	2 (7.4)

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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
神経系障害 (Cont.)			
パーキンソニズム	0	1 (20.0)	1 (3.7)
Reasonable possibility	0	1 (20.0)	1 (3.7)
側反弓	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
精神障害	11 (50.0)	3 (60.0)	14 (51.9)
No reasonable possibility	1 (4.5)	2 (40.0)	3 (11.1)
Reasonable possibility	10 (45.5)	1 (20.0)	11 (40.7)
不安障害	0	1 (20.0)	1 (3.7)
No reasonable possibility	0	1 (20.0)	1 (3.7)
妄想	5 (22.7)	0	5 (18.5)
Reasonable possibility	5 (22.7)	0	5 (18.5)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
精神障害 (Cont.)			
うつ病	0	1 (20.0)	1 (3.7)
No reasonable possibility	0	1 (20.0)	1 (3.7)
抑うつ症状	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
幻覚	8 (36.4)	1 (20.0)	9 (33.3)
Reasonable possibility	8 (36.4)	1 (20.0)	9 (33.3)
幻視	1 (4.5)	1 (20.0)	2 (7.4)
No reasonable possibility	0	1 (20.0)	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
不眠症	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
精神障害 (Cont.)			
嫉妬妄想	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
レム睡眠異常	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
腎および尿路障害	2 (9.1)	0	2 (7.4)
No reasonable possibility	2 (9.1)	0	2 (7.4)
膀胱結石	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
尿失禁	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
生殖系および乳房障害	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
良性前立腺肥大症	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
皮膚および皮下組織障害	4 (18.2)	1 (20.0)	5 (18.5)
No reasonable possibility	2 (9.1)	1 (20.0)	3 (11.1)
Reasonable possibility	2 (9.1)	0	2 (7.4)
皮膚嚢腫	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
おむつ皮膚炎	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
皮膚および皮下組織障害 (Cont.)			
皮膚乾燥	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
そう痒症	0	1 (20.0)	1 (3.7)
No reasonable possibility	0	1 (20.0)	1 (3.7)
発疹	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
蕁麻疹	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
外科および内科処置	0	1 (20.0)	1 (3.7)
No reasonable possibility	0	1 (20.0)	1 (3.7)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
外科および内科処置 (Cont.)			
抜歯	0	1 (20.0)	1 (3.7)
No reasonable possibility	0	1 (20.0)	1 (3.7)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period	N=22	N=5	N=27
Any adverse event	15 (68.2)	4 (80.0)	19 (70.4)
Reasonable possibility	15 (68.2)	4 (80.0)	19 (70.4)
胃腸障害	2 (9.1)	0	2 (7.4)
No reasonable possibility	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
下痢	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
悪心	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
一般・全身障害および投与部位の状態	12 (54.5)	2 (40.0)	14 (51.9)
No reasonable possibility	2 (9.1)	0	2 (7.4)
Reasonable possibility	10 (45.5)	2 (40.0)	12 (44.4)

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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27
一般・全身障害および投与部位の状態 (Cont.)			
投与部位紅斑	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
注入部位紅斑	5 (22.7)	2 (40.0)	7 (25.9)
Reasonable possibility	5 (22.7)	2 (40.0)	7 (25.9)
注入部位硬結	3 (13.6)	0	3 (11.1)
Reasonable possibility	3 (13.6)	0	3 (11.1)
注入部位腫瘤	2 (9.1)	0	2 (7.4)
Reasonable possibility	2 (9.1)	0	2 (7.4)
注入部位疼痛	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27
一般・全身障害および投与部位の状態 (Cont.)			
注入部位発疹	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
注射部位紅斑	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
限局性浮腫	0	1 (20.0)	1 (3.7)
Reasonable possibility	0	1 (20.0)	1 (3.7)
末梢性浮腫	0	1 (20.0)	1 (3.7)
Reasonable possibility	0	1 (20.0)	1 (3.7)
穿刺部位内出血	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27
一般・全身障害および投与部位の状態 (Cont.)			
穿刺部位硬結	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
発熱	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
口渇	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
傷害、中毒および処置合併症	2 (9.1)	1 (20.0)	3 (11.1)
No reasonable possibility	2 (9.1)	1 (20.0)	3 (11.1)
転倒	2 (9.1)	1 (20.0)	3 (11.1)
No reasonable possibility	2 (9.1)	1 (20.0)	3 (11.1)

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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27
筋骨格系および結合組織障害	2 (9.1)	0	2 (7.4)
No reasonable possibility	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
筋肉痛	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
横紋筋融解症	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
神経系障害	6 (27.3)	1 (20.0)	7 (25.9)
No reasonable possibility	1 (4.5)	0	1 (3.7)
Reasonable possibility	5 (22.7)	1 (20.0)	6 (22.2)
運動失調	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27
神経系障害 (Cont.)			
浮動性めまい	2 (9.1)	0	2 (7.4)
Reasonable possibility	2 (9.1)	0	2 (7.4)
頭痛	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
パーキンソン病	2 (9.1)	0	2 (7.4)
Reasonable possibility	2 (9.1)	0	2 (7.4)
パーキンソニズム	0	1 (20.0)	1 (3.7)
Reasonable possibility	0	1 (20.0)	1 (3.7)
精神障害	7 (31.8)	2 (40.0)	9 (33.3)
No reasonable possibility	1 (4.5)	1 (20.0)	2 (7.4)
Reasonable possibility	6 (27.3)	1 (20.0)	7 (25.9)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27
精神障害 (Cont.)			
妄想	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
抑うつ症状	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
幻覚	5 (22.7)	1 (20.0)	6 (22.2)
Reasonable possibility	5 (22.7)	1 (20.0)	6 (22.2)
幻視	0	1 (20.0)	1 (3.7)
No reasonable possibility	0	1 (20.0)	1 (3.7)
嫉妬妄想	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27
腎および尿路障害	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
尿失禁	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
皮膚および皮下組織障害	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
発疹	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period	N=17	N=3	N=20
Any adverse event	15 (88.2)	3 (100)	18 (90.0)
No reasonable possibility	0	1 (33.3)	1 (5.0)
Reasonable possibility	15 (88.2)	2 (66.7)	17 (85.0)
耳および迷路障害	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
感音性難聴	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
眼障害	1 (5.9)	1 (33.3)	2 (10.0)
No reasonable possibility	1 (5.9)	1 (33.3)	2 (10.0)
白内障	1 (5.9)	1 (33.3)	2 (10.0)
No reasonable possibility	1 (5.9)	1 (33.3)	2 (10.0)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20
眼障害 (Cont.)			
ドライアイ	0	1 (33.3)	1 (5.0)
No reasonable possibility	0	1 (33.3)	1 (5.0)
胃腸障害	6 (35.3)	1 (33.3)	7 (35.0)
No reasonable possibility	5 (29.4)	1 (33.3)	6 (30.0)
Reasonable possibility	1 (5.9)	0	1 (5.0)
上腹部痛	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
便秘	2 (11.8)	0	2 (10.0)
No reasonable possibility	2 (11.8)	0	2 (10.0)
齲歯	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20
胃腸障害 (Cont.)			
下痢	2 (11.8)	1 (33.3)	3 (15.0)
No reasonable possibility	2 (11.8)	1 (33.3)	3 (15.0)
口唇乾燥	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
メレナ	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
悪心	2 (11.8)	0	2 (10.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
Reasonable possibility	1 (5.9)	0	1 (5.0)
一般・全身障害および投与部位の状態	11 (64.7)	3 (100)	14 (70.0)
No reasonable possibility	1 (5.9)	1 (33.3)	2 (10.0)
Reasonable possibility	10 (58.8)	2 (66.7)	12 (60.0)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20
一般・全身障害および投与部位の状態 (Cont.)			
注入部位内出血	1 (5.9)	0	1 (5.0)
Reasonable possibility	1 (5.9)	0	1 (5.0)
注入部位皮膚炎	2 (11.8)	0	2 (10.0)
Reasonable possibility	2 (11.8)	0	2 (10.0)
注入部位紅斑	4 (23.5)	1 (33.3)	5 (25.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
Reasonable possibility	3 (17.6)	1 (33.3)	4 (20.0)
注入部位硬結	3 (17.6)	1 (33.3)	4 (20.0)
Reasonable possibility	3 (17.6)	1 (33.3)	4 (20.0)
注入部位腫瘤	0	1 (33.3)	1 (5.0)
Reasonable possibility	0	1 (33.3)	1 (5.0)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20
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 (33.3)	1 (5.0)
No reasonable possibility	0	1 (33.3)	1 (5.0)
注入部位腫脹	1 (5.9)	0	1 (5.0)
Reasonable possibility	1 (5.9)	0	1 (5.0)
注射部位紅斑	1 (5.9)	0	1 (5.0)
Reasonable possibility	1 (5.9)	0	1 (5.0)
注射部位腫脹	1 (5.9)	1 (33.3)	2 (10.0)
Reasonable possibility	1 (5.9)	1 (33.3)	2 (10.0)
末梢性浮腫	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20
一般・全身障害および投与部位の状態 (Cont.)			
穿刺部位硬結	2 (11.8)	0	2 (10.0)
Reasonable possibility	2 (11.8)	0	2 (10.0)
血管穿刺部位硬結	1 (5.9)	0	1 (5.0)
Reasonable possibility	1 (5.9)	0	1 (5.0)
感染症および寄生虫症	5 (29.4)	2 (66.7)	7 (35.0)
No reasonable possibility	2 (11.8)	1 (33.3)	3 (15.0)
Reasonable possibility	3 (17.6)	1 (33.3)	4 (20.0)
蜂巣炎	0	1 (33.3)	1 (5.0)
No reasonable possibility	0	1 (33.3)	1 (5.0)
結膜炎	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20
感染症および寄生虫症 (Cont.)			
爪の皮膚糸状菌症	0	1 (33.3)	1 (5.0)
No reasonable possibility	0	1 (33.3)	1 (5.0)
麦粒腫	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
注入部位蜂巣炎	3 (17.6)	1 (33.3)	4 (20.0)
Reasonable possibility	3 (17.6)	1 (33.3)	4 (20.0)
上咽頭炎	0	1 (33.3)	1 (5.0)
No reasonable possibility	0	1 (33.3)	1 (5.0)
術後膿瘍	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20
傷害、中毒および処置合併症	5 (29.4)	1 (33.3)	6 (30.0)
No reasonable possibility	4 (23.5)	1 (33.3)	5 (25.0)
Reasonable possibility	1 (5.9)	0	1 (5.0)
脳挫傷	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
挫傷	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
転倒	5 (29.4)	1 (33.3)	6 (30.0)
No reasonable possibility	4 (23.5)	1 (33.3)	5 (25.0)
Reasonable possibility	1 (5.9)	0	1 (5.0)
頭部損傷	1 (5.9)	0	1 (5.0)
Reasonable possibility	1 (5.9)	0	1 (5.0)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20
傷害、中毒および処置合併症 (Cont.)			
靭帯捻挫	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
肋骨骨折	1 (5.9)	1 (33.3)	2 (10.0)
No reasonable possibility	1 (5.9)	1 (33.3)	2 (10.0)
皮膚損傷	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
臨床検査	3 (17.6)	0	3 (15.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
Reasonable possibility	2 (11.8)	0	2 (10.0)
血中クレアチンホスホキナーゼ増加	1 (5.9)	0	1 (5.0)
Reasonable possibility	1 (5.9)	0	1 (5.0)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20
臨床検査 (Cont.)			
血中ホモシステイン増加	1 (5.9)	0	1 (5.0)
Reasonable possibility	1 (5.9)	0	1 (5.0)
体重減少	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
代謝および栄養障害	2 (11.8)	1 (33.3)	3 (15.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
Reasonable possibility	1 (5.9)	1 (33.3)	2 (10.0)
低ナトリウム血症	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
ビタミンB12欠乏	0	1 (33.3)	1 (5.0)
Reasonable possibility	0	1 (33.3)	1 (5.0)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20
代謝および栄養障害 (Cont.)			
ビタミンB6欠乏	1 (5.9)	1 (33.3)	2 (10.0)
Reasonable possibility	1 (5.9)	1 (33.3)	2 (10.0)
筋骨格系および結合組織障害	4 (23.5)	1 (33.3)	5 (25.0)
No reasonable possibility	4 (23.5)	1 (33.3)	5 (25.0)
関節痛	0	1 (33.3)	1 (5.0)
No reasonable possibility	0	1 (33.3)	1 (5.0)
背部痛	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
四肢痛	2 (11.8)	0	2 (10.0)
No reasonable possibility	2 (11.8)	0	2 (10.0)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20
筋骨格系および結合組織障害 (Cont.)			
弾発指	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
神経系障害	5 (29.4)	1 (33.3)	6 (30.0)
No reasonable possibility	4 (23.5)	0	4 (20.0)
Reasonable possibility	1 (5.9)	1 (33.3)	2 (10.0)
浮動性めまい	0	1 (33.3)	1 (5.0)
Reasonable possibility	0	1 (33.3)	1 (5.0)
頭痛	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
意識消失	1 (5.9)	0	1 (5.0)
Reasonable possibility	1 (5.9)	0	1 (5.0)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20
神経系障害 (Cont.)			
パーキンソン病	2 (11.8)	0	2 (10.0)
No reasonable possibility	2 (11.8)	0	2 (10.0)
側反弓	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
精神障害	8 (47.1)	1 (33.3)	9 (45.0)
No reasonable possibility	0	1 (33.3)	1 (5.0)
Reasonable possibility	8 (47.1)	0	8 (40.0)
不安障害	0	1 (33.3)	1 (5.0)
No reasonable possibility	0	1 (33.3)	1 (5.0)
妄想	4 (23.5)	0	4 (20.0)
Reasonable possibility	4 (23.5)	0	4 (20.0)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20
精神障害 (Cont.)			
うつ病	0	1 (33.3)	1 (5.0)
No reasonable possibility	0	1 (33.3)	1 (5.0)
幻覚	5 (29.4)	0	5 (25.0)
Reasonable possibility	5 (29.4)	0	5 (25.0)
幻視	1 (5.9)	0	1 (5.0)
Reasonable possibility	1 (5.9)	0	1 (5.0)
不眠症	1 (5.9)	0	1 (5.0)
Reasonable possibility	1 (5.9)	0	1 (5.0)
レム睡眠異常	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20
腎および尿路障害	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
膀胱結石	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
生殖系および乳房障害	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
良性前立腺肥大症	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
皮膚および皮下組織障害	4 (23.5)	1 (33.3)	5 (25.0)
No reasonable possibility	2 (11.8)	1 (33.3)	3 (15.0)
Reasonable possibility	2 (11.8)	0	2 (10.0)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20
皮膚および皮下組織障害 (Cont.)			
皮膚嚢腫	1 (5.9)	0	1 (5.0)
Reasonable possibility	1 (5.9)	0	1 (5.0)
おむつ皮膚炎	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
皮膚乾燥	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
そう痒症	0	1 (33.3)	1 (5.0)
No reasonable possibility	0	1 (33.3)	1 (5.0)
蕁麻疹	1 (5.9)	0	1 (5.0)
Reasonable possibility	1 (5.9)	0	1 (5.0)

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.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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20
外科および内科処置	0	1 (33.3)	1 (5.0)
No reasonable possibility	0	1 (33.3)	1 (5.0)
抜歯	0	1 (33.3)	1 (5.0)
No reasonable possibility	0	1 (33.3)	1 (5.0)

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45　重篤な有害事象（安全性解析対象集団，日本人部分集団）：M15-741試験

[redacted]20[redacted] 10:56 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - CLINICAL/STATISTICAL

TABLE 14.3 1.11.1.J

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period	N=22	N=5	N=27
Any adverse event	6 (27.3)	1 (20.0)	7 (25.9)
感染症および寄生虫症	0	1 (20.0)	1 (3.7)
蜂巣炎	0	1 (20.0)	1 (3.7)
筋骨格系および結合組織障害	1 (4.5)	0	1 (3.7)
横紋筋融解症	1 (4.5)	0	1 (3.7)
神経系障害	4 (18.2)	0	4 (14.8)
意識消失	1 (4.5)	0	1 (3.7)
パーキンソン病	3 (13.6)	0	3 (11.1)
精神障害	3 (13.6)	0	3 (11.1)
妄想	1 (4.5)	0	1 (3.7)
幻覚	3 (13.6)	0	3 (11.1)

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__1.11.1.J

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period	N=22	N=5	N=27
Any adverse event	4 (18.2)	0	4 (14.8)
筋骨格系および結合組織障害	1 (4.5)	0	1 (3.7)
横紋筋融解症	1 (4.5)	0	1 (3.7)
神経系障害	2 (9.1)	0	2 (7.4)
パーキンソン病	2 (9.1)	0	2 (7.4)
精神障害	3 (13.6)	0	3 (11.1)
妄想	1 (4.5)	0	1 (3.7)
幻覚	3 (13.6)	0	3 (11.1)

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__1.11.1.J

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period	N=17	N=3	N=20
Any adverse event	2 (11.8)	1 (33.3)	3 (15.0)
感染症および寄生虫症	0	1 (33.3)	1 (5.0)
蜂巣炎	0	1 (33.3)	1 (5.0)
神経系障害	2 (11.8)	0	2 (10.0)
意識消失	1 (5.9)	0	1 (5.0)
パーキンソン病	1 (5.9)	0	1 (5.0)

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

Program Source Code: [redacted]

表46　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）：M15-741試験

[redacted]20[redacted] 10:56 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - 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 by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period	N=22	N=5	N=27
Any adverse event	6 (27.3)	1 (20.0)	7 (25.9)
一般・全身障害および投与部位の状態	2 (9.1)	0	2 (7.4)
注入部位腫瘤	1 (4.5)	0	1 (3.7)
注入部位発疹	1 (4.5)	0	1 (3.7)
筋骨格系および結合組織障害	1 (4.5)	0	1 (3.7)
横紋筋融解症	1 (4.5)	0	1 (3.7)
神経系障害	2 (9.1)	1 (20.0)	3 (11.1)
パーキンソン病	2 (9.1)	0	2 (7.4)
パーキンソニズム	0	1 (20.0)	1 (3.7)
精神障害	2 (9.1)	0	2 (7.4)
幻覚	1 (4.5)	0	1 (3.7)
幻視	1 (4.5)	0	1 (3.7)
皮膚および皮下組織障害	1 (4.5)	0	1 (3.7)
蕁麻疹	1 (4.5)	0	1 (3.7)

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__1.8.1.J

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period	N=22	N=5	N=27
Any adverse event	4 (18.2)	1 (20.0)	5 (18.5)
一般・全身障害および投与部位の状態	2 (9.1)	0	2 (7.4)
注入部位腫瘤	1 (4.5)	0	1 (3.7)
注入部位発疹	1 (4.5)	0	1 (3.7)
筋骨格系および結合組織障害	1 (4.5)	0	1 (3.7)
横紋筋融解症	1 (4.5)	0	1 (3.7)
神経系障害	2 (9.1)	1 (20.0)	3 (11.1)
パーキンソン病	2 (9.1)	0	2 (7.4)
パーキンソニズム	0	1 (20.0)	1 (3.7)
精神障害	1 (4.5)	0	1 (3.7)
幻覚	1 (4.5)	0	1 (3.7)

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__1.8.1.J

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period	N=17	N=3	N=20
Any adverse event	2 (11.8)	0	2 (10.0)
精神障害	1 (5.9)	0	1 (5.0)
幻視	1 (5.9)	0	1 (5.0)
皮膚および皮下組織障害	1 (5.9)	0	1 (5.0)
蕁麻疹	1 (5.9)	0	1 (5.0)

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
注入部位蜂巣炎				X
注入部位紅斑				X
耳下腺膿瘍	X			

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

Medical History	Onset Year
STROKE	19[redacted]
ASTHMA	19[redacted]
DEPRESSION	20[redacted]
HYPERTENSION	20[redacted]
SLEEP APNEA	20[redacted]
VITAMIN D DEFICIENCY	20[redacted]
OVERACTIVE BLADDER	20[redacted]
MRSA INFECTION RIGHT ELBOW	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
ONSET OF MOTOR FLUCTUATION	19[redacted]
PARKINSON'S DISEASE	19[redacted]
PARKINSON'S DISEASE DIAGNOSIS	19[redacted]

Prior Procedures	Procedure Year
VASECTOMY	19[redacted]
TONSILLECTOMY	19[redacted]
DEEP BRAIN STIMULATION	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	0.2	0.27	0.17	60	0.19	[redacted]/1
ABBV-951	0.2	0.27	0.17	60	0.19	[redacted]/2
ABBV-951	0.23	0.27	0.2	60	0.24	[redacted]/7
ABBV-951	0.3	0.33	0.27	60	0.24	[redacted]/14
ABBV-951	0.3	0.33	0.27	60	0.24	[redacted]/20
ABBV-951	0.37	0.4	0.33	60	0.24	[redacted]/28
ABBV-951	0.4	0.43	0.37	60	0.24	[redacted]/42
ABBV-951	0.43	0.47	0.4	60	0.24	[redacted]/64
ABBV-951	0.43	0.47	0.4	60	0.24	[redacted]/92
ABBV-951	0.47	0.5	0.43	60	0.24	[redacted]/168
ABBV-951	0.53	0.57	0.5	60	0.24	[redacted]/272
ABBV-951	0.53	0.57	0.5	60	0.24	[redacted]/366

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	443.95		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951		32.44	SC / ONCE	[redacted] / 2	
ABBV-951	816.18		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951		97.32	SC / ONCE	[redacted] / 3	
ABBV-951	802.52		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951		227.09	SC / ONCE	[redacted] / 4	
ABBV-951	802.52		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951		227.09	SC / ONCE	[redacted] / 5	
ABBV-951	809.35		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951		194.65	SC / ONCE	[redacted] / 6	
ABBV-951	809.35		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6

ABBV-951		286.86	SC / ONCE	[redacted]20[redacted] / 7	
ABBV-951	879.19		SC / CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 7
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 8	
ABBV-951	1042.94		SC / CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 8
ABBV-951		245.88	SC / ONCE	[redacted]20[redacted] / 9	
ABBV-951	1097.23		SC / CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 9
ABBV-951		368.82	SC / ONCE	[redacted]20[redacted] / 10	
ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 10
ABBV-951		327.84	SC / ONCE	[redacted]20[redacted] / 11	
ABBV-951	1101.84		SC / CONTINUOUS	[redacted]20[redacted] / 11	[redacted]20[redacted] / 11
ABBV-951		450.78	SC / ONCE	[redacted]20[redacted] / 12	
ABBV-951	1055.74		SC / CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
ABBV-951		286.86	SC / ONCE	[redacted]20[redacted] / 13	
ABBV-951	1074.18		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951		204.9	SC / ONCE	[redacted]20[redacted] / 14	
ABBV-951	1250.40		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951		204.9	SC / ONCE	[redacted]20[redacted] / 15	
ABBV-951	1227.86		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 16	
ABBV-951	459.48		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951	321.18		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 21	
ABBV-951	1324.16		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951		122.94	SC / ONCE	[redacted]20[redacted] / 22	
ABBV-951	1318.53		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951		163.92	SC / ONCE	[redacted]20[redacted] / 23	
ABBV-951	1312.89		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951		163.92	SC / ONCE	[redacted]20[redacted] / 24	
ABBV-951	1324.16		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951		204.9	SC / ONCE	[redacted]20[redacted] / 25	
ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951		286.86	SC / ONCE	[redacted]20[redacted] / 26	
ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951		204.9	SC / ONCE	[redacted]20[redacted] / 27	
ABBV-951	1312.89		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951		327.84	SC / ONCE	[redacted]20[redacted] / 28	
ABBV-951	1366.51		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28

ABBV-951		245.88	SC / ONCE	[redacted]20[redacted] / 29	
ABBV-951	1459.40		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951		286.86	SC / ONCE	[redacted]20[redacted] / 30	
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951		163.92	SC / ONCE	[redacted]20[redacted] / 31	
ABBV-951	1494.06		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951		450.78	SC / ONCE	[redacted]20[redacted] / 32	
ABBV-951	1611.88		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951		286.86	SC / ONCE	[redacted]20[redacted] / 33	
ABBV-951	1584.56		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951		245.88	SC / ONCE	[redacted]20[redacted] / 34	
ABBV-951	1625.54		SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951		204.9	SC / ONCE	[redacted]20[redacted] / 35	
ABBV-951	1591.39		SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951		122.94	SC / ONCE	[redacted]20[redacted] / 36	
ABBV-951	1625.54		SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951		163.92	SC / ONCE	[redacted]20[redacted] / 37	
ABBV-951	1584.56		SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951		286.86	SC / ONCE	[redacted]20[redacted] / 38	
ABBV-951	1632.37		SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951		245.88	SC / ONCE	[redacted]20[redacted] / 39	
ABBV-951	1550.41		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951		204.9	SC / ONCE	[redacted]20[redacted] / 40	
ABBV-951	1625.54		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 41	
ABBV-951	1570.9		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 42	
ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951		204.9	SC / ONCE	[redacted]20[redacted] / 43	
ABBV-951	1668.39		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951		163.92	SC / ONCE	[redacted]20[redacted] / 44	
ABBV-951	1754.79		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 45	
ABBV-951	1747.45		SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951		163.92	SC / ONCE	[redacted]20[redacted] / 46	
ABBV-951	1688.71		SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951		245.88	SC / ONCE	[redacted]20[redacted] / 47	

ABBV-951	1747.45		SC / CONTINUOUS	[redacted] / 47	[redacted] / 47
ABBV-951		204.9	SC / ONCE	[redacted] / 48	
ABBV-951	1718.08		SC / CONTINUOUS	[redacted] / 48	[redacted] / 48
ABBV-951		163.92	SC / ONCE	[redacted] / 49	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 49	[redacted] / 49
ABBV-951		286.86	SC / ONCE	[redacted] / 50	
ABBV-951	1710.74		SC / CONTINUOUS	[redacted] / 50	[redacted] / 50
ABBV-951		122.94	SC / ONCE	[redacted] / 51	
ABBV-951	1754.79		SC / CONTINUOUS	[redacted] / 51	[redacted] / 51
ABBV-951		122.94	SC / ONCE	[redacted] / 52	
ABBV-951	1688.71		SC / CONTINUOUS	[redacted] / 52	[redacted] / 52
ABBV-951		204.9	SC / ONCE	[redacted] / 53	
ABBV-951	1754.79		SC / CONTINUOUS	[redacted] / 53	[redacted] / 53
ABBV-951		204.9	SC / ONCE	[redacted] / 54	
ABBV-951	1740.11		SC / CONTINUOUS	[redacted] / 54	[redacted] / 54
ABBV-951		122.94	SC / ONCE	[redacted] / 55	
ABBV-951	1740.11		SC / CONTINUOUS	[redacted] / 55	[redacted] / 55
ABBV-951		245.88	SC / ONCE	[redacted] / 56	
ABBV-951	1747.45		SC / CONTINUOUS	[redacted] / 56	[redacted] / 56
ABBV-951		122.94	SC / ONCE	[redacted] / 57	
ABBV-951	1696.05		SC / CONTINUOUS	[redacted] / 57	[redacted] / 57
ABBV-951		163.92	SC / ONCE	[redacted] / 58	
ABBV-951	1747.45		SC / CONTINUOUS	[redacted] / 58	[redacted] / 58
ABBV-951		81.96	SC / ONCE	[redacted] / 59	
ABBV-951	1754.79		SC / CONTINUOUS	[redacted] / 59	[redacted] / 59
ABBV-951		122.94	SC / ONCE	[redacted] / 60	
ABBV-951	1754.79		SC / CONTINUOUS	[redacted] / 60	[redacted] / 60
ABBV-951		204.9	SC / ONCE	[redacted] / 61	
ABBV-951	1696.05		SC / CONTINUOUS	[redacted] / 61	[redacted] / 61
ABBV-951		122.94	SC / ONCE	[redacted] / 62	
ABBV-951	1754.79		SC / CONTINUOUS	[redacted] / 62	[redacted] / 62
ABBV-951		204.9	SC / ONCE	[redacted] / 63	
ABBV-951	1754.79		SC / CONTINUOUS	[redacted] / 63	[redacted] / 63
ABBV-951		81.96	SC / ONCE	[redacted] / 64	
ABBV-951	1740.11		SC / CONTINUOUS	[redacted] / 64	[redacted] / 64
ABBV-951	1674.03		SC / CONTINUOUS	[redacted] / 65	[redacted] / 65
ABBV-951		81.96	SC / ONCE	[redacted] / 66	

ABBV-951	1688.71		SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 67	
ABBV-951	1740.11		SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 68	
ABBV-951	1607.95		SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951		122.94	SC / ONCE	[redacted]20[redacted] / 69	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951		122.94	SC / ONCE	[redacted]20[redacted] / 70	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 71	
ABBV-951	1688.71		SC / CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
ABBV-951		122.94	SC / ONCE	[redacted]20[redacted] / 72	
ABBV-951	1754.79		SC / CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
ABBV-951		122.94	SC / ONCE	[redacted]20[redacted] / 73	
ABBV-951	1710.74		SC / CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
ABBV-951		122.94	SC / ONCE	[redacted]20[redacted] / 74	
ABBV-951	1710.74		SC / CONTINUOUS	[redacted]20[redacted] / 74	[redacted]20[redacted] / 74
ABBV-951		163.92	SC / ONCE	[redacted]20[redacted] / 75	
ABBV-951	1718.08		SC / CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
ABBV-951		163.92	SC / ONCE	[redacted]20[redacted] / 76	
ABBV-951	1703.40		SC / CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 76
ABBV-951		163.92	SC / ONCE	[redacted]20[redacted] / 77	
ABBV-951	1769.31		SC / CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 77
ABBV-951	1869.88		SC / CONTINUOUS	[redacted]20[redacted] / 78	[redacted]20[redacted] / 78
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 79	
ABBV-951	1918.03		SC / CONTINUOUS	[redacted]20[redacted] / 79	[redacted]20[redacted] / 79
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 80	
ABBV-951	1918.03		SC / CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 80
ABBV-951		245.88	SC / ONCE	[redacted]20[redacted] / 81	
ABBV-951	1893.95		SC / CONTINUOUS	[redacted]20[redacted] / 81	[redacted]20[redacted] / 81
ABBV-951		163.92	SC / ONCE	[redacted]20[redacted] / 82	
ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 82	[redacted]20[redacted] / 82
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 83	
ABBV-951	1918.03		SC / CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
ABBV-951		122.94	SC / ONCE	[redacted]20[redacted] / 84	
ABBV-951	1869.88		SC / CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 85	

ABBV-951	1910.00		SC / CONTINUOUS	[redacted] / 85	[redacted] / 85
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ABBV-951	1910.00		SC / CONTINUOUS	[redacted] / 86	[redacted] / 86
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ABBV-951	1910.00		SC / CONTINUOUS	[redacted] / 87	[redacted] / 87
ABBV-951		81.96	SC / ONCE	[redacted] / 88	
ABBV-951	1918.03		SC / CONTINUOUS	[redacted] / 88	[redacted] / 88
ABBV-951		40.98	SC / ONCE	[redacted] / 89	
ABBV-951	1861.85		SC / CONTINUOUS	[redacted] / 89	[redacted] / 89
ABBV-951		40.98	SC / ONCE	[redacted] / 90	
ABBV-951	1877.90		SC / CONTINUOUS	[redacted] / 90	[redacted] / 90
ABBV-951		81.96	SC / ONCE	[redacted] / 91	
ABBV-951	1918.03		SC / CONTINUOUS	[redacted] / 91	[redacted] / 91
ABBV-951		163.92	SC / ONCE	[redacted] / 92	
ABBV-951	1926.06		SC / CONTINUOUS	[redacted] / 92	[redacted] / 92
ABBV-951		122.94	SC / ONCE	[redacted] / 93	
ABBV-951	1910.00		SC / CONTINUOUS	[redacted] / 93	[redacted] / 93
ABBV-951		163.92	SC / ONCE	[redacted] / 94	
ABBV-951	1821.73		SC / CONTINUOUS	[redacted] / 94	[redacted] / 94
ABBV-951		122.94	SC / ONCE	[redacted] / 95	
ABBV-951	1926.06		SC / CONTINUOUS	[redacted] / 95	[redacted] / 95
ABBV-951		40.98	SC / ONCE	[redacted] / 96	
ABBV-951	1910.00		SC / CONTINUOUS	[redacted] / 96	[redacted] / 96
ABBV-951	890.80		SC / CONTINUOUS	[redacted] / 97	[redacted] / 97
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ABBV-951	1918.03		SC / CONTINUOUS	[redacted] / 101	[redacted] / 101
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ABBV-951	1837.78		SC / CONTINUOUS	[redacted] / 102	[redacted] / 102
ABBV-951	1918.03		SC / CONTINUOUS	[redacted] / 103	[redacted] / 103
ABBV-951		81.96	SC / ONCE	[redacted] / 104	
ABBV-951	1918.03		SC / CONTINUOUS	[redacted] / 104	[redacted] / 104
ABBV-951	1918.03		SC / CONTINUOUS	[redacted] / 105	[redacted] / 105
ABBV-951		40.98	SC / ONCE	[redacted] / 106	

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ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 109	
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ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 110	
ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 110	[redacted]20[redacted] / 110
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ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 112	
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ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 114	
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ABBV-951		163.92	SC / ONCE	[redacted]20[redacted] / 115	
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ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 123	
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ABBV-951	1918.03		SC / CONTINUOUS	[redacted]20[redacted] / 126	[redacted]20[redacted] / 126

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ABBV-951	1901.98		SC / CONTINUOUS	[redacted]20[redacted] / 129	[redacted]20[redacted] / 129
ABBV-951	1829.75		SC / CONTINUOUS	[redacted]20[redacted] / 130	[redacted]20[redacted] / 130
ABBV-951	1918.03		SC / CONTINUOUS	[redacted]20[redacted] / 131	[redacted]20[redacted] / 131
ABBV-951	1918.03		SC / CONTINUOUS	[redacted]20[redacted] / 132	[redacted]20[redacted] / 132
ABBV-951	1845.80		SC / CONTINUOUS	[redacted]20[redacted] / 133	[redacted]20[redacted] / 133
ABBV-951	1918.03		SC / CONTINUOUS	[redacted]20[redacted] / 134	[redacted]20[redacted] / 134
ABBV-951	1753.60		SC / CONTINUOUS	[redacted]20[redacted] / 135	[redacted]20[redacted] / 135
ABBV-951	1740.11		SC / CONTINUOUS	[redacted]20[redacted] / 136	[redacted]20[redacted] / 136
ABBV-951	1754.79		SC / CONTINUOUS	[redacted]20[redacted] / 137	[redacted]20[redacted] / 137
ABBV-951	1754.79		SC / CONTINUOUS	[redacted]20[redacted] / 138	[redacted]20[redacted] / 138
ABBV-951	1688.71		SC / CONTINUOUS	[redacted]20[redacted] / 139	[redacted]20[redacted] / 139
ABBV-951	1747.45		SC / CONTINUOUS	[redacted]20[redacted] / 140	[redacted]20[redacted] / 140
ABBV-951	1703.40		SC / CONTINUOUS	[redacted]20[redacted] / 141	[redacted]20[redacted] / 141
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ABBV-951	1674.03		SC / CONTINUOUS	[redacted]20[redacted] / 144	[redacted]20[redacted] / 144
ABBV-951	1754.79		SC / CONTINUOUS	[redacted]20[redacted] / 145	[redacted]20[redacted] / 145
ABBV-951	1747.45		SC / CONTINUOUS	[redacted]20[redacted] / 146	[redacted]20[redacted] / 146
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 147	
ABBV-951	1754.79		SC / CONTINUOUS	[redacted]20[redacted] / 147	[redacted]20[redacted] / 147
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 148	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 148	[redacted]20[redacted] / 148
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 149	
ABBV-951	1666.69		SC / CONTINUOUS	[redacted]20[redacted] / 149	[redacted]20[redacted] / 149
ABBV-951	1754.79		SC / CONTINUOUS	[redacted]20[redacted] / 150	[redacted]20[redacted] / 150
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ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 152	
ABBV-951	1754.79		SC / CONTINUOUS	[redacted]20[redacted] / 152	[redacted]20[redacted] / 152
ABBV-951		122.94	SC / ONCE	[redacted]20[redacted] / 153	
ABBV-951	1725.42		SC / CONTINUOUS	[redacted]20[redacted] / 153	[redacted]20[redacted] / 153
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 154	
ABBV-951	1754.79		SC / CONTINUOUS	[redacted]20[redacted] / 154	[redacted]20[redacted] / 154

ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 155	
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ABBV-951	1688.71		SC / CONTINUOUS	[redacted]20[redacted] / 156	[redacted]20[redacted] / 156
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ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 159	
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ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 160	
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ABBV-951	1725.42		SC / CONTINUOUS	[redacted]20[redacted] / 162	[redacted]20[redacted] / 162
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ABBV-951	1718.08		SC / CONTINUOUS	[redacted]20[redacted] / 163	[redacted]20[redacted] / 163
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 164	
ABBV-951	1725.42		SC / CONTINUOUS	[redacted]20[redacted] / 164	[redacted]20[redacted] / 164
ABBV-951	1666.69		SC / CONTINUOUS	[redacted]20[redacted] / 165	[redacted]20[redacted] / 165
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 166	
ABBV-951	1710.74		SC / CONTINUOUS	[redacted]20[redacted] / 166	[redacted]20[redacted] / 166
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 167	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 167	[redacted]20[redacted] / 167
ABBV-951	1854.51		SC / CONTINUOUS	[redacted]20[redacted] / 168	[redacted]20[redacted] / 168
ABBV-951	1992.82		SC / CONTINUOUS	[redacted]20[redacted] / 169	[redacted]20[redacted] / 169
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 170	
ABBV-951	1989.23		SC / CONTINUOUS	[redacted]20[redacted] / 170	[redacted]20[redacted] / 170
ABBV-951	2031.92		SC / CONTINUOUS	[redacted]20[redacted] / 171	[redacted]20[redacted] / 171
ABBV-951	2049		SC / CONTINUOUS	[redacted]20[redacted] / 172	[redacted]20[redacted] / 172
ABBV-951	1989.23		SC / CONTINUOUS	[redacted]20[redacted] / 173	[redacted]20[redacted] / 173
ABBV-951	2040.46		SC / CONTINUOUS	[redacted]20[redacted] / 174	[redacted]20[redacted] / 174
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 175	
ABBV-951	1980.7		SC / CONTINUOUS	[redacted]20[redacted] / 175	[redacted]20[redacted] / 175
ABBV-951	2014.85		SC / CONTINUOUS	[redacted]20[redacted] / 176	[redacted]20[redacted] / 176
ABBV-951	1955.08		SC / CONTINUOUS	[redacted]20[redacted] / 177	[redacted]20[redacted] / 177
ABBV-951	2040.46		SC / CONTINUOUS	[redacted]20[redacted] / 178	[redacted]20[redacted] / 178
ABBV-951	1963.62		SC / CONTINUOUS	[redacted]20[redacted] / 179	[redacted]20[redacted] / 179
ABBV-951	2031.92		SC / CONTINUOUS	[redacted]20[redacted] / 180	[redacted]20[redacted] / 180

ABBV-951	1955.08		SC / CONTINUOUS	[redacted]20[redacted] / 181	[redacted]20[redacted] / 181
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ABBV-951	1963.62		SC / CONTINUOUS	[redacted]20[redacted] / 183	[redacted]20[redacted] / 183
ABBV-951	1972.16		SC / CONTINUOUS	[redacted]20[redacted] / 184	[redacted]20[redacted] / 184
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 185	
ABBV-951	2006.31		SC / CONTINUOUS	[redacted]20[redacted] / 185	[redacted]20[redacted] / 185
ABBV-951	2049		SC / CONTINUOUS	[redacted]20[redacted] / 186	[redacted]20[redacted] / 186
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 187	
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ABBV-951	2040.46		SC / CONTINUOUS	[redacted]20[redacted] / 188	[redacted]20[redacted] / 188
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ABBV-951	2040.46		SC / CONTINUOUS	[redacted]20[redacted] / 204	[redacted]20[redacted] / 204
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ABBV-951	1963.62		SC / CONTINUOUS	[redacted]20[redacted] / 205	[redacted]20[redacted] / 205
ABBV-951	1997.77		SC / CONTINUOUS	[redacted]20[redacted] / 206	[redacted]20[redacted] / 206
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ABBV-951	2006.31		SC / CONTINUOUS	[redacted]20[redacted] / 221	[redacted]20[redacted] / 221
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ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 224	
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ABBV-951	1997.77		SC / CONTINUOUS	[redacted]20[redacted] / 225	[redacted]20[redacted] / 225
ABBV-951	2040.46		SC / CONTINUOUS	[redacted]20[redacted] / 226	[redacted]20[redacted] / 226
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 227	
ABBV-951	2049		SC / CONTINUOUS	[redacted]20[redacted] / 227	[redacted]20[redacted] / 227
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 228	
ABBV-951	2049		SC / CONTINUOUS	[redacted]20[redacted] / 228	[redacted]20[redacted] / 228
ABBV-951	2040.46		SC / CONTINUOUS	[redacted]20[redacted] / 229	[redacted]20[redacted] / 229
ABBV-951	2040.46		SC / CONTINUOUS	[redacted]20[redacted] / 230	[redacted]20[redacted] / 230
ABBV-951	2049		SC / CONTINUOUS	[redacted]20[redacted] / 231	[redacted]20[redacted] / 231
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 232	
ABBV-951	1980.7		SC / CONTINUOUS	[redacted]20[redacted] / 232	[redacted]20[redacted] / 232
ABBV-951	1955.08		SC / CONTINUOUS	[redacted]20[redacted] / 233	[redacted]20[redacted] / 233
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 234	
ABBV-951	2031.92		SC / CONTINUOUS	[redacted]20[redacted] / 234	[redacted]20[redacted] / 234

ABBV-951	2040.46		SC / CONTINUOUS	[redacted]20[redacted] / 235	[redacted]20[redacted] / 235
ABBV-951	2049		SC / CONTINUOUS	[redacted]20[redacted] / 236	[redacted]20[redacted] / 236
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 237	
ABBV-951	2040.46		SC / CONTINUOUS	[redacted]20[redacted] / 237	[redacted]20[redacted] / 237
ABBV-951	2040.46		SC / CONTINUOUS	[redacted]20[redacted] / 238	[redacted]20[redacted] / 238
ABBV-951	2049		SC / CONTINUOUS	[redacted]20[redacted] / 239	[redacted]20[redacted] / 239
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 240	
ABBV-951	2040.46		SC / CONTINUOUS	[redacted]20[redacted] / 240	[redacted]20[redacted] / 240
ABBV-951	2031.92		SC / CONTINUOUS	[redacted]20[redacted] / 241	[redacted]20[redacted] / 241
ABBV-951	2040.46		SC / CONTINUOUS	[redacted]20[redacted] / 242	[redacted]20[redacted] / 242
ABBV-951	2014.85		SC / CONTINUOUS	[redacted]20[redacted] / 243	[redacted]20[redacted] / 243
ABBV-951	2040.46		SC / CONTINUOUS	[redacted]20[redacted] / 244	[redacted]20[redacted] / 244
ABBV-951	2031.92		SC / CONTINUOUS	[redacted]20[redacted] / 245	[redacted]20[redacted] / 245
ABBV-951	2040.46		SC / CONTINUOUS	[redacted]20[redacted] / 246	[redacted]20[redacted] / 246
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 247	
ABBV-951	2049		SC / CONTINUOUS	[redacted]20[redacted] / 247	[redacted]20[redacted] / 247
ABBV-951	2040.46		SC / CONTINUOUS	[redacted]20[redacted] / 248	[redacted]20[redacted] / 248
ABBV-951	2049		SC / CONTINUOUS	[redacted]20[redacted] / 249	[redacted]20[redacted] / 249
ABBV-951	2040.46		SC / CONTINUOUS	[redacted]20[redacted] / 250	[redacted]20[redacted] / 250
ABBV-951	2040.46		SC / CONTINUOUS	[redacted]20[redacted] / 251	[redacted]20[redacted] / 251
ABBV-951	1989.23		SC / CONTINUOUS	[redacted]20[redacted] / 252	[redacted]20[redacted] / 252
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 253	
ABBV-951	2006.31		SC / CONTINUOUS	[redacted]20[redacted] / 253	[redacted]20[redacted] / 253
ABBV-951		122.94	SC / ONCE	[redacted]20[redacted] / 254	
ABBV-951	2023.38		SC / CONTINUOUS	[redacted]20[redacted] / 254	[redacted]20[redacted] / 254
ABBV-951	2040.46		SC / CONTINUOUS	[redacted]20[redacted] / 255	[redacted]20[redacted] / 255
ABBV-951	2031.92		SC / CONTINUOUS	[redacted]20[redacted] / 256	[redacted]20[redacted] / 256
ABBV-951	2031.92		SC / CONTINUOUS	[redacted]20[redacted] / 257	[redacted]20[redacted] / 257
ABBV-951	1955.08		SC / CONTINUOUS	[redacted]20[redacted] / 258	[redacted]20[redacted] / 258
ABBV-951	2031.92		SC / CONTINUOUS	[redacted]20[redacted] / 259	[redacted]20[redacted] / 259
ABBV-951	1989.23		SC / CONTINUOUS	[redacted]20[redacted] / 260	[redacted]20[redacted] / 260
ABBV-951	2049		SC / CONTINUOUS	[redacted]20[redacted] / 261	[redacted]20[redacted] / 261
ABBV-951	1955.08		SC / CONTINUOUS	[redacted]20[redacted] / 262	[redacted]20[redacted] / 262
ABBV-951	1997.77		SC / CONTINUOUS	[redacted]20[redacted] / 263	[redacted]20[redacted] / 263
ABBV-951	2040.46		SC / CONTINUOUS	[redacted]20[redacted] / 264	[redacted]20[redacted] / 264
ABBV-951	2049		SC / CONTINUOUS	[redacted]20[redacted] / 265	[redacted]20[redacted] / 265
ABBV-951	1972.16		SC / CONTINUOUS	[redacted]20[redacted] / 266	[redacted]20[redacted] / 266

ABBV-951	2031.92		SC / CONTINUOUS	[redacted] / 267	[redacted] / 267
ABBV-951	1972.16		SC / CONTINUOUS	[redacted] / 268	[redacted] / 268
ABBV-951	2040.46		SC / CONTINUOUS	[redacted] / 269	[redacted] / 269
ABBV-951		81.96	SC / ONCE	[redacted] / 270	
ABBV-951	2006.31		SC / CONTINUOUS	[redacted] / 270	[redacted] / 270
ABBV-951		81.96	SC / ONCE	[redacted] / 271	
ABBV-951	2040.46		SC / CONTINUOUS	[redacted] / 271	[redacted] / 271
ABBV-951		40.98	SC / ONCE	[redacted] / 272	
ABBV-951	2092.37		SC / CONTINUOUS	[redacted] / 272	[redacted] / 272
ABBV-951	2153.84		SC / CONTINUOUS	[redacted] / 273	[redacted] / 273
ABBV-951		40.98	SC / ONCE	[redacted] / 274	
ABBV-951	2090.49		SC / CONTINUOUS	[redacted] / 274	[redacted] / 274
ABBV-951	2171.94		SC / CONTINUOUS	[redacted] / 275	[redacted] / 275
ABBV-951		40.98	SC / ONCE	[redacted] / 276	
ABBV-951	2072.39		SC / CONTINUOUS	[redacted] / 276	[redacted] / 276
ABBV-951	2162.89		SC / CONTINUOUS	[redacted] / 277	[redacted] / 277
ABBV-951	2153.84		SC / CONTINUOUS	[redacted] / 278	[redacted] / 278
ABBV-951	2144.79		SC / CONTINUOUS	[redacted] / 279	[redacted] / 279
ABBV-951	2126.69		SC / CONTINUOUS	[redacted] / 280	[redacted] / 280
ABBV-951	1194.56		SC / CONTINUOUS	[redacted] / 281	[redacted] / 281
ABBV-951	2162.89		SC / CONTINUOUS	[redacted] / 282	[redacted] / 282
ABBV-951	2135.74		SC / CONTINUOUS	[redacted] / 283	[redacted] / 283
ABBV-951	2153.84		SC / CONTINUOUS	[redacted] / 284	[redacted] / 284
ABBV-951	2045.24		SC / CONTINUOUS	[redacted] / 285	[redacted] / 285
ABBV-951	2162.89		SC / CONTINUOUS	[redacted] / 286	[redacted] / 286
ABBV-951	2171.94		SC / CONTINUOUS	[redacted] / 287	[redacted] / 287
ABBV-951		40.98	SC / ONCE	[redacted] / 288	
ABBV-951	2162.89		SC / CONTINUOUS	[redacted] / 288	[redacted] / 288
ABBV-951	2126.69		SC / CONTINUOUS	[redacted] / 289	[redacted] / 289
ABBV-951	2162.89		SC / CONTINUOUS	[redacted] / 290	[redacted] / 290
ABBV-951	2171.94		SC / CONTINUOUS	[redacted] / 291	[redacted] / 291
ABBV-951	2144.79		SC / CONTINUOUS	[redacted] / 292	[redacted] / 292
ABBV-951	2126.69		SC / CONTINUOUS	[redacted] / 293	[redacted] / 293
ABBV-951	2171.94		SC / CONTINUOUS	[redacted] / 294	[redacted] / 294
ABBV-951	2153.84		SC / CONTINUOUS	[redacted] / 295	[redacted] / 295
ABBV-951	2081.44		SC / CONTINUOUS	[redacted] / 296	[redacted] / 296
ABBV-951	2162.89		SC / CONTINUOUS	[redacted] / 297	[redacted] / 297

ABBV-951	2054.29	SC / CONTINUOUS	[redacted]20[redacted] / 298	[redacted]20[redacted] / 298
ABBV-951	2162.89	SC / CONTINUOUS	[redacted]20[redacted] / 299	[redacted]20[redacted] / 299
ABBV-951	2126.69	SC / CONTINUOUS	[redacted]20[redacted] / 300	[redacted]20[redacted] / 300
ABBV-951	2162.89	SC / CONTINUOUS	[redacted]20[redacted] / 301	[redacted]20[redacted] / 301
ABBV-951	2162.89	SC / CONTINUOUS	[redacted]20[redacted] / 302	[redacted]20[redacted] / 302
ABBV-951	2126.69	SC / CONTINUOUS	[redacted]20[redacted] / 303	[redacted]20[redacted] / 303
ABBV-951	2153.84	SC / CONTINUOUS	[redacted]20[redacted] / 304	[redacted]20[redacted] / 304
ABBV-951	2153.84	SC / CONTINUOUS	[redacted]20[redacted] / 305	[redacted]20[redacted] / 305
ABBV-951	2117.64	SC / CONTINUOUS	[redacted]20[redacted] / 306	[redacted]20[redacted] / 306
ABBV-951	2162.89	SC / CONTINUOUS	[redacted]20[redacted] / 307	[redacted]20[redacted] / 307
ABBV-951	2162.89	SC / CONTINUOUS	[redacted]20[redacted] / 308	[redacted]20[redacted] / 308
ABBV-951	2144.79	SC / CONTINUOUS	[redacted]20[redacted] / 309	[redacted]20[redacted] / 309
ABBV-951	2162.89	SC / CONTINUOUS	[redacted]20[redacted] / 310	[redacted]20[redacted] / 310
ABBV-951	2135.74	SC / CONTINUOUS	[redacted]20[redacted] / 311	[redacted]20[redacted] / 311
ABBV-951	2171.94	SC / CONTINUOUS	[redacted]20[redacted] / 312	[redacted]20[redacted] / 312
ABBV-951	2171.94	SC / CONTINUOUS	[redacted]20[redacted] / 313	[redacted]20[redacted] / 313
ABBV-951	2126.69	SC / CONTINUOUS	[redacted]20[redacted] / 314	[redacted]20[redacted] / 314
ABBV-951	2153.84	SC / CONTINUOUS	[redacted]20[redacted] / 315	[redacted]20[redacted] / 315
ABBV-951	2162.89	SC / CONTINUOUS	[redacted]20[redacted] / 316	[redacted]20[redacted] / 316
ABBV-951	2162.89	SC / CONTINUOUS	[redacted]20[redacted] / 317	[redacted]20[redacted] / 317
ABBV-951	2045.24	SC / CONTINUOUS	[redacted]20[redacted] / 318	[redacted]20[redacted] / 318
ABBV-951	2162.89	SC / CONTINUOUS	[redacted]20[redacted] / 319	[redacted]20[redacted] / 319
ABBV-951	2144.79	SC / CONTINUOUS	[redacted]20[redacted] / 320	[redacted]20[redacted] / 320
ABBV-951	2162.89	SC / CONTINUOUS	[redacted]20[redacted] / 321	[redacted]20[redacted] / 321
ABBV-951	2162.89	SC / CONTINUOUS	[redacted]20[redacted] / 322	[redacted]20[redacted] / 322
ABBV-951	2117.64	SC / CONTINUOUS	[redacted]20[redacted] / 323	[redacted]20[redacted] / 323
ABBV-951	2081.44	SC / CONTINUOUS	[redacted]20[redacted] / 324	[redacted]20[redacted] / 324
ABBV-951	2162.89	SC / CONTINUOUS	[redacted]20[redacted] / 325	[redacted]20[redacted] / 325
ABBV-951	2162.89	SC / CONTINUOUS	[redacted]20[redacted] / 326	[redacted]20[redacted] / 326
ABBV-951	2153.84	SC / CONTINUOUS	[redacted]20[redacted] / 327	[redacted]20[redacted] / 327
ABBV-951	2162.89	SC / CONTINUOUS	[redacted]20[redacted] / 328	[redacted]20[redacted] / 328
ABBV-951	2153.84	SC / CONTINUOUS	[redacted]20[redacted] / 329	[redacted]20[redacted] / 329
ABBV-951	2171.94	SC / CONTINUOUS	[redacted]20[redacted] / 330	[redacted]20[redacted] / 330
ABBV-951	2153.84	SC / CONTINUOUS	[redacted]20[redacted] / 331	[redacted]20[redacted] / 331
ABBV-951	2162.89	SC / CONTINUOUS	[redacted]20[redacted] / 332	[redacted]20[redacted] / 332
ABBV-951	2171.94	SC / CONTINUOUS	[redacted]20[redacted] / 333	[redacted]20[redacted] / 333
ABBV-951	2144.79	SC / CONTINUOUS	[redacted]20[redacted] / 334	[redacted]20[redacted] / 334

ABBV-951	2144.79		SC / CONTINUOUS	[redacted] / 335	[redacted] / 335
ABBV-951		40.98	SC / ONCE	[redacted] / 336	
ABBV-951	2171.94		SC / CONTINUOUS	[redacted] / 336	[redacted] / 336
ABBV-951	2162.89		SC / CONTINUOUS	[redacted] / 337	[redacted] / 337
ABBV-951	2153.84		SC / CONTINUOUS	[redacted] / 338	[redacted] / 338
ABBV-951	2135.74		SC / CONTINUOUS	[redacted] / 339	[redacted] / 339
ABBV-951	2099.54		SC / CONTINUOUS	[redacted] / 340	[redacted] / 340
ABBV-951	2162.89		SC / CONTINUOUS	[redacted] / 341	[redacted] / 341
ABBV-951	2171.94		SC / CONTINUOUS	[redacted] / 342	[redacted] / 342
ABBV-951	2162.89		SC / CONTINUOUS	[redacted] / 343	[redacted] / 343
ABBV-951	2135.74		SC / CONTINUOUS	[redacted] / 344	[redacted] / 344
ABBV-951	2162.89		SC / CONTINUOUS	[redacted] / 345	[redacted] / 345
ABBV-951	2117.64		SC / CONTINUOUS	[redacted] / 346	[redacted] / 346
ABBV-951	2153.84		SC / CONTINUOUS	[redacted] / 347	[redacted] / 347
ABBV-951	2171.94		SC / CONTINUOUS	[redacted] / 348	[redacted] / 348
ABBV-951	2153.84		SC / CONTINUOUS	[redacted] / 349	[redacted] / 349
ABBV-951	2162.89		SC / CONTINUOUS	[redacted] / 350	[redacted] / 350
ABBV-951		40.98	SC / ONCE	[redacted] / 351	
ABBV-951	2144.79		SC / CONTINUOUS	[redacted] / 351	[redacted] / 351
ABBV-951		40.98	SC / ONCE	[redacted] / 352	
ABBV-951	2171.94		SC / CONTINUOUS	[redacted] / 352	[redacted] / 352
ABBV-951	2162.89		SC / CONTINUOUS	[redacted] / 353	[redacted] / 353
ABBV-951	2153.84		SC / CONTINUOUS	[redacted] / 354	[redacted] / 354
ABBV-951	2171.94		SC / CONTINUOUS	[redacted] / 355	[redacted] / 355
ABBV-951		40.98	SC / ONCE	[redacted] / 356	
ABBV-951	2144.79		SC / CONTINUOUS	[redacted] / 356	[redacted] / 356
ABBV-951		40.98	SC / ONCE	[redacted] / 357	
ABBV-951	2162.89		SC / CONTINUOUS	[redacted] / 357	[redacted] / 357
ABBV-951		40.98	SC / ONCE	[redacted] / 358	
ABBV-951	2072.39		SC / CONTINUOUS	[redacted] / 358	[redacted] / 358
ABBV-951	2162.89		SC / CONTINUOUS	[redacted] / 359	[redacted] / 359
ABBV-951	2081.44		SC / CONTINUOUS	[redacted] / 360	[redacted] / 360
ABBV-951	2171.94		SC / CONTINUOUS	[redacted] / 361	[redacted] / 361
ABBV-951	2090.49		SC / CONTINUOUS	[redacted] / 362	[redacted] / 362
ABBV-951	2144.79		SC / CONTINUOUS	[redacted] / 363	[redacted] / 363
ABBV-951	2162.89		SC / CONTINUOUS	[redacted] / 364	[redacted] / 364
ABBV-951	2099.54		SC / CONTINUOUS	[redacted] / 365	[redacted] / 365

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
HYDROCHLOROTHIAZIDE	25 mg	QD	Y-M: 20[redacted]
ROTIGOTINE	6.000 mg	QD	Y-M: 20[redacted]
CHONDROITIN	1200 mg	BID	Y-M: 20[redacted]
GLUCOSAMINE	1500 mg	BID	Y-M: 20[redacted]
TERAZOSIN	5 mg	QD	Y-M: 20[redacted]
VITAMIN D NOS	10000 IU	QD	Y-M: 20[redacted]
VENLAFAXINE	75 mg	QD	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	145.000 mg	5 TIMES PER DAY	Y-M: 20[redacted] / -179
CARBIDOPA;LEVODOPA	245.000 mg	5 TIMES PER DAY	Y-M: 20[redacted] / -114
SULFAMETHOXAZOLE;TRIMETHOPRIM	800/160 2 TABS mg	BID	Y-M: 20[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
HYDROCHLOROTHIAZIDE	25 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 308
CHONDROITIN	1200 mg	BID	Y-M: 20[redacted]	ONGOING
GLUCOSAMINE	1500 mg	BID	Y-M: 20[redacted]	ONGOING
VITAMIN D NOS	10000 IU	QD	Y-M: 20[redacted]	ONGOING
TERAZOSIN	5 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 147
VENLAFAXINE	75 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 112
SULFAMETHOXAZOLE;TRIMETHOPRIM	800/160 2 TABS mg	BID	Y-M: 20[redacted] / -15	Y-M: 20[redacted] / -7
SULFAMETHOXAZOLE;TRIMETHOPRIM	800/160 mg	BID	Y-M: 20[redacted] / 15	Y-M: 20[redacted] / 16
CEFAZOLIN SODIUM	2 g	OTHER: ONCE	Y-M: 20[redacted] / 16	Y-M: 20[redacted] / 16
CEFALEXIN	500 mg	BID	Y-M: 20[redacted] / 16	Y-M: 20[redacted] / 25
VENLAFAXINE	225 mg	QD	Y-M: 20[redacted] / 113	ONGOING
RAMIPRIL	5 mg	QD	Y-M: 20[redacted] / 147	ONGOING
AMOXICILLIN	500 mg	TID	Y-M: 20[redacted] / 233	Y-M: 20[redacted] / 234
MORPHINE	4 mg	OTHER: ONCE	Y-M: 20[redacted] / 234	Y-M: 20[redacted] / 234
ONDANSETRON HYDROCHLORIDE	4 mg	OTHER: ONCE	Y-M: 20[redacted] / 234	Y-M: 20[redacted] / 234
AMPICILLIN SODIUM;SULBACTA	3 g	OTHER: CONTINUAL	Y-M: 20[redacted] / 235	Y-M: 20[redacted] / 240

M SODIUM				
VANCOMYCIN	1500 mg	OTHER: CONTINUAL	Y-M: 20[redacted] / 235	Y-M: 20[redacted] / 240
DOXYCYCLINE	100 mg	BID	Y-M: 20[redacted] / 240	Y-M: 20[redacted] / 250

Event #1: Event of Interest - Infusion Site Related Infections

Event Description	RIGHT ABDOMINAL CELLULITIS AT INFUSION SITE
Preferred term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 15
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	26
Duration of AE	12 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 -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] / 92
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	97
Duration of AE	6 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: Serious Adverse Event

Event Description	PAROTID ABSCESS
Preferred term	耳下腺膿瘍
AE Onset Date / Rx Day	[redacted]20[redacted] / 234
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 234): LEUKOCYTES: 17.3 [3.8 - 11] 10^9/L; NEUTROPHILS/LEUKOCYTES: 87.8 [40 - 75] %

Microbiology

[redacted]20[redacted] (RX DAY 234): OTHER BODY FLUID ABSCESS CULTURE: POSITIVE-MRSA

AE Stopped Rx Day	254
Duration of AE	21 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	RISK FACTOR MRSA
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

generated: [redacted]20[redacted]:10:45

program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

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 が投与され，耳下腺膿瘍を発現した。

Event 3 の臨床経過：

関連する病歴は，脳卒中，喘息，扁桃摘出，パーキンソン病，うつ病，高血圧，睡眠時無呼吸，右肘 MRSA 感染，非喫煙者，及び非飲酒者であった。

投与 1 日目から投与 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治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 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 234 日目，被験者は耳下腺膿瘍を発現した。投与 254 日目，耳下腺膿瘍は消失した。

投与 230 日目，被験者は顔面左側の腫脹が増大したため自宅近くの緊急治療室を受診した。被験者は入院せず，アモキシシリンを処方された。被験者は左側の顔面痛及び腫脹を発現し，同時に嚥下及び会話が困難であった。投与 234 日目，被験者はかかりつけ医を受診し，直ちに耳鼻咽喉科に紹介された。同日，排膿を試みたが成功せず，被験者は緊急治療室を受診するよう指示された。同日，被験者は左側の顔面及び頚部の腫瘤のため緊急治療室を受診した。被験者に MRSA 感染歴があったため，予防としてバンコマイシンとユナシンの投与が開始された。頭部及び頚部の軟部組織の CT 検査，並びに超音波検査が実施された。被験者は耳下腺膿瘍と診断された。翌日，被験者は超音波ガイド下耳下腺膿瘍ドレナージを受け，排出液は培養に送られた。培養で MRSA 及び大量の好中球が認められたが，扁平上皮細胞は認められず，ブドウ球菌に類似したグラム陽性球菌が認められた。胸部 X 線検査などの画像検査は陰性であった。投与 243 日目，被験者の治療は経口ドキシサイクリンに移行し，退院した。

被験者にユナシン，ZOFRAN，アモキシシリン，バンコマイシン，ドキシサイクリン，及びモルヒネが投与された。

Causality for ABBV-951 (Open Label)

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1) Parotid abscess (10034019) (Parotid abscess (10034019)) [v.23.0] [10034019]

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 PAROTID ABSCESS

- Investigator: Risk factor MRSA

- **AbbVie:** More likely related to a history of MRSA right elbow in an advanced aged patient with concomitant use of Venlafaxine, hydrochlorothiazide and Ramipril.

Relevant Laboratory & Other Diagnostic Tests

[redacted] 20[redacted] ABSCESS CULTURE: Positive MRSA

[redacted] 20[redacted] CHEST X-RAY: negative

[redacted] **20[redacted] CT SOFT TISSUE NECK WITH CONTRAST:** Multi spatial infectious disease process primarily involving the left parotid gland extending into the left masticator space. There is overlying subcutaneous abscess and skin thickening. Soft tissue hypoattenuation peripheral enhancement is partially confluent and more well-defined compared compatible with phlegmon/organizing abscesses. Separate collection in the right paraharyngeal space, posterior to the right medial pterygoid measures 1.3x2.0x2.6 cm. Largest enhancing collection in the left superficial parotid lobe measures 1.6x2.5x3.3 cm. Left retro mandibular collection measures 1.6x2.5x3.3 cm. Left retro mandibular collection measures 1.7x2.3x3.7 cm. Mild asymmetric mucosal thickening of the right oropharynx.

[redacted] **20[redacted] NEUTROPHILS %:** 87.8% (normal 40.0 to 75.0)

[redacted] **20[redacted] US HEAD NECK SOFT TISSUE:** Focused sonographic examination of the left lateral neck demonstrates echogenic fluid collection with surrounding hyperemia and finger-like extension into adjacent tissues. The largest defined fluid collection measures 3.4x1.7x1.0 cm just deep to the skin and 2.8x1.3x1.5 cm deep to the skin. These likely communicate. Substancial edema of the adjacent inflamed tissue.

[redacted] **20[redacted] WHITE BLOOD CELLS:** 17.25 K/UL (normal 3.8 to 11.0)

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
妄想性障害，詳細不明	X			X
眼挫傷				X
転倒				X
幻覚				X
幻聴				X
幻視				X
注入部位膿瘍				X
注入部位蜂巣炎				X
注入部位皮膚炎				X
注入部位紅斑		X		X
注入部位刺激感				X
注入部位結節		X		X
注入部位浮腫		X		X
注入部位疼痛				X
** Disc. due to adverse event				X

Disc = Discontinued.

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

Medical History	Onset Year
POST- MENOPAUSAL	NOT REPORTED
TONSILLITIS	19[redacted]
CONSTIPATION	19[redacted]
INSOMNIA	19[redacted]
PSYCHOLOGICAL SWALLOWING DIFFICULTIES	19[redacted]
ATTENTION DEFICIT HYPERACTIVITY DISORDER	19[redacted]
APPENDICITIS	20[redacted]
BENIGN GROWTH IN ABDOMEN	20[redacted]

PARKINSONS	20[redacted]
COMPULSIVE BEHAVIOR	20[redacted]
DIFFICULTY RECALLING NAMES	20[redacted]
CERVICAL DYSTONIA	20[redacted]
SURGICAL SCAR BELOW UMBILICUS FROM BENIGN GROWTH IN ABDOMEN	20[redacted]
NEUROGENIC ORTHOSTATIC HYPOTENSION	20[redacted]
OVERACTIVE BLADDER WITH URGENCY	20[redacted]
HIGH RISK FOR FALLS	20[redacted]
ABNORMAL WEIGHTLOSS	20[redacted]
ANXIETY	20[redacted]
DRUG INDUCED DYSKINESIA	20[redacted]
NUMBNESS IN TOES	20[redacted]
RESTLESSNESS	20[redacted]
TINGLING IN BOTH LOWER EXTREMITIES	20[redacted]
HEMORRHOIDS	20[redacted]
LOSS OF APPETITE	20[redacted]
LEG WEAKNESS	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
TONSILLECTOMY	19[redacted]
ABDOMINAL SURGERY	20[redacted]
APPENDECTOMY	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	0.3	0.37	0.44	240	0.3	[redacted]/1
ABBV-951	0.44	0.51	0.37	120	0.3	[redacted]/3
ABBV-951	0.44	0.51	0.37	120	0.3	[redacted]/9
ABBV-951	0.54	0.6	0.51	60	0.3	[redacted]/17
ABBV-951	0.54	0.6	0.51	60	0.3	[redacted]/23
ABBV-951	0.54	0.6	0.51	60	0.3	[redacted]/29
ABBV-951	0.45	0.51	0.39	60	0.15	[redacted]/37
ABBV-951	0.45	0.51	0.39	60	0.15	[redacted]/43
ABBV-951	0.6	0.63	0.54	60	0.15	[redacted]/94

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	912.65		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951	1803.12		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951		153.67	SC / ONCE	[redacted] / 3	
ABBV-951	1807.55		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951		51.22	SC / ONCE	[redacted] / 4	
ABBV-951	1803.12		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951		102.45	SC / ONCE	[redacted] / 5	
ABBV-951	1803.12		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951	1682.91		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951		51.22	SC / ONCE	[redacted] / 7	
ABBV-951	1803.12		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951	1803.12		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951		51.22	SC / ONCE	[redacted] / 9	
ABBV-951	1766.23		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951		102.45	SC / ONCE	[redacted] / 10	
ABBV-951	1976.77		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951		153.67	SC / ONCE	[redacted] / 11	
ABBV-951	130.62		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11

ABBV-951	1062.40		SC / CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 13	
ABBV-951	1889.69		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 14	
ABBV-951	1079.82		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 15	
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 16	
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951	1330.31		SC / CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 18	
ABBV-951	2307.17		SC / CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951		461.02	SC / ONCE	[redacted]20[redacted] / 19	
ABBV-951	2443.43		SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951		307.35	SC / ONCE	[redacted]20[redacted] / 20	
ABBV-951	2160.15		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951		204.9	SC / ONCE	[redacted]20[redacted] / 21	
ABBV-951	2028.51		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 22	
ABBV-951	2166.81		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951	2330.73		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	2356.35		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 25	
ABBV-951	2212.92		SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951		204.9	SC / ONCE	[redacted]20[redacted] / 26	
ABBV-951	2356.35		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951		256.12	SC / ONCE	[redacted]20[redacted] / 27	
ABBV-951	2366.59		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951		204.9	SC / ONCE	[redacted]20[redacted] / 28	
ABBV-951	2417.82		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 29	
ABBV-951	2458.8		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951	2458.8		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	2458.8		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	2458.8		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	2458.8		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	2458.8		SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34

ABBV-951	1872.27		SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951	2080.24		SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951	1715.01		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951	1010.15		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951	1785.19		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 42	
ABBV-951	2063.85		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 44	
ABBV-951	1933.23		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	2029.02		SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951	1985.48		SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 47	
ABBV-951	2055.14		SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951	2063.85		SC / CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 49	
ABBV-951	2046.43		SC / CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951	1959.35		SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	1950.64		SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951	2029.02		SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951	2029.02		SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	2029.02		SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951	1968.06		SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951	2011.60		SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951	1698.10		SC / CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951	2063.85		SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 61	
ABBV-951	1941.93		SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
ABBV-951	1941.93		SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 63	
ABBV-951	2037.73		SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 64	
ABBV-951	2020.31		SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64

ABBV-951		204.9	SC / ONCE	[redacted]20[redacted] / 65	
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 66	
ABBV-951	2020.31		SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951		179.28	SC / ONCE	[redacted]20[redacted] / 67	
ABBV-951	2037.73		SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951		179.28	SC / ONCE	[redacted]20[redacted] / 68	
ABBV-951	1759.06		SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 69	
ABBV-951	1462.98		SC / CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 70	
ABBV-951	1706.81		SC / CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
ABBV-951		179.28	SC / ONCE	[redacted]20[redacted] / 71	
ABBV-951	1968.06		SC / CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 72	
ABBV-951	1985.48		SC / CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 73	
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 74	
ABBV-951	1985.48		SC / CONTINUOUS	[redacted]20[redacted] / 74	[redacted]20[redacted] / 74
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 75	
ABBV-951	2029.02		SC / CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 76	
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 76
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 77	
ABBV-951	2002.89		SC / CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 77
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 78	
ABBV-951	1950.64		SC / CONTINUOUS	[redacted]20[redacted] / 78	[redacted]20[redacted] / 78
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 79	
ABBV-951	1941.93		SC / CONTINUOUS	[redacted]20[redacted] / 79	[redacted]20[redacted] / 79
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 80	
ABBV-951	2037.73		SC / CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 80
ABBV-951	1828.73		SC / CONTINUOUS	[redacted]20[redacted] / 81	[redacted]20[redacted] / 81
ABBV-951	235.12		SC / CONTINUOUS	[redacted]20[redacted] / 82	[redacted]20[redacted] / 82
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 83	
ABBV-951	2037.73		SC / CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
ABBV-951		179.28	SC / ONCE	[redacted]20[redacted] / 84	

ABBV-951	2081.27		SC / CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 85	
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 85	[redacted]20[redacted] / 85
ABBV-951		204.9	SC / ONCE	[redacted]20[redacted] / 86	
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 86	[redacted]20[redacted] / 86
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 87	
ABBV-951	1436.86		SC / CONTINUOUS	[redacted]20[redacted] / 87	[redacted]20[redacted] / 87
ABBV-951		230.51	SC / ONCE	[redacted]20[redacted] / 88	
ABBV-951	2029.02		SC / CONTINUOUS	[redacted]20[redacted] / 88	[redacted]20[redacted] / 88
ABBV-951		179.28	SC / ONCE	[redacted]20[redacted] / 89	
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 89	[redacted]20[redacted] / 89
ABBV-951		332.96	SC / ONCE	[redacted]20[redacted] / 90	
ABBV-951	1898.39		SC / CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 90
ABBV-951		307.35	SC / ONCE	[redacted]20[redacted] / 91	
ABBV-951	2011.60		SC / CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 92	
ABBV-951	2020.31		SC / CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 92
ABBV-951		179.28	SC / ONCE	[redacted]20[redacted] / 93	
ABBV-951	2002.89		SC / CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 93
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 94	
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 94	[redacted]20[redacted] / 94
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 95	
ABBV-951	2189.35		SC / CONTINUOUS	[redacted]20[redacted] / 95	[redacted]20[redacted] / 95
ABBV-951	2391.69		SC / CONTINUOUS	[redacted]20[redacted] / 96	[redacted]20[redacted] / 96
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 97	
ABBV-951	2388.10		SC / CONTINUOUS	[redacted]20[redacted] / 97	[redacted]20[redacted] / 97
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 98	
ABBV-951	2471.60		SC / CONTINUOUS	[redacted]20[redacted] / 98	[redacted]20[redacted] / 98
ABBV-951		204.9	SC / ONCE	[redacted]20[redacted] / 99	
ABBV-951	2581.74		SC / CONTINUOUS	[redacted]20[redacted] / 99	[redacted]20[redacted] / 99
ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 100	
ABBV-951	2431.13		SC / CONTINUOUS	[redacted]20[redacted] / 100	[redacted]20[redacted] / 100
ABBV-951		256.12	SC / ONCE	[redacted]20[redacted] / 101	
ABBV-951	2465.45		SC / CONTINUOUS	[redacted]20[redacted] / 101	[redacted]20[redacted] / 101
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 102	
ABBV-951	2458.8		SC / CONTINUOUS	[redacted]20[redacted] / 102	[redacted]20[redacted] / 102
ABBV-951		204.9	SC / ONCE	[redacted]20[redacted] / 103	

ABBV-951	2320.49		SC / CONTINUOUS	[redacted]20[redacted] / 103	[redacted]20[redacted] / 103
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 104	
ABBV-951	2538.71		SC / CONTINUOUS	[redacted]20[redacted] / 104	[redacted]20[redacted] / 104
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 105	
ABBV-951	2059.24		SC / CONTINUOUS	[redacted]20[redacted] / 105	[redacted]20[redacted] / 105
ABBV-951		179.28	SC / ONCE	[redacted]20[redacted] / 106	
ABBV-951	2180.64		SC / CONTINUOUS	[redacted]20[redacted] / 106	[redacted]20[redacted] / 106
ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 107	
ABBV-951	2441.89		SC / CONTINUOUS	[redacted]20[redacted] / 107	[redacted]20[redacted] / 107
ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 108	
ABBV-951	2506.43		SC / CONTINUOUS	[redacted]20[redacted] / 108	[redacted]20[redacted] / 108
ABBV-951		230.51	SC / ONCE	[redacted]20[redacted] / 109	
ABBV-951	2484.92		SC / CONTINUOUS	[redacted]20[redacted] / 109	[redacted]20[redacted] / 109
ABBV-951		230.51	SC / ONCE	[redacted]20[redacted] / 110	
ABBV-951	2474.16		SC / CONTINUOUS	[redacted]20[redacted] / 110	[redacted]20[redacted] / 110
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 111	
ABBV-951	2420.38		SC / CONTINUOUS	[redacted]20[redacted] / 111	[redacted]20[redacted] / 111
ABBV-951		281.73	SC / ONCE	[redacted]20[redacted] / 112	
ABBV-951	2527.95		SC / CONTINUOUS	[redacted]20[redacted] / 112	[redacted]20[redacted] / 112
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 113	
ABBV-951	2581.74		SC / CONTINUOUS	[redacted]20[redacted] / 113	[redacted]20[redacted] / 113
ABBV-951	2581.74		SC / CONTINUOUS	[redacted]20[redacted] / 114	[redacted]20[redacted] / 114
ABBV-951	2581.74		SC / CONTINUOUS	[redacted]20[redacted] / 115	[redacted]20[redacted] / 115
ABBV-951	2581.74		SC / CONTINUOUS	[redacted]20[redacted] / 116	[redacted]20[redacted] / 116
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 117	
ABBV-951	2493.63		SC / CONTINUOUS	[redacted]20[redacted] / 117	[redacted]20[redacted] / 117
ABBV-951		230.51	SC / ONCE	[redacted]20[redacted] / 118	
ABBV-951	2517.19		SC / CONTINUOUS	[redacted]20[redacted] / 118	[redacted]20[redacted] / 118
ABBV-951		204.9	SC / ONCE	[redacted]20[redacted] / 119	
ABBV-951	2371.20		SC / CONTINUOUS	[redacted]20[redacted] / 119	[redacted]20[redacted] / 119
ABBV-951		307.35	SC / ONCE	[redacted]20[redacted] / 120	
ABBV-951	2560.22		SC / CONTINUOUS	[redacted]20[redacted] / 120	[redacted]20[redacted] / 120
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 121	
ABBV-951	2495.68		SC / CONTINUOUS	[redacted]20[redacted] / 121	[redacted]20[redacted] / 121
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 122	
ABBV-951	2549.46		SC / CONTINUOUS	[redacted]20[redacted] / 122	[redacted]20[redacted] / 122
ABBV-951	2506.43		SC / CONTINUOUS	[redacted]20[redacted] / 123	[redacted]20[redacted] / 123

ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 124	
ABBV-951	2527.95		SC / CONTINUOUS	[redacted]20[redacted] / 124	[redacted]20[redacted] / 124
ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 125	
ABBV-951	2506.43		SC / CONTINUOUS	[redacted]20[redacted] / 125	[redacted]20[redacted] / 125
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 126	
ABBV-951	2527.95		SC / CONTINUOUS	[redacted]20[redacted] / 126	[redacted]20[redacted] / 126
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 127	
ABBV-951	2506.43		SC / CONTINUOUS	[redacted]20[redacted] / 127	[redacted]20[redacted] / 127
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 128	
ABBV-951	2527.95		SC / CONTINUOUS	[redacted]20[redacted] / 128	[redacted]20[redacted] / 128
ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 129	
ABBV-951	2441.89		SC / CONTINUOUS	[redacted]20[redacted] / 129	[redacted]20[redacted] / 129
ABBV-951		307.35	SC / ONCE	[redacted]20[redacted] / 130	
ABBV-951	2538.71		SC / CONTINUOUS	[redacted]20[redacted] / 130	[redacted]20[redacted] / 130
ABBV-951	2474.16		SC / CONTINUOUS	[redacted]20[redacted] / 131	[redacted]20[redacted] / 131
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 132	
ABBV-951	2538.71		SC / CONTINUOUS	[redacted]20[redacted] / 132	[redacted]20[redacted] / 132
ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 133	
ABBV-951	2581.74		SC / CONTINUOUS	[redacted]20[redacted] / 133	[redacted]20[redacted] / 133
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 134	
ABBV-951	2420.38		SC / CONTINUOUS	[redacted]20[redacted] / 134	[redacted]20[redacted] / 134
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 135	
ABBV-951	2581.74		SC / CONTINUOUS	[redacted]20[redacted] / 135	[redacted]20[redacted] / 135
ABBV-951	2581.74		SC / CONTINUOUS	[redacted]20[redacted] / 136	[redacted]20[redacted] / 136
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 137	
ABBV-951	2527.95		SC / CONTINUOUS	[redacted]20[redacted] / 137	[redacted]20[redacted] / 137
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 138	
ABBV-951	2495.68		SC / CONTINUOUS	[redacted]20[redacted] / 138	[redacted]20[redacted] / 138
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 139	
ABBV-951	2355.83		SC / CONTINUOUS	[redacted]20[redacted] / 139	[redacted]20[redacted] / 139
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 140	
ABBV-951	2517.19		SC / CONTINUOUS	[redacted]20[redacted] / 140	[redacted]20[redacted] / 140
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 141	
ABBV-951	1194.05		SC / CONTINUOUS	[redacted]20[redacted] / 141	[redacted]20[redacted] / 141
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 142	
ABBV-951	2506.43		SC / CONTINUOUS	[redacted]20[redacted] / 142	[redacted]20[redacted] / 142
ABBV-951	2506.43		SC / CONTINUOUS	[redacted]20[redacted] / 143	[redacted]20[redacted] / 143

ABBV-951		51.22	SC / ONCE	[redacted] / 144	
ABBV-951	2527.95		SC / CONTINUOUS	[redacted] / 144	[redacted] / 144
ABBV-951		51.22	SC / ONCE	[redacted] / 145	
ABBV-951	2420.38		SC / CONTINUOUS	[redacted] / 145	[redacted] / 145
ABBV-951		76.83	SC / ONCE	[redacted] / 146	
ABBV-951	2538.71		SC / CONTINUOUS	[redacted] / 146	[redacted] / 146
ABBV-951		51.22	SC / ONCE	[redacted] / 147	
ABBV-951	2474.16		SC / CONTINUOUS	[redacted] / 147	[redacted] / 147
ABBV-951		51.22	SC / ONCE	[redacted] / 148	
ABBV-951	2441.89		SC / CONTINUOUS	[redacted] / 148	[redacted] / 148
ABBV-951		25.61	SC / ONCE	[redacted] / 149	
ABBV-951	2431.13		SC / CONTINUOUS	[redacted] / 149	[redacted] / 149
ABBV-951	2377.35		SC / CONTINUOUS	[redacted] / 150	[redacted] / 150
ABBV-951		76.83	SC / ONCE	[redacted] / 151	
ABBV-951	2495.68		SC / CONTINUOUS	[redacted] / 151	[redacted] / 151
ABBV-951		76.83	SC / ONCE	[redacted] / 152	
ABBV-951	2506.43		SC / CONTINUOUS	[redacted] / 152	[redacted] / 152
ABBV-951		128.06	SC / ONCE	[redacted] / 153	
ABBV-951	2441.89		SC / CONTINUOUS	[redacted] / 153	[redacted] / 153
ABBV-951		51.22	SC / ONCE	[redacted] / 154	
ABBV-951	2476.21		SC / CONTINUOUS	[redacted] / 154	[redacted] / 154
ABBV-951		51.22	SC / ONCE	[redacted] / 155	
ABBV-951	2325.61		SC / CONTINUOUS	[redacted] / 155	[redacted] / 155
ABBV-951		25.61	SC / ONCE	[redacted] / 156	
ABBV-951	2361.47		SC / CONTINUOUS	[redacted] / 156	[redacted] / 156
ABBV-951		25.61	SC / ONCE	[redacted] / 157	
ABBV-951	2188.84		SC / CONTINUOUS	[redacted] / 157	[redacted] / 157
ABBV-951		25.61	SC / ONCE	[redacted] / 158	
ABBV-951	2389.13		SC / CONTINUOUS	[redacted] / 158	[redacted] / 158
ABBV-951		25.61	SC / ONCE	[redacted] / 159	
ABBV-951	2448.55		SC / CONTINUOUS	[redacted] / 159	[redacted] / 159
ABBV-951		25.61	SC / ONCE	[redacted] / 160	
ABBV-951	2454.18		SC / CONTINUOUS	[redacted] / 160	[redacted] / 160
ABBV-951		25.61	SC / ONCE	[redacted] / 161	
ABBV-951	1772.38		SC / CONTINUOUS	[redacted] / 161	[redacted] / 161
ABBV-951	2439.33		SC / CONTINUOUS	[redacted] / 162	[redacted] / 162
ABBV-951		25.61	SC / ONCE	[redacted] / 163	

ABBV-951	2418.84		SC / CONTINUOUS	[redacted]20[redacted] / 163	[redacted]20[redacted] / 163
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 164	
ABBV-951	2197.55		SC / CONTINUOUS	[redacted]20[redacted] / 164	[redacted]20[redacted] / 164
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 165	
ABBV-951	2288.73		SC / CONTINUOUS	[redacted]20[redacted] / 165	[redacted]20[redacted] / 165
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 166	
ABBV-951	2452.65		SC / CONTINUOUS	[redacted]20[redacted] / 166	[redacted]20[redacted] / 166
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 167	
ABBV-951	2527.95		SC / CONTINUOUS	[redacted]20[redacted] / 167	[redacted]20[redacted] / 167
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 168	
ABBV-951	2441.89		SC / CONTINUOUS	[redacted]20[redacted] / 168	[redacted]20[redacted] / 168
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 169	
ABBV-951	2352.76		SC / CONTINUOUS	[redacted]20[redacted] / 169	[redacted]20[redacted] / 169
ABBV-951	1245.79		SC / CONTINUOUS	[redacted]20[redacted] / 170	[redacted]20[redacted] / 170
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 171	
ABBV-951	1866.63		SC / CONTINUOUS	[redacted]20[redacted] / 171	[redacted]20[redacted] / 171
ABBV-951	2458.8		SC / CONTINUOUS	[redacted]20[redacted] / 172	[redacted]20[redacted] / 172
ABBV-951	2458.8		SC / CONTINUOUS	[redacted]20[redacted] / 173	[redacted]20[redacted] / 173
ABBV-951	2458.8		SC / CONTINUOUS	[redacted]20[redacted] / 174	[redacted]20[redacted] / 174
ABBV-951	2458.8		SC / CONTINUOUS	[redacted]20[redacted] / 175	[redacted]20[redacted] / 175
ABBV-951	2376.84		SC / CONTINUOUS	[redacted]20[redacted] / 176	[redacted]20[redacted] / 176
ABBV-951	1862.54		SC / CONTINUOUS	[redacted]20[redacted] / 177	[redacted]20[redacted] / 177
ABBV-951	641.33		SC / CONTINUOUS	[redacted]20[redacted] / 178	[redacted]20[redacted] / 178
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 179	
ABBV-951	2165.79		SC / CONTINUOUS	[redacted]20[redacted] / 179	[redacted]20[redacted] / 179
ABBV-951	2277.46		SC / CONTINUOUS	[redacted]20[redacted] / 180	[redacted]20[redacted] / 180

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
CARBIDOPA MONOHYDRATE;LEVODOPA	1.000 mg	BID	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	1.000 mg	TID	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	BID	Y-M: 20[redacted]-[redacted] / -125
CARBIDOPA;LEVODOPA	145.000 mg	5 TIMES PER DAY	Y-M: 20[redacted]-[redacted] / -125
LEVODOPA	84.000 mg	PRN	Y-M: 20[redacted]-[redacted] / -125

PRAMIPEXOLE	1.000 mg	TID	Y-M: 20[redacted] / -124
CALCIUM	1000 mg	QD	Y-M: 20[redacted] / -59
GLUCOSAMINE	2000 mg	QD	Y-M: 20[redacted] / -59
CITALOPRAM	20 mg	QD	Y-M: 20[redacted] / -34
BIOTIN;CARBOHYDRATES NOS;FATS NOS;MINERALS NOS;POTASSIUM;PROTEINS NOS;SODIUM;VITAMINS NOS	1 SHAKE OTHER: LIQUID SHAKE	QD	Y-M: 20[redacted] / -29

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
CALCIUM	1000 mg	QD	Y-M: 20[redacted] / -59	ONGOING
GLUCOSAMINE	2000 mg	QD	Y-M: 20[redacted] / -59	Y-M: 20[redacted] / 27
CITALOPRAM	20 mg	QD	Y-M: 20[redacted] / -34	ONGOING
BIOTIN;CARBOHYDRATES NOS;FATS NOS;MINERALS NOS;POTASSIUM;PROTEINS NOS;SODIUM;VITAMINS NOS	1 SHAKE OTHER: LIQUID SHAKE	QD	Y-M: 20[redacted] / -29	ONGOING
PROBIOTICS NOS	1 CHEWABLE OTHER: 1 CHEWABLE	QD	Y-M: 20[redacted] / 3	Y-M: 20[redacted] / 50
MIRTAZAPINE	15 mg	QD	Y-M: 20[redacted] / 27	Y-M: 20[redacted] / 37
CYAMOPSIS TETRAGONOLOBA GUM	2 TEASPOONS OTHER: POWDER	OTHER: 2 TABLESPOONS OF POWDER;3-4 8 OZ GLASSES OF WATER	Y-M: 20[redacted] / 50	Y-M: 20[redacted] / 52
CEFALEXIN	500 mg	QID	Y-M: 20[redacted] / 50	Y-M: 20[redacted] / 57
CEFALEXIN	500 mg	QD	Y-M: 20[redacted] / 82	Y-M: 20[redacted] / 88
CEFALEXIN	500 mg	QD	Y-M: 20[redacted] / 89	Y-M: 20[redacted] / 96
SULFAMETHOXAZOLE	800/160 mg	OTHER: EVERY 12HR FOR 7 DAYS	Y-M: 20[redacted] / 92	Y-M: 20[redacted] / 98
DOXYCYCLINE	100 mg	BID	Y-M: 20[redacted] / 137	Y-M: 20[redacted] / 143
MUPIROCIN	2%	QD	Y-M: 20[redacted] / 140	ONGOING
TRIAMCINOLONE ACETONIDE	0.5 OTHER: CC	OTHER: ONCE	Y-M: 20[redacted] / 157	Y-M: 20[redacted] / 157
PIMAVANSERIN TARTRATE	.34 mg	QD	Y-M: 20[redacted] / 161	ONGOING

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE PAIN WITH EXTRA DOSE ONLY
Preferred term	注入部位疼痛
AE Onset Date / Rx Day	[redacted]20[redacted] / 16
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	39
Duration of AE	24 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 -Falls And Associated Injuries

Event Description	FALL- NO INJURIES
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 19
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	19
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 #3: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ERYTHEMA AT INFUSION SITE- RIGHT OF UMBILICUS
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 23
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	29
Duration of AE	7 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	NODULES AT INFUSION SITE- RIGHT OF UMBILICUS
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 23
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	29
Duration of AE	7 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: Serious Adverse Event, Event of Interest - Hallucinations/Psychosis

Event Description	DELUSIONAL DISORDER UNSPECIFIED
Preferred term	妄想性障害，詳細不明
AE Onset Date / Rx Day	[redacted]20[redacted] / 34
Age at AE Onset	6[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 34): ERYTHROCYTES: 6 [NOT REPORTED - 2] UNIT NOT REPORTED; ERYTHROCYTES: 3.7 [3.9 - 5.2] 10^12/L; GLUCOSE: NEGATIVE [0 - 0] UNIT NOT REPORTED; HEMATOCRIT: 0.35 [0.34 - 0.45] FRACTION OF 1; HEMOGLOBIN: 111 [112 - 157] G/L; KETONES: 20 [NOT REPORTED - NOT REPORTED] MG/DL; LEUKOCYTES: 56 [NOT REPORTED - 2] /HPF; LEUKOCYTES: 7.2 [4 - 10.4] 10^9/L; NPTST178-LYMPH AUTO: 0.88 [1.18 - 3.74] 10^3/UL; NPTST181-MCH: 29.8 [25.6 - 32.2] PG; NPTST182-MCHC: 31.5 [32.5 - 36] G/DL; NPTST183-MCV: 94.6 [79.4 - 94.8] FL; NPTST193-MPV: 10 [9.4 - 12.3] FL; NPTST196-NEUT AUTO: 5.61 [1.56 - 6.13] 10^3/UL; NPTST249-POC AGAP: 15 [5 - 16] UNIT NOT REPORTED; NPTST250-POC BUN: 26 [7 - 23] MG/DL; NPTST251-POC CA ION: 1.13 [1.05 - 1.32] MMOL/L; NPTST252-POC CHLORIDE: 104 [98 - 109] MMOL/L; NPTST253-POC K: 3.4 [3.5 - 5.3] MMOL/L; NPTST254-POC KEYTONES: 15 [NOT REPORTED - NOT REPORTED] MG/DL; NPTST255-POC TCO2M: 26 [21 - 32] MMOL/L; NPTST256-POC URINE UROBILINOGEN: 0.2 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST257-POCI GLUCOSE: 98 [70 - 200] MG/DL; NPTST273-RDW: 12.8 [11.7 - 14.4] %; NPTST289-SQUAM EPI: 2 [NOT REPORTED - 2] HPF; NPTST311-UROBILINOGEN: 2.0 [NOT REPORTED - NOT REPORTED] MG/DL; PLATELETS: 280 [182 - 369] 10^9/L; PROTEIN: 30 [NOT REPORTED - NOT REPORTED] MG/DL; SPECIFIC GRAVITY: 1.033 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; PH: 5.0 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED

Microbiology

NOT REPORTED

AE Stopped Rx Day	94
Duration of AE	61 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 REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #6: Event of Interest -Falls And Associated Injuries

Event Description	BRUISE ON LEFT EYE
Preferred term	眼挫傷
AE Onset Date / Rx Day	[redacted]20[redacted] / 36
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	50
Duration of AE	15 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 #7: Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS AT RIGHT LOWER ABDOMEN AT INFUSION SITE
Preferred term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 50

Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	64
Duration of AE	15 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 #8: Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS LOWER LEFT QUADRANT OF ABDOMEN AT INFUSION SITE
Preferred term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 82
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	101
Duration of AE	20 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 #9: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ERYTHEMA AT INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 94
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
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 v	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #10: Event of Interest - Hallucinations/Psychosis

Event Description	HALLUCINATION
Preferred term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 126
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING

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 #11: Event of Interest - Hallucinations/Psychosis

Event Description	HEARING VOICES
Preferred term	幻聴
AE Onset Date / Rx Day	[redacted]20[redacted] / 126
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
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 #12: Event of Interest - Hallucinations/Psychosis

Event Description	FIGURES IN PERIPHERAL VISION- HALLUCINATIONS
Preferred term	幻視
AE Onset Date / Rx Day	[redacted]20[redacted] / 126

Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
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 #13: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	EDEMA AT INFUSION SITE
Preferred term	注入部位浮腫
AE Onset Date / Rx Day	[redacted]20[redacted] / 126
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
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 #14: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	PAIN AT INFUSION SITE
Preferred term	注入部位疼痛
AE Onset Date / Rx Day	[redacted]20[redacted] / 126
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
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 #15: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE IRRITATION-LEFT LATERAL ABDOMEN
Preferred term	注入部位刺激感
AE Onset Date / Rx Day	[redacted]20[redacted] / 133
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
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 #16: Event of Interest - Infusion Site Related Infections

Event Description	ABSCESS AT INFUSION SITE- LEFT LATERAL ABDOMEN
Preferred term	注入部位膿瘍
AE Onset Date / Rx Day	[redacted]20[redacted] / 137
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
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 #17: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	DERMATITIS AT INFUSION SITE
Preferred term	注入部位皮膚炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 172
Age at AE Onset	6[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

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 #18: AE Leading to Discontinuation of Study Drug, Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ERYTHEMA AT MULTIPLE INFUSION SITES
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 183
Age at AE Onset	6[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
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	YES
SAE Criteria	NONE

Event #19: AE Leading to Discontinuation of Study Drug, Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MULTIPLE INFUSION SITE NODULES
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 183
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
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	YES
SAE Criteria	NONE

Event #20: AE Leading to Discontinuation of Study Drug, Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	EDEMA AT MULTIPLE INFUSION SITES
Preferred term	注入部位浮腫
AE Onset Date / Rx Day	[redacted]20[redacted] / 183
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING

Duration of AE	ONGOING
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	YES
SAE Criteria	NONE

generated: [redacted] 20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

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 の治験で ABBV-951 が投与され，詳細不明の妄想性障害を発現した。

Event 5 の臨床経過：

関連する病歴は，不眠症，注意欠如・多動性障害，パーキンソン病，強迫行動，名前の思い出しが困難，神経原性起立性低血圧，不安，落ち着きのなさ，非喫煙者，及び元飲酒者（1 日 2 杯未満）であった。

投与 34 日目，被験者は詳細不明の妄想性障害を発現した。

投与 34 日目，被験者は車に乗った数人の男性に追われているという妄想のため緊急治療室を受診した。被験者は高速ででたらめに運転し救急診療部に行った。救急診療部は被験者がそこで警察官を探そうとしていたとわかった。同日，被験者は入院し観察下に置かれた。被験者は急性精神病エピソード下にあったと判断された。投与 36 日目，精神病症状の改善後，退院して被験者の配偶者による介護下に置かれた。投与 37 日目，被験者は経過観察のため受診した。精神病エピソードはミルタザピン投与開始 3 日後に始まっていたことが確認された。ミルタザピンの投与は中止され，治験薬の注入速度は低下された。

The patient's past medications include:

SINEMET CR for PARKINSON'S DISEASE (20[redacted] - 20[redacted])

SINEMET IR for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])
INBRIJA for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])
RYTARY for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Delusional disorder, unspecified type (10012255) (Delusional disorder, unspecified type (10012255)) [v.21] [10012255]

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 DELUSIONAL DISORDER UNSPECIFIED

- Investigator: Not applicable

- AbbVie: Not applicable

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] CT HEAD W/O CONTRAST:** Impression is normal head CT

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
錯乱状態	X	X		
譫妄	X			
歩行障害				X
幻覚		X		X
注入部位膿瘍	X	X		X
注入部位蜂巣炎	X	X		X
注入部位紅斑				X
腰椎骨折				X
代謝性脳症		X		
** Disc. due to adverse event				X

Disc = Discontinued.

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

Medical History	Onset Year
DIFFICULTY HEARING	19[redacted]
CONSTIPATION	19[redacted]
PARKINSONS	20[redacted]
GAIT ABNORMALITY	20[redacted]
RIGHT LEG WEAKNESS	20[redacted]
HYPERTENSION	20[redacted]
DIABETES	20[redacted]
DIFFICULTY SLEEPING	20[redacted]
DREAM ENACTMENT	20[redacted]
RESTLESS LEG SYNDROME	20[redacted]
URINARY INCONTINENCE	20[redacted]
DYSARTHRIA	20[redacted]
SOFT SLURRED SPEECH	20[redacted]

TROUBLE WITH TRAIN OF THOUGHT	20[redacted]
HALLUCINATIONS	20[redacted]
HIGH RISK FOR FALLS	20[redacted]
ONYCHOMYCOSIS	20[redacted]
WATER RENTENSION	20[redacted]
BACK TENDERNESS OVER T12-L1	20[redacted]
LEFT SHIN SCRAPE	20[redacted]
MULTIPLE BENIGN NEVI	20[redacted]
FALL	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
BILATERAL SUBTHALAMIC NUCLEUS -DEEP BRAIN STIMULATION	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	CURRENT	10 CIGARETTE	20	
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	FORMER			

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	0.7	0	0.63	120	0.3	[redacted]20[redacted]/1
ABBV-951	0.7	0	0.63	120	0.3	[redacted]20[redacted]/2
ABBV-951	0.7	0	0.63	120	0.3	[redacted]20[redacted]/8
ABBV-951	0.77	0	0.7	120	0.3	[redacted]20[redacted]/15
ABBV-951	0.77	0	0.7	120	0.3	[redacted]20[redacted]/22

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	1398.44		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951		51.22	SC / ONCE	[redacted] / 2	
ABBV-951	2820.79		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951		51.22	SC / ONCE	[redacted] / 3	
ABBV-951	2820.79		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951		51.22	SC / ONCE	[redacted] / 4	
ABBV-951	2844.69		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951		51.22	SC / ONCE	[redacted] / 5	
ABBV-951	2796.88		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951		51.22	SC / ONCE	[redacted] / 6	
ABBV-951	2844.69		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951	2856.64		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951		102.45	SC / ONCE	[redacted] / 8	
ABBV-951	2784.93		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951	2856.64		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	2832.74		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951		51.22	SC / ONCE	[redacted] / 11	
ABBV-951	2749.07		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951	2844.69		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951	2772.98		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951	2844.69		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951	2924.77		SC / CONTINUOUS	[redacted] / 15	[redacted] / 15
ABBV-951		51.22	SC / ONCE	[redacted] / 16	
ABBV-951	3129.16		SC / CONTINUOUS	[redacted] / 16	[redacted] / 16
ABBV-951	3037.13		SC / CONTINUOUS	[redacted] / 17	[redacted] / 17
ABBV-951		51.22	SC / ONCE	[redacted] / 18	
ABBV-951	3142.31		SC / CONTINUOUS	[redacted] / 18	[redacted] / 18
ABBV-951	3142.31		SC / CONTINUOUS	[redacted] / 19	[redacted] / 19
ABBV-951	3023.98		SC / CONTINUOUS	[redacted] / 20	[redacted] / 20
ABBV-951	3129.16		SC / CONTINUOUS	[redacted] / 21	[redacted] / 21
ABBV-951	3116.01		SC / CONTINUOUS	[redacted] / 22	[redacted] / 22
ABBV-951	3142.31		SC / CONTINUOUS	[redacted] / 23	[redacted] / 23

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
CARBIDOPA MONOHYDRATE;LEVODOPA	1.000 mg	5 TIMES PER DAY	Y-M: 20[redacted]
RASAGILINE	1.000 mg	BID	Y-M: 20[redacted]
PRAMIPEXOLE	0.000 mg	BID	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	780.000 mg	QID	Y-M: 20[redacted]
MINERALS NOS;VITAMINS NOS	1 TABLET OTHER: 1 TABLET	QD	Y-M: 20[redacted]
CLONAZEPAM	0.5 mg	OTHER: 1 TAB EVERY OTHER NIGHT	Y-M: 20[redacted]
COLECALCIFEROL	2000 IU	QD	Y-M: 20[redacted]
DILTIAZEM	240 mg	QD	Y-M: 20[redacted]
DOCUSATE SODIUM	400 MG-1 CAPSULE ON WEEKDAY ONLY mg	OTHER: 1 CAPSULE ON WEEKDAY ONLY	Y-M: 20[redacted]
LIRAGLUTIDE	0.6 SUB-Q mg	QD	Y-M: 20[redacted]
METFORMIN	500 mg	OTHER: 2 TABLETS BID	Y-M: 20[redacted]
METOPROLOL	50 mg	QD	Y-M: 20[redacted]
ROPINIROLE	2.000 mg	TID	Y-M: 20[redacted]
ROPINIROLE	1.000 mg	TID	Y-M: 20[redacted] / -255
FUROSEMIDE	20 mg	QD	Y-M: 20[redacted] / -206
BENAZEPRIL	5 mg	QD	Y-M: 20[redacted] / -175
PARACETAMOL	625 mg	PRN	Y-M: 20[redacted] / -84

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
MINERALS NOS;VITAMINS NOS	1 TABLET OTHER: 1 TABLET	QD	Y-M: 20[redacted]	ONGOING
CLONAZEPAM	0.5 mg	OTHER: 1 TAB EVERY OTHER NIGHT	Y-M: 20[redacted]	ONGOING
COLECALCIFEROL	2000 IU	QD	Y-M: 20[redacted]	ONGOING
DILTIAZEM	240 mg	QD	Y-M: 20[redacted]	ONGOING
DOCUSATE SODIUM	400 MG-1 CAPSULE ON WEEKDAY ONLY mg	OTHER: 1 CAPSULE ON WEEKDAY ONLY	Y-M: 20[redacted]	ONGOING

LIRAGLUTIDE	0.6 SUB-Q mg	QD	Y-M: 20[redacted]	ONGOING
METFORMIN	500 mg	OTHER: 2 TABLETS BID	Y-M: 20[redacted]	ONGOING
METOPROLOL	50 mg	QD	Y-M: 20[redacted]	ONGOING
FUROSEMIDE	20 mg	QD	Y-M: 20[redacted] / -206	ONGOING
BENAZEPRIL	5 mg	QD	Y-M: 20[redacted] / -175	ONGOING
PARACETAMOL	625 mg	PRN	Y-M: 20[redacted] / -84	ONGOING
CALCITONIN, SALMON	2200 USP IN EACH NOSTRIL EVERY OTHER DAY OTHER: SPRAY	OTHER: 1 SPRAY IN EACH NOSTRIL EVERY OTHER DAY	Y-M: 20[redacted] / 11	ONGOING
CEFALEXIN	500 mg	QID	Y-M: 20[redacted] / 21	Y-M: 20[redacted] / 23
SULFAMETHOXAZOLE;TRIMETHOPRIM	800/160 mg	BID	Y-M: 20[redacted] / 21	Y-M: 20[redacted] / 23
CEFTRIAXONE SODIUM	2 g	QD	Y-M: 20[redacted] / 23	Y-M: 20[redacted] / 26
VANCOMYCIN	1 g	OTHER: Q12HRS	Y-M: 20[redacted] / 23	Y-M: 20[redacted] / 26
SODIUM CHLORIDE	2 L	QD	Y-M: 20[redacted] / 34	Y-M: 20[redacted] / 34
OLANZAPINE	2.5 mg	OTHER: EVERY EVENING	Y-M: 20[redacted] / 34	Y-M: 20[redacted] / 38

Event #1: Event of Interest -Falls And Associated Injuries

Event Description	L-1 VERTEBRAL FRACTURE
Preferred term	腰椎骨折
AE Onset Date / Rx Day	[redacted]20[redacted] / 8
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
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: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MINIMAL ERYTHEMA AT INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 15
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	58 (35 DAYS AFTER LAST TREATMENT)
Duration of AE	44 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: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, Event of Interest - Infusion Site Related Infections

Event Description	ABSCESS RIGHT LOWER QUADRANT OF ABDOMEN AT INFUSION SITE
Preferred term	注入部位膿瘍
AE Onset Date / Rx Day	[redacted]20[redacted] / 21
Age at AE Onset	7[redacted]
Laboratory Testing	

[redacted]20[redacted] (RX DAY 23): ERYTHROCYTES: 4.6 [3.8 - 5.9] 10^12/L; GLUCOSE: 6.4 [3.9 - 5.5] MMOL/L; HEMATOCRIT: 0.41 [0.34 - 0.51] FRACTION OF 1; HEMOGLOBIN: 143 [126 - 174] G/L; LEUKOCYTES: 7.4 [4 - 11] 10^9/L; NPTST181-MCH: 31.4 [27 - 33.5] PG; NPTST182-MCHC: 35.3 [32 - 36] G/DL; NPTST183-MCV: 88.9 [78 - 99] FL; NPTST193-MPV: 8.2 [7.2 - 11.7] FL; NPTST274-RDW-CV: 14.2 [10 - 15] %; PLATELETS: 253 [140 - 440] 10^9/L

Microbiology

NOT REPORTED

AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
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	CAREGIVER HAD TO GIVE MULTIPLE STICKS OF THE [redacted] NEEDLE, THIS IS THE AREA OF INFECTION. EVENTUALLY THEY WERE ABLE TO FIND AN INFUSION SITE
Discontinued Study Drug Due to the Event	YES
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #4: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS RIGHT LOWER QUADRANT OF ABDOMEN AT INFUSION SITE
Preferred term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 21
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 23): ERYTHROCYTES: 4.6 [3.8 - 5.9] 10^12/L; GLUCOSE: 6.4 [3.9 - 5.5] MMOL/L; HEMATOCRIT: 0.41 [0.34 - 0.51] FRACTION OF 1; HEMOGLOBIN: 143 [126 - 174] G/L; LEUKOCYTES: 7.4 [4 - 11] 10^9/L; NPTST181-MCH: 31.4 [27 - 33.5] PG; NPTST182-MCHC: 35.3 [32 - 36] G/DL; NPTST183-MCV: 88.9 [78 - 99] FL; NPTST193-MPV: 8.2 [7.2 - 11.7] FL; NPTST274-RDW-CV: 14.2 [10 - 15] %; PLATELETS: 253 [140 - 440] 10^9/L

Microbiology

NOT REPORTED

AE Stopped Rx Day	34 (11 DAYS AFTER LAST TREATMENT)
Duration of AE	14 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	CAREGIVER DID MULTIPLE STICKS WITH THE [redacted] NEEDLE UNSUCCESSFULLY, THIS IS THE AREA OF INFECTION. ULTIMATELY WAS ABLE FIND AN INFUSION SITE
Discontinued Study Drug Due to the Event	YES
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #5: Event of Interest - Polyneuropathy

Event Description	WORSENING OF GAIT
Preferred term	歩行障害
AE Onset Date / Rx Day	[redacted]20[redacted] / 22
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
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 #6: Serious Adverse Event, AE Leading to Discontinuation of Study Drug

Event Description	COGNITIVE CONFUSION
Preferred term	錯乱状態
AE Onset Date / Rx Day	[redacted]20[redacted] / 23
Age at AE Onset	7[redacted]
Laboratory Testing	

[redacted]20[redacted] (RX DAY 23): ERYTHROCYTES: 4.6 [3.8 - 5.9] 10^12/L; GLUCOSE: 6.4 [3.9 - 5.5] MMOL/L; HEMATOCRIT: 0.41 [0.34 - 0.51] FRACTION OF 1; HEMOGLOBIN: 143 [126 - 174] G/L; LEUKOCYTES: 7.4 [4 - 11]

10^9/L; NPTST181-MCH: 31.4 [27 - 33.5] PG; NPTST182-MCHC: 35.3 [32 - 36] G/DL; NPTST183-MCV: 88.9 [78 - 99] FL; NPTST193-MPV: 8.2 [7.2 - 11.7] FL; NPTST274-RDW-CV: 14.2 [10 - 15] %; PLATELETS: 253 [140 - 440] 10^9/L

Microbiology

NOT REPORTED

AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
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 REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	YES
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #7: Serious Adverse Event

Event Description	ACUTE DELIRIUM
Preferred term	譫妄
AE Onset Date / Rx Day	[redacted]20[redacted] / 23
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 23): ERYTHROCYTES: 4.6 [3.8 - 5.9] 10^12/L; GLUCOSE: 6.4 [3.9 - 5.5] MMOL/L; HEMATOCRIT: 0.41 [0.34 - 0.51] FRACTION OF 1; HEMOGLOBIN: 143 [126 - 174] G/L; LEUKOCYTES: 7.4 [4 - 11] 10^9/L; NPTST181-MCH: 31.4 [27 - 33.5] PG; NPTST182-MCHC: 35.3 [32 - 36] G/DL; NPTST183-MCV: 88.9 [78 - 99] FL; NPTST193-MPV: 8.2 [7.2 - 11.7] FL; NPTST274-RDW-CV: 14.2 [10 - 15] %; PLATELETS: 253 [140 - 440] 10^9/L

Microbiology

NOT REPORTED

AE Stopped Rx Day	54 (31 DAYS AFTER LAST TREATMENT)
Duration of AE	32 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	NOT RELATED TO STUDY PROCEDURES, TEMPORAL IMPLAUSIBILITY.
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #8: AE Leading to Discontinuation of Study Drug, Event of Interest - Hallucinations/Psychosis

Event Description	HALLUCINATION
Preferred term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 23
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
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	YES
SAE Criteria	NONE

Event #9: AE Leading to Discontinuation of Study Drug

Event Description	METABOLIC ENCEPHALOPATHY
Preferred term	代謝性脳症
AE Onset Date / Rx Day	[redacted]20[redacted] / 23
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING

Duration of AE	ONGOING
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	YES
SAE Criteria	NONE

generated: [redacted] 20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

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 が投与され，右下腹部の注入部位膿瘍，右下腹部の注入部位蜂巣炎，認知的錯乱，及び急性譫妄を発現した。

Event 3，4，6，及び 7 の臨床経過：

関連する病歴は，パーキンソン病，歩行異常，高血圧，糖尿病，睡眠困難，夢の行動化，下肢静止不能症候群，両側視床下核–脳深部刺激療法，構語障害，口蓋化した不明瞭言語，一連の思考の困難，幻覚，高い転倒リスク，水分貯留，現喫煙者（紙巻きタバコ 1 日 10 本を 20 年間），元パイプタバコ喫煙者，及び元飲酒者（1 日 2 杯未満）であった。

投与 21 日目，被験者は右下腹部の注入部位膿瘍及び右下腹部の注入部位蜂巣炎を発現した。投与 23 日目，被験者は認知的錯乱及び急性譫妄を発現した。投与 34 日目，右下腹部の注入部位蜂巣炎は消失した。投与 54 日目，急性譫妄は消失した。

投与日 21 後，被験者は右下腹壁の注入部位膿瘍及び注入部位蜂巣炎を発現した。治験責任医師によると，介護者が注入部位に注入針を複数回刺していた。その後その部位は，発赤，紅斑，熱感，及び圧痛があることから明らかに感染が認められた。投与 23 日目被験者は認知的錯乱を発現し同日入院した。代謝性脳症が認められた。入院中，被験者は注入部位の切開及びドレナージを受けた。投与 26 日目，被験者は退院し，感染症ケア及び認知的錯乱の管理が継続して必要なため，リハビリ施設に移った。

投与 34 日目，被験者は腹壁膿瘍，急性譫妄及び非重篤の脱水のため入院した。蜂巣炎は消失したが，検査で小膿瘍が認められた。膿瘍は 3 cm 切開後化膿性分泌物が圧出され，培養が行われた。創傷は開放創のままガーゼを当て包帯で巻かれた。急性譫妄のためジプレキサが投与された。臨床検査及び胸部X線検査が完了し，被験者は再びリハビリ施設に戻った（日付不明）。その後，ジプレキサの投与はリハビリ施設で中止された。

被験者の治験は中止された。

被験者にバンコマイシン，スルファメトキサゾール／トリメトプリム，セファレキシン，ロセフィン，及びジプレキサが投与された。

The patient's past medications include:

SINEMET for PARKINSON'S DISEASE (20[redacted] - 20[redacted])

RASAGILINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

PRAMIPEXOLE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Infusion site abscess (10058464) (Infusion site abscess (10058464)) [v.23.1] [10058464]

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

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: No

2) Infusion site cellulitis (10065455) (Infusion site cellulitis (10065455)) [v.23.1] [10065455]

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

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Yes

Rechallenge: No rechallenge was done, recurrence is not applicable

3) Confusion (10010300) (Confusional state (10010305)) [v.23.1] [10010300]

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

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

Dechallenge: No

4) Acute delirium (10000702) (Delirium (10012218)) [v.23.1] [10000702]

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 ABSCESS RIGHT LOWER QUADRANT OF ABDOMEN AT INFUSION SITE

- **Investigator:** Caregiver had to give multiple sticks of the [redacted] needle, this is the area of infection. Eventually they were able to find an infusion site.

- **AbbVie:** Not applicable.

Event of CELLULITIS RIGHT LOWER QUADRANT OF ABDOMEN AT INFUSION SITE

- **Investigator:** Caregiver did multiple sticks with the [redacted] needle unsuccessfully, this is the area of infection. Ultimately was able find an infusion site.

- **AbbVie:** Not applicable.

Event of COGNITIVE CONFUSION

- **Investigator:** Not applicable.

- **AbbVie:** More likely related to a history of Parkinson's disease, hallucinations, and trouble with train of thought in a patient with advanced age.

Event of ACUTE DELIRIUM

- Investigator: Not related to study procedures, temporal implausibility.

- **AbbVie:** More likely related to a report of concurrent dehydration in an advanced aged patient with a history of Parkinson's disease, diabetes, smoking and hallucinations.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] CHEST XRAY:** impression: no acute pulmonary process

[redacted] **20[redacted] EKG:** NORMAL SINUS RHYTHM

[redacted] **20[redacted] GLUCOSE:** 116 mg/dL (normal 70 to 99)

[redacted] **20[redacted] HEMATOCRIT:** 40.6% (normal 34.0 to 51.0)

[redacted] **20[redacted] HEMOGLOBIN:** 14.3 G/DL (normal 12.36 to 17.4)

[redacted] **20[redacted] MCH:** 31.4 PG (normal 27.0 to 33.5)

[redacted] **20[redacted] MCHC:** 35.3 G/DL (normal 32.0 to 36.0)

[redacted] **20[redacted] MCV:** 88.9 FL (normal 78.0 to 99.0)

[redacted] **20[redacted] PLATELET COUNT:** 253 K/uL (normal 140 to 440)

[redacted] **20[redacted] RDW-CV:** 14.2% (normal 10.0 to 15.0)

[redacted] **20[redacted] RED BLOOD CELLS:** 4.56 m/UL (normal 3.8 to 5.9)

[redacted] **20[redacted] WHITE BLOOD CELLS:** 7.4 K/UL (normal 4.0 to 11.0)

[redacted] **20[redacted] WOUND CULTURE:** Not Reported

[redacted] **20[redacted] MPV:** 8.2 FL (normal 7.2 to 11.7)

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 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	0.23	0.25	0.21	60	0.11	[redacted]/1
ABBV-951	0.23	0.25	0.21	60	0.11	[redacted]/2
ABBV-951	0.24	0.25	0.23	60	0.11	[redacted]/8
ABBV-951	0.24	0.25	0.23	60	0.11	[redacted]/14
ABBV-951	0.24	0.25	0.23	60	0.11	[redacted]/21
ABBV-951	0.24	0.25	0.23	60	0.11	[redacted]/29
ABBV-951	0.25	0.26	0.24	60	0.11	[redacted]/42
ABBV-951	0.25	0.26	0.24	60	0.11	[redacted]/94
ABBV-951	0.26	0.27	0.24	60	0.11	[redacted]/183
ABBV-951	0.25	0.27	0.24	60	0.11	[redacted]/274
ABBV-951	0.27	0.26	0.24	60	0.11	[redacted]/381

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	635.19		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951	983.52		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	983.52		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	983.52		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951	983.52		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951	983.52		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951	983.52		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951	983.52		SC / CONTINUOUS	[redacted] / 15	[redacted] / 15
ABBV-951	983.52		SC / CONTINUOUS	[redacted] / 16	[redacted] / 16
ABBV-951	983.52		SC / CONTINUOUS	[redacted] / 17	[redacted] / 17
ABBV-951	983.52		SC / CONTINUOUS	[redacted] / 18	[redacted] / 18
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ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 219	[redacted]20[redacted] / 219
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 220	[redacted]20[redacted] / 220
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 221	[redacted]20[redacted] / 221
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 222	[redacted]20[redacted] / 222
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 223	[redacted]20[redacted] / 223
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 224	[redacted]20[redacted] / 224
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 225	[redacted]20[redacted] / 225
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 226	[redacted]20[redacted] / 226
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 227	[redacted]20[redacted] / 227
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 228	[redacted]20[redacted] / 228
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 229	[redacted]20[redacted] / 229
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 230	[redacted]20[redacted] / 230
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 231	[redacted]20[redacted] / 231
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 232	[redacted]20[redacted] / 232
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 233	[redacted]20[redacted] / 233
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 234	[redacted]20[redacted] / 234
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 235	[redacted]20[redacted] / 235
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 236	[redacted]20[redacted] / 236
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 237	[redacted]20[redacted] / 237
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 238	[redacted]20[redacted] / 238
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 239	[redacted]20[redacted] / 239

ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 240	[redacted]20[redacted] / 240
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 241	[redacted]20[redacted] / 241
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 242	[redacted]20[redacted] / 242
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 243	[redacted]20[redacted] / 243
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 244	[redacted]20[redacted] / 244
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 245	[redacted]20[redacted] / 245
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 246	[redacted]20[redacted] / 246
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 247	[redacted]20[redacted] / 247
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 248	[redacted]20[redacted] / 248
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 249	[redacted]20[redacted] / 249
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 250	[redacted]20[redacted] / 250
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 251	[redacted]20[redacted] / 251
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 252	[redacted]20[redacted] / 252
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 253	[redacted]20[redacted] / 253
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 254	[redacted]20[redacted] / 254
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 255	[redacted]20[redacted] / 255
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 256	[redacted]20[redacted] / 256
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 257	[redacted]20[redacted] / 257
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 258	[redacted]20[redacted] / 258
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 259	[redacted]20[redacted] / 259
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 260	[redacted]20[redacted] / 260
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 261	[redacted]20[redacted] / 261
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 262	[redacted]20[redacted] / 262
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 263	[redacted]20[redacted] / 263
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 264	[redacted]20[redacted] / 264
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 265	[redacted]20[redacted] / 265
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 266	[redacted]20[redacted] / 266
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 267	[redacted]20[redacted] / 267
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 268	[redacted]20[redacted] / 268
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 269	[redacted]20[redacted] / 269
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 270	[redacted]20[redacted] / 270
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 271	[redacted]20[redacted] / 271
ABBV-951	1059.16	SC / CONTINUOUS	[redacted]20[redacted] / 272	[redacted]20[redacted] / 272
ABBV-951	1088.01	SC / CONTINUOUS	[redacted]20[redacted] / 273	[redacted]20[redacted] / 273

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]
MACROGOL 3350	17 OTHER: GRAM	QD	Y-M: 20[redacted]
OMEPRAZOLE	40 mg	QD	Y-M: 20[redacted]
PROPRANOLOL	20 mg	QD	Y-M: 20[redacted]
MIRABEGRON	50 mg	QD	Y-M: 20[redacted]
RASAGILINE	1.000 mg	QD	Y-M: 20[redacted] / -358
CICLOSPORIN	1 gtt	PRN	Y-M: 20[redacted] / -309
CARBIDOPA MONOHYDRATE;LEVODOPA	200.000 mg	QID	Y-M: 20[redacted] / -274
MELATONIN	5 mg	QD	Y-M: 20[redacted] / -133
AMANTADINE	100.000 mg	TID	Y-M: 20[redacted] / -121
SERTRALINE HYDROCHLORIDE	50 mg	QD	Y-M: 20[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]	ONGOING
ONDANSETRON	4 mg	OTHER: Q8HOURS	Y-M: 20[redacted]	ONGOING
MACROGOL 3350	17 OTHER: GRAM	QD	Y-M: 20[redacted]	ONGOING
OMEPRAZOLE	40 mg	QD	Y-M: 20[redacted]	ONGOING
PROPRANOLOL	20 mg	QD	Y-M: 20[redacted]	ONGOING
MIRABEGRON	50 mg	QD	Y-M: 20[redacted]	ONGOING
CICLOSPORIN	1 gtt	PRN	Y-M: 20[redacted] / -309	ONGOING
MELATONIN	5 mg	QD	Y-M: 20[redacted] / -133	ONGOING
SERTRALINE HYDROCHLORIDE	50 mg	QD	Y-M: 20[redacted] / -121	ONGOING
SODIUM CHLORIDE	125 ML/HR OTHER: ML/HR	OTHER: ONCE	Y-M: 20[redacted] / 39	Y-M: 20[redacted] / 39

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	

[redacted]20[redacted] (RX DAY 37): SODIUM: 124 [136 - 145] MMOL/L

Microbiology

NOT REPORTED

AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
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 RELATED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

generated: [redacted]20[redacted]:10:45

program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

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 を投与中にナトリウム低値を発現した。

Event 1 の臨床経過：

関連する病歴は，パーキンソン病，ナトリウム濃度の低下，悪心，便秘，胃食道逆流症，高血圧，両側軽度足関節浮腫，過活動膀胱，うつ病，非喫煙者，及び飲酒者（1 日 2 杯未満）であった。

投与 38 日目，被験者はナトリウム低値を発現した。投与 42 日目，ナトリウム低値は消失した。

投与 37 日目，被験者は定期的な臨床血液検査を受けた。投与 39 日目，被験者は疲労，錯乱及びナトリウム低値が認められたため入院した。治験責任医師によると，被験者にはナトリウム低値の病歴があった。対症療法として輸液療法を開始した。被験者は，塩分の摂取量を増やすよう指示された。投与 40 日目，被験者は退院した。

被験者に 0.9%塩化ナトリウムが投与された。

The patient's past medications include:

RASAGILINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])
CARBIDOPA/LEVODOPA IMMEDIATE RELEASE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])
CARBIDOPA/ LEVODOPA IMMEDIATE RELEASE 25/100 for PARKINSON'S 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.24.1] [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 history of low sodium, 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
幻覚	X			X
反射減弱				X
注入部位結節				X
注射部位紅斑				X

Treatment Group	Age at 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]
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	0	720	0.11	[redacted]/1
ABBV-951	0.3	0	0	720	0.11	[redacted]/2
ABBV-951	0.32	0	0	720	0.11	[redacted]/8
ABBV-951	0.32	0	0	720	0.11	[redacted]/14
ABBV-951	0.32	0	0	720	0.11	[redacted]/22
ABBV-951	0.32	0	0	720	0.11	[redacted]/29
ABBV-951	0.33	0.35	0.32	120	0.15	[redacted]/42
ABBV-951	0.33	0.35	0.32	60	0.15	[redacted]/91
ABBV-951	0.33	0.35	0.32	60	0.15	[redacted]/184
ABBV-951	0.32	0.33	0.35	60	0.15	[redacted]/212
ABBV-951	0.33	0.35	0.32	60	0.15	[redacted]/275
ABBV-951	0.33	0.35	0.32	60	0.15	[redacted]/366

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	480.83		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	1311.36		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	781.35		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951	448.04		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951	1305.89		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951	901.56		SC / CONTINUOUS	[redacted] / 15	[redacted] / 15
ABBV-951	109.28		SC / CONTINUOUS	[redacted] / 16	[redacted] / 16
ABBV-951	5.46		SC / CONTINUOUS	[redacted] / 20	[redacted] / 20

ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 21	
ABBV-951	404.33		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951	1213.00		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 23	
ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951	1256.72		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 28	
ABBV-951	945.27		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 31	
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 36	
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 37	
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 38	
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 39	
ABBV-951	300.52		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 40	
ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 41	
ABBV-951	1289.50		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 42	
ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 43	
ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 44	
ABBV-951	1256.72		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 45	
ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 46	
ABBV-951	1262.18		SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 48	
ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 49	
ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 50	

ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 51	
ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 52	
ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 53	
ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 54	
ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 55	
ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 56	
ABBV-951	1245.79		SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951	1131.04		SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951	300.52		SC / CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 59	
ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951	1218.47		SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 61	
ABBV-951	152.99		SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
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ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 230	
ABBV-951	1308.79		SC / CONTINUOUS	[redacted]20[redacted] / 230	[redacted]20[redacted] / 230
ABBV-951	1434.3		SC / CONTINUOUS	[redacted]20[redacted] / 231	[redacted]20[redacted] / 231
ABBV-951	1344.65		SC / CONTINUOUS	[redacted]20[redacted] / 232	[redacted]20[redacted] / 232

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]

MAGNESIUM	400 mg	QD	Y-M: 20[redacted]
ACETYLSALICYLIC ACID	81 mg	QD	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	150.000 mg	6 TIMES PER DAY	Y-M: 20[redacted]-[redacted] / -342
ARMODAFINIL	75 mg	QD	Y-M: 20[redacted]-[redacted] / -272

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]	ONGOING
ASCORBIC ACID	1000 mg	QD	Y-M: 19[redacted]	ONGOING
FEXOFENADINE	180 mg	PRN	Y-M: 20[redacted]	ONGOING
FLUNISOLIDE	1 OTHER: SPRAY	PRN	Y-M: 20[redacted]	ONGOING
ACETYLSALICYLIC ACID	81 mg	QD	Y-M: 20[redacted]	ONGOING
ARMODAFINIL	75 mg	QD	Y-M: 20[redacted]-[redacted] / -272	ONGOING
BACITRACIN;NEOMYCIN SULFATE;POLYMYXIN B SULFATE	1 OTHER: APPLICATION	PRN	Y-M: 20[redacted]-[redacted] / 42	ONGOING
AZELASTINE	1 OTHER: SPRAY	PRN	Y-M: 20[redacted]-[redacted] / 154	ONGOING

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MILD ERYTHEMA AT INJECTION SITE
Preferred term	注射部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 14
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	22
Duration of AE	9 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	ERYTHEMA AT PREVIOUS INJECTION SITE
Preferred term	注射部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 29
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	184
Duration of AE	156 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 - Hallucinations/Psychosis

Event Description	HALLUCINATIONS
Preferred term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 184
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	191
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 #4: Event of Interest - Polyneuropathy

Event Description	HYPOACTIVE REFLEXES
Preferred term	反射減弱
AE Onset Date / Rx Day	[redacted]20[redacted] / 184
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	366
Duration of AE	183 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 #5: Serious Adverse Event, Event of Interest - Hallucinations/Psychosis

Event Description	HALLUCINATIONS
Preferred term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 191

Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	192
Duration of AE	2 DAYS
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	PD PROGRESSION VS LEVODOPA COMPLICATION
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #6: Event of Interest -Falls And Associated Injuries

Event Description	FALL ACCIDENTAL
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 235
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	235
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 #7: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	NODULE RUQ AT INFUSION SITE
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 275
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
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]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

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 が投与され，幻覚を発現した。

Event 5 の臨床経過：

関連する病歴は，パーキンソン病，不安，日中の傾眠，非喫煙者，及び非飲酒者であった。

投与 1 日目から投与 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治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 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，被験者は幻覚を発現した。投与 192 日目，幻覚は消失した。

投与 184 日目，本事象の発現に先立ち，被験者は非重篤の幻覚を発現した。

被験者は間欠的な幻覚を発現し，評価のため緊急治療室を受診した。投与 191 日目，被験者は治療のため精神科に入院した。投与 192 日目，被験者は退院した。

The patient's past medications include:

SINEMET for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Hallucinations (10019077) (Hallucination (10019063)) [v.23.0] [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: PD progression vs Levodopa complication

- AbbVie: More likely related to a history of Parkinson's disease and use of concomitant medication Armodafinil in an advanced aged patient.

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
脳圧排効果	X	X	X	X
転倒				X
幻覚				X
反射減弱				X
注射部位紅斑				X
注射部位結節				X
硬膜下血腫	X	X	X	X
体重減少				X
** Disc. due to adverse event				X

Disc = Discontinued.

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

Medical History	Onset Year
CERVICAL DISK COMPRESSION	19[redacted]
ELEVATED CHOLESTEROL	19[redacted]
HYPERTENSION	19[redacted]
ARTHRITIS JOINTS	20[redacted]
ALLERGY PENICILLIN	20[redacted]
ANXIETY	20[redacted]
DEPRESSION	20[redacted]
ROTATOR CUFF TEAR, BILATERAL	20[redacted]
ARTHRITIC CHANGES BILATERAL KNEES	20[redacted]
CONSTIPATION	20[redacted]
POSTMENOPAUSAL	20[redacted]
DAYTIME SOMNOLENCE	20[redacted]
OVERACTIVE BLADDER	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
NECK FUSION	19[redacted]
SURGERY BILATERAL SHOULDERS	20[redacted]
BILATERAL KNEE REPLACEMENTS	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	0.27	0	0	360	0.11	[redacted]20[redacted]/1
ABBV-951	0.26	0.27	0.24	360	0.11	[redacted]20[redacted]/2
ABBV-951	0.26	0.3	0.35	60	0.24	[redacted]20[redacted]/8
ABBV-951	0.26	0.3	0.35	60	0.24	[redacted]20[redacted]/15
ABBV-951	0.38	0.4	0.42	60	0.3	[redacted]20[redacted]/22
ABBV-951	0.36	0.38	0.42	60	0.3	[redacted]20[redacted]/29
ABBV-951	0.4	0.42	0.45	60	0.3	[redacted]20[redacted]/43
ABBV-951	0.42	0.45	0.4	60	0.3	[redacted]20[redacted]/92
ABBV-951	0.47	0.5	0.45	60	0.3	[redacted]20[redacted]/180
ABBV-951	0.55	0.6	0.5	60	0.3	[redacted]20[redacted]/244
ABBV-951	0.55	0.56	0.57	60	0.3	[redacted]20[redacted]/273

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	298.81		SC / CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 13	
ABBV-951	1374.53		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 14	
ABBV-951	1434.3		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 15	
ABBV-951	1434.3		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 16	
ABBV-951	1434.3		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951	1434.3		SC / CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 18	
ABBV-951	1434.3		SC / CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 19	
ABBV-951	1434.3		SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 20	
ABBV-951	1434.3		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 21	
ABBV-951	1434.3		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 22	
ABBV-951	690.85		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 23	
ABBV-951	1388.53		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	1485.86		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951	1492.35		SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951	1492.35		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951	1524.79		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951	1518.30		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 29	
ABBV-951	1537.77		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951	1518.30		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 31	
ABBV-951	1511.82		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 32	
ABBV-951	1498.84		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32

ABBV-951	1505.33		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 34	
ABBV-951	1492.35		SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 35	
ABBV-951	1557.24		SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 36	
ABBV-951	1544.26		SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 37	
ABBV-951	1511.82		SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 38	
ABBV-951	1498.84		SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951	1531.28		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951	1537.77		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951	1453.42		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 42	
ABBV-951	1485.86		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951	1547.33		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951	1692.47		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	1649.44		SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951	1685.30		SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951	1692.47		SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951	1699.64		SC / CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951	1699.64		SC / CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951	1706.81		SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951	1649.44		SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	1685.30		SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951	1713.98		SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951	1721.16		SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	1721.16		SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951	1721.16		SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951	1670.95		SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 58	
ABBV-951	1706.81		SC / CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951	1706.81		SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951	1656.61		SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 61	
ABBV-951	1706.81		SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61

ABBV-951	1706.81		SC / CONTINUOUS	[redacted] / 62	[redacted] / 62
ABBV-951	1692.47		SC / CONTINUOUS	[redacted] / 63	[redacted] / 63
ABBV-951	1706.81		SC / CONTINUOUS	[redacted] / 64	[redacted] / 64
ABBV-951	1685.30		SC / CONTINUOUS	[redacted] / 65	[redacted] / 65
ABBV-951	1721.16		SC / CONTINUOUS	[redacted] / 66	[redacted] / 66
ABBV-951	1706.81		SC / CONTINUOUS	[redacted] / 67	[redacted] / 67
ABBV-951		51.22	SC / ONCE	[redacted] / 68	
ABBV-951	1685.30		SC / CONTINUOUS	[redacted] / 68	[redacted] / 68
ABBV-951		153.67	SC / ONCE	[redacted] / 69	
ABBV-951	1721.16		SC / CONTINUOUS	[redacted] / 69	[redacted] / 69
ABBV-951	1699.64		SC / CONTINUOUS	[redacted] / 70	[redacted] / 70
ABBV-951		153.67	SC / ONCE	[redacted] / 71	
ABBV-951	1649.44		SC / CONTINUOUS	[redacted] / 71	[redacted] / 71
ABBV-951		51.22	SC / ONCE	[redacted] / 72	
ABBV-951	1670.95		SC / CONTINUOUS	[redacted] / 72	[redacted] / 72
ABBV-951		51.22	SC / ONCE	[redacted] / 73	
ABBV-951	1685.30		SC / CONTINUOUS	[redacted] / 73	[redacted] / 73
ABBV-951		102.45	SC / ONCE	[redacted] / 74	
ABBV-951	1706.81		SC / CONTINUOUS	[redacted] / 74	[redacted] / 74
ABBV-951		51.22	SC / ONCE	[redacted] / 75	
ABBV-951	1699.64		SC / CONTINUOUS	[redacted] / 75	[redacted] / 75
ABBV-951		153.67	SC / ONCE	[redacted] / 76	
ABBV-951	1721.16		SC / CONTINUOUS	[redacted] / 76	[redacted] / 76
ABBV-951		102.45	SC / ONCE	[redacted] / 77	
ABBV-951	1649.44		SC / CONTINUOUS	[redacted] / 77	[redacted] / 77
ABBV-951		102.45	SC / ONCE	[redacted] / 78	
ABBV-951	1721.16		SC / CONTINUOUS	[redacted] / 78	[redacted] / 78
ABBV-951		51.22	SC / ONCE	[redacted] / 79	
ABBV-951	1649.44		SC / CONTINUOUS	[redacted] / 79	[redacted] / 79
ABBV-951	1721.16		SC / CONTINUOUS	[redacted] / 80	[redacted] / 80
ABBV-951		51.22	SC / ONCE	[redacted] / 81	
ABBV-951	1721.16		SC / CONTINUOUS	[redacted] / 81	[redacted] / 81
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ABBV-951	1836.41		SC / CONTINUOUS	[redacted]20[redacted] / 113	[redacted]20[redacted] / 113
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ABBV-951	2376.84	SC / CONTINUOUS	[redacted]20[redacted] / 269	[redacted]20[redacted] / 269
ABBV-951	1997.77	SC / CONTINUOUS	[redacted]20[redacted] / 270	[redacted]20[redacted] / 270
ABBV-951	2428.06	SC / CONTINUOUS	[redacted]20[redacted] / 271	[redacted]20[redacted] / 271
ABBV-951	2397.33	SC / CONTINUOUS	[redacted]20[redacted] / 272	[redacted]20[redacted] / 272
ABBV-951	2262.09	SC / CONTINUOUS	[redacted]20[redacted] / 273	[redacted]20[redacted] / 273
ABBV-951	2189.86	SC / CONTINUOUS	[redacted]20[redacted] / 274	[redacted]20[redacted] / 274
ABBV-951	2170.40	SC / CONTINUOUS	[redacted]20[redacted] / 275	[redacted]20[redacted] / 275
ABBV-951	2170.40	SC / CONTINUOUS	[redacted]20[redacted] / 276	[redacted]20[redacted] / 276
ABBV-951	2306.66	SC / CONTINUOUS	[redacted]20[redacted] / 277	[redacted]20[redacted] / 277
ABBV-951	2287.19	SC / CONTINUOUS	[redacted]20[redacted] / 278	[redacted]20[redacted] / 278
ABBV-951	2296.92	SC / CONTINUOUS	[redacted]20[redacted] / 279	[redacted]20[redacted] / 279
ABBV-951	2287.19	SC / CONTINUOUS	[redacted]20[redacted] / 280	[redacted]20[redacted] / 280
ABBV-951	2219.06	SC / CONTINUOUS	[redacted]20[redacted] / 281	[redacted]20[redacted] / 281
ABBV-951	2228.79	SC / CONTINUOUS	[redacted]20[redacted] / 282	[redacted]20[redacted] / 282
ABBV-951	2238.53	SC / CONTINUOUS	[redacted]20[redacted] / 283	[redacted]20[redacted] / 283
ABBV-951	2160.67	SC / CONTINUOUS	[redacted]20[redacted] / 284	[redacted]20[redacted] / 284
ABBV-951	2121.73	SC / CONTINUOUS	[redacted]20[redacted] / 285	[redacted]20[redacted] / 285
ABBV-951	2296.92	SC / CONTINUOUS	[redacted]20[redacted] / 286	[redacted]20[redacted] / 286
ABBV-951	2316.39	SC / CONTINUOUS	[redacted]20[redacted] / 287	[redacted]20[redacted] / 287
ABBV-951	2287.19	SC / CONTINUOUS	[redacted]20[redacted] / 288	[redacted]20[redacted] / 288

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
ESTRADIOL;NORETHISTERONE	1 OTHER: TABLET	QD	Y-M: 20[redacted]-[redacted]
METOPROLOL	50 mg	QD	Y-M: 20[redacted]-[redacted]
AMLODIPINE BESILATE;ATORVASTATIN CALCIUM	1 OTHER: TAB	QD	Y-M: 20[redacted]-[redacted]
DICLOFENAC	75 mg	QD	Y-M: 20[redacted]-[redacted]
MISOPROSTOL	200 ug	BID	Y-M: 20[redacted]-[redacted]
ROPINIROLE	8.000 mg	QD	Y-M: 20[redacted]-[redacted]
CITALOPRAM	20 mg	QD	Y-M: 20[redacted]-[redacted]
AMANTADINE HYDROCHLORIDE	137.000 mg	QD	Y-M: 20[redacted]-[redacted]
ATOMOXETINE HYDROCHLORIDE	40 mg	QD	Y-M: 20[redacted]-[redacted] / -232

CARBIDOPA MONOHYDRATE;LEVODOPA	150.000 mg	5 TIMES PER DAY	Y-M: 20[redacted] / -232
MIRABEGRON	50 mg	QD	Y-M: 20[redacted] / -189

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
ESTRADIOL;NORETHISTERONE	1 OTHER: TABLET	QD	Y-M: 20[redacted]	ONGOING
METOPROLOL	50 mg	QD	Y-M: 20[redacted]	ONGOING
AMLODIPINE BESILATE;ATORVASTATIN CALCIUM	1 OTHER: TAB	QD	Y-M: 20[redacted]	ONGOING
DICLOFENAC	75 mg	QD	Y-M: 20[redacted]	ONGOING
MISOPROSTOL	200 ug	BID	Y-M: 20[redacted]	ONGOING
CITALOPRAM	20 mg	QD	Y-M: 20[redacted]	ONGOING
ATOMOXETINE HYDROCHLORIDE	40 mg	QD	Y-M: 20[redacted] / -232	ONGOING
MIRABEGRON	50 mg	QD	Y-M: 20[redacted] / -189	ONGOING
MUPIROCIN	SMALL AMOUNT OTHER: SMALL AMOUNT	TID	Y-M: 20[redacted] / 84	ONGOING
SULFAMETHOXAZOLE;TRIMETHOPRIM	400 - 80 mg	QD	Y-M: 20[redacted] / 84	ONGOING
PIMAVANSERIN	34 mg	QD	Y-M: 20[redacted] / 184	ONGOING
MELATONIN	3 mg	QD	Y-M: 20[redacted] / 244	Y-M: 20[redacted] / 261
MELATONIN	10 mg	QD	Y-M: 20[redacted] / 261	Y-M: 20[redacted] / 267
QUETIAPINE FUMARATE	12.5 mg	QD	Y-M: 20[redacted] / 267	Y-M: 20[redacted] / 273
QUETIAPINE FUMARATE	25 mg	QD	Y-M: 20[redacted] / 273	Y-M: 20[redacted] / 286
QUETIAPINE FUMARATE	37.5 mg	QD	Y-M: 20[redacted] / 286	ONGOING
LORAZEPAM	1 mg	OTHER: Q1H	Y-M: 20[redacted] / 289	ONGOING
MORPHINE	4 mg	OTHER: Q1H	Y-M: 20[redacted] / 289	ONGOING

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ERYTHEMA AT INJECTION SITE
Preferred term	注射部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 8
Age at AE Onset	6[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	14
Duration of AE	7 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	ERYTHEMA AT INJECTION SITE
Preferred term	注射部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 14
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	180
Duration of AE	167 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	NODULE AT INJECTION SITE

Preferred term	注射部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 14
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	180
Duration of AE	167 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	ERYTHEMA AT INJECTION SITE
Preferred term	注射部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 29
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	273
Duration of AE	245 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: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	NODULE AT INJECTION SITE
Preferred term	注射部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 29
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
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 - Hallucinations/Psychosis

Event Description	HALLUCINATIONS
Preferred term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 90
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
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 #7: Event of Interest - Polyneuropathy

Event Description	HYPOACTIVE REFLEX (1+ PATELLARS)
Preferred term	反射減弱
AE Onset Date / Rx Day	[redacted]20[redacted] / 180
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	273
Duration of AE	94 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 #8: Event of Interest - Weight Loss

Event Description	WEIGHT LOSS
Preferred term	体重減少
AE Onset Date / Rx Day	[redacted]20[redacted] / 244
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
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 #9: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, Death, Event of Interest -Falls And Associated Injuries, Event of Interest - Concurrent Events of Falls and Associated Injuries

Event Description	CEREBRAL MARKED MASS EFFECT
Preferred term	脳圧排効果
AE Onset Date / Rx Day	[redacted]20[redacted] / 289
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	289
Duration of AE	1 DAY
Severity	SEVERE
Relation to Study Drug by Investigator	NO 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 REPORTED
Other cause of event	PATIENT DOES NOT HAVE GOOD MOBILITY DUE TO PARKINSON'S DISEASE AND GOT OUT OF BED WITHOUT ASSISTANCE
Discontinued Study Drug Due to the Event	YES
SAE Criteria	LIFE THREATENING, RESULTS IN DEATH

Event #10: Event of Interest -Falls And Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 289
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	289
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 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: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, Death, Event of Interest -Falls And Associated Injuries, Event of Interest - Concurrent Events of Falls and Associated Injuries

Event Description	ACUTE LARGE RIGHT CEREBRAL SUBDURAL HEMATOMA
Preferred term	硬膜下血腫
AE Onset Date / Rx Day	[redacted]20[redacted] / 289
Age at AE Onset	6[redacted]

Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	289
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 REPORTED
Other cause of event	PATIENT DOES NOT HAVE GOOD MOBILITY DUE TO PARKINSON'S DISEASE AND GOT OUT OF BED WITHOUT ASSISTANCE
Discontinued Study Drug Due to the Event	YES
SAE Criteria	LIFE THREATENING, RESULTS IN DEATH

generated: [redacted] 20[redacted]:10:45

program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

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 が投与され，死亡に至った急性広範右側脳硬膜下血腫及び顕著な脳圧排効果を発現した。

Event 9 及び 11 の臨床経過：

関連する病歴は，高血圧，関節炎のある関節，不安，うつ病，パーキンソン病，両膝の関節炎変化，両膝関節置換術，閉経後，日中の傾眠，過活動膀胱，非喫煙者，及び現飲酒者（1 日 2 杯未満）であった。

投与 289 日目，被験者は急性広範右側脳硬膜下血腫及び顕著な脳圧排効果を発現した。同日，被験者は死亡した。死因は脳出血と報告された。剖検の実施の有無は不明であった。

投与 289 日目，被験者は転倒のため入院した。入院前に，被験者は目覚めてベッドから出ようとしたが，転倒し頭部を打った。入院時，被験者は「脳出血」と診断された後，集中治療室で治療を受けた。同日，被験者は死亡した。これは被験者の介護者により報告された。治験実施施設は本事象に関する詳細な情報を待っていた。

被験者はパーキンソン病による移動能力の低下のリスク因子があった。被験者に本事象に関連する家族歴はなかった。

The patient's past medications include:

CARBIDOPA/LEVODOPA IMMEDIATE RELEASE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

MELATONIN for HALLUCINATIONS ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

PENICILLIN for UNKNOWN INDICATION

Causality for ABBV-951 (Open Label)

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1) Acute subdural hematoma (10066659) (Subdural haematoma (10042361)) [v.23.1] [10066659]

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

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

Dechallenge: Not Applicable

2) Cerebral mass effect (10067086) (Intracranial mass (10077667)) [v.23.1] [10067086]

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 ACUTE LARGE RIGHT CEREBRAL SUBDURAL HEMATOMA, CEREBRAL MARKED MASS EFFECT

- Investigator: The patient does not have good mobility due to Parkinson's disease and got out of bed without assistance.

- AbbVie: More likely related to a traumatic injury from an accidental fall due to reported poor mobility and getting out of bed without assistance in an advanced aged patient with a history of Parkinson's disease and arthritis joints

ADVERSE EVENTS OF SPECIAL INTEREST AND **OTHER AREAS OF SAFETY INTEREST

Weight Decreased: Day 1 weight 10[redacted] pounds. Weight at time of event 9[redacted] pounds. Weight loss occurred over a period of 9 months. No change in diet or mobility level with pump/infusion therapy. Onset of weight loss did not coincide with worsening PD symptoms or eating difficulties and no other prevalent circumstances or reasons provided for weight loss.

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
脳血管発作	X	X	X	
注入部位蜂巣炎				X
注入部位紅斑				X
注入部位血管外漏出				X
注入部位疼痛				X
肺炎	X			
** Disc. due to adverse event				X

Disc = Discontinued.

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

Medical History	Onset Year
ALLERGIES	NOT REPORTED
IRON DEFICIENCY ANEMIA	NOT REPORTED
PENICILLIN ALLERGY	NOT REPORTED
TONSILITIS	19[redacted]
COPD	20[redacted]
GERD	20[redacted]
CORONARY ARTERY DISEASE	20[redacted]
HEART ATTACK	20[redacted]
INTRAVENTRICULAR CONDUCTION DEFECT	20[redacted]
GENERALIZED HEADACHES	20[redacted]
HYPERLIPIDEMIA	20[redacted]
R WRIST FRACTURE	20[redacted]
PNEUMOTHORAX	20[redacted]
ABDOMINAL AORTIC ANEURYSM WITHOUT RUPTURE	20[redacted]
EMBOLISM AND THROMBOSIS IN UNSPECIFIED ARTERY OF R LEG	20[redacted]
PEPTIC ULCER	20[redacted]
ASPIRATION PNEUMONIA	20[redacted]

SILENT ASPIRATION	20[redacted]
GAIT DISTURBANCE	20[redacted]
ASPIRATION PNEUMONIA	20[redacted]
L ELBOW FRACTURE	20[redacted]
HYPOXIA, SLEEP RELATED	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
TONSILLECTOMY	19[redacted]
KNEE SURGERY	19[redacted]
CATH LAB WITH STENT PLACEMENT	20[redacted]
R WRIST FRACTURE REPAIR	20[redacted]
CHEST TUBE PLACEMENT	20[redacted]
LARYNGOSCOPY	20[redacted]
L ELBOW FRACTURE REPAIR	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	20 CIGARETTE	45	20[redacted]
CIGARS	FORMER			
E-CIGARETTES	FORMER	1 SESSIONS	45	20[redacted]
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	0.43	0.52	0.34	60	0.11	[redacted]20[redacted]/1
ABBV-951	0.47	0.56	0.38	60	0.11	[redacted]20[redacted]/2
ABBV-951	0.5	0.6	0.4	60	0.11	[redacted]20[redacted]/6
ABBV-951	0.5	0.6	0.4	60	0.11	[redacted]20[redacted]/20

ABBV-951	0.6	0.72	0.48	60	0.11	[redacted]/29
ABBV-951	0.53	0.64	0.42	60	0.11	[redacted]/36
ABBV-951	0.57	0.68	0.46	60	0.11	[redacted]/41
ABBV-951	0.57	0.68	0.46	60	0.11	[redacted]/90

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	697.51		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951		37.56	SC / ONCE	[redacted] / 2	
ABBV-951	1821.39		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951	1877.90		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951		37.56	SC / ONCE	[redacted] / 4	
ABBV-951	1901.98		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951		18.78	SC / ONCE	[redacted] / 5	
ABBV-951	1893.95		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951		37.56	SC / ONCE	[redacted] / 6	
ABBV-951	1935.10		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951	2031.92		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951	2040.46		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951		56.34	SC / ONCE	[redacted] / 9	
ABBV-951	2006.31		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951		18.78	SC / ONCE	[redacted] / 10	
ABBV-951	2040.46		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	2103.64		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951		37.56	SC / ONCE	[redacted] / 12	
ABBV-951	2031.92		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951		56.34	SC / ONCE	[redacted] / 13	
ABBV-951	2014.85		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951		75.13	SC / ONCE	[redacted] / 14	
ABBV-951	2014.85		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951		56.34	SC / ONCE	[redacted] / 15	
ABBV-951	1869.71		SC / CONTINUOUS	[redacted] / 15	[redacted] / 15
ABBV-951		75.13	SC / ONCE	[redacted] / 16	
ABBV-951	1881.66		SC / CONTINUOUS	[redacted] / 16	[redacted] / 16
ABBV-951		18.78	SC / ONCE	[redacted] / 17	
ABBV-951	2006.31		SC / CONTINUOUS	[redacted] / 17	[redacted] / 17

ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 18	
ABBV-951	2031.92		SC / CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 19	
ABBV-951	2189.01		SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 20	
ABBV-951	2397.33		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951	2407.57		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 22	
ABBV-951	2387.08		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 23	
ABBV-951	2428.06		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 24	
ABBV-951	2428.06		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 25	
ABBV-951	2428.06		SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 26	
ABBV-951	2387.08		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951		93.91	SC / ONCE	[redacted]20[redacted] / 27	
ABBV-951	2458.8		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 28	
ABBV-951	2438.31		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 29	
ABBV-951	2587.88		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 30	
ABBV-951	2407.57		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 31	
ABBV-951	2335.86		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	1901.47		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 33	
ABBV-951	1885.08		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	1950.64		SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 35	
ABBV-951	1950.64		SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 36	
ABBV-951	1897.37		SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 37	
ABBV-951	2153.84		SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37

ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 38	
ABBV-951	2162.89		SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 39	
ABBV-951	2108.59		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 40	
ABBV-951	2162.89		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 41	
ABBV-951	2263.12		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951	2326.12		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 43	
ABBV-951	2287.19		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 44	
ABBV-951	2267.73		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	2219.06		SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951	2326.12		SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 47	
ABBV-951	2257.99		SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951	2326.12		SC / CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951	2326.12		SC / CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951	2277.46		SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 51	
ABBV-951	2326.12		SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	2326.12		SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 53	
ABBV-951	2267.73		SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 54	
ABBV-951	2326.12		SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 55	
ABBV-951	2326.12		SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 56	
ABBV-951	2267.73		SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951	2326.12		SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951	2326.12		SC / CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951	2287.19		SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951	2326.12		SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 61	
ABBV-951	2326.12		SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61

ABBV-951	2306.66		SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 63	
ABBV-951	2287.19		SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951	2326.12		SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 65	
ABBV-951	2326.12		SC / CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
ABBV-951	2316.39		SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951	2287.19		SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951	2326.12		SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951	2296.92		SC / CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 70	
ABBV-951	2326.12		SC / CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
ABBV-951	2316.39		SC / CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
ABBV-951	2335.86		SC / CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
ABBV-951	2326.12		SC / CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
ABBV-951	2326.12		SC / CONTINUOUS	[redacted]20[redacted] / 74	[redacted]20[redacted] / 74
ABBV-951	2267.73		SC / CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
ABBV-951	2326.12		SC / CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 76
ABBV-951	2238.53		SC / CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 77
ABBV-951	2287.19		SC / CONTINUOUS	[redacted]20[redacted] / 78	[redacted]20[redacted] / 78
ABBV-951	2316.39		SC / CONTINUOUS	[redacted]20[redacted] / 79	[redacted]20[redacted] / 79
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 80	
ABBV-951	2277.46		SC / CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 80
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 81	
ABBV-951	2316.39		SC / CONTINUOUS	[redacted]20[redacted] / 81	[redacted]20[redacted] / 81
ABBV-951	2326.12		SC / CONTINUOUS	[redacted]20[redacted] / 82	[redacted]20[redacted] / 82
ABBV-951	2287.19		SC / CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 84	
ABBV-951	2326.12		SC / CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 85	
ABBV-951	2326.12		SC / CONTINUOUS	[redacted]20[redacted] / 85	[redacted]20[redacted] / 85
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 86	
ABBV-951	2017.92		SC / CONTINUOUS	[redacted]20[redacted] / 86	[redacted]20[redacted] / 86
ABBV-951	1877.22		SC / CONTINUOUS	[redacted]20[redacted] / 87	[redacted]20[redacted] / 87
ABBV-951	1869.37		SC / CONTINUOUS	[redacted]20[redacted] / 88	[redacted]20[redacted] / 88
ABBV-951	1814.38		SC / CONTINUOUS	[redacted]20[redacted] / 89	[redacted]20[redacted] / 89
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 90	

ABBV-951	2101.07		SC / CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 90
ABBV-951	2326.12		SC / CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
ABBV-951	2287.19		SC / CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 92
ABBV-951	2326.12		SC / CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 93
ABBV-951	2306.66		SC / CONTINUOUS	[redacted]20[redacted] / 94	[redacted]20[redacted] / 94
ABBV-951	2335.86		SC / CONTINUOUS	[redacted]20[redacted] / 95	[redacted]20[redacted] / 95
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 96	
ABBV-951	2326.12		SC / CONTINUOUS	[redacted]20[redacted] / 96	[redacted]20[redacted] / 96
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 97	
ABBV-951	2316.39		SC / CONTINUOUS	[redacted]20[redacted] / 97	[redacted]20[redacted] / 97
ABBV-951	2326.12		SC / CONTINUOUS	[redacted]20[redacted] / 98	[redacted]20[redacted] / 98
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 99	
ABBV-951	2257.99		SC / CONTINUOUS	[redacted]20[redacted] / 99	[redacted]20[redacted] / 99
ABBV-951	2335.86		SC / CONTINUOUS	[redacted]20[redacted] / 100	[redacted]20[redacted] / 100
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 101	
ABBV-951	2316.39		SC / CONTINUOUS	[redacted]20[redacted] / 101	[redacted]20[redacted] / 101
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 102	
ABBV-951	2228.79		SC / CONTINUOUS	[redacted]20[redacted] / 102	[redacted]20[redacted] / 102
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 103	
ABBV-951	2306.66		SC / CONTINUOUS	[redacted]20[redacted] / 103	[redacted]20[redacted] / 103
ABBV-951	2306.66		SC / CONTINUOUS	[redacted]20[redacted] / 104	[redacted]20[redacted] / 104
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 105	
ABBV-951	2287.19		SC / CONTINUOUS	[redacted]20[redacted] / 105	[redacted]20[redacted] / 105
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 106	
ABBV-951	2287.19		SC / CONTINUOUS	[redacted]20[redacted] / 106	[redacted]20[redacted] / 106
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 107	
ABBV-951	2306.66		SC / CONTINUOUS	[redacted]20[redacted] / 107	[redacted]20[redacted] / 107
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 108	
ABBV-951	2326.12		SC / CONTINUOUS	[redacted]20[redacted] / 108	[redacted]20[redacted] / 108
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 109	
ABBV-951	2287.19		SC / CONTINUOUS	[redacted]20[redacted] / 109	[redacted]20[redacted] / 109
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 110	
ABBV-951	2335.86		SC / CONTINUOUS	[redacted]20[redacted] / 110	[redacted]20[redacted] / 110
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 111	
ABBV-951	2296.92		SC / CONTINUOUS	[redacted]20[redacted] / 111	[redacted]20[redacted] / 111
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 112	
ABBV-951	2326.12		SC / CONTINUOUS	[redacted]20[redacted] / 112	[redacted]20[redacted] / 112

ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 113	
ABBV-951	2287.19		SC / CONTINUOUS	[redacted]20[redacted] / 113	[redacted]20[redacted] / 113
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 114	
ABBV-951	2267.73		SC / CONTINUOUS	[redacted]20[redacted] / 114	[redacted]20[redacted] / 114
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 115	
ABBV-951	2326.12		SC / CONTINUOUS	[redacted]20[redacted] / 115	[redacted]20[redacted] / 115
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 116	
ABBV-951	2267.73		SC / CONTINUOUS	[redacted]20[redacted] / 116	[redacted]20[redacted] / 116

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
PSEUDOEPHEDRINE HYDROCHLORIDE	60 mg	PRN	Y-M: 20[redacted]
CALCIUM CARBONATE	2 OTHER: TABS	PRN	Y-M: 20[redacted]
LORATADINE	10 mg	QD	Y-M: 20[redacted]-[redacted]
OMEPRAZOLE	40 mg	QD	Y-M: 20[redacted]-[redacted]
PARACETAMOL	1,000 mg	TID	Y-M: 20[redacted]-[redacted]
TIOTROPIUM BROMIDE MONOHYDRATE	18 OTHER: MCG	QD	Y-M: 20[redacted]-[redacted]
RASAGILINE MESYLATE	1.000 mg	QD	Y-M: 20[redacted]-[redacted]
ACETYLSALICYLIC ACID	81 mg	QD	Y-M: 20[redacted]-[redacted]
ATORVASTATIN CALCIUM	40 mg	QD	Y-M: 20[redacted]-[redacted]
OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM	1 OTHER: TAB	QD	Y-M: 20[redacted]-[redacted]
FERROUS FUMARATE	2 OTHER: TABS	QD	Y-M: 20[redacted]-[redacted]
CALCIUM PHOSPHATE;COLECALCIFEROL	1 OTHER: TAB	QD	Y-M: 20[redacted]-[redacted]
OXYGEN	3 OTHER: L	OTHER: BEDTIME	Y-M: 20[redacted]-[redacted]
SALBUTAMOL	2 MG/5 ML OTHER: MG/ML	QD	Y-M: 20[redacted]-[redacted] / -328
FLUTICASONE FUROATE;VILANTEROL TRIFENATATE	1 OTHER: PUFF	QD	Y-M: 20[redacted]-[redacted] / -170
ROPINIROLE	2.000 mg	TID	Y-M: 20[redacted]-[redacted] / -158
APOMORPHINE HYDROCHLORIDE	6.000 mg	PRN	Y-M: 20[redacted]-[redacted] / -155
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	7 TIMES PER DAY	Y-M: 20[redacted]-[redacted] / -155
CARBIDOPA MONOHYDRATE;LEVODOPA	150.000 mg	QID	Y-M: 20[redacted]-[redacted] / -155

CYANOCOBALAMIN;FOLIC ACID;PYRIDOXINE HYDROCHLORIDE	2 OTHER: TABLETS	BID	Y-M: 20[redacted] / -20
INFLUENZA VACCINE	1 OTHER: SHOT	OTHER: ONCE	Y-M: 20[redacted] / -6

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
PSEUDOEPHEDRINE HYDROCHLORIDE	60 mg	PRN	Y-M: 20[redacted]	Y-M: 20[redacted] / 117
CALCIUM CARBONATE	2 OTHER: TABS	PRN	Y-M: 20[redacted]	Y-M: 20[redacted] / 117
LORATADINE	10 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 117
OMEPRAZOLE	40 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 117
PARACETAMOL	1,000 mg	TID	Y-M: 20[redacted]	Y-M: 20[redacted] / 117
TIOTROPIUM BROMIDE MONOHYDRATE	18 OTHER: MCG	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 117
ACETYLSALICYLIC ACID	81 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 117
ATORVASTATIN CALCIUM	40 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 117
OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM	1 OTHER: TAB	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 117
FERROUS FUMARATE	2 OTHER: TABS	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 117
CALCIUM PHOSPHATE;COLECALCIFEROL	1 OTHER: TAB	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 117
OXYGEN	3 OTHER: L	OTHER: BEDTIME	Y-M: 20[redacted]	Y-M: 20[redacted] / 117
SALBUTAMOL	2 MG/5 ML OTHER: MG/ML	QD	Y-M: 20[redacted] / -328	Y-M: 20[redacted] / 117
FLUTICASONE FUROATE;VILANTEROL TRIFENATATE	1 OTHER: PUFF	QD	Y-M: 20[redacted] / -170	Y-M: 20[redacted] / 117
CYANOCOBALAMIN; FOLIC ACID;PYRIDOXINE HYDROCHLORIDE	2 OTHER: TABLETS	BID	Y-M: 20[redacted] / -20	Y-M: 20[redacted] / 117
INFLUENZA VACCINE	1 OTHER: SHOT	OTHER: ONCE	Y-M: 20[redacted] / -6	Y-M: 20[redacted] / -6

SODIUM CHLORIDE	3,225 mL	OTHER: ONCE	Y-M: 20[redacted] / 12	Y-M: 20[redacted] / 12
AZITHROMYCIN	500 mg	QD	Y-M: 20[redacted] / 12	Y-M: 20[redacted] / 14
CEFTRIAXONE	1,000 mg	QD	Y-M: 20[redacted] / 12	Y-M: 20[redacted] / 14
LEVOFLOXACIN	750 mg	QD	Y-M: 20[redacted] / 16	Y-M: 20[redacted] / 21
NYSTATIN	500,000 OTHER: UNITS/5 ML	QD	Y-M: 20[redacted] / 16	Y-M: 20[redacted] / 21
OXYGEN	2-4 L	QD	Y-M: 20[redacted] / 16	Y-M: 20[redacted] / 61
CEFALEXIN	500 mg	QD	Y-M: 20[redacted] / 47	Y-M: 20[redacted] / 48
DOXYCYCLINE	100 mg	TID	Y-M: 20[redacted] / 49	Y-M: 20[redacted] / 59
LEVOFLOXACIN	750 mg	QD	Y-M: 20[redacted] / 94	Y-M: 20[redacted] / 101

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	STINGING SENSATION WHEN INFUSION FIRST STARTED
Preferred term	注入部位疼痛
AE Onset Date / Rx Day	[redacted]20[redacted] / 1
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	117
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: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	REDNESS (1) AND (B) NOTED ON INFUSION SITE ASSESSMENT PERFORMED BY RAJESH PAHWA, MD ON [redacted]/[redacted]/20[redacted].
Preferred term	注入部位紅斑

AE Onset Date / Rx Day	[redacted]20[redacted] / 6
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	117
Duration of AE	112 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: Serious Adverse Event

Event Description	BILATERAL PNEUMONIA
Preferred term	肺炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 12
Age at AE Onset	6[redacted]
Laboratory Testing	

[redacted]20[redacted] (RX DAY 12): ALBUMIN: 43 [32 - 55] G/L; ALKALINE PHOSPHATASE: 70 [42 - 121] U/L; BILIRUBIN: 10 [3 - 17] UMOL/L; GLUCOSE: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; KETONES: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST010-ALT: 5 [10 - 60] U/L; NPTST033-AST: 16 [10 - 42] U/L; NPTST035-BACTERIA, UA: NEGATIVE [NOT REPORTED - NOT REPORTED] U/L; NPTST046-BILIRUBIN, UA: NEGATIVE [NOT REPORTED - NOT REPORTED] MG/DL; NPTST050-BLOOD, UA: NEGATIVE [NOT REPORTED - NOT REPORTED] MG/DL; NPTST082-CLARITY: CLEAR [NOT REPORTED - NOT REPORTED] CLARITY; NPTST089-COLOR, UA: LIGHT YELLOW [NOT REPORTED - NOT REPORTED] COLOR; NPTST144-HYALINE CAST: 0-2 [0 - 5] IPF; NPTST156-INR: 1.17 [0.85 - 1.13] RATIO; NPTST165-LACTIC ACID LEVEL: 2 [0.5 - 2] MMOL/L; NPTST172-LEUKOCYTE ESTERASE: NEGATIVE [NOT REPORTED - NOT REPORTED] LEU/UL; NPTST200-NITRITES, UA: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST261-PROCALCITONIN: 0.22 [0 - 0.49] NG/ML; NPTST264-PROTEIN, UA: NEGATIVE [NOT REPORTED - NOT REPORTED] MG/DL; NPTST267-PT: 14.7 [11.5 - 14.5] SEC; NPTST272-RBC, UA: 0-5 [0 - 5] HPF; NPTST290-SQUAMOUS EPITHELIAL: NEGATIVE/FEW [1 - 5] HPF; NPTST312-UROBILINOGEN, UA: NORMAL [NOT REPORTED - NOT REPORTED] MG/DL; NPTST320-WBC, UA: 0-5 [0 - 5] HPF; PROTEIN: 74 [60 - 80] G/L; SPECIFIC GRAVITY: 1.010 [1.003 - 1.03] UNIT NOT REPORTED; PH: 6.5 [4.5 - 8] UNIT NOT REPORTED; [redacted]20[redacted] (RX DAY 14): BASOPHILS: 30 [0 - 105]

10^9/L; BASOPHILS/LEUKOCYTES: 0.2 [0.2 - 1] %; CALCIUM: 2.25 [2.12 - 2.62] MMOL/L; CREATININE: 71 [44 - 106] UMOL/L; EOSINOPHILS: 50 [40 - 315] 10^9/L; EOSINOPHILS/LEUKOCYTES: 0.3 [0.9 - 2.9] %; ERYTHROCYTES: 3.2 [4.5 - 6] 10^12/L; GLUCOSE: 5.7 [3.9 - 5.6] MMOL/L; HEMATOCRIT: 0.3 [0.42 - 0.52] FRACTION OF 1; HEMOGLOBIN: 97 [130 - 175] G/L; LEUKOCYTES: 16.8 [4 - 10.5] 10^9/L; LYMPHOCYTES: 2480 [840 - 4830] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 14.7 [20.5 - 45] %; MONOCYTES: 1170 [240 - 1260] 10^9/L; MONOCYTES/LEUKOCYTES: 7 [5.5 - 11.7] %; NPTST014-ANION GAP: 8 [3 - 10] MMOL/L; NPTST049-BLOOD UREA NITROGEN: 18 [6 - 20] MG/DL; NPTST075-CHLORIDE: 106 [101 - 111] MMOL/L; NPTST086-CO2: 27 [21 - 31] MMOL/L; NPTST182-MCHC: 32.3 [32 - 36] G/DL; NPTST183-MCV: 93.5 [78 - 100] FL; NPTST186-MEAN CORPUSCULAR HEMOGLOBIN: 30.2 [27 - 31] PG; NPTST193-MPV: 9.7 [8 - 11.7] FL; NPTST273-RDW: 14.4 [11.5 - 14] %; NEUTROPHILS: 12930 [1720 - 6825] 10^9/L; NEUTROPHILS/LEUKOCYTES: 76.8 [43 - 65] %; PLATELETS: 328 [150 - 450] 10^9/L; POTASSIUM: 4.3 [3.6 - 5] MMOL/L; SODIUM: 141 [135 - 145] MMOL/L

Microbiology

[redacted]20[redacted] (RX DAY 12): SPUTUM FLU A BY PCR: NEGATIVE; SPUTUM FLU B BY PCR: NEGATIVE; URINE LEGIONELLA AG, URINE: NEGATIVE; SPUTUM RSV BY PCR: NEGATIVE; URINE STREP. PNEUMO. AG, URINE: NEGATIVE

AE Stopped Rx Day	61
Duration of AE	50 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	PT HISTORY OF ASPIRATION PNEUMONIA IN PAST AS WELL AS COPD MEDICAL CONDITION.
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #4: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	LEAKING AT SITE OF INFUSION
Preferred term	注入部位血管外漏出
AE Onset Date / Rx Day	[redacted]20[redacted] / 26
Age at AE Onset	6[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	117
Duration of AE	92 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	REDNESS NOTED ON INFUSION SITE ASSESSMENT (1) AND (B) PERFORMED BY RAJESH PAHWA ON [redacted]/[redacted]/20[redacted]
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 36
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	117
Duration of AE	82 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	REDNESS (1) AND (B) NOTED ON INFUSION SITE ASSESSMENT PERFORMED BY RAJESH PAHWA, MD ON [redacted]/[redacted]/[redacted].

Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 41
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	117
Duration of AE	77 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 Infections

Event Description	CELLULITIS AT INFUSION SITE LL ABDOMEN
Preferred term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 47
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	59
Duration of AE	13 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 #8: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	REDNESS (2) AND (B) NOTED ON INFUSION SITE ASSESSMENT PERFORMED BY RAJESH PAHWA, MD ON [redacted]/20[redacted].
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 90
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	117
Duration of AE	28 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: Serious Adverse Event

Event Description	PNEUMONIA
Preferred term	肺炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 114
Age at AE Onset	6[redacted]
Laboratory Testing	

[redacted]20[redacted] (RX DAY 114): ALBUMIN: 47 [32 - 55] G/L; ALKALINE PHOSPHATASE: 73 [42 - 121] U/L; NPTST010-ALT: 8 [10 - 60] U/L; NPTST033-AST: 65 [10 - 42] U/L; NPTST037-BASE EXCESS, VENOUS: -2 [-2 - 2] MMOL/L; NPTST045-BILIRUBIN TOTAL: 0.5 [0.2 - 1] MG/DL; NPTST080-CK-MB ISOENZYME: 25 [0 - 7] NG/ML;

NPTST137-HCO3 VENOUS: 26 [22 - 28] MMOL/L; NPTST156-INR: 1.16 [0.85 - 1.13] RATIO; NPTST165-LACTIC ACID LEVEL: 1.2 [0.5 - 2] MMOL/L; NPTST195-MYOGLOBIN: 239 [0 - 70] NG/ML; NPTST205-O2 SAT VEN: 46 [94 - 100] %; NPTST214-PCO2, VENOUS: 55 [40 - 52] MMHG; NPTST240-PH VENOUS: 7.29 [7.31 - 7.41] PH; NPTST248-PO2, VENOUS: 28 [30 - 50] MMHG; NPTST260-PRO B-TYPE NATRIURETIC PEPTIDE: 1604 [0 - 900] PG/ML; NPTST261-PROCALCITONIN: 0.22 [0 - 0.49] NG/ML; NPTST267-PT: 14.2 [11.5 - 14.5] SEC; PROTEIN: 79 [60 - 80] G/L; [redacted]20[redacted] (RX DAY 115): BASOPHILS: 20 [0 - 105] 10^9/L; BASOPHILS/LEUKOCYTES: 0.2 [0.2 - 1] %; CALCIUM: 2.17 [2.12 - 2.62] MMOL/L; CREATININE: 62 [44 - 106] UMOL/L; EOSINOPHILS: 80 [40 - 315] 10^9/L; EOSINOPHILS/LEUKOCYTES: 0.7 [0.9 - 2.9] %; ERYTHROCYTES: 3.7 [4.5 - 6] 10^12/L; GLUCOSE: 6.4 [3.9 - 5.6] MMOL/L; HEMATOCRIT: 0.33 [0.42 - 0.52] FRACTION OF 1; HEMOGLOBIN: 106 [130 - 175] G/L; LEUKOCYTES: 11.2 [4 - 10.5] 10^9/L; LYMPHOCYTES: 880 [840 - 4830] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 7.9 [20.5 - 45] %; MONOCYTES: 1100 [240 - 1260] 10^9/L; MONOCYTES/LEUKOCYTES: 9.8 [5.5 - 11.7] %; NPTST014-ANION GAP: 11 [3 - 10] MMOL/L; NPTST052-BUN: 14 [6 - 20] MG/DL; NPTST075-CHLORIDE: 100 [101 - 111] MMOL/L; NPTST086-CO2: 23 [21 - 31] MMOL/L; NPTST181-MCH: 29 [27 - 31] PG; NPTST182-MCHC: 32.6 [32 - 36] G/DL; NPTST183-MCV: 89 [78 - 100] FL; NPTST193-MPV: 9.7 [8 - 11.7] FL; NPTST204-NUCLEATED RBC ABSOLUTE: 0 [0.3 - 339] U/L; NPTST273-RDW: 17.2 [11.5 - 14] %; NPTST303-TROPONIN T: 0.02 [0 - 0.02] NG/ML; NEUTROPHILS: 9010 [1720 - 6825] 10^9/L; NEUTROPHILS/LEUKOCYTES: 80.6 [43 - 65] %; PLATELETS: 294 [150 - 450] 10^9/L; POTASSIUM: 4 [3.6 - 5] MMOL/L; SODIUM: 134 [135 - 145] MMOL/L

Microbiology

[redacted]20[redacted] (RX DAY 114): SPUTUM ADENOVIRUS (A-F): NEGATIVE; URINE BACTERIA, UA: NEGATIVE; URINE BILIRUBIN, UA: NEGATIVE; URINE BLOOD, UA: NEGATIVE; SPUTUM CHLAMYDIA PNEUMONIAE: NEGATIVE; URINE CLARITY, UA: NEGATIVE-CLEAR; URINE COLOR, UA: NEGATIVE-YELLOW; SPUTUM CORONAVIRUS (229E, HKU1, NL63,: NEGATIVE; SPUTUM FLU A BY PCR: POSITIVE-INFLUENZA A FOUND TO BE POSITIVE; SPUTUM FLU B BY PCR: NEGATIVE; URINE GLUCOSE, UA: NEGATIVE; SPUTUM HUMAN METAPNEUMOVIRUS: NEGATIVE; SPUTUM HUMAN RHINOVIRUS/ENTEROVIRUS: NEGATIVE; URINE HYALINE CAST: NEGATIVE-0-2/LPF; SPUTUM INFLUENZA A BY PCR: NEGATIVE; SPUTUM INFLUENZA A H1: NEGATIVE; SPUTUM INFLUENZA A H1-20[redacted]: NEGATIVE; SPUTUM INFLUENZA A H3: NEGATIVE; SPUTUM INFLUENZA B BY PCR: NEGATIVE; URINE KETONES, UA: POSITIVE-TRACE MG/DL; URINE LEGIONELLA AG: NEGATIVE; URINE LEUKOCYTES ESTERASE: NEGATIVE; SPUTUM MYCOPLASMA PNEUMONIAE: NEGATIVE; URINE NITRITES, UA: NEGATIVE; SPUTUM PARAINFLUENZA VIRUS 1: NEGATIVE; SPUTUM PARAINFLUENZA VIRUS 2: NEGATIVE; SPUTUM PARAINFLUENZA VIRUS 3: NEGATIVE; SPUTUM PARAINFLUENZA VIRUS 4: NEGATIVE; URINE PH, UA: NEGATIVE-5.5; URINE PROTEIN, UA: POSITIVE-20 MG/DL; URINE RBC, UA: NEGATIVE-0-2/HPF; SPUTUM RESPIRATORY PANEL BY PCR: NEGATIVE; SPUTUM RESPIRATORY SYNCYTIAL VIRUS A: NEGATIVE; SPUTUM RESPIRATORY SYNCYTIAL VIRUS B: NEGATIVE; SPUTUM RSV BY PCR: NEGATIVE; URINE SPECIFIC GRAVITY, UA: NEGATIVE-NORMAL: 1.0036 AND 1.030; URINE SQUAMOUS EPITHELIAL: NEGATIVE-FEW/HPF; URINE STREP. PNEUMO. AG: NEGATIVE; URINE UROBILINOGEN, UA: NEGATIVE-NORMAL MG/DL; URINE WBC, UA: NEGATIVE-0-5/ HPF

AE Stopped Rx Day	116
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	NOT REPORTED

[redacted] **Infusion Set**	
Other cause of event	COPD, HISTORY OF ASPIRATION PNEUMONIA
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #10: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, Death

Event Description	CEREBRAL VASCULAR ACCIDENT
Preferred term	脳血管発作
AE Onset Date / Rx Day	[redacted]20[redacted] / 117
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	117
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 REPORTED
Other cause of event	MEDICAL HISTORY OF: CAD, INFERIOR MI [redacted]/[redacted]/20[redacted], INFRARENAL ABDOMINAL AORTIC ANEURYSM, BILATERAL LOWER LOBE CAP, EMPHYSEMA/COPD
Discontinued Study Drug Due to the Event	YES
SAE Criteria	PERSIST OR SIGNIF DISABILITY/INCAPACITY, OTHER MEDICALLY IMPORTANT SERIOUS EVENT, LIFE THREATENING, RESULTS IN DEATH

generated: [redacted]20[redacted]:10:45

program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

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 が投与され，両側肺炎を発現した。

Event 3 の臨床経過：

関連する病歴は，パーキンソン病，心臓発作，気胸，非破裂性腹部大動脈瘤，誤嚥性肺炎，不顕性誤嚥，低酸素症，睡眠関連，高脂血症，胃食道逆流症，慢性閉塞性肺疾患，右脚部位不明の動脈血栓塞栓症，冠動脈疾患，元喫煙者（紙巻きタバコ 1 日 20 本を 45 年間，パイプタバコ，及び葉巻），及び現飲酒者（1 日 2 杯未満）であった。

投与 12 日目，被験者は両側肺炎を発現した。投与 61 日目，両側肺炎は消失した。

本事象の発現に先立ち，投与の約 11 ヵ月前 及び投与の約 3 ヵ月前，被験者は誤嚥性肺炎を発現していた。

投与 12 日目，被験者は発熱のため緊急治療室を受診した。被験者の妻は，聴診器で被験者の呼吸音を聴取したとき，「被験者の呼吸音がしなかった」と知らせた。救急診療部到着前の被験者の体温は 101.4°F であった。被験者は継続中の誤嚥に起因することが強く疑われる両側市中感染性肺炎と診断された。被験者は入院し，抗生物質の静脈内投与が開始された。投与 14 日目，被験者は退院した。

本事象に関連するリスク因子には，被験者が夜間に酸素補給を必要としていたことがあった。

被験者にナイスタチン，酸素，アジスロマイシン，セフトリアキソン，レボフロキサシン，及び塩化ナトリウムが投与された。

The patient's past medications include:

APOKYN for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

INFLUENZA VACCINE for FLU PREVENTION ([redacted] 20[redacted] - [redacted])

PENICILLIN for UNKNOWN INDICATION

Causality for ABBV-951 (Open Label)

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1) Bilateral pneumonia (10058686) (Pneumonia (10035664)) [v.22.1] [10058686]

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 BILATERAL PNEUMONIA

- Investigator: Patient history of aspiration pneumonia in past as well as COPD medical condition

- AbbVie: More likely related to a history of aspiration pneumonia, chronic pulmonary obstructive disease, sleep related hypoxia, gastro-esophageal reflux disease and Parkinson's disease in a patient with advanced age.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ALT:** <5 U/L

[redacted] **20[redacted] ANION GAP:** 8 MMOL/L (normal 3 to 10)

[redacted] **20[redacted] BILIRUBIN, UA:** Negative

[redacted] **20[redacted] BLOOD UREA NITROGEN:** 18 mg/dL (normal 6 to 20)

[redacted] **20[redacted] BLOOD, UA:** Negative

[redacted] **20[redacted] CALCIUM:** 9.0 mg/dL (normal 8.5 to 10.5)

[redacted] **20[redacted] CHEST X-RAY:** XR Chest 1 View- Aspiration Pneumonia

[redacted] **20[redacted] CREATININE:** 0.8 mg/dL (normal 0.5 to 1.2)

[redacted] **20[redacted] EOSINOPHILS %:** 0.3% (normal 0.9 to 2.9)

[redacted] **20[redacted] GLUCOSE:** 102 mg/dL (normal 70 to 100)

[redacted] **20[redacted] HEMATOCRIT:** 30% (normal 42 to 52)

[redacted] **20[redacted] HEMOGLOBIN:** 9.7 G/DL (normal 13 to 17.5)

[redacted] **20[redacted] INR:** 1.17 Ratio (normal 0.85 to 1.13)

[redacted] **20[redacted] LACTIC ACID LEVEL:** 2.0 MMOL/L (normal 0.5 to 2.0)

[redacted] **20[redacted] LYMPHOCYTES %:** 14.7% (normal 20.5 to 45.0)

[redacted] **20**[redacted] **LYMPHOCYTES ABS:** 2480 U/L (normal 840 to 4830)

[redacted] **20**[redacted] **MCHC:** 32.3 G/DL (normal 32.0 to 36.0)

[redacted] **20**[redacted] **MCV:** 93.5 FL (normal 78.0 to 100.0)

[redacted] **20**[redacted] **MEAN CORPUSCULAR HEMOGLOBIN:** 30.2 PG (normal 27.0 to 31.0)

[redacted] **20**[redacted] **MONOCYTES %:** 7.0% (normal 5.5 to 11.7)

[redacted] **20**[redacted] **MONOCYTES ABS:** 1170 U/L (normal 240 to 1260)

[redacted] **20**[redacted] **MPV:** 9.7 FL (normal 8.0 to 11.7)

[redacted] **20**[redacted] **NEUTROPHILS %:** 76.8% (normal 43.0 to 65.0)

[redacted] **20**[redacted] **NEUTROPHILS ABS:** 12930 U/L (normal 1720 to 6825)

[redacted] **20**[redacted] **PLATELET COUNT:** 328 KU/L (normal 150 to 450)

[redacted] **20**[redacted] **POTASSIUM:** 4.3 MMOL/L (normal 3.6 to 5.0)

[redacted] **20**[redacted] **PROCALCITONIN:** 0.22 NG/ML (normal 0.00 to 0.49)

[redacted] **20**[redacted] **PT:** 14.70 SEC (normal 11.50 to 14.50)

[redacted] **20**[redacted] **RDW:** 14.4% (normal 11.5 to 14.0)

[redacted] **20**[redacted] **RED BLOOD CELLS:** 3.21 M/uL (normal 4.50 to 6.00)

[redacted] **20**[redacted] **SODIUM:** 141 MMOL/L (normal 135 to 145)

[redacted] **20**[redacted] **SPUTUM CULTURE:** Flu A by PCR - Negative

[redacted] **20**[redacted] **SPUTUM RSV BY PCR:** Negative

[redacted] **20**[redacted] **TOTAL BILIRUBIN:** 0.6 mg/dL (normal 0.2 to 1.0)

[redacted] **20**[redacted] **URINE:** Clarity- Clear

[redacted] **20**[redacted] **URINE:** Color-Light Yellow

[redacted] **20**[redacted] **URINE BACTERIA, UA:** Negative

[redacted] **20**[redacted] **URINE GLUCOSE:** Negative

[redacted] **20**[redacted] **URINE HYALINE CAST:** 0-2 IPF

[redacted] 20[redacted] **URINE KETONES:** Negative

[redacted] 20[redacted] **URINE LEGIONELLA AG:** Negative

[redacted] 20[redacted] **URINE LEUKOCYTE ESTERASE:** Negative

[redacted] 20[redacted] **URINE NITRITES:** Negative

[redacted] 20[redacted] **URINE PH:** 6.5 PH (normal 4.5 to 8)

[redacted] 20[redacted] **URINE PROTEIN:** Negative

[redacted] 20[redacted] **URINE RBC:** 0-5 (HPF)

[redacted] 20[redacted] **URINE SPECIFIC GRAVITY:** 1.010 No units (normal 1.003 to 1.030)

[redacted] 20[redacted] **URINE SQUAMOUS EPITHELIAL:** Negative/Few HPF

[redacted] 20[redacted] **URINE STREP. PNEUMO. AG:** Negative

[redacted] 20[redacted] **URINE UROBILINOGEN:** Normal

[redacted] 20[redacted] **URINE WBC:** 0-5 (HPF)

[redacted] 20[redacted] **WHITE BLOOD CELLS:** 16.8 k/uL (normal 4.0 to 10.5)

[redacted] 20[redacted] **XR SWALLOWING FUNCTION ESOPH VIDEO:** ZR SWALLOWING FUNCTION ESOPH VIDEO: 1. ASPIRATION WITH THIN CONSISTENCY BARIUM 2. LARYNGEAL PENETRATION AND EVENTUAL COATING OF THE CORDS WITH NECTAR AND HONEY CONSISTENCY, 3. THINNNING AND THICKER CONSISTENCIES APPEAR TO BE SAFE WITHOUT SIGNIFICANT LARYNGEAL PENETRATION OR EVIDENCE FOR ASPIRATION.

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

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 が投与され，死亡に至った脳血管障害及び肺炎を発現した。

<u>Event 9 及び 10 の臨床経過：</u>

関連する病歴は，パーキンソン病，慢性閉塞性肺疾患，胃食道逆流症，心臓発作，高脂血症，非破裂性腹部大動脈瘤，右脚部位不明の動脈血栓塞栓症，誤嚥性肺炎，低酸素症，睡眠関連，冠動脈疾患，不顕性誤嚥，鉄欠乏性貧血，冠動脈ステント留置，元喫煙者（紙巻きタバコ 1 日 20 本を 45 年間），及び現飲酒者（1 日 2 杯未満）であった。

投与 1 日目から投与 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治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 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 114 日目，被験者は肺炎を発現した。投与 116 日目，肺炎は消失した。投与 117 日目，被験者は脳血管障害を発現した。同日，被験者は死亡した。死因は脳血管障害であった。剖検は実施されなかった。

投与 114 日目，被験者は肺炎及び A 型インフルエンザ感染のため入院した。投与 116 日目，被験者は退院し帰宅した。投与 117 日目，被験者の妻が被験者の死亡に気づいたと報告した。

主な死因は脳血管障害とした死亡証明書を入手した。副次的要因は敗血症及び肺炎であった。被験者は低酸素症及び高炭酸ガス血症を伴う急性呼吸不全を発現した。

本事象に関連するリスク因子：誤嚥，低酸素症，A 型インフルエンザ感染，及び市中感染性肺炎による重度敗血症。また，以下の病歴：冠動脈疾患，下壁心筋梗塞（20[redacted] 年 [redacted] 月 [redacted] 日），腎臓下腹部大動脈瘤，両下葉市中肺炎，肺気腫／慢性閉塞性肺疾患。

The patient's past medications include:

APOKYN for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

CARBIDOPA/LEVODOPA IMMEDITE RELEASE (SINEMET IR) for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

INFLUENZA VACCINE for FLU PREVENTION; VACCINE ([redacted] 20[redacted] - [redacted] 20[redacted])

LEVOFOXACIN for BILATERAL PNEUMONIA and COUGH ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

NYSTATIN for BILATERAL PNEUMONIA ([redacted] 20[redacted] - [redacted] 20[redacted])

OXYGEN SUPPLEMENT for BILATERAL PNEUMONIA ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Cerebrovascular accident (10008190) (Cerebrovascular accident (10008190)) [v.23.0] [10008190]

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

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

Dechallenge: Not Applicable

2) Pneumonia (10035664) (Pneumonia (10035664)) [v.23.0] [10035664]

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 CEREBRAL VASCULAR ACCIDENT

- Investigator: Medical History of: CAD, Inferior MI [redacted]/[redacted]/20[redacted], Infrarenal abdominal aortic aneurysm, Bilateral lower lobe CAP, Emphysema/COPD

- AbbVie: More likely related to a history of aspiration pneumonia, silent aspiration, chronic obstructive pulmonary disease, coronary artery disease with stent placement, right leg arterial thrombosis, right leg arterial embolism and Parkinson's disease in an advanced aged patient with an increased BMI and a recent event of pneumonia.

Event of PNEUMONIA

- Investigator: COPD and history of aspiration pneumonia.

- AbbVie: More likely related to a history of aspiration pneumonia, silent aspiration, chronic obstructive pulmonary disease and Parkinson's disease in an advanced aged patient with increased BMI.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ABSOLUTE NEUTROPHILS:** 9010 k/uL (normal 1720 to 6825)

[redacted] **20[redacted] ALT:** 8 UNIT/L (normal 10 to 60)

[redacted] **20[redacted] ANION GAP:** 11 MMOL/L (normal 3 to 10)

[redacted] **20[redacted] AST:** 65 UNIT/L (normal 10 to 42)

[redacted] **20[redacted] BASE EXCESS, VENOUS:** -2 mmol/L. Lower normal range: -2, Upper normal range: +2

[redacted] **20**[redacted] **CHLORIDE:** 100 MMOL/L (normal 101 to 111)

[redacted] **20**[redacted] **CK-MB:** 25 NG/ML (normal 0 to 7)

[redacted] **20**[redacted] **EOSINOPHILS:** 0.7% (normal 0.9 to 2.9)

[redacted] **20**[redacted] **GLUCOSE:** 116 mg/dL (normal 70 to 100)

[redacted] **20**[redacted] **HEMATOCRIT:** 32.5% (normal 42.0to 52.0)

[redacted] **20**[redacted] **HEMOGLOBIN:** 10.6 G/DL (normal 13.0 to 17.5)

[redacted] **20**[redacted] **INR:** 1.16 RATIO (normal 0.85 to 1.13)

[redacted] **20**[redacted] **LYMPHOCYTES:** 7.9% (normal 20.5 to 45.0)

[redacted] **20**[redacted] **MYOGLOBIN:** 239 NG/ML (normal 0 to 70)

[redacted] **20**[redacted] **NEUTROPHILS:** 80.6% (normal 43.0 to 65.0)

[redacted] **20**[redacted] **NEUTROPHILS ABS:** 9010 k/uL (normal 1720 to 6825)

[redacted] **20**[redacted] **NUCLEATED RBC ABSOLUTE:** 0.0 U/L (normal 0.3 to 339)

[redacted] **20**[redacted] **PCO2:** 55 mmHg (normal 40 to 52)

[redacted] **20**[redacted] **PH:** 7.29 PH (normal 7.31 to 7.41)

[redacted] **20**[redacted] **PO2:** 28 mmHg (normal 30 to 50)

[redacted] **20**[redacted] **PRO B-TYPE NATRIURETIC PEPTIDE:** 1604 PG/ML (normal 0 to 900)

[redacted] **20**[redacted] **RBC:** 3.65 M/UL (normal 4.50 to 6.00)

[redacted] **20**[redacted] **RDW:** 17.2% (normal 11.5 to 14.0)

[redacted] **20**[redacted] **SODIUM:** 134 MMOL/L (normal 135 to 145)

[redacted] **20**[redacted] **TROPONIN T:** 0.02 NG/ML (normal 0.00 to 0.02)

[redacted] **20**[redacted] **VENOUS OXYGEN SATURATION:** 46% (normal 94 to 100)

[redacted] **20**[redacted] **WBC:** 11.2 KU/L (normal 4.0 to 10.5)

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
無力症	X			
脱水	X			
注入部位蜂巣炎	X			X
注入部位紅斑				X
注入部位結節				X
注入部位浮腫				X
注入部位丘疹				X
敗血症	X			
尿路感染	X			
体重減少				X

Treatment Group	Age at 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]
CELIAC -NON TROPICAL SPRUE	20[redacted]
WALKING PNEUMONIA	20[redacted]
BILATERAL CATARACTS	20[redacted]
MACULAR DEGENERATION BOTH EYES	20[redacted]
RESTLESS LEG SYNDROME	20[redacted]
LEFT BUNDLE BRANCH BLOCK	20[redacted]
EPIRETINAL MEMBRANE	20[redacted]
POLYMYALGIA RHEUMATICA	20[redacted]

OSTEOARTHRITIS	20[redacted]
CARPAL TUNNEL SYNDROME LEFT HAND	20[redacted]
URINARY TRACT INFECTION	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	0.43	0.52	0.34	60	0.15	[redacted]20[redacted]/1
ABBV-951	0.28	0.34	0.23	60	0.15	[redacted]20[redacted]/2
ABBV-951	0.28	0.34	0.23	60	0.15	[redacted]20[redacted]/8
ABBV-951	0.28	0.34	0.23	60	0.15	[redacted]20[redacted]/17
ABBV-951	0.28	0.34	0.23	60	0.15	[redacted]20[redacted]/24
ABBV-951	0.28	0.34	0.23	60	0.15	[redacted]20[redacted]/32

ABBV-951	0.28	0.34	0.23	60	0.15	[redacted]/43
ABBV-951	0.34	0.4	0.28	60	0.15	[redacted]/92
ABBV-951	0.38	0.46	0.3	60	0.15	[redacted]/184
ABBV-951	0.38	0.46	0.3	60	0.15	[redacted]/269
ABBV-951	0.38	0.46	0.3	60	0.15	[redacted]/297
ABBV-951	0.38	0.46	0.3	60	0.15	[redacted]/303
ABBV-951	0.4	0.48	0.32	60	0.15	[redacted]/338
ABBV-951	0.46	0.55	0.37	60	0.15	[redacted]/352
ABBV-951	0.57	0.68	0.46	60	0.15	[redacted]/367

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	669.34		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951		25.61	SC / ONCE	[redacted] / 4	
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951		76.83	SC / ONCE	[redacted] / 5	
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951		51.22	SC / ONCE	[redacted] / 6	
ABBV-951	1105.77		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951		25.61	SC / ONCE	[redacted] / 7	
ABBV-951	1056.77		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951	1393.32		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951	1393.32		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	1393.32		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	1393.32		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951	1393.32		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951		153.67	SC / ONCE	[redacted] / 13	
ABBV-951	1234.52		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951		76.83	SC / ONCE	[redacted] / 14	
ABBV-951	1066.33		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951		51.22	SC / ONCE	[redacted] / 15	
ABBV-951	1055.57		SC / CONTINUOUS	[redacted] / 15	[redacted] / 15
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 16	[redacted] / 16
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 17	[redacted] / 17
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 18	[redacted] / 18
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 19	[redacted] / 19

ABBV-951		51.22	SC / ONCE	[redacted] / 20	
ABBV-951	1128.31		SC / CONTINUOUS	[redacted] / 20	[redacted] / 20
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 21	[redacted] / 21
ABBV-951		102.45	SC / ONCE	[redacted] / 22	
ABBV-951	1111.75		SC / CONTINUOUS	[redacted] / 22	[redacted] / 22
ABBV-951		51.22	SC / ONCE	[redacted] / 23	
ABBV-951	1220.17		SC / CONTINUOUS	[redacted] / 23	[redacted] / 23
ABBV-951	1393.32		SC / CONTINUOUS	[redacted] / 24	[redacted] / 24
ABBV-951	1393.32		SC / CONTINUOUS	[redacted] / 25	[redacted] / 25
ABBV-951	1393.32		SC / CONTINUOUS	[redacted] / 26	[redacted] / 26
ABBV-951	1393.32		SC / CONTINUOUS	[redacted] / 27	[redacted] / 27
ABBV-951	1393.32		SC / CONTINUOUS	[redacted] / 28	[redacted] / 28
ABBV-951	1393.32		SC / CONTINUOUS	[redacted] / 29	[redacted] / 29
ABBV-951		51.22	SC / ONCE	[redacted] / 30	
ABBV-951	1166.05		SC / CONTINUOUS	[redacted] / 30	[redacted] / 30
ABBV-951		76.83	SC / ONCE	[redacted] / 31	
ABBV-951	1171.00		SC / CONTINUOUS	[redacted] / 31	[redacted] / 31
ABBV-951	942.54		SC / CONTINUOUS	[redacted] / 32	[redacted] / 32
ABBV-951	942.54		SC / CONTINUOUS	[redacted] / 33	[redacted] / 33
ABBV-951	942.54		SC / CONTINUOUS	[redacted] / 34	[redacted] / 34
ABBV-951	942.54		SC / CONTINUOUS	[redacted] / 35	[redacted] / 35
ABBV-951	942.54		SC / CONTINUOUS	[redacted] / 36	[redacted] / 36
ABBV-951	942.54		SC / CONTINUOUS	[redacted] / 37	[redacted] / 37
ABBV-951	942.54		SC / CONTINUOUS	[redacted] / 38	[redacted] / 38
ABBV-951	942.54		SC / CONTINUOUS	[redacted] / 39	[redacted] / 39
ABBV-951	942.54		SC / CONTINUOUS	[redacted] / 40	[redacted] / 40
ABBV-951		25.61	SC / ONCE	[redacted] / 41	
ABBV-951	1036.79		SC / CONTINUOUS	[redacted] / 41	[redacted] / 41
ABBV-951		51.22	SC / ONCE	[redacted] / 42	
ABBV-951	1070.77		SC / CONTINUOUS	[redacted] / 42	[redacted] / 42
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 43	[redacted] / 43
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 44	[redacted] / 44
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 45	[redacted] / 45
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 46	[redacted] / 46
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 47	[redacted] / 47
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 48	[redacted] / 48
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 49	[redacted] / 49

ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 74	[redacted]20[redacted] / 74
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 76
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 77
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 78	[redacted]20[redacted] / 78
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 79	[redacted]20[redacted] / 79
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 80
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 81	[redacted]20[redacted] / 81
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 82	[redacted]20[redacted] / 82
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 85	[redacted]20[redacted] / 85
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 86	[redacted]20[redacted] / 86

ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 87	[redacted]20[redacted] / 87
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 88	[redacted]20[redacted] / 88
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 89	[redacted]20[redacted] / 89
ABBV-951	1058.99	SC / CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 90
ABBV-951	928.53	SC / CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
ABBV-951	942.54	SC / CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 92
ABBV-951	942.54	SC / CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 93
ABBV-951	942.54	SC / CONTINUOUS	[redacted]20[redacted] / 94	[redacted]20[redacted] / 94
ABBV-951	942.54	SC / CONTINUOUS	[redacted]20[redacted] / 95	[redacted]20[redacted] / 95
ABBV-951	942.54	SC / CONTINUOUS	[redacted]20[redacted] / 96	[redacted]20[redacted] / 96
ABBV-951	942.54	SC / CONTINUOUS	[redacted]20[redacted] / 97	[redacted]20[redacted] / 97
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ABBV-951	942.54	SC / CONTINUOUS	[redacted]20[redacted] / 99	[redacted]20[redacted] / 99
ABBV-951	942.54	SC / CONTINUOUS	[redacted]20[redacted] / 100	[redacted]20[redacted] / 100
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ABBV-951	942.54	SC / CONTINUOUS	[redacted]20[redacted] / 102	[redacted]20[redacted] / 102
ABBV-951	942.54	SC / CONTINUOUS	[redacted]20[redacted] / 103	[redacted]20[redacted] / 103
ABBV-951	942.54	SC / CONTINUOUS	[redacted]20[redacted] / 104	[redacted]20[redacted] / 104
ABBV-951	942.54	SC / CONTINUOUS	[redacted]20[redacted] / 105	[redacted]20[redacted] / 105
ABBV-951	942.54	SC / CONTINUOUS	[redacted]20[redacted] / 106	[redacted]20[redacted] / 106
ABBV-951	942.54	SC / CONTINUOUS	[redacted]20[redacted] / 107	[redacted]20[redacted] / 107
ABBV-951	942.54	SC / CONTINUOUS	[redacted]20[redacted] / 108	[redacted]20[redacted] / 108
ABBV-951	942.54	SC / CONTINUOUS	[redacted]20[redacted] / 109	[redacted]20[redacted] / 109
ABBV-951	942.54	SC / CONTINUOUS	[redacted]20[redacted] / 110	[redacted]20[redacted] / 110
ABBV-951	942.54	SC / CONTINUOUS	[redacted]20[redacted] / 111	[redacted]20[redacted] / 111
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ABBV-951	942.54	SC / CONTINUOUS	[redacted]20[redacted] / 114	[redacted]20[redacted] / 114
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ABBV-951	942.54	SC / CONTINUOUS	[redacted]20[redacted] / 143	[redacted]20[redacted] / 143
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ABBV-951	1229.4	SC / CONTINUOUS	[redacted]20[redacted] / 219	[redacted]20[redacted] / 219
ABBV-951	1229.4	SC / CONTINUOUS	[redacted]20[redacted] / 220	[redacted]20[redacted] / 220
ABBV-951	1229.4	SC / CONTINUOUS	[redacted]20[redacted] / 221	[redacted]20[redacted] / 221
ABBV-951	1229.4	SC / CONTINUOUS	[redacted]20[redacted] / 222	[redacted]20[redacted] / 222
ABBV-951	1229.4	SC / CONTINUOUS	[redacted]20[redacted] / 223	[redacted]20[redacted] / 223
ABBV-951	1229.4	SC / CONTINUOUS	[redacted]20[redacted] / 224	[redacted]20[redacted] / 224
ABBV-951	1229.4	SC / CONTINUOUS	[redacted]20[redacted] / 225	[redacted]20[redacted] / 225
ABBV-951	1229.4	SC / CONTINUOUS	[redacted]20[redacted] / 226	[redacted]20[redacted] / 226
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ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 235	[redacted]20[redacted] / 235
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ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 243	[redacted]20[redacted] / 243
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 244	[redacted]20[redacted] / 244
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 245	[redacted]20[redacted] / 245
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 246	[redacted]20[redacted] / 246
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 247	[redacted]20[redacted] / 247
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ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 263	[redacted]20[redacted] / 263
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ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 266	[redacted]20[redacted] / 266
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 267	
ABBV-951	507.12		SC / CONTINUOUS	[redacted]20[redacted] / 267	[redacted]20[redacted] / 267
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 268	
ABBV-951	680.26		SC / CONTINUOUS	[redacted]20[redacted] / 268	[redacted]20[redacted] / 268

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
PREDNISOLONE	5 mg	QD	Y-M: 20[redacted]
ROPINIROLE	2.000 mg	BID	Y-M: 20[redacted]
ROPINIROLE HYDROCHLORIDE	200.000 mg	6 TIMES PER DAY	Y-M: 20[redacted]
GABAPENTIN	100 mg	OTHER: EVERY MORNING	Y-M: 20[redacted]
LEVOTHYROXINE	100 OTHER: MCG	QD	Y-M: 20[redacted]
SOLIFENACIN	5 mg	QD	Y-M: 20[redacted]
ASCORBIC ACID;BETACAROTENE;COPPER;TOCOFERSOLAN;ZINC	1 OTHER: TABLET	QD	Y-M: 20[redacted]
COLECALCIFEROL	2000 IU	QD	Y-M: 20[redacted]
FLUDROCORTISONE	0.1 mg	QD	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	95.000 mg	TID	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	150.000 mg	8 TIMES PER DAY	Y-M: 20[redacted]
ENTACAPONE	200.000 mg	6 TIMES PER DAY	Y-M: 20[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
PREDNISOLONE	5 mg	QD	Y-M: 20[redacted]	ONGOING
GABAPENTIN	100 mg	OTHER: EVERY MORNING	Y-M: 20[redacted]	ONGOING
LEVOTHYROXINE	100 OTHER: MCG	QD	Y-M: 20[redacted]	ONGOING
SOLIFENACIN	5 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 288
ASCORBIC ACID;BETACAROTENE;COPPER;TOCOFERSOLAN;ZINC	1 OTHER: TABLET	QD	Y-M: 20[redacted]	ONGOING
COLECALCIFEROL	2000 IU	QD	Y-M: 20[redacted]	ONGOING
FLUDROCORTISONE	0.1 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 289
GABAPENTIN	400 mg	OTHER: EVERY NIGHT	Y-M: 20[redacted] / 66	ONGOING
CEFTRIAXONE	1 g	OTHER: ONCE	Y-M: 20[redacted] / 104	Y-M: 20[redacted] / 104
DEXAMETHASONE	10 mg	OTHER: ONCE	Y-M: 20[redacted] / 104	Y-M: 20[redacted] / 104
FENTANYL CITRATE	25 OTHER: MCG	OTHER: ONCE	Y-M: 20[redacted] / 104	Y-M: 20[redacted] / 104

SODIUM CHLORIDE	500 mL	OTHER: ONCE	Y-M: 20[redacted] / 104	Y-M: 20[redacted] / 104
CEFALEXIN	500 mg	BID	Y-M: 20[redacted] / 184	Y-M: 20[redacted] / 191
CEFTRIAXONE	1 g	OTHER: ONCE	Y-M: 20[redacted] / 281	Y-M: 20[redacted] / 281
LORAZEPAM	0.5 mg	OTHER: ONCE	Y-M: 20[redacted] / 281	Y-M: 20[redacted] / 281
PARACETAMOL	650 mg	OTHER: ONCE	Y-M: 20[redacted] / 281	Y-M: 20[redacted] / 281
VANCOMYCIN	1000 mg	BID	Y-M: 20[redacted] / 281	Y-M: 20[redacted] / 288
CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE	3 L	QD	Y-M: 20[redacted] / 281	Y-M: 20[redacted] / 289
CEFALEXIN	500 mg	QID	Y-M: 20[redacted] / 288	Y-M: 20[redacted] / 296
FLUDROCORTISONE	0.3 mg	QD	Y-M: 20[redacted] / 289	ONGOING
FOLIC ACID	1 mg	QD	Y-M: 20[redacted] / 289	ONGOING
PYRIDOXINE HYDROCHLORIDE	100 mg	QD	Y-M: 20[redacted] / 289	ONGOING
SOLIFENACIN	10 mg	QD	Y-M: 20[redacted] / 289	ONGOING
PREDNISONE	15 mg	QD	Y-M: 20[redacted] / 289	Y-M: 20[redacted] / 290
PREDNISONE	10 mg	QD	Y-M: 20[redacted] / 291	Y-M: 20[redacted] / 292
CEFALEXIN	500 mg	QID	Y-M: 20[redacted] / 297	Y-M: 20[redacted] / 304
CEFALEXIN	500 mg	QID	Y-M: 20[redacted] / 359	Y-M: 20[redacted] / 364

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ERYTHEMA AT INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 8
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	17
Duration of AE	10 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	NOT APPLICABLE

[redacted] Infusion Set	
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	ERYTHEMA AT INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 9
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	43
Duration of AE	35 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: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	NODULE AT INFUSION SITE
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 9
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	43

Duration of AE	35 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	EDEMA AT INFUSION SITE
Preferred term	注入部位浮腫
AE Onset Date / Rx Day	[redacted]20[redacted] / 9
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	43
Duration of AE	35 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: Event of Interest - Weight Loss

Event Description	WEIGHT LOSS
Preferred term	体重減少

AE Onset Date / Rx Day	[redacted]20[redacted] / 43
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
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 #6: Serious Adverse Event

Event Description	WEAKNESS
Preferred term	無力症
AE Onset Date / Rx Day	[redacted]20[redacted] / 104
Age at AE Onset	7[redacted]
Laboratory Testing	
[redacted]20[redacted] (RX DAY 104): NPTST309-URINALYSIS BACTERIAL: MANY [NOT REPORTED - NOT REPORTED] CELL COUNT	
Microbiology	
[redacted]20[redacted] (RX DAY 105): BLOOD CULTURE, BACTERIAL, BLOOD: NEGATIVE	
AE Stopped Rx Day	107
Duration of AE	4 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	UNLIKELY
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to	NOT REPORTED

[redacted] **Infusion Set**	
Other cause of event	URINARY TRACT INFECTION (UTI) CAUSED BY BACTERIA, WITH DEHYDRATION AND WEAKNESS SECONDARY TO UTI.
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #7: Serious Adverse Event

Event Description	DEHYDRATION
Preferred term	脱水
AE Onset Date / Rx Day	[redacted]20[redacted] / 104
Age at AE Onset	7[redacted]
Laboratory Testing	

[redacted]20[redacted] (RX DAY 104): NPTST309-URINALYSIS BACTERIAL: MANY [NOT REPORTED - NOT REPORTED] CELL COUNT

Microbiology

[redacted]20[redacted] (RX DAY 105): BLOOD CULTURE, BACTERIAL, BLOOD: NEGATIVE

AE Stopped Rx Day	107
Duration of AE	4 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	UNLIKELY
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	URINARY TRACT INFECTION (UTI) CAUSED BY BACTERIA, WITH DEHYDRATION AND WEAKNESS SECONDARY TO UTI.
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #8: Serious Adverse Event

Event Description	URINARY TRACT INFECTION
Preferred term	尿路感染
AE Onset Date / Rx Day	[redacted]20[redacted] / 104
Age at AE Onset	7[redacted]
Laboratory Testing	

[redacted]20[redacted] (RX DAY 104): NPTST309-URINALYSIS BACTERIAL: MANY [NOT REPORTED - NOT REPORTED] CELL COUNT

Microbiology

[redacted]20[redacted] (RX DAY 105): BLOOD CULTURE, BACTERIAL, BLOOD: NEGATIVE

AE Stopped Rx Day	107
Duration of AE	4 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	UNLIKELY
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	URINARY TRACT INFECTION (UTI) CAUSED BY BACTERIA, WITH DEHYDRATION AND WEAKNESS SECONDARY TO UTI.
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #9: 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] / 181
Age at AE Onset	7[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	188
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 [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, 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] / 281
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 281): LEUKOCYTES: 17.9 [4.5 - 10] 10^9/L; SODIUM: 130 [136 - 144] MMOL/L; [redacted]20[redacted] (RX DAY 284): SODIUM: 122 [136 - 144] MMOL/L; [redacted]20[redacted] (RX DAY 285): NPTST180-MAGNESIUM: 1.2 [1.6 - 2.6] MEQ/L; NPTST243-PHOSPHORUS: 1.8 [2.5 - 4.6] MG/DL; POTASSIUM: 3.3 [3.6 - 5.1] MMOL/L

Microbiology

NOT REPORTED

AE Stopped Rx Day	367
Duration of AE	87 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	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	REQUIRES OR PROLONGS HOSPITALIZATION

Event #11: Serious Adverse Event

Event Description	SEPSIS
Preferred term	敗血症
AE Onset Date / Rx Day	[redacted]20[redacted] / 281
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 281): LEUKOCYTES: 17.9 [4.5 - 10] 10^9/L; SODIUM: 130 [136 - 144] MMOL/L; [redacted]20[redacted] (RX DAY 284): SODIUM: 122 [136 - 144] MMOL/L; [redacted]20[redacted] (RX DAY 285): NPTST180-MAGNESIUM: 1.2 [1.6 - 2.6] MEQ/L; NPTST243-PHOSPHORUS: 1.8 [2.5 - 4.6] MG/DL; POTASSIUM: 3.3 [3.6 - 5.1] MMOL/L

Microbiology

NOT REPORTED

AE Stopped Rx Day	289
Duration of AE	9 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	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	REQUIRES OR PROLONGS HOSPITALIZATION

Event #12: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	NODULE RIGHT UPPER ABDOMEN, AT INFUSION SITE
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 337
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	367
Duration of AE	31 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 #13: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MODERATE ERYTHEMA AT INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 352

Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
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 #14: Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS AT PRIOR INFUSION SITE
Preferred term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 359
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	367
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 #15: 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	
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 #16: 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	
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]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

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 が投与され，尿路感染，脱水，及び脱力感を発現した。

Event 6，7，及び 8 の臨床経過：

関連する病歴は，混合性尿失禁，膀胱修復，アジソン病，橋本病，パーキンソン病，非熱帯性セリアックスプルー，尿路感染，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 104 日目，被験者は尿路感染，脱水，及び脱力感を発現した。投与 107 日目，尿路感染，脱水，及び脱力感は消失した。

投与 104 日目，被験者は全身の脱力感の悪化並びに摂食量及び摂水量の減少が徐々に発現したため緊急治療室を受診した。被験者は入院し，脱水及び脱力感の原因となっている尿路感染の治療を受けた。被験者はアジソン病のクリーゼと考えられたため，デキサメタゾンの静脈内投与を一度受けたが，後に尿路感染，脱力感，及び脱水と診断された。被験者は脱水のため塩化ナトリウムが投与され，尿路感染のためセフトリアキソンが投与され回復した。投与 107 日目，被験者は退院した。

被験者に塩化ナトリウム，セフトリアキソン，塩化ナトリウム，デキサメタゾン，フェンタニルが投与された。

The patient's past medications include:

ROPINIROLE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

REQUIP XL for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

RYTARY for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

SINEMET IR for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Urinary tract infection (10046571) (Urinary tract infection (10046571)) [v.23.0] [10046571]

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

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

Dechallenge: Not Applicable

2) Dehydration (10012174) (Dehydration (10012174)) [v.23.0] [10012174]

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

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

Dechallenge: Not Applicable

3) Weakness (10047862) (Asthenia (10003549)) [v.23.0] [10047862]

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 URINARY TRACT INFECTION, DEHYDRATION, WEAKNESS

- Investigator: Urinary tract infection (UTI) caused by bacteria, with dehydration and weakness secondary to UTI.- AbbVie: More likely related to a history of mixed incontinence, bladder repair, Addison's disease and Parkinson's disease in a patient with advanced age.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BLOOD CULTURE:** Negative

[redacted] **20[redacted] URINALYSIS:** Many cells

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

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 が投与され，注入部位蜂巣炎及び敗血症を発現した。

Event 10 及び 11 の臨床経過：

関連する病歴は，アジソン病，橋本病，パーキンソン病，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 1 日目から投与 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治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 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 281 日目，被験者は注入部位蜂巣炎及び敗血症を発現した。投与 289 日目，敗血症は消失した。投与 367 日目，注入部位蜂巣炎は消失した。

投与 281 日目の朝，注入部位がより紅斑化し硬くなった。被験者は次第に気分が悪くなり，被験者の夫が被験者を病院に連れて行った。同日，被験者は敗血症のため入院したが，これは被験者のポンプ挿入部位からの腹壁蜂巣炎に続発するものであった。徴候や症状として，精神状態の変化，発熱，脱水，並びに，注入部位周囲の紅斑及び硬結がみられた。被験者はアジソン病の病歴がありそれが脱水のリスクを高めていたが，原因は敗血症による可能性が高いと考えられた。被験者は静脈内投与による抗生物質と輸液の治療を受けた。投与 289 日目，被験者は退院した。

病院の診療記録：

被験者は，前腹部に過去の皮下ポンプ挿入部位の発赤及び硬結があり，白血球が 17.9 と増加し，プロカルシトニン値が 6.95 と上昇したが，乳酸値は正常であった。超音波で膿瘍は認められなかった。被験者は最初にバンコマイシン及びセファゾリンの抗生物質による治療を受けた。後にバンコマイシンの投与は中止された。MRSA について，鼻のスクリーニングは陰性で，血液培養でも認められなかった。被験者は慢性副腎機能不全があり，ナトリウム値は 130 であったが，その後投与 285 日目には 117 と減少傾向がみられた。被験者は等張液とステロイドによる治療を受けた。また被験者は，副腎機能障害／低ナトリウム血症の悪化，脱水，及び入院関連譫妄に起因して間をあけて悪化した敗血症による急性代謝性脳症を発現した。

敗血症は消失し白血球数は正常化したため，投与 288 日目，抗生物質による治療はケフレックスに移行した。被験者の精神状態は著しく改善し，退院時のナトリウム値も 135 と安定した。

皮膚科医の診療記録：

投与 313 日目，被験者は腹部の注入部位発疹の評価のため，皮膚科医を受診した。検査により，以前のポンプ挿入位置に多数の赤青色 1-2 cm で硬結性の皮膚／皮下局面が認められた。非挿入部や関与する他の範囲には病変が認められなかった。投与から約 10 ヵ月目の上旬，直近に被験者はセファレキシンを投与されていたが，改善がみられなかった。この来院時に右中間腹部の穿刺生検が行われた。

投与 319 日目，被験者は経過観察のため皮膚科医を受診した。診察で，右中腹部の穿刺部位に，良好に治癒したピンク色の斑が認められた。生検の結果は被験者に共有された。皮膚科医は，腹部の発疹は注射部位反応に一致しているようであり，おそらく薬物の刺激効果が組織壊死及び漿液腫形成を引き起こしたと示唆した。

被験者にロラゼパム，乳酸リンゲル液，セフトリアキソン，タイレノール，ケフレックス，及びバンコマイシンが投与された。

The patient's past medications include:

ROPINIROLE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

REQUIP XL for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

CARBIDOPA/LEVODOPA EXTENDED RELEASE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

SINEMET IR for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

ENTACAPONE for PARKINSON'S DISEASE ([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.23.1] [10065455]

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

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Not Applicable

2) Sepsis (10040047) (Sepsis (10040047)) [v.23.1] [10040047]

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 CELLULITIS AT INFUSION SITE

- Investigator: Not applicable.

- AbbVie: Not applicable.

Event of SEPSIS

- Investigator: Not applicable.

- AbbVie: Not applicable.

ADVERSE EVENTS OF SPECIAL INTEREST AND **OTHER AREAS OF SAFETY INTEREST

Weight Decreased: Day 1 weight 4[redacted] kg. Weight at time of event 4[redacted] kg. 4[redacted] kg at Week 26 visit. Weight loss occurred over a period of 10 months. No change in diet or mobility level with pump/infusion therapy. Onset of weight loss did not coincide with worsening PD symptoms or eating difficulties. Subject experienced temporal cognitive decline, temporal and previous episodes of dyskinesia worsening since treatment began, temporal and previous episodes of malnutrition, temporal episode of infection, and previous episode of anosmia.

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
急性心筋梗塞	X			
心停止	X			
冠動脈疾患	X			
低ナトリウム血症	X			
注入部位蜂巣炎				X
注入部位不快感				X

Treatment Group	Age at 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]

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	0.2	0.24	0.17	60	0.11	[redacted]20[redacted]/1
ABBV-951	0.21	0.24	0.18	60	0.11	[redacted]20[redacted]/2
ABBV-951	0.2	0.24	0.18	60	0.11	[redacted]20[redacted]/8
ABBV-951	0.2	0.24	0.18	60	0.11	[redacted]20[redacted]/15
ABBV-951	0.2	0.23	0.18	60	0.11	[redacted]20[redacted]/22
ABBV-951	0.21	0.23	0.19	60	0.11	[redacted]20[redacted]/29
ABBV-951	0.21	0.23	0.19	60	0.11	[redacted]20[redacted]/44
ABBV-951	0.21	0.23	0.19	60	0.11	[redacted]20[redacted]/85
ABBV-951	0.21	0.23	0.19	60	0.11	[redacted]20[redacted]/183
ABBV-951	0.21	0.23	0.19	60	0.11	[redacted]20[redacted]/273
ABBV-951	0.21	0.23	0.19	60	0.11	[redacted]20[redacted]/363

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	375.65		SC / CONTINUOUS	[redacted]20[redacted] / 1	[redacted]20[redacted] / 1
ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 2	[redacted]20[redacted] / 2

ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 3	[redacted]20[redacted] / 3
ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 4	[redacted]20[redacted] / 4
ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 5	[redacted]20[redacted] / 5
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 6	
ABBV-951	815.16		SC / CONTINUOUS	[redacted]20[redacted] / 6	[redacted]20[redacted] / 6
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 7	
ABBV-951	912.82		SC / CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 7
ABBV-951	983.52		SC / CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 8
ABBV-951	983.52		SC / CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 9
ABBV-951	983.52		SC / CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 10
ABBV-951	983.52		SC / CONTINUOUS	[redacted]20[redacted] / 11	[redacted]20[redacted] / 11
ABBV-951	983.52		SC / CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 13	
ABBV-951	946.63		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951		75.13	SC / ONCE	[redacted]20[redacted] / 14	
ABBV-951	889.26		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951	849.65		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951	848.96		SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 20	
ABBV-951	950.05		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951	846.23		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951	935.36		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951	934.85		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 27	
ABBV-951	749.59		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 28	
ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32

ABBV-951	942.54		SC / CONTINUOUS	[redacted] / 33	[redacted] / 33
ABBV-951	942.54		SC / CONTINUOUS	[redacted] / 34	[redacted] / 34
ABBV-951	942.54		SC / CONTINUOUS	[redacted] / 35	[redacted] / 35
ABBV-951	942.54		SC / CONTINUOUS	[redacted] / 36	[redacted] / 36
ABBV-951	942.54		SC / CONTINUOUS	[redacted] / 37	[redacted] / 37
ABBV-951	942.54		SC / CONTINUOUS	[redacted] / 38	[redacted] / 38
ABBV-951	942.54		SC / CONTINUOUS	[redacted] / 39	[redacted] / 39
ABBV-951	942.54		SC / CONTINUOUS	[redacted] / 40	[redacted] / 40
ABBV-951	942.54		SC / CONTINUOUS	[redacted] / 41	[redacted] / 41
ABBV-951		37.56	SC / ONCE	[redacted] / 42	
ABBV-951	914.19		SC / CONTINUOUS	[redacted] / 42	[redacted] / 42
ABBV-951		18.78	SC / ONCE	[redacted] / 43	
ABBV-951	877.65		SC / CONTINUOUS	[redacted] / 43	[redacted] / 43
ABBV-951	860.58		SC / CONTINUOUS	[redacted] / 44	[redacted] / 44
ABBV-951	860.58		SC / CONTINUOUS	[redacted] / 45	[redacted] / 45
ABBV-951	860.58		SC / CONTINUOUS	[redacted] / 46	[redacted] / 46
ABBV-951	860.58		SC / CONTINUOUS	[redacted] / 47	[redacted] / 47
ABBV-951	860.58		SC / CONTINUOUS	[redacted] / 48	[redacted] / 48
ABBV-951	860.58		SC / CONTINUOUS	[redacted] / 49	[redacted] / 49
ABBV-951	860.58		SC / CONTINUOUS	[redacted] / 50	[redacted] / 50
ABBV-951	860.58		SC / CONTINUOUS	[redacted] / 51	[redacted] / 51
ABBV-951	860.58		SC / CONTINUOUS	[redacted] / 52	[redacted] / 52
ABBV-951	860.58		SC / CONTINUOUS	[redacted] / 53	[redacted] / 53
ABBV-951	860.58		SC / CONTINUOUS	[redacted] / 54	[redacted] / 54
ABBV-951	860.58		SC / CONTINUOUS	[redacted] / 55	[redacted] / 55
ABBV-951	860.58		SC / CONTINUOUS	[redacted] / 56	[redacted] / 56
ABBV-951	860.58		SC / CONTINUOUS	[redacted] / 57	[redacted] / 57
ABBV-951	860.58		SC / CONTINUOUS	[redacted] / 58	[redacted] / 58
ABBV-951	860.58		SC / CONTINUOUS	[redacted] / 59	[redacted] / 59
ABBV-951	860.58		SC / CONTINUOUS	[redacted] / 60	[redacted] / 60
ABBV-951	860.58		SC / CONTINUOUS	[redacted] / 61	[redacted] / 61
ABBV-951	860.58		SC / CONTINUOUS	[redacted] / 62	[redacted] / 62
ABBV-951	860.58		SC / CONTINUOUS	[redacted] / 63	[redacted] / 63
ABBV-951	860.58		SC / CONTINUOUS	[redacted] / 64	[redacted] / 64
ABBV-951	860.58		SC / CONTINUOUS	[redacted] / 65	[redacted] / 65
ABBV-951	860.58		SC / CONTINUOUS	[redacted] / 66	[redacted] / 66
ABBV-951	860.58		SC / CONTINUOUS	[redacted] / 67	[redacted] / 67

ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 74	[redacted]20[redacted] / 74
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 76
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 77
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 78	[redacted]20[redacted] / 78
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 79	[redacted]20[redacted] / 79
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 80
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 81	[redacted]20[redacted] / 81
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 82	[redacted]20[redacted] / 82
ABBV-951	894.73		SC / CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
ABBV-951		75.13	SC / ONCE	[redacted]20[redacted] / 84	
ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 85	[redacted]20[redacted] / 85
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 86	[redacted]20[redacted] / 86
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 87	[redacted]20[redacted] / 87
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 88	[redacted]20[redacted] / 88
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 89	[redacted]20[redacted] / 89
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 90
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 92
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 93
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 94	[redacted]20[redacted] / 94
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 95	[redacted]20[redacted] / 95
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 96	[redacted]20[redacted] / 96
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 97	[redacted]20[redacted] / 97
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 98	[redacted]20[redacted] / 98
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 99	[redacted]20[redacted] / 99
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 100	[redacted]20[redacted] / 100
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 101	[redacted]20[redacted] / 101
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 102	[redacted]20[redacted] / 102
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 103	[redacted]20[redacted] / 103

ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 104	[redacted]20[redacted] / 104
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 105	[redacted]20[redacted] / 105
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 106	[redacted]20[redacted] / 106
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 107	[redacted]20[redacted] / 107
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 108	[redacted]20[redacted] / 108
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 109	[redacted]20[redacted] / 109
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 110	[redacted]20[redacted] / 110
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 111	[redacted]20[redacted] / 111
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 112	[redacted]20[redacted] / 112
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 113	[redacted]20[redacted] / 113
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 114	[redacted]20[redacted] / 114
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 115	[redacted]20[redacted] / 115
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 116	[redacted]20[redacted] / 116
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 117	[redacted]20[redacted] / 117
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 118	[redacted]20[redacted] / 118
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 119	[redacted]20[redacted] / 119
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 120	[redacted]20[redacted] / 120
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 121	[redacted]20[redacted] / 121
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 122	[redacted]20[redacted] / 122
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 123	[redacted]20[redacted] / 123
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 124	[redacted]20[redacted] / 124
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 125	[redacted]20[redacted] / 125
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 126	[redacted]20[redacted] / 126
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 127	[redacted]20[redacted] / 127
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 128	[redacted]20[redacted] / 128
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 129	[redacted]20[redacted] / 129
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 130	[redacted]20[redacted] / 130
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 131	[redacted]20[redacted] / 131
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 132	[redacted]20[redacted] / 132
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 133	[redacted]20[redacted] / 133
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 134	[redacted]20[redacted] / 134
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 135	[redacted]20[redacted] / 135
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 136	[redacted]20[redacted] / 136
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 137	[redacted]20[redacted] / 137
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 138	[redacted]20[redacted] / 138
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 139	[redacted]20[redacted] / 139
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ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 331	[redacted]20[redacted] / 331
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 332	[redacted]20[redacted] / 332
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 333	[redacted]20[redacted] / 333
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 334	[redacted]20[redacted] / 334
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 335	[redacted]20[redacted] / 335
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 336	[redacted]20[redacted] / 336
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 337	[redacted]20[redacted] / 337
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 338	[redacted]20[redacted] / 338
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 339	[redacted]20[redacted] / 339
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 340	[redacted]20[redacted] / 340
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 341	[redacted]20[redacted] / 341
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 342	[redacted]20[redacted] / 342
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 343	[redacted]20[redacted] / 343
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 344	[redacted]20[redacted] / 344
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 345	[redacted]20[redacted] / 345
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 346	[redacted]20[redacted] / 346
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 347	[redacted]20[redacted] / 347
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 348	[redacted]20[redacted] / 348
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 349	[redacted]20[redacted] / 349
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 350	[redacted]20[redacted] / 350
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 351	[redacted]20[redacted] / 351
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 352	[redacted]20[redacted] / 352
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 353	[redacted]20[redacted] / 353
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 354	[redacted]20[redacted] / 354
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 355	[redacted]20[redacted] / 355
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 356	[redacted]20[redacted] / 356
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 357	[redacted]20[redacted] / 357
ABBV-951	860.58	SC / CONTINUOUS	[redacted]20[redacted] / 358	[redacted]20[redacted] / 358

ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 359	[redacted]20[redacted] / 359
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 360	[redacted]20[redacted] / 360
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 361	
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 361	[redacted]20[redacted] / 361
ABBV-951		112.69	SC / ONCE	[redacted]20[redacted] / 362	
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 362	[redacted]20[redacted] / 362

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]
ROPINIROLE	1.000 mg	TID	Y-M: 20[redacted]-[redacted]
SILDENAFIL	20 mg	PRN	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	5 TIMES PER DAY	Y-M: 20[redacted]-[redacted]
CLOPIDOGREL BISULFATE	75 mg	QD	Y-M: 20[redacted]-[redacted]
INSULIN DEGLUDEC	12 OTHER: UNITS	QD	Y-M: 20[redacted]-[redacted]
GLUTATHIONE	100%	QD	Y-M: 20[redacted]-[redacted]
UBIDECARENONE	1 OTHER: TAB	QD	Y-M: 20[redacted]-[redacted]
DICLOFENAC	1%	BID	Y-M: 20[redacted]-[redacted] / -265
HYDROCHLOROTHIAZIDE	12.5 mg	QD	Y-M: 20[redacted]-[redacted] / -265
LOSARTAN	25 mg	QD	Y-M: 20[redacted]-[redacted] / -150
PARACETAMOL	500-1000 mg	PRN	Y-M: 20[redacted]-[redacted] / -150
HYDROCHLOROTHIAZIDE	25 mg	QD	Y-M: 20[redacted]-[redacted] / -126
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

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,	OTHER: INSULIN	Y-M: 19[redacted]	ONGOING

	VIA INSULIN PUMP	PUMP		
SILDENAFIL	20 mg	PRN	Y-M: 20[redacted]	ONGOING
INSULIN DEGLUDEC	12 OTHER: UNITS	QD	Y-M: 20[redacted]	ONGOING
CLOPIDOGREL BISULFATE	75 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 327
LOSARTAN	25 mg	QD	Y-M: 20[redacted] / -150	ONGOING
PARACETAMOL	500-1000 mg	PRN	Y-M: 20[redacted] / -150	ONGOING
HYDROCHLOROTHIAZIDE	25 mg	QD	Y-M: 20[redacted] / -126	Y-M: 20[redacted] / 330
CLOPIDOGREL	75 mg	QD	Y-M: 20[redacted] / -113	ONGOING
ASTAXANTHIN	4 mg	QD	Y-M: 20[redacted] / -35	ONGOING
COLECALCIFEROL	5000 IU	QD	Y-M: 20[redacted] / -35	ONGOING
CURCUMA LONGA	400 mg	BID	Y-M: 20[redacted] / -35	ONGOING
IBUPROFEN	200 mg	PRN	Y-M: 20[redacted] / -35	ONGOING
MAGNESIUM OXIDE	400 mg	QD	Y-M: 20[redacted] / -35	ONGOING
MELATONIN	300 OTHER: MCG	OTHER: QHS	Y-M: 20[redacted] / -35	ONGOING
TRAMADOL	50 mg	PRN	Y-M: 20[redacted] / -35	ONGOING
CLINDAMYCIN	300 mg	QID	Y-M: 20[redacted] / 16	Y-M: 20[redacted] / 30
ROSUVASTATIN	5 mg	QD	Y-M: 20[redacted] / 291	Y-M: 20[redacted] / 330
PANTOPRAZOLE	40 mg	QD	Y-M: 20[redacted] / 326	Y-M: 20[redacted] / 326
SODIUM CHLORIDE	1 L	QD	Y-M: 20[redacted] / 326	Y-M: 20[redacted] / 326
METOPROLOL TARTRATE	50 mg	QD	Y-M: 20[redacted] / 327	ONGOING
CALCIUM CHLORIDE DIHYDRATE;GLUCOSE;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE	1 L	QD	Y-M: 20[redacted] / 328	Y-M: 20[redacted] / 328
DOCUSATE SODIUM;SENNOSIDE A+B	100 mg	BID	Y-M: 20[redacted] / 331	ONGOING
LISINOPRIL	15 mg	BID	Y-M: 20[redacted] / 331	ONGOING
LORAZEPAM	0.5 mg	PRN	Y-M: 20[redacted] / 331	ONGOING
MACROGOL 3350	17 g	PRN	Y-M: 20[redacted] / 331	ONGOING
OMEPRAZOLE	20 mg	BID	Y-M: 20[redacted] / 331	Y-M: 20[redacted] / 348
SALBUTAMOL	4 OTHER: PUFFS	PRN	Y-M: 20[redacted] / 336	Y-M: 20[redacted] / 345
CLOPIDOGREL BISULFATE	75 mg	QD	Y-M: 20[redacted] / 337	Y-M: 20[redacted] / 338
LIDOCAINE	1-2 OTHER: PATCHES	QD	Y-M: 20[redacted] / 338	ONGOING

CLOPIDOGREL BISULFATE	75 mg	QD	Y-M: 20[redacted] / 339	ONGOING
FLUTICASONE PROPIONATE	2 OTHER: SPRAYS	QD	Y-M: 20[redacted] / 345	ONGOING
SALBUTAMOL	1-2 OTHER: PUFFS	PRN	Y-M: 20[redacted] / 345	Y-M: 20[redacted] / 355
CETIRIZINE	10 mg	QD	Y-M: 20[redacted] / 346	Y-M: 20[redacted] / 355
POTASSIUM CHLORIDE	10 mEq	QD	Y-M: 20[redacted] / 352	ONGOING
FUROSEMIDE	20 mg	BID	Y-M: 20[redacted] / 355	Y-M: 20[redacted] / 356

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	DISCOMFORT AT THE INFUSION SITE
Preferred term	注入部位不快感
AE Onset Date / Rx Day	[redacted]20[redacted] / 2
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	6
Duration of AE	5 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 Infections

Event Description	CELLULITIS OF ABDOMEN AT INFUSION SITE
Preferred term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 16
Age at AE Onset	6[redacted]
Laboratory Testing	

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	44
Duration of AE	29 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 Description	NSTEMI
Preferred term	急性心筋梗塞
AE Onset Date / Rx Day	[redacted]20[redacted] / 326
Age at AE Onset	6[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 326): NPTST096-CREATININE KINASE: 445 [25 - 300] IU/L; NPTST207-OCCULT BLOOD, GASTRIC: POSITIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; SODIUM: 117 [135 - 144] MMOL/L; [redacted]20[redacted] (RX DAY 327): NPTST300-TROPONIN: 3.79 [0 - 0.03] NG/ML; [redacted]20[redacted] (RX DAY 330): SODIUM: 127 [136 - 145] MMOL/L

Microbiology

NOT REPORTED

AE Stopped Rx Day	326
Duration of AE	1 DAY
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	UNLIKELY
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	LIKELY UNDERLYING CORONARY ARTERY DISEASE (FOR NSTEMI). HYPONATREMIA DUE TO DEHYDRATION AND POOR PO INTAKE (WHICH COULD BE DUE TO NSTEMI). RHABDOMYOLYSIS IS DUE TO STATIN THERAPY (DISCONTINUED)
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT, LIFE THREATENING

Event #4: Serious Adverse Event

Event Description	HYPONATREMIA
Preferred term	低ナトリウム血症
AE Onset Date / Rx Day	[redacted]20[redacted] / 326
Age at AE Onset	6[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 326): NPTST096-CREATININE KINASE: 445 [25 - 300] IU/L; NPTST207-OCCULT BLOOD, GASTRIC: POSITIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; SODIUM: 117 [135 - 144] MMOL/L; [redacted]20[redacted] (RX DAY 327): NPTST300-TROPONIN: 3.79 [0 - 0.03] NG/ML; [redacted]20[redacted] (RX DAY 330): SODIUM: 127 [136 - 145] MMOL/L

Microbiology

NOT REPORTED

AE Stopped Rx Day	335
Duration of AE	10 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	HYPONATREMIA DUE TO DEHYDRATION AND POOR PO INTAKE (WHICH COULD BE DUE TO NSTEMI).
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #5: 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	
[redacted]20[redacted] (RX DAY 336): HEMOGLOBIN: 69 [136 - 180] G/L; LEUKOCYTES: 20.3 [4 - 10] 10^9/L; NPTST162-LACTATE: 6.4 [0.5 - 2] MMOL/L; PH: 7.28 [7.35 - 7.45] UNIT NOT REPORTED; [redacted]20[redacted] (RX DAY 337): POTASSIUM: 3.3 [3.6 - 5] MMOL/L; PH: 7.48 [7.35 - 7.45] UNIT NOT REPORTED; [redacted]20[redacted] (RX DAY 342): HEMOGLOBIN: 92 [136 - 180] G/L	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
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	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT, LIFE THREATENING

Event #6: Serious Adverse Event

Event Description	CARDIAC ARREST
Preferred term	心停止
AE Onset Date / Rx Day	[redacted]20[redacted] / 336
Age at AE Onset	6[redacted]
Laboratory Testing	
[redacted]20[redacted] (RX DAY 336): HEMOGLOBIN: 69 [136 - 180] G/L; LEUKOCYTES: 20.3 [4 - 10] 10^9/L; NPTST162-LACTATE: 6.4 [0.5 - 2] MMOL/L; PH: 7.28 [7.35 - 7.45] UNIT NOT REPORTED; [redacted]20[redacted] (RX DAY 337): POTASSIUM: 3.3 [3.6 - 5] MMOL/L; PH: 7.48 [7.35 - 7.45] UNIT NOT REPORTED; [redacted]20[redacted] (RX DAY 342): HEMOGLOBIN: 92 [136 - 180] G/L	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	336
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 REPORTED
Other cause of event	POST-SURGICAL VASOVAGAL REACTION
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT, LIFE THREATENING

generated: [redacted]20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

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 が投与され，非 ST 上昇型心筋梗塞，冠動脈疾患，心停止，及び低ナトリウム血症を発現した。

Event 3，4，5，及び 6 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，頚動脈狭窄症，脳血管障害，高血圧，パーキンソン病，全般性不安障害，父親の糖尿病歴，父親の高血圧歴，父親の冠動脈疾患歴，母親の脳卒中歴，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。

投与 1 日目から投与 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治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 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，被験者は非 ST 上昇型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。同日，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を受診した。被験者はこれらの症状は約 1 週間続いており，おおむね 2 つの新しい薬剤（ロスバスタチン及びヒドロクロロチアジド）を開始していた期間だと述べた。被験者はヒドロクロロチアジドを断続的に

使用してきたと述べた。被験者は数回嘔吐し，嘔吐物は「古い血液」のように見えると言われたと報告した。被験者は最近の旅行や病人との接触を否定した。被験者は妻と 2 階建の家に住み，大きな困難もなく階段を使用していた。被験者は経口摂取の低下も述べた。被験者はインスリンポンプを使用し自分でグルコース値の管理をしていた。被験者は，SINEMET 用ポンプも所有し，これまで治験に参加していた。被験者は低ナトリウム血症及び脱水のため入院した。また，非重篤の横紋筋融解症も診断された。更に，頚部痛及び嘔吐症状も認められた。初期のトロポニン検査は陰性であったが，後にトロポニン値が上昇した（非 ST 上昇型心筋梗塞）。

被験者は別の病院に移送され，低ナトリウム血症，非 ST 上昇型心筋梗塞，及び上部消化管出血の可能性のため集中治療室に収容された。被験者に脱力感，便秘，悪心，嘔吐，及び不安が認められた。被験者は発熱，悪寒，咳嗽，息切れ，及び下痢を否定した。投与 327 日目遅くまでトロポニン値は上昇した。投与 328 日目，被験者は心臓カテーテル手術を受け，びまん性，糖尿病型心疾患が認められた。投与 335 日目，非重篤の横紋筋融解症は消失した。投与 336 日目，被験者は 3 ヵ所冠動脈バイパス手術を受けた。その夜，被験者は血管迷走神経反射から心停止を起こした。被験者は心肺蘇生を受け自発循環を取り戻し再挿管されたが，最終的に抜管された。最初にラシックスの投与が必要とされた。両側に胸腔チューブが挿入され，後に抜去された。血圧は集中治療室にいる間ずっと不安定であった。利尿から数日安静後，フロセミドの静脈注射に移行し，その後経口に移行した。被験者への酸素補給は徐々に離脱された。体重は手術前約 12[redacted] ポンドで，退院時は 14[redacted] ポンドであった。被験者は室内気酸素飽和度 97%，経口ラシックス 20 mg を 1 日 2 回 7 日間及びカリウム値 4.3 の高値を維持するための塩化カリウム 10 mEq 連日投与にて退院した。クレアチニン値は安定しており，術後の最高値は 1.19 であった。

被験者にラシックス，リシノプリル，メトプロロール酒石酸塩，5%ブドウ糖加乳酸リンゲル液，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
転倒				X
注入部位蜂巣炎				X
注入部位紅斑				X
注入部位血管外漏出				X
注入部位硬結				X
注入部位浮腫				X
注入部位丘疹				X
注入部位反応				X
靭帯捻挫				X
変形性関節症	X			
皮膚裂傷				X
体重減少				X

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

Medical History	Onset Year
ASTHMA	19[redacted]
FOOD ALLERGIES	19[redacted]
SEASONAL ALLERGIES	19[redacted]
ESOPHAGEAL WEBS	19[redacted]
CHRONIC SHOULDER PAIN	19[redacted]
SHOULDER NUMBNESS	19[redacted]
SHOULDER TINGLING	19[redacted]
CATARACT RIGHT EYE	20[redacted]
PINCHED NERVE NECK	20[redacted]
CONSTIPATION	20[redacted]
SCOLIOSIS	20[redacted]
INTERMITTENT INSOMNIA	20[redacted]
SHOULDER ARTHRITIS BOTH	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
NECK SURGERY	20[redacted]
BACK 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	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	0.67	0.8	0.54	75	0.19	[redacted]20[redacted]/1
ABBV-951	0.67	0.8	0.54	75	0.19	[redacted]20[redacted]/2
ABBV-951	0.8	0.96	0.64	120	0.19	[redacted]20[redacted]/9
ABBV-951	0.8	0.96	0.64	180	0.19	[redacted]20[redacted]/16
ABBV-951	0.8	0.96	0.64	180	0.19	[redacted]20[redacted]/21
ABBV-951	0.67	0.8	0.54	180	0.19	[redacted]20[redacted]/23
ABBV-951	0.8	0.96	0.64	180	0.24	[redacted]20[redacted]/30
ABBV-951	0.8	0.96	0.64	180	0.19	[redacted]20[redacted]/44
ABBV-951	0.8	0.96	0.64	180	0.19	[redacted]20[redacted]/93
ABBV-951	0.8	0.96	0.64	180	0.19	[redacted]20[redacted]/183
ABBV-951	0.96	1.14	0.8	180	0.19	[redacted]20[redacted]/259
ABBV-951	0.96	1.14	0.8	180	0.19	[redacted]20[redacted]/274
ABBV-951	0.96	1.04	0.83	180	0	[redacted]20[redacted]/357
ABBV-951	0.96	1.04	0.83	0	0	[redacted]20[redacted]/365

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	1601.63		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951	2471.09		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951	274.56		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951	2745.66		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951	2745.66		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951	2745.66		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951	3123.01		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951	3278.4		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951	3278.4		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	3278.4		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	3278.4		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951	3278.4		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951	3696.39		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951	3934.08		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951	3934.08		SC / CONTINUOUS	[redacted] / 15	[redacted] / 15
ABBV-951	1426.10		SC / CONTINUOUS	[redacted] / 16	[redacted] / 16
ABBV-951	458.97		SC / CONTINUOUS	[redacted] / 22	[redacted] / 22
ABBV-951	1828.39		SC / CONTINUOUS	[redacted] / 23	[redacted] / 23
ABBV-951	2745.66		SC / CONTINUOUS	[redacted] / 24	[redacted] / 24
ABBV-951	2745.66		SC / CONTINUOUS	[redacted] / 25	[redacted] / 25
ABBV-951	2745.66		SC / CONTINUOUS	[redacted] / 26	[redacted] / 26
ABBV-951	1029.62		SC / CONTINUOUS	[redacted] / 27	[redacted] / 27
ABBV-951	1681.71		SC / CONTINUOUS	[redacted] / 28	[redacted] / 28
ABBV-951	1304.18		SC / CONTINUOUS	[redacted] / 29	[redacted] / 29
ABBV-951	3109.69		SC / CONTINUOUS	[redacted] / 30	[redacted] / 30
ABBV-951	3278.4		SC / CONTINUOUS	[redacted] / 31	[redacted] / 31
ABBV-951	3278.4		SC / CONTINUOUS	[redacted] / 32	[redacted] / 32
ABBV-951	3278.4		SC / CONTINUOUS	[redacted] / 33	[redacted] / 33
ABBV-951	3278.4		SC / CONTINUOUS	[redacted] / 34	[redacted] / 34
ABBV-951	3278.4		SC / CONTINUOUS	[redacted] / 35	[redacted] / 35
ABBV-951	3278.4		SC / CONTINUOUS	[redacted] / 36	[redacted] / 36
ABBV-951	3278.4		SC / CONTINUOUS	[redacted] / 37	[redacted] / 37
ABBV-951	3278.4		SC / CONTINUOUS	[redacted] / 38	[redacted] / 38
ABBV-951	3278.4		SC / CONTINUOUS	[redacted] / 39	[redacted] / 39

ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951	3223.76	SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951	2923.24	SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951	3073.5	SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
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ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 132	[redacted]20[redacted] / 132
ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 133	[redacted]20[redacted] / 133
ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 134	[redacted]20[redacted] / 134
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ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 136	[redacted]20[redacted] / 136
ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 137	[redacted]20[redacted] / 137
ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 138	[redacted]20[redacted] / 138
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ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 141	[redacted]20[redacted] / 141
ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 142	[redacted]20[redacted] / 142
ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 143	[redacted]20[redacted] / 143
ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 144	[redacted]20[redacted] / 144
ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 145	[redacted]20[redacted] / 145
ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 146	[redacted]20[redacted] / 146
ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 147	[redacted]20[redacted] / 147
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ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 342	[redacted]20[redacted] / 342
ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 343	[redacted]20[redacted] / 343
ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 344	[redacted]20[redacted] / 344
ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 345	[redacted]20[redacted] / 345
ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 346	[redacted]20[redacted] / 346
ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 347	[redacted]20[redacted] / 347
ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 348	[redacted]20[redacted] / 348
ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 349	[redacted]20[redacted] / 349
ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 350	[redacted]20[redacted] / 350
ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 351	[redacted]20[redacted] / 351
ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 352	[redacted]20[redacted] / 352
ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 353	[redacted]20[redacted] / 353
ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 354	[redacted]20[redacted] / 354
ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 355	[redacted]20[redacted] / 355
ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 356	[redacted]20[redacted] / 356
ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 357	[redacted]20[redacted] / 357
ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 358	[redacted]20[redacted] / 358
ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 359	[redacted]20[redacted] / 359
ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 360	[redacted]20[redacted] / 360
ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 361	[redacted]20[redacted] / 361
ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 362	[redacted]20[redacted] / 362
ABBV-951	3278.4	SC / CONTINUOUS	[redacted]20[redacted] / 363	[redacted]20[redacted] / 363
ABBV-951	3360.36	SC / CONTINUOUS	[redacted]20[redacted] / 364	[redacted]20[redacted] / 364

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
CETIRIZINE HYDROCHLORIDE	10 mg	PRN	Y-M: 19[redacted]
PRAMIPEXOLE	0.500 mg	7 TIMES PER DAY	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	7 TIMES PER DAY	Y-M: 20[redacted]-[redacted]
SENNA ALEXANDRINA	1 OTHER: CAPSULE	PRN	Y-M: 20[redacted]

SELEGILINE	5.000 mg	QD	Y-M: 20[redacted]
AMANTADINE	100.000 mg	BID	Y-M: 20[redacted]
CANNABIDIOL	1 OTHER: CAPSULE	PRN	Y-M: 20[redacted] / -148
CYANOCOBALAMIN	100 OTHER: MCG	QD	Y-M: 20[redacted] / -21
PYRIDOXINE HYDROCHLORIDE	5 mg	QD	Y-M: 20[redacted] / -21

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: 19[redacted]	ONGOING
SENNA ALEXANDRINA	1 OTHER: CAPSULE	PRN	Y-M: 20[redacted]	ONGOING
CYANOCOBALAMIN	100 OTHER: MCG	QD	Y-M: 20[redacted] / -21	ONGOING
PYRIDOXINE HYDROCHLORIDE	5 mg	QD	Y-M: 20[redacted] / -21	ONGOING
CEFALEXIN	500 mg	BID	Y-M: 20[redacted] / 21	Y-M: 20[redacted] / 28
LACTOBACILLUS NOS	1 OTHER: CAPSULE	BID	Y-M: 20[redacted] / 21	Y-M: 20[redacted] / 28
CEFALEXIN	500 mg	BID	Y-M: 20[redacted] / 35	Y-M: 20[redacted] / 42
LACTOBACILLUS NOS	1 OTHER: CAPSULE	BID	Y-M: 20[redacted] / 35	Y-M: 20[redacted] / 42
BUPIVACAINE	5 mL	QD	Y-M: 20[redacted] / 224	Y-M: 20[redacted] / 224
DEXAMETHASONE	4 mg	QD	Y-M: 20[redacted] / 224	Y-M: 20[redacted] / 224
METHYLPREDNISOLONE	40 mg	QD	Y-M: 20[redacted] / 224	Y-M: 20[redacted] / 224
TRANEXAMIC ACID	1 g	QD	Y-M: 20[redacted] / 224	Y-M: 20[redacted] / 224
CEFAZOLIN SODIUM	2 g	BID	Y-M: 20[redacted] / 224	Y-M: 20[redacted] / 225
OXYCODONE	5 mg	PRN	Y-M: 20[redacted] / 224	Y-M: 20[redacted] / 254
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE;TETANUS VACCINE TOXOID	0.5 mL	OTHER: ONCE	Y-M: 20[redacted] / 258	Y-M: 20[redacted] / 258
HYDROCODONE BITARTRATE;PARACETAMOL	5-325 mg	OTHER: ONCE	Y-M: 20[redacted] / 258	Y-M: 20[redacted] / 258

Event #1: 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] / 1
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	14
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 #2: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE PAPULE
Preferred term	注入部位丘疹
AE Onset Date / Rx Day	[redacted]20[redacted] / 1
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	14
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 #3: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE REACTION
Preferred term	注入部位反応
AE Onset Date / Rx Day	[redacted]20[redacted] / 1
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	14
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 #4: 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] / 4
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	

AE Stopped Rx Day	30
Duration of AE	27 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	INFUSION SITE PAPULE
Preferred term	注入部位丘疹
AE Onset Date / Rx Day	[redacted]20[redacted] / 4
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	30
Duration of AE	27 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	SLIGHT GLAZED APPEARANCE INFUSION SITE

Preferred term	注入部位反応
AE Onset Date / Rx Day	[redacted]20[redacted] / 4
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	30
Duration of AE	27 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	POOLING OF STUDY DRUG UNDER INFUSION SITE
Preferred term	注入部位血管外漏出
AE Onset Date / Rx Day	[redacted]20[redacted] / 11
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	21
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: Event of Interest - Infusion Site Related Infections

Event Description	INFUSION SITE CELLULITIS
Preferred term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 20
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	30
Duration of AE	11 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 #9: Event of Interest - Weight Loss

Event Description	WEIGHT LOSS
Preferred term	体重減少
AE Onset Date / Rx Day	[redacted]20[redacted] / 44
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
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 #10: Event of Interest -Falls And Associated Injuries

Event Description	LEFT FOOT SPRAIN
Preferred term	靭帯捻挫
AE Onset Date / Rx Day	[redacted]20[redacted] / 132
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	135
Duration of AE	4 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 #11: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE INDURATION

Preferred term	注入部位硬結
AE Onset Date / Rx Day	[redacted]20[redacted] / 183
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	365
Duration of AE	183 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 #12: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE REACTION
Preferred term	注入部位反応
AE Onset Date / Rx Day	[redacted]20[redacted] / 183
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	365
Duration of AE	183 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 #13: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE GLAZING
Preferred term	注入部位反応
AE Onset Date / Rx Day	[redacted]20[redacted] / 183
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	365
Duration of AE	183 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 #14: Serious Adverse Event

Event Description	WORSENING RIGHT SHOULDER DEGENERATIVE JOINT DISEASE
Preferred term	変形性関節症
AE Onset Date / Rx Day	[redacted]20[redacted] / 224
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	

NOT REPORTED

AE Stopped Rx Day	224
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	PATIENT HAS SEVERE DJD AND THUS REQUIRED TOTAL SHOULDER ARTHROPLASTY AFTER SEVERAL NON-SURGICAL OPTIONS FAILED.
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #15: Event of Interest -Falls And Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 258
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	258
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 #16: Event of Interest -Falls And Associated Injuries

Event Description	LEFT HAND LACERATION
Preferred term	皮膚裂傷
AE Onset Date / Rx Day	[redacted]20[redacted] / 258
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	271
Duration of AE	14 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 #17: 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] / 259
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	365
Duration of AE	107 DAYS
Severity	MILD
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 #18: 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] / 274
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	365
Duration of AE	92 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 #19: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE MARKED GLAZING
Preferred term	注入部位反応
AE Onset Date / Rx Day	[redacted]20[redacted] / 274
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	

Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	365
Duration of AE	92 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 #20: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE REACTION
Preferred term	注入部位反応
AE Onset Date / Rx Day	[redacted]20[redacted] / 274
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	365
Duration of AE	92 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 #21: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE EDEMA
Preferred term	注入部位浮腫
AE Onset Date / Rx Day	[redacted]20[redacted] / 356
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	364
Duration of AE	9 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 #22: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE EDEMA
Preferred term	注入部位浮腫
AE Onset Date / Rx Day	[redacted]20[redacted] / 357
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	365
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 #23: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE SLIGHT GLAZED APPEARANCE
Preferred term	注入部位反応
AE Onset Date / Rx Day	[redacted]20[redacted] / 357
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	365
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 #24: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE REACTION
Preferred term	注入部位反応
AE Onset Date / Rx Day	[redacted]20[redacted] / 357
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	

Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	365
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 #25: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE EDEMA
Preferred term	注入部位浮腫
AE Onset Date / Rx Day	[redacted]20[redacted] / 363
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
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]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

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 が投与され，右肩変形性関節疾患の悪化を発現した。

Event 14 の臨床経過：

関連する病歴は，慢性肩痛，肩のしびれ，肩のひりひり感，頚部の圧迫神経痛，頚部手術，圧迫神経痛，パーキンソン病，脊柱側彎，脊柱側彎手術，非喫煙者，及び現飲酒者（1 日 2 杯未満）であった。

投与 1 日目から投与 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治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 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 224 日目，被験者は右肩変形性関節疾患の悪化を発現した。同日，右肩変形性関節疾患の悪化は消失した。

投与 224 日目，被験者は過去数年間にわたる右肩痛の悪化のため入院した。治験責任医師によると，被験者は長年両肩に進行した一次性関節炎があり，疼痛は関節炎によるものであった。過去，被験者は長期間保存療法を受けていたが，結局疼痛及び機能障害の緩和にならなかった。同日，被験者は計画された右肩関節全置換術を無事に受けた。

診療記録によると，被験者は良好な状態で退院した。

被験者にオキシコドンが投与された。

The patient's past medications include:

SINEMET CR for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

SELEGILINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

AMANTADINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Osteoarthritis aggravated (10031162) (Osteoarthritis (10031161)) [v.23.1] [10031162]

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 RIGHT SHOULDER DEGENERATIVE JOINT DISEASE

- **Investigator:** Patient had severe DJD and thus required total shoulder arthroplasty after several non-surgical options failed.

- **AbbVie:** More likely related to a history of chronic shoulder pain, shoulder numbness, shoulder tingling, pinched nerve neck, scoliosis and Parkinson's disease in an advanced aged patient

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] X-RAY SHOULDER:** From medical records: The orthopedic component appears well positioned and intact. Air is seen within the surrounding tissues. IMPRESSION: Expected findings of a recent right shoulder arthroplasty.

ADVERSE EVENTS OF SPECIAL INTEREST AND **OTHER AREAS OF SAFETY INTEREST

Weight Decreased: Day 1 weight 7[redacted] kg. Weight at time of event 7[redacted] kg. 7[redacted] kg at Week 52 visit. Weight loss occurred over a period of 11 months. No change in diet or mobility level with pump/infusion therapy. Onset of weight loss did not coincide with worsening PD symptoms or eating difficulties. Subject experienced temporal activity increase/more active since treatment began, temporal and previous episodes of dysphagia, and temporal episode of infection.

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			
注入部位紅斑				X
注入部位感染				X
注入部位浮腫				X
肺塞栓症	X			
穿刺部位紅斑				X
尿路感染	X			

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

Medical History	Onset Year
ANXIETY	NOT REPORTED
HYPERCHOLESTEROLEMIA	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]
HEARTBURN	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	0.63	0	0	0	0	[redacted]20[redacted]/1
ABBV-951	0.63	0	0	0	0	[redacted]20[redacted]/2
ABBV-951	0.64	0	0	0	0	[redacted]20[redacted]/8
ABBV-951	0.65	0	0	0	0	[redacted]20[redacted]/9
ABBV-951	0.65	0	0	0	0	[redacted]20[redacted]/12
ABBV-951	0.64	0	0	0	0	[redacted]20[redacted]/15
ABBV-951	0.67	0	0	60	0.11	[redacted]20[redacted]/22
ABBV-951	0.68	0	0.66	0	0	[redacted]20[redacted]/29
ABBV-951	0.68	0	0.66	0	0	[redacted]20[redacted]/37
ABBV-951	0.7	0	0.66	0	0	[redacted]20[redacted]/43

ABBV-951	0.7	0	0	0	0	[redacted]/51
ABBV-951	0.7	0	0.66	0	0	[redacted]/53
ABBV-951	0.7	0	0.66	0	0	[redacted]/57
ABBV-951	0.7	0	0.66	0	0	[redacted]/64
ABBV-951	0.7	0	0	0	0	[redacted]/78
ABBV-951	0.7	0.71	0.68	0	0	[redacted]/92
ABBV-951	0.7	0.71	0.68	0	0	[redacted]/96
ABBV-951	0.7	0.71	0.68	0	0	[redacted]/106
ABBV-951	0.7	0.71	0.68	0	0	[redacted]/134
ABBV-951	0.7	0.71	0.68	0	0	[redacted]/162
ABBV-951	0.7	0.71	0.68	0	0	[redacted]/177
ABBV-951	0.7	0.71	0.68	0	0	[redacted]/183
ABBV-951	0.7	0.71	0.68	0	0	[redacted]/212
ABBV-951	0.7	0.71	0	0	0	[redacted]/226
ABBV-951	0.7	0.71	0.68	0	0	[redacted]/240
ABBV-951	0.7	0.71	0.68	0	0	[redacted]/254
ABBV-951	0.7	0.71	0.68	0	0	[redacted]/270
ABBV-951	0.7	0.71	0.68	0	0	[redacted]/282
ABBV-951	0.7	0.71	0.68	0	0	[redacted]/297
ABBV-951	0.7	0.71	0.68	0	0	[redacted]/310
ABBV-951	0.7	0.71	0.68	0	0	[redacted]/316
ABBV-951	0.7	0.71	0.68	0	0	[redacted]/330
ABBV-951	0.7	0.71	0.68	0	0	[redacted]/344
ABBV-951	0.7	0.71	0.68	0	0	[redacted]/358
ABBV-951	0.7	0.71	0.68	0	0	[redacted]/365

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	1506.01		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951	2581.74		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951	2581.74		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951	2581.74		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951	2581.74		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951	2560.22		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951		0	SC / ONCE	[redacted] / 7	
ABBV-951	2506.43		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7

ABBV-951	2581.74		SC / CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 8
ABBV-951	2581.74		SC / CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 9
ABBV-951	2581.74		SC / CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 10
ABBV-951	2581.74		SC / CONTINUOUS	[redacted]20[redacted] / 11	[redacted]20[redacted] / 11
ABBV-951	2581.74		SC / CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
ABBV-951	2559.03		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951	2597.10		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951	2663.7		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951	2663.7		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951	2663.7		SC / CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951	2663.7		SC / CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951	2663.7		SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951	2663.7		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951		0	SC / ONCE	[redacted]20[redacted] / 21	
ABBV-951	2591.98		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 22	
ABBV-951	2627.15		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951	2745.66		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	2745.66		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951	2745.66		SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951	2745.66		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951	2688.45		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951	2699.89		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951	2745.66		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951	2745.66		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	2745.66		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	2745.66		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	2745.66		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951		0	SC / ONCE	[redacted]20[redacted] / 34	
ABBV-951	2693.23		SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951	2685.89		SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951	2704.68		SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951	2704.68		SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951	2704.68		SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951	2704.68		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951	2704.68		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951	2705.02		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41

ABBV-951	2688.28	SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
ABBV-951	2733.02	SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
ABBV-951	2659.60	SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
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ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 74	[redacted]20[redacted] / 74
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 76
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 77
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 78	[redacted]20[redacted] / 78

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ABBV-951	2704.68		SC / CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 80
ABBV-951	2704.68		SC / CONTINUOUS	[redacted]20[redacted] / 81	[redacted]20[redacted] / 81
ABBV-951	2704.68		SC / CONTINUOUS	[redacted]20[redacted] / 82	[redacted]20[redacted] / 82
ABBV-951	2704.68		SC / CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
ABBV-951	2704.68		SC / CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
ABBV-951	2704.68		SC / CONTINUOUS	[redacted]20[redacted] / 85	[redacted]20[redacted] / 85
ABBV-951	2704.68		SC / CONTINUOUS	[redacted]20[redacted] / 86	[redacted]20[redacted] / 86
ABBV-951	2704.68		SC / CONTINUOUS	[redacted]20[redacted] / 87	[redacted]20[redacted] / 87
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ABBV-951	2704.68		SC / CONTINUOUS	[redacted]20[redacted] / 89	[redacted]20[redacted] / 89
ABBV-951		0	SC / ONCE	[redacted]20[redacted] / 90	
ABBV-951	2608.71		SC / CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 90
ABBV-951		0	SC / ONCE	[redacted]20[redacted] / 91	
ABBV-951	2796.88		SC / CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 92
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 93
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 94	[redacted]20[redacted] / 94
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 95	[redacted]20[redacted] / 95
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 96	[redacted]20[redacted] / 96
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 97	[redacted]20[redacted] / 97
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 98	[redacted]20[redacted] / 98
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 99	[redacted]20[redacted] / 99
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 100	[redacted]20[redacted] / 100
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 101	[redacted]20[redacted] / 101
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 102	[redacted]20[redacted] / 102
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 103	[redacted]20[redacted] / 103
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 104	[redacted]20[redacted] / 104
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 105	[redacted]20[redacted] / 105
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 106	[redacted]20[redacted] / 106
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 107	[redacted]20[redacted] / 107
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 108	[redacted]20[redacted] / 108
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 109	[redacted]20[redacted] / 109
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 110	[redacted]20[redacted] / 110
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ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 314	[redacted]20[redacted] / 314
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 315	[redacted]20[redacted] / 315
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 316	[redacted]20[redacted] / 316
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 317	[redacted]20[redacted] / 317
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 318	[redacted]20[redacted] / 318
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 319	[redacted]20[redacted] / 319
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 320	[redacted]20[redacted] / 320
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 321	[redacted]20[redacted] / 321
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 322	[redacted]20[redacted] / 322
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 323	[redacted]20[redacted] / 323
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 324	[redacted]20[redacted] / 324
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 325	[redacted]20[redacted] / 325
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 326	[redacted]20[redacted] / 326
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 327	[redacted]20[redacted] / 327
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 328	[redacted]20[redacted] / 328
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 329	[redacted]20[redacted] / 329
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 330	[redacted]20[redacted] / 330
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 331	[redacted]20[redacted] / 331
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 332	[redacted]20[redacted] / 332
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 333	[redacted]20[redacted] / 333
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 334	[redacted]20[redacted] / 334
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 335	[redacted]20[redacted] / 335

ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 336	[redacted]20[redacted] / 336
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 337	[redacted]20[redacted] / 337
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 338	[redacted]20[redacted] / 338
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 339	[redacted]20[redacted] / 339
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 340	[redacted]20[redacted] / 340
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 341	[redacted]20[redacted] / 341
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 342	[redacted]20[redacted] / 342
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 343	[redacted]20[redacted] / 343
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 344	[redacted]20[redacted] / 344
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 345	[redacted]20[redacted] / 345
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 346	[redacted]20[redacted] / 346
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 347	[redacted]20[redacted] / 347
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 348	[redacted]20[redacted] / 348
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 349	[redacted]20[redacted] / 349
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 350	[redacted]20[redacted] / 350
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 351	[redacted]20[redacted] / 351
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 352	[redacted]20[redacted] / 352
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 353	[redacted]20[redacted] / 353
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 354	[redacted]20[redacted] / 354
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 355	[redacted]20[redacted] / 355
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 356	[redacted]20[redacted] / 356
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 357	[redacted]20[redacted] / 357
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 358	[redacted]20[redacted] / 358
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 359	[redacted]20[redacted] / 359
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 360	[redacted]20[redacted] / 360
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 361	[redacted]20[redacted] / 361
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 362	[redacted]20[redacted] / 362
ABBV-951	2780.15	SC / CONTINUOUS	[redacted]20[redacted] / 363	[redacted]20[redacted] / 363
ABBV-951	2716.97	SC / CONTINUOUS	[redacted]20[redacted] / 364	[redacted]20[redacted] / 364

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]
CARBIDOPA MONOHYDRATE;LEVODOPA	200.000 mg	QID	Y-M: 20[redacted]
CALCIUM CARBONATE	1 OTHER: TAB	PRN	Y-M: 20[redacted]
MIRABEGRON	25 mg	QD	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	63.000 mg	6 TIMES PER DAY	Y-M: 20[redacted]
CURCUMA LONGA	500 mg	BID	Y-M: 20[redacted]
PYRIDOSTIGMINE	60 mg	TID	Y-M: 20[redacted]
MELATONIN	3 mg	OTHER: QHS	Y-M: 20[redacted]
AMANTADINE	137.000 mg	QD	Y-M: 20[redacted] / -335
VITAMIN B12 NOS	1000 OTHER: UG	OTHER: QIW	Y-M: 20[redacted] / -101
PYRIDOXINE HYDROCHLORIDE	25 OTHER: MCG	QD	Y-M: 20[redacted] / -70
VITAMIN B12 NOS	1000 MCG OTHER: MCG	OTHER: MONTHLY	Y-M: 20[redacted] / -40

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]	ONGOING
ROPINIROLE	1 mg	TID	Y-M: 20[redacted]	ONGOING
ROSUVASTATIN	10 mg	OTHER: QHS	Y-M: 20[redacted]	ONGOING
IBUPROFEN	200 mg	PRN	Y-M: 20[redacted]	ONGOING
CITALOPRAM	40 mg	OTHER: QAM	Y-M: 20[redacted]	ONGOING
MAGNESIUM CARBONATE	1 OTHER: TBSP	OTHER: QHS	Y-M: 20[redacted]	ONGOING
CALCIUM CARBONATE	1 OTHER: TAB	PRN	Y-M: 20[redacted]	ONGOING
MIRABEGRON	25 mg	QD	Y-M: 20[redacted]	ONGOING
CURCUMA LONGA	500 mg	BID	Y-M: 20[redacted]	ONGOING
PYRIDOSTIGMINE	60 mg	TID	Y-M: 20[redacted]	ONGOING
MELATONIN	3 mg	OTHER: QHS	Y-M: 20[redacted]	ONGOING
VITAMIN B12 NOS	1000 MCG OTHER: MCG	OTHER: MONTHLY	Y-M: 20[redacted] / -40	Y-M: 20[redacted] / 305
SULFAMETHOXAZOLE;TRIMETHOPRIM	800 MG mg	BID	Y-M: 20[redacted] / 29	Y-M: 20[redacted] / 38
SULFAMETHOXAZOLE;TRIMETHOPRIM	800 MG BID mg	BID	Y-M: 20[redacted] / 49	Y-M: 20[redacted] / 59
SULFAMETHOXAZOLE;TRIMETHOPRIM	800 MG mg	BID	Y-M: 20[redacted] / 112	Y-M: 20[redacted] / 122

DOXYCYCLINE	100 MG mg	BID	Y-M: 20[redacted] / 114	Y-M: 20[redacted] / 125
DOXYCYCLINE	100 mg	BID	Y-M: 20[redacted] / 131	Y-M: 20[redacted] / 141
SULFAMETHOXAZOLE;TRIMETHOPRIM	800 mg	BID	Y-M: 20[redacted] / 131	Y-M: 20[redacted] / 141
CEFDINIR	300 MG mg	BID	Y-M: 20[redacted] / 147	Y-M: 20[redacted] / 157
CEFDINIR	300 MG mg	BID	Y-M: 20[redacted] / 178	Y-M: 20[redacted] / 189
ACETYLSALICYLIC ACID	81 mg	QD	Y-M: 20[redacted] / 191	ONGOING
CLOPIDOGREL BISULFATE	75 mg	QD	Y-M: 20[redacted] / 191	Y-M: 20[redacted] / 297
METOPROLOL	25 mg	QD	Y-M: 20[redacted] / 191	Y-M: 20[redacted] / 297
SULFAMETHOXAZOLE;TRIMETHOPRIM	800 mg	BID	Y-M: 20[redacted] / 221	Y-M: 20[redacted] / 231
SULFAMETHOXAZOLE;TRIMETHOPRIM	800 MG mg	BID	Y-M: 20[redacted] / 248	Y-M: 20[redacted] / 258
AMIODARONE	200 mg	QD	Y-M: 20[redacted] / 263	ONGOING
APIXABAN	5 mg	BID	Y-M: 20[redacted] / 263	Y-M: 20[redacted] / 297
CEFDINIR	300 MG mg	BID	Y-M: 20[redacted] / 267	Y-M: 20[redacted] / 277
DOXYCYCLINE	100 mg	BID	Y-M: 20[redacted] / 269	Y-M: 20[redacted] / 279
CEFDINIR	300 mg	BID	Y-M: 20[redacted] / 284	Y-M: 20[redacted] / 294
DOXYCYCLINE	100 mg	BID	Y-M: 20[redacted] / 284	Y-M: 20[redacted] / 294
SULFAMETHOXAZOLE;TRIMETHOPRIM	800 mg	BID	Y-M: 20[redacted] / 323	Y-M: 20[redacted] / 333
DOXYCYCLINE	100 MG mg	BID	Y-M: 20[redacted] / 341	Y-M: 20[redacted] / 344
SULFAMETHOXAZOLE;TRIMETHOPRIM	800 MG mg	BID	Y-M: 20[redacted] / 341	Y-M: 20[redacted] / 344
CEFTRIAXONE	250 mg	OTHER: ONCE	Y-M: 20[redacted] / 344	Y-M: 20[redacted] / 344
CLINDAMYCIN	600 mg	TID	Y-M: 20[redacted] / 344	Y-M: 20[redacted] / 354

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MILD ERYTHEMA TO LEFT LOWER QUADRANT OLD INSERTION SITE
Preferred term	穿刺部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 29
Age at AE Onset	7[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	39
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 #2: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MILD ERYTHEMA TO LEFT LOWER QUADERATANT OLD INSERTION SITE
Preferred term	穿刺部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 49
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	62
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 #3: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	RIGHT UPPER ABDOMINAL QUADRANT SUBCUTANEOUS EDEMA AROUND INFUSION SITE
Preferred term	注入部位浮腫
AE Onset Date / Rx Day	[redacted]20[redacted] / 67
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	67
Duration of AE	1 DAY
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	GRADE 1 ERYTHEMA TO INFUSION SITE LEFT LOWER QUADERANT
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 112
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	129
Duration of AE	18 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	GRADE 1 ERYTHEMA TO RIGHT LOWER QUADRANT ABDOMEN INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 127
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	131
Duration of AE	5 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	GRADE 1 ERYTHEMA TO RIGHT UPPER QUADRANT INSERTION SITE
Preferred term	穿刺部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 131

Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	141
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 #7: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	GRADE 1 ERYTHEMA MILD TO RIGHT UPPER QUADRANT ABDOMINAL INSERTION SITE.
Preferred term	穿刺部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 147
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	155
Duration of AE	9 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	LEFT LOWER ABDOMINAL QUADRANT INFUSION SITE ERYTHEMA
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 177
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	186
Duration of AE	10 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: 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	
AE Stopped Rx Day	ONGOING

Duration of AE	ONGOING
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	UNLIKELY
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	REQUIRES OR PROLONGS HOSPITALIZATION

Event #10: 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	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
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	UNLIKELY
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	REQUIRES OR PROLONGS HOSPITALIZATION

Event #11: Serious Adverse Event

Event Description	URINARY TRACT INFECTION
Preferred term	尿路感染

AE Onset Date / Rx Day	[redacted]20[redacted] / 195
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	199
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	UNLIKELY
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	RISK FACTOR, URINARY RETENTION DUE TO PARKINSON'S DISEASE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #12: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ERYTHEMA TO LEFT LOWER ABDOMINAL QUADRANT INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 221
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	225
Duration of AE	5 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 #13: 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	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
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	UNLIKELY
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	REQUIRES OR PROLONGS HOSPITALIZATION

Event #14: Event of Interest - Infusion Site Related Infections

Event Description	INFUSION SITE INFECTION
Preferred term	注入部位感染
AE Onset Date / Rx Day	[redacted]20[redacted] / 341
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	

NOT APPLICABLE

AE Stopped Rx Day	365
Duration of AE	25 DAYS
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]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

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 が投与され，冠動脈疾患，尿路感染，及び心房細動を発現した。

Event 9，10，及び 11 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 日目から投与 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治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 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を受診した。投与 192 日目，被験者は心臓カテーテル手術を受け，2 本のステントが留置された。投与 195 日目，被験者は尿路感染を発現し入院延長となった。被験者に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。被験者は入院中の心臓モニタリング時に無症候性の心房細動が認められた。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ったことを指摘した。
被験者にアミオダロン，メトプロロール，プラビックス，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: M15-741

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 が投与され，肺塞栓症を発現した。

Event 13 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。

本事象の発現前，被験者は投与から約 6 ヵ月後に発現した尿路感染のため入院延長となっていた。投与から約 6 ヵ月後の入院中，被験者に心房細動（間欠性）とみなされる心拍リズム異常が認められた。

投与から約 10 ヵ月後，被験者は胸痛及び最近発現した心房細動のため入院した。被験者は胸部 CT 検査後に肺塞栓症と診断された。大静脈フィルターが留置され，心臓専門医により抗凝固薬は使用しないと判断された。投与 334 日目，被験者は退院した。

治験責任医師によると，被験者には心房細動のリスク因子があった。

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:** 101/57mmHg

[redacted] **20[redacted] BLOOD PRESSURE - SCREENING:** 128/88mmHg

[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
注入部位膿瘍				X
注入部位蜂巣炎	X	X		X
注入部位紅斑				X
注射部位紅斑				X
** Disc. due to adverse event				X

Disc = Discontinued.

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

Medical History	Onset Year
DEPRESSION	19[redacted]
ANXIETY	20[redacted]
CONSTIPATION	20[redacted]
INSOMNIA	20[redacted]
ANAL FISSURE	20[redacted]
PERIPHERAL EDEMA BILATERAL	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
TONSILLECTOMY ADENOIDECTOMY	19[redacted]
CHOLECYSTECTOMY	20[redacted]
DEEP BRAIN STIMULATION IMPLANT	20[redacted]
HERNIA REPAIR INGUINAL (RIGHT)	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	0.7	0	0	0	0	[redacted]/1
ABBV-951	0.7	0	0	0	0	[redacted]/2
ABBV-951	0.7	0	0	60	0.15	[redacted]/8
ABBV-951	0.55	0	0.53	60	0.11	[redacted]/15
ABBV-951	0.55	0	0.53	0	0	[redacted]/22
ABBV-951	0.55	0	0.53	0	0	[redacted]/29
ABBV-951	0.55	0.57	0.53	0	0	[redacted]/45
ABBV-951	0.55	0.57	0.53	0	0	[redacted]/53
ABBV-951	0.55	0	0	0	0	[redacted]/68
ABBV-951	0.55	0.57	0.53	0	0	[redacted]/80
ABBV-951	0.55	0.57	0.53	0	0	[redacted]/87
ABBV-951	0.55	0.57	0.53	0	0	[redacted]/101
ABBV-951	0.56	0.57	0.55	0	0	[redacted]/116

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	1517.96		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951	2868.6		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951	2868.6		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951	2868.6		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951	2868.6		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951	1255.01		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951	1278.91		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7

ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 8
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 9
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 10
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 11	[redacted]20[redacted] / 11
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 12	
ABBV-951	1434.3		SC / CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 13	
ABBV-951	2450.26		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951	1410.39		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951	1315.62		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951	2196.18		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951	2195.84		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951	2209.50		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	2172.79		SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951	2166.81		SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951	2198.23		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951	2185.42		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47

ABBV-951	2207.79	SC / CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951	2263.29	SC / CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951	2234.09	SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 74	[redacted]20[redacted] / 74
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 76
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 77
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 78	[redacted]20[redacted] / 78
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 79	[redacted]20[redacted] / 79
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 80
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 81	[redacted]20[redacted] / 81
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 82	[redacted]20[redacted] / 82
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84

ABBV-951	2284.63	SC / CONTINUOUS	[redacted]20[redacted] / 85	[redacted]20[redacted] / 85
ABBV-951	2274.39	SC / CONTINUOUS	[redacted]20[redacted] / 86	[redacted]20[redacted] / 86

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
BUPROPION	100 mg	BID	Y-M: 20[redacted]
AMANTADINE	100.000 mg	QD	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	100.000 mg	6 TIMES PER DAY	Y-M: 20[redacted]
CLONAZEPAM	0.5 mg	OTHER: QHS	Y-M: 20[redacted]
ROPINIROLE	2.000 mg	QD	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;ENTACAPONE;LEVODOPA	200.000 mg	QID	Y-M: 20[redacted]
DOCUSATE SODIUM	50 mg	PRN	Y-M: 20[redacted]
MACROGOL 3350	1 OTHER: CAPFUL	QD	Y-M: 20[redacted]
MELATONIN	10 mg	OTHER: QHS	Y-M: 20[redacted]
UBIDECARENONE	100 mg	QD	Y-M: 20[redacted]
AMANTADINE	500.000 mg	BID	Y-M: 20[redacted]
BUSPIRONE HYDROCHLORIDE	7.5 mg	TID	Y-M: 20[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
BUPROPION	100 mg	BID	Y-M: 20[redacted]	ONGOING
CLONAZEPAM	0.5 mg	OTHER: QHS	Y-M: 20[redacted]	ONGOING
DOCUSATE SODIUM	50 mg	PRN	Y-M: 20[redacted]	ONGOING
MACROGOL 3350	1 OTHER: CAPFUL	QD	Y-M: 20[redacted]	ONGOING
MELATONIN	10 mg	OTHER: QHS	Y-M: 20[redacted]	ONGOING
UBIDECARENONE	100 mg	QD	Y-M: 20[redacted]	ONGOING
BUSPIRONE HYDROCHLORIDE	7.5 mg	TID	Y-M: 20[redacted]	ONGOING
CEFALEXIN	500 mg	TID	Y-M: 20[redacted]-[redacted] / 51	Y-M: 20[redacted]-[redacted] / 53
SULFAMETHOXAZOLE;TRIMETHOPRIM	800 mg	BID	Y-M: 20[redacted]-[redacted] / 53	Y-M: 20[redacted]-[redacted] / 57
VANCOMYCIN	1250 mg	OTHER: EVERY 8 HOURS	Y-M: 20[redacted]-[redacted] / 57	Y-M: 20[redacted]-[redacted] / 59
CEFDINIR	300 mg	OTHER: EVERY 12 HOURS	Y-M: 20[redacted]-[redacted] / 60	Y-M: 20[redacted]-[redacted] / 70

DOXYCYCLINE	100 mg	BID	Y-M: 20[redacted] / 60	Y-M: 20[redacted] / 70
SULFAMETHOXAZOLE;TRIMETHOPRIM	800 mg	BID	Y-M: 20[redacted] / 120	Y-M: 20[redacted] / 130
DOXYCYCLINE	100 MG mg	BID	Y-M: 20[redacted] / 122	Y-M: 20[redacted] / 132
CEFDINIR	300 MG mg	BID	Y-M: 20[redacted] / 124	ONGOING

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MINIMAL ERYTHEMA AREA TO RIGHT UPPER QUADRANT ABDOMEN, INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 11
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	15
Duration of AE	5 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	LEFT UPPER AND LOWER QUADRANT GRADE 2 MODERATE ERYTHEMA AT INJECTION SITE
Preferred term	注射部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 50
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	

NOT APPLICABLE

AE Stopped Rx Day	54
Duration of AE	5 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 - Infusion Site Related Infections

Event Description	CELLULITIS TO LEFT UPPER/LOWER ABDOMINAL QUADERANT AT INFUSION SITE
Preferred term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 56
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	100
Duration of AE	45 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	UNLIKELY
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #4: Event of Interest - Infusion Site Related Infections

Event Description	LEFT ABDOMINAL WALL ABSCESS X 2 AT INFUSION SITE
Preferred term	注入部位膿瘍
AE Onset Date / Rx Day	[redacted]20[redacted] / 57
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	100
Duration of AE	44 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: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	RIGHT UPPER ABDOMINAL QUADRANT ERYTHEMA TO INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 120
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
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	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 #6: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MODERATE ERYTHEMA TO THE RIGHT MIDDLE ABDOMINAL QUADRANT AT THE INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 121
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	124
Duration of AE	4 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: AE Leading to Discontinuation of Study Drug, Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS TO RIGHT MIDDLE QUADRANT ABDOMEN AT THE INFUSION SITE
Preferred term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 124
Age at AE Onset	6[redacted]

Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
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	YES
SAE Criteria	NONE

generated: [redacted]20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

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 が投与され，左上下腹部の注入部位蜂巣炎を発現した。

Event 3 の臨床経過：

関連する病歴は，うつ病，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 1 日目から投与 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治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 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 10 日目から投与 17 日目まで，被験者は非盲検下プレドニゾロン漸減療法を受け，投与 18 日目，盲検下プレドニゾロン漸減療法を開始した。

投与 56 日目，被験者は左上下腹部の注入部位蜂巣炎を発現した。投与 100 日目，左上下腹部の注入部位蜂巣炎は消失した。

本事象の発現前，投与 11 日目，被験者は右上腹部注入部位に非重篤の軽微な紅斑を発現した。投与 50 日目，被験者はまた左上下挿入部位に非重篤でグレード 2 の紅斑を発現した。

投与 56 日目，被験者は抗生物質経口投与中に多少症状の進行がみられ，左腹壁挿入部の膿瘍及び蜂巣炎の可能性があるため入院した。

退院時サマリ：

入院前，被験者は非重篤の事象のため外来にてケフレックス投与後，3 日間 BACTRIM 投与による治療を受けていたが，持続的に悪化していた。

被験者は腹壁紅斑，軽度発熱，及び注入部位に「触れると熱い」を発現したため，緊急治療室を受診した。膿瘍及び蜂巣炎の可能性が懸念された。腹部骨盤の CT 検査が実施され，腹壁蜂巣炎及び皮膚炎，並びに左中腹部に限局性の液貯留が認められた。被験者は救急診療部でバンコマイシンの投与を開始し，一般外科を受診した。治験薬の投与は外科的治療のため中断された。被験者は左腹壁の 2 か所の感染膿瘍の切開及びドレナージを無事に完了した。術後の経過は特記なし。被験者は反対側の腹壁で注入を継続するよう指導された。被験者は蜂巣炎の良好な改善がみられ，投与 59 日目，自宅で抗生物質治療をすることとし退院帰宅した。

被験者にバンコマイシン，OMNICEF，及びドキシサイクリンが投与された。

The patient's past medications include:

ROPINIROLE for PARKINSON'S DISEASE (20[redacted] - 20[redacted])

RYTARY for PARKINSON'S DISEASE (20[redacted] - 20[redacted])

STALEVO for PARKINSON'S DISEASE (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.22.1] [10065455]

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

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

Alternative Etiology for ABBV-951 (Open Label)

Event of CELLULITIS TO LEFT UPPER/LOWER ABDOMINAL QUADRANT AT INFUSION SITE

- Investigator: Not applicable

- AbbVie: Not applicable

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] CT ABDOMEN PELVIS:** MULTIFOCAL ABDOMINAL WALL CELLULITIS AND DERMATITIS CHANGES AND FOCAL FLUID COLLECTION OVER THE LEFT MID ABDOMEN, ALSO SOME RETAINED STOOL IN THE COLON

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
顔面骨骨折				X
転倒				X
注入部位蜂巣炎	X			X
注入部位紅斑				X
注入部位浮腫				X
注入部位蒼白				X
穿刺部位紅斑				X
鼻痛				X
皮膚裂傷				X

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

Medical History	Onset Year
ALLERGIES (SEASONAL)	19[redacted]
CONSTIPATION	19[redacted]
DEPRESSION	19[redacted]
MUSCULOSKELETAL PAIN	20[redacted]
HYPERTENSION	20[redacted]
SLEEP DISORDER	20[redacted]
HYPERCHOLESTEROLEMIA	20[redacted]
HYPOTHYROIDISM	20[redacted]
FALL	20[redacted]
ORTHOSTATIC HYPOTENSION	20[redacted]
IRRITABILITY	20[redacted]
GLAUCOMA	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
SEPTOPLASTY	19[redacted]
ANGIOPLASTY AND STENT PLACEMENT	20[redacted]
CATARACT SURGERY (RIGHT)	20[redacted]
CATARACT SURGERY (LEFT)	20[redacted]
CYSTOURETHROSCOPY WITH RIGHT RETROGRADE URETERAL PYOLOGRAMS	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	20 CIGARETTE	2	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	0.68	0	0	0	0	[redacted]20[redacted]/1
ABBV-951	0.63	0	0	0	0	[redacted]20[redacted]/2
ABBV-951	0.65	0	0	0	0	[redacted]20[redacted]/8
ABBV-951	0.65	0	0	0	0	[redacted]20[redacted]/15
ABBV-951	0.66	0	0	0	0	[redacted]20[redacted]/22
ABBV-951	0.66	0	0	0	0	[redacted]20[redacted]/29
ABBV-951	0.66	0	0	0	0	[redacted]20[redacted]/43
ABBV-951	0.66	0	0	0	0	[redacted]20[redacted]/61
ABBV-951	0.65	0	0	0	0	[redacted]20[redacted]/64
ABBV-951	0.67	0	0	0	0	[redacted]20[redacted]/75
ABBV-951	0.67	0	0	0	0	[redacted]20[redacted]/92
ABBV-951	0.67	0	0	0	0	[redacted]20[redacted]/107
ABBV-951	0.68	0	0	0	0	[redacted]20[redacted]/122
ABBV-951	0.68	0	0	0	0	[redacted]20[redacted]/124
ABBV-951	0.68	0.69	0	0	0	[redacted]20[redacted]/142

ABBV-951	0.68	0.7	0	0	0	[redacted]/145
ABBV-951	0.68	0.7	0	0	0	[redacted]/152
ABBV-951	0.68	0.7	0	0	0	[redacted]/155
ABBV-951	0.68	0.7	0	0	0	[redacted]/180
ABBV-951	0.68	0.7	0	0	0	[redacted]/197
ABBV-951	0.68	0.7	0	0	0	[redacted]/206
ABBV-951	0.68	0.7	0	0	0	[redacted]/220
ABBV-951	0.68	0.7	0.67	0	0	[redacted]/234
ABBV-951	0.68	0.7	0	0	0	[redacted]/248
ABBV-951	0.68	0.7	0	0	0	[redacted]/262
ABBV-951	0.68	0.7	0	0	0	[redacted]/270
ABBV-951	0.68	0.69	0	0	0	[redacted]/276
ABBV-951	0.68	0.69	0.67	0	0	[redacted]/290
ABBV-951	0.68	0.7	0	0	0	[redacted]/304
ABBV-951	0.68	0.7	0	0	0	[redacted]/318
ABBV-951	0.66	0.68	0	0	0	[redacted]/332
ABBV-951	0.66	0.68	0	0	0	[redacted]/346
ABBV-951	0.66	0.68	0	0	0	[redacted]/358
ABBV-951	0.67	0.68	0	0	0	[redacted]/374

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	1602.31		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951	2786.64		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951	2786.64		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951	2786.64		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951	2786.64		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951	1395.71		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951	2527.95		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951	2581.74		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951	2581.74		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	2581.74		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	2581.74		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951	2581.74		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951	2563.81		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951	2619.30		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14

ABBV-951	2663.7	SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951	2663.7	SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951	2663.7	SC / CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951	2663.7	SC / CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951	2663.7	SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951	2552.71	SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951	2608.20	SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951	2663.7	SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951	2663.7	SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	2663.7	SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951	2663.7	SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951	2663.7	SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951	2612.98	SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951	2670.87	SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951	2659.60	SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951	2670.87	SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51

ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
ABBV-951	2704.68	SC / CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
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ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 284	[redacted]20[redacted] / 284
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 285	[redacted]20[redacted] / 285
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 286	[redacted]20[redacted] / 286
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 287	[redacted]20[redacted] / 287
ABBV-951	2600.86	SC / CONTINUOUS	[redacted]20[redacted] / 288	[redacted]20[redacted] / 288
ABBV-951	2751.80	SC / CONTINUOUS	[redacted]20[redacted] / 289	[redacted]20[redacted] / 289
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 290	[redacted]20[redacted] / 290
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 291	[redacted]20[redacted] / 291
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 292	[redacted]20[redacted] / 292
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 293	[redacted]20[redacted] / 293
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 294	[redacted]20[redacted] / 294
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 295	[redacted]20[redacted] / 295
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 296	[redacted]20[redacted] / 296
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 297	[redacted]20[redacted] / 297
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 298	[redacted]20[redacted] / 298
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 299	[redacted]20[redacted] / 299
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 300	[redacted]20[redacted] / 300
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 301	[redacted]20[redacted] / 301
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 302	[redacted]20[redacted] / 302
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 303	[redacted]20[redacted] / 303
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 304	[redacted]20[redacted] / 304
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 305	[redacted]20[redacted] / 305
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 306	[redacted]20[redacted] / 306
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 307	[redacted]20[redacted] / 307
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 308	[redacted]20[redacted] / 308
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 309	[redacted]20[redacted] / 309
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 310	[redacted]20[redacted] / 310

ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 311	[redacted]20[redacted] / 311
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 312	[redacted]20[redacted] / 312
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 313	[redacted]20[redacted] / 313
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 314	[redacted]20[redacted] / 314
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 315	[redacted]20[redacted] / 315
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 316	[redacted]20[redacted] / 316
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 317	[redacted]20[redacted] / 317
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 318	[redacted]20[redacted] / 318
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 319	[redacted]20[redacted] / 319
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 320	[redacted]20[redacted] / 320
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 321	[redacted]20[redacted] / 321
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 322	[redacted]20[redacted] / 322
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 323	[redacted]20[redacted] / 323
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 324	[redacted]20[redacted] / 324
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 325	[redacted]20[redacted] / 325
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 326	[redacted]20[redacted] / 326
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 327	[redacted]20[redacted] / 327
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 328	[redacted]20[redacted] / 328
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 329	[redacted]20[redacted] / 329
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 330	[redacted]20[redacted] / 330
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 331	[redacted]20[redacted] / 331
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 332	[redacted]20[redacted] / 332
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 333	[redacted]20[redacted] / 333
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 334	[redacted]20[redacted] / 334
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 335	[redacted]20[redacted] / 335
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 336	[redacted]20[redacted] / 336
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 337	[redacted]20[redacted] / 337
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 338	[redacted]20[redacted] / 338
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 339	[redacted]20[redacted] / 339
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 340	[redacted]20[redacted] / 340
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 341	[redacted]20[redacted] / 341
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 342	[redacted]20[redacted] / 342
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 343	[redacted]20[redacted] / 343
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 344	[redacted]20[redacted] / 344
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 345	[redacted]20[redacted] / 345
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 346	[redacted]20[redacted] / 346
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 347	[redacted]20[redacted] / 347

ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 348	[redacted]20[redacted] / 348
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 349	[redacted]20[redacted] / 349
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 350	[redacted]20[redacted] / 350
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 351	[redacted]20[redacted] / 351
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 352	[redacted]20[redacted] / 352
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 353	[redacted]20[redacted] / 353
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 354	[redacted]20[redacted] / 354
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 355	[redacted]20[redacted] / 355
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 356	[redacted]20[redacted] / 356
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 357	[redacted]20[redacted] / 357
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 358	[redacted]20[redacted] / 358
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 359	[redacted]20[redacted] / 359
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 360	[redacted]20[redacted] / 360
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 361	[redacted]20[redacted] / 361
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 362	[redacted]20[redacted] / 362
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 363	[redacted]20[redacted] / 363
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 364	[redacted]20[redacted] / 364
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 365	[redacted]20[redacted] / 365
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 366	[redacted]20[redacted] / 366
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 367	[redacted]20[redacted] / 367
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 368	[redacted]20[redacted] / 368
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 369	[redacted]20[redacted] / 369
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 370	[redacted]20[redacted] / 370
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 371	[redacted]20[redacted] / 371
ABBV-951	2713.55	SC / CONTINUOUS	[redacted]20[redacted] / 372	[redacted]20[redacted] / 372
ABBV-951	2670.87	SC / CONTINUOUS	[redacted]20[redacted] / 373	[redacted]20[redacted] / 373

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
FEXOFENADINE HYDROCHLORIDE	180 mg	PRN	Y-M: 19[redacted]
VITAMINS NOS	1 OTHER: TAB	QD	Y-M: 19[redacted]
ACETYLSALICYLIC ACID	81 mg	QD	Y-M: 20[redacted]
IBUPROFEN	200 mg	PRN	Y-M: 20[redacted]
CITALOPRAM	40 mg	QD	Y-M: 20[redacted]
ATORVASTATIN	40 mg	OTHER: QHS	Y-M: 20[redacted]
LEVOTHYROXINE	50 ug	OTHER: QAM	Y-M: 20[redacted]

VITAMIN D NOS	4000 IU	QD	Y-M: 20[redacted]
SENNA ALEXANDRINA	6-8 mg	PRN	Y-M: 20[redacted]
DRONABINOL	1000 mg	QD	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	200.000 mg	QD	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	400.000 mg	QD	Y-M: 20[redacted]
FLUDROCORTISONE	0.1 mg	QD	Y-M: 20[redacted]
MELATONIN	5 mg	OTHER: QHS	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	980.000 mg	BID	Y-M: 20[redacted] / -286
LISINOPRIL	40 mg	OTHER: QAM	Y-M: 20[redacted] / -237
EZETIMIBE	10 mg	OTHER: QAM	Y-M: 20[redacted] / -105
METOPROLOL	50 mg	BID	Y-M: 20[redacted] / -58

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
FEXOFENADINE HYDROCHLORIDE	180 mg	PRN	Y-M: 19[redacted]	ONGOING
VITAMINS NOS	1 OTHER: TAB	QD	Y-M: 19[redacted]	ONGOING
ACETYLSALICYLIC ACID	81 mg	QD	Y-M: 20[redacted]	ONGOING
IBUPROFEN	200 mg	PRN	Y-M: 20[redacted]	ONGOING
CITALOPRAM	40 mg	QD	Y-M: 20[redacted]	ONGOING
LEVOTHYROXINE	50 ug	OTHER: QAM	Y-M: 20[redacted]	ONGOING
VITAMIN D NOS	4000 IU	QD	Y-M: 20[redacted]	ONGOING
ATORVASTATIN	40 mg	OTHER: QHS	Y-M: 20[redacted]	Y-M: 20[redacted] / 346
SENNA ALEXANDRINA	6-8 mg	PRN	Y-M: 20[redacted]	ONGOING
DRONABINOL	1000 mg	QD	Y-M: 20[redacted]	ONGOING
FLUDROCORTISONE	0.1 mg	QD	Y-M: 20[redacted]	ONGOING
MELATONIN	5 mg	OTHER: QHS	Y-M: 20[redacted]	ONGOING
LISINOPRIL	40 mg	OTHER: QAM	Y-M: 20[redacted] / -237	ONGOING
EZETIMIBE	10 mg	OTHER: QAM	Y-M: 20[redacted] / -105	ONGOING
METOPROLOL	50 mg	BID	Y-M: 20[redacted] / -58	Y-M: 20[redacted] / 61
NIFEDIPINE	30 mg	QD	Y-M: 20[redacted] / 20	ONGOING
CEFALEXIN	500 mg	TID	Y-M: 20[redacted] / 24	Y-M: 20[redacted] / 31
SULFAMETHOXAZOLE;TRIMETHOPRIM	800 mg	BID	Y-M: 20[redacted] / 31	Y-M: 20[redacted] / 41

HYDROCHLOROTHIAZIDE	25 mg	QD	Y-M: 20[redacted] / 62	Y-M: 20[redacted] / 276
SULFAMETHOXAZOLE;TRIMETHOPRIM	800 MG mg	BID	Y-M: 20[redacted] / 122	Y-M: 20[redacted] / 130
LATANOPROST	0.005% 1 DROP EACH EYE gtt	QD	Y-M: 20[redacted] / 157	ONGOING
CEFDINIR	300 MG mg	BID	Y-M: 20[redacted] / 197	Y-M: 20[redacted] / 207
SULFAMETHOXAZOLE;TRIMETHOPRIM	800 MG mg	BID	Y-M: 20[redacted] / 232	Y-M: 20[redacted] / 241
SULFAMETHOXAZOLE;TRIMETHOPRIM	800 MG mg	BID	Y-M: 20[redacted] / 266	Y-M: 20[redacted] / 269
SULFAMETHOXAZOLE;TRIMETHOPRIM	800 mg	BID	Y-M: 20[redacted] / 266	Y-M: 20[redacted] / 276
CEFDINIR	300 mg	BID	Y-M: 20[redacted] / 268	Y-M: 20[redacted] / 269
CEFEPIME	2 GM g	BID	Y-M: 20[redacted] / 269	Y-M: 20[redacted] / 271
VANCOMYCIN	1500 MG mg	BID	Y-M: 20[redacted] / 269	Y-M: 20[redacted] / 271

Event #1: Event of Interest -Falls And Associated Injuries

Event Description	ACUTE LEFT NASAL BONE FRACTURE
Preferred term	顔面骨骨折
AE Onset Date / Rx Day	[redacted]20[redacted] / 16
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	49
Duration of AE	34 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 #2: Event of Interest -Falls And Associated Injuries

Event Description	FRACTURE NASAL SEPTUM
Preferred term	顔面骨骨折
AE Onset Date / Rx Day	[redacted]20[redacted] / 16
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	49
Duration of AE	34 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	FALL, ACCIDENTAL
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 16
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	16
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

Event #4: Event of Interest -Infusion Site Related Non Infection Reactions, Event of Interest -Falls And Associated Injuries, Event of Interest - Concurrent Events of Falls and Associated Injuries

Event Description	1/2 INCH WHITE RING AROUND UPPER LEFT ABDOMINAL QUADRANT INFUSION SITE
Preferred term	注入部位蒼白
AE Onset Date / Rx Day	[redacted]20[redacted] / 16
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	16
Duration of AE	1 DAY
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 of Interest - Concurrent Events of Falls and Associated Injuries

Event Description	NASAL PAIN
Preferred term	鼻痛
AE Onset Date / Rx Day	[redacted]20[redacted] / 16
Age at AE Onset	6[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	49
Duration of AE	34 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 #6: Event of Interest -Falls And Associated Injuries

Event Description	CUT TO RIGHT HAND MEDIAL ASPECT POSTERIOR
Preferred term	皮膚裂傷
AE Onset Date / Rx Day	[redacted]20[redacted] / 16
Age at AE Onset	6[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	49
Duration of AE	34 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 #7: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	GRADE 2 MODERATE ERYTHEMA AT THE INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 24
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	43
Duration of AE	20 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 #8: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MILD EDEMA TO RIGHT LOWER QUADRANT INSERTION SITE, INFUSION
Preferred term	注入部位浮腫
AE Onset Date / Rx Day	[redacted]20[redacted] / 24
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	43
Duration of AE	20 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 Infections

Event Description	PHLEGMON RIGHT LATERAL ABDOMEN INFUSION SITE
Preferred term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 30
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	43
Duration of AE	14 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 #10: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ERYTHEMA MODERATE TO LOWER ABDOMEN AT INSERTION SITE
Preferred term	穿刺部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 115

Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	122
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 [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	GRADE 1 ERYTHEMA TO RIGHT UPPER QUADRANT INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 197
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	210
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 #12: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ERYTHEMA TO RIGHT LOWER ABDOMINAL QUADRANT INFUSION SITE.
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 232
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	248
Duration of AE	17 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 #13: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ERYTHEMA TO MID-LOWER ABDOMINAL AREA INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 266
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	270

Duration of AE	5 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: Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS TO MID-LOWER ABDOMINAL AREA INFUSION SITE
Preferred term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 268
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	269
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 #15: Serious Adverse Event, Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS TO MID-LOWER ABDOMINAL INFUSION SITE
Preferred term	注入部位蜂巣炎