TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	Day	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE									
[redacted] Age: 6[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg									
		TRT	1 TO 364	63	63	R: PSYCHOSIS S: 精神障害 P: 精神病性障害 L: Psychosis	E: 86 L: 24 Days	S: SEVERE R1: REASONABLE POSSIBILITY R4: No A1: Other: DOSE WAS LOWERED O: HOSPITALIZATION AT THE PSYCHIATRIC WARD	S: Yes, Hospitalization or prolonged hospitalization R: PROBABLE A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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: 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P: 硬膜下血腫 L: Acute subdural hematoma	E: 289 L: 1 Day	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DRUG WITHDRAWN	S: Yes, Life threatening, Death of subject R: NOT RELATED O: PATIENT DOES NOT HAVE GOOD MOBILITY DUE TO PARKINSON'S DISEASE AND GOT OUT OF BED WITHOUT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 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted] Age: 7[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg								
	TRT	1 TO 366	191	191	R: HALLUCINATIONS S: 精神障害 P: 幻覚 L: Hallucinations	E: 192 L: 2 Days	S: MODERATE R1: REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: PD PROGRESSION VS LEVODOPA COMPLICATION A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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: 7[redacted] Sex: Male Race: ASIAN Weight: 7[redacted].[redacted] kg									
	TRT	1 TO 364	199	199		R: CELLULITIS(LEFT LOWER LIMB) S: 感染症および寄生虫症 P: 蜂巣炎 L: Cellulitis of leg	E: 219 L: 21 Days	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: INFECTION. A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted]# Age: 5[redacted] Sex: Female Race: ASIAN Weight: 4[redacted].[redacted] kg								
	TRT	1 TO 167	18	18	R: HALLUCINATION S: 精神障害 P: 幻覚 L: Hallucination	E: 83 L: 66 Days	S: SEVERE R1: REASONABLE POSSIBILITY A1: DOSE NOT CHANGED O: CONCOMITANT MEDICATION CHANGE.	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED A: REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted] Age: 7[redacted] Sex: Female Race: ASIAN Weight: 3[redacted].[redacted] kg								
	TRT	1 TO 364	70	70	R: WORSENING OF PARKINSON'S DISEASE S: 神経系障害 P: パーキンソン病 L: Parkinson's disease aggravated	E: 94 L: 25 Days	S: MODERATE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: DUE TO THE SPREAD OF COVID-19 INFECTION, THE USUAL REHABILITATION COULD NOT BE PERFORMED, AND THE PATIENT WAS HOSPITALIZED FOR IMPROVEMENT OF MOTOR SYMPTOMS. A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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: 5[redacted] Sex: Female Race: WHITE Weight: 9[redacted].[redacted] kg								
[redacted]	TRT	1 TO 32	2	2	R: RIGHT ARM PARESTESIAS S: 神経系障害 P: 錯感覚 L: Paresthesia upper limb	E: 4 L: 3 Days	S: MODERATE R1: REASONABLE POSSIBILITY A1: Other: FLOW CHANGES FROM 0.50 ML/H TO 0.35 ML/H AND AFTER TO 0.45 ML/H O: CT-SCAN	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED A: NO REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	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: 5[redacted] Sex: Female Race: WHITE Weight: 9[redacted].[redacted] kg									
[redacted]	TRT	1 TO 32	2	2		R: SEVERE DYSARTRIA S: 神経系障害 P: 構語障害 L: Dysarthria	E: 4 L: 3 Days	S: MODERATE R1: REASONABLE POSSIBILITY A1: Other: FLOW CHANGES FROM 0.50 ML/H TO 0.35 ML/H AND AFTER TO 0.45 ML/H O: CT-SCAN	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED A: NO REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted] Age: 4[redacted] Sex: Male Race: ASIAN Weight: 7[redacted].[redacted] kg								
	TRT	1 TO 365	28	28	R: WORSENING OF DELUSION S: 精神障害 P: 妄想 L: Delusion	E: 42 L: 15 Days I: Yes	S: MODERATE R1: REASONABLE POSSIBILITY R4: No A1: DRUG INTERRUPTED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED A: REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted] Age: 4[redacted] Sex: Male Race: ASIAN Weight: 7[redacted].[redacted] kg								
	TRT	1 TO 365	28	28	R: WORSENING OF HALLUCINATION S: 精神障害 P: 幻覚 L: Hallucinations aggravated	E: 42 L: 15 Days I: Yes	S: MODERATE R1: REASONABLE POSSIBILITY R4: No A1: DRUG INTERRUPTED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED A: REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted]# Age: 6[redacted] Sex: Female Race: ASIAN Weight: 5[redacted].[redacted] kg								
	TRT	1 TO 18	14	14	R: HALLUCINATION S: 精神障害 P: 幻覚 L: Hallucination	E: 84 L: 71 Days	S: MODERATE R1: REASONABLE POSSIBILITY A1: DRUG WITHDRAWN O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED A: REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted]# Age: 6[redacted] Sex: Female Race: ASIAN Weight: 5[redacted].[redacted] kg								
	TRT	1 TO 18	14	14	R: RHABDOMYOLYSIS S: 筋骨格系および結合組織障害 P: 横紋筋融解症 L: Rhabdomyolysis	E: 22 L: 9 Days	S: SEVERE R1: REASONABLE POSSIBILITY A1: DRUG WITHDRAWN O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED A: NO REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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 LOW DOSE [redacted]# Age: 6[redacted] Sex: Female Race: ASIAN Weight: 5[redacted].[redacted] kg							
[redacted]	TRT	1 TO 18	18	R: WORSENING OF PARKINSON'S SYMPTOMS S: 神経系障害 P: パーキンソン病 L: Parkinson's disease aggravated	E: 84 L: 67 Days	S: SEVERE R1: REASONABLE POSSIBILITY A1: DRUG WITHDRAWN	S: Yes, Hospitalization or prolonged hospitalization R: CAUSAL RELATIONSHIP A: NO REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted]# Age: 5[redacted] Sex: Male Race: ASIAN Weight: 4[redacted].[redacted] kg								
	TRT	1 TO 16	15	15	R: WORSENING OF PARKINSON'S SYMPTOMS S: 神経系障害 P: パーキンソン病 L: Parkinson's disease aggravated	E: 91 L: 77 Days I: Yes	S: SEVERE R1: REASONABLE POSSIBILITY A1: DRUG WITHDRAWN	S: Yes, Hospitalization or prolonged hospitalization R: CAUSAL RELATIONSHIP A: NO REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted]# Age: 6[redacted] Sex: Female Race: ASIAN Weight: 3[redacted].[redacted] kg								
	TRT	1 TO 103	102	102	R: LOSS OF CONSCIOUSNESS ATTACK S: 神経系障害 P: 意識消失 L: Loss of consciousness	E: 103 L: 2 Days	S: MODERATE R1: REASONABLE POSSIBILITY A1: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization R: PROBABLE A: NO REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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: 6[redacted] Sex: Male Race: WHITE Weight: 10[redacted].[redacted] kg								
	TRT	1 TO 117	12	12	R: BILATERAL PNEUMONIA S: 感染症および寄生虫症 P: 肺炎 L: Bilateral pneumonia	E: 61 L: 50 Days	S: MODERATE R1: NO REASONABLE POSSIBILITY A1: DOSE NOT CHANGED O: ADMITTED TO HOSPITAL, STARTED ON IV ANTIBIOTICS	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: PT HISTORY OF ASPIRATION PNEUMONIA IN PAST AS WELL AS COPD MEDICAL CONDITION. A: NO REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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: 6[redacted] Sex: Male Race: WHITE Weight: 10[redacted].[redacted] kg								
	TRT	1 TO 117	114	114	R: PNEUMONIA S: 感染症および寄生虫症 P: 肺炎 L: Pneumonia	E: 116 L: 3 Days	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: COPD, HISTORY OF ASPIRATION PNEUMONIA A: NO REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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: Male Race: WHITE Weight: 10[redacted].[redacted] kg									
		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]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted] Age: 6[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg								
	TRT	1 TO 365	258	258	R: RIGHT GLUTEAL ABSCESS AT INFUSION SITE S: 感染症および寄生虫症 P: 注入部位膿瘍 L: Infusion site abscess	E: 269 L: 12 Days	S: SEVERE R1: REASONABLE POSSIBILITY R4: No A1: DRUG INTERRUPTED	S: Yes, Hospitalization or prolonged hospitalization R: CAUSAL RELATIONSHIP A: REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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 R1: ABBV-951 Relationship R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted] Age: 6[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg								
	TRT	1 TO 365	336	336	R: DOPAMINERGIC DYSREGULATION S: 精神障害 P: ドーパミン調節障害症候群 L: Dopamine dysregulation syndrome	E: 346 L: 11 Days I: Yes	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: CONTROL OF SINEMET INTAKE IN HOSPITALIZATION AND TREATMENT OF INCREASED ANXIETY	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: PARKINSON'S DISEASE A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted]# Age: 6[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg								
	TRT	1 TO 149	81	81	R: ABSCESS AT INFUSION SITE S: 感染症および寄生虫症 P: 注入部位膿瘍 L: Infusion site abscess	E: 101 L: 21 Days	S: MODERATE R1: REASONABLE POSSIBILITY R4: No A1: DRUG INTERRUPTED	S: Yes, Hospitalization or prolonged hospitalization R: PROBABLE A: REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted]# Age: 6[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg								
	TRT	1 TO 149	81	81	R: CELLULITIS AT INFUSION SITE S: 感染症および寄生虫症 P: 注入部位蜂巣炎 L: Infusion site cellulitis	E: 101 L: 21 Days	S: MODERATE R1: REASONABLE POSSIBILITY R4: No A1: DRUG INTERRUPTED	S: Yes, Hospitalization or prolonged hospitalization R: PROBABLE A: REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted]# Age: 6[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg								
	TRT	1 TO 149	81	81	R: SEPSIS S: 感染症および寄生虫症 P: 敗血症 L: Sepsis	E: 101 L: 21 Days	S: MODERATE R1: REASONABLE POSSIBILITY R4: No A1: DRUG INTERRUPTED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED A: REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted] Age: 7[redacted] Sex: Male Race: WHITE Weight: 9[redacted].[redacted] kg								
[redacted]	TRT	1 TO	33	33	R: SUBCUTANEOUS ABSCESS ABDOMINAL AN INFUSION SITE S: 感染症および寄生虫症 P: 注入部位膿瘍 L: Infusion site abscess	E: 42 L: 10 Days I: Yes	S: MODERATE R1: REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: SURGERY	S: Yes, Hospitalization or prolonged hospitalization R: POSSIBLE A: REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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 LOW DOSE									
[redacted]	Age: 7[redacted] Sex: Male Race: WHITE Weight: 9[redacted].[redacted] kg								
		TRT	1 TO	129	129	R: INTESTINAL BLEEDING S: 胃腸障害 P: 腸出血 L: Intestinal bleeding	E: 133 L: 5 Days I: Yes	S: MODERATE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: ISCHAEMIC COLITIS AS A RESULT OF AN OCCLUSIVE EMBOLISM A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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 LOW DOSE									
[redacted] Age: 7[redacted] Sex: Male Race: WHITE Weight: 9[redacted].[redacted] kg									
		TRT	1 TO	129	129	R: ISCHEMIC COLITIS WITH S: 胃腸障害 P: 虚血性大腸炎 L: Ischemic colitis	E: 133 L: 5 Days I: Yes	S: MODERATE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: ISCHAEMIC COLITIS AS A RESULT OF AN OCCLUSIVE EMBOLISM A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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 LOW DOSE									
[redacted] Age: 7[redacted] Sex: Male Race: WHITE Weight: 9[redacted].[redacted] kg									
	TRT	1 TO	236	236		R: PNEUMONIA S: 感染症および寄生虫症 P: 肺炎 L: Pneumonia	E: 240 L: 5 Days	S: MODERATE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: BACTERIAL INFECTION OF THE LUNGS A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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: 7[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg									
	TRT	1 TO 365	224	224		R: WORSENING RIGHT SHOULDER DEGENERATIVE JOINT DISEASE S: 筋骨格系および結合組織障害 P: 変形性関節症 L: Osteoarthritis aggravated	E: 224 L: 1 Day	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: RIGHT SHOULDER TOTAL ARTHROPLASTY (SHOULDER HARDWARE PLACED)	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: PATIENT HAS SEVERE DJD AND THUS REQUIRED TOTAL SHOULDER ARTHROPLASTY AFTER SEVERAL NON-SURGICAL OPTIONS FAILED. A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted] Age: 7[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg								
	TRT	1 TO 367	104	104	R: DEHYDRATION S: 代謝および栄養障害 P: 脱水 L: Dehydration	E: 107 L: 4 Days	S: SEVERE R1: NO REASONABLE POSSIBILITY A1: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization R: UNLIKELY O: URINARY TRACT INFECTION (UTI) CAUSED BY BACTERIA, WITH DEHYDRATION AND WEAKNESS SECONDARY TO UTI. A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted] Age: 7[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg								
	TRT	1 TO 367	104	104	R: URINARY TRACT INFECTION S: 感染症および寄生虫症 P: 尿路感染 L: Urinary tract infection	E: 107 L: 4 Days	S: SEVERE R1: NO REASONABLE POSSIBILITY A1: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization R: UNLIKELY O: URINARY TRACT INFECTION (UTI) CAUSED BY BACTERIA, WITH DEHYDRATION AND WEAKNESS SECONDARY TO UTI. A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted] Age: 7[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg								
	TRT	1 TO 367	104	104	R: WEAKNESS S: 一般・全身障害および投与部位の状態 P: 無力症 L: Weakness	E: 107 L: 4 Days	S: SEVERE R1: NO REASONABLE POSSIBILITY A1: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization R: UNLIKELY O: URINARY TRACT INFECTION (UTI) CAUSED BY BACTERIA, WITH DEHYDRATION AND WEAKNESS SECONDARY TO UTI. A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted] Age: 7[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg								
	TRT	1 TO 367	281	281	R: CELLULITIS AT INFUSION SITE S: 感染症および寄生虫症 P: 注入部位蜂巣炎 L: Infusion site cellulitis	E: 367 L: 87 Days	S: SEVERE R1: REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization R: CAUSAL RELATIONSHIP A: REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted] Age: 7[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg								
	TRT	1 TO 367	281	281	R: SEPSIS S: 感染症および寄生虫症 P: 敗血症 L: Sepsis	E: 289 L: 9 Days	S: SEVERE R1: REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization R: PROBABLE A: REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted] Age: 6[redacted] Sex: Male Race: WHITE Weight: 6[redacted].[redacted] kg								
	TRT	1 TO 363	326	326	R: HYPONATREMIA S: 代謝および栄養障害 P: 低ナトリウム血症 L: Hyponatremia	E: 335 L: 10 Days	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: HYPONATREMIA DUE TO DEHYDRATION AND POOR PO INTAKE (WHICH COULD BE DUE TO NSTEMI). A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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 LOW DOSE									
[redacted] Age: 6[redacted] Sex: Male Race: WHITE Weight: 6[redacted].[redacted] kg									
	TRT	1 TO 363	326	326		R: NSTEMI S: 心臓障害 P: 急性心筋梗塞 L: Non ST segment elevation myocardial infarction	E: 326 L: 1 Day	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: MULTIPLE: (CONCOMITANT MEDICATION OR THERAPY DISCONTINUED; Other: CARDIAC CATHETERIZATION; CONCOMITANT MEDICATION OR THERAPY STARTED)	S: Yes, Life threatening, Hospitalization or prolonged hospitalization, Other medically important serious event R: UNLIKELY O: 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) A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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 LOW DOSE									
[redacted] Age: 6[redacted] Sex: Male Race: WHITE Weight: 6[redacted].[redacted] kg									
		TRT	1 TO 363	328	328	R: CORONARY ARTERY DISEASE S: 心臓障害 P: 冠動脈疾患 L: Coronary artery disease	O: Yes	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: CABG PERFORMED ON [redacted]20[redacted].	S: Yes, Life threatening, Hospitalization or prolonged hospitalization, Other medically important serious event R: NOT RELATED O: 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] A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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 LOW DOSE									
[redacted] Age: 6[redacted] Sex: Male Race: WHITE Weight: 6[redacted].[redacted] kg									
		TRT	1 TO 363	336	336	R: CARDIAC ARREST S: 心臓障害 P: 心停止 L: Cardiac arrest	E: 336 L: 1 Day	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DRUG INTERRUPTED O: CPR	S: Yes, Life threatening, Hospitalization or prolonged hospitalization, Other medically important serious event R: NOT RELATED O: POST-SURGICAL VASOVAGAL REACTION A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted]# Age: 7[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg								
	TRT	1 TO 153	23	23	R: DIZZINESS S: 神経系障害 P: 浮動性めまい L: Dizziness	E: 23 L: 1 Day I: Yes	S: MODERATE R1: REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: PHYSICAL EXAMINATION, BLOOD TESTS, ORTHOSTATIC BP - ALL UNREMARKABLE (BP RAISED)	S: Yes, Hospitalization or prolonged hospitalization R: POSSIBLE A: NO REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted]# Age: 7[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg								
	TRT	1 TO 153	23	23	R: FALL (ACCIDENTAL), NO TRIP OR SLIP. S: 傷害、中毒および処置合併症 P: 転倒 L: Fall	E: 23 L: 1 Day	S: MILD R1: REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization R: POSSIBLE A: NO REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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: 6[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg								
	TRT	1 TO 228	228	R: ABSCESS RIGHT FOREARM S: 感染症および寄生虫症 P: 四肢膿瘍 L: Abscess limb	E: 234 L: 7 Days	S: MODERATE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: DIRTY SPLINTER WAS ACQURED DURING GARDENING. A SEVERE WOUND INFECTION OCCURRED, SURGERY WAS NECESSARY TO REMOVE THE DIRTY WOODEN PARTICLES. A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	Day	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE									
[redacted]# Age: 6[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg									
	FU	20 TO	25	44		R: WORSENING OF PD SYMPTOMS S: 神経系障害 P: パーキンソン病 L: Parkinson's disease aggravated	E: 49 L: 6 Days	S: MILD R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: ADJUSTMENT OF PD MEDICATION A: NO REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	Day	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 HIGH DOSE									
[redacted]# Age: 6[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg									
		TRT	1 TO 196	33	33	R: MULTIPLE SMALL NO DRAINABLE POST INFLAMMATORY ABSCESSES (INFUSION SITE ABSCESSES) S: 感染症および寄生虫症 P: 注入部位膿瘍 L: Infusion site abscess	E: 120 L: 88 Days	S: SEVERE R1: REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization R: UNLIKELY A: REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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: 6[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg								
	TRT	1 TO 196	48	48	R: ABCESS OF ABDOMINAL WALL (BILATERAL) AT INFUSION SITE THIS DIAGNOSIS HAS BEEN TAKEN DIRECTLY FROM THE DISCHARGE SUMMARY. S: 感染症および寄生虫症 P: 注入部位膿瘍 L: Infusion site abscess	E: 120 L: 73 Days	S: SEVERE R1: REASONABLE POSSIBILITY R4: No A1: DRUG INTERRUPTED O: INCISION AND DRAINAGE OF ABCESS	S: Yes, Hospitalization or prolonged hospitalization, Other medically important serious event R: PROBABLE A: REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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: 6[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg								
[redacted]	TRT	1 TO 196	195	195	R: CELLULITS AT INFUSION SITE S: 感染症および寄生虫症 P: 注入部位蜂巣炎 L: Infusion site cellulitis	E: 205 L: 11 Days	S: MODERATE R1: REASONABLE POSSIBILITY R4: No A1: DRUG WITHDRAWN	S: Yes, Hospitalization or prolonged hospitalization R: UNLIKELY A: REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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 LOW DOSE									
[redacted]	Age: 6[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg								
		TRT	1 TO	120	120	R: RECTAL ADENOCARCINOMA S: 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） P: 直腸腺癌 L: Rectal adenocarcinoma	I: Yes	S: MODERATE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: COLOSCOPY ORDERED FROM ER.	S: Yes, Life threatening R: NOT RELATED O: AGE AND SEX ARE THE STRONGEST RISK FACTORS FOR RECTAL CANCER. A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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 LOW DOSE									
[redacted] Age: 7[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg									
		TRT	1 TO	188	188	R: ANXIETY S: 精神障害 P: 不安 L: Anxiety	E: 189 L: 2 Days	S: SEVERE R1: NO REASONABLE POSSIBILITY R3: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: ANXIETY A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	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: 5[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg									
	TRT	1 TO 353	294	294		R: PSYCHOSIS S: 精神障害 P: 精神病性障害 L: Psychosis	E: 295 L: 2 Days	S: SEVERE R1: REASONABLE POSSIBILITY R4: No A1: DRUG INTERRUPTED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch / Interval	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: 7[redacted] Sex: Male Race: WHITE Weight: 9[redacted].[redacted] kg								
	TRT	1 TO 367	108	108	R: ACTIVE FACIAL BLEEDING RELATED TO AE [redacted] S: 血管障害 P: 出血 L: Bleeding	E: 120 L: 13 Days	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: GAIT DISORDER A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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: 7[redacted] Sex: Male Race: WHITE Weight: 9[redacted].[redacted] kg									
	TRT	1 TO 367	108	108		R: FALL (ACCIDENTAL) S: 傷害、中毒および処置合併症 P: 転倒 L: Fall	E: 108 L: 1 Day	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: GAIT DISORDER PARKINSON DISEASE A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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: 7[redacted] Sex: Male Race: WHITE Weight: 9[redacted].[redacted] kg									
	TRT	1 TO 367	108	108		R: LOSS OF CONSCIOUSNESS S: 神経系障害 P: 意識消失 L: Loss of consciousness	E: 108 L: 1 Day	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: GAIT DISORDER PARKINSON DISEASE A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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: 7[redacted] Sex: Male Race: WHITE Weight: 9[redacted].[redacted] kg									
		TRT	1 TO 367	108	108	R: PAIN SURROUNDING EYE RELATED TO AE [redacted] S: 眼障害 P: 眼窩周囲痛 L: Periorbital pain	E: 120 L: 13 Days	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: GAIT DISORDER A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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: 7[redacted] Sex: Male Race: WHITE Weight: 9[redacted].[redacted] kg									
	TRT	1 TO 367	108	108		R: RIGHT FACE TRAUMA S: 傷害、中毒および処置合併症 P: 顔面損傷 L: Face injury	E: 108 L: 1 Day	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: GAIT DISORDER PARKINSON DISEASE A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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: 7[redacted] Sex: Male Race: WHITE Weight: 9[redacted].[redacted] kg									
	TRT	1 TO 367	108	108		R: RIGHT PERIORBITAL SWELLING S: 眼障害 P: 眼窩周囲腫脹 L: Periorbital swelling	E: 108 L: 1 Day	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: GAIT DISORDER PARKINSON DISEASE A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

表2.7.4.7-48　重篤な有害事象を発現した被験者一覧（安全性解析対象集団）：M15-737試験（更新時）

[redacted]20[redacted] 10:47 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.3__2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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	160	160		R: CLOSED DISPLACED FRACTURE OF LEFT FEMORAL NECK S: 傷害、中毒および処置合併症 P: 転位骨折 L: Fracture displacement	E: 162 L: 3 Days	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: LEFT HIP REPLACEMENT SURGERY	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: MECHANICAL FALL A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	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	160	160	R: MECHANICAL FALL S: 傷害、中毒および処置合併症 P: 転倒 L: Fall	E: 160 L: 1 Day	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: POOR BALANCE DUE TO PD A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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	337	337	R: CLOSED FRACTURE OF NECK OF RIGHT FEMUR S: 傷害、中毒および処置合併症 P: 大腿骨頚部骨折 L: Fracture of neck of femur	E: 351 L: 15 Days	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: RIGHT HIP TOTAL ARTHROPLASTY SURGERY	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: OSTEOPENIA A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	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	337	337		R: MECHANICAL FALL S: 傷害、中毒および処置合併症 P: 転倒 L: Fall	E: 337 L: 1 Day	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: RIGHT HIP TOTAL ARTHROPLASTY SURGERY	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: PARKINSON'S DISEASE PROGRESSION A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted] Age: 5[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg								
	TRT	1 TO 554	554	R: RIGHT SHOULDER CHRONIC MASSIVE ROTATOR CUFF TEAR S: 筋骨格系および結合組織障害 P: 肩回旋筋腱板症候群 L: Rotator cuff tear	E: 555 L: 2 Days	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: AES OF RIGHT SHOULDER CHRONIC MASSIVE ROTATOR CUFF TEAR ON [redacted]20[redacted], RIGHT SHOULDER GLENOHUMORAL DEGENERATIVE JOINT DISEASE ON [redacted]20[redacted] REQ. REPAIR WITH RIGHT REVERSE TOTAL SHOULDER ARTHROPLASTY A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted] Age: 5[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg								
[redacted]	TRT	1 TO	554	554	R: RIGHT SHOULDER GLENOHUMORAL DEGENERATIVE JOINT DISEASE S: 筋骨格系および結合組織障害 P: 変形性関節症 L: Osteoarthritis shoulders	E: 555 L: 2 Days	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: AES OF RIGHT SHOULDER CHRONIC MASSIVE ROTATOR CUFF TEAR ON [redacted]20[redacted], RIGHT SHOULDER GLENOHUMORAL DEGENERATIVE JOINT DISEASE ON [redacted]20[redacted] REQ. REPAIR WITH RIGHT REVERSE TOTAL SHOULDER ARTHROPLASTY A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 HIGH DOSE								
[redacted]# Age: 8[redacted] Sex: Male Race: WHITE Weight: 5[redacted].[redacted] kg								
	TRT	1 TO 174	15	15	R: DIVERTICULAR HEMORRHAGE S: 胃腸障害 P: 出血性腸憩室 L: Diverticulum intestinal hemorrhagic	E: 19 L: 5 Days	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: HISTORY OF DIVERTICULAR BLEEDING A: NO REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 HIGH DOSE								
[redacted]# Age: 8[redacted] Sex: Male Race: WHITE Weight: 5[redacted].[redacted] kg								
	TRT	1 TO 174	22	22	R: DIVERTICULAR HEMMORHAGE S: 胃腸障害 P: 出血性腸憩室 L: Diverticulum intestinal hemorrhagic	E: 134 L: 113 Days	S: MODERATE R1: NO REASONABLE POSSIBILITY A1: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: HISTORY OF DIVERTICULAR BLEEDING A: NO REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 HIGH DOSE								
[redacted]# Age: 8[redacted] Sex: Male Race: WHITE Weight: 5[redacted].[redacted] kg								
	TRT	1 TO 174	32	32	R: HIP FRACTURE S: 傷害、中毒および処置合併症 P: 股関節部骨折 L: Hip fracture	E: 32 L: 1 Day	S: MODERATE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: ACCIDENTAL FALL A: NO REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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 LOW DOSE									
[redacted]	Age: 7[redacted] Sex: Male Race: WHITE Weight: 5[redacted].[redacted] kg								
		TRT	1 TO	14	14	R: TRONCHATERITIS LEFT S: 筋骨格系および結合組織障害 P: 滑液包炎 L: Trochanteritis		S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: EVENT CAUSED BY FALL, THIS IS DUE TO PARKINSON DISEASE A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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 LOW DOSE									
[redacted]	Age: 7[redacted] Sex: Male Race: WHITE Weight: 5[redacted].[redacted] kg								
		TRT	1 TO	320	320	R: WORSENING PARKINSON DISEASE SYMPTOMS S: 神経系障害 P: パーキンソン病 L: Parkinson's disease aggravated	E: 323 L: 4 Days	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DRUG INTERRUPTED	S: Yes, Hospitalization or prolonged hospitalization R: CAUSAL RELATIONSHIP A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch / Interval	Rx Day of 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: 7[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg								
	TRT	1 TO	178	178	R: INCREASED HALLUCINATIONS S: 精神障害 P: 幻覚 L: Hallucinations aggravated	E: 200 L: 23 Days	S: SEVERE R1: REASONABLE POSSIBILITY R4: No A1: Other: FLOW RATE LOWERED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED A: REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 HIGH DOSE								
[redacted] Age: 7[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg								
	TRT	1 TO	178	178	R: PSYCHOTIC STATE S: 精神障害 P: 精神病性障害 L: Psychotic state	E: 200 L: 23 Days	S: SEVERE R1: REASONABLE POSSIBILITY R4: No A1: Other: FLOW RATE LOWERED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED A: REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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: 5[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg								
	TRT	1 TO	53	53	R: UTI S: 感染症および寄生虫症 P: 尿路感染 L: UTI		S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: HOSPITAL ADMISSION	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: CURRENTLY UNKNOWN BACTERIA A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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: 5[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg								
	TRT	1 TO 57	57		R: UROSEPSIS S: 感染症および寄生虫症 P: 尿路性敗血症 L: Urosepsis	E: 65 L: 9 Days	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: HOSPITAL ADMISSION	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: UNKNOWN BACTERIA A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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: 5[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg								
	TRT	1 TO 79	79		R: UROSEPSIS S: 感染症および寄生虫症 P: 尿路性敗血症 L: Urosepsis	E: 90 L: 12 Days	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: INITIAL GP REVIEW FOLLOWED BY ADMISSION TO HOSPITAL AT REQUEST OF SUB-I	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: VAGINAL PROLAPSE A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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: 5[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg								
	TRT	1 TO 80	80		R: ACUTE KIDNEY INJURY S: 腎および尿路障害 P: 急性腎障害 L: Acute kidney injury	E: 90 L: 11 Days	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: HOSPITAL ADMISSION AND REVIEW	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: UROSEPSIS SECONDARY TO VAGINAL PROLAPSE A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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: 5[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg							
	TRT	1 TO 97	97	R: FURTHER WORSENING VAGINAL PROLAPSE S: 生殖系および乳房障害 P: 膣脱 L: Vaginal prolapse		S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: ADMISSION FOR SURGERY	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: WEAKENED MUSCLE FLOOR A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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: 5[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg								
	TRT	1 TO	104	104	R: SEIZURE S: 神経系障害 P: 痙攣発作 L: Seizure	E: 104 L: 1 Day	S: SEVERE R1: REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: ATTENDANCE AT ED	S: Yes, Other medically important serious event R: NOT RELATED A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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: 5[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg								
	TRT	1 TO	107	107	R: SEIZURE S: 神経系障害 P: 痙攣発作 L: Seizure	E: 107 L: 1 Day	S: SEVERE R1: REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: ED ADMISSION	S: Yes, Other medically important serious event R: NOT RELATED A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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: 5[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg								
	TRT	1 TO 108	108	R: TRAUMATIC SUB-ARACHNOID HAEMORRHAGE S: 傷害、中毒および処置合併症 P: 外傷性頭蓋内出血 L: Cerebral haemorrhage traumatic		S: MILD R1: REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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: 5[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg								
	TRT	1 TO 109	109		R: SEIZURE S: 神経系障害 P: 痙攣発作 L: Seizure	E: 109 L: 1 Day	S: SEVERE R1: REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	Day	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 HIGH DOSE									
[redacted] Age: 5[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg									
		TRT	1 TO	110	110	R: DELIRIUM (FLUCTUATING SEVERITY) S: 精神障害 P: 譫妄 L: Delirium		S: SEVERE R1: REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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: 5[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg								
	TRT	1 TO	112	112	R: ASYMPTOMATIC COVID-19 S: 感染症および寄生虫症 P: 無症候性COVID-19 L: Asymptomatic COVID-19	E: 128 L: 17 Days	S: MILD R1: NO REASONABLE POSSIBILITY R4: Yes A1: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: SARS-COV-2 (OMICRON VARIANT) A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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: 5[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg								
	TRT	1 TO 117	117	R: SEIZURE S: 神経系障害 P: 痙攣発作 L: Seizure	E: 117 L: 1 Day	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: NONE	S: Yes, Other medically important serious event R: NOT RELATED O: SURMISED CAUSED BY FALL, WHICH CAUSED THE SUB-ARACHNOID HAEMORRHAGE WHICH CAUSED THE SEIZURE A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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: 5[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg								
	TRT	1 TO 120	120	R: SEIZURES S: 神経系障害 P: 痙攣発作 L: Seizures	I: Yes	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: SURMISED THIS ORIGINATED FROM FALL, WHICH LED TO SUB-ARACHNOID HAEMORRHAGE, WHICH LED TO SEIZURES A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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: 5[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg								
	TRT	1 TO 122	122	122	R: LOW HAEMOGLOBIN S: 臨床検査 P: ヘモグロビン減少 L: Hemoglobin low		S: MODERATE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: NONE	S: Yes, Other medically important serious event R: NOT RELATED O: WORSENING ANAEMIA. CAUSE UNCERTAIN. A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	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: 5[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg									
	TRT	1 TO	128	128		R: DIFFICULTY SWALLOWING S: 胃腸障害 P: 嚥下障害 L: Swallowing difficult	I: Yes	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: INVESTIGATIONS STILL ONGOING A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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: 5[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg								
	TRT	1 TO 129	129	129	R: HYPERNATREMIA (151) S: 代謝および栄養障害 P: 高ナトリウム血症 L: Hypernatremia		S: MODERATE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: LOW SODIUM LEVELS A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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: 5[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg								
	TRT	1 TO	130	130	R: SEPSIS S: 感染症および寄生虫症 P: 敗血症 L: Sepsis		S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED	S: Yes, Life threatening, Hospitalization or prolonged hospitalization R: NOT RELATED O: BACTERIAL INFECTION A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted] Age: 6[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg								
	TRT	1 TO	434	434	R: DISORIENTATION S: 精神障害 P: 失見当識 L: Disorientation		S: SEVERE R1: REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: ADMITTED TO ED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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 LOW DOSE									
[redacted] Age: 6[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg									
	TRT	1 TO	434	434	R: NON ST ELEVATION MYOCARDIAL INFARCTION (NSTEMI) S: 心臓障害 P: 急性心筋梗塞 L: Non ST segment elevation myocardial infarction	E: 435 L: 2 Days	S: MODERATE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: ED ADMISSION	S: Yes, Other medically important serious event R: NOT RELATED O: POSSIBLE VASCULAR STENOSIS A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of 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: 7[redacted] Sex: Male Race: WHITE Weight: 8[redacted].[redacted] kg									
	TRT	1 TO		59	59	R: TRANSIENT ISCHEMIC ATTACK S: 神経系障害 P: 一過性脳虚血発作 L: Transient ischemic attack		S: MODERATE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: AGE AND STRESED AT THE TIME OF EVENT, A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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: 6[redacted] Sex: Male Race: WHITE Weight: 10[redacted].[redacted] kg								
	TRT	1 TO 399	399		R: KIDNEY STONE S: 腎および尿路障害 P: 腎結石症 L: Kidney stone		S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: MEDICAL HISTORY OF KIDNEY STONES A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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: 5[redacted] Sex: Male Race: WHITE Weight: 8[redacted].[redacted] kg									
	TRT	1 TO	148	148		R: POSTOPERATIVE/PROCEDURAL PAIN S: 傷害、中毒および処置合併症 P: 処置による疼痛 L: Procedural pain	E: 315 L: 168 Days	S: MODERATE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: THIS WAS A CONSEQUENCE OF THE FIRST SURGERY A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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 LOW DOSE									
[redacted] Age: 4[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg									
	TRT	1 TO	270	270		R: WORSENING OF LEFT ABDOMINAL ABSCESS AT INFUSION SITE S: 感染症および寄生虫症 P: 注入部位膿瘍 L: Infusion site abscess	E: 271 L: 2 Days	S: SEVERE R1: REASONABLE POSSIBILITY R4: No A1: DRUG INTERRUPTED O: INCISION AND DRAINAGE OF ABSCESS PERFORMED. WOUND CULTURES TAKEN AND SENT TO PATHOLOGY.	S: Yes, Hospitalization or prolonged hospitalization R: CAUSAL RELATIONSHIP A: REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	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 LOW DOSE									
[redacted] Age: 4[redacted] Sex: Female Race: WHITE Weight: 8[redacted].[redacted] kg									
	TRT	1 TO	388	388		R: WORSENING OF ANXIETY S: 精神障害 P: 不安 L: Anxiety aggravated	E: 389 L: 2 Days I: Yes	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization O: WORSENING OF ANXIETY A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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 LOW DOSE									
[redacted] Age: 5[redacted] Sex: Female Race: WHITE Weight: 9[redacted].[redacted] kg									
		TRT	1 TO	87	87	R: MUSCULOSKELETAL PAIN TO LEFT CHEST S: 筋骨格系および結合組織障害 P: 筋骨格系胸痛 L: Musculoskeletal chest pain		S: SEVERE R1: NO REASONABLE POSSIBILITY R3: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: PRESUMED INTERCOSTAL MUSCLE STRAIN A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	Day	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE									
[redacted] Age: 6[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg									
		TRT	1 TO	162	162	R: WORSENING PSYCHOSIS S: 精神障害 P: 精神病性障害 L: Psychosis aggravated	E: 176 L: 15 Days I: Yes	S: SEVERE R1: REASONABLE POSSIBILITY R4: No A1: Other: INFUSION RATE F2 LOWERED O: HOSPITALISATION PSYCHIATRIC WARD	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	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 LOW DOSE									
[redacted] Age: 7[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg									
	TRT	1 TO	254	254		R: FALL W/ SEQUALAE S: 傷害、中毒および処置合併症 P: 転倒 L: Fall	E: 254 L: 1 Day	S: MODERATE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: FALL RELATED TO IMBALANCE A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	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 LOW DOSE [redacted] Age: 7[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg									
	TRT	1 TO	254	254	R: INTRACRANIAL HEMORRHAGE S: 神経系障害 P: 頭蓋内出血 L: Intracranial hemorrhage		S: MODERATE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: IMBALANCE A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted] Age: 7[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg								
	TRT	1 TO 299	299	299	R: ACCIDENTAL FALL S: 傷害、中毒および処置合併症 P: 転倒 L: Fall	E: 299 L: 1 Day	S: MODERATE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization, Other medically important serious event R: NOT RELATED O: FALL DUE TO INSTABILITY, FALL WAS UNINTENTIONAL. SUBJECT REPORTED NO DIZZINESS OR FREEZING PRECEDING FALL. A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted] Age: 7[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg								
	TRT	1 TO 299	299	R: LEFT HUMERUS FRACTURE S: 傷害、中毒および処置合併症 P: 上腕骨骨折 L: Humerus fracture	E: 300 L: 2 Days	S: MODERATE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization, Other medically important serious event R: NOT RELATED O: SUBJECT FELL AND FRACTURED HER LEFT HUMERUS A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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: 5[redacted] Sex: Male Race: WHITE Weight: 8[redacted].[redacted] kg									
	TRT	1 TO	182	182		R: GASTROENTERITIS S: 感染症および寄生虫症 P: 胃腸炎 L: Gastroenteritis	E: 183 L: 2 Days	S: MODERATE R1: NO REASONABLE POSSIBILITY A1: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: PI DETERMINED THAT THE PATIENT WAS ADMITTED FOR GASTROENTERITIS BASED ON LAB, IMAGING AND ADMISSIONS A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch / Interval	Rx Day of 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: 7[redacted] Sex: Male Race: ASIAN Weight: 7[redacted].[redacted] kg							
		TRT	1 TO	73	73	R: RIGHT SCAPULA FRACTURE S: 傷害、中毒および処置合併症 P: 肩甲骨骨折 L: Scapula fracture	E: 97 L: 25 Days I: Yes	S: MODERATE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: REHABILITATION THERAPY, EXTERNAL IMMOBILIZATION IN A SLING	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: ACCIDENTAL FALL A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted] Age: 6[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg								
	TRT	1 TO 69	69		R: ABDOMINAL WALL CELLULITIS, RIGHT FLANK, AT INFUSION SITE S: 感染症および寄生虫症 P: 注入部位蜂巣炎 L: Infusion site cellulitis		S: MODERATE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: PROBABLY RELATED TO THE CANNULA A: REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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 LOW DOSE									
[redacted] Age: 6[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg									
		TRT	1 TO	115	115	R: WORSENING RIGHT HIP OSTEOARTHRITIS S: 筋骨格系および結合組織障害 P: 変形性関節症 L: Osteoarthritis aggravated		S: MODERATE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: DISEASE PROGRESSION OF OSTEOARTHRITIS A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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 LOW DOSE									
[redacted] Age: 4[redacted] Sex: Male Race: ASIAN Weight: 6[redacted].[redacted] kg									
	TRT	1 TO	135	135	R: COVID-19 INFECTION S: 感染症および寄生虫症 P: COVID-19 L: COVID-19	E: 142 L: 8 Days	S: MILD R1: NO REASONABLE POSSIBILITY R4: Yes A1: DOSE NOT CHANGED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: BECAUSE OF AN ACCIDENTAL EVENT A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of 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: 5[redacted] Sex: Male Race: ASIAN Weight: 7[redacted].[redacted] kg									
	TRT	1 TO		447	447	R: CELLULITIS OF INFUSION SITE S: 感染症および寄生虫症 P: 注入部位蜂巣炎 L: Infusion site cellulitis	E: 491 L: 45 Days	S: MODERATE R1: REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED	S: Yes, Hospitalization or prolonged hospitalization R: CAUSAL RELATIONSHIP A: REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	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 LOW DOSE									
[redacted] Age: 7[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg									
	TRT	1 TO	21	21		R: FALL S: 傷害、中毒および処置合併症 P: 転倒 L: Fall	E: 21 L: 1 Day	S: MODERATE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: STUMBLING OVER A STEP A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted] Age: 7[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg								
	TRT	1 TO 21	21		R: FEMUR FRACTURE S: 傷害、中毒および処置合併症 P: 大腿骨骨折 L: Femur fracture		S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: SURGERY	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: PATIENT STAMBLED OVER DOORSTEP AND FELL. FEMUR FRACTURE WAS DIAGNOSED IN HOSPITAL. SURGERY WAS PERFORMED ON [redacted].[redacted] 20[redacted]. DRUG WAS NOT INTERRUPTED. MEDICAL REPORT PENDING. A: NO REASONABLE POSSIBILITY

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	Day	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE									
[redacted] Age: 6[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg									
	TRT	1 TO		313	313	R: CELLULITIS ABDOMINAL WALL AT INFUSION SITE PLEASE NOTE THIS IS THE PRINCIPAL DIAGNOSIS ON THE SUBSEQUENT DISCHARGE SUMMARY S: 感染症および寄生虫症 P: 注入部位蜂巣炎 L: Infusion site cellulitis		S: SEVERE R1: REASONABLE POSSIBILITY R4: No A1: DRUG INTERRUPTED	S: Yes, Hospitalization or prolonged hospitalization R: POSSIBLE

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted]# Age: 7[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg								
	TRT	1 TO 434	140	140	R: FRACTURED HIP S: 傷害、中毒および処置合併症 P: 股関節部骨折 L: Fractured hip	E: 201 L: 62 Days	S: MODERATE R1: NO REASONABLE POSSIBILITY R4: No A1: DRUG INTERRUPTED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: SUBJECT TRIPPED A: NO REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted]# Age: 7[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg								
	TRT	1 TO 434	348	348	R: CELLULITIS AT INFUSION SITE S: 感染症および寄生虫症 P: 注入部位蜂巣炎 L: Infusion site cellulitis	E: 365 L: 18 Days	S: SEVERE R1: REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED	S: Yes, Other medically important serious event A: REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted]# Age: 7[redacted] Sex: Male Race: WHITE Weight: 7[redacted].[redacted] kg								
	TRT	1 TO 434	430	430	R: CELLULITIS AT INFUSION SITE S: 感染症および寄生虫症 P: 注入部位蜂巣炎 L: Infusion site cellulitis	O: Yes	S: SEVERE R1: REASONABLE POSSIBILITY R4: No A1: DRUG WITHDRAWN	S: Yes, Other medically important serious event R: POSSIBLE A: REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 LOW DOSE								
[redacted]# Age: 7[redacted] Sex: Female Race: WHITE Weight: 7[redacted].[redacted] kg								
	TRT	1 TO	294	294	R: PAIN LEFT LEG S: 筋骨格系および結合組織障害 P: 四肢痛 L: Leg pain	E: 344 L: 51 Days	S: MODERATE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: HIP RADIOGRAPHY THAT SHOWED ONLY ARTHROSIS (KNOWN IN MH). HIP ECHOGRAPHY PLANNED IN ORDER TO EVALUATE DIAGNOSIS OF GLUTEUS MEDIUS TENDONITIS, BUT NOT DONE. EXERCICES INCREASED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: PATIENT HOSPITALIZED IN ORDER TO BE EVALUATED BY KINESIOLOGIST AND LOGOPEDE. THIS IS MORE LIKE AND HOSPITALIZATION TO REVIEW THE PATIENT'S CONDITION THEN A SEVERE AE THAT NEEDED TO BE HOSPITALIZED A: NO REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.2

Listing of All Treatment-Emergent Serious Adverse Events
(Safety Analysis Set)

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: Male Race: WHITE Weight: 9[redacted].[redacted] kg								
	TRT	1 TO 197	161	161	R: CELLULITIS AT THE INFUSION SITE S: 感染症および寄生虫症 P: 注入部位蜂巣炎 L: Infusion site cellulitis	E: 197 L: 37 Days I: Yes	S: SEVERE R1: REASONABLE POSSIBILITY R4: No A1: DRUG WITHDRAWN O: BLOOD CX, WOUND CX PERFORMED AWAITING RESULTS TO BOTH	S: Yes, Hospitalization or prolonged hospitalization R: PROBABLE A: REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

表2.7.4.7-49　特に注目すべき有害事象の概要（安全性解析対象集団）：M15-741試験（更新時）

[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__1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Entire study period - polyneuropathy (narrow)	N=132	N=112	N=244
Subjects with:			
Any TEAE	2 (1.5)	6 (5.4)	8 (3.3)
Any severe TEAE	0	1 (0.9)	1 (0.4)
Any TEAE that is considered associated with study drug$	1 (0.8)	3 (2.7)	4 (1.6)
Any TEAE 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
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	0	0	0
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with [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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Optimization period - polyneuropathy (narrow)	N=132	N=112	N=244
Subjects with:			
Any TEAE	0	0	0
Any severe TEAE	0	0	0
Any TEAE that is considered associated with study drug$	0	0	0
Any TEAE 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
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	0	0	0
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with [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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Maintenance period - polyneuropathy (narrow)	N=111	N=95	N=206
Subjects with:			
Any TEAE	2 (1.8)	6 (6.3)	8 (3.9)
Any severe TEAE	0	1 (1.1)	1 (0.5)
Any TEAE that is considered associated with study drug$	1 (0.9)	3 (3.2)	4 (1.9)
Any TEAE 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
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	0	0	0
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with [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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Entire study period - weight loss	N=132	N=112	N=244
Subjects with:			
Any TEAE	12 (9.1)	15 (13.4)	27 (11.1)
Any severe TEAE	0	1 (0.9)	1 (0.4)
Any TEAE that is considered associated with study drug$	5 (3.8)	11 (9.8)	16 (6.6)
Any TEAE 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
Any TEAE that is considered associated with loading dose$	0	0	0
Any TEAE that is considered associated with rescue dose$	0	1 (0.9)	1 (0.4)
Any TEAE that is considered associated with COVID-19 infection	0	0	0
Any TEAE leading to prematurely discontinuation of study drug	0	0	0
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with [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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Optimization period - weight loss	N=132	N=112	N=244
Subjects with:			
Any TEAE	1 (0.8)	1 (0.9)	2 (0.8)
Any severe TEAE	0	0	0
Any TEAE that is considered associated with study drug$	1 (0.8)	1 (0.9)	2 (0.8)
Any TEAE 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
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	0	0	0
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with [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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Maintenance period - weight loss	N=111	N=95	N=206
Subjects with:			
Any TEAE	11 (9.9)	14 (14.7)	25 (12.1)
Any severe TEAE	0	1 (1.1)	1 (0.5)
Any TEAE that is considered associated with study drug$	4 (3.6)	10 (10.5)	14 (6.8)
Any TEAE 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
Any TEAE that is considered associated with loading dose$	0	0	0
Any TEAE that is considered associated with rescue dose$	0	1 (1.1)	1 (0.5)
Any TEAE that is considered associated with COVID-19 infection	0	0	0
Any TEAE leading to prematurely discontinuation of study drug	0	0	0
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with [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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category: Low Dose n (%)	Dose Category: High Dose n (%)	All Subjects n (%)
Entire study period - hallucinations/psychosis	N=132	N=112	N=244
Subjects with:			
Any TEAE	32 (24.2)	29 (25.9)	61 (25.0)
Any severe TEAE	5 (3.8)	6 (5.4)	11 (4.5)
Any TEAE that is considered associated with study drug$	32 (24.2)	23 (20.5)	55 (22.5)
Any TEAE that is considered associated with product complaint$	2 (1.5)	0	2 (0.8)
ABBV-951	1 (0.8)	0	1 (0.4)
Infusion pump	1 (0.8)	0	1 (0.4)
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
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	7 (5.3)	6 (5.4)	13 (5.3)
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	9 (6.8)	5 (4.5)	14 (5.7)

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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	5 (3.8)	3 (2.7)	8 (3.3)
Possible	3 (2.3)	2 (1.8)	5 (2.0)
Probable	2 (1.5)	0	2 (0.8)
Causal relationship	1 (0.8)	1 (0.9)	2 (0.8)
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$	2 (1.5)	0	2 (0.8)
ABBV-951	1 (0.8)	0	1 (0.4)
Infusion pump	1 (0.8)	0	1 (0.4)
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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	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	1 (0.9)	1 (0.4)
Possible	0	1 (0.9)	1 (0.4)
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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Optimization period - hallucinations/psychosis	N=132	N=112	N=244
Subjects with:			
Any TEAE	17 (12.9)	8 (7.1)	25 (10.2)
Any severe TEAE	2 (1.5)	0	2 (0.8)
Any TEAE that is considered associated with study drug$	16 (12.1)	5 (4.5)	21 (8.6)
Any TEAE that is considered associated with product complaint$	2 (1.5)	0	2 (0.8)
ABBV-951	1 (0.8)	0	1 (0.4)
Infusion pump	1 (0.8)	0	1 (0.4)
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
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	3 (2.3)	1 (0.9)	4 (1.6)
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	6 (4.5)	0	6 (2.5)

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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	2 (1.5)	0	2 (0.8)
Possible	2 (1.5)	0	2 (0.8)
Probable	0	0	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$	2 (1.5)	0	2 (0.8)
ABBV-951	1 (0.8)	0	1 (0.4)
Infusion pump	1 (0.8)	0	1 (0.4)
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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category: Low Dose n (%)	Dose Category: High Dose n (%)	All Subjects n (%)
Maintenance period - hallucinations/psychosis	N=111	N=95	N=206
Subjects with:			
Any TEAE	23 (20.7)	23 (24.2)	46 (22.3)
Any severe TEAE	3 (2.7)	6 (6.3)	9 (4.4)
Any TEAE that is considered associated with study drug$	23 (20.7)	19 (20.0)	42 (20.4)
Any TEAE 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
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 (3.6)	5 (5.3)	9 (4.4)
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	4 (3.6)	5 (5.3)	9 (4.4)

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

Program Source Code: [redacted]

TABLE 14.3 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	3 (2.7)	3 (3.2)	6 (2.9)
Possible	1 (0.9)	2 (2.1)	3 (1.5)
Probable	2 (1.8)	0	2 (1.0)
Causal relationship	1 (0.9)	1 (1.1)	2 (1.0)
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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	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	1 (1.1)	1 (0.5)
Possible	0	1 (1.1)	1 (0.5)
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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Entire study period - somnolence	N=132	N=112	N=244
Subjects with:			
Any TEAE	9 (6.8)	3 (2.7)	12 (4.9)
Any severe TEAE	0	0	0
Any TEAE that is considered associated with study drug$	5 (3.8)	3 (2.7)	8 (3.3)
Any TEAE that is considered associated with product complaint$	1 (0.8)	0	1 (0.4)
ABBV-951	0	0	0
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	1 (0.8)	0	1 (0.4)
[redacted] infusion set 6 mm	1 (0.8)	0	1 (0.4)
[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
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	0	0	0
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with [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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Optimization period - somnolence	N=132	N=112	N=244
Subjects with:			
Any TEAE	2 (1.5)	2 (1.8)	4 (1.6)
Any severe TEAE	0	0	0
Any TEAE that is considered associated with study drug$	2 (1.5)	2 (1.8)	4 (1.6)
Any TEAE 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
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	0	0	0
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with [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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category: Low Dose n (%)	Dose Category: High Dose n (%)	All Subjects n (%)
Maintenance period - somnolence	N=111	N=95	N=206
Subjects with:			
Any TEAE	8 (7.2)	1 (1.1)	9 (4.4)
Any severe TEAE	0	0	0
Any TEAE that is considered associated with study drug$	3 (2.7)	1 (1.1)	4 (1.9)
Any TEAE that is considered associated with product complaint$	1 (0.9)	0	1 (0.5)
ABBV-951	0	0	0
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	1 (0.9)	0	1 (0.5)
[redacted] infusion set 6 mm	1 (0.9)	0	1 (0.5)
[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
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	0	0	0
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with [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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Entire study period - infusion site related infections	N=132	N=112	N=244
Subjects with:			
Any TEAE	42 (31.8)	44 (39.3)	86 (35.2)
Any severe TEAE	6 (4.5)	7 (6.3)	13 (5.3)
Any TEAE that is considered associated with study drug$	40 (30.3)	40 (35.7)	80 (32.8)
Any TEAE that is considered associated with product complaint$	30 (22.7)	31 (27.7)	61 (25.0)
ABBV-951	14 (10.6)	16 (14.3)	30 (12.3)
Infusion pump	0	3 (2.7)	3 (1.2)
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	14 (10.6)	13 (11.6)	27 (11.1)
[redacted] infusion set 6 mm	7 (5.3)	5 (4.5)	12 (4.9)
[redacted] infusion set 9 mm	8 (6.1)	9 (8.0)	17 (7.0)
Neria guard infusion set (total)	6 (4.5)	5 (4.5)	11 (4.5)
Neria guard infusion set 6 mm	3 (2.3)	1 (0.9)	4 (1.6)
Neria guard infusion set 9 mm	3 (2.3)	4 (3.6)	7 (2.9)
[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	1 (0.9)	1 (0.4)
Any TEAE that is considered associated with COVID-19 infection	0	0	0
Any TEAE leading to prematurely discontinuation of study drug	5 (3.8)	7 (6.3)	12 (4.9)
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	8 (6.1)	8 (7.1)	16 (6.6)

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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	6 (4.5)	3 (2.7)	9 (3.7)
Possible	1 (0.8)	0	1 (0.4)
Probable	1 (0.8)	2 (1.8)	3 (1.2)
Causal relationship	4 (3.0)	1 (0.9)	5 (2.0)
Any SAE that is considered associated with [redacted] infusion set$	1 (0.8)	1 (0.9)	2 (0.8)
Possible	1 (0.8)	1 (0.9)	2 (0.8)
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with neria guards infusion set$	1 (0.8)	0	1 (0.4)
Possible	1 (0.8)	0	1 (0.4)
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with product complaint$	7 (5.3)	6 (5.4)	13 (5.3)
ABBV-951	3 (2.3)	3 (2.7)	6 (2.5)
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	2 (1.5)	2 (1.8)	4 (1.6)
[redacted] infusion set 6 mm	1 (0.8)	1 (0.9)	2 (0.8)
[redacted] infusion set 9 mm	1 (0.8)	1 (0.9)	2 (0.8)
Neria guard infusion set (total)	2 (1.5)	1 (0.9)	3 (1.2)
Neria guard infusion set 6 mm	2 (1.5)	1 (0.9)	3 (1.2)
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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any AE (non-SAE) that is considered associated with infusion pump$&	0	1 (0.9)	1 (0.4)
Possible	0	1 (0.9)	1 (0.4)
Probable	0	0	0
Causal relationship	0	0	0
Any AE (non-SAE) that is considered associated with [redacted] infusion set$&	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category: Low Dose n (%)	Dose Category: High Dose n (%)	All Subjects n (%)
Optimization period - infusion site related infections	N=132	N=112	N=244
Subjects with:			
Any TEAE	11 (8.3)	18 (16.1)	29 (11.9)
Any severe TEAE	2 (1.5)	1 (0.9)	3 (1.2)
Any TEAE that is considered associated with study drug$	9 (6.8)	15 (13.4)	24 (9.8)
Any TEAE that is considered associated with product complaint$	8 (6.1)	15 (13.4)	23 (9.4)
ABBV-951	4 (3.0)	5 (4.5)	9 (3.7)
Infusion pump	0	2 (1.8)	2 (0.8)
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	3 (2.3)	8 (7.1)	11 (4.5)
[redacted] infusion set 6 mm	2 (1.5)	3 (2.7)	5 (2.0)
[redacted] infusion set 9 mm	1 (0.8)	5 (4.5)	6 (2.5)
Neria guard infusion set (total)	2 (1.5)	1 (0.9)	3 (1.2)
Neria guard infusion set 6 mm	1 (0.8)	0	1 (0.4)
Neria guard infusion set 9 mm	1 (0.8)	1 (0.9)	2 (0.8)
[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	3 (2.3)	3 (2.7)	6 (2.5)
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	1 (0.8)	2 (1.8)	3 (1.2)

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

Program Source Code: [redacted]

TABLE 14.3 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	1 (0.8)	1 (0.9)	2 (0.8)
Possible	0	0	0
Probable	0	1 (0.9)	1 (0.4)
Causal relationship	1 (0.8)	0	1 (0.4)
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$	1 (0.8)	2 (1.8)	3 (1.2)
ABBV-951	1 (0.8)	0	1 (0.4)
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	0	2 (1.8)	2 (0.8)
[redacted] infusion set 6 mm	0	1 (0.9)	1 (0.4)
[redacted] infusion set 9 mm	0	1 (0.9)	1 (0.4)
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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category: Low Dose n (%)	Dose Category: High Dose n (%)	All Subjects n (%)
Maintenance period - infusion site related infections	N=111	N=95	N=206
Subjects with:			
Any TEAE	34 (30.6)	34 (35.8)	68 (33.0)
Any severe TEAE	4 (3.6)	6 (6.3)	10 (4.9)
Any TEAE that is considered associated with study drug$	32 (28.8)	32 (33.7)	64 (31.1)
Any TEAE that is considered associated with product complaint$	25 (22.5)	23 (24.2)	48 (23.3)
ABBV-951	10 (9.0)	13 (13.7)	23 (11.2)
Infusion pump	0	1 (1.1)	1 (0.5)
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	12 (10.8)	10 (10.5)	22 (10.7)
[redacted] infusion set 6 mm	5 (4.5)	3 (3.2)	8 (3.9)
[redacted] infusion set 9 mm	7 (6.3)	8 (8.4)	15 (7.3)
Neria guard infusion set (total)	6 (5.4)	4 (4.2)	10 (4.9)
Neria guard infusion set 6 mm	3 (2.7)	1 (1.1)	4 (1.9)
Neria guard infusion set 9 mm	3 (2.7)	3 (3.2)	6 (2.9)
[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	1 (1.1)	1 (0.5)
Any TEAE that is considered associated with COVID-19 infection	0	0	0
Any TEAE leading to prematurely discontinuation of study drug	2 (1.8)	4 (4.2)	6 (2.9)
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	7 (6.3)	6 (6.3)	13 (6.3)

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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	5 (4.5)	2 (2.1)	7 (3.4)
Possible	1 (0.9)	0	1 (0.5)
Probable	1 (0.9)	1 (1.1)	2 (1.0)
Causal relationship	3 (2.7)	1 (1.1)	4 (1.9)
Any SAE that is considered associated with [redacted] infusion set$	1 (0.9)	1 (1.1)	2 (1.0)
Possible	1 (0.9)	1 (1.1)	2 (1.0)
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with neria guards infusion set$	1 (0.9)	0	1 (0.5)
Possible	1 (0.9)	0	1 (0.5)
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with product complaint$	6 (5.4)	4 (4.2)	10 (4.9)
ABBV-951	2 (1.8)	3 (3.2)	5 (2.4)
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	2 (1.8)	0	2 (1.0)
[redacted] infusion set 6 mm	1 (0.9)	0	1 (0.5)
[redacted] infusion set 9 mm	1 (0.9)	0	1 (0.5)
Neria guard infusion set (total)	2 (1.8)	1 (1.1)	3 (1.5)
Neria guard infusion set 6 mm	2 (1.8)	1 (1.1)	3 (1.5)
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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any AE (non-SAE) that is considered associated with infusion pump$&	0	1 (1.1)	1 (0.5)
Possible	0	1 (1.1)	1 (0.5)
Probable	0	0	0
Causal relationship	0	0	0
Any AE (non-SAE) that is considered associated with [redacted] infusion set$&	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category: Low Dose n (%)	Dose Category: High Dose n (%)	All Subjects n (%)
Entire study period - infusion site related non infection reactions	N=132	N=112	N=244
Subjects with:			
Any TEAE	104 (78.8)	96 (85.7)	200 (82.0)
Any severe TEAE	3 (2.3)	5 (4.5)	8 (3.3)
Any TEAE that is considered associated with study drug$	100 (75.8)	95 (84.8)	195 (79.9)
Any TEAE that is considered associated with product complaint$	84 (63.6)	72 (64.3)	156 (63.9)
ABBV-951	44 (33.3)	39 (34.8)	83 (34.0)
Infusion pump	2 (1.5)	4 (3.6)	6 (2.5)
Vial adapter	0	1 (0.9)	1 (0.4)
Syringes	0	0	0
[redacted] infusion set (total)	48 (36.4)	37 (33.0)	85 (34.8)
[redacted] infusion set 6 mm	37 (28.0)	23 (20.5)	60 (24.6)
[redacted] infusion set 9 mm	20 (15.2)	21 (18.8)	41 (16.8)
Neria guard infusion set (total)	12 (9.1)	14 (12.5)	26 (10.7)
Neria guard infusion set 6 mm	6 (4.5)	9 (8.0)	15 (6.1)
Neria guard infusion set 9 mm	9 (6.8)	10 (8.9)	19 (7.8)
[redacted]	0	0	0
Any TEAE that is considered associated with loading dose$	1 (0.8)	0	1 (0.4)
Any TEAE that is considered associated with rescue dose$	4 (3.0)	5 (4.5)	9 (3.7)
Any TEAE that is considered associated with COVID-19 infection	0	0	0
Any TEAE leading to prematurely discontinuation of study drug	13 (9.8)	7 (6.3)	20 (8.2)
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	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.
$ As assessed by investigator.

Program Source Code: [redacted]

TABLE 14.3 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	0	1 (0.9)	1 (0.4)
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	1 (0.9)	1 (0.4)
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	1 (0.9)	1 (0.4)
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	1 (0.9)	1 (0.4)
Neria guard infusion set 6 mm	0	1 (0.9)	1 (0.4)
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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any AE (non-SAE) that is considered associated with infusion pump$&	0	1 (0.9)	1 (0.4)
Possible	0	1 (0.9)	1 (0.4)
Probable	0	0	0
Causal relationship	0	0	0
Any AE (non-SAE) that is considered associated with [redacted] infusion set$&	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	1 (0.9)	1 (0.4)
Possible	0	1 (0.9)	1 (0.4)
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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category: Low Dose n (%)	Dose Category: High Dose n (%)	All Subjects n (%)
Optimization period - infusion site related non infection reactions	N=132	N=112	N=244
Subjects with:			
Any TEAE	88 (66.7)	82 (73.2)	170 (69.7)
Any severe TEAE	1 (0.8)	1 (0.9)	2 (0.8)
Any TEAE that is considered associated with study drug$	82 (62.1)	79 (70.5)	161 (66.0)
Any TEAE that is considered associated with product complaint$	62 (47.0)	57 (50.9)	119 (48.8)
ABBV-951	32 (24.2)	30 (26.8)	62 (25.4)
Infusion pump	1 (0.8)	1 (0.9)	2 (0.8)
Vial adapter	0	1 (0.9)	1 (0.4)
Syringes	0	0	0
[redacted] infusion set (total)	37 (28.0)	28 (25.0)	65 (26.6)
[redacted] infusion set 6 mm	27 (20.5)	13 (11.6)	40 (16.4)
[redacted] infusion set 9 mm	15 (11.4)	16 (14.3)	31 (12.7)
Neria guard infusion set (total)	4 (3.0)	6 (5.4)	10 (4.1)
Neria guard infusion set 6 mm	2 (1.5)	5 (4.5)	7 (2.9)
Neria guard infusion set 9 mm	2 (1.5)	3 (2.7)	5 (2.0)
[redacted]	0	0	0
Any TEAE that is considered associated with loading dose$	1 (0.8)	0	1 (0.4)
Any TEAE that is considered associated with rescue dose$	2 (1.5)	1 (0.9)	3 (1.2)
Any TEAE that is considered associated with COVID-19 infection	0	0	0
Any TEAE leading to prematurely discontinuation of study drug	7 (5.3)	2 (1.8)	9 (3.7)
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with [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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Maintenance period - infusion site related non infection reactions	N=111	N=95	N=206
Subjects with:			
Any TEAE	64 (57.7)	71 (74.7)	135 (65.5)
Any severe TEAE	2 (1.8)	4 (4.2)	6 (2.9)
Any TEAE that is considered associated with study drug$	63 (56.8)	70 (73.7)	133 (64.6)
Any TEAE that is considered associated with product complaint$	52 (46.8)	55 (57.9)	107 (51.9)
ABBV-951	24 (21.6)	30 (31.6)	54 (26.2)
Infusion pump	1 (0.9)	3 (3.2)	4 (1.9)
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	26 (23.4)	26 (27.4)	52 (25.2)
[redacted] infusion set 6 mm	19 (17.1)	15 (15.8)	34 (16.5)
[redacted] infusion set 9 mm	12 (10.8)	13 (13.7)	25 (12.1)
Neria guard infusion set (total)	11 (9.9)	12 (12.6)	23 (11.2)
Neria guard infusion set 6 mm	4 (3.6)	7 (7.4)	11 (5.3)
Neria guard infusion set 9 mm	8 (7.2)	9 (9.5)	17 (8.3)
[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$	2 (1.8)	4 (4.2)	6 (2.9)
Any TEAE that is considered associated with COVID-19 infection	0	0	0
Any TEAE leading to prematurely discontinuation of study drug	6 (5.4)	5 (5.3)	11 (5.3)
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	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.
$ As assessed by investigator.

Program Source Code: [redacted]

TABLE 14.3 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	0	1 (1.1)	1 (0.5)
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	1 (1.1)	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$	0	1 (1.1)	1 (0.5)
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	1 (1.1)	1 (0.5)
Neria guard infusion set 6 mm	0	1 (1.1)	1 (0.5)
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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any AE (non-SAE) that is considered associated with infusion pump$&	0	1 (1.1)	1 (0.5)
Possible	0	1 (1.1)	1 (0.5)
Probable	0	0	0
Causal relationship	0	0	0
Any AE (non-SAE) that is considered associated with [redacted] infusion set$&	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	1 (1.1)	1 (0.5)
Possible	0	1 (1.1)	1 (0.5)
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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Entire study period - Falls and associated injuries (combined CMQ)	N=132	N=112	N=244
Subjects with:			
Any TEAE	36 (27.3)	37 (33.0)	73 (29.9)
Any severe TEAE	0	4 (3.6)	4 (1.6)
Any TEAE that is considered associated with study drug$	23 (17.4)	17 (15.2)	40 (16.4)
Any TEAE that is considered associated with product complaint$	2 (1.5)	0	2 (0.8)
ABBV-951	2 (1.5)	0	2 (0.8)
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
Any TEAE that is considered associated with loading dose$	0	2 (1.8)	2 (0.8)
Any TEAE that is considered associated with rescue dose$	0	1 (0.9)	1 (0.4)
Any TEAE that is considered associated with COVID-19 infection	0	0	0
Any TEAE leading to prematurely discontinuation of study drug	0	0	0
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	2 (1.5)	1 (0.9)	3 (1.2)

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

Program Source Code: [redacted]

TABLE 14.3 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	2 (1.5)	0	2 (0.8)
Possible	2 (1.5)	0	2 (0.8)
Probable	0	0	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category: Low Dose n (%)	Dose Category: High Dose n (%)	All Subjects n (%)
Optimization period - Falls and associated injuries (combined CMQ)	N=132	N=112	N=244
Subjects with:			
Any TEAE	19 (14.4)	19 (17.0)	38 (15.6)
Any severe TEAE	0	0	0
Any TEAE that is considered associated with study drug$	14 (10.6)	10 (8.9)	24 (9.8)
Any TEAE that is considered associated with product complaint$	1 (0.8)	0	1 (0.4)
ABBV-951	1 (0.8)	0	1 (0.4)
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
Any TEAE that is considered associated with loading dose$	0	2 (1.8)	2 (0.8)
Any TEAE that is considered associated with rescue dose$	0	1 (0.9)	1 (0.4)
Any TEAE that is considered associated with COVID-19 infection	0	0	0
Any TEAE leading to prematurely discontinuation of study drug	0	0	0
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	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.
$ As assessed by investigator.

Program Source Code: [redacted]

TABLE 14.3 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	1 (0.8)	0	1 (0.4)
Possible	1 (0.8)	0	1 (0.4)
Probable	0	0	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Maintenance period - Falls and associated injuries (combined CMQ)	N=111	N=95	N=206
Subjects with:			
Any TEAE	22 (19.8)	25 (26.3)	47 (22.8)
Any severe TEAE	0	4 (4.2)	4 (1.9)
Any TEAE that is considered associated with study drug$	10 (9.0)	8 (8.4)	18 (8.7)
Any TEAE that is considered associated with product complaint$	1 (0.9)	0	1 (0.5)
ABBV-951	1 (0.9)	0	1 (0.5)
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
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	0	0	0
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	1 (0.9)	1 (1.1)	2 (1.0)

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

Program Source Code: [redacted]

TABLE 14.3 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	1 (0.9)	0	1 (0.5)
Possible	1 (0.9)	0	1 (0.5)
Probable	0	0	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Entire study period - Falls and associated injuries CMQ	N=132	N=112	N=244
Subjects with:			
Any TEAE	17 (12.9)	25 (22.3)	42 (17.2)
Any severe TEAE	0	3 (2.7)	3 (1.2)
Any TEAE that is considered associated with study drug$	5 (3.8)	5 (4.5)	10 (4.1)
Any TEAE 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
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	0	0	0
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	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.
$ As assessed by investigator.

Program Source Code: [redacted]

TABLE 14.3 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	1 (0.8)	0	1 (0.4)
Possible	1 (0.8)	0	1 (0.4)
Probable	0	0	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Optimization period - Falls and associated injuries CMQ	N=132	N=112	N=244
Subjects with:			
Any TEAE	7 (5.3)	10 (8.9)	17 (7.0)
Any severe TEAE	0	0	0
Any TEAE that is considered associated with study drug$	2 (1.5)	3 (2.7)	5 (2.0)
Any TEAE 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
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	0	0	0
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	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.
$ As assessed by investigator.

Program Source Code: [redacted]

TABLE 14.3 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	1 (0.8)	0	1 (0.4)
Possible	1 (0.8)	0	1 (0.4)
Probable	0	0	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Maintenance period - Falls and associated injuries CMQ	N=111	N=95	N=206
Subjects with:			
Any TEAE	12 (10.8)	20 (21.1)	32 (15.5)
Any severe TEAE	0	3 (3.2)	3 (1.5)
Any TEAE that is considered associated with study drug$	3 (2.7)	3 (3.2)	6 (2.9)
Any TEAE 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
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	0	0	0
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	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.
$ As assessed by investigator.

Program Source Code: [redacted]

TABLE 14.3 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with [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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Entire study period - Orthostatic hypotension CMQ	N=132	N=112	N=244
Subjects with:			
Any TEAE	23 (17.4)	17 (15.2)	40 (16.4)
Any severe TEAE	0	1 (0.9)	1 (0.4)
Any TEAE that is considered associated with study drug$	19 (14.4)	13 (11.6)	32 (13.1)
Any TEAE that is considered associated with product complaint$	2 (1.5)	0	2 (0.8)
ABBV-951	2 (1.5)	0	2 (0.8)
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
Any TEAE that is considered associated with loading dose$	0	2 (1.8)	2 (0.8)
Any TEAE that is considered associated with rescue dose$	0	1 (0.9)	1 (0.4)
Any TEAE that is considered associated with COVID-19 infection	0	0	0
Any TEAE leading to prematurely discontinuation of study drug	0	0	0
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	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.
$ As assessed by investigator.

Program Source Code: [redacted]

TABLE 14.3 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	2 (1.5)	0	2 (0.8)
Possible	2 (1.5)	0	2 (0.8)
Probable	0	0	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Optimization period - Orthostatic hypotension CMQ	N=132	N=112	N=244
Subjects with:			
Any TEAE	14 (10.6)	11 (9.8)	25 (10.2)
Any severe TEAE	0	0	0
Any TEAE that is considered associated with study drug$	13 (9.8)	8 (7.1)	21 (8.6)
Any TEAE that is considered associated with product complaint$	1 (0.8)	0	1 (0.4)
ABBV-951	1 (0.8)	0	1 (0.4)
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
Any TEAE that is considered associated with loading dose$	0	2 (1.8)	2 (0.8)
Any TEAE that is considered associated with rescue dose$	0	1 (0.9)	1 (0.4)
Any TEAE that is considered associated with COVID-19 infection	0	0	0
Any TEAE leading to prematurely discontinuation of study drug	0	0	0
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	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.
$ As assessed by investigator.

Program Source Code: [redacted]

TABLE 14.3 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	1 (0.8)	0	1 (0.4)
Possible	1 (0.8)	0	1 (0.4)
Probable	0	0	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Maintenance period - Orthostatic hypotension CMQ	N=111	N=95	N=206
Subjects with:			
Any TEAE	11 (9.9)	7 (7.4)	18 (8.7)
Any severe TEAE	0	1 (1.1)	1 (0.5)
Any TEAE that is considered associated with study drug$	7 (6.3)	5 (5.3)	12 (5.8)
Any TEAE that is considered associated with product complaint$	1 (0.9)	0	1 (0.5)
ABBV-951	1 (0.9)	0	1 (0.5)
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
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	0	0	0
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	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.
$ As assessed by investigator.

Program Source Code: [redacted]

TABLE 14.3 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	1 (0.9)	0	1 (0.5)
Possible	1 (0.9)	0	1 (0.5)
Probable	0	0	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI and by Time Interval
(Safety Analysis Set)

	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]

表2.7.4.7-50　特に注目すべき有害事象の概要（安全性解析対象集団）：M15-737試験（更新時）

[redacted]20[redacted] 10:47 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.3__1.12.1

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=55) n (%)	High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Polyneuropathy (narrow)			
Subjects with:			
Any TEAE	0	0	0
Any severe TEAE	0	0	0
Any TEAE that is considered associated with study drug$	0	0	0
Any TEAE 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
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	0	0	0
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=55) n (%)	High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Polyneuropathy (narrow)			
Any SAE that is considered associated with infusion pump$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with neria guards infusion set$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with product complaint$	0	0	0
ABBV-951	0	0	0
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	0	0	0
[redacted] infusion set 6 mm	0	0	0
[redacted] infusion set 9 mm	0	0	0
Neria guard infusion set (total)	0	0	0
Neria guard infusion set 6 mm	0	0	0
Neria guard infusion set 9 mm	0	0	0

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

Program Source Code: [redacted]

TABLE 14.3 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=55) n (%)	High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Polyneuropathy (narrow)			
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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set)

	Dose Category: Low Dose (N=55) n (%)	Dose Category: High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Weight loss			
Subjects with:			
Any TEAE	1 (1.8)	5 (8.2)	6 (5.2)
Any severe TEAE	0	1 (1.6)	1 (0.9)
Any TEAE that is considered associated with study drug$	0	2 (3.3)	2 (1.7)
Any TEAE 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
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	0	0	0
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	0	1 (1.6)	1 (0.9)

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

Program Source Code: [redacted]

TABLE 14.3 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=55) n (%)	High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Weight loss			
Any SAE that is considered associated with infusion pump$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with neria guards infusion set$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with product complaint$	0	0	0
ABBV-951	0	0	0
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	0	0	0
[redacted] infusion set 6 mm	0	0	0
[redacted] infusion set 9 mm	0	0	0
Neria guard infusion set (total)	0	0	0
Neria guard infusion set 6 mm	0	0	0
Neria guard infusion set 9 mm	0	0	0

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

Program Source Code: [redacted]

TABLE 14.3 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=55) n (%)	High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Weight loss			
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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=55) n (%)	High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Hallucinations/psychosis			
Subjects with:			
Any TEAE	8 (14.5)	8 (13.1)	16 (13.8)
Any severe TEAE	1 (1.8)	1 (1.6)	2 (1.7)
Any TEAE that is considered associated with study drug$	6 (10.9)	5 (8.2)	11 (9.5)
Any TEAE 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
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	0	0	0
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	1 (1.8)	1 (1.6)	2 (1.7)

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

Program Source Code: [redacted]

TABLE 14.3 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=55) n (%)	High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Hallucinations/psychosis			
Any SAE that is considered associated with infusion pump$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with neria guards infusion set$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with product complaint$	0	0	0
ABBV-951	0	0	0
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	0	0	0
[redacted] infusion set 6 mm	0	0	0
[redacted] infusion set 9 mm	0	0	0
Neria guard infusion set (total)	0	0	0
Neria guard infusion set 6 mm	0	0	0
Neria guard infusion set 9 mm	0	0	0

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

Program Source Code: [redacted]

TABLE 14.3 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=55) n (%)	High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Hallucinations/psychosis			
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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=55) n (%)	High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Somnolence			
Subjects with:			
Any TEAE	0	0	0
Any severe TEAE	0	0	0
Any TEAE that is considered associated with study drug$	0	0	0
Any TEAE 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
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	0	0	0
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set)

	Dose Category: Low Dose (N=55) n (%)	Dose Category: High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Somnolence			
Any SAE that is considered associated with infusion pump$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with neria guards infusion set$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with product complaint$	0	0	0
ABBV-951	0	0	0
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	0	0	0
[redacted] infusion set 6 mm	0	0	0
[redacted] infusion set 9 mm	0	0	0
Neria guard infusion set (total)	0	0	0
Neria guard infusion set 6 mm	0	0	0
Neria guard infusion set 9 mm	0	0	0

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

Program Source Code: [redacted]

TABLE 14.3 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=55) n (%)	High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Somnolence			
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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set)

	Dose Category: Low Dose (N=55) n (%)	Dose Category: High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Infusion site related infections			
Subjects with:			
Any TEAE	11 (20.0)	11 (18.0)	22 (19.0)
Any severe TEAE	3 (5.5)	1 (1.6)	4 (3.4)
Any TEAE that is considered associated with study drug$	9 (16.4)	11 (18.0)	20 (17.2)
Any TEAE that is considered associated with product complaint$	9 (16.4)	10 (16.4)	19 (16.4)
ABBV-951	3 (5.5)	7 (11.5)	10 (8.6)
Infusion pump	1 (1.8)	0	1 (0.9)
Vial adapter	0	0	0
Syringes	0	1 (1.6)	1 (0.9)
[redacted] infusion set (total)	2 (3.6)	0	2 (1.7)
[redacted] infusion set 6 mm	0	0	0
[redacted] infusion set 9 mm	2 (3.6)	0	2 (1.7)
Neria guard infusion set (total)	4 (7.3)	6 (9.8)	10 (8.6)
Neria guard infusion set 6 mm	3 (5.5)	2 (3.3)	5 (4.3)
Neria guard infusion set 9 mm	1 (1.8)	4 (6.6)	5 (4.3)
Any TEAE that is considered associated with loading dose$	0	0	0
Any TEAE that is considered associated with rescue dose$	0	1 (1.6)	1 (0.9)
Any TEAE that is considered associated with COVID-19 infection	0	0	0
Any TEAE leading to prematurely discontinuation of study drug	2 (3.6)	1 (1.6)	3 (2.6)
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	4 (7.3)	2 (3.3)	6 (5.2)

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

Program Source Code: [redacted]

TABLE 14.3 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=55) n (%)	High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Infusion site related infections			
Any SAE that is considered associated with infusion pump$	3 (5.5)	2 (3.3)	5 (4.3)
Possible	2 (3.6)	0	2 (1.7)
Probable	0	1 (1.6)	1 (0.9)
Causal relationship	1 (1.8)	1 (1.6)	2 (1.7)
Any SAE that is considered associated with neria guards infusion set$	2 (3.6)	2 (3.3)	4 (3.4)
Possible	0	1 (1.6)	1 (0.9)
Probable	2 (3.6)	0	2 (1.7)
Causal relationship	0	1 (1.6)	1 (0.9)
Any SAE that is considered associated with product complaint$	3 (5.5)	2 (3.3)	5 (4.3)
ABBV-951	1 (1.8)	2 (3.3)	3 (2.6)
Infusion pump	1 (1.8)	0	1 (0.9)
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)	2 (3.6)	1 (1.6)	3 (2.6)
Neria guard infusion set 6 mm	2 (3.6)	0	2 (1.7)
Neria guard infusion set 9 mm	0	1 (1.6)	1 (0.9)

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

Program Source Code: [redacted]

TABLE 14.3 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=55) n (%)	High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Infusion site related infections			
Any AE (non-SAE) that is considered associated with infusion pump$&	1 (1.8)	0	1 (0.9)
Possible	1 (1.8)	0	1 (0.9)
Probable	0	0	0
Causal relationship	0	0	0
Any AE (non-SAE) that is considered associated with [redacted] infusion set$&	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$&	3 (5.5)	4 (6.6)	7 (6.0)
Possible	0	2 (3.3)	2 (1.7)
Probable	2 (3.6)	0	2 (1.7)
Causal relationship	1 (1.8)	2 (3.3)	3 (2.6)

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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set)

	Dose Category: Low Dose (N=55) n (%)	Dose Category: High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Infusion site related non infection reactions			
Subjects with:			
Any TEAE	18 (32.7)	21 (34.4)	39 (33.6)
Any severe TEAE	0	1 (1.6)	1 (0.9)
Any TEAE that is considered associated with study drug$	17 (30.9)	20 (32.8)	37 (31.9)
Any TEAE that is considered associated with product complaint$	14 (25.5)	15 (24.6)	29 (25.0)
ABBV-951	4 (7.3)	7 (11.5)	11 (9.5)
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	4 (7.3)	2 (3.3)	6 (5.2)
[redacted] infusion set 6 mm	1 (1.8)	2 (3.3)	3 (2.6)
[redacted] infusion set 9 mm	3 (5.5)	0	3 (2.6)
Neria guard infusion set (total)	7 (12.7)	7 (11.5)	14 (12.1)
Neria guard infusion set 6 mm	4 (7.3)	2 (3.3)	6 (5.2)
Neria guard infusion set 9 mm	3 (5.5)	5 (8.2)	8 (6.9)
Any TEAE that is considered associated with loading dose$	0	0	0
Any TEAE that is considered associated with rescue dose$	0	2 (3.3)	2 (1.7)
Any TEAE that is considered associated with COVID-19 infection	0	0	0
Any TEAE leading to prematurely discontinuation of study drug	0	1 (1.6)	1 (0.9)
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=55) n (%)	High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Infusion site related non infection reactions			
Any SAE that is considered associated with infusion pump$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with neria guards infusion set$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with product complaint$	0	0	0
ABBV-951	0	0	0
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	0	0	0
[redacted] infusion set 6 mm	0	0	0
[redacted] infusion set 9 mm	0	0	0
Neria guard infusion set (total)	0	0	0
Neria guard infusion set 6 mm	0	0	0
Neria guard infusion set 9 mm	0	0	0

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

Program Source Code: [redacted]

TABLE 14.3 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set)

	Dose Category: Low Dose (N=55) n (%)	Dose Category: High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Infusion site related non infection reactions			
Any AE (non-SAE) that is considered associated with infusion pump$&	0	1 (1.6)	1 (0.9)
Possible	0	1 (1.6)	1 (0.9)
Probable	0	0	0
Causal relationship	0	0	0
Any AE (non-SAE) that is considered associated with [redacted] infusion set$&	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$&	4 (7.3)	4 (6.6)	8 (6.9)
Possible	2 (3.6)	1 (1.6)	3 (2.6)
Probable	1 (1.8)	1 (1.6)	2 (1.7)
Causal relationship	2 (3.6)	3 (4.9)	5 (4.3)

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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set)

	Dose Category: Low Dose (N=55) n (%)	Dose Category: High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Falls and associated injuries (combined CMQ)			
Subjects with:			
Any TEAE	8 (14.5)	15 (24.6)	23 (19.8)
Any severe TEAE	1 (1.8)	1 (1.6)	2 (1.7)
Any TEAE that is considered associated with study drug$	1 (1.8)	4 (6.6)	5 (4.3)
Any TEAE 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
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	0	0	0
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	3 (5.5)	4 (6.6)	7 (6.0)

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

Program Source Code: [redacted]

TABLE 14.3 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set)

	Dose Category: Low Dose (N=55) n (%)	Dose Category: High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Falls and associated injuries (combined CMQ)			
Any SAE that is considered associated with infusion pump$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with neria guards infusion set$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with product complaint$	0	0	0
ABBV-951	0	0	0
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	0	0	0
[redacted] infusion set 6 mm	0	0	0
[redacted] infusion set 9 mm	0	0	0
Neria guard infusion set (total)	0	0	0
Neria guard infusion set 6 mm	0	0	0
Neria guard infusion set 9 mm	0	0	0

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

Program Source Code: [redacted]

TABLE 14.3 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=55) n (%)	High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Falls and associated injuries (combined CMQ)			
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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=55) n (%)	High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Falls and associated injuries CMQ			
Subjects with:			
Any TEAE	7 (12.7)	12 (19.7)	19 (16.4)
Any severe TEAE	1 (1.8)	1 (1.6)	2 (1.7)
Any TEAE that is considered associated with study drug$	0	2 (3.3)	2 (1.7)
Any TEAE 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
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	0	0	0
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	3 (5.5)	4 (6.6)	7 (6.0)

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

Program Source Code: [redacted]

TABLE 14.3 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=55) n (%)	High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Falls and associated injuries CMQ			
Any SAE that is considered associated with infusion pump$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with neria guards infusion set$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with product complaint$	0	0	0
ABBV-951	0	0	0
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	0	0	0
[redacted] infusion set 6 mm	0	0	0
[redacted] infusion set 9 mm	0	0	0
Neria guard infusion set (total)	0	0	0
Neria guard infusion set 6 mm	0	0	0
Neria guard infusion set 9 mm	0	0	0

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

Program Source Code: [redacted]

TABLE 14.3 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=55) n (%)	High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Falls and associated injuries CMQ			
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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=55) n (%)	High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Orthostatic hypotension CMQ			
Subjects with:			
Any TEAE	2 (3.6)	4 (6.6)	6 (5.2)
Any severe TEAE	0	0	0
Any TEAE that is considered associated with study drug$	1 (1.8)	2 (3.3)	3 (2.6)
Any TEAE 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
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	0	0	0
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	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 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=55) n (%)	High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Orthostatic hypotension CMQ			
Any SAE that is considered associated with infusion pump$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with neria guards infusion set$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with product complaint$	0	0	0
ABBV-951	0	0	0
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	0	0	0
[redacted] infusion set 6 mm	0	0	0
[redacted] infusion set 9 mm	0	0	0
Neria guard infusion set (total)	0	0	0
Neria guard infusion set 6 mm	0	0	0
Neria guard infusion set 9 mm	0	0	0

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

Program Source Code: [redacted]

TABLE 14.3 1.12.1

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=55) n (%)	High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Orthostatic hypotension CMQ			
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]

表2.7.4.7-51　注入部位感染の発現割合（安全性解析対象集団）：M15-741試験（更新時）

[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 1.12.2.1

Subjects with Treatment-Emergent Adverse Events: Adverse Events of Special Interest (AESI) - Infusion Site Related Infections in Descending Frequency by Preferred Term by Time Interval
(Safety Analysis Set)

MedDRA 24.0 Preferred Term	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	42 (31.8)	44 (39.3)	86 (35.2)
注入部位蜂巣炎	29 (22.0)	27 (24.1)	56 (23.0)
注入部位膿瘍	14 (10.6)	13 (11.6)	27 (11.1)
注入部位感染	7 (5.3)	11 (9.8)	18 (7.4)
蜂巣炎	1 (0.8)	2 (1.8)	3 (1.2)
注射部位蜂巣炎	0	3 (2.7)	3 (1.2)
カテーテル留置部位感染	1 (0.8)	0	1 (0.4)
Optimization period	N=132	N=112	N=244
Any adverse event	11 (8.3)	18 (16.1)	29 (11.9)
注入部位蜂巣炎	10 (7.6)	13 (11.6)	23 (9.4)
注入部位膿瘍	3 (2.3)	5 (4.5)	8 (3.3)
注入部位感染	1 (0.8)	3 (2.7)	4 (1.6)
注射部位蜂巣炎	0	1 (0.9)	1 (0.4)
Maintenance period	N=111	N=95	N=206
Any adverse event	34 (30.6)	34 (35.8)	68 (33.0)
注入部位蜂巣炎	21 (18.9)	19 (20.0)	40 (19.4)
注入部位膿瘍	11 (9.9)	9 (9.5)	20 (9.7)
注入部位感染	6 (5.4)	9 (9.5)	15 (7.3)
蜂巣炎	1 (0.9)	2 (2.1)	3 (1.5)
注射部位蜂巣炎	0	2 (2.1)	2 (1.0)
カテーテル留置部位感染	1 (0.9)	0	1 (0.5)

Program Source Code: [redacted]

表2.7.4.7-52　注入部位感染の発現割合（安全性解析対象集団）：M15-737試験（更新時）

[redacted]20[redacted] 10:48 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.3__1.12.2

Subjects with Treatment-Emergent Adverse Events: Adverse Events of Special Interest (AESI) - Infusion Site Related Infections
in Descending Frequency by Preferred Term
(Safety Analysis Set)

	Dose Category		
MedDRA 24.0 Preferred Term	Low Dose (N=55) n (%)	High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Any adverse event	11 (20.0)	11 (18.0)	22 (19.0)
注入部位蜂巣炎	6 (10.9)	10 (16.4)	16 (13.8)
注入部位膿瘍	3 (5.5)	0	3 (2.6)
注入部位感染	3 (5.5)	0	3 (2.6)
注射部位蜂巣炎	0	1 (1.6)	1 (0.9)
注射部位感染	0	1 (1.6)	1 (0.9)

Program Source Code: [redacted]

表2.7.4.7-53　注入部位非感染反応の発現割合（安全性解析対象集団）：M15-741試験（更新時）

[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 1.12.3

Subjects with Treatment-Emergent Adverse Events: Adverse Events of Special Interest (AESI) - Infusion Site Non Infection Reactions
in Descending Frequency by Preferred Term by Time Interval
(Safety Analysis Set)

MedDRA 24.0 search strategy 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 in infusion site related non infection reactions CMQ	104 (78.8)	96 (85.7)	200 (82.0)
Nodule PTs@	37 (28.0)	37 (33.0)	74 (30.3)
注入部位結節	35 (26.5)	34 (30.4)	69 (28.3)
注射部位結節	3 (2.3)	6 (5.4)	9 (3.7)
小結節	1 (0.8)	0	1 (0.4)
Other PTs	97 (73.5)	91 (81.3)	188 (77.0)
注入部位紅斑	65 (49.2)	61 (54.5)	126 (51.6)
注入部位浮腫	19 (14.4)	28 (25.0)	47 (19.3)
注入部位疼痛	18 (13.6)	20 (17.9)	38 (15.6)
注入部位反応	13 (9.8)	17 (15.2)	30 (12.3)
注入部位血管外漏出	8 (6.1)	12 (10.7)	20 (8.2)
注入部位内出血	10 (7.6)	8 (7.1)	18 (7.4)
注入部位血腫	10 (7.6)	8 (7.1)	18 (7.4)
注入部位丘疹	7 (5.3)	11 (9.8)	18 (7.4)
注射部位紅斑	6 (4.5)	8 (7.1)	14 (5.7)
注入部位硬結	7 (5.3)	3 (2.7)	10 (4.1)
注入部位出血	4 (3.0)	5 (4.5)	9 (3.7)
注入部位炎症	3 (2.3)	6 (5.4)	9 (3.7)
注入部位腫瘤	5 (3.8)	3 (2.7)	8 (3.3)
注射部位疼痛	2 (1.5)	6 (5.4)	8 (3.3)
注入部位そう痒感	5 (3.8)	2 (1.8)	7 (2.9)

@ All PTs that include the text 'nodule'.
Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Includes events in the infusion site related non infection reactions CMQ.

Program Source Code: [redacted]

TABLE 14.3 1.12.3

Subjects with Treatment-Emergent Adverse Events: Adverse Events of Special Interest (AESI) - Infusion Site Non Infection Reactions in Descending Frequency by Preferred Term by Time Interval
(Safety Analysis Set)

MedDRA 24.0 search strategy Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
注入部位発疹	3 (2.3)	4 (3.6)	7 (2.9)
注入部位皮膚剥脱	3 (2.3)	3 (2.7)	6 (2.5)
注入部位腫脹	4 (3.0)	2 (1.8)	6 (2.5)
注射部位炎症	2 (1.5)	4 (3.6)	6 (2.5)
注入部位刺激感	1 (0.8)	4 (3.6)	5 (2.0)
注入部位蒼白	3 (2.3)	2 (1.8)	5 (2.0)
注射部位浮腫	2 (1.5)	3 (2.7)	5 (2.0)
注入部位皮膚炎	2 (1.5)	2 (1.8)	4 (1.6)
注入部位不快感	3 (2.3)	1 (0.9)	4 (1.6)
注射部位腫脹	2 (1.5)	2 (1.8)	4 (1.6)
注射部位内出血	2 (1.5)	1 (0.9)	3 (1.2)
穿刺部位紅斑	0	3 (2.7)	3 (1.2)
カテーテル留置部位紅斑	1 (0.8)	1 (0.9)	2 (0.8)
カテーテル留置部位疼痛	0	2 (1.8)	2 (0.8)
注入部位分泌物	1 (0.8)	1 (0.9)	2 (0.8)
注入部位変色	2 (1.5)	0	2 (0.8)
注入部位びらん	1 (0.8)	1 (0.9)	2 (0.8)
注入部位損傷	0	2 (1.8)	2 (0.8)
注入部位異常感覚	0	2 (1.8)	2 (0.8)
注入部位小水疱	0	2 (1.8)	2 (0.8)
注射部位漏出	1 (0.8)	1 (0.9)	2 (0.8)
注射部位丘疹	0	2 (1.8)	2 (0.8)

@ All PTs that include the text 'nodule'.
Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Includes events in the infusion site related non infection reactions CMQ.

Program Source Code: [redacted]

TABLE 14.3 1.12.3

Subjects with Treatment-Emergent Adverse Events: Adverse Events of Special Interest (AESI) - Infusion Site Non Infection Reactions in Descending Frequency by Preferred Term by Time Interval
(Safety Analysis Set)

MedDRA 24.0 search strategy Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
注射部位反応	1 (0.8)	1 (0.9)	2 (0.8)
穿刺部位硬結	2 (1.5)	0	2 (0.8)
投与部位内出血	0	1 (0.9)	1 (0.4)
投与部位紅斑	1 (0.8)	0	1 (0.4)
投与部位漏出	0	1 (0.9)	1 (0.4)
カテーテル留置部位漏出	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)
カテーテル留置部位炎症	0	1 (0.9)	1 (0.4)
カテーテル留置部位刺激感	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)
注入に伴う反応	1 (0.8)	0	1 (0.4)
注入部位壊死	0	1 (0.9)	1 (0.4)
注入部位膿疱	0	1 (0.9)	1 (0.4)
注入部位痂皮	0	1 (0.9)	1 (0.4)
注入部位熱感	0	1 (0.9)	1 (0.4)
注射部位変色	1 (0.8)	0	1 (0.4)
注射部位血腫	0	1 (0.9)	1 (0.4)
注射部位出血	0	1 (0.9)	1 (0.4)
注射部位蕁麻疹	0	1 (0.9)	1 (0.4)
滴下投与部位熱傷	0	1 (0.9)	1 (0.4)
滴下投与部位痛	0	1 (0.9)	1 (0.4)
処置後挫傷	1 (0.8)	0	1 (0.4)

@ All PTs that include the text 'nodule'.
Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Includes events in the infusion site related non infection reactions CMQ.

Program Source Code: [redacted]

TABLE 14.3 1.12.3

Subjects with Treatment-Emergent Adverse Events: Adverse Events of Special Interest (AESI) - Infusion Site Non Infection Reactions
in Descending Frequency by Preferred Term by Time Interval
(Safety Analysis Set)

MedDRA 24.0 search strategy Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
穿刺部位内出血	1 (0.8)	0	1 (0.4)
穿刺部位出血	1 (0.8)	0	1 (0.4)
穿刺部位浮腫	0	1 (0.9)	1 (0.4)
穿刺部位腫脹	0	1 (0.9)	1 (0.4)

@ All PTs that include the text 'nodule'.
Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Includes events in the infusion site related non infection reactions CMQ.

Program Source Code: [redacted]

TABLE 14.3 1.12.3

Subjects with Treatment-Emergent Adverse Events: Adverse Events of Special Interest (AESI) - Infusion Site Non Infection Reactions in Descending Frequency by Preferred Term by Time Interval
(Safety Analysis Set)

MedDRA 24.0 search strategy Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period	N=132	N=112	N=244
Any adverse event in infusion site related non infection reactions CMQ	88 (66.7)	82 (73.2)	170 (69.7)
Nodule PTs@	23 (17.4)	19 (17.0)	42 (17.2)
注入部位結節	21 (15.9)	18 (16.1)	39 (16.0)
注射部位結節	1 (0.8)	2 (1.8)	3 (1.2)
小結節	1 (0.8)	0	1 (0.4)
Other PTs	79 (59.8)	76 (67.9)	155 (63.5)
注入部位紅斑	50 (37.9)	45 (40.2)	95 (38.9)
注入部位浮腫	14 (10.6)	16 (14.3)	30 (12.3)
注入部位疼痛	13 (9.8)	14 (12.5)	27 (11.1)
注入部位反応	9 (6.8)	11 (9.8)	20 (8.2)
注入部位血管外漏出	4 (3.0)	7 (6.3)	11 (4.5)
注入部位内出血	3 (2.3)	7 (6.3)	10 (4.1)
注射部位紅斑	5 (3.8)	5 (4.5)	10 (4.1)
注入部位血腫	4 (3.0)	4 (3.6)	8 (3.3)
注射部位疼痛	2 (1.5)	4 (3.6)	6 (2.5)
注入部位硬結	4 (3.0)	1 (0.9)	5 (2.0)
注入部位腫瘤	4 (3.0)	1 (0.9)	5 (2.0)
注入部位丘疹	1 (0.8)	4 (3.6)	5 (2.0)
注入部位炎症	1 (0.8)	3 (2.7)	4 (1.6)
注入部位腫脹	3 (2.3)	1 (0.9)	4 (1.6)
注射部位浮腫	2 (1.5)	2 (1.8)	4 (1.6)

@ All PTs that include the text 'nodule'.
Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Includes events in the infusion site related non infection reactions CMQ.

Program Source Code: [redacted]

TABLE 14.3 1.12.3

Subjects with Treatment-Emergent Adverse Events: Adverse Events of Special Interest (AESI) - Infusion Site Non Infection Reactions
in Descending Frequency by Preferred Term by Time Interval
(Safety Analysis Set)

MedDRA 24.0 search strategy Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
注入部位不快感	2 (1.5)	1 (0.9)	3 (1.2)
注入部位出血	0	3 (2.7)	3 (1.2)
注入部位蒼白	2 (1.5)	1 (0.9)	3 (1.2)
注入部位そう痒感	2 (1.5)	1 (0.9)	3 (1.2)
注入部位発疹	2 (1.5)	1 (0.9)	3 (1.2)
注射部位炎症	1 (0.8)	2 (1.8)	3 (1.2)
カテーテル留置部位疼痛	0	2 (1.8)	2 (0.8)
注入部位分泌物	1 (0.8)	1 (0.9)	2 (0.8)
注入部位変色	2 (1.5)	0	2 (0.8)
注射部位漏出	1 (0.8)	1 (0.9)	2 (0.8)
投与部位紅斑	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)
カテーテル留置部位炎症	0	1 (0.9)	1 (0.4)
注入に伴う反応	1 (0.8)	0	1 (0.4)
注入部位びらん	0	1 (0.9)	1 (0.4)
注入部位皮膚剥脱	0	1 (0.9)	1 (0.4)
注入部位壊死	0	1 (0.9)	1 (0.4)
注入部位異常感覚	0	1 (0.9)	1 (0.4)
注射部位内出血	1 (0.8)	0	1 (0.4)
注射部位血腫	0	1 (0.9)	1 (0.4)
注射部位反応	0	1 (0.9)	1 (0.4)
注射部位腫脹	1 (0.8)	0	1 (0.4)

@ All PTs that include the text 'nodule'.
Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Includes events in the infusion site related non infection reactions CMQ.

Program Source Code: [redacted]

TABLE 14.3 1.12.3

Subjects with Treatment-Emergent Adverse Events: Adverse Events of Special Interest (AESI) - Infusion Site Non Infection Reactions in Descending Frequency by Preferred Term by Time Interval
(Safety Analysis Set)

MedDRA 24.0 search strategy Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
滴下投与部位熱傷	0	1 (0.9)	1 (0.4)
処置後挫傷	1 (0.8)	0	1 (0.4)
穿刺部位内出血	1 (0.8)	0	1 (0.4)
穿刺部位紅斑	0	1 (0.9)	1 (0.4)
穿刺部位出血	1 (0.8)	0	1 (0.4)
穿刺部位硬結	1 (0.8)	0	1 (0.4)
穿刺部位浮腫	0	1 (0.9)	1 (0.4)
穿刺部位腫脹	0	1 (0.9)	1 (0.4)

@ All PTs that include the text 'nodule'.
Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Includes events in the infusion site related non infection reactions CMQ.

Program Source Code: [redacted]

TABLE 14.3 1.12.3

Subjects with Treatment-Emergent Adverse Events: Adverse Events of Special Interest (AESI) - Infusion Site Non Infection Reactions in Descending Frequency by Preferred Term by Time Interval
(Safety Analysis Set)

MedDRA 24.0 search strategy Preferred Term	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period	N=111	N=95	N=206
Any adverse event in infusion site related non infection reactions CMQ	64 (57.7)	71 (74.7)	135 (65.5)
Nodule PTs@	21 (18.9)	28 (29.5)	49 (23.8)
注入部位結節	20 (18.0)	25 (26.3)	45 (21.8)
注射部位結節	3 (2.7)	5 (5.3)	8 (3.9)
Other PTs	60 (54.1)	67 (70.5)	127 (61.7)
注入部位紅斑	36 (32.4)	44 (46.3)	80 (38.8)
注入部位浮腫	8 (7.2)	18 (18.9)	26 (12.6)
注入部位疼痛	8 (7.2)	11 (11.6)	19 (9.2)
注入部位反応	8 (7.2)	11 (11.6)	19 (9.2)
注入部位丘疹	6 (5.4)	8 (8.4)	14 (6.8)
注入部位血管外漏出	5 (4.5)	6 (6.3)	11 (5.3)
注入部位血腫	6 (5.4)	4 (4.2)	10 (4.9)
注射部位紅斑	5 (4.5)	5 (5.3)	10 (4.9)
注入部位内出血	7 (6.3)	2 (2.1)	9 (4.4)
注入部位炎症	2 (1.8)	6 (6.3)	8 (3.9)
注入部位硬結	5 (4.5)	2 (2.1)	7 (3.4)
注入部位出血	4 (3.6)	2 (2.1)	6 (2.9)
注射部位炎症	2 (1.8)	4 (4.2)	6 (2.9)
注入部位皮膚剥脱	3 (2.7)	2 (2.1)	5 (2.4)
注入部位刺激感	1 (0.9)	4 (4.2)	5 (2.4)
注入部位皮膚炎	2 (1.8)	2 (2.1)	4 (1.9)

@ All PTs that include the text 'nodule'.
Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Includes events in the infusion site related non infection reactions CMQ.

Program Source Code: [redacted]

TABLE 14.3 1.12.3

Subjects with Treatment-Emergent Adverse Events: Adverse Events of Special Interest (AESI) - Infusion Site Non Infection Reactions
in Descending Frequency by Preferred Term by Time Interval
(Safety Analysis Set)

MedDRA 24.0 search strategy Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
注入部位そう痒感	3 (2.7)	1 (1.1)	4 (1.9)
注入部位発疹	1 (0.9)	3 (3.2)	4 (1.9)
注入部位腫瘤	1 (0.9)	2 (2.1)	3 (1.5)
注入部位腫脹	2 (1.8)	1 (1.1)	3 (1.5)
注射部位腫脹	1 (0.9)	2 (2.1)	3 (1.5)
カテーテル留置部位紅斑	1 (0.9)	1 (1.1)	2 (1.0)
注入部位損傷	0	2 (2.1)	2 (1.0)
注入部位蒼白	1 (0.9)	1 (1.1)	2 (1.0)
注入部位異常感覚	0	2 (2.1)	2 (1.0)
注入部位小水疱	0	2 (2.1)	2 (1.0)
注射部位内出血	1 (0.9)	1 (1.1)	2 (1.0)
注射部位浮腫	1 (0.9)	1 (1.1)	2 (1.0)
注射部位疼痛	0	2 (2.1)	2 (1.0)
注射部位丘疹	0	2 (2.1)	2 (1.0)
穿刺部位紅斑	0	2 (2.1)	2 (1.0)
穿刺部位硬結	2 (1.8)	0	2 (1.0)
投与部位内出血	0	1 (1.1)	1 (0.5)
投与部位漏出	0	1 (1.1)	1 (0.5)
カテーテル留置部位漏出	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)
カテーテル留置部位刺激感	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)

@ All PTs that include the text 'nodule'.
Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Includes events in the infusion site related non infection reactions CMQ.

Program Source Code: [redacted]

TABLE 14.3 1.12.3

Subjects with Treatment-Emergent Adverse Events: Adverse Events of Special Interest (AESI) - Infusion Site Non Infection Reactions
in Descending Frequency by Preferred Term by Time Interval
(Safety Analysis Set)

MedDRA 24.0 search strategy Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
カテーテル留置部位疼痛	0	1 (1.1)	1 (0.5)
注入部位分泌物	0	1 (1.1)	1 (0.5)
注入部位不快感	1 (0.9)	0	1 (0.5)
注入部位びらん	1 (0.9)	0	1 (0.5)
注入部位膿疱	0	1 (1.1)	1 (0.5)
注入部位痂皮	0	1 (1.1)	1 (0.5)
注入部位熱感	0	1 (1.1)	1 (0.5)
注射部位変色	1 (0.9)	0	1 (0.5)
注射部位出血	0	1 (1.1)	1 (0.5)
注射部位反応	1 (0.9)	0	1 (0.5)
注射部位蕁麻疹	0	1 (1.1)	1 (0.5)
滴下投与部位痛	0	1 (1.1)	1 (0.5)

@ All PTs that include the text 'nodule'.
Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Includes events in the infusion site related non infection reactions CMQ.

Program Source Code: [redacted]

表2.7.4.7-54　注入部位非感染反応の発現割合（安全性解析対象集団）：M15-737試験（更新時）

[redacted]20[redacted] 10:47 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.3 1.12.3

Subjects with Treatment-Emergent Adverse Events: Adverse Events of Special Interest (AESI) - Infusion Site Non Infection Reactions
in Descending Frequency by Preferred Term
(Safety Analysis Set)

MedDRA 24.0 search strategy Preferred Term	Dose Category Low Dose (N=55) n (%)	Dose Category High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Any adverse event in infusion site related non infection reactions CMQ	18 (32.7)	21 (34.4)	39 (33.6)
Nodule PTs@	3 (5.5)	3 (4.9)	6 (5.2)
注入部位結節	2 (3.6)	3 (4.9)	5 (4.3)
注射部位結節	1 (1.8)	0	1 (0.9)
Other PTs	17 (30.9)	20 (32.8)	37 (31.9)
注入部位紅斑	11 (20.0)	8 (13.1)	19 (16.4)
注入部位内出血	2 (3.6)	3 (4.9)	5 (4.3)
注入部位丘疹	1 (1.8)	3 (4.9)	4 (3.4)
カテーテル留置部位内出血	1 (1.8)	2 (3.3)	3 (2.6)
注入部位硬結	1 (1.8)	2 (3.3)	3 (2.6)
注射部位紅斑	1 (1.8)	2 (3.3)	3 (2.6)
注入部位血管外漏出	0	2 (3.3)	2 (1.7)
注入部位血腫	1 (1.8)	1 (1.6)	2 (1.7)
注入部位刺激感	2 (3.6)	0	2 (1.7)
注入部位浮腫	1 (1.8)	1 (1.6)	2 (1.7)
注入部位疼痛	1 (1.8)	1 (1.6)	2 (1.7)
注入部位腫脹	1 (1.8)	1 (1.6)	2 (1.7)
注射部位内出血	1 (1.8)	1 (1.6)	2 (1.7)
投与部位内出血	0	1 (1.6)	1 (0.9)
投与部位漏出	1 (1.8)	0	1 (0.9)
カテーテル留置部位紅斑	1 (1.8)	0	1 (0.9)
カテーテル留置部位漏出	0	1 (1.6)	1 (0.9)

@ All PTs that include the text 'nodule'.
Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Includes events in the infusion site related non infection reactions CMQ.

Program Source Code: [redacted]

TABLE 14.3 1.12.3

Subjects with Treatment-Emergent Adverse Events: Adverse Events of Special Interest (AESI) - Infusion Site Non Infection Reactions
in Descending Frequency by Preferred Term
(Safety Analysis Set)

MedDRA 24.0 search strategy Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
カテーテル留置部位炎症	0	1 (1.6)	1 (0.9)
カテーテル留置部位疼痛	1 (1.8)	0	1 (0.9)
カテーテル留置部位腫脹	1 (1.8)	0	1 (0.9)
注入部位皮膚炎	1 (1.8)	0	1 (0.9)
注入部位変色	0	1 (1.6)	1 (0.9)
注入部位炎症	0	1 (1.6)	1 (0.9)
注入部位腫瘤	1 (1.8)	0	1 (0.9)
注入部位異常感覚	0	1 (1.6)	1 (0.9)
注入部位発疹	0	1 (1.6)	1 (0.9)
注入部位反応	0	1 (1.6)	1 (0.9)
注入部位痂皮	0	1 (1.6)	1 (0.9)
注入部位熱感	1 (1.8)	0	1 (0.9)
注射部位硬結	0	1 (1.6)	1 (0.9)
注射部位炎症	0	1 (1.6)	1 (0.9)
注射部位浮腫	0	1 (1.6)	1 (0.9)
穿刺部位紅斑	1 (1.8)	0	1 (0.9)

@ All PTs that include the text 'nodule'.
Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Includes events in the infusion site related non infection reactions CMQ.

Program Source Code: [redacted]

表2.7.4.7-55　幻覚及び精神病の発現割合（安全性解析対象集団）：M15-741試験（更新時）

[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__1.12.6

Subjects with Treatment-Emergent Adverse Events: Adverse Events of Special Interest (AESI) - Hallucinations/Psychosis
in Descending Frequency by Preferred Term by Time Interval
(Safety Analysis Set)

MedDRA 24.0 search strategy 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 in the hallucinations CMQ or psychosis and psychotic disorder SMQ	32 (24.2)	29 (25.9)	61 (25.0)
Hallucination PTs@	29 (22.0)	27 (24.1)	56 (23.0)
幻覚	20 (15.2)	22 (19.6)	42 (17.2)
幻視	10 (7.6)	5 (4.5)	15 (6.1)
幻聴	3 (2.3)	3 (2.7)	6 (2.5)
幻嗅	0	1 (0.9)	1 (0.4)
混合性幻覚	1 (0.8)	0	1 (0.4)
Other PTs	14 (10.6)	6 (5.4)	20 (8.2)
妄想	8 (6.1)	2 (1.8)	10 (4.1)
精神病性障害	4 (3.0)	2 (1.8)	6 (2.5)
錯覚	1 (0.8)	1 (0.9)	2 (0.8)
妄想症	2 (1.5)	0	2 (0.8)
寄生虫妄想	1 (0.8)	0	1 (0.4)
妄想性障害、詳細不明	0	1 (0.9)	1 (0.4)
嫉妬妄想	1 (0.8)	0	1 (0.4)
精神病症状	1 (0.8)	0	1 (0.4)

@ All PTs that include the text 'hallucination'.
Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Includes events in the hallucinations CMQ and psychosis and psychotic disorders SMQ - narrow search.

Program Source Code: [redacted]

TABLE 14.3 1.12.6

Subjects with Treatment-Emergent Adverse Events: Adverse Events of Special Interest (AESI) - Hallucinations/Psychosis
in Descending Frequency by Preferred Term by Time Interval
(Safety Analysis Set)

MedDRA 24.0 search strategy Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period	N=132	N=112	N=244
Any adverse event in the hallucinations CMQ or psychosis and psychotic disorder SMQ	17 (12.9)	8 (7.1)	25 (10.2)
Hallucination PTs@	16 (12.1)	7 (6.3)	23 (9.4)
幻覚	13 (9.8)	5 (4.5)	18 (7.4)
幻視	4 (3.0)	1 (0.9)	5 (2.0)
幻聴	0	1 (0.9)	1 (0.4)
Other PTs	4 (3.0)	1 (0.9)	5 (2.0)
妄想	1 (0.8)	1 (0.9)	2 (0.8)
精神病性障害	2 (1.5)	0	2 (0.8)
嫉妬妄想	1 (0.8)	0	1 (0.4)

@ All PTs that include the text 'hallucination'.
Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Includes events in the hallucinations CMQ and psychosis and psychotic disorders SMQ - narrow search.

Program Source Code: [redacted]

TABLE 14.3 1.12.6

Subjects with Treatment-Emergent Adverse Events: Adverse Events of Special Interest (AESI) - Hallucinations/Psychosis
in Descending Frequency by Preferred Term by Time Interval
(Safety Analysis Set)

MedDRA 24.0 search strategy Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period	N=111	N=95	N=206
Any adverse event in the hallucinations CMQ or psychosis and psychotic disorder SMQ	23 (20.7)	23 (24.2)	46 (22.3)
Hallucination PTs@	19 (17.1)	22 (23.2)	41 (19.9)
幻覚	12 (10.8)	19 (20.0)	31 (15.0)
幻視	6 (5.4)	4 (4.2)	10 (4.9)
幻聴	3 (2.7)	2 (2.1)	5 (2.4)
幻嗅	0	1 (1.1)	1 (0.5)
混合性幻覚	1 (0.9)	0	1 (0.5)
Other PTs	11 (9.9)	5 (5.3)	16 (7.8)
妄想	7 (6.3)	1 (1.1)	8 (3.9)
精神病性障害	3 (2.7)	2 (2.1)	5 (2.4)
錯覚	1 (0.9)	1 (1.1)	2 (1.0)
妄想症	2 (1.8)	0	2 (1.0)
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)
精神病症状	1 (0.9)	0	1 (0.5)

@ All PTs that include the text 'hallucination'.
Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Includes events in the hallucinations CMQ and psychosis and psychotic disorders SMQ - narrow search.

Program Source Code: [redacted]

表2.7.4.7-56　幻覚及び精神病の発現割合（安全性解析対象集団）：M15-737試験（更新時）

[redacted]20[redacted] 10:47 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.3__1.12.6

Subjects with Treatment-Emergent Adverse Events: Adverse Events of Special Interest (AESI) - Hallucinations/Psychosis
in Descending Frequency by Preferred Term
(Safety Analysis Set)

MedDRA 24.0 search strategy Preferred Term	Dose Category Low Dose (N=55) n (%)	Dose Category High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Any adverse event in the hallucinations CMQ or psychosis and psychotic disorder SMQ	8 (14.5)	8 (13.1)	16 (13.8)
Hallucination PTs@	6 (10.9)	6 (9.8)	12 (10.3)
幻覚	4 (7.3)	5 (8.2)	9 (7.8)
幻視	1 (1.8)	1 (1.6)	2 (1.7)
幻嗅	1 (1.8)	0	1 (0.9)
Other PTs	3 (5.5)	3 (4.9)	6 (5.2)
妄想	1 (1.8)	1 (1.6)	2 (1.7)
錯覚	1 (1.8)	1 (1.6)	2 (1.7)
精神病性障害	1 (1.8)	1 (1.6)	2 (1.7)
妄想症	1 (1.8)	0	1 (0.9)

@ All PTs that include the text 'hallucination'.
Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Includes events in the hallucinations CMQ and psychosis and psychotic disorders SMQ - narrow search.

Program Source Code: [redacted]

表2.7.4.7-57　多発ニューロパチーの発現割合（安全性解析対象集団）：M15-741試験（更新時）

[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__1.12.4

Subjects with Treatment-Emergent Adverse Events: Adverse Events of Special Interest (AESI) - Polyneuropathy
in Descending Frequency by Preferred Term by Time Interval
(Safety Analysis Set)

MedDRA 24.0 search strategy Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period	N=132	N=112	N=244
Any PT in the SMQ broad search	13 (9.8)	14 (12.5)	27 (11.1)
Any PT in the SMQ narrow search	2 (1.5)	6 (5.4)	8 (3.3)
末梢性ニューロパチー	1 (0.8)	1 (0.9)	2 (0.8)
多発ニューロパチー	0	2 (1.8)	2 (0.8)
振動覚低下	1 (0.8)	0	1 (0.4)
神経痛	0	1 (0.9)	1 (0.4)
末梢性感覚ニューロパチー	0	1 (0.9)	1 (0.4)
感覚障害	0	1 (0.9)	1 (0.4)
感覚消失	0	1 (0.9)	1 (0.4)
Any other PT	11 (8.3)	9 (8.0)	20 (8.2)
錯感覚	4 (3.0)	3 (2.7)	7 (2.9)
筋力低下	4 (3.0)	1 (0.9)	5 (2.0)
感覚鈍麻	1 (0.8)	2 (1.8)	3 (1.2)
反射減弱	2 (1.5)	1 (0.9)	3 (1.2)
歩行障害	0	2 (1.8)	2 (0.8)
筋萎縮	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.
Includes events in the peripheral neuropathy SMQ - broad search.

Program Source Code: [redacted]

TABLE 14.3 1.12.4

Subjects with Treatment-Emergent Adverse Events: Adverse Events of Special Interest (AESI) - Polyneuropathy
in Descending Frequency by Preferred Term by Time Interval
(Safety Analysis Set)

MedDRA 24.0 search strategy Preferred Term	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period	N=132	N=112	N=244
Any PT in the SMQ broad search	2 (1.5)	2 (1.8)	4 (1.6)
Any PT in the SMQ narrow search	0	0	0
Any other PT	2 (1.5)	2 (1.8)	4 (1.6)
筋力低下	2 (1.5)	0	2 (0.8)
歩行障害	0	1 (0.9)	1 (0.4)
錯感覚	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.
Includes events in the peripheral neuropathy SMQ - broad search.

Program Source Code: [redacted]

TABLE 14.3 1.12.4

Subjects with Treatment-Emergent Adverse Events: Adverse Events of Special Interest (AESI) - Polyneuropathy
in Descending Frequency by Preferred Term by Time Interval
(Safety Analysis Set)

MedDRA 24.0 search strategy Preferred Term	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period	N=111	N=95	N=206
Any PT in the SMQ broad search	11 (9.9)	12 (12.6)	23 (11.2)
Any PT in the SMQ narrow search	2 (1.8)	6 (6.3)	8 (3.9)
末梢性ニューロパチー	1 (0.9)	1 (1.1)	2 (1.0)
多発ニューロパチー	0	2 (2.1)	2 (1.0)
振動覚低下	1 (0.9)	0	1 (0.5)
神経痛	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)
感覚障害	0	1 (1.1)	1 (0.5)
感覚消失	0	1 (1.1)	1 (0.5)
Any other PT	9 (8.1)	7 (7.4)	16 (7.8)
錯感覚	4 (3.6)	2 (2.1)	6 (2.9)
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)
筋力低下	2 (1.8)	1 (1.1)	3 (1.5)
歩行障害	0	1 (1.1)	1 (0.5)
筋萎縮	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.
Includes events in the peripheral neuropathy SMQ - broad search.

Program Source Code: [redacted]

表2.7.4.7-58　転倒及び関連する損傷の発現割合（安全性解析対象集団）：M15-741試験（更新時）

[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__1.12.8

Subjects with Treatment-Emergent Adverse Events: Adverse Events of Special Interest (AESI) - Falls and Associated Injuries
in Descending Frequency by Preferred Term by Time Interval
(Safety Analysis Set)

MedDRA 24.0 search strategy 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 in either the falls and associated injuries CMQ or the orthostatic hypotension CMQ	36 (27.3)	37 (33.0)	73 (29.9)
Falls and associated injuries CMQ	17 (12.9)	25 (22.3)	42 (17.2)
転倒	16 (12.1)	24 (21.4)	40 (16.4)
挫傷	2 (1.5)	6 (5.4)	8 (3.3)
皮膚裂傷	1 (0.8)	6 (5.4)	7 (2.9)
頭部損傷	2 (1.5)	3 (2.7)	5 (2.0)
肋骨骨折	1 (0.8)	2 (1.8)	3 (1.2)
骨挫傷	1 (0.8)	1 (0.9)	2 (0.8)
顔面骨骨折	0	2 (1.8)	2 (0.8)
靭帯捻挫	1 (0.8)	1 (0.9)	2 (0.8)
腱断裂	1 (0.8)	1 (0.9)	2 (0.8)
足関節部骨折	0	1 (0.9)	1 (0.4)
脳挫傷	1 (0.8)	0	1 (0.4)
眼挫傷	0	1 (0.9)	1 (0.4)
顔面損傷	0	1 (0.9)	1 (0.4)
関節脱臼	0	1 (0.9)	1 (0.4)
腰椎骨折	0	1 (0.9)	1 (0.4)
皮膚損傷	1 (0.8)	0	1 (0.4)
ストレス骨折	1 (0.8)	0	1 (0.4)
Orthostatic hypotension CMQ	23 (17.4)	17 (15.2)	40 (16.4)
浮動性めまい	15 (11.4)	10 (8.9)	25 (10.2)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Includes events in the falls and associated injuries CMQ and orthostatic hypotension CMQ.

Program Source Code: [redacted]

TABLE 14.3 1.12.8

Subjects with Treatment-Emergent Adverse Events: Adverse Events of Special Interest (AESI) - Falls and Associated Injuries
in Descending Frequency by Preferred Term by Time Interval
(Safety Analysis Set)

MedDRA 24.0 search strategy Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
起立性低血圧	7 (5.3)	6 (5.4)	13 (5.3)
体位性めまい	5 (3.8)	0	5 (2.0)
失神	0	3 (2.7)	3 (1.2)
起立血圧低下	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.
Includes events in the falls and associated injuries CMQ and orthostatic hypotension CMQ.

Program Source Code: [redacted]

TABLE 14.3 1.12.8

Subjects with Treatment-Emergent Adverse Events: Adverse Events of Special Interest (AESI) - Falls and Associated Injuries in Descending Frequency by Preferred Term by Time Interval
(Safety Analysis Set)

MedDRA 24.0 search strategy Preferred Term	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period	N=132	N=112	N=244
Any adverse event in either the falls and associated injuries CMQ or the orthostatic hypotension CMQ	19 (14.4)	19 (17.0)	38 (15.6)
Falls and associated injuries CMQ	7 (5.3)	10 (8.9)	17 (7.0)
転倒	7 (5.3)	9 (8.0)	16 (6.6)
顔面骨骨折	0	2 (1.8)	2 (0.8)
皮膚裂傷	0	2 (1.8)	2 (0.8)
挫傷	1 (0.8)	0	1 (0.4)
頭部損傷	1 (0.8)	0	1 (0.4)
腰椎骨折	0	1 (0.9)	1 (0.4)
肋骨骨折	0	1 (0.9)	1 (0.4)
Orthostatic hypotension CMQ	14 (10.6)	11 (9.8)	25 (10.2)
浮動性めまい	10 (7.6)	8 (7.1)	18 (7.4)
起立性低血圧	1 (0.8)	4 (3.6)	5 (2.0)
体位性めまい	3 (2.3)	0	3 (1.2)
起立血圧低下	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.
Includes events in the falls and associated injuries CMQ and orthostatic hypotension CMQ.

Program Source Code: [redacted]

TABLE 14.3 1.12.8

Subjects with Treatment-Emergent Adverse Events: Adverse Events of Special Interest (AESI) - Falls and Associated Injuries in Descending Frequency by Preferred Term by Time Interval
(Safety Analysis Set)

MedDRA 24.0 search strategy Preferred Term	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period	N=111	N=95	N=206
Any adverse event in either the falls and associated injuries CMQ or the orthostatic hypotension CMQ	22 (19.8)	25 (26.3)	47 (22.8)
Falls and associated injuries CMQ	12 (10.8)	20 (21.1)	32 (15.5)
転倒	11 (9.9)	18 (18.9)	29 (14.1)
挫傷	1 (0.9)	6 (6.3)	7 (3.4)
皮膚裂傷	1 (0.9)	4 (4.2)	5 (2.4)
頭部損傷	1 (0.9)	3 (3.2)	4 (1.9)
骨挫傷	1 (0.9)	1 (1.1)	2 (1.0)
靭帯捻挫	1 (0.9)	1 (1.1)	2 (1.0)
肋骨骨折	1 (0.9)	1 (1.1)	2 (1.0)
腱断裂	1 (0.9)	1 (1.1)	2 (1.0)
足関節部骨折	0	1 (1.1)	1 (0.5)
脳挫傷	1 (0.9)	0	1 (0.5)
眼挫傷	0	1 (1.1)	1 (0.5)
顔面損傷	0	1 (1.1)	1 (0.5)
関節脱臼	0	1 (1.1)	1 (0.5)
皮膚損傷	1 (0.9)	0	1 (0.5)
ストレス骨折	1 (0.9)	0	1 (0.5)
Orthostatic hypotension CMQ	11 (9.9)	7 (7.4)	18 (8.7)
起立性低血圧	7 (6.3)	3 (3.2)	10 (4.9)
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)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Includes events in the falls and associated injuries CMQ and orthostatic hypotension CMQ.

Program Source Code: [redacted]

TABLE 14.3 1.12.8

Subjects with Treatment-Emergent Adverse Events: Adverse Events of Special Interest (AESI) - Falls and Associated Injuries in Descending Frequency by Preferred Term by Time Interval
(Safety Analysis Set)

MedDRA 24.0 search strategy Preferred Term	Dose Category: Low Dose n (%)	Dose Category: High Dose n (%)	All Subjects n (%)
失神	0	3 (3.2)	3 (1.5)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Includes events in the falls and associated injuries CMQ and orthostatic hypotension CMQ.

Program Source Code: [redacted]

表2.7.4.7-59　転倒及び関連する損傷の発現割合（安全性解析対象集団）：M15-737試験（更新時）

[redacted]20[redacted] 10:47 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.3__1.12.8

Subjects with Treatment-Emergent Adverse Events: Adverse Events of Special Interest (AESI) - Falls and Associated Injuries
in Descending Frequency by Preferred Term
(Safety Analysis Set)

MedDRA 24.0 search strategy Preferred Term	Dose Category Low Dose (N=55) n (%)	Dose Category High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Any adverse event in either the falls and associated injuries CMQ or the orthostatic hypotension CMQ	8 (14.5)	15 (24.6)	23 (19.8)
Falls and associated injuries CMQ	7 (12.7)	12 (19.7)	19 (16.4)
転倒	5 (9.1)	9 (14.8)	14 (12.1)
手骨折	1 (1.8)	2 (3.3)	3 (2.6)
股関節部骨折	1 (1.8)	1 (1.6)	2 (1.7)
上腕骨骨折	1 (1.8)	1 (1.6)	2 (1.7)
挫傷	0	1 (1.6)	1 (0.9)
顔面骨骨折	0	1 (1.6)	1 (0.9)
大腿骨頚部骨折	0	1 (1.6)	1 (0.9)
大腿骨骨折	1 (1.8)	0	1 (0.9)
転位骨折	0	1 (1.6)	1 (0.9)
靭帯捻挫	0	1 (1.6)	1 (0.9)
四肢損傷	0	1 (1.6)	1 (0.9)
肉離れ	1 (1.8)	0	1 (0.9)
開放骨折	0	1 (1.6)	1 (0.9)
肩甲骨骨折	0	1 (1.6)	1 (0.9)
外傷性頭蓋内出血	0	1 (1.6)	1 (0.9)
Orthostatic hypotension CMQ	2 (3.6)	4 (6.6)	6 (5.2)
起立性低血圧	1 (1.8)	2 (3.3)	3 (2.6)
浮動性めまい	1 (1.8)	1 (1.6)	2 (1.7)
失神	0	2 (3.3)	2 (1.7)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Includes events in the falls and associated injuries CMQ and orthostatic hypotension CMQ.

Program Source Code: [redacted]

表2.7.4.7-60　傾眠の発現割合（安全性解析対象集団）：M15-741試験（更新時）

[redacted]20[redacted] 10:56 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 1

TABLE 14.3__1.12.7

Subjects with Treatment-Emergent Adverse Events: Adverse Events of Special Interest (AESI) - Somnolence
in Descending Frequency by Preferred Term by Time Interval
(Safety Analysis Set)

MedDRA 24.0 Preferred Term	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	9 (6.8)	3 (2.7)	12 (4.9)
傾眠	9 (6.8)	3 (2.7)	12 (4.9)
Optimization period	N=132	N=112	N=244
Any adverse event	2 (1.5)	2 (1.8)	4 (1.6)
傾眠	2 (1.5)	2 (1.8)	4 (1.6)
Maintenance period	N=111	N=95	N=206
Any adverse event	8 (7.2)	1 (1.1)	9 (4.4)
傾眠	8 (7.2)	1 (1.1)	9 (4.4)

Program Source Code: [redacted]

表2.7.4.7-61　体重減少の発現割合（安全性解析対象集団）：M15-741試験（更新時）

[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__1.12.5

Subjects with Treatment-Emergent Adverse Events: Adverse Events of Special Interest (AESI) - Weight Loss
in Descending Frequency by Preferred Term by Time Interval
(Safety Analysis Set)

MedDRA 24.0 Preferred Term	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	12 (9.1)	15 (13.4)	27 (11.1)
体重減少	10 (7.6)	14 (12.5)	24 (9.8)
食欲減退	3 (2.3)	3 (2.7)	6 (2.5)
悪液質	1 (0.8)	0	1 (0.4)
嚥下障害	0	1 (0.9)	1 (0.4)
栄養障害	0	1 (0.9)	1 (0.4)
Optimization period	N=132	N=112	N=244
Any adverse event	1 (0.8)	1 (0.9)	2 (0.8)
食欲減退	1 (0.8)	1 (0.9)	2 (0.8)
体重減少	0	1 (0.9)	1 (0.4)
Maintenance period	N=111	N=95	N=206
Any adverse event	11 (9.9)	14 (14.7)	25 (12.1)
体重減少	10 (9.0)	13 (13.7)	23 (11.2)
食欲減退	2 (1.8)	2 (2.1)	4 (1.9)
悪液質	1 (0.9)	0	1 (0.5)
嚥下障害	0	1 (1.1)	1 (0.5)
栄養障害	0	1 (1.1)	1 (0.5)

Program Source Code: [redacted]

表2.7.4.7-62　体重減少の発現割合（安全性解析対象集団）：M15-737試験（更新時）

[redacted]20[redacted] 10:48 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 1

TABLE 14.3__1.12.5

Subjects with Treatment-Emergent Adverse Events: Adverse Events of Special Interest (AESI) - Weight Loss
in Descending Frequency by Preferred Term
(Safety Analysis Set)

	Dose Category		
MedDRA 24.0 Preferred Term	Low Dose (N=55) n (%)	High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Any adverse event	1 (1.8)	5 (8.2)	6 (5.2)
嚥下障害	1 (1.8)	2 (3.3)	3 (2.6)
体重減少	0	3 (4.9)	3 (2.6)
食欲減退	0	1 (1.6)	1 (0.9)

Program Source Code: [redacted]

表2.7.4.7-63　治験薬曝露期間（安全性解析対象集団，日本人部分集団）：M15-741試験（更新時）

[redacted]20[redacted] 10:41 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - CLINICAL/STATISTICAL

TABLE 14.1__10.J

Duration of Study Drug Exposure
(Safety Analysis Set - Japan Subjects)

	Dose Category		
	Low Dose (N=22)	High Dose (N=5)	All Subjects (N=27)
Duration of ABBV-951 exposure (days) &			
n	22	5	27
Mean (SD)	194.8 (156.90)	226.4 (189.34)	200.7 (159.86)
Median	178.5	364.0	190.0
Min, Max	3, 366	17, 365	3, 366
By time intervals - n(%) &			
1 - 7 Days	1 (4.5)	0	1 (3.7)
8 - 14 Days	1 (4.5)	0	1 (3.7)
15 - 21 Days	2 (9.1)	2 (40.0)	4 (14.8)
22 - 28 Days	1 (4.5)	0	1 (3.7)
29 - 42 Days	2 (9.1)	0	2 (7.4)
43 - 91 Days	1 (4.5)	0	1 (3.7)
92 - 182 Days	3 (13.6)	0	3 (11.1)
183 - 273 Days	2 (9.1)	0	2 (7.4)
>= 274 Days	9 (40.9)	3 (60.0)	12 (44.4)
At least 6 months (>= 180 days)	11 (50.0)	3 (60.0)	14 (51.9)
At least 1 year (>= 360 days)	9 (40.9)	3 (60.0)	12 (44.4)
Patient-years of exposure &	11.7	3.1	14.8

Note: Percentages calculated on non-missing values.
&: Duration of ABBV-951 exposure (days) = Date of ABBV-951 stopped - Date of ABBV-951 started + 1.
*: Duration of ABBV-951 exposure (days) excluding study drug interruption = Duration of ABBV-951 exposure (days) - Duration of interruption (days).

Program Source Code: [redacted]

TABLE 14.1 10.J

Duration of Study Drug Exposure
(Safety Analysis Set - Japan Subjects)

	Dose Category: Low Dose (N=22)	Dose Category: High Dose (N=5)	All Subjects (N=27)
Duration of ABBV-951 exposure (days) without interruption *			
n	22	5	27
Mean (SD)	181.5 (154.12)	226.0 (188.97)	189.8 (158.08)
Median	143.0	363.0	167.0
Min, Max	3, 366	17, 365	3, 366
By time intervals - n(%) *			
1 - 7 Days	1 (4.5)	0	1 (3.7)
8 - 14 Days	1 (4.5)	0	1 (3.7)
15 - 21 Days	2 (9.1)	2 (40.0)	4 (14.8)
22 - 28 Days	1 (4.5)	0	1 (3.7)
29 - 42 Days	3 (13.6)	0	3 (11.1)
43 - 91 Days	1 (4.5)	0	1 (3.7)
92 - 182 Days	4 (18.2)	0	4 (14.8)
183 - 273 Days	0	0	0
>= 274 Days	9 (40.9)	3 (60.0)	12 (44.4)
At least 6 months (>= 180 days)	9 (40.9)	3 (60.0)	12 (44.4)
At least 1 year (>= 360 days)	7 (31.8)	3 (60.0)	10 (37.0)
Patient-years of exposure *	10.9	3.1	14.0

Note: Percentages calculated on non-missing values.
&: Duration of ABBV-951 exposure (days) = Date of ABBV-951 stopped - Date of ABBV-951 started + 1.
*: Duration of ABBV-951 exposure (days) excluding study drug interruption = Duration of ABBV-951 exposure (days) - Duration of interruption (days).

Program Source Code: [redacted]

表2.7.4.7-64　LDの1日あたりの投与量（安全性解析対象集団，日本人部分集団）：M15-741試験（更新時）

[redacted]20[redacted] 10:41 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - CLINICAL/STATISTICAL

TABLE 14.1__8.1.J

Daily Levodopa Dose (mg LD)
(Safety Analysis Set - Japan Subjects)

Enrollment Sample Week		ABBV-951 CSCI: Continuous Infusion	ABBV-951 CSCI: Extra Dose	ABBV-951 CSCI: Total	Oral: Rescue Dose	Oral: Loading Dose	Oral: Total	Overall Total
Sample 1								
WEEK 1	n	18	8	18	1	0	1	18
	Mean	1255.4	77.9	1290.0	100.0		100.0	1295.5
	SD	363.89	42.18	380.69	NA		NA	380.06
	Median	1195.4	81.1	1227.9	100.0		100.0	1253.5
	Min	682.1	28.2	682.1	100.0		100.0	682.1
	Max	2213.3	153.7	2294.5	100.0		100.0	2294.5
WEEK 2	n	17	9	17	2	1	2	17
	Mean	1438.9	94.1	1488.7	100.0	100.0	150.0	1506.3
	SD	276.36	64.54	310.25	0.00	NA	70.71	311.71
	Median	1354.7	81.1	1494.9	100.0	100.0	150.0	1494.9
	Min	1030.5	32.4	1030.5	100.0	100.0	100.0	1030.5
	Max	1977.8	210.9	2162.2	100.0	100.0	200.0	2262.2
WEEK 3	n	15	9	15	3	1	4	15
	Mean	1467.0	63.4	1505.0	150.0	100.0	137.5	1541.7
	SD	379.74	23.74	392.72	50.00	NA	47.87	403.15
	Median	1338.0	61.5	1370.4	150.0	100.0	125.0	1520.4
	Min	1024.5	32.4	1056.6	100.0	100.0	100.0	1056.6
	Max	2345.3	97.3	2426.4	200.0	100.0	200.0	2426.4
WEEK 4	n	11	6	11	0	0	0	11
	Mean	1483.6	78.5	1526.5				1526.5
	SD	380.31	28.87	388.68				388.68
	Median	1423.7	81.1	1423.7				1423.7
	Min	1001.1	32.4	1001.1				1001.1
	Max	2099.9	112.7	2099.9				2099.9

Program Source Code: [redacted]

TABLE 14.1 8.1.J

Daily Levodopa Dose (mg LD)
(Safety Analysis Set - Japan Subjects)

Enrollment Sample Week		ABBV-951 CSCI: Continuous Infusion	ABBV-951 CSCI: Extra Dose	ABBV-951 CSCI: Total	Oral: Rescue Dose	Oral: Loading Dose	Oral: Total	Overall Total
Sample 1 (Cont.)								
WEEK 6	n	10	6	10	2	0	2	10
	Mean	1533.5	77.8	1580.2	350.0		350.0	1650.2
	SD	450.68	22.61	457.00	353.55		353.55	532.52
	Median	1716.7	81.1	1759.1	350.0		350.0	1809.0
	Min	800.8	41.0	800.8	100.0		100.0	800.8
	Max	2179.6	102.5	2179.6	600.0		600.0	2446.7
WEEK 13	n	10	8	10	2	1	3	10
	Mean	1523.6	68.5	1578.5	525.0	200.0	416.7	1703.5
	SD	411.33	28.98	411.65	601.04	NA	464.58	466.37
	Median	1654.6	62.8	1725.0	525.0	200.0	200.0	1913.6
	Min	937.2	32.4	1034.6	100.0	200.0	100.0	1034.6
	Max	1992.7	113.5	1993.4	950.0	200.0	950.0	2221.2
WEEK 26	n	9	7	9	1	0	1	9
	Mean	1426.6	55.0	1469.4	100.0		100.0	1480.5
	SD	386.50	31.97	389.38	NA		NA	390.74
	Median	1401.5	41.0	1467.3	100.0		100.0	1567.3
	Min	932.8	25.6	997.4	100.0		100.0	997.4
	Max	1919.0	97.3	1951.4	100.0		100.0	1951.4
WEEK 39	n	6	4	6	1	0	1	6
	Mean	1450.2	81.1	1504.2	150.0		150.0	1529.2
	SD	479.65	22.95	452.92	NA		NA	488.69
	Median	1539.8	73.4	1572.7	150.0		150.0	1572.7
	Min	837.5	64.0	951.1	150.0		150.0	951.1
	Max	1930.6	113.5	2003.1	150.0		150.0	2153.1

Program Source Code: [redacted]

TABLE 14.1 8.1.J

Daily Levodopa Dose (mg LD)
(Safety Analysis Set - Japan Subjects)

Enrollment Sample Week		ABBV-951 CSCI: Continuous Infusion	ABBV-951 CSCI: Extra Dose	ABBV-951 CSCI: Total	Oral: Rescue Dose	Oral: Loading Dose	Oral: Total	Overall Total
Sample 1 (Cont.)								
WEEK 52	n	5	4	5	1	0	1	5
	Mean	1558.2	82.6	1624.3	100.0		100.0	1644.3
	SD	419.36	33.56	407.70	NA		NA	423.80
	Median	1627.5	97.3	1660.2	100.0		100.0	1660.2
	Min	856.8	32.4	954.2	100.0		100.0	954.2
	Max	1930.2	103.3	2027.5	100.0		100.0	2027.5

Program Source Code: [redacted]

TABLE 14.1 8.1.J

Daily Levodopa Dose (mg LD)
(Safety Analysis Set - Japan Subjects)

Enrollment Sample Week		ABBV-951 CSCI: Continuous Infusion	ABBV-951 CSCI: Extra Dose	ABBV-951 CSCI: Total	Oral: Rescue Dose	Oral: Loading Dose	Oral: Total	Overall Total
Sample 2								
WEEK 1	n	9	7	9	1	0	1	9
	Mean	945.1	57.4	989.8	200.0		200.0	1012.0
	SD	196.29	25.89	198.52	NA		NA	221.28
	Median	1007.4	65.7	1078.6	200.0		200.0	1078.6
	Min	644.1	18.8	702.3	200.0		200.0	702.3
	Max	1183.3	84.5	1220.9	200.0		200.0	1291.9
WEEK 2	n	8	8	8	0	0	0	8
	Mean	1023.9	53.7	1077.6				1077.6
	SD	205.34	26.60	219.36				219.36
	Median	1068.1	49.5	1101.0				1101.0
	Min	683.6	18.8	721.2				721.2
	Max	1311.4	89.6	1386.5				1386.5
WEEK 3	n	8	7	8	1	1	2	8
	Mean	1070.6	67.9	1130.1	100.0	100.0	100.0	1155.1
	SD	258.37	32.71	274.68	NA	NA	0.00	291.86
	Median	1093.9	61.5	1122.0	100.0	100.0	100.0	1172.0
	Min	686.5	18.8	737.7	100.0	100.0	100.0	737.7
	Max	1413.8	122.9	1488.9	100.0	100.0	100.0	1488.9
WEEK 4	n	8	8	8	0	0	0	8
	Mean	1121.5	57.1	1178.6				1178.6
	SD	334.86	31.82	342.97				342.97
	Median	1179.8	53.8	1198.5				1198.5
	Min	672.0	18.8	709.6				709.6
	Max	1638.0	102.5	1694.4				1694.4

Program Source Code: [redacted]

TABLE 14.1 8.1.J

Daily Levodopa Dose (mg LD)
(Safety Analysis Set - Japan Subjects)

Enrollment Sample / Week		ABBV-951 CSCI: Continuous Infusion	ABBV-951 CSCI: Extra Dose	ABBV-951 CSCI: Total	Oral: Rescue Dose	Oral: Loading Dose	Oral: Total	Overall Total
Sample 2 (Cont.)								
WEEK 6	n	8	7	8	1	0	1	8
	Mean	1133.9	55.9	1182.8	100.0		100.0	1195.3
	SD	349.28	39.18	357.13	NA		NA	338.73
	Median	1106.5	51.2	1148.2	100.0		100.0	1148.2
	Min	672.0	18.8	690.8	100.0		100.0	779.6
	Max	1617.9	122.9	1646.0	100.0		100.0	1646.0
WEEK 13	n	8	8	8	1	0	1	8
	Mean	1058.5	66.4	1124.9	100.0		100.0	1137.4
	SD	200.18	28.24	221.80	NA		NA	197.15
	Median	1083.1	64.0	1145.1	100.0		100.0	1145.1
	Min	682.1	37.6	719.7	100.0		100.0	819.7
	Max	1324.2	102.5	1426.6	100.0		100.0	1426.6
WEEK 26	n	8	7	8	3	0	3	8
	Mean	1083.3	91.2	1163.1	100.0		100.0	1200.6
	SD	290.92	56.78	343.02	0.00		0.00	383.06
	Median	1038.5	76.8	1102.5	100.0		100.0	1140.2
	Min	669.1	37.6	706.6	100.0		100.0	706.6
	Max	1610.5	179.3	1764.2	100.0		100.0	1864.2
WEEK 39	n	8	7	8	0	0	0	8
	Mean	1120.3	78.9	1189.4				1189.4
	SD	325.58	46.71	365.02				365.02
	Median	1053.4	64.0	1091.8				1091.8
	Min	672.0	18.8	690.8				690.8
	Max	1788.9	153.7	1917.0				1917.0

Program Source Code: [redacted]

TABLE 14.1 8.1.J

Daily Levodopa Dose (mg LD)
(Safety Analysis Set - Japan Subjects)

Enrollment Sample Week		ABBV-951 CSCI: Continuous Infusion	ABBV-951 CSCI: Extra Dose	ABBV-951 CSCI: Total	Oral: Rescue Dose	Oral: Loading Dose	Oral: Total	Overall Total
Sample 2 (Cont.)								
WEEK 52	n	7	5	7	0	0	0	7
	Mean	1150.5	111.3	1230.0				1230.0
	SD	302.62	82.57	364.10				364.10
	Median	1099.5	89.6	1099.5				1099.5
	Min	690.9	18.8	709.6				709.6
	Max	1686.0	230.5	1839.7				1839.7

Program Source Code: [redacted]

TABLE 14.1 8.1.J

Daily Levodopa Dose (mg LD)
(Safety Analysis Set - Japan Subjects)

Enrollment Sample	Week	ABBV-951 CSCI: Continuous Infusion	ABBV-951 CSCI: Extra Dose	ABBV-951 CSCI: Total	Oral: Rescue Dose	Oral: Loading Dose	Oral: Total	Overall Total
Both Enrollment Samples								
	WEEK 1 n	27	15	27	2	0	2	27
	Mean	1151.9	68.4	1189.9	150.0		150.0	1201.0
	SD	347.35	35.90	357.33	70.71		70.71	357.86
	Median	1121.1	76.8	1162.2	150.0		150.0	1220.9
	Min	644.1	18.8	682.1	100.0		100.0	682.1
	Max	2213.3	153.7	2294.5	200.0		200.0	2294.5
	WEEK 2 n	25	17	25	2	1	2	25
	Mean	1306.1	75.1	1357.1	100.0	100.0	150.0	1369.1
	SD	319.75	53.15	341.33	0.00	NA	70.71	347.09
	Median	1292.2	64.9	1343.5	100.0	100.0	150.0	1343.5
	Min	683.6	18.8	721.2	100.0	100.0	100.0	721.2
	Max	1977.8	210.9	2162.2	100.0	100.0	200.0	2262.2
	WEEK 3 n	23	16	23	4	2	6	23
	Mean	1329.1	65.4	1374.6	137.5	100.0	125.0	1407.2
	SD	387.65	27.09	394.34	47.87	0.00	41.83	407.41
	Median	1221.7	61.5	1303.9	125.0	100.0	100.0	1403.9
	Min	686.5	18.8	737.7	100.0	100.0	100.0	737.7
	Max	2345.3	122.9	2426.4	200.0	100.0	200.0	2426.4
	WEEK 4 n	19	14	19	0	0	0	19
	Mean	1331.2	66.3	1380.0				1380.0
	SD	397.12	31.42	401.02				401.02
	Median	1258.6	71.3	1357.2				1357.2
	Min	672.0	18.8	709.6				709.6
	Max	2099.9	112.7	2099.9				2099.9

Program Source Code: [redacted]

TABLE 14.1 8.1.J

Daily Levodopa Dose (mg LD)
(Safety Analysis Set - Japan Subjects)

Enrollment Sample	Week	ABBV-951 CSCI: Continuous Infusion	ABBV-951 CSCI: Extra Dose	ABBV-951 CSCI: Total	Oral: Rescue Dose	Oral: Loading Dose	Oral: Total	Overall Total
Both Enrollment Samples (Cont.)								
	WEEK 6 n	18	13	18	3	0	3	18
	Mean	1355.9	66.0	1403.6	266.7		266.7	1448.0
	SD	446.68	33.32	452.09	288.68		288.68	501.49
	Median	1391.4	64.0	1468.8	100.0		100.0	1468.8
	Min	672.0	18.8	690.8	100.0		100.0	779.6
	Max	2179.6	122.9	2179.6	600.0		600.0	2446.7
	WEEK 13 n	18	16	18	3	1	4	18
	Mean	1316.9	67.4	1376.9	383.3	200.0	337.5	1451.9
	SD	403.29	27.66	404.67	490.75	NA	411.05	463.61
	Median	1160.0	62.8	1235.8	100.0	200.0	150.0	1277.6
	Min	682.1	32.4	719.7	100.0	200.0	100.0	819.7
	Max	1992.7	113.5	1993.4	950.0	200.0	950.0	2221.2
	WEEK 26 n	17	14	17	4	0	4	17
	Mean	1265.0	73.1	1325.3	100.0		100.0	1348.8
	SD	378.05	48.09	390.02	0.00		0.00	401.58
	Median	1065.5	58.5	1167.4	100.0		100.0	1192.1
	Min	669.1	25.6	706.6	100.0		100.0	706.6
	Max	1919.0	179.3	1951.4	100.0		100.0	1951.4
	WEEK 39 n	14	11	14	1	0	1	14
	Mean	1261.7	79.7	1324.3	150.0		150.0	1335.0
	SD	417.44	38.32	420.46	NA		NA	440.52
	Median	1082.3	65.7	1144.2	150.0		150.0	1144.2
	Min	672.0	18.8	690.8	150.0		150.0	690.8
	Max	1930.6	153.7	2003.1	150.0		150.0	2153.1

Program Source Code: [redacted]

TABLE 14.1 8.1.J

Daily Levodopa Dose (mg LD)
(Safety Analysis Set - Japan Subjects)

Enrollment Sample	Week		ABBV-951 CSCI			Oral			
			Continuous Infusion	Extra Dose	Total	Rescue Dose	Loading Dose	Total	Overall Total
Both Enrollment Samples (Cont.)									
	WEEK 52	n	12	9	12	1	0	1	12
		Mean	1320.4	98.6	1394.3	100.0		100.0	1402.6
		SD	397.48	63.72	417.11	NA		NA	427.94
		Median	1245.9	97.3	1406.0	100.0		100.0	1406.0
		Min	690.9	18.8	709.6	100.0		100.0	709.6
		Max	1930.2	230.5	2027.5	100.0		100.0	2027.5

Program Source Code: [redacted]

表2.7.4.7-65　治験薬曝露期間（安全性解析対象集団，日本人部分集団）：M15-737試験（更新時）

[redacted]20[redacted] 10:45 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.1__10.J

Duration of Study Drug Exposure
(Safety Analysis Set - Japan Subjects)

	Dose Category		
	Low Dose (N=8)	High Dose (N=4)	All Subjects (N=12)
Duration of ABBV-951 exposure (days) &			
n	8	4	12
Mean (SD)	198.0 (124.31)	426.3 (181.61)	274.1 (177.37)
Median	163.5	512.5	176.5
Min, Max	79, 483	154, 526	79, 526
By time intervals - n(%) &			
1 - 84 Days	1 (12.5)	0	1 (8.3)
85 - 168 Days	3 (37.5)	1 (25.0)	4 (33.3)
169 - 252 Days	3 (37.5)	0	3 (25.0)
253 - 336 Days	0	0	0
337 - 420 Days	0	0	0
421 - 504 Days	1 (12.5)	0	1 (8.3)
505 - 588 Days	0	3 (75.0)	3 (25.0)
589 - 672 Days	0	0	0
>= 673 Days	0	0	0
Patient-years of exposure &	4.3	4.7	9.0

Note: Percentages calculated on non-missing values.
&: Duration of ABBV-951 exposure (days) = Date of ABBV-951 stopped - Date of ABBV-951 started + 1.
*: Duration of ABBV-951 exposure (days) excluding study drug interruption = Duration of ABBV-951 exposure (days) - Duration of interruption (days).

Program Source Code: [redacted]

TABLE 14.1 10.J

Duration of Study Drug Exposure
(Safety Analysis Set - Japan Subjects)

	Dose Category		
	Low Dose (N=8)	High Dose (N=4)	All Subjects (N=12)
Duration of ABBV-951 exposure (days) without interruption *			
n	8	4	12
Mean (SD)	198.0 (124.31)	426.0 (181.45)	274.0 (177.24)
Median	163.5	512.0	176.5
Min, Max	79, 483	154, 526	79, 526
By time intervals - n(%) *			
1 - 84 Days	1 (12.5)	0	1 (8.3)
85 - 168 Days	3 (37.5)	1 (25.0)	4 (33.3)
169 - 252 Days	3 (37.5)	0	3 (25.0)
253 - 336 Days	0	0	0
337 - 420 Days	0	0	0
421 - 504 Days	1 (12.5)	0	1 (8.3)
505 - 588 Days	0	3 (75.0)	3 (25.0)
589 - 672 Days	0	0	0
>= 673 Days	0	0	0
Patient-years of exposure *	4.3	4.7	9.0

Note: Percentages calculated on non-missing values.
&: Duration of ABBV-951 exposure (days) = Date of ABBV-951 stopped - Date of ABBV-951 started + 1.
*: Duration of ABBV-951 exposure (days) excluding study drug interruption = Duration of ABBV-951 exposure (days) - Duration of interruption (days).

Program Source Code: [redacted]

表2.7.4.7-66　LDの1日あたりの投与量（安全性解析対象集団，日本人部分集団）：M15-737試験（更新時）

[redacted]20[redacted] 10:45 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.1__8.1.J

Daily Levodopa Dose (mg LD)
(Safety Analysis Set - Japan Subjects)

		ABBV-951 CSCI			Oral			
Week		Continuous Infusion	Extra Dose	Total	Rescue Dose	Loading Dose	Total	Overall Total
WEEK 12	n	11	9	11	4	0	4	11
	Mean	1409.5	90.9	1483.8	112.5		112.5	1524.7
	SD	501.86	40.67	498.58	25.00		25.00	488.74
	Median	1363.2	93.9	1465.6	100.0		100.0	1465.6
	Min	685.0	41.0	779.0	100.0		100.0	879.0
	Max	2178.8	179.3	2243.7	150.0		150.0	2243.7
WEEK 24	n	11	8	11	2	0	2	11
	Mean	1407.9	102.2	1482.3	100.0		100.0	1500.4
	SD	559.36	45.25	567.59	0.00		0.00	560.19
	Median	1293.9	93.5	1359.7	100.0		100.0	1459.7
	Min	688.0	61.5	688.0	100.0		100.0	688.0
	Max	2183.5	204.9	2264.6	100.0		100.0	2264.6
WEEK 36	n	6	4	6	0	0	0	6
	Mean	1558.7	70.9	1605.9				1605.9
	SD	534.05	31.07	522.28				522.28
	Median	1582.1	74.3	1607.7				1607.7
	Min	857.5	37.6	954.8				954.8
	Max	2183.5	97.3	2280.8				2280.8
WEEK 48	n	4	3	4	0	0	0	4
	Mean	1743.1	57.2	1786.0				1786.0
	SD	621.90	36.61	591.05				591.05
	Median	1919.5	48.7	1932.3				1932.3
	Min	855.8	25.6	953.1				953.1
	Max	2277.5	97.3	2326.1				2326.1

Program Source Code: [redacted]

TABLE 14.1 8.1.J

Daily Levodopa Dose (mg LD)
(Safety Analysis Set - Japan Subjects)

Week		ABBV-951 CSCI			Oral			Overall Total
		Continuous Infusion	Extra Dose	Total	Rescue Dose	Loading Dose	Total	
WEEK 60	n	4	2	4	1	1	1	4
	Mean	1721.1	64.9	1753.5	100.0	200.0	300.0	1828.5
	SD	603.76	45.88	567.65	N/A	N/A	N/A	622.69
	Median	1885.8	64.9	1885.8	100.0	200.0	300.0	2035.8
	Min	859.4	32.4	956.7	100.0	200.0	300.0	956.7
	Max	2253.1	97.3	2285.6	100.0	200.0	300.0	2285.6
WEEK 72	n	4	2	4	0	0	0	4
	Mean	1810.7	29.0	1825.2				1825.2
	SD	684.05	4.83	693.70				693.70
	Median	2043.6	29.0	2056.4				2056.4
	Min	819.6	25.6	819.6				819.6
	Max	2335.9	32.4	2368.3				2368.3

Program Source Code: [redacted]

表2.7.4.7-67　特に注目すべき有害事象の概要（安全性解析対象集団，日本人部分集団）：M15-737試験（更新時）

[redacted]20[redacted] 10:48 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.3__1.12.1.J

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set - Japan Subjects)

	Dose Category		
	Low Dose (N=8) n (%)	High Dose (N=4) n (%)	All Subjects (N=12) n (%)
Polyneuropathy (narrow)			
Subjects with:			
Any TEAE	0	0	0
Any severe TEAE	0	0	0
Any TEAE that is considered associated with study drug$	0	0	0
Any TEAE 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
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	0	0	0
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	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 1.12.1.J

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set - Japan Subjects)

	Dose Category		
	Low Dose (N=8) n (%)	High Dose (N=4) n (%)	All Subjects (N=12) n (%)
Polyneuropathy (narrow)			
Any SAE that is considered associated with infusion pump$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with neria guards infusion set$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with product complaint$	0	0	0
ABBV-951	0	0	0
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	0	0	0
[redacted] infusion set 6 mm	0	0	0
[redacted] infusion set 9 mm	0	0	0
Neria guard infusion set (total)	0	0	0
Neria guard infusion set 6 mm	0	0	0
Neria guard infusion set 9 mm	0	0	0

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

Program Source Code: [redacted]

TABLE 14.3 1.12.1.J

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set - Japan Subjects)

	Dose Category: Low Dose (N=8) n (%)	Dose Category: High Dose (N=4) n (%)	All Subjects (N=12) n (%)
Polyneuropathy (narrow)			
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 1.12.1.J

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set - Japan Subjects)

	Dose Category		
	Low Dose (N=8) n (%)	High Dose (N=4) n (%)	All Subjects (N=12) n (%)
Weight loss			
Subjects with:			
Any TEAE	0	0	0
Any severe TEAE	0	0	0
Any TEAE that is considered associated with study drug$	0	0	0
Any TEAE 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
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	0	0	0
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	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 1.12.1.J

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set - Japan Subjects)

	Dose Category		
	Low Dose (N=8) n (%)	High Dose (N=4) n (%)	All Subjects (N=12) n (%)
Weight loss			
Any SAE that is considered associated with infusion pump$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with neria guards infusion set$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with product complaint$	0	0	0
ABBV-951	0	0	0
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	0	0	0
[redacted] infusion set 6 mm	0	0	0
[redacted] infusion set 9 mm	0	0	0
Neria guard infusion set (total)	0	0	0
Neria guard infusion set 6 mm	0	0	0
Neria guard infusion set 9 mm	0	0	0

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

Program Source Code: [redacted]

TABLE 14.3 1.12.1.J

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set - Japan Subjects)

	Dose Category		
	Low Dose (N=8) n (%)	High Dose (N=4) n (%)	All Subjects (N=12) n (%)
Weight loss			
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 1.12.1.J

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set - Japan Subjects)

	Dose Category: Low Dose (N=8) n (%)	Dose Category: High Dose (N=4) n (%)	All Subjects (N=12) n (%)
Hallucinations/psychosis			
Subjects with:			
Any TEAE	2 (25.0)	0	2 (16.7)
Any severe TEAE	0	0	0
Any TEAE that is considered associated with study drug$	1 (12.5)	0	1 (8.3)
Any TEAE 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
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	0	0	0
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	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 1.12.1.J

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set - Japan Subjects)

	Dose Category: Low Dose (N=8) n (%)	Dose Category: High Dose (N=4) n (%)	All Subjects (N=12) n (%)
Hallucinations/psychosis			
Any SAE that is considered associated with infusion pump$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with neria guards infusion set$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with product complaint$	0	0	0
ABBV-951	0	0	0
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	0	0	0
[redacted] infusion set 6 mm	0	0	0
[redacted] infusion set 9 mm	0	0	0
Neria guard infusion set (total)	0	0	0
Neria guard infusion set 6 mm	0	0	0
Neria guard infusion set 9 mm	0	0	0

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

Program Source Code: [redacted]

TABLE 14.3 1.12.1.J

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set - Japan Subjects)

	Dose Category		
	Low Dose (N=8) n (%)	High Dose (N=4) n (%)	All Subjects (N=12) n (%)
Hallucinations/psychosis			
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 1.12.1.J

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set - Japan Subjects)

	Dose Category		
	Low Dose (N=8) n (%)	High Dose (N=4) n (%)	All Subjects (N=12) n (%)
Somnolence			
Subjects with:			
Any TEAE	0	0	0
Any severe TEAE	0	0	0
Any TEAE that is considered associated with study drug$	0	0	0
Any TEAE 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
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	0	0	0
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	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 1.12.1.J

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set - Japan Subjects)

	Dose Category: Low Dose (N=8) n (%)	Dose Category: High Dose (N=4) n (%)	All Subjects (N=12) n (%)
Somnolence			
Any SAE that is considered associated with infusion pump$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with neria guards infusion set$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with product complaint$	0	0	0
ABBV-951	0	0	0
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	0	0	0
[redacted] infusion set 6 mm	0	0	0
[redacted] infusion set 9 mm	0	0	0
Neria guard infusion set (total)	0	0	0
Neria guard infusion set 6 mm	0	0	0
Neria guard infusion set 9 mm	0	0	0

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

Program Source Code: [redacted]

TABLE 14.3 1.12.1.J

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set - Japan Subjects)

	Dose Category		
	Low Dose (N=8) n (%)	High Dose (N=4) n (%)	All Subjects (N=12) n (%)
Somnolence			
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 1.12.1.J

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set - Japan Subjects)

	Dose Category: Low Dose (N=8) n (%)	Dose Category: High Dose (N=4) n (%)	All Subjects (N=12) n (%)
Infusion site related infections			
Subjects with:			
Any TEAE	1 (12.5)	2 (50.0)	3 (25.0)
Any severe TEAE	0	0	0
Any TEAE that is considered associated with study drug$	1 (12.5)	2 (50.0)	3 (25.0)
Any TEAE that is considered associated with product complaint$	1 (12.5)	2 (50.0)	3 (25.0)
ABBV-951	1 (12.5)	2 (50.0)	3 (25.0)
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	1 (25.0)	1 (8.3)
Neria guard infusion set 6 mm	0	0	0
Neria guard infusion set 9 mm	0	1 (25.0)	1 (8.3)
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	0	0	0
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	0	1 (25.0)	1 (8.3)

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 1.12.1.J

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set - Japan Subjects)

	Dose Category		
	Low Dose (N=8) n (%)	High Dose (N=4) n (%)	All Subjects (N=12) n (%)
Infusion site related infections			
Any SAE that is considered associated with infusion pump$	0	1 (25.0)	1 (8.3)
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	1 (25.0)	1 (8.3)
Any SAE that is considered associated with neria guards infusion set$	0	1 (25.0)	1 (8.3)
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	1 (25.0)	1 (8.3)
Any SAE that is considered associated with product complaint$	0	1 (25.0)	1 (8.3)
ABBV-951	0	1 (25.0)	1 (8.3)
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	0	0	0
[redacted] infusion set 6 mm	0	0	0
[redacted] infusion set 9 mm	0	0	0
Neria guard infusion set (total)	0	0	0
Neria guard infusion set 6 mm	0	0	0
Neria guard infusion set 9 mm	0	0	0

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

Program Source Code: [redacted]

TABLE 14.3 1.12.1.J

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set - Japan Subjects)

	Dose Category		
	Low Dose (N=8) n (%)	High Dose (N=4) n (%)	All Subjects (N=12) n (%)
Infusion site related infections			
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$&	1 (12.5)	2 (50.0)	3 (25.0)
Possible	0	0	0
Probable	0	0	0
Causal relationship	1 (12.5)	2 (50.0)	3 (25.0)

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 1.12.1.J

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set - Japan Subjects)

	Dose Category		
	Low Dose (N=8) n (%)	High Dose (N=4) n (%)	All Subjects (N=12) n (%)
Infusion site related non infection reactions			
Subjects with:			
Any TEAE	2 (25.0)	3 (75.0)	5 (41.7)
Any severe TEAE	0	0	0
Any TEAE that is considered associated with study drug$	2 (25.0)	3 (75.0)	5 (41.7)
Any TEAE that is considered associated with product complaint$	2 (25.0)	3 (75.0)	5 (41.7)
ABBV-951	1 (12.5)	2 (50.0)	3 (25.0)
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	0	0	0
[redacted] infusion set 6 mm	0	0	0
[redacted] infusion set 9 mm	0	0	0
Neria guard infusion set (total)	1 (12.5)	1 (25.0)	2 (16.7)
Neria guard infusion set 6 mm	0	0	0
Neria guard infusion set 9 mm	1 (12.5)	1 (25.0)	2 (16.7)
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	0	0	0
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	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 1.12.1.J

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set - Japan Subjects)

	Dose Category: Low Dose (N=8) n (%)	Dose Category: High Dose (N=4) n (%)	All Subjects (N=12) n (%)
Infusion site related non infection reactions			
Any SAE that is considered associated with infusion pump$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with neria guards infusion set$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with product complaint$	0	0	0
ABBV-951	0	0	0
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	0	0	0
[redacted] infusion set 6 mm	0	0	0
[redacted] infusion set 9 mm	0	0	0
Neria guard infusion set (total)	0	0	0
Neria guard infusion set 6 mm	0	0	0
Neria guard infusion set 9 mm	0	0	0

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

Program Source Code: [redacted]

TABLE 14.3 1.12.1.J

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set - Japan Subjects)

	Dose Category		
	Low Dose (N=8) n (%)	High Dose (N=4) n (%)	All Subjects (N=12) n (%)
Infusion site related non infection reactions			
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	1 (25.0)	1 (8.3)
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	1 (25.0)	1 (8.3)

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 1.12.1.J

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set - Japan Subjects)

	Dose Category: Low Dose (N=8) n (%)	Dose Category: High Dose (N=4) n (%)	All Subjects (N=12) n (%)
Falls and associated injuries (combined CMQ)			
Subjects with:			
Any TEAE	0	1 (25.0)	1 (8.3)
Any severe TEAE	0	0	0
Any TEAE that is considered associated with study drug$	0	0	0
Any TEAE 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
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	0	0	0
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	0	1 (25.0)	1 (8.3)

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 1.12.1.J

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set - Japan Subjects)

	Dose Category		
	Low Dose (N=8) n (%)	High Dose (N=4) n (%)	All Subjects (N=12) n (%)
Falls and associated injuries (combined CMQ)			
Any SAE that is considered associated with infusion pump$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with neria guards infusion set$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with product complaint$	0	0	0
ABBV-951	0	0	0
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	0	0	0
[redacted] infusion set 6 mm	0	0	0
[redacted] infusion set 9 mm	0	0	0
Neria guard infusion set (total)	0	0	0
Neria guard infusion set 6 mm	0	0	0
Neria guard infusion set 9 mm	0	0	0

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

Program Source Code: [redacted]

TABLE 14.3 1.12.1.J

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set - Japan Subjects)

	Dose Category		
	Low Dose (N=8) n (%)	High Dose (N=4) n (%)	All Subjects (N=12) n (%)
Falls and associated injuries (combined CMQ)			
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 1.12.1.J

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set - Japan Subjects)

	Dose Category: Low Dose (N=8) n (%)	Dose Category: High Dose (N=4) n (%)	All Subjects (N=12) n (%)
Falls and associated injuries CMQ			
Subjects with:			
Any TEAE	0	1 (25.0)	1 (8.3)
Any severe TEAE	0	0	0
Any TEAE that is considered associated with study drug$	0	0	0
Any TEAE 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
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	0	0	0
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	0	1 (25.0)	1 (8.3)

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 1.12.1.J

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set - Japan Subjects)

	Dose Category		
	Low Dose (N=8) n (%)	High Dose (N=4) n (%)	All Subjects (N=12) n (%)
Falls and associated injuries CMQ			
Any SAE that is considered associated with infusion pump$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with neria guards infusion set$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with product complaint$	0	0	0
ABBV-951	0	0	0
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	0	0	0
[redacted] infusion set 6 mm	0	0	0
[redacted] infusion set 9 mm	0	0	0
Neria guard infusion set (total)	0	0	0
Neria guard infusion set 6 mm	0	0	0
Neria guard infusion set 9 mm	0	0	0

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

Program Source Code: [redacted]

TABLE 14.3 1.12.1.J

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set - Japan Subjects)

	Dose Category		
	Low Dose (N=8) n (%)	High Dose (N=4) n (%)	All Subjects (N=12) n (%)
Falls and associated injuries CMQ			
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 1.12.1.J

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set - Japan Subjects)

	Dose Category		
	Low Dose (N=8) n (%)	High Dose (N=4) n (%)	All Subjects (N=12) n (%)
Orthostatic hypotension CMQ			
Subjects with:			
Any TEAE	0	0	0
Any severe TEAE	0	0	0
Any TEAE that is considered associated with study drug$	0	0	0
Any TEAE 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
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	0	0	0
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	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 1.12.1.J

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set - Japan Subjects)

	Dose Category: Low Dose (N=8) n (%)	Dose Category: High Dose (N=4) n (%)	All Subjects (N=12) n (%)
Orthostatic hypotension CMQ			
Any SAE that is considered associated with infusion pump$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with neria guards infusion set$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with product complaint$	0	0	0
ABBV-951	0	0	0
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	0	0	0
[redacted] infusion set 6 mm	0	0	0
[redacted] infusion set 9 mm	0	0	0
Neria guard infusion set (total)	0	0	0
Neria guard infusion set 6 mm	0	0	0
Neria guard infusion set 9 mm	0	0	0

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

Program Source Code: [redacted]

TABLE 14.3 1.12.1.J

Overview of Treatment-Emergent Adverse Events by AESI
(Safety Analysis Set - Japan Subjects)

	Dose Category		
	Low Dose (N=8) n (%)	High Dose (N=4) n (%)	All Subjects (N=12) n (%)
Orthostatic hypotension CMQ			
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]

表2.7.4.7-68　注入部位非感染反応の発現割合（安全性解析対象集団，日本人部分集団）：M15-737試験（更新時）

[redacted]20[redacted] 10:48 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 1

TABLE 14.3__1.12.3.J

Subjects with Treatment-Emergent Adverse Events: Adverse Events of Special Interest (AESI) - Infusion Site Non Infection Reactions
in Descending Frequency by Preferred Term
(Safety Analysis Set - Japan Subjects)

MedDRA 24.0 search strategy Preferred Term	Dose Category Low Dose (N=8) n (%)	Dose Category High Dose (N=4) n (%)	All Subjects (N=12) n (%)
Any adverse event in infusion site related non infection reactions CMQ	2 (25.0)	3 (75.0)	5 (41.7)
Nodule PTs@	0	0	0
Other PTs	2 (25.0)	3 (75.0)	5 (41.7)
注入部位硬結	1 (12.5)	1 (25.0)	2 (16.7)
注射部位紅斑	0	2 (50.0)	2 (16.7)
注入部位皮膚炎	1 (12.5)	0	1 (8.3)
注射部位硬結	0	1 (25.0)	1 (8.3)

@ All PTs that include the text 'nodule'.
Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Includes events in the infusion site related non infection reactions CMQ.

Program Source Code: [redacted]

2.7.5 参考文献

参考文献は，各セクションの末尾に記載した。

M17-220 試験

治験の標題： 健康被験者を対象とした ABBV-951 投与後のバイオアベイラビリティとレボドパ・カルビドパ水和物配合経腸用液及び経口カルビドパ・レボドパ製剤投与後のバイオアベイラビリティを比較する薬物動態試験	
施設数 / 実施国名： 1 施設 / 米国	
治験責任医師： [redacted]，MD	
公表文献 (参考資料) ： なし	
治験期間： 最初の被験者の初回来院日：20[redacted] 年 [redacted] 月 [redacted] 日 最後の被験者の最終来院日：20[redacted] 年 [redacted] 月 [redacted] 日	開発のフェーズ：I
目的： ABBV-951 を 24 時間持続注入したときのレボドパ（LD）の薬物動態とデュオドーパを 16 時間持続注入後に夜間に経口 LD/カルビドパ（CD）製剤を投与したときの LD の薬物動態を比較する。	
被験者数 (計画時と解析時) ： 計画時：20 名，登録：25 名，完了：20 名，安全性評価：24 名，薬物動態評価：20 名	
診断と主要な組入れ基準： 46 歳から 70 歳の健康な男女	
治験方法： 本試験は，健康被験者を対象とした，非盲検，ランダム化及び 2 期クロスオーバーデザインの第 I 相試験であった。レジメン A 又はレジメン B の 2 つの投与順序のいずれかに被験者を同数ずつ無作為に割り付けた。 レジメン A：レボドパ・カルビドパ水和物配合経腸用液（LCIG） LCIG は携帯型注入ポンプを用いて経鼻空腸（NJ）チューブから投与した。LCIG を CD/LD 12.5/50 mg の用量で負荷投与後，16 時間かけて CD/LD 87.5/350 mg の用量を注入投与した。その後，投与開始後 18 時間後及び 21 時間後に経口 CD/LD 製剤をそれぞれ 25/100 mg の用量で経口投与した。 レジメン B：ABBV-951 ABBV-951 は携帯型注入ポンプを用いて腹部皮下（SC）から投与した。ABBV-951 をカルビドパ一リン酸塩/レボドパ一リン酸塩（CDP/LDP）4/80 mg の用量で負荷投与後，24 時間かけて CDP/LDP 35/700 mg の用量を注入投与した。 CD，LD，CDP，LDP 及び 3-O-メチルドパ（3-OMD）濃度測定用の血液検体は，各投与期の Day 1 の投与開始後から 36 時間まで採取した。	
被験薬，用量 / 含量 / 濃度，投与方法及びロット番号： LCIG 懸濁液，CD/LD 5/20 mg/mL，NJ チューブを介して携帯型注入ポンプを用いて投与，ロット番号 [redacted] ABBV-951 溶液，CDP/LDP 12/240 mg/mL，腹部皮下から携帯型注入ポンプを用いて投与，ロット番号 [redacted] CD/LD 速放錠，CD/LD 25/100 mg，経口投与，ロット番号 [redacted] 治療期間： 2 つの各投与期において，以下のいずれかをそれぞれ投与した。各投与期では投与開始までに 72 時間以上の休薬期間を設けた。 LCIG：16 時間かけて LCIG 注入投与後，投与開始後 18 時間後及び 21 時間後に 2 回経口製剤を投与した。	

ABBV-951：24 時間かけて ABBV-951 を注入投与した。

評価基準：

薬物動態：

$C_{max0-16}$，AUC_{0-16} 及び AUC_{inf}

統計手法：

薬物動態：

主要なパラメータである LD の AUC_{0-16}，AUC_{inf} 及び $C_{max0-16}$ について線形混合効果モデルを用いて解析した。LCIG レジメン（標準）における中心値に対する ABBV-951 レジメン（試験）における中心値の比の点推定値及び 90%信頼区間を算出した。

要約 / 結論

薬物動態の結果：

レジメン 試験 vs.標準	薬物動態 パラメータ	中心値		相対的バイオアベイラビリティ	
		試験	標準	点推定値	90%信頼区間
レジメン B vs.レジメン A	$C_{max0-16}$	606	656	0.923	0.873, 0.975
	AUC_{0-16}	7810	8220	0.951	0.893, 1.012
	AUC_{inf}	14900	14700	1.009	0.969, 1.049

レジメン A：LCIG を CD/LD 12.5/50 mg で負荷投与後，16 時間かけて CD/LD 87.5/350 mg を注入投与した。その後，投与開始後 18 及び 21 時間後にそれぞれ CD/LD 25/100 mg を経口投与した。

レジメン B：ABBV-951 を CDP/LDP 4/80 mg で負荷投与後，24 時間かけて CDP/LDP 35/700 mg を注入投与した。

CD/LD 87.5/350 mg の LCIG を 16 時間かけて注入投与したときと比べ，CDP/LDP 35/700 mg の ABBV-951 を 24 時間かけて注入投与したときのレボドパの $C_{max0-16}$ 及び AUC_{0-16} はそれぞれ 8%及び 5%低く，AUC_{inf} は 0.9%高かった。

安全性の結果：

治験薬投与後に発現した有害事象を 1 回以上報告した被験者の割合は，LCIG を投与したとき（4/20，20%）と比べ，ABBV-951 を投与したときで高かった（19/24，79%）。この ABBV-951 を投与した際に認められた有害事象の増加は，注入部位反応に関連する事象であった。ABBV-951 を投与した 18 名の被験者で軽度の注入部位反応が報告された。注入部位の評価では，グレード 2 又はグレード A を超える被験者はいなかった。1 名の被験者が重篤な有害事象である痙攣発作により治験を中止したが，治験責任医師により治験薬と関連なしと判断された。試験期間中に臨床的に重要な臨床検査値，バイタルサイン，自殺行動/自殺念慮及び注入部位反応は認められなかった。本試験において新たな安全性の問題は認められなかった

結論：

CDP/LDP 35/700 mg の ABBV-951 を 24 時間かけて注入投与したときのレボドパの曝露量は，CD/LD 87.5/350 mg の LCIG を 16 時間かけて注入投与した後，投与開始後 18 及び 21 時間後に CD/LD 25/100 mg を経口投与したときの曝露量と同程度であった。ABBV-951 を投与した被験者において，軽度の注入部位反応が報告された。試験期間中に臨床的に重要な臨床検査値，バイタルサイン，自殺行動/自殺念慮及び注入部位反応は認められなかった。本試験において新たな安全性の問題は認められなかった。

重篤な有害事象発現例の経過を以下に示した。

被験者番号 [redacted]

Event #1 of 1 : Serious Adverse Event, AE Leading to Discontinuation of Study Drug

Preferred term	痙攣発作

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，米国アッヴィ社の ABBV-951 の試験で ABBV-951 が投与され，全身性痙攣発作を発現した。

Event 1 の臨床経過：

関連する病歴は，1 日 0.33 箱の喫煙経験が 4 年間ある元喫煙者，非飲酒者，投与の約 3 年前に行った「良性腫瘍」のための脳外科手術であった。

投与 2 日目，被験者は全身性痙攣発作を発現した。

投与 2 日目，全身性痙攣発作は消失した。

投与の 2 日前，被験者は治験実施医療機関に入院した。投与 1 日目被験者は第 1 ピリオドのレジメン B（ABBV-951）の投与を 06:30 頃開始した。投与 2 日目，被験者は 24 時間の点滴を 06:30 頃完了した。被験者は点滴に対して良好な忍容性を示し，有害事象は報告されなかった。投与 2 日目 09:21，本被験者と一緒に座って話していた同試験に参加していた別の被験者が，本被験者が答えなくなったことに気付き，助けを求めた。その際，本被験者は硬直した姿勢で椅子から滑り落ちかけており，言葉による指示に反応しなかった。被験者の上肢に激しい痙動が認められた。これは最初に対応した看護師により，「重く深い呼吸とうめき声を伴う強直間代発作」と報告された。収集されたすべての情報から，この発作の持続時間は 3 分以内であったと推測された。痙攣発作は 09:23 に止まり，発作後の状態であると判断された。

被験者は床に下ろされ（看護師の報告によるとここでも硬直した姿勢であった），バイタルサインは血圧が 139/89，心拍数が 106，動脈血酸素飽和度が室内気下で 98%であった。アキュチェックによる血糖値は 101 であった。膀胱の調節不能は認められなかった。18 ゲージの血管カテーテルが留置され，鼻カニューレによる酸素供給が開始された。床に下ろされた直後の被験者は嗜眠状態と報告されたが，提供された対症療法へ反応した。その後間もなく，被験者は痛みがないことを報告することができ，自身の名前と年齢をわかっており，痙攣発作の既往歴について否定した。被験者が救急医療サービスにより病院の緊急治療室に移される前に，医師は限られた検査を行うことが可能であった。注目すべきこととして，左手の握力欠如，右手の強い握力が認められ，被験者は両足で体重を支え，自分で体の向きを変えて担架に乗ることが可能であった。被験者はすべての四肢を動かしていた。発話は遅く，ゆっくりであったが，不明瞭ではなかったと報告された。

被験者は緊急治療室で神経科医による診察を受け，入院した。入院先の医師は被験者が安定していることを報告した。造影剤なしの頭部 CT スキャン及び CT 血管造影は陰性であったと報告された。入院時の診断は「ほぼ確実な新規発症の痙攣発作及び左半身の脱力」であった。被験者は痙攣発作の既往歴又はアルコール乱用歴若しくは薬物乱用歴を否定した。その時点で入

手できた情報は，事象の発現後に認められた左半身の脱力を伴う全身性痙攣発作という診断と当該事象が一致していることを示唆した。

投与 3 日目の午後に，被験者は keppra 500 mg 1 日 2 回を処方され，退院した。被験者は最終評価のために治験実施医療機関に戻った。被験者は体調がいいことを報告した。被験者のバイタルサインは安定しており，神経学的検査は局所障害を伴わず，完全に正常であった。被験者は，投与の約 7 年前に研究試験のために受けた MRI により偶然発見された「良性腫瘍」のため，投与の約 3 年前に脳外科手術を受けたことを報告した。被験者は，この状態に関連した症状が今までになかったとした。被験者は，術後に抗痙攣薬を「3–4 ヵ月服用し，やめた」と述べ，「その後はもう必要なかった」と話した。これらの情報はスクリーニング時又は実施医療機関への入院手続きの際に報告されていなかった。被験者は再び（術前又は術後の）痙攣発作の既往歴について否定した。被験者は神経科医の診察を帰宅後に受けるよう指示を受けた。

被験者は keppra による治療を受けた。

M18-764 試験

治験の標題： 健康被験者を対象とした ABBV-951 製剤及びレボドパ・カルビドパ水和物配合経腸用液のバイオアベイラビリティを比較する予備的試験	
施設数 / 実施国： 1 施設 / 米国	
治験責任医師： [redacted]，MD	
公表文献 (参考資料) ： なし	
治験期間： 最初の被験者の初回来院日：20[redacted] 年 [redacted] 月 [redacted] 日 最後の被験者の最終来院日：20[redacted] 年 [redacted] 月 [redacted] 日	開発のフェーズ：I

目的：

本試験の 3 つの目的を以下に示す。

1. 健康成人に ABBV-951 又はレボドパ・カルビドパ水和物配合経腸用液（LCIG）を 16 時間注入投与したときのカルビドパ（CD）及びレボドパ（LD）のバイオアベイラビリティを比較する。
2. 健康成人に ABBV-951 を 24 時間注入投与，又は LCIG を 16 時間注入投与後に夜間に CD/LD を 2 回経口投与したときの CD 及び LD のバイオアベイラビリティを比較する。
3. 低用量の ABBV-951 を 24 時間注入投与，又は LCIG を 16 時間注入投与後に夜間に CD/LD を 2 回経口投与したときの CD 及び LD のバイオアベイラビリティを比較する。

被験者数 (計画時と解析時) ：

計画時：24 名，登録：31 名，完了：24 名，安全性評価：31 名，薬物動態評価：31 名

診断と主要な組入れ基準：

45 歳から 75 歳の健康な男女

治験方法：

パート 1 及びパート 2 は非盲検，ランダム化，2 期クロスオーバーデザインである。各パートにおいて被験者は 2 つの投与レジメン順序のいずれかに同数ずつ無作為に割付けられた（パート 1 ではレジメン A 及び B，並びにパート 2 ではレジメン C 及び D）。パート 3 は非盲検，2 期逐次デザインであり，すべての被験者に 2 つの投与レジメン（レジメン E 及び F）を同じ投与順序で薬剤を投与した。

以下に 6 つの投与レジメンを示す。LCIG は携帯型注入ポンプを用いて経鼻空腸（NJ）チューブを介して投与し，ABBV-951 は携帯型注入ポンプを用いて腹部から皮下（SC）投与した。

レジメン A（LCIG）：CD/LD 25/100 mg を負荷投与後，CD/LD 125/500 mg を一定速度で 16 時間持続注入投与する。

レジメン B（ABBV-951）：カルビドパ一リン酸塩/レボドパ一リン酸塩（CDP/LDP）10/200 mg を負荷投与後，CDP/LDP 37.5/750 mg を一定速度で 16 時間持続注入投与する。

レジメン C（LCIG）：CD/LD 12.5/50 mg を負荷投与後，CD/LD 87.5/350 mg を一定速度で 16 時間持続注入投与し，その後，負荷投与開始後 18 時間及び 21 時間に CD/LD 25/100 mg を経口投与する。

レジメン D（ABBV-951）：CDP/LDP 5/100 mg を負荷投与後，CDP/LDP 42.5/850 mg を一定速度で 24 時間持続注入投与する。

レジメン E（LCIG）：CD/LD 12.5/50 mg を負荷投与後，CD/LD 87.5/350 mg を一定速度で 16 時間持続注入投与し，その後，CD/LD 25/100 mg を負荷投与開始後 18 時間及び 21 時間に経口投与する。

レジメン F（ABBV-951）：CDP/LDP 4/80 mg を負荷投与後，CDP/LDP 35/700 mg を一定速度で 24 時間持続注入投与する。
各期 Day 1 での治験薬投与開始後から 36 時間まで，CD，LD，CDP，LDP 及び 3-O メチルドパ（3-OMD）測定用の血液検体を連続的に採取した。

被験薬，用量 / 含量 / 濃度，投与方法及びロット番号：
LCIG 懸濁液，CD/LD 5/20 mg/mL，NJ チューブを介して注入投与，ロット番号 [redacted]
ABBV-951 凍結乾燥粉末，CDP/LDP 20/400 mg，SC 注入投与，ロット番号 [redacted]（パート 1 のレジメン B 及びパート 2 のレジメン D）
ABBV-951 溶液，CDP/LDP 12/240 mg/mL，SC 注入投与，ロット番号 [redacted]（パート 3 のレジメン F）
CD/LD 錠，CD/LD 25/100 mg，経口投与，ロット番号 [redacted]
治療期間：
投与開始後 18 及び 21 時間に経口投与を含む又は含まない 16 時間注入投与，あるいは，24 時間注入投与

評価基準：
薬物動態：
C_{max} 及び AUC

統計手法：
薬物動態：
各パートにおける LD 及び CD のパラメータ（T_{max}，β 並びに C_{max} 及び AUC の自然対数変換値）について，線形混合効果モデルを用いて解析した。モデルのフレームワークにおいて，各レジメンでの C_{max} 及び AUC の中心値を推定し，ABBV-951 レジメンと LCIG レジメンとの中心値の比の点推定値及びその 90%信頼区間を評価した。

要約 / 結論
薬物動態の結果：

レジメン 試験 vs.標準	薬物動態 パラメータ	中心値 試験	中心値 標準	相対的バイオアベイラビリティ 点推定値	相対的バイオアベイラビリティ 90%信頼区間
				カルビドパ	
レジメン B vs. レジメン A	C_{max}	161	174	0.929	0.777, 1.109
	AUC_t	2490	1820	1.368	1.203, 1.556
	AUC_{inf}	2570	1900	1.348	1.198, 1.517
	AUC_{0-16}	1980	1580	1.257	1.100, 1.436
				レボドパ	
	C_{max}	1250	1110	1.121	0.985, 1.277
	AUC_t	18100	13800	1.304	1.255, 1.355
	AUC_{inf}	18100	13900	1.301	1.253, 1.352
	AUC_{0-16}	14500	12200	1.190	1.128, 1.255

レジメン A：CD/LD 25/100 mg を負荷投与後，CD/LD 125/500 mg を一定速度で 16 時間持続投与
レジメン B：CDP/LDP 10/200 mg を負荷投与後，CDP/LDP 37.5/750 mg を一定速度で 16 時間持続投与

レジメン 試験 vs.標準	薬物動態 パラメータ	中心値 試験	中心値 標準	相対的バイオアベイラビリティ 点推定値	相対的バイオアベイラビリティ 90%信頼区間
				カルビドパ	
	$C_{max0-16}$	96.4	104	0.925	0.746, 1.147
	AUC_t	2410	1810	1.329	1.193, 1.480
	AUC_{inf}	2500	1850	1.348	1.211, 1.500
	AUC_{0-16}	1320	903	1.464	1.300, 1.649
	AUC_{0-24}	2090	1510	1.387	1.257, 1.530
レジメン D vs. レジメン C				レボドパ	
	$C_{max0-16}$	780	624	1.250	1.097, 1.425
	AUC_t	19100	14600	1.313	1.264, 1.363
	AUC_{inf}	19200	14600	1.313	1.266, 1.361
	AUC_{0-16}	10300	8200	1.261	1.223, 1.301
	AUC_{0-24}	16500	13600	1.211	1.181, 1.241

レジメン C：CD/LD 12.5/50 mg を負荷投与後，CD/LD 87.5/350 mg を一定速度で 16 時間持続投与し，その後，CD/LD 25/100 mg を負荷投与開始後 18 時間及び 21 時間に経口投与

レジメン D：CDP/LDP 5/100 mg を負荷投与後，CDP/LDP 42.5/850 mg を一定速度で 24 時間持続投与

レジメン 試験 vs.標準	薬物動態 パラメータ	中心値 試験	中心値 標準	相対的バイオアベイラビリティ 点推定値	相対的バイオアベイラビリティ 90%信頼区間
				カルビドパ	
	$C_{max0-16}$	90.0	123	0.732	0.654, 0.820
	AUC_t	2160	2250	0.959	0.865, 1.062
	AUC_{inf}	2230	2300	0.967	0.867, 1.079
	AUC_{16}	1180	1190	0.990	0.926, 1.058
	AUC_{24}	1870	1880	0.995	0.927, 1.067
レジメン F vs. レジメン E				レボドパ	
	$C_{max0-16}$	590	598	0.986	0.839, 1.160
	AUC_t	13400	12700	1.056	1.013, 1.100
	AUC_{inf}	13600	12800	1.062	1.020, 1.106
	AUC_{0-16}	7400	7250	1.022	0.971, 1.075
	AUC_{0-24}	11800	11800	0.999	0.963, 1.036

レジメン E：CD/LD 12.5/50 mg を負荷投与後，CD/LD 87.5/350 mg を一定速度で 16 時間持続投与し，その後，CD/LD 25/100 mg を負荷投与開始後 18 時間及び 21 時間に経口投与

レジメン F：CDP/LDP 4/80 mg を負荷投与後，CDP/LDP 35/700 mg を一定速度で 24 時間持続投与

安全性の結果：

いずれのレジメンにおいても忍容性はおおむね良好であった。重篤な有害事象及び重度の有害事象は認められなかった。ABBV-951 を投与した一部の被験者に軽度の注入部位反応の有害事象がみられた。注入部位の評価では，注入部位評価尺度で数値グレード 5，あるいはレターグレード C を超える被験者はいなかった。試験期間中，臨床的に重要な臨床検査値，バイタルサイン，自殺行動/自殺念慮及び注入部位反応は認められなかった。

結論

CDP/LDP 37.5/750 mg の ABBV-951 を 16 時間かけて注入投与したとき（レジメン B）の CD 及び LD の推定曝露量（$AUC_{0\text{-}16}$，AUC_t 及び AUC_{inf}）は，CD/LD 125/500 mg の LCIG を 16 時間かけて注入投与したとき（レジメン A）と比べ，19%～37%高かった。

CDP/LDP 42.5/850 mg の ABBV-951 を 24 時間かけて注入投与したとき（レジメン D）の CD 及び LD の推定曝露量（$AUC_{0\text{-}16}$，$AUC_{0\text{-}24}$，AUC_t 及び AUC_{inf}）は，CD/LD 87.5/350 mg の LCIG を 16 時間かけて注入投与後，25/100 mg の CD/LD を投与開始後 18 時間及び 21 時間に経口投与したとき（レジメン C）と比べ，21%～46%高かった。

CDP/LDP 35/700 mg の ABBV-951 を 24 時間かけて注入投与したとき（レジメン F）の CD の $C_{max0\text{-}16}$ は，CD/LD 87.5/350 mg の LCIG を 16 時間かけて注入投与後，CD/LD 25/100 mg を投与開始後 18 時間及び 21 時間に経口投与したとき（レジメン E）と比べ，低かった。CD の $AUC_{0\text{-}16}$，$AUC_{0\text{-}24}$，AUC_t 及び AUC_{inf}，並びに，LD の $C_{max0\text{-}16}$，$AUC_{0\text{-}16}$，$AUC_{0\text{-}24}$，AUC_t 及び AUC_{inf} の中心値の比の点推定値は 1 に近く，90%信頼区間は狭かった。

いずれのレジメンにおいても忍容性は良好であった。重篤な有害事象及び重度の有害事象は認められなかった。大部分の有害事象の重症度は軽度であった。懸念すべき有害事象の傾向，又は，臨床検査所見は報告されなかった。

M15-733 試験

治験の標題： 健康被験者を対象とした ABBV-951 の安全性，忍容性及び薬物動態を評価する単回投与試験	
施設数 / 実施国： 1 施設 / 米国	
治験責任医師： [redacted]，MD	
公表文献 (参考資料) ： なし	
治験期間： 最初の被験者の初回来院日：20[redacted] 年 [redacted] 月 [redacted] 日 最後の被験者の最終来院日：20[redacted] 年 [redacted] 月 [redacted] 日	開発のフェーズ：I

目的：

本試験の各グループにおける目的を以下に示す。

グループ 1

- ABBV-951 を用量漸増で単回持続皮下注入（CSCI）したときの安全性，忍容性及び薬物動態を評価する。
- ABBV-951 を皮下投与したとき及びカルビドパ（CD）とレボドパ（LD）を経口投与したときの CD 及び LD の薬物動態を比較する。

グループ 2

- 高用量の ABBV-951 を CSCI したときの安全性，忍容性及び薬物動態を評価する。
- 3 つの異なるカルビドパ 4'一リン酸塩（CD4'）/レボドパ 4'一リン酸塩（LD4'）比で皮下投与したときの薬物動態を比較する。

グループ 3

- ABBV-951 を異なる投与部位から CSCI したとき，及び腹部から注入ポンプを用いて 1 分間で単回ボーラス投与したときの安全性，忍容性及び薬物動態を評価する。

グループ 4

- ABBV-951 を初回ボーラス投与後，72 時間かけて CSCI したときの安全性，忍容性及び薬物動態を評価する。

被験者数 (計画時と解析時) ：

計画時：34 名，登録：34 名，完了：34 名，安全性評価：34 名，薬物動態評価：31 名

診断と主要な組入れ基準：

45 歳から 75 歳の健康な男女

治験方法：

健康状態が概して良好な 34 名（N=34）の成人男性及び女性被験者を，4 グループ（6～12 名/1 グループ）から成る単一施設 first-in-human（FIH）試験に登録した。

グループ 1 では，8 名の被験者（N=8）を，CD4'/LD4' 90/360 mg の ABBV-951 投与群とプラセボ投与群に 3:1 の割合で無作為に割付け，24 時間にわたり一定速度で腹部に単回 CSCI した。第 1 期では ABBV-951 が投与され，第 2 期では総用量として 75/300 mg の CD/LD が投与された。第 1 期と第 2 期の治験薬投与開始の間には 72 時間以上の期間を設けた。

グループ 2 では，被験者 8 名（N=8）を対象とした単盲検，プラセボ対照，3 期クロスオーバーの試験デザインで，ABBV-951 の安全性，忍容性及び薬物動態を評価した。レジメン A，B，C 及び D では，CD4'/LD4' 160/640 mg，64/640 mg，32/640 mg の ABBV-951 又はプラセボを，それぞれ 16 時間にわたり一定速度で腹部に

CSCI した。

グループ 3 は，被験者 12 名（N=12）を対象とした非盲検，ランダム化，クロスオーバー，単回投与試験デザインであり，CD4'/LD4' 240/960 mg の ABBV-951 を異なる投与部位（レジメン A，B 及び C として，それぞれ腹部，腕及び大腿部）から 24 時間にわたり一定速度で CSCI した。また，CD4'/LD4' 25/100 mg の ABBV-951 を，注入ポンプを用いて 1 分間で単回ボーラス皮下投与した（レジメン D）。ABBV-951 の投与間隔は 72 時間以上とした。

グループ 4 は，被験者 6 名（N=6）を対象とした非盲検，単回投与試験デザインであり，CD4'/LD4' 10/200 mg の ABBV-951 を初回ボーラス皮下投与後，CD4'/LD4' 48/960 mg の ABBV-951 を同一投与部位から 72 時間かけて CSCI した。

ABBV-951 の濃度測定用の血液検体は，以下に示す時点で採取した。

- グループ 1，第 1 期，ABBV-951 又はプラセボを CSCI：カテーテルプライミング前，注入投与前（0 時間）及び Day 1 の投与開始から 48 時間まで。
- グループ 1，第 2 期，CD/LD 経口投与：初回投与前（0 時間）及び Day 1 の投与開始から 24 時間まで。
- グループ 2（全期）：カテーテルプライミング前，注入投与前（0 時間）及び Day 1 の投与開始から 28 時間まで。
- グループ 3，レジメン A，B 及び C，ABBV-951 投与：カテーテルプライミング前，注入投与前（0 時間）及び Day 1 の投与開始から 36 時間まで。
- グループ 3，レジメン D，ABBV-951 皮下ボーラス投与：カテーテルプライミング前，投与前（0 時間）及び Day 1 の投与開始から 24 時間まで。
- グループ 4：カテーテルプライミング前，投与前（0 時間）及び Day 1 の投与開始から 96 時間まで。

被験薬，用量 / 含量 / 濃度，投与方法及びロット番号：

ABBV-951：凍結乾燥粉末，CD4'/LD4' 107.5/430.0 mg，CSCI，ロット番号 [redacted]

CD/LD：速放（IR）錠，CD/LD 25/100 mg，経口投与，ロット番号 [redacted]

プラセボ：0.9%生理食塩液，CSCI，ロット番号該当なし

治療期間：

単回注入投与又は 3 回経口投与

評価基準：

薬物動態：

C_{max}，T_{max}，AUC_t，AUC_{inf}，$t_{1/2}$，CL/F 及び変動度（DFL）

安全性：

有害事象，バイタルサイン，身体的検査，心電図（ECG），コロンビア自殺評価スケール（C-SSRS）及び臨床検査評価

統計手法：

薬物動態：

グループ 1 では，ABBV-951 を CSCI したとき及び CD/LD を経口投与したときの CD 及び LD の薬物動態を比較した。CD 及び LD の AUC 及び C_{max} について，CD/LD を経口投与したときの中心値に対する ABBV-951 を CSCI したときの中心値の比の点推定値及び近似的な 95%信頼区間を算出した。

グループ 2 では，3 つの異なる CD4'/LD4'比がレボドパの薬物動態パラメータに及ぼす影響を評価するため，クロスオーバー試験に適した線形混合効果モデルを用いて薬物動態パラメータを解析した。本モデルではレジメン及び投与期を固定効果とした。被験者を無作為標本とみなし，被験者のばらつきはランダム効果とした。モデルのフレームワークにおいて，レボドパの AUC 及び C_{max} の中心値の比の点推定値とその 95%信頼区間を算出した。

グループ 3 では，クロスオーバー試験に適した線形混合効果モデルを用いて薬物動態パラメータを解析した。3 つの CSCI レジメン（レジメン A，B 及び C）の AUC，C_{max} 及び T_{max} の対数値を用いて解析した。本モデルではレジメン及び投与期を固定効果とした。被験者を無作為標本とみなし，被験者のばらつきをランダム効果，又

は，モデルのランダムコンポーネントとして適切にするためにより複雑な構造とした。モデルのフレームワークにおいて，3 つの CSCI レジメンに差異がないという仮説について検定した。対数平均値の差の点推定値とその信頼区間を指数変換することにより，点推定値及びその信頼区間を算出した。

グループ 4 では，各時点でのレボドパ及びカルビドパの血漿中濃度の適切な代表値（平均）をプロットした。Day 3（48～72 時間）の血漿中濃度が Day 2（24～48 時間）と比べ高い傾向があるかどうかを検討するため，2 つの統計解析を実施した。Day 2 の 28～48 時間及び Day 3 の 52～72 時間の最後の 5 測定値（各 Day での 4，8，12，16 及び 24 時間）について反復測定の解析を実施した。本モデルは，Day 及び時間によるクラス分けがあり，Day と時間の交互効果を含めた。Day の主効果に対する検定（5 時点の平均値に対する検定）は片側検定で，Day 3 の平均値が Day 2 と比べ高いという対立仮説について実施した。

要約 / 結論

薬物動態の結果：

ABBV-951 を単回 CSCI したとき及び CD/LD を経口投与したときの，CD 及び LD の相対的バイオアベイラビリティを以下の表に示す（グループ 1）。

レジメン 試験 [a] vs. 標準 [b]	薬物動態 パラメータ	中心値		中心値の比	
		試験	標準	点推定値	95%信頼区間
カルビドパ					
ABBV-951 vs. 経口 CD/LD	C_{max}	209	111	1.88	1.37, 2.58
	AUC_t	4460	847	5.27	4.29, 6.46
	AUC_{inf}	4550	865	5.26	4.30, 6.44
レボドパ					
ABBV-951 vs. 経口 CD/LD	C_{max}	327	1490	0.219	0.180, 0.266
	AUC_t	6700	6150	1.09	0.895, 1.324
	AUC_{inf}	6640	6510	1.02	0.931, 1.12

a. CD4'/LD4' 90/360 mg の ABBV-951 を腹部から一定速度で 24 時間かけて単回 CSCI

b. 総用量として CD/LD 75/300 mg を経口投与（CD/LD 25/100 mg を 5 時間あけて 3 回投与）

異なる CD4'/LD4'比の ABBV-951 を腹部から一定速度で 16 時間かけて投与したときのレボドパの相対的バイオアベイラビリティを以下の表に示す（グループ 2）。

レジメン 試験 vs. 標準	薬物動態 パラメータ	中心値		相対的バイオアベイラビリティ	
		試験	標準	点推定値	95%信頼区間
レジメン A vs. レジメン C	C_{max}	984	872	1.13	0.969, 1.31
	AUC_t	14400	12600	1.14	0.979, 1.33
	AUC_{inf}	14500	12800	1.13	0.949, 1.35

レジメン A：CD4'/LD4' 160/640 mg の ABBV-951 を 16 時間かけて CSCI

レジメン C：CD4'/LD4' 32/640 mg の ABBV-951 を 16 時間かけて CSCI

ABBV-951 を腹部，腕，及び，大腿部から 24 時間にわたり一定速度で CSCI したときの CD 及び LD の相対的バイオアベイラビリティを以下の表に示す（グループ 3）。

レジメン 試験 vs.標準	薬物動態 パラメータ [a]	中心値 試験	中心値 標準	相対的バイオアベイラビリティ 点推定値	相対的バイオアベイラビリティ 95%信頼区間
		カルビドパ			
レジメン B vs.レジメン A	C_{max}	607	611	0.993	0.908, 1.09
	AUC_t	13600	13600	1.00	0.933, 1.08
	AUC_{inf}	13700	13700	1.00	0.934, 1.08
レジメン C vs.レジメン A	C_{max}	629	611	1.03	0.941, 1.13
	AUC_t	13600	13600	1.00	0.930, 1.08
	AUC_{inf}	13800	13700	1.01	0.941, 1.09
		レボドパ			
レジメン B vs.レジメン A	C_{max}	1030	1030	1.00	0.918, 1.09
	AUC_t	22600	22600	1.00	0.930, 1.07
	AUC_{inf}	22800	22700	1.00	0.931, 1.07
レジメン C vs.レジメン A	C_{max}	1080	1030	1.04	0.957, 1.14
	AUC_t	22500	22600	0.994	0.927, 1.07
	AUC_{inf}	22800	22700	1.00	0.933, 1.08

レジメン A：CD4'/LD4' 240/960 mg の ABBV-951 を腹部から 24 時間かけて一定速度で CSCI

レジメン B：CD4'/LD4' 240/960 mg の ABBV-951 を腕から 24 時間かけて一定速度で CSCI

レジメン C：CD4'/LD4' 240/960 mg の ABBV-951 を大腿部から 24 時間かけて一定速度で CSCI

安全性の結果：

プラセボ投与と比較して，ABBV-951 を CSCI 又はボーラス投与後に発現した有害事象の種類や頻度について明らかな傾向は認められなかった。検討した全てのレジメンにおいて忍容性は良好であった。有害事象及び臨床検査値において懸念すべき傾向は報告されなかった。血圧及び脈拍数の個々の測定値並びに心電図の定量的測定値に特記すべき所見は認められなかった。

結論：

ABBV-951 を CD4'/LD4' 90/360～240/960 mg の用量範囲で単回 CSCI したとき，CD4'及び LD4'は速やかに CD 及び LD に変換された。全てのグループにおいて，AUC に基づく CD 及び LD の曝露量の変動は全体的に小さかった（変動係数［CV］ 7～26%）。ABBV-951 を皮下投与したときの CD 及び LD の $t_{1/2}$ は，それぞれ 2.1～3.4 時間及び 1.8～2.7 時間であった。

CD4'/LD4'比が 1:20 の ABBV-951 を投与したとき，LD の曝露量は，CD4'/LD4'比が 1:4 の ABBV-951 を投与したときと比べ約 14%低かった。また，CD と LD の曝露量比は，CD/LD を 1:4 の比で経口投与したときと同程度であった。

ABBV-951 を 3 つの異なる投与部位（腕，腹部及び大腿部）から投与したとき，CD 及び LD の曝露量，並びに薬物動態の変動はいずれも類似していた。

ABBV-951 をボーラス皮下投与したときの吸収，及び CD 又は LD への変換は速やかであり，CD 及び LD の T_{max} は 1.3～1.5 時間であった。

CD 及び LD はいずれも速やかに定常状態に達し，72 時間の投与期間を通して曝露量が維持された。ABBV-951

を投与したときの 2～16 時間での LD の DFL は 0.2 であった。過去の試験（S187-1-002 試験）でデュオドーパを投与したときの DFL は 0.52 であった。

検討したレジメンにおいて忍容性はおおむね良好であった。有害事象は全体的に軽度で散発的であった。身体的検査，臨床検査，並びに，自殺傾向尺度及び刺激部位尺度のデータにおいて，臨床的に重要な所見は認められなかった。血圧及び脈拍数の個々の測定値，並びに，心電図に関する定量的測定値において，特記すべき所見は認められなかった。

血圧及び脈拍数，並びに，心電図変数（心拍数，PR 間隔，QT 間隔，補正 QT 間隔及び QRS 期間）の平均値を解析したところ，有意に又はほぼ有意に ABBV-951 の影響を示唆する結果が部分的に認められた。CD4'/LD4' 90/360 mg 及び 160/640 mg の用量では，5 bpm 未満の心拍数減少が報告された。また，CD4'/LD4' 160/640 mg の用量では，治験薬投与開始後 2 時間から 12 時間の間の 4 回の測定において，PR 間隔が 7.1 msec から 12.0 msec に増加した。補正式による補正 QT 間隔においては，ABBV-951 による影響を示唆する結果は認められず，また，QRS 間隔においては，臨床的に意味のない程度の減少が示唆された。

M15-738 試験

治験の標題： パーキンソン病患者を対象とした ABBV-951 を 24 時間及び 72 時間皮下注入投与したときの安全性，忍容性及び薬物動態を評価する単回漸増投与試験	
施設数 / 実施国： 7 施設 / 米国	
治験責任医師： [redacted]，MD	
公表文献 (参考資料) ： なし	
治験期間： 最初の被験者の初回来院日：20[redacted] 年 [redacted] 月 [redacted] 日 最後の被験者の最終来院日：20[redacted] 年 [redacted] 月 [redacted] 日	開発のフェーズ：I

目的：

本試験の主要目的を以下に示す。

- ABBV-951 をパーキンソン病（PD）患者にボーラス皮下（SC）投与後，シリンジポンプを用いて 24 時間又は 72 時間単回持続皮下注入（CSCI）したときの局所及び全身の安全性及び忍容性を評価する。ABBV-951 は 2 つの製剤を用いて臨床的に意味のある 4 用量を投与する。
- ABBV-951 を PD 患者に投与したときの定常状態におけるカルビドパ（CD）及びレボドパ（LD）の血漿中濃度を測定する。ABBV-951 は 2 つの製剤を用いて 4 用量を投与する。

副次目的は ABBV-951 を投与したときの曝露量（血漿中 LD 濃度）が心拍数で補正した QT 間隔（QTc）に及ぼす影響を評価する。

被験者数 (計画時と解析時) ：

計画時：30 名，登録：28 名，完了：27 名，安全性評価：28 名，薬物動態評価：27 名

診断と主要な組入れ基準：

LD 反応性があり，おおむね良好な健康状態であり，かつ，経口 LD レジメンで 1 日 3 回以上の投与を安定的に受けている，45 歳から 85 歳の特発性 PD と診断されている男女

治験方法：

本試験は，第 I 相，単回漸増投与（SAD），単盲検試験であり，米国の 7 施設で計 28 名（N=28）が参加した（パート 1：13 名，パート 2：15 名）。

パート 1 は 4 つの投与群から成り，各群最大 6 名の被験者に ABBV-951（カルビドパ一リン酸塩/レボドパ一リン酸塩［CDP/LDP］50/200 mg）をボーラス SC 投与した後，腹部より注入ポンプを用いて ABBV-951 を 24 時間（グループ 1a，2a 及び 4a：CDP/LDP 240/960 mg～1200/4800 mg）又は 72 時間（グループ 1b 及び 2b：CDP/LDP 240/960 mg～600/2400 mg）にわたり一定速度で CSCI した。

パート 2 は 4 つの投与群から成り，各群最大 4 名の被験者に ABBV-951（CDP/LDP 10/200 mg）をボーラス SC 投与後，腹部より注入ポンプを用いて ABBV-951（グループ 5～8：CDP/LPD 48/960～240/4800 mg）を 72 時間にわたり一定速度で CSCI した。

パート 1 及びパート 2 では異なる処方の治験薬が使用された（CDP/LDP の比が，それぞれ 1:4 及び 1:20）。

被験薬，用量 / 含量 / 濃度，投与方法及びロット番号：

パート 1：CDP/LDP 107.5/430.0 mg の凍結乾燥粉末の ABBV-951（ロット番号：[redacted]）を 0.9%生理食塩液で溶解し，CSCI した。

パート 2：CDP/LDP 20.0/400.0 mg/mL の凍結乾燥粉末の ABBV-951（ロット番号：[redacted]）を 0.9%生理食塩

液で溶解し，CSCI した。

治療期間：

単回 SC ボーラス投与後，24 時間又は 72 時間 CSCI

評価基準：

薬物動態：

C_{max} 及び AUC

安全性：

有害事象のモニタリング，バイタルサイン，医療機器不具合情報の収集，心電図（ECG）及び臨床検査評価，注入部位の評価，コロンビア自殺評価スケール（C-SSRS），並びに QTc と血漿中薬物濃度との関連性

統計手法：

薬物動態：

用量比例性を評価するため，本試験のパート 2 のデータを解析した。用量で標準化した CD 及び LD の AUC，並びに CD，LD，CDP 及び LDP の C_{max} の対数値を用いて，用量及び体重を共変量として区別した一元配置共分散分析（ANCOVA）を行った。以下 2 つの仮説検定を有意水準 0.050 で実施した。1 つ目は，最高用量と最低用量の間に差がない仮説について実施した。2 つ目は，4 用量における平均値が一致しない仮説について実施した。2 つ目の検定では差を規定する係数を用い，これは 4 用量における平均値が 72 時間投与した LDP（又は CDP）の用量とおおむね比例関係であれば，十分な検出力を持つ検定であると考えられる。

安全性：

有害事象コーディング辞書として ICH 国際医薬用語集（MedDRA）を用いた。試験のパートごとに，治験薬投与後に発現した有害事象を報告した被験者の数及び割合を MedDRA の基本語及び器官別大分類（SOC）別に一覧表示し，更にグループ別（24 時間あたりの投与量）に内訳を示し，パート 1 では被験者数を更に投与期間別に内訳を示した。治験薬投与開始後 24 時間以内に発現した有害事象についても同様に要約した。

各パートの注入部位評価スケールのデータを，各評価時点の二つの注入部位について要約した（ABBV-951 及びプラセボ）。

事前に規定した基準に従って，臨床的に重要と考えられる臨床検査値及びバイタルサインの測定値を特定した。バイタルサイン（血圧及び脈拍数），起立時のバイタルサイン及び ECG について，各評価時点の要約統計量を投与量別に算出した。

補正式による補正 QT 間隔（QTcF）と血漿中 LD 濃度との関係について，パート 1 及びパート 2 の併合データを用いて解析した。0 時間時点での ECG と同様の条件（時刻及び食事後時間）で採取された QTcF に関する曝露量－反応解析を実施した。実際に投与される最高用量を想定した非常に高い血漿中 LD 濃度における影響を 95%信頼上限と共に推定した。

要約 / 結論

薬物動態の結果：

規制当局の勧告に従い，試験中に市販予定製剤と同じ CD:LD 比の製剤に変更した。このため，用量比例性に関する統計解析はパート 2 のみで実施した。パート 2 において 4 つの異なる用量で ABBV-951 を注入投与したとき，LD は安定した薬物動態を示した。用量で標準化した LD の曝露量（C_{max}，AUC_t 及び AUC_{inf}）は，LDP の用量範囲（960 mg から 4800 mg）で顕著に重複していたことから，検討した LDP の用量範囲では LD の曝露量は用量に比例して増加することが示された。同様に，CD の曝露量も CDP の用量範囲（48 mg から 240 mg）では用量比例性が示された。CDP/LDP 48/960 から 240/4800 mg の用量範囲における LD 及び CD の曝露量に対する用量比例性の検定統計量はいずれも有意ではなかった（$p \geq 0.192$）。

安全性の結果：

いずれのレジメンにおいても忍容性はおおむね良好であった。治験を中止した 1 名に報告された重度の不安の有害事象 1 件を除き，有害事象は全て軽度又は中等度であった。ABBV-951 を投与した一部の被験者に軽度の注入部位反応の有害事象が認められ，1 名で中等度の注入部位疼痛が報告された。注入部位の評価では，評価尺度に基づく注入部位での顕著な皮膚反応は認められなかった。試験期間中，ベースライン反応後に臨床的に重要な臨床検査値，バイタルサイン，自殺行動/自殺念慮及び注入部位反応は認められなかった。本試験で報告された有

害事象に傾向はみられず，新たな安全性上の懸念は認められなかった。

LD は 50 年以上にわたり PD に対する治療法として確立した薬物であり，現在市販されている製剤において，安全性の懸念として QTcF 延長は特定されていない。経口製剤投与期間から ABBV-951 注入投与期間の QTcF の変化を解析したところ，ABBV-951 の QTcF に関する安全性プロファイルは，現在市販されている製剤と同様であることが示された。QTcF 延長は ABBV-951 投与開始時の安全性上の懸念ではないと考えられる。

結論

パート 1 の薬物動態データから，24 時間及び 72 時間のいずれの注入投与においても，安定した CD 及び LD の曝露量が維持されることが示された。パート 2 では，異なる用量の ABBV-951 を 72 時間かけて注入投与したとき，安定した CD 及び LD の曝露量が維持されることが示された。パート 2 では製剤比の変更により CD の曝露量は低下したものの，LD の薬物動態の変動に影響を与えなかった。パート 1 及び 2 において CDP 及び LDP の C_{max} は CD 及び LD と比べて非常に低かったことから，プロドラッグから活性体である CD 及び LD に速やかに変換されることが示された。パート 2 の結果から，LD 及び CD の曝露量は検討した用量範囲（CDP/LPD 48/960~240/4800 mg）で用量比例性が示されたことから，この用量範囲では用量に対し線形的に曝露量が増加することが示唆された。

検討した全てのレジメンにおいて忍容性は良好であった。ほとんどの有害事象は軽度であった。有害事象に関する懸念すべき傾向や臨床検査所見は報告されなかった。本試験で報告された有害事象に傾向はみられず，新たな安全性上の懸念は認められなかった。

QTcF 延長は ABBV-951 投与開始時の安全性上の懸念ではないと考えられる。

M15-739 試験

治験の標題： パーキンソン病患者を対象とした，外来環境下における最大 4 週間の ABBV-951 の用量調節及び持続皮下注入の安全性及び忍容性を評価する非盲検試験	
施設数 / 実施国名： 10 施設 / 米国	
治験責任医師： [redacted]，他	
公表文献 (参考資料) ： なし	
治験期間： 治験開始日：20[redacted] 年 [redacted] 月 [redacted] 日 治験終了日：20[redacted] 年 [redacted] 月 [redacted] 日	開発のフェーズ：Ib
目的： 主要目的： 外来環境下における最大 4 週間の持続皮下注入（以下「CSCI」）による ABBV-951 投与時の局所及び全身の安全性及び忍容性の評価 副次目的： CSCI による ABBV-951 投与時の定常状態における血漿中レボドパ濃度の評価 探索的目的： 既存の療法では運動合併症を十分にコントロールできない患者における ABBV-951 の有効性の評価	
被験者数 (計画時と解析時) ： 計画時：24 例，解析時：21 例	
診断と主要な組入れ基準： レボドパ反応性の特発性パーキンソン病と確定診断された 30 歳から 85 歳の成人男女	
治験方法： 本試験はスクリーニング期，観察期，用量調節期及び投与期から構成された，外来環境下の単群，非盲検試験であった。 各被験者の初回持続注入速度は，被験者の 1 日あたりのレボドパ換算投与量並びに ABBV-951 の 24 時間投与による曝露及びバイオアベイラビリティを考慮した ABBV-951 の換算アルゴリズムに基づき算出した。 パーキンソン病症状のコントロールにより評価した ABBV-951 の探索的有効性データを収集した。 カルビドパ，レボドパ，ホスカルビドパ，ホスレボドパ及び 3-O-メチルドパの測定のため，投与 1，7，14，21 及び 28 日目（又は ABBV-951 の投与中止前）に血液検体を連続して採取した。	
被験薬，用量，投与方法及びバッチ番号： ABBV-951 20/400 mg（カルビドパ-4′-リン酸塩 / レボドパ-4′-リン酸塩）凍結乾燥粉末を溶液で調製し，携帯式ポンプに接続した注入セットを介して CSCI により投与 バルクロット番号：[redacted]，[redacted]，[redacted]	
治療期間：用量調節期に設定された投与量を 24 時間注入で 28 日間投与	
対照薬，用量，投与方法及びバッチ番号： 該当なし	

評価基準：

有効性：

以下の探索的有効性評価項目をベースラインからの変化量により評価した。

- パーキンソン病日誌により評価した標準化した 1 日あたりの平均 OFF 時間及び ON 時間
- 国際パーキンソン病・運動障害学会統一パーキンソン病評価尺度（以下「MDS-UPDRS」）により評価したパーキンソン病症状
- パーキンソン病質問票（以下「PDQ-39」）により評価した生活の質
- Great Lakes NeuroTechnologies 社のウェアラブルデバイスである Kinesia 360 により評価した運動症状
- パーキンソン病における睡眠評価尺度改訂版（以下「PDSS-2」）により評価した睡眠症状
- キングのパーキンソン病の疼痛評価尺度（以下「KPPS」）により評価した疼痛症状
- パーキンソン病の不安評価尺度（以下「PAS」）により評価した不安症状

安全性：

局所忍容性（注入部位評価），有害事象，臨床検査値，バイタルサイン，心電図及びコロンビア自殺評価スケール（以下「C-SSRS」）などの安全性評価尺度

薬物動態：

カルビドパ，レボドパ，ホスカルビドパ，ホスレボドパ及び 3-O-メチルドパの血漿中濃度

統計手法：

有効性：

統計学的検定を両側検定により実施し，有意水準 $\alpha = 0.050$ で帰無仮説を棄却することとした。統計学的有意性の評価前に，P 値を小数点以下 3 桁に四捨五入した。特に記載がない限り，すべての解析は最大の解析対象集団を用いて実施した。

有効性及び健康関連効果の各評価項目について，各評価時点及び最終評価時点でのベースラインからの変化量を要約統計量を用いて要約した。要約統計量には，欠測でない観察回数，ベースライン平均値（標準偏差［以下「SD」］），各評価時点の平均値（SD），各評価時点の中央値（範囲），ベースラインからの平均変化量（SD 及び標準誤差）並びにベースラインからの変化量の中央値（範囲）を含めた。ベースラインから変化なしという帰無仮説を，各評価時点において 1 標本 t 検定を用いて評価した。有効性評価において，投与期の開始日は治験薬注入の初日とし，終了日は治験薬注入の最終日とした。

安全性：

有害事象は ICH 国際医薬用語集（MedDRA）version 21.1 を用いて読み替えた。有害事象（治験薬投与開始後に発現又は重症度が悪化した事象）が発現した被験者数と割合を，器官別大分類（SOC）及び基本語（PT）別に表に示した。有害事象が発現した被験者数については更に，重症度及び治験薬との因果関係別に表に示した。

2 つの注入部位評価尺度（順序尺度）の結果については，別途要約した。各尺度について，各評価時点の値及び全期間における最高値を度数分布表で示した。事前に定義した基準に基づき，臨床的な意義があると判断した臨床検査値及びバイタルサイン測定値を特定した。臨床検査項目について，基準値範囲（低値，正常又は高値）に基づいたシフトテーブルを示した。臨床検査項目及びバイタルサインについて，ベースラインからの変化量の要約を含む要約統計量を評価時点別に示した。

薬物動態：

各規定採血時点におけるカルビドパ，レボドパ，ホスカルビドパ，ホスレボドパ及び 3-O-メチルドパの血漿中濃度の要約統計量を算出した。各測定物について，投与 7，14，21 及び 28 日目における中心値（平均値，幾何平均値又はその他の値）の経時的推移を図示した。投与 1 日目の血漿中濃度データは要約したが，この解析には含めなかった。経時的な傾向に関するエビデンスとして，投与 7，14，21 及び 28 日目のデータを評価した。

要約 / 結論

有効性の結果：

ABBV-951 の注入後，統計学的に有意なベースラインからの変化量が以下で認められた。

- ジスキネジアに関するパーキンソン病における ON 時間及び OFF 時間
- MDS-UPDRS の総スコア，日常生活における非運動症状，日常生活における運動症状及び運動合併症
- PDQ-39 の要約指標並びに日常生活動作，情動的健康，認知能力，コミュニケーション，運動能力，恥辱感及び身体的苦痛の構成要素
- KPPS の総スコア及び変動関連スコア
- PAS の総スコア及び回避行動スコア

有効性解析において，20 例中 17 例の被験者で OFF 時間の改善が認められた。すべての被験者における試験終了時のベースラインからの標準化した OFF 時間の減少の平均値（SD）は 3.24（3.65）時間であった（46.2%の改善）。試験終了時に 4 例の被験者が 1 日あたり 90%を超える OFF 時間の減少を報告した。標準化した OFF 時間，日常生活に支障のないジスキネジアを伴う ON 時間及び日常生活に支障のあるジスキネジアを伴う ON 時間の平均値において減少が認められた結果，標準化したジスキネジアを伴わない ON 時間の改善の平均値（SD）は 3.99（5.37）時間であった。

ベースラインからの平均減少量（SD）は，MDS-UPDRS の総スコアが 9.0（11.87），PDQ-39 の要約指標が 6.9（8.39），PDSS-2 の総スコアが 2.0（11.48），KPPS の総スコアが 6.0（9.82）及び PAS の総スコアが 2.9（5.39）であった。

Kinesia 360 については，統計学的に有意なベースラインからの変化は認められなかった。

OFF 時間の減少及び ON 時間の改善と関連した全体的な探索的有効性の結果は，過去に報告されたデュオドーパの試験結果と一貫していた。予想より高いばらつきは，治験手順の不遵守（自己投与機器の誤った使用，輸液セットの操作の困難，シリンジ及びバイアルを毎日交換することになっていたが治験薬を使い切るまで待った）が原因で治験薬の曝露が予想より低く，治験薬によるベネフィットを受けなかった外れ値による可能性が考えられた。被験者 [redacted] 及び [redacted] は，治験実施計画書どおりに残薬を廃棄して毎日新しいバイアルを使用せずに，バイアルからシリンジに移された治験薬がポンプによりすべて皮下注入されるまで誤って待った。これが夜間のバイアル交換の原因となり，睡眠の質及び全般的な状態に悪影響を及ぼした。

安全性の結果：

本試験におけるパーキンソン病の患者集団において，ABBV-951 の忍容性はおおむね良好であった。認められた全身性の有害事象は，レボドパ / カルビドパの既知の作用及びパーキンソン病を有する患者に認められる事象とおおむね一致していた。最も多く認められた有害事象は，注入部位疼痛，注入部位紅斑及び注入部位刺激感を含む注入部位に関連する症状であった。これらの有害事象のほとんどは，軽度又は中等度であった。重篤な有害事象の蜂巣炎が発現した 1 例を含む 3 例の被験者において注入部位感染が発現し，このうち 2 例が試験を中止した。評価尺度に基づいた注入部位の評価において，ほとんどの被験者で明らかな注入部位の皮膚反応は認められなかった。臨床的に重要な評価は，感染に関連する有害事象の発現と同時期に行われた。ベースライン来院時（投与–29 日目）に自殺行動の陽性反応（C-SSRS 質問票）が認められた 1 例の被験者は，来院 1，2 及び 3（それぞれ投与–8，1 及び 2 日目）では陰性反応であったが，来院 4（投与 7 日目）で再び陽性反応が認められ，治験薬のベネフィットを受けていないと被験者自身が考えたため，試験を中止した。本試験中，臨床的に意義のある神経学的所見，バイタルサイン，心電図又は臨床検査値は認められなかった。有害事象又は臨床検査所見において懸念される傾向は認められなかった。

薬物動態の結果：

カルビドパ及びレボドパの血漿中濃度は投与 7 日目で定常状態又はほぼ定常状態と考えられた。

結論：

認められた全身性の有害事象は，レボドパ / カルビドパの既知の作用及びパーキンソン病を有する患者に認め

られる事象とおおむね一致していた。最も多く認められた有害事象は，ほとんどが軽度又は中等度の注入部位反応であり，試験終了時までに消失した。重篤な有害事象の蜂巣炎を含む注入部位感染が 3 例の被験者において発現し，このうち 2 例が試験を中止した。本試験中，臨床的に意義のある神経学的所見，バイタルサイン，心電図又は臨床検査値は認められなかった。本試験におけるパーキンソン病の患者集団において，ABBV-951 の忍容性はおおむね良好であった。有害事象又は臨床検査所見において懸念される傾向は認められなかった。

カルビドパ及びレボドパの血漿中濃度は投与 7 日目で定常状態又はほぼ定常状態と考えられた。

ABBV-951 の投与後，パーキンソン病日誌から得られたジスキネジアに関する ON 時間及び OFF 時間，MDS-UPDRS のスコア（総スコア，日常生活における非運動症状，日常生活における運動症状及び運動合併症）並びに PDQ-39 のほぼすべての項目において，統計学的に有意なベースラインからの変化量が認められた。また，KPPS 及び PAS においても有意な改善が認められた。PDSS-2 及び Kinesia 360 における ABBV-951 の効果についてのエビデンスは得られなかった。

M16-769 試験

治験の標題： 日本人，中国人（漢民族）及び白人の健康被験者を対象とした ABBV-951 の安全性，忍容性及び薬物動態を評価する第 I 相試験	
施設数 / 実施国名： 1 施設 / 米国	
治験責任医師： [redacted]，MD	
公表文献 (参考資料) ： なし	
治験期間： 最初の被験者の初回来院日：20[redacted] 年 [redacted] 月 [redacted] 日 最後の被験者の最終来院日：20[redacted] 年 [redacted] 月 [redacted] 日	開発のフェーズ：I
目的： 異なる用量の ABBV-951 を単回 24 時間持続皮下注入したときの安全性，忍容性及び薬物動態を評価し，また，日本人及び中国人（漢民族）の健康被験者の薬物動態を白人の健康被験者の薬物動態と比較する。	
被験者数 (計画時と解析時) ： 計画時：59 名，登録：56 名，完了：55 名，安全性評価：56 名，薬物動態評価：54 名	
診断と主要な組入れ基準： 45 歳から 75 歳の健康な日本人，中国人（漢民族）及び白人の男女	
治験方法： 日本人，中国人（漢民族）及び白人の健康被験者を対象とした非盲検試験で，ABBV-951 を単回 24 時間持続皮下注入（CSCI）した。 カルビドパ（CD），レボドパ（LD），カルビドパ 4'一リン酸塩（CDP），レボドパ 4'一リン酸塩（LDP）及び 3-O-メチルドパ（3-OMD）濃度測定用の血液検体を投与開始後 48 時間まで採取した。	

グループ	総投与量（mg）	持続投与 注入速度（mL/h）	持続投与 期間
1	CDP/LDP 24/480	0.1	24 時間 CSCI
2	CDP/LDP 48/960	0.2	24 時間 CSCI
3	CDP/LDP 72/1440	0.3	24 時間 CSCI

被験薬，用量 / 含量 / 濃度，投与方法及びロット番号： ABBV-951 凍結乾燥粉末，CDP4'（CDP）/LDP4'（LDP）20 mg/400 mg，CSCI，ロット番号 [redacted] 治療期間： ABBV-951 を単回 24 時間持続注入	
評価基準： 薬物動態： C_{max}，T_{max}，AUC_{inf}，AUC_t，AUC_{0-16} 及び AUC_{0-24}	
統計手法： 薬物動態： LD 及び CD のそれぞれについて日本人と白人で比較するため，用量で標準化した AUC 及び C_{max} の自然対数変	

換値について共分散分析を実施した。また，中国人（漢民族）と白人を比較するための解析も実施し，この解析では中国人被験者のデータと中国人被験者と同一の用量を投与された白人被験者のデータを含むデータセットを用いた。LD 及び CD の見かけの終末相消失速度定数（β）については二元配置共分散分析を実施し，T_{max} については共分散分析を実施した。LDP，CDP 及び 3-OMD については用量で標準化した C_{max} について二元配置共分散分析を実施した。

要約 / 結論

薬物動態の結果：

民族 試験 vs.標準	用量で標準化した 薬物動態パラメータ	中心値		中心値の比	
		試験	標準	点推定値	95%信頼区間
		カルビドパ			
日本人 vs.白人	C_{max}	2.30	2.54	0.905	0.828, 0.989
	AUC_t	49.4	54.0	0.914	0.842, 0.993
	AUC_{inf}	50.9	55.7	0.914	0.842, 0.991
	AUC_{0-16}	25.9	28.0	0.928	0.856, 1.01
	AUC_{0-24}	43.4	47.0	0.923	0.852, 1.00
		レボドパ			
日本人 vs.白人	C_{max}	0.883	0.944	0.935	0.863, 1.01
	AUC_t	18.4	19.6	0.935	0.866, 1.01
	AUC_{inf}	18.5	19.7	0.937	0.867, 1.01
	AUC_{0-16}	9.52	10.2	0.935	0.865, 1.01
	AUC_{0-24}	16.2	17.3	0.937	0.868, 1.01

民族 試験 vs.標準	用量で標準化した 薬物動態パラメータ	中心値		中心値の比	
		試験	標準	点推定値	95%信頼区間
		カルビドパ			
中国人 vs.白人	C_{max}	2.47	2.69	0.917	0.793, 1.06
	AUC_t	51.6	59.1	0.873	0.759, 1.01
	AUC_{inf}	53.3	61.0	0.874	0.760, 1.00
	AUC_{0-16}	25.8	29.8	0.866	0.759, 0.988
	AUC_{0-24}	44.7	50.4	0.887	0.778, 1.01
		レボドパ			
中国人 vs.白人	C_{max}	1.07	1.03	1.03	0.915, 1.16
	AUC_t	21.7	22.3	0.973	0.867, 1.09
	AUC_{inf}	21.7	22.3	0.972	0.866, 1.09
	AUC_{0-16}	10.7	11.3	0.953	0.845, 1.08
	AUC_{0-24}	18.8	19.2	0.978	0.873, 1.10

安全性の結果：

治験薬投与後に発現した有害事象を 1 回以上報告した被験者の割合は，CDP/LDP 24/480 mg から 72/1440 mg へ増量することに伴いわずかに増加した。ほとんどの有害事象は悪心及び嘔吐の増加に関連しており，これは CD 及び LD の有害事象としてよく報告されるものである。

試験期間中に臨床的に重要なバイタルサイン又は臨床検査異常は認められなかった。本試験において新たな安全性の問題は認められなかった。

結論：

ABBV-951 を投与したときの CD 及び LD の曝露量において，臨床的に意味のある人種間の差は認められなかった。日本人及び中国人で認められた CD 及び LD の曝露量（C_{max} 及び AUC）は，白人と同程度であった。

M18-763 試験

治験の標題： 健康被験者を対象とした ABBV-951 を 24 時間 10 日間皮下注入したときの安全性及び局所忍容性を評価する試験	
施設数 / 実施国： 1 施設 / 米国	
治験責任医師： [redacted]，MD	
公表文献 (参考資料) ： なし	
治験期間： 最初の被験者の初回来院日：20[redacted] 年 [redacted] 月 [redacted] 日 最後の被験者の最終来院日：20[redacted] 年 [redacted] 月 [redacted] 日	開発のフェーズ：I
目的： 本試験の主要な目的として，ABBV-951 を腹部から 24 時間 10 日間持続皮下注入（CSCI）したときの皮膚における忍容性を評価する。	
被験者数 (計画時と解析時) ： 計画時：33 名，登録：34 名，完了：33 名，安全性評価：34 名，薬物動態評価：34 名	
診断と主要な組入れ基準： 45 歳から 75 歳の健康な男女	
治験方法： 本試験は，健康被験者を対象とした ABBV-951 を 24 時間持続注入したときの安全性及び局所忍容性を評価するランダム化，盲検，プラセボ対照試験である。被験者は，ABBV-951 及び生理食塩水（プラセボ）を腹部から 10 日間投与された。プラセボでは，ABBV-951 注入部位と反対側の腹部側面から同量の生理食塩水を投与した。また，ABBV-951 を腹部右側又は左側から注入する被験者数がおおむね同数となるように，登録された被験者をランダムに割り当てた。 Day 1 及び Day 8 での投与開始後から約 8 時間にカルビドパ（CD），レボドパ（LD），カルビドパ一リン酸塩（CDP），レボドパ一リン酸塩（LDP）及び 3-O メチルドパ（3-OMD）測定用の血液検体を採取した。	
被験薬，用量 / 含量 / 濃度，投与方法及びロット番号： ABBV-951 凍結乾燥粉末，カルビドパ 4'一リン酸塩（CD4'）/レボドパ 4'一リン酸塩（LD4'）20/400 mg，CD4'/LD4' 48/960 mg を 24 時間 CSCI，ロット番号 [redacted] 治療期間： 24 時間 CSCI を 10 日間	
評価基準： 安全性： 注入部位評価尺度で数値グレード 6 又は 7，あるいは，レターグレード D，E，F 又は G の反応を，顕著な皮膚反応として事前に規定した。	
統計手法： 安全性： 主要な解析として，ABBV-951 注入部位の顕著な皮膚反応について，各被験者の ABBV-951 注入部位にみられた顕著な皮膚反応が 2 回以下かどうかの 2 値変数を用いて解析した。 ABBV-951 注入部位に 2 回以下の顕著な皮膚反応が見られた集団の比率（P）の点推定値及び 95%信頼区間の下	

限を算出した。本解析では，ABBV-951 注入部位に 1 回又は 2 回の顕著な皮膚反応が見られたが 10 日間の薬物投与レジメンを完了しなかった被験者については，ABBV-951 注入部位に 2 回を超える顕著な皮膚反応が見られた集団に分類した。また ABBV-951 注入部位において局所忍容性の懸念（注入部位疼痛等）により 10 日間の薬物投与レジメンを完了しなかった被験者についても，ABBV-951 注入部位に 2 回を超える顕著な皮膚反応が見られた集団に分類した。信頼限界は小数点以下第 3 位まで正確に算出した。また，それに対応する ABBV-951 注入部位に 2 回を超える顕著な皮膚反応が見られた集団の比率の信頼区間の上限も算出した。

注入部位の顕著な皮膚反応の発現に対する，注入の物理的過程及び ABBV-951 の寄与を検討するための解析を実施した。上述した P と同様に，生理食塩水注入部位に 2 回以下の顕著な皮膚反応が見られた集団の比率（P'）の点推定値及び 95%信頼区間の下限を算出した。また，ABBV-951 注入部位及び生理食塩水注入部位での結果の差について仮説検定を実施した。

要約 / 結論

安全性の結果：

いずれのレジメンにおいても忍容性はおおむね良好であった。ほとんどの有害事象は全体的に軽度であった。身体所見，臨床検査値又は自殺評価スケールの結果において臨床的に意味のある所見は認められなかった。

最も高頻度に認められた有害事象は注入部位反応であり，そのほとんどは軽度であった。注入部位疼痛及び浮腫は，ABBV-951 注入部位でより高頻度に認められた。全ての事象は試験終了までに回復した。注入部位評価尺度で，ABBV-951 及びプラセボを腹部に 10 日間 24 時間 CSCI 中に 1 名の被験者で顕著な皮膚反応が認められ，これはプラセボ注入部位であった。注入部位評価尺度を用いた統計解析の結果から，10 日間注入後に見られた顕著な皮膚反応又は皮膚刺激性に対する ABBV-951 の影響は示唆されなかった。

結論

最も高頻度に認められた有害事象は注入部位反応であった。そのほとんどは軽度であり，全ての事象は試験終了までに回復した。注入部位疼痛及び浮腫は，ABBV-951 注入部位でより高頻度に認められた。注入部位の顕著な皮膚反応は 1 件のみであり，プラセボ注入部位で認められた。注入部位評価では，2 つの尺度のいずれの場合でも，評価最終日において ABBV-951 投与及びプラセボ投与に有意な差は認められなかった。

事前に規定した顕著な皮膚反応において，ABBV-951 投与部位で 10 回（10 日）中 2 回を超える顕著な皮膚反応が見られた集団の比率の 95%信頼区間の上限は 0.087 であった。

いずれのレジメンにおいても忍容性は良好であった。懸念すべき有害事象の傾向，又は，臨床検査所見は報告されなかった。

M15-736 試験

治験の標題： 進行期パーキンソン病患者を対象として，経口カルビドパ / レボドパ製剤に対する ABBV-951 の有効性，安全性及び忍容性を比較する，ランダム化，二重盲検，ダブルダミー，実薬対照試験	
施設数 / 実施国名： 米国及びオーストラリアの 65 施設で被験者のスクリーニングを行い，60 施設で被験者を経口カルビドパ / レボドパ（以下「CD / LD」）安定化期に組み入れ，57 施設で被験者を二重盲検期にランダム化した。	
治験責任医師： [redacted], MD	
公表文献 (参考資料) ： 1 件の抄録	
治験期間： 最初の被験者の初回来院日：20[redacted] 年 [redacted] 月 [redacted] 日 最後の被験者の最終来院日：20[redacted] 年 [redacted] 月 [redacted] 日	開発のフェーズ：III
目的： 主要目的： 進行期パーキンソン病患者を対象として，投与 12 週時の運動症状の日内変動について，CD / LD 速放性（以下「IR」）製剤経口投与に対する ABBV-951 持続皮下注入（以下「CSCI」）の優越性を確認する。 副次目的： ABBV-951 を 12 週間 1 日 24 時間 CSCI したときの，局所及び全身の安全性，並びに忍容性を評価する。	
被験者数 (計画時と解析時) ： 計画時：約 130 例，解析時：141 例	
診断と主要な組入れ基準： レボドパ反応性の特発性パーキンソン病と診断された 30 歳以上の患者。少なくとも 1 日 400 mg 相当のレボドパ（以下「LD」）投与を受け，治験責任医師により現在の治療ではコントロール不十分な運動症状を持つと判断され，識別可能な / はっきりとしたオフとオンの状態（運動症状の日内変動）があり，連続する 3 日間のパーキンソン病日誌で 1 日あたり平均 2.5 時間以上のオフ時間があり，かつ各日のオフ時間が最低 2 時間である患者。	
治験方法： 本試験は，現在の治療ではコントロール不十分な運動症状の日内変動を持つ進行期パーキンソン病患者を対象に，ABBV-951 を 1 日 24 時間 CSCI したときの有効性，安全性及び忍容性を評価した，第 III 相，ランダム化，二重盲検，ダブルダミー，実薬対照，並行群間，多施設共同試験であった。 被験者は，6 日から 60 日間のスクリーニング期を経て 14 日から 21 日間の経口 CD / LD 安定化期に移行した。安定化期を通して，製剤を問わずすべての LD 含有治療薬，及びカテコール-O-メチル基転移酵素（以下「COMT」）阻害剤含有治療薬を相当量の CD / LD IR 製剤に切り換えた。その他のすべての併用パーキンソン病治療薬は使用可能としたが，特定の安全性の条件により調節が必要とされる場合を除き，治験完了まで不変のまま使用することとした。経口 CD / LD の用量及びスケジュールは，必要かつ被験者と治験責任医師が合意した場合の夜間投与の使用も含めて，経口 CD / LD 安定化期の最初の 7 日から 14 日間にわたって治験責任医師により調節され，被験者の運動症状を最適にコントロールできるようにした。この投与レジメンは，12 週間の二重盲検期開始時のランダム化前少なくとも 7 日間は変更不可とした。 二重盲検期は，投与 1 日目のランダム化に続く 4 週間の CSCI 最適化期と 8 週間の維持期で構成された。被験者は，事実上オフと規定された状態でランダム化のために来院した。疾患の未治療時の症状が明白になるように，ランダム化前少なくとも 12 時間はパーキンソン病治療薬の投与を許容しないこととした。	

治験方法（続き）： 適格となった被験者は以下の投与群にランダム化された： • ABBV-951 24 時間持続皮下注入群（以下「ABBV-951 投与群」） • カルビドパ / レボドパ速放性製剤経口投与群（以下「CD / LD 経口投与群」） 被験者は CSCI 最適化期の開始時に，盲検化された経口治験薬と治験薬溶液の 2 剤負荷投与を受け，その後，盲検化された治験薬溶液の注入と盲検化された経口治験薬の併用を開始した。治験責任医師は，最適化期を通して，盲検化された治験薬溶液の各被験者の CSCI 速度について，最適な臨床反応を得るために必要なすべての調節を行えることとした。最適な臨床反応は，1 日を通しての機能的オン時間の最大化と，オフエピソード数及び日常生活に支障のあるジスキネジアを伴うオン時間の最小化として規定した。経口治験薬及び許容される併用パーキンソン病治療薬は既に安定化されたランダム化前の用量及びスケジュールを維持することとし，安全性上の理由により必要な場合を除き，併用パーキンソン病治療薬の変更は不可とした。CSCI 最適化期の終了時に被験者は維持期に移行し，維持期では，盲検化された治験薬溶液及び盲検化された経口治験薬，並びに投与を継続しているパーキンソン病治療薬を含むその他の併用薬の安定した投与レジメンを維持することとした。非治験薬の用量調節は，医学的に必要と判断された場合にのみ可能とした。CD / LD IR 救済薬は，臨床状態の突然の悪化又は 1 時間を超えるポンプ故障の場合に使用可能とした。経口治験薬の夜間投与は，各被験者の個別の治療の必要に応じて柔軟に対応できるようにするために，経口 CD / LD 安定化期に必要かつ被験者と治験責任医師が合意した場合に許容した。この夜間投与量が確定した後は，本試験の二重盲検期の安定的な経口投与レジメンの一部としてこれを維持し，被験者は投与群に応じて夜間に CD / LD IR 製剤充填カプセル又はプラセボカプセルを服用した。 M15-736 試験の 12 週間の二重盲検期を完了し，適格性が認められた被験者は，別の非盲検継続投与試験（M20-098 試験）に移行し，ABBV-951 を最大 96 週間継続投与することが可能であった。 本試験の治験実施スケジュールを表 1 に示す。
被験薬，用量，投与方法及びバッチ番号： • ABBV-951 12/240 mg/mL（カルビドパ-4′-リン酸塩 / レボドパ-4′-リン酸塩）注入用溶液を，経口 CD / LD 安定化期における経口 CD / LD 製剤投与量及び換算アルゴリズムに基づいて注入速度を算出し，携帯式ポンプに接続した注入セットを介して 1 日 24 時間 CSCI により投与（バルクロット番号：[redacted]，[redacted]，[redacted]） • ABBV-951 プラセボ注入用溶液を，携帯式ポンプに接続した注入セットを介して 1 日 24 時間 CSCI により投与（バルクロット番号：[redacted]，[redacted]） • [redacted] 投与システム 治療期間：最大 12 週間
対照薬，用量，投与方法及びバッチ番号： • CD / LD IR 製剤充填カプセル（CD / LD：25/100 mg）を，経口 CD / LD 安定化期と同じ用量で経口投与（バルクロット番号：[redacted]，[redacted]，[redacted]） • CD / LD IR 製剤プラセボカプセルを経口投与（バルクロット番号：[redacted]）
評価基準： 有効性： 主要評価項目は，パーキンソン病日誌に基づく日常生活に支障のあるジスキネジアを伴わない標準化した 1 日あたりの平均オン時間のベースラインから二重盲検期の投与 12 週時までの変化量（時間）とした。

評価基準（続き）：

副次評価項目は固定順位で検定し，主な副次評価項目は，パーキンソン病日誌に基づく標準化した 1 日あたりの平均オフ時間のベースラインから二重盲検期の投与 12 週時までの変化量（時間），国際パーキンソン病・運動障害学会統一パーキンソン病評価尺度（以下「MDS-UPDRS」）Part II スコアにより評価した日常生活における運動症状（以下「M-EDL」）のベースラインから二重盲検期の投与 12 週時までの変化量，及びパーキンソン病日誌に基づく投与 12 週時の朝の無動（起床時以降に確認された最初の朝の症状としてのオフ状態）の有無とした。

その他の副次評価項目は，パーキンソン病日誌に基づくジスキネジアを伴わない標準化した 1 日あたりの平均オン時間のベースラインから二重盲検期の投与 12 週時までの変化量（時間），パーキンソン病における睡眠評価尺度改訂版（以下「PDSS-2」）合計スコアにより評価した睡眠症状，パーキンソン病質問票（以下「PDQ-39」）要約指標により評価したパーキンソン病に関連した生活の質，及び EuroQol 5 項目質問票（以下「EQ-5D-5L」）要約指標により評価した健康に関連した生活の質のベースラインから最終来院日までの変化量，並びに [redacted] 又は [redacted]（米国）（以下「[redacted]」）[redacted]を用いて評価した動作緩慢スコア中央値，動作緩慢スコア 75–25%タイル，ジスキネジアスコア中央値，及びジスキネジアスコア 75–25%タイルのベースラインから投与 12 週時までの変化量とした。

安全性：

安全性評価項目は全身及び局所の忍容性であり，有害事象，臨床検査値，バイタルサイン，心電図，注入部位評価尺度（Infusion Site Evaluation Scale），コロンビア自殺評価スケール（以下「C-SSRS」），及びパーキンソン病における衝動制御障害の評価尺度（以下「QUIP-RS」）により評価した。

統計手法：

有効性：

最大の解析対象集団（以下「FAS」）は，二重盲検期に盲検化された治験薬の投与を受け，かつ 1 つ以上の有効性評価に関するベースライン及び 1 つ以上のベースライン後の観測値が得られたすべてのランダム化された被験者からなり，すべての有効性解析についてこれを用いた。主要解析には反復測定混合効果モデル（以下「MMRM」）を用いた。主な副次評価項目及びその他の副次評価項目には，試験全体について両側有意水準 0.05 のファミリーワイズエラー率を制御するために，第一種過誤の多重比較調整を適用した。主要評価項目に用いたものと同様の MMRM を，パーキンソン病日誌に基づくその他の評価項目，並びに MDS-UPDRS Part II スコア及び [redacted] 変数の解析に関するベースラインから投与 12 週時までの変化量に対して用いた。PDSS-2 合計スコア，PDQ-39 要約指標及び EQ-5D-5L 要約指標のベースラインから最終来院日までの変化量については，共分散分析モデルを用いて解析した。ベースライン後の各来院時の起床時以降の最初の朝の状態については，朝の無動状態を呈する被験者の割合を群間比較するために，ロジットリンク関数による一般化線形混合モデルにより解析した。

安全性：

安全性解析対象集団は，二重盲検期に治験薬の投与を受けたすべての被験者からなり，すべての安全性解析についてこれを用いた。二重盲検期の有害事象は，二重盲検期の二重盲検下での治療開始以降，二重盲検治療の終了後 30 日以内に発現又は悪化したすべての事象と定義した。安全性転帰に関する連続変数について，ベースラインからの変化量を投与群別及び来院別に記述的に解析した。安全性転帰のカテゴリー変数について，各カテゴリーの数及び割合を投与群別及び来院別に要約した。ベースラインから規定した時点までの臨床検査値の変化を表に示した。安全性のパラメータについて仮説検定は実施しなかった。すべての有害事象は ICH 国際医薬用語集（以下「MedDRA」）version 24.0 を用いて要約した。

表 1.　　治験実施スケジュール

	スクリーニング期 6–60 日間		経口 CD / LD 安定化期 14–21 日間			二重盲検期 (12 週間)								後観察期 早期中止及び継続試験に移行しない治験完了者
			安定化		変更なし	CSCI 最適化期						維持期		
	V1	V2	V3	任意 V4	V5 ベースライン (別の記載がない限り)	V6 ランダム化	V7	V8	V9	任意 V10	V11	V12	V13 / 早期中止	
治験の実施項目	(最低 6 日間)		(最低 7 日間)		(7 日間)	Day 1	Day 2	Day 8	Day 15	Day 22	Day 29	Day 57	Day 85	30 日後
問診及び質問票														
被験者情報及び同意取得 (該当する場合，介護者も同意書を提出)	√													

表 1. 治験実施スケジュール（続き）

	スクリーニング期 6–60 日間		経口 CD / LD 安定化期 14–21 日間			二重盲検期 (12 週間)								後観察期 早期中止及び継続試験に移行しない治験完了者
			安定化		変更なし	CSCI 最適化期						維持期		
	V1	V2	V3	任意 V4	V5 ベースライン (別の記載がない限り)	V6 ランダム化	V7	V8	V9	任意 V10	V11	V12	V13 / 早期中止	
治験の実施項目	(最低 6 日間)		(最低 7 日間)		(7 日間)	Day 1	Day 2	Day 8	Day 15	Day 22	Day 29	Day 57	Day 85	30 日後
適格基準 *治験責任医師又は被指名者が EDC で適格性を確認する (治験依頼者は特定の被験者の試験参加又は適格基準の妥当性に関する問題を協議するために入手可能)	√	√*	√	√	√	√ (投与前)								

表 1. 治験実施スケジュール（続き）

	スクリーニング期 6–60 日間		経口 CD / LD 安定化期 14–21 日間			二重盲検期 (12 週間)								後観察期 早期中止及び継続試験に移行しない治験完了者
			安定化		変更なし	CSCI 最適化期						維持期		
	V1	V2	V3	任意 V4	V5 ベースライン (別の記載がない限り)	V6 ランダム化	V7	V8	V9	任意 V10	V11	V12	V13 / 早期中止	
治験の実施項目	(最低 6 日間)		(最低 7 日間)		(7 日間)	Day 1	Day 2	Day 8	Day 15	Day 22	Day 29	Day 57	Day 85	30 日後
[redacted] Knowledge and Skills Checklist (*V3 前の規定外来院時に反復してもよい)		√*			√									
病歴 / 手術歴	√ ベースライン													
アルコール及びニコチン使用	√													
臨床評価	√													

表 1. 治験実施スケジュール（続き）

	スクリーニング期 6–60 日間		経口 CD / LD 安定化期 14–21 日間			二重盲検期 (12 週間)								後観察期 早期中止及び継続試験に移行しない治験完了者
			安定化		変更なし	CSCI 最適化期						維持期		
	V1	V2	V3	任意 V4	V5 ベースライン (別の記載がない限り)	V6 ランダム化	V7	V8	V9	任意 V10	V11	V12	V13 / 早期中止	
治験の実施項目	(最低 6 日間)		(最低 7 日間)		(7 日間)	Day 1	Day 2	Day 8	Day 15	Day 22	Day 29	Day 57	Day 85	30 日後
注入部位の評価 (該当する場合は皮膚科学的評価)							√	√	√	√	√	√	√	√
有害事象の評価	√	√	√	√	√	√	√	√	√	√	√	√	√	√
製品に関する苦情・不具合	√	√	√	√	√	√	√	√	√	√	√	√	√	√
前治療 / 併用療法	√	√	√	√	√	√	√	√	√	√	√	√	√	
終了時問診 (他のすべての治験手順の後に行う)													√	

表 1. 治験実施スケジュール（続き）

	スクリーニング期 6–60 日間		経口 CD / LD 安定化期 14–21 日間			二重盲検期 (12 週間)								後観察期 早期中止及び継続試験に移行しない治験完了者
			安定化		変更なし	CSCI 最適化期						維持期		
	V1	V2	V3	任意 V4	V5 ベースライン (別の記載がない限り)	V6 ランダム化	V7	V8	V9	任意 V10	V11	V12	V13 / 早期中止	
治験の実施項目	(最低 6 日間)		(最低 7 日間)		(7 日間)	Day 1	Day 2	Day 8	Day 15	Day 22	Day 29	Day 57	Day 85	30 日後
患者報告アウトカム：患者による評価 (特定の時点)														
被験者投与日誌 (各来院前連続 3 日間)								√	√	√	√	√	√	
すべての経口 CD / LD IR 救済薬を記録する被験者投与日誌						√	√	√	√	√	√	√	√	
注入部位変更ツール (注入部位を変更するごと)						√	√	√	√	√	√	√	√	
パーキンソン病日誌の一致	√													

表 1. 治験実施スケジュール（続き）

	スクリーニング期 6–60 日間		経口 CD / LD 安定化期 14–21 日間			二重盲検期 (12 週間)								後観察期 早期中止及び継続試験に移行しない治験完了者
			安定化		変更なし	CSCI 最適化期						維持期		
	V1	V2	V3	任意 V4	V5 ベースライン (別の記載がない限り)	V6 ランダム化	V7	V8	V9	任意 V10	V11	V12	V13 / 早期中止	
治験の実施項目	(最低 6 日間)		(最低 7 日間)		(7 日間)	Day 1	Day 2	Day 8	Day 15	Day 22	Day 29	Day 57	Day 85	30 日後
パーキンソン病日誌 (各来院前連続 3 日間) *48 項目中 44 項目は 24 時間ごとに記入する **投与 1 日目の 4 日以上前に開始する，すなわちパーキンソン病日誌を投与 1 日前までに完成させる		√*				√*, ** ベースライン		√	√	√	√	√	√	
EQ-5D-5L					√								√	

表 1.　　治験実施スケジュール（続き）

	スクリーニング期 6–60 日間		経口 CD / LD 安定化期 14–21 日間			二重盲検期 (12 週間)								後観察期 早期中止及び継続試験に移行しない治験完了者
			安定化		変更なし	CSCI 最適化期						維持期		
	V1	V2	V3	任意 V4	V5 ベースライン (別の記載がない限り)	V6 ランダム化	V7	V8	V9	任意 V10	V11	V12	V13 / 早期中止	
治験の実施項目	(最低 6 日間)		(最低 7 日間)		(7 日間)	Day 1	Day 2	Day 8	Day 15	Day 22	Day 29	Day 57	Day 85	30 日後
[redacted] ([redacted])	√	√	√	√	√	√	√	√	√	√	√	√	√	
患者報告アウトカム：実施医療機関の評価者による評価 (特定の時点)														
MMSE	√													
MDS-UPDRS	√				√		√	√	√	√	√	√	√	
C-SSRS *ベースライン	√*	√			√	√ (投与前)	√	√	√	√	√	√	√	
QUIP-RS	√				√				√		√		√	
患者報告アウトカム：中央検査機関の評価者による評価 (特定の時点)														
PDSS-2	√				√								√	

表 1. 治験実施スケジュール（続き）

	スクリーニング期 6–60 日間		経口 CD / LD 安定化期 14–21 日間			二重盲検期 (12 週間)								後観察期 早期中止及び継続試験に移行しない治験完了者
			安定化		変更なし	CSCI 最適化期						維持期		
	V1	V2	V3	任意 V4	V5 ベースライン (別の記載がない限り)	V6 ランダム化	V7	V8	V9	任意 V10	V11	V12	V13 / 早期中止	
治験の実施項目	(最低 6 日間)		(最低 7 日間)		(7 日間)	Day 1	Day 2	Day 8	Day 15	Day 22	Day 29	Day 57	Day 85	30 日後
PDQ-39	√				√								√	
診察及び検査														
身長 (V1 のみ) / 体重	√	√	√	√	√	√ (投与前)	√	√	√	√	√	√	√	
バイタルサイン (立位)	√	√	√	√	√ (3 セット)	√ (投与前及び投与後)	√	√	√	√	√	√	√	
身体検査 *ベースライン	√*				√				√		√		√	
神経学的検査	√				√								√	
12 誘導心電図	√				√	√			√		√		√	

表 1. 治験実施スケジュール（続き）

	スクリーニング期 6–60 日間		経口 CD / LD 安定化期 14–21 日間			二重盲検期 (12 週間)								後観察期 早期中止及び継続試験に移行しない治験完了者
			安定化		変更なし	CSCI 最適化期						維持期		
	V1	V2	V3	任意 V4	V5 ベースライン (別の記載がない限り)	V6 ランダム化	V7	V8	V9	任意 V10	V11	V12	V13 / 早期中止	
治験の実施項目	(最低 6 日間)		(最低 7 日間)		(7 日間)	Day 1	Day 2	Day 8	Day 15	Day 22	Day 29	Day 57	Day 85	30 日後
臨床検査	√				√								√	
特別な臨床検査 (ビタミン B_6 及び B_{12}，葉酸，メチルマロン酸，ホモシステイン)	√				√								√	
薬物スクリーニング	√													
血清妊娠検査	√													
尿妊娠検査			√			√ (投与前)					√	√	√	

表 1. 治験実施スケジュール（続き）

	スクリーニング期 6–60 日間		経口 CD / LD 安定化期 14–21 日間			二重盲検期 (12 週間)								後観察期 早期中止及び継続試験に移行しない治験完了者
			安定化		変更なし	CSCI 最適化期						維持期		
	V1	V2	V3	任意 V4	V5 ベースライン (別の記載がない限り)	V6 ランダム化	V7	V8	V9	任意 V10	V11	V12	V13 / 早期中止	
治験の実施項目	(最低 6 日間)		(最低 7 日間)		(7 日間)	Day 1	Day 2	Day 8	Day 15	Day 22	Day 29	Day 57	Day 85	30 日後
治療														
経口安定化用 CD / LD IR 製剤の交付，供給確認及び照合			√	√	√	√								
治験薬処方記録			√		√	√	√	√	√	√	√	√	√	
被験者及び介護者 (該当する場合) の [redacted] Pump Delivery System 使用の初回トレーニング	√				√									

表 1. 治験実施スケジュール（続き）

	スクリーニング期 6–60 日間		経口 CD / LD 安定化期 14–21 日間			二重盲検期 (12 週間)								後観察期 早期中止及び継続試験に移行しない治験完了者
			安定化		変更なし	CSCI 最適化期						維持期		
	V1	V2	V3	任意 V4	V5 ベースライン (別の記載がない限り)	V6 ランダム化	V7	V8	V9	任意 V10	V11	V12	V13 / 早期中止	
治験の実施項目	(最低 6 日間)		(最低 7 日間)		(7 日間)	Day 1	Day 2	Day 8	Day 15	Day 22	Day 29	Day 57	Day 85	30 日後
[redacted] Pump Delivery System 使用の継続トレーニング		必要に応じて												
ランダム化 / 治験薬の割付け						√								
治験薬, [redacted] Pump Delivery System 及び救済療法用 CD / LD IR 製剤の交付 / 返却						√	√	√	√	√	√	√	√	

表 1. 治験実施スケジュール（続き）

	スクリーニング期 6–60 日間		経口 CD / LD 安定化期 14–21 日間			二重盲検期 (12 週間)								後観察期 早期中止及び継続試験に移行しない治験完了者
			安定化		変更なし	CSCI 最適化期						維持期		
	V1	V2	V3	任意 V4	V5 ベースライン (別の記載がない限り)	V6 ランダム化	V7	V8	V9	任意 V10	V11	V12	V13 / 早期中止	
治験の実施項目	(最低 6 日間)		(最低 7 日間)		(7 日間)	Day 1	Day 2	Day 8	Day 15	Day 22	Day 29	Day 57	Day 85	30 日後
治験薬, [redacted] Pump Delivery System 及び付属品の供給確認						√	√	√	√	√	√	√		
治験薬及び [redacted] Pump Delivery System の照合						√	√	√	√	√	√	√	√	

EDC = 電子データ収集，MMSE = ミニメンタルステート検査，[redacted] = [redacted]，V = 来院

被験者の内訳

被験者の内訳を表 2 に示す。

本試験では，145 例が二重盲検期にランダム化され，141 例が治験薬を投与された。

解析対象集団については，FAS が 141 例，安全性解析対象集団が 141 例であった。

治験薬の投与を完了した被験者は全体で 110 例（78.0%），治験薬投与中止は 31 例（22.0%）であった。治験薬の投与を中止した主な理由で最も多かったのは有害事象 15 例（10.6%）であった。

被験者背景

人口統計学的特性及びその他のベースラインの特性

人口統計学的特性及びその他のベースラインの特性の要約を表 3 に，パーキンソン病の病歴を表 4 に示す。

安全性解析対象集団では，年齢の平均値が 66.4 歳（範囲：39～85 歳），65 歳以上の割合が 63.8%，体重の平均値が 80.65 kg（範囲：39.1～142.6 kg），居住地域は米国 85.1%，女性が 29.8%，民族は非ヒスパニック（非ラテン含む）が 96.5%，人種は白人が 92.9%，パーキンソン病罹病期間は 10 年以上が 32.6%であった。

併用薬

被験者は，治験組入れ時に少なくとも 1 日 400 mg 相当の LD 投与を受けていることとした。経口 CD / LD 安定化期における LD 含有薬剤及び COMT 阻害薬の CD / LD IR 製剤への換算後，99 例（70.2%）がランダム化前のベースライン時に経口 CD / LD IR 製剤に追加して併用パーキンソン病治療薬の投与を受けた。42 例（29.8%）は他のパーキンソン病治療薬を使用せず，60 例（42.6%）は 1 つの他のクラスのパーキンソン病治療薬，33 例（23.4%）は 2 つの他のクラスのパーキンソン病治療薬，6 例（4.3%）は 3 つの他のクラスのパーキンソン病治療薬を服用した。4 つ以上の他のクラスのパーキンソン病治療薬を服用した被験者はいなかった（M15-736 試験 CSR Table 14.1__3.2.2）。

ベースライン時にモノアミン酸化酵素 B 阻害薬，イストラデフィリン，及びいずれかのアマンタジン製剤を使用していた被験者の割合は，投与群間でおおむね同程度であった（M15-736 試験 CSR Table 14.1__3.2.2）。試験期間中にドパミンアゴニストを使用した被験者の割合は，CD / LD 経口投与群と比較して ABBV-951 投与群の方がわずかに高かった。この割合はベースラインから試験期間を通して変化しなかった（M15-736 試験 CSR Table 14.1__3.2.5）。このことは，本試験デザインが，医学的に必要とされる場合を除き，二重盲検期中に被験者の併用薬を変更することを前提としなかったことから予期されていた。

非パーキンソン病治療の前治療薬及び併用療法の使用は，本試験対象集団で予期していたとおりであった。

曝露状況

別の記載がない限り，ABBV-951 用量の概要は，ホスレボドパを分子量に基づき LD に換算した LD 換算投与量として示す（ホスレボドパ 100 mg は LD 71 mg に相当）。

1 日規定投与量を表 5 に，経口 CD / LD 投与量及び規定注入速度を表 6 に示す。

ABBV-951 又はプラセボ溶液の CSCI のための各被験者の注入負荷投与量及び開始注入速度は，初回の朝の経口投与量及び経口 CD / LD 安定化期終了時の平均的な 1 日（覚醒時間 16 時間）を通して服用した CD / LD IR 製剤の総量，並びにホスレボドパにおける LD 分子量，薬物濃度，24 時間曝露時間及び薬物動態データを考慮した換算アルゴリズムによって計算した。

ABBV-951 は 1 日 24 時間持続投与されたため，予期したとおり，1 日あたりの規定投与量は ABBV-951 投与群と比較して CD / LD 経口投与群の方が低かった。また，同じく予期したとおり，最適化期終了時の ABBV-951 投与群の 1 日投与量は，換算アルゴリズム及び試験デザインによる当初の規定投与量よりもわずかに高かった。換算アルゴリズムは，24 時間にわたって運動症状を十分にコントロールできるホスレボドパの 1 時間あたりの開始注入速度を提供するようにデザインされている。従来のアプローチと同様に，過量投与によりジスキネジア又はその他の用量関連の有害事象を発現する被験者のリスクを適切に考慮して値を切り下げた。

各被験者の初期の最適化は，15 日以上注入速度の変更がなかったときに完了したとみなした。投与期間が 15 日以上であった ABBV-951 投与群の 55 例では，初期最適化のための来院回数の平均値は 2.4 回であった（M15-736 試験 CSR Table 14.1__7.2）。この 55 例のうち合計 40.0%が 1 回の来院で最適化を完了し，20.0%が 2 回の来院で最適化を完了した。

ABBV-951 投与群における開始注入速度から最初の維持注入速度，及び開始注入速度から最終の維持注入速度の変化量の平均値は，それぞれわずか 5.5 LD mg/hr 及び 4.7 LD mg/hr に相当し，用量換算アルゴリズムの正確度が確認された。

二重盲検期の LD の 1 日あたりの投与量を表 7 に，二重盲検期の救済薬投与を表 8 に示す。

非盲検 CD / LD IR 製剤は，救済療法として使用するために二重盲検期を通してすべての被験者に提供された。盲検化された溶液の CSCI と盲検化された経口カプセル剤の併用投与が開始された後は，1 時間を超えるポンプ故障又は運動症状の急速な悪化など，重大な医学的必要性がある場合にのみ救済療法を使用可能とした。被験者はこれらのデータを投与日誌に記録した。

ABBV-951 は 1 日 24 時間持続投与されたため，予期したとおり，1 日あたりの総投与量は ABBV-951 投与群と比較して CD / LD 経口投与群の方が低かった。救済薬の投与量の平均値は，おおむね，ABBV-951 投与群と比較して CD / LD 経口投与群の方がわずかに高かった。

各投与群についての 1 日あたりの総投与量の最頻値の分布を M15-736 試験 CSR Figure 2 に示す。1 日あたりの総投与量の最頻値は，ABBV-951 投与群及び CD / LD 経口投与群について盲検化された治験薬の実薬から導き出した。100 mg 間隔の LD 換算投与量で表した 1 日あたりの投与量の最頻値を各被験者について入手し，ABBV-951 投与群については被験者が実際に使用した注入速度及び被験者の注入期間から計算し，CD / LD 経口投与群については被験者が実際に服用した CD / LD IR 製剤の数から計算した。

1 日あたりの LD 換算投与量で約 600 mg から約 4250 mg までの範囲での ABBV-951 の投与量の分布は，第 I 相試験，並びに第 III 相試験である M15-741 試験及び M15-737 試験と同様であり，ABBV-951 が進行期パーキンソン病患者の多様な集団における運動症状を十分にコントロールするために必要な広範囲の LD 投与量をカバーできることが確認された。

二重盲検期の治験薬曝露期間を表 9 に示す。

被験者が盲検化された治験薬に曝露した日数の平均値は，ABBV-951 投与群で 62.4 日，CD / LD 経口投与群で 81.5 日であった。ABBV-951 投与群の被験者の合計 64.9%及び CD / LD 経口投与群の被験者の合計 94.0%は，盲検化された治験薬に 58 日以上曝露され，それぞれ 64.9%及び 92.5%の被験者が 12 週間の治療を完了した（表 2）。

全体で 42 例が注入を中断した（ABBV-951 投与群 22 例，CD / LD 経口投与群 20 例）（表 2）。複数回答を可とした注入中断の理由は，「その他」（24 例），ポンプ故障（12 例），有害事象（新型コロナウイルス感染症［以下「COVID-19」］感染でない）（10 例）及び COVID-19 感染（1 例）であった。注入中断理由「その他」の多くは，個人的な衛生 / シャワー若しくは水泳，偶発的なポンプの停止に気づかなかった，又は不注意でポンプの再起動を忘れたなどであった。

治験薬の中断日数の平均値は，ABBV-951 投与群の 22 例で 4.9 日，CD / LD 経口投与群の 19 例で 2.5 日であった。治験薬の中断期間は 1 日未満から 10 日以上までの日数間隔ごとに分類した。治験薬を中断した被験者の最も多くは 1 日未満の中断であった。

CD / LD 経口投与群の 1 例が COVID-19 のために 1 日治験薬を中断し，バーチャル環境で試験来院を行った（M15-736 試験 CSR Table 14.1__14）。COVID-19 のために数回の試験来院がバーチャル環境で実施されたが，来院が省略されたことはなかった（M15-736 試験 CSR Table 14.1__13）。

有効性の結果

主要評価項目

パーキンソン病日誌に基づく，標準化した 1 日あたりの平均オフ時間及びオン時間の要約を表 10 に示す。

主要評価項目は，パーキンソン病日誌に基づく日常生活に支障のあるジスキネジアを伴わない標準化した 1 日あたりの平均オン時間のベースラインから二重盲検期の投与 12 週時までの変化量（時間）とした。日常生活に支障のあるジスキネジアを伴わないオン時間は，ジスキネジアを伴わないオン時間と日常生活に支障のないジスキネジアを伴うオン時間の合計とした。

日常生活に支障のあるジスキネジアを伴わない平均オン時間のベースラインから投与 12 週時までの変化量において，CD / LD 経口投与群と比較して ABBV-951 投与群で統計学的に有意な改善が認められた。これらの改善は，ベースライン後の初回評価時点である投与 8 日目と早期から認められ，二重盲検期の終了の投与 12 週時まで持続した。CD / LD 経口投与群と比較した ABBV-951 投与群の改善は，被験者数が少なかった任意の来院である投与 22 日目を除き，すべての評価時点で nominal $P < 0.05$ であった。

日常生活に支障のあるジスキネジアを伴わない標準化した 1 日あたりの平均オン時間について，レスポンダーの定義は容認されていないが，最終来院時における日常生活に支障のあるジスキネジアを伴わない標準化した 1 日あたりの平均オン時間の少なくとも所定の改善割合（5%の増加幅で 0%から 100%まで）を示した被験者の割合は，CD / LD 経口投与群と比較して ABBV-951 投与群の方が各閾値で一貫して大きい改善を示した（M15-736 試験 CSR Figure 4）。

日常生活に支障のあるジスキネジアを伴わない標準化した 1 日あたりの平均オン時間のベースラインから投与 12 週時までの変化量の最小二乗平均（標準誤差）は，ABBV-951 投与群で 2.72（0.52）時間，CD / LD 経口投与群で 0.97（0.50）時間であり，群間差は 1.75 時間であった（$P = 0.0083$）。

主要評価項目について，年齢（65 歳未満又は 65 歳以上），性別（男性又は女性），人種（白人又はその他），実施国（米国又はオーストラリア），（診断からランダム化までの）パーキンソン病罹病期間（10 年未満又は 10 年以上），ドパミンアゴニスト併用の有無（はい又はいいえ），LD の用量（低用量又は高用量）の部分集団ごとに解析した。部分集団解析の結果は，性別，人種，実施国，パーキンソン病罹病期間，ドパミンアゴニスト併用の有無，又は LD の用量に関して，治療と部分集団の間の相互作用（$P \leq 0.10$ の場合に相互作用が予測される）を示唆しなかった（M15-736 試験 CSR Table 14.2__9.1 及び Figure 5）。治療と年齢の相互作用は $P = 0.0702$ であったが，両年齢層の投与群間差は ABBV-951 に有利であった。すべての部分集団について各層の投与群間差は有効性の主要解析の結果とおおむね一致していた。

副次評価項目

副次評価項目は，第 1 の主な副次評価項目，第 2 の主な副次評価項目，第 3 の主な副次評価項目，続いてその他の副次評価項目を固定順位で検定した。

主な副次評価項目

主な副次評価項目は以下のとおり：

- パーキンソン病日誌に基づく標準化した 1 日あたりの平均オフ時間のベースラインから二重盲検期の投与 12 週時までの変化量
- MDS-UPDRS Part II スコアにより評価した M-EDL のベースラインから二重盲検期の投与 12 週時までの変化量
- パーキンソン病日誌に基づく投与 12 週時の朝の無動（起床時以降に確認された最初の朝の症状としてのオフ状態）の有無

パーキンソン病日誌に基づく標準化した 1 日あたりの平均オフ時間

標準化した 1 日あたりの平均オフ時間は，CD / LD 経口投与群と比較して ABBV-951 投与群で統計学的に有意な改善が認められた。これらの改善は，ベースライン後の初回評価時点である投与 8 日目と早期から認められ，二重盲検期の終了の投与 12 週時まで持続した。CD / LD 経口投与群と比較した ABBV-951 投与群の改善は，被験者数が少なかった任意の来院である投与 22 日目を除き，すべての評価時点で nominal $P < 0.05$ であった（表 10）。

標準化した 1 日あたりの平均オフ時間のベースラインから投与 12 週時までの変化量の最小二乗平均（標準誤差）は，ABBV-951 投与群で–2.75（0.50）時間，CD / LD 経口投与群で–0.96（0.49）時間であり，群間差は–1.79 時間であった（$P = 0.0054$）。

標準化した 1 日あたりの平均オフ時間について，レスポンダーの定義は容認されていないが，最終来院時における標準化した 1 日あたりの平均オフ時間の少なくとも所定の改善割合（5%の増加幅で 0%から 100%まで）を示した被験者の割合は，CD / LD 経口投与群と比較して ABBV-951 投与群の方が各閾値で一貫して大きい改善を示した（M15-736 試験 CSR Figure 7）。オフ時間の 0%から 100%までの改善は，オフ時間が 100%減少し著効を達成した被験者を含む治療効果の全範囲を表すため，オフ時間に対するこの「レスポンダー解析」は，日常生活に支障のあるジスキネジアを伴わないオン時間に対する同様の解析よりも良好に治療効果を証明している。

MDS-UPDRS Part II により評価した M-EDL

MDS-UPDRS スコアを表 11 に示す。

投与 12 週時の M-EDL は，CD / LD 経口投与群と比較して ABBV-951 投与群で数値的な改善が認められたが，0.05 の統計学的有意水準は達成されなかった。

投与 12 週時における，MDS-UPDRS Part II スコアのベースラインからの変化量は，ABBV-951 投与群で–3.76，CD / LD 経口投与群で–0.48 であった。

パーキンソン病日誌に基づく朝の無動（起床時以降に観察された最初の朝の症状としてのオフ状態）

朝の無動を表 12 に，パーキンソン病日誌に基づく早朝覚醒時状態の分布を表 13 に示す。

ABBV-951 投与群では，CD / LD 経口投与群と比較して，朝の無動状態は改善（nominal $P \leq 0.001$）を示した。

朝の無動状態を呈する被験者の割合は，ベースライン時では ABBV-951 投与群で 78.9%，CD / LD 経口投与群で 76.1%，投与 12 週時では ABBV-951 投与群で 17.0%，CD / LD 経口投与群で 63.3%であった。

ABBV-951 投与群では，朝の無動状態を呈する被験者の割合はベースラインから大きく減少し，多くの被験者が ABBV-951 投与後に覚醒時のジスキネジアを伴わないオン状態を報告した。この改善は，ベースライン後の初回評価時点である投与 8 日目と早期から認められ，覚醒時のジスキネジアを伴わないオン状態を報告した被験者の割合は投与 12 週時まで増加した。

本試験デザインでは，経口 CD / LD 安定化期に経口 CD / LD の用量及びスケジュールを調節し，必要かつ被験者と治験責任医師が合意した場合に，経口治験薬の夜間投与を許容した。このことは直近の盲検下経口投与から最初の覚醒状態までの時間の平均値に反映され，投与 12 週時の ABBV-951 投与群と CD / LD 経口投与群で同様であった（M15-736 試験 CSR Table 14.2__4.3）。CD / LD 経口投与群では，直近の経口投与から非オフ状態までの時間の平均値は 4.48 時間（22 例），直近の経口投与からオフ状態までの時間の平均値は 5.63 時間（38 例）であった。

その他の副次評価項目

PDSS-2 スコアを表 14 に，PDQ-39 スコアを表 15 に，EQ-5D-5L スコアを表 16 に示す。

以下の 3 つのその他の副次評価項目において，ABBV-951 投与群で CD / LD 経口投与群と比較した改善が認められた（nominal $P < 0.05$）。

- パーキンソン病日誌に基づくジスキネジアを伴わない標準化した 1 日あたりの平均オン時間のベースラインから投与 12 週時までの変化量
- PDSS-2 合計スコアにより評価した睡眠症状のベースラインから最終来院日までの変化量
- PDQ-39 要約指標により評価したパーキンソン病に関連した生活の質のベースラインから最終来院日までの変化量

他の評価項目

パーキンソン病日誌

日常生活に支障のあるジスキネジアを伴わない標準化した 1 日あたりの平均オン時間のベースラインから投与 12 週時までの変化量（主要評価項目），標準化した 1 日あたりの平均オフ時間のベースラインから投与 12 週時までの変化量（第 1 の主な副次評価項目），及び投与 12 週時の朝の無動（起床時以降に確認された最初の朝の症状としてのオフ状態）（第 3 の主な副次評価項目）に加えて，以下のその他の有効性評価項目を，二重盲検期中にパーキンソン病日誌により評価した。

- 以下の標準化した 1 日あたりの平均の，ベースラインから投与 12 週時までの変化量
  - 日常生活に支障のないジスキネジアを伴うオン時間
  - 日常生活に支障のあるジスキネジアを伴うオン時間
- 以下の標準化した 1 日あたりの平均の，ベースラインから投与 12 週時までの変化率
  - オフ時間
  - 日常生活に支障のあるジスキネジアを伴わないオン時間
  - ジスキネジアを伴わないオン時間
  - 日常生活に支障のないジスキネジアを伴うオン時間
  - 日常生活に支障のあるジスキネジアを伴うオン時間
- 以下の 1 日あたりの絶対平均の，ベースラインから投与 12 週時までの変化量
  - オフ時間
  - 日常生活に支障のあるジスキネジアを伴わないオン時間
  - ジスキネジアを伴わないオン時間
  - 日常生活に支障のないジスキネジアを伴うオン時間
  - 日常生活に支障のあるジスキネジアを伴うオン時間
  - 睡眠時間

ABBV-951 投与は，標準化した 1 日あたりの平均オフ時間，及び比較的良好な状態である日常生活に支障のないジスキネジアを伴うオン時間の減少，並びに最も望ましい状態であるジスキネジアを伴わないオン時間の増加をもたらした（表 10）。ベースライン及び各来院時の，異なる運動症状で経過した時間の覚醒 16 時間に標準化した分布を M15-736 試験 CSR Figure 11 に示す。

様々な運動状態についての標準化したベースラインからの変化率及び絶対時間数のベースラインからの変化量の解析結果は，これらの運動状態の標準化したベースラインからの変化量の解析結果と一致していた（表 10，M15-736 試験 CSR Table 14.2__2.2 及び Table 14.2__2.3）。

MDS-UPDRS

MDS-UPDRS Part II スコアにおけるベースラインからの変化量（第 2 の主な副次評価項目）に加えて，二重盲検期のその他の有効性評価項目として MDS-UPDRS Part I，III 及び IV，並びに Part I から III の合計スコアにおけるベースラインから投与 12 週時までの変化量を評価した。ABBV-951 投与群では，CD / LD 経口投与群と比較して，投与 8 週時及び投与 12 週時の MDS-UPDRS Part IV スコアに改善が認められた（nominal $P < 0.05$）（表 11）。

PDSS-2

PDSS-2 合計スコアのベースラインから最終来院日までの変化量（副次評価項目）に加えて，二重盲検期のその他の有効性評価項目として PDSS-2 ドメインスコアのベースラインから最終来院日までの変化量を評価した。ABBV-951 投与群では，CD / LD 経口投与群と比較して，夜の運動症状及び睡眠障害のドメインスコアに改善が認められた（nominal $P < 0.05$）（表 14）。

PDQ-39

PDQ-39 要約指標のベースラインから最終来院日までの変化量（副次評価項目）に加えて，二重盲検期のその他の有効性評価項目として PDQ-39 ドメインスコアのベースラインから最終来院日までの変化量を評価した。ABBV-951 投与群では，CD / LD 経口投与群と比較して，可動性及びスティグマのドメインスコアに改善が認められた（nominal $P < 0.05$）（表 15）。

EQ-5D-5L

EQ-5D-5L 要約指標のベースラインから最終来院日までの変化量（副次評価項目）に加えて，二重盲検期のその他の有効性評価項目として EQ-5D-5L 視覚的評価尺度のベースラインから最終来院日までの変化量を評価した。ABBV-951 投与群では，CD / LD 経口投与群と比較して，視覚的評価尺度に改善が認められた（nominal $P < 0.05$）（表 16）。

安全性の結果

二重盲検期における有害事象の発現状況を以下に示す。

有害事象の発現割合は，ABBV-951 投与群 85.1%（63 / 74 例），CD / LD 経口投与群 62.7%（42 / 67 例）であった。有害事象の多くは非重篤であり，重症度は軽度又は中等度であった。

いずれかの投与群で発現割合が 5%以上の有害事象は，注入部位紅斑（ABBV-951 投与群 27.0%［20 / 74 例］，CD / LD 経口投与群 1.5%［1 / 67 例］，以下同順），注入部位疼痛（25.7%［19 / 74 例］，1.5%［1 / 67 例］），注入部位蜂巣炎（18.9%［14 / 74 例］，0%［0 / 67 例］），注入部位浮腫（12.2%［9 / 74 例］，0%［0 / 67 例］），ジスキネジア（10.8%［8 / 74 例］，6.0%［4 / 67 例］），転倒（8.1%［6 / 74 例］，17.9%［12 / 67 例］），注入部位内出血（8.1%［6 / 74 例］，3.0%［2 / 67 例］），注入部位出血（8.1%［6 / 74 例］，0%［0 / 67 例］），注入部位結節（8.1%［6 / 74 例］，0%［0 / 67 例］），オンオフ現象（8.1%［6 / 74 例］，0%［0 / 67 例］），幻覚（6.8%［5 / 74 例］，1.5%［1 / 67 例］），平衡障害（5.4%［4 / 74 例］，0%［0 / 67 例］），便秘（5.4%［4 / 74 例］，0%［0 / 67 例］），幻視（5.4%［4 / 74 例］，0%［0 / 67 例］），注入部位硬結（5.4%［4 / 74 例］，0%［0 / 67 例］），注入部位感染（5.4%［4 / 74 例］，0%［0 / 67 例］），注入部位そう痒感（5.4%［4 / 74 例］，0%［0 / 67 例］），及び末梢腫脹（5.4%［4 / 74 例］，0%［0 / 67 例］）であった。ABBV-951 投与群で発現割合が 10%以上の有害事象は，注入部位の有害事象（紅斑，疼痛，蜂巣炎，浮腫）及びジスキネジアであった。

治験薬と関連ありの有害事象の発現割合は，ABBV-951 投与群 70.3%（52 / 74 例），CD / LD 経口投与群 22.4%（15 / 67 例）であった。いずれかの投与群で発現割合が 10%以上の治験薬と関連ありの有害事象は，注入部位紅斑（ABBV-951 投与群 21.6%［16 / 74 例］，CD / LD 経口投与群 1.5%［1 / 67 例］，以下同順），注入部位疼痛（18.9%［14 / 74 例］，1.5%［1 / 67 例］），及び注入部位蜂巣炎（16.2%［12 / 74 例］，0%［0 / 67 例］）であった。

ABBV-951 投与群では死亡は報告されなかったが，CD / LD 経口投与群では急性呼吸不全による 1 件の死亡が報告された。

重篤な有害事象の発現割合は，ABBV-951 投与群 8.1%（6 / 74 例），CD / LD 経口投与群 6.0%（4 / 67 例）であった。いずれかの投与群で 2 例以上に発現した重篤な有害事象はなかった。

中止に至った有害事象の発現割合は，ABBV-951 投与群 21.6%（16 / 74 例），CD / LD 経口投与群 1.5%（1 / 67 例）であった。いずれかの投与群で 2 例以上に発現した中止に至った有害事象は，注入部位蜂巣炎（ABBV-951 投与群 5.4%［4 / 74 例］，CD / LD 経口投与群 0%［0 / 67 例］，以下同順），注入部位疼痛（4.1%［3 / 74 例］，0%［0 / 67 例］），注入部位内出血（2.7%［2 / 74 例］，0%［0 / 67 例］），注入部位出血（2.7%［2 / 74 例］，0%［0 / 67 例］），及び注入部位浮腫（2.7%［2 / 74 例］，0%［0 / 67 例］）であった。

年齢，性別，体格指数，人種，実施国，ドパニンアゴニストの併用の有無，LD の用量，又はパーキンソン病罹病期間の部分集団別の有害事象の解析では，各投与期にわたって ABBV-951 投与群と CD / LD 経口投与群の間に意味のある差は認められなかった。

注入部位の事象の発現割合は，CD / LD 経口投与群と比較して ABBV-951 投与群の方が高かった。注入部位非感染反応は ABBV-951 投与群で 62.2%（46 / 74 例），CD / LD 経口投与群で 7.5%（5 / 67 例），注入部位感染は ABBV-951 投与群で 28.4%（21 / 74 例），CD / LD 経口投与群で 3.0%（2 / 67 例）に報告された。各投与群の多くの被験者において，注入部位の有害事象は

非重篤で，重症度は軽度又は中等度であり，回復した。いくつかの事象で治療を要したが，全身性の合併症に至ったものはなかった。

幻覚 / 精神病の事象の発現割合は，CD / LD 経口投与群と比較して ABBV-951 投与群の方が高かったが，これらの事象の多くは非重篤で，重症度は軽度又は中等度であり，他の CD / LD 製剤を投与されている進行期パーキンソン病患者において一般に予期されるものと一致していた。

転倒及び関連する損傷の発現割合は，ABBV-951 投与群と比較して CD / LD 経口投与群の方が高かった。

臨床検査値，バイタルサイン又は心電図について，臨床的に意義のあるベースラインからの変化は認められなかった。C-SSRS データのレビューに基づき，ABBV-951 投与による自殺行動の増加は認められなかった。QUIP-RS スコアに臨床的に意義のあるベースラインからの変化は認められなかった。

本試験で二重盲検期に発現した有害事象を以下のとおり示す。

項目	
二重盲検期に発現した有害事象の概要	表 17
二重盲検期に発現したすべての有害事象	表 18
二重盲検期に発現した治験薬との因果関係別の有害事象	表 19
死亡した被験者一覧	表 20
二重盲検期に発現した重篤な有害事象	表 21
二重盲検期に発現した中止に至った有害事象	表 22

結論

ABBV-951 は，日常生活に支障のあるジスキネジアを伴わないオン時間及び 1 日を通してのオフ時間において統計学的に有意かつ臨床的に意義のある改善を示しており，進行期パーキンソン病患者の運動症状の日内変動の治療として経口 CD / LD より優れていた。これらの改善は，主に，最も望ましい状態であるジスキネジアを伴わないオン時間への移行によるもので，ベースライン後の初回評価で観察され，二重盲検期の終了時である投与 12 週時まで持続した。

経口 CD / LD と比較して，ABBV-951 で観察された朝の無動状態の改善及び睡眠症状の臨床的に意義のある改善は，ABBV-951 の 24 時間使用の予期されたベネフィットと一致している。

ABBV-951 はおおむね安全であり，忍容性は良好であった。ABBV-951 投与で観察された注入部位の事象の大半は非重篤で，重症度は軽度又は中等度であり，回復した。ABBV-951 の全身の安全性プロファイルは，CD / LD 薬剤の確立された安全性プロファイルとおおむね一致していた。

全体として，M15-736 試験のデータは，進行期パーキンソン病患者における ABBV-951 の良好なベネフィット / リスクプロファイルを裏付けている。

表2　被験者の内訳（All Screened Subjects）：M15-736試験

[redacted]20[redacted] 19:30 <[redacted]>
ABBV-951
STUDY M15-736
R&D/20/1640 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 7

TABLE 14.1__1.1

Subject Disposition
(All Screened Subjects)

	Randomized and Received any Blinded Study Drug								
	Oral CD/LD			ABBV-951			Total	Total Randomized	Total Screened
	Low Dose (N=56) n (%)	High Dose (N=11) n (%)	All (N=67) n (%)	Low Dose (N=45) n (%)	High Dose (N=29) n (%)	All (N=74) n (%)	(N=141) n (%)	(N=145) n (%)	(N=270) n (%)
Total subject screened									270 (100)
Total subject screened failed									96 (35.6)
By primary reason									
Eligibility criteria									50 (18.5)
Withdrew consent									36 (13.3)
Lost to follow-up									6 (2.2)
COVID-19 infection									0
COVID-19 logistical restrictions									0
Other									4 (1.5)
By all reasons									
Eligibility criteria									60 (22.2)
Withdrew consent									45 (16.7)
Lost to follow-up									6 (2.2)
COVID-19 infection									0
COVID-19 logistical restrictions									0
Other									9 (3.3)

Note: One subject can be counted multiple times.

Program Source Code: [redacted]

TABLE 14.1 1.1

Subject Disposition
(All Screened Subjects)

	Randomized and Received any Blinded Study Drug								
	Oral CD/LD			ABBV-951				Total	Total
	Low Dose (N=56) n (%)	High Dose (N=11) n (%)	All (N=67) n (%)	Low Dose (N=45) n (%)	High Dose (N=29) n (%)	All (N=74) n (%)	Total (N=141) n (%)	Randomized (N=145) n (%)	Screened (N=270) n (%)
Oral CD/LD stabilization period									
Total enrolled									174 (64.4)
Study prematurely discontinued									29 (10.7)
By primary reason for study discontinuation									
Adverse event									3 (1.1)
Withdrew consent									4 (1.5)
Lost to follow-up									1 (0.4)
Lack of efficacy									1 (0.4)
COVID-19 infection									0
COVID-19 logistical restrictions									0
Difficulty with Drug Delivery System									2 (0.7)
Other									18 (6.7)

Note: One subject can be counted multiple times.

Program Source Code: [redacted]

TABLE 14.1 1.1

Subject Disposition
(All Screened Subjects)

	Randomized and Received any Blinded Study Drug								
	Oral CD/LD			ABBV-951				Total	Total
	Low Dose (N=56) n (%)	High Dose (N=11) n (%)	All (N=67) n (%)	Low Dose (N=45) n (%)	High Dose (N=29) n (%)	All (N=74) n (%)	Total (N=141) n (%)	Randomized (N=145) n (%)	Screened (N=270) n (%)
Oral CD/LD stabilization period (Cont.)									
By all reasons for study discontinuation									
Adverse event									3 (1.1)
Withdrew consent									4 (1.5)
Lost to follow-up									1 (0.4)
Lack of efficacy									1 (0.4)
COVID-19 infection									0
COVID-19 logistical restrictions									0
Difficulty with Drug Delivery System									2 (0.7)
Other									18 (6.7)
Double-Blind treatment period									
Total randomized								145 (100)	
Randomized but not receive any blinded study drug									4 (1.5)
Took any blinded study drug	56 (100)	11 (100)	67 (100)	45 (100)	29 (100)	74 (100)	141 (100)		

Note: One subject can be counted multiple times.

Program Source Code: [redacted]

TABLE 14.1 1.1

Subject Disposition
(All Screened Subjects)

	Randomized and Received any Blinded Study Drug								
	Oral CD/LD			ABBV-951				Total	Total
	Low Dose (N=56) n (%)	High Dose (N=11) n (%)	All (N=67) n (%)	Low Dose (N=45) n (%)	High Dose (N=29) n (%)	All (N=74) n (%)	Total (N=141) n (%)	Randomized (N=145) n (%)	Screened (N=270) n (%)
Double-Blind treatment period (Cont.)									
Total completed	51 (91.1)	11 (100)	62 (92.5)	28 (62.2)	20 (69.0)	48 (64.9)	110 (78.0)		
Study drug prematurely discontinued	5 (8.9)	0	5 (7.5)	17 (37.8)	9 (31.0)	26 (35.1)	31 (22.0)		
By primary reason for study drug discontinuation									
Adverse event	1 (1.8)	0	1 (1.5)	11 (24.4)	3 (10.3)	14 (18.9)	15 (10.6)		
Infusion site related infections	1 (1.8)	0	1 (1.5)	3 (6.7)	1 (3.4)	4 (5.4)	5 (3.5)		
Infusion site related non infection reactions	0	0	0	6 (13.3)	0	6 (8.1)	6 (4.3)		
Polyneuropathy	0	0	0	0	0	0	0		
Weight loss	0	0	0	0	0	0	0		
Hallucinations/psychosis	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)		
Somnolence	0	0	0	0	0	0	0		
Falls and associated injuries	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)		
Withdrew consent	3 (5.4)	0	3 (4.5)	4 (8.9)	1 (3.4)	5 (6.8)	8 (5.7)		
Lost to follow-up	0	0	0	0	0	0	0		
Lack of efficacy	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)		
COVID-19 infection	0	0	0	0	0	0	0		
COVID-19 logistical restrictions	0	0	0	0	0	0	0		
Difficulty with Drug Delivery System	1 (1.8)	0	1 (1.5)	2 (4.4)	2 (6.9)	4 (5.4)	5 (3.5)		
Other	0	0	0	0	2 (6.9)	2 (2.7)	2 (1.4)		

Note: One subject can be counted multiple times.

Program Source Code: [redacted]

TABLE 14.1 1.1

Subject Disposition
(All Screened Subjects)

	Randomized and Received any Blinded Study Drug								
	Oral CD/LD			ABBV-951				Total	Total
	Low Dose (N=56) n (%)	High Dose (N=11) n (%)	All (N=67) n (%)	Low Dose (N=45) n (%)	High Dose (N=29) n (%)	All (N=74) n (%)	Total (N=141) n (%)	Randomized (N=145) n (%)	Screened (N=270) n (%)
Double-Blind treatment period (Cont.)									
By all reasons for study drug discontinuation									
Adverse event	1 (1.8)	0	1 (1.5)	12 (26.7)	4 (13.8)	16 (21.6)	17 (12.1)		
Infusion site related infections	1 (1.8)	0	1 (1.5)	3 (6.7)	1 (3.4)	4 (5.4)	5 (3.5)		
Infusion site related non infection reactions	0	0	0	7 (15.6)	0	7 (9.5)	7 (5.0)		
Polyneuropathy	0	0	0	0	0	0	0		
Weight loss	0	0	0	0	0	0	0		
Hallucinations/psychosis	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)		
Somnolence	0	0	0	0	0	0	0		
Falls and associated injuries	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)		
Withdrew consent	3 (5.4)	0	3 (4.5)	5 (11.1)	1 (3.4)	6 (8.1)	9 (6.4)		
Lost to follow-up	0	0	0	0	0	0	0		
Lack of efficacy	1 (1.8)	0	1 (1.5)	0	5 (17.2)	5 (6.8)	6 (4.3)		
COVID-19 infection	0	0	0	0	0	0	0		
COVID-19 logistical restrictions	0	0	0	0	0	0	0		
Difficulty with Drug Delivery System	2 (3.6)	0	2 (3.0)	2 (4.4)	3 (10.3)	5 (6.8)	7 (5.0)		
Other	0	0	0	0	3 (10.3)	3 (4.1)	3 (2.1)		

Note: One subject can be counted multiple times.

Program Source Code: [redacted]

TABLE 14.1 1.1

Subject Disposition
(All Screened Subjects)

	Randomized and Received any Blinded Study Drug								
	Oral CD/LD			ABBV-951				Total	Total
	Low Dose (N=56) n (%)	High Dose (N=11) n (%)	All (N=67) n (%)	Low Dose (N=45) n (%)	High Dose (N=29) n (%)	All (N=74) n (%)	Total (N=141) n (%)	Randomized (N=145) n (%)	Screened (N=270) n (%)
Double-Blind treatment period (Cont.)									
Study prematurely discontinued	5 (8.9)	0	5 (7.5)	17 (37.8)	9 (31.0)	26 (35.1)	31 (22.0)		
By primary reason for study discontinuation									
Adverse event	1 (1.8)	0	1 (1.5)	11 (24.4)	3 (10.3)	14 (18.9)	15 (10.6)		
Withdrew consent	3 (5.4)	0	3 (4.5)	5 (11.1)	1 (3.4)	6 (8.1)	9 (6.4)		
Lost to follow-up	0	0	0	0	0	0	0		
Lack of efficacy	0	0	0	0	2 (6.9)	2 (2.7)	2 (1.4)		
COVID-19 infection	0	0	0	0	0	0	0		
COVID-19 logistical restrictions	0	0	0	0	0	0	0		
Difficulty with Drug Delivery System	1 (1.8)	0	1 (1.5)	1 (2.2)	2 (6.9)	3 (4.1)	4 (2.8)		
Other	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)		
By all reasons for study discontinuation									
Adverse event	1 (1.8)	0	1 (1.5)	12 (26.7)	3 (10.3)	15 (20.3)	16 (11.3)		
Withdrew consent	3 (5.4)	0	3 (4.5)	6 (13.3)	1 (3.4)	7 (9.5)	10 (7.1)		
Lost to follow-up	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)		
Lack of efficacy	1 (1.8)	0	1 (1.5)	0	4 (13.8)	4 (5.4)	5 (3.5)		
COVID-19 infection	0	0	0	0	0	0	0		
COVID-19 logistical restrictions	0	0	0	0	0	0	0		
Difficulty with Drug Delivery System	2 (3.6)	0	2 (3.0)	1 (2.2)	3 (10.3)	4 (5.4)	6 (4.3)		
Other	0	0	0	0	2 (6.9)	2 (2.7)	2 (1.4)		

Note: One subject can be counted multiple times.

Program Source Code: [redacted]

TABLE 14.1 1.1

Subject Disposition
(All Screened Subjects)

	Randomized and Received any Blinded Study Drug								
	Oral CD/LD			ABBV-951				Total	Total
	Low Dose (N=56) n (%)	High Dose (N=11) n (%)	All (N=67) n (%)	Low Dose (N=45) n (%)	High Dose (N=29) n (%)	All (N=74) n (%)	Total (N=141) n (%)	Randomized (N=145) n (%)	Screened (N=270) n (%)
Double-Blind treatment period (Cont.)									
Total infusion interruptions	17 (30.4)	3 (27.3)	20 (29.9)	15 (33.3)	7 (24.1)	22 (29.7)	42 (29.8)		
Reasons for infusion interruptions									
COVID-19 infection	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)		
COVID-19 logistical restrictions	0	0	0	0	0	0	0		
Pump malfunction	5 (8.9)	1 (9.1)	6 (9.0)	4 (8.9)	2 (6.9)	6 (8.1)	12 (8.5)		
Adverse event (not COVID-19 infection)	1 (1.8)	0	1 (1.5)	6 (13.3)	3 (10.3)	9 (12.2)	10 (7.1)		
Other	11 (19.6)	2 (18.2)	13 (19.4)	7 (15.6)	4 (13.8)	11 (14.9)	24 (17.0)		
Analysis population									
Oral CD/LD analysis set									174 (64.4)
Full analysis set	56 (100)	11 (100)	67 (100)	45 (100)	29 (100)	74 (100)	141 (100)		
Safety analysis set	56 (100)	11 (100)	67 (100)	45 (100)	29 (100)	74 (100)	141 (100)		

Note: One subject can be counted multiple times.

Program Source Code: [redacted]

表3　人口統計学的特性及びその他のベースラインの特性（安全性解析対象集団）：M15-736試験

[redacted]20[redacted] 19:30 <[redacted]>
ABBV-951
STUDY M15-736
R&D/20/1640 - CLINICAL/STATISTICAL

TABLE 14.1__2.1

Demographic and Baseline Characteristics
(Safety Analysis Set)

	Oral CD/LD			ABBV-951			
	Low Dose (N=56)	High Dose (N=11)	All (N=67)	Low Dose (N=45)	High Dose (N=29)	All (N=74)	Total (N=141)
Age (years)							
n	56	11	67	45	29	74	141
Mean (SD)	67.6 (9.51)	61.9 (10.44)	66.6 (9.82)	66.6 (10.11)	65.8 (7.73)	66.3 (9.20)	66.4 (9.47)
Median	69.0	60.0	69.0	68.0	66.0	67.0	68.0
Min, Max	45, 85	45, 78	45, 85	39, 83	47, 81	39, 83	39, 85
Age Category - n (%)							
< 50 Years	2 (3.6)	2 (18.2)	4 (6.0)	2 (4.4)	1 (3.4)	3 (4.1)	7 (5.0)
50 - < 65 Years	15 (26.8)	5 (45.5)	20 (29.9)	12 (26.7)	12 (41.4)	24 (32.4)	44 (31.2)
65 - < 75 Years	24 (42.9)	3 (27.3)	27 (40.3)	21 (46.7)	11 (37.9)	32 (43.2)	59 (41.8)
>= 75 Years	15 (26.8)	1 (9.1)	16 (23.9)	10 (22.2)	5 (17.2)	15 (20.3)	31 (22.0)
Weight (kg)							
n	56	11	67	45	29	74	141
Mean (SD)	80.52 (16.737)	88.59 (24.791)	81.85 (18.320)	78.14 (17.236)	81.79 (19.408)	79.57 (18.077)	80.65 (18.164)
Median	79.45	82.55	79.60	76.57	84.00	80.04	79.79
Min, Max	51.3, 130.2	57.8, 138.2	51.3, 138.2	39.1, 125.8	42.6, 142.6	39.1, 142.6	39.1, 142.6
Height (cm)							
n	56	10	66	44	28	72	138
Mean (SD)	172.58 (9.631)	173.12 (10.379)	172.66 (9.666)	172.52 (10.281)	173.42 (11.419)	172.87 (10.667)	172.77 (10.164)
Median	175.26	172.00	175.10	172.70	175.15	172.86	174.00
Min, Max	147.3, 192.0	162.0, 193.0	147.3, 193.0	154.5, 198.1	150.1, 190.5	150.1, 198.1	147.3, 198.1
BMI (kg/m^2)							
n	56	10	66	44	28	72	138
Mean (SD)	26.99 (4.987)	30.16 (9.429)	27.47 (5.888)	26.15 (4.944)	27.33 (6.149)	26.61 (5.433)	27.02 (5.651)
Median	26.34	27.34	26.34	25.78	26.37	26.31	26.34
Min, Max	19.1, 43.9	19.8, 45.5	19.1, 45.5	15.3, 42.2	16.7, 43.3	15.3, 43.3	15.3, 45.5

Note: For categorical variables, 'Missing' row is only presented when there are missing data presented.

Program Source Code: [redacted]

TABLE 14.1 2.1

Demographic and Baseline Characteristics
(Safety Analysis Set)

	Oral CD/LD			ABBV-951			
	Low Dose (N=56)	High Dose (N=11)	All (N=67)	Low Dose (N=45)	High Dose (N=29)	All (N=74)	Total (N=141)
BMI Category - n (%)							
< 18.5	0	0	0	1 (2.3)	1 (3.6)	2 (2.8)	2 (1.4)
18.5 - < 25.0	22 (39.3)	5 (50.0)	27 (40.9)	20 (45.5)	8 (28.6)	28 (38.9)	55 (39.9)
25.0 - < 30.0	19 (33.9)	0	19 (28.8)	13 (29.5)	11 (39.3)	24 (33.3)	43 (31.2)
>= 30.0	15 (26.8)	5 (50.0)	20 (30.3)	10 (22.7)	8 (28.6)	18 (25.0)	38 (27.5)
Missing	0	1	1	1	1	2	3
Mini-Mental State Examination (MMSE) total score							
n	55	11	66	45	29	74	140
Mean (SD)	28.84 (1.229)	28.82 (1.537)	28.83 (1.272)	28.62 (1.723)	28.86 (1.407)	28.72 (1.601)	28.77 (1.451)
Median	29.00	29.00	29.00	29.00	29.00	29.00	29.00
Min, Max	24.0, 30.0	26.0, 30.0	24.0, 30.0	24.0, 30.0	25.0, 30.0	24.0, 30.0	24.0, 30.0
Country - n (%)							
Australia	8 (14.3)	1 (9.1)	9 (13.4)	6 (13.3)	6 (20.7)	12 (16.2)	21 (14.9)
United States	48 (85.7)	10 (90.9)	58 (86.6)	39 (86.7)	23 (79.3)	62 (83.8)	120 (85.1)
Sex - n (%)							
Male	39 (69.6)	10 (90.9)	49 (73.1)	30 (66.7)	20 (69.0)	50 (67.6)	99 (70.2)
Female	17 (30.4)	1 (9.1)	18 (26.9)	15 (33.3)	9 (31.0)	24 (32.4)	42 (29.8)
Ethnicity - n (%)							
Hispanic or Latino	1 (1.8)	0	1 (1.5)	1 (2.2)	3 (10.3)	4 (5.4)	5 (3.5)
Not Hispanic or Latino	55 (98.2)	11 (100)	66 (98.5)	44 (97.8)	26 (89.7)	70 (94.6)	136 (96.5)

Note: For categorical variables, 'Missing' row is only presented when there are missing data presented.

Program Source Code: [redacted]

TABLE 14.1 2.1

Demographic and Baseline Characteristics
(Safety Analysis Set)

	Oral CD/LD			ABBV-951			
	Low Dose (N=56)	High Dose (N=11)	All (N=67)	Low Dose (N=45)	High Dose (N=29)	All (N=74)	Total (N=141)
Race - n (%)							
White	52 (92.9)	9 (81.8)	61 (91.0)	42 (93.3)	28 (96.6)	70 (94.6)	131 (92.9)
Black or African American	2 (3.6)	0	2 (3.0)	2 (4.4)	0	2 (2.7)	4 (2.8)
Asian	1 (1.8)	2 (18.2)	3 (4.5)	0	0	0	3 (2.1)
American Indian or Alaska Native	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Native Hawaiian or Other Pacific Islander	1 (1.8)	0	1 (1.5)	0	1 (3.4)	1 (1.4)	2 (1.4)
Tobacco - n (%)							
Current	5 (8.9)	0	5 (7.5)	2 (4.4)	1 (3.4)	3 (4.1)	8 (5.7)
Former	21 (37.5)	2 (18.2)	23 (34.3)	12 (26.7)	12 (41.4)	24 (32.4)	47 (33.3)
Never	30 (53.6)	9 (81.8)	39 (58.2)	31 (68.9)	16 (55.2)	47 (63.5)	86 (61.0)
Unknown	0	0	0	0	0	0	0
Alcohol - n (%)							
Current	35 (62.5)	4 (36.4)	39 (58.2)	24 (53.3)	14 (48.3)	38 (51.4)	77 (54.6)
Former	9 (16.1)	6 (54.5)	15 (22.4)	8 (17.8)	10 (34.5)	18 (24.3)	33 (23.4)
Never	12 (21.4)	1 (9.1)	13 (19.4)	13 (28.9)	5 (17.2)	18 (24.3)	31 (22.0)
Unknown	0	0	0	0	0	0	0
Brief neurological examination							
Mental status - n (%)							
Normal	56 (100)	10 (90.9)	66 (98.5)	43 (95.6)	28 (96.6)	71 (95.9)	137 (97.2)
Abnormal	0	1 (9.1)	1 (1.5)	2 (4.4)	1 (3.4)	3 (4.1)	4 (2.8)
Cranial nerves - n (%)							
Normal	51 (91.1)	10 (90.9)	61 (91.0)	39 (86.7)	29 (100)	68 (91.9)	129 (91.5)
Abnormal	5 (8.9)	1 (9.1)	6 (9.0)	6 (13.3)	0	6 (8.1)	12 (8.5)

Note: For categorical variables, 'Missing' row is only presented when there are missing data presented.

Program Source Code: [redacted]

TABLE 14.1 2.1

Demographic and Baseline Characteristics
(Safety Analysis Set)

	Oral CD/LD			ABBV-951			
	Low Dose (N=56)	High Dose (N=11)	All (N=67)	Low Dose (N=45)	High Dose (N=29)	All (N=74)	Total (N=141)
Motor system - n (%)							
Normal	29 (51.8)	8 (72.7)	37 (55.2)	26 (57.8)	13 (44.8)	39 (52.7)	76 (53.9)
Abnormal	27 (48.2)	3 (27.3)	30 (44.8)	19 (42.2)	16 (55.2)	35 (47.3)	65 (46.1)
Sensory system - n (%)							
Normal	51 (91.1)	11 (100)	62 (92.5)	40 (88.9)	26 (89.7)	66 (89.2)	128 (90.8)
Abnormal	5 (8.9)	0	5 (7.5)	5 (11.1)	3 (10.3)	8 (10.8)	13 (9.2)
Reflexes - n (%)							
Normal	45 (80.4)	10 (90.9)	55 (82.1)	38 (84.4)	23 (79.3)	61 (82.4)	116 (82.3)
Abnormal	11 (19.6)	1 (9.1)	12 (17.9)	7 (15.6)	6 (20.7)	13 (17.6)	25 (17.7)
Coordination - n (%)							
Normal	38 (67.9)	6 (54.5)	44 (65.7)	34 (75.6)	23 (79.3)	57 (77.0)	101 (71.6)
Abnormal	18 (32.1)	5 (45.5)	23 (34.3)	11 (24.4)	6 (20.7)	17 (23.0)	40 (28.4)
Gait - n (%)							
Normal	24 (42.9)	3 (27.3)	27 (40.3)	20 (44.4)	10 (34.5)	30 (40.5)	57 (40.4)
Abnormal	32 (57.1)	8 (72.7)	40 (59.7)	25 (55.6)	19 (65.5)	44 (59.5)	84 (59.6)
Station - n (%)							
Normal	42 (76.4)	9 (81.8)	51 (77.3)	37 (82.2)	24 (82.8)	61 (82.4)	112 (80.0)
Abnormal	13 (23.6)	2 (18.2)	15 (22.7)	8 (17.8)	5 (17.2)	13 (17.6)	28 (20.0)
Missing	1	0	1	0	0	0	1
Concomitant dopamine agonist use - n (%)							
Yes	22 (39.3)	3 (27.3)	25 (37.3)	21 (46.7)	13 (44.8)	34 (45.9)	59 (41.8)
No	34 (60.7)	8 (72.7)	42 (62.7)	24 (53.3)	16 (55.2)	40 (54.1)	82 (58.2)

Note: For categorical variables, 'Missing' row is only presented when there are missing data presented.

Program Source Code: [redacted]

表4　パーキンソン病の病歴（安全性解析対象集団）：M15-736試験

[redacted]20[redacted] 19:30 <[redacted]>
ABBV-951
STUDY M15-736
R&D/20/1640 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 3

TABLE 14.1__3.1

Parkinson's Disease History
(Safety Analysis Set)

	Oral CD/LD			ABBV-951			
	Low Dose (N=56) n (%)	High Dose (N=11) n (%)	All (N=67) n (%)	Low Dose (N=45) n (%)	High Dose (N=29) n (%)	All (N=74) n (%)	Total (N=141) n (%)
Duration of PD since diagnosis							
< 10 years	38 (67.9)	6 (54.5)	44 (65.7)	35 (77.8)	16 (55.2)	51 (68.9)	95 (67.4)
>= 10 years	18 (32.1)	5 (45.5)	23 (34.3)	10 (22.2)	13 (44.8)	23 (31.1)	46 (32.6)
History of levodopa induced dyskinesia							
Yes	35 (62.5)	8 (72.7)	43 (64.2)	30 (66.7)	15 (51.7)	45 (60.8)	88 (62.4)
No	21 (37.5)	3 (27.3)	24 (35.8)	15 (33.3)	14 (48.3)	29 (39.2)	53 (37.6)
Missing	0	0	0	0	0	0	0
Levodopa response of more than 5 years							
Yes	38 (67.9)	8 (72.7)	46 (68.7)	30 (66.7)	27 (93.1)	57 (77.0)	103 (73.0)
No	18 (32.1)	3 (27.3)	21 (31.3)	15 (33.3)	2 (6.9)	17 (23.0)	38 (27.0)
Missing	0	0	0	0	0	0	0
Baseline Parkinson's Disease Hoehn and Yahr Stage (MDS-UPDRS)							
0	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
1	3 (5.4)	1 (9.1)	4 (6.0)	5 (11.1)	4 (13.8)	9 (12.2)	13 (9.2)
2	38 (67.9)	7 (63.6)	45 (67.2)	26 (57.8)	17 (58.6)	43 (58.1)	88 (62.4)
3	11 (19.6)	3 (27.3)	14 (20.9)	12 (26.7)	8 (27.6)	20 (27.0)	34 (24.1)
4	2 (3.6)	0	2 (3.0)	2 (4.4)	0	2 (2.7)	4 (2.8)
5	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)

Note: * Duration and time are duration and time since onset or diagnosis to randomization.

Program Source Code: [redacted]

TABLE 14.1 3.1

Parkinson's Disease History
(Safety Analysis Set)

	Oral CD/LD			ABBV-951			
	Low Dose (N=56) n (%)	High Dose (N=11) n (%)	All (N=67) n (%)	Low Dose (N=45) n (%)	High Dose (N=29) n (%)	All (N=74) n (%)	Total (N=141) n (%)
Age at onset, year							
n	56	11	67	45	29	74	141
Mean (SD)	57.0 (12.64)	51.7 (9.31)	56.1 (12.25)	56.8 (10.70)	54.3 (8.24)	55.8 (9.83)	56.0 (11.01)
Median	59.1	50.5	57.0	59.0	55.9	57.0	57.0
Min, Max	24, 78	38, 68	24, 78	31, 75	36, 68	31, 75	24, 78
Duration of PD (time* since onset), year							
n	56	11	67	45	29	74	141
Mean (SD)	10.93 (6.840)	10.46 (4.892)	10.85 (6.531)	10.10 (4.207)	11.74 (5.247)	10.75 (4.677)	10.80 (5.614)
Median	10.27	10.17	10.19	9.40	11.27	9.43	9.65
Min, Max	2.0, 36.5	4.2, 21.4	2.0, 36.5	2.5, 22.3	6.4, 31.5	2.5, 31.5	2.0, 36.5
Age at first diagnosis by a physician, year							
n	56	11	67	45	29	74	141
Mean (SD)	59.1 (11.95)	53.4 (8.60)	58.2 (11.61)	59.2 (9.89)	56.7 (7.29)	58.2 (8.99)	58.2 (10.28)
Median	60.8	53.0	59.3	61.0	56.9	58.9	59.0
Min, Max	30, 82	40, 70	30, 82	33, 77	43, 71	33, 77	30, 82
Duration* of PD since first diagnosis by a physician, year							
n	56	11	67	45	29	74	141
Mean (SD)	8.79 (5.769)	8.78 (3.955)	8.79 (5.486)	7.75 (4.244)	9.36 (4.070)	8.38 (4.224)	8.58 (4.851)
Median	8.33	8.76	8.45	6.72	8.47	7.28	8.11
Min, Max	1.0, 25.4	3.3, 15.2	1.0, 25.4	1.2, 18.3	4.7, 17.3	1.2, 18.3	1.0, 25.4

Note: * Duration and time are duration and time since onset or diagnosis to randomization.

Program Source Code: [redacted]

TABLE 14.1 3.1

Parkinson's Disease History
(Safety Analysis Set)

	Oral CD/LD			ABBV-951			
	Low Dose (N=56) n (%)	High Dose (N=11) n (%)	All (N=67) n (%)	Low Dose (N=45) n (%)	High Dose (N=29) n (%)	All (N=74) n (%)	Total (N=141) n (%)
Age at onset of motor fluctuation, year							
n	56	11	67	45	29	74	141
Mean (SD)	62.3 (10.69)	57.0 (8.47)	61.4 (10.48)	61.3 (9.77)	60.6 (8.63)	61.0 (9.29)	61.2 (9.84)
Median	62.6	56.0	62.0	63.0	61.0	63.0	62.2
Min, Max	34, 80	43, 68	34, 80	37, 80	41, 75	37, 80	34, 80
Duration since onset of motor fluctuation, year							
n	56	11	67	45	29	74	141
Mean (SD)	5.63 (4.337)	5.17 (2.742)	5.56 (4.104)	5.64 (3.896)	5.52 (3.831)	5.59 (3.845)	5.57 (3.956)
Median	4.33	4.23	4.25	5.08	4.49	4.80	4.47
Min, Max	0.5, 19.3	2.4, 10.7	0.5, 19.3	0.3, 18.2	1.2, 17.7	0.3, 18.2	0.3, 19.3

Note: * Duration and time are duration and time since onset or diagnosis to randomization.

Program Source Code: [redacted]

表5　1日規定投与量（安全性解析対象集団）：M15-736試験

[redacted]20[redacted] 19:30 <[redacted]>
ABBV-951
STUDY M15-736
R&D/20/1640 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 5

TABLE 14.1__6.1

Daily Prescribed Dose
(Safety Analysis Set)

	Oral CD/LD			ABBV-951		
	Low Dose (N=56)	High Dose (N=11)	All (N=67)	Low Dose (N=45)	High Dose (N=29)	All (N=74)
Loading Dose on Day 1 - Levodopa (mg LD)						
n				45	29	74
Mean (SD)				168.5 (56.58)	252.6 (69.42)	201.4 (74.08)
Median				187.8	273.2	187.8
Min, Max				85.4, 273.2	187.8, 375.7	85.4, 375.7
Loading Dose Volume - n (%)						
0.0 mL				0	0	0
0.5 mL				6 (13.3)	0	6 (8.1)
0.6 mL				8 (17.8)	0	8 (10.8)
1.1 mL				26 (57.8)	13 (44.8)	39 (52.7)
1.6 mL				5 (11.1)	11 (37.9)	16 (21.6)
2.2 mL				0	5 (17.2)	5 (6.8)
Missing				0	0	0
ABBV-951 Continuous Infusion Rate - LD mg/hr						
Initial CSCI Prescription						
n				45	29	74
Mean (SD)				48.8 (12.79)	95.6 (32.56)	67.1 (32.15)
Median				46.1	85.4	58.1
Min, Max				27.3, 85.4	58.1, 177.6	27.3, 177.6

Percentages calculated on non-missing values.

Program Source Code: [redacted]

TABLE 14.1 6.1

Daily Prescribed Dose
(Safety Analysis Set)

	Oral CD/LD			ABBV-951		
	Low Dose (N=56)	High Dose (N=11)	All (N=67)	Low Dose (N=45)	High Dose (N=29)	All (N=74)
ABBV-951 Continuous Infusion Rate - LD mg/hr						
First Prescription& in 8-Week Maintenance Phase						
n				31	25	56
Mean (SD)				51.8 (12.28)	100.6 (31.38)	73.6 (33.35)
Median				51.2	85.4	68.3
Min, Max				27.3, 73.4	75.1, 177.6	27.3, 177.6
Final Prescription& in 8-Week Maintenance Phase						
n				31	25	56
Mean (SD)				51.8 (12.62)	98.7 (28.58)	72.7 (31.58)
Median				51.2	85.4	69.2
Min, Max				27.3, 73.4	75.1, 167.3	27.3, 167.3
Final Prescription in Study						
n				45	29	74
Mean (SD)				52.8 (14.21)	101.4 (28.26)	71.8 (31.61)
Median				51.2	88.8	64.0
Min, Max				27.3, 85.4	75.1, 167.3	27.3, 167.3
Change from Initial to First Maintenance&						
n				31	25	56
Mean (SD)				3.0 (8.33)	8.7 (20.75)	5.5 (15.30)
Median				1.7	8.5	5.1
Min, Max				-25.6, 17.1	-68.3, 39.3	-68.3, 39.3

&: Defined as the first prescription record after day 28.

Program Source Code: [redacted]

TABLE 14.1 6.1

Daily Prescribed Dose
(Safety Analysis Set)

	Oral CD/LD			ABBV-951		
	Low Dose (N=56)	High Dose (N=11)	All (N=67)	Low Dose (N=45)	High Dose (N=29)	All (N=74)
ABBV-951 Continuous Infusion Rate - LD mg/hr						
Change from Initial to Maintenace Final						
n				31	25	56
Mean (SD)				3.0 (8.36)	6.8 (18.62)	4.7 (13.90)
Median				1.7	6.8	5.1
Min, Max				-25.6, 17.1	-56.3, 35.9	-56.3, 35.9
Change from Initial to Final						
n				45	29	74
Mean (SD)				4.0 (10.28)	5.8 (17.46)	4.7 (13.47)
Median				1.7	6.8	4.3
Min, Max				-25.6, 39.3	-56.3, 35.9	-56.3, 39.3
Change from Maintenance First& to Final						
n				31	25	56
Mean (SD)				0 (1.87)	-1.9 (9.33)	-0.9 (6.39)
Median				0	0	0
Min, Max				-5.1, 6.8	-39.3, 12.0	-39.3, 12.0
Levodopa Dose (from Blinded Study Drug) (LD mg/day) $						
Initial Prescription						
n	56	11	67	45	29	74
Mean (SD)	933.9 (363.96)	2072.7 (460.63)	1120.9 (568.50)	1171.1 (306.98)	2293.5 (781.50)	1611.0 (771.60)
Median	850.0	2100.0	1000.0	1106.5	2049.0	1393.3
Min, Max	400.0, 1700.0	1100.0, 2700.0	400.0, 2700.0	655.7, 2049.0	1393.3, 4261.9	655.7, 4261.9

$: Assume ABBV-951 subjects have continuous infusion for 24 hr/day.
&: Defined as the first prescription record after day 28.

Program Source Code: [redacted]

TABLE 14.1 6.1

Daily Prescribed Dose
(Safety Analysis Set)

	Oral CD/LD			ABBV-951		
	Low Dose (N=56)	High Dose (N=11)	All (N=67)	Low Dose (N=45)	High Dose (N=29)	All (N=74)
Levodopa Dose (from Blinded Study Drug) (LD mg/day) $						
First Maintenance Prescription& Following Optimization Phase						
n	52	11	63	31	25	56
Mean (SD)	944.2 (375.43)	2172.7 (328.91)	1158.7 (595.31)	1242.6 (294.64)	2414.5 (753.21)	1765.8 (800.31)
Median	850.0	2200.0	1000.0	1229.4	2049.0	1639.2
Min, Max	400.0, 1700.0	1800.0, 2700.0	400.0, 2700.0	655.7, 1762.1	1803.1, 4261.9	655.7, 4261.9
Final Prescription in 8-Week Maintenance Phase						
n	52	11	63	31	25	56
Mean (SD)	944.2 (375.43)	2172.7 (328.91)	1158.7 (595.31)	1242.6 (302.88)	2368.6 (685.93)	1745.3 (757.88)
Median	850.0	2200.0	1000.0	1229.4	2049.0	1659.7
Min, Max	400.0, 1700.0	1800.0, 2700.0	400.0, 2700.0	655.7, 1762.1	1803.1, 4016.0	655.7, 4016.0
Final Prescription in Study						
n	56	11	67	45	29	74
Mean (SD)	937.5 (367.58)	2172.7 (328.91)	1140.3 (584.41)	1266.7 (341.06)	2433.4 (678.29)	1723.9 (758.53)
Median	850.0	2200.0	1000.0	1229.4	2131.0	1536.8
Min, Max	400.0, 1700.0	1800.0, 2700.0	400.0, 2700.0	655.7, 2049.0	1803.1, 4016.0	655.7, 4016.0
Change from Initial to First Maintenance&						
n	52	11	63	31	25	56
Mean (SD)	3.8 (27.74)	100.0 (331.66)	20.6 (140.46)	71.4 (199.91)	209.8 (497.89)	133.2 (367.14)
Median	0	0	0	41.0	204.9	122.9
Min, Max	0, 200.0	0, 1100.0	0, 1100.0	-614.7, 409.8	-1639.2, 942.5	-1639.2, 942.5

$: Assume ABBV-951 subjects have continuous infusion for 24 hr/day.
&: Defined as the first prescription record after day 28.

Program Source Code: [redacted]

TABLE 14.1 6.1

Daily Prescribed Dose
(Safety Analysis Set)

	Oral CD/LD			ABBV-951		
	Low Dose (N=56)	High Dose (N=11)	All (N=67)	Low Dose (N=45)	High Dose (N=29)	All (N=74)
Levodopa Dose (from Blinded Study Drug) (LD mg/day) $						
Change from Initial to Maintenance Final						
n	52	11	63	31	25	56
Mean (SD)	3.8 (27.74)	100.0 (331.66)	20.6 (140.46)	71.4 (200.75)	163.9 (446.88)	112.7 (333.59)
Median	0	0	0	41.0	163.9	122.9
Min, Max	0, 200.0	0, 1100.0	0, 1100.0	-614.7, 409.8	-1352.3, 860.6	-1352.3, 860.6
Change from Initial to Final						
n	56	11	67	45	29	74
Mean (SD)	3.6 (26.73)	100.0 (331.66)	19.4 (136.22)	95.6 (246.65)	139.9 (419.14)	113.0 (323.30)
Median	0	0	0	41.0	163.9	102.4
Min, Max	0, 200.0	0, 1100.0	0, 1100.0	-614.7, 942.5	-1352.3, 860.6	-1352.3, 942.5
Change from Maintenance First& to Final						
n	52	11	63	31	25	56
Mean (SD)	0 (0)	0 (0)	0 (0)	0 (44.89)	-45.9 (223.93)	-20.5 (153.33)
Median	0	0	0	0	0	0
Min, Max	0, 0	0, 0	0, 0	-122.9, 163.9	-942.5, 286.9	-942.5, 286.9

$: Assume ABBV-951 subjects have continuous infusion for 24 hr/day.
&: Defined as the first prescription record after day 28.

Program Source Code: [redacted]

表6　経口CD/LD投与量及び規定注入速度（安全性解析対象集団）：M15-736試験

[redacted]20[redacted] 19:30 <[redacted]>
ABBV-951
STUDY M15-736
R&D/20/1640 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 2

TABLE 14.1__6.2

Most Frequenctly Prescribed Daily Oral Encapsulated CD/LD and Pump Infusion Flow Rate
(Safety Analysis Set)

	Oral CD/LD (N=67) n (%)	ABBV-951 (N=74) n (%)
Daily oral CD/LD tablets < 5 or flow rate <= 0.16 mL/hr	3 (4.5)	1 (1.4)
Daily oral CD/LD tablets = 5 or 0.16 < flow rate <= 0.18 mL/hr	4 (6.0)	2 (2.7)
Daily oral CD/LD tablets = 6 or 0.18 < flow rate <= 0.20 mL/hr	11 (16.4)	2 (2.7)
Daily oral CD/LD tablets = 7 or 0.20 < flow rate <= 0.24 mL/hr	3 (4.5)	5 (6.8)
Daily oral CD/LD tablets = 8 or 0.24 < flow rate <= 0.27 mL/hr	7 (10.4)	12 (16.2)
Daily oral CD/LD tablets = 9 or 0.27 < flow rate <= 0.30 mL/hr	4 (6.0)	4 (5.4)
Daily oral CD/LD tablets = 10 or 0.30 < flow rate <= 0.34 mL/hr	4 (6.0)	6 (8.1)
Daily oral CD/LD tablets = 11 or 0.34 < flow rate <= 0.37 mL/hr	1 (1.5)	6 (8.1)
Daily oral CD/LD tablets = 12 or 0.37 < flow rate <= 0.40 mL/hr	5 (7.5)	3 (4.1)
Daily oral CD/LD tablets = 13 or 0.40 < flow rate <= 0.44 mL/hr	3 (4.5)	9 (12.2)
Daily oral CD/LD tablets = 14 or 0.44 < flow rate <= 0.47 mL/hr	4 (6.0)	3 (4.1)
Daily oral CD/LD tablets = 15 or 0.47 < flow rate <= 0.50 mL/hr	5 (7.5)	5 (6.8)
Daily oral CD/LD tablets = 16 or 0.50 < flow rate <= 0.54 mL/hr	1 (1.5)	3 (4.1)
Daily oral CD/LD tablets = 17 or 0.54 < flow rate <= 0.57 mL/hr	1 (1.5)	0
Daily oral CD/LD tablets = 18 or 0.57 < flow rate <= 0.60 mL/hr	3 (4.5)	3 (4.1)

Program Source Code: [redacted]

TABLE 14.1 6.2

Most Frequenctly Prescribed Daily Oral Encapsulated CD/LD and Pump Infusion Flow Rate
(Safety Analysis Set)

	Oral CD/LD (N=67) n (%)	ABBV-951 (N=74) n (%)
Daily oral CD/LD tablets = 19 or 0.60 < flow rate <= 0.64 mL/hr	1 (1.5)	2 (2.7)
Daily oral CD/LD tablets = 20 or 0.64 < flow rate <= 0.67 mL/hr	0	2 (2.7)
Daily oral CD/LD tablets = 21 or 0.67 < flow rate <= 0.70 mL/hr	1 (1.5)	0
Daily oral CD/LD tablets = 22 or 0.70 < flow rate <= 0.74 mL/hr	2 (3.0)	0
Daily oral CD/LD tablets = 23 or 0.74 < flow rate <= 0.78 mL/hr	1 (1.5)	1 (1.4)
Daily oral CD/LD tablets = 24 or 0.78 < flow rate <= 0.81 mL/hr	0	2 (2.7)
Daily oral CD/LD tablets = 25 or 0.81 < flow rate <= 0.84 mL/hr	1 (1.5)	0
Daily oral CD/LD tablets = 26 or 0.84 < flow rate <= 0.88 mL/hr	1 (1.5)	1 (1.4)
Daily oral CD/LD tablets = 27 or 0.88 < flow rate <= 0.91 mL/hr	1 (1.5)	0
Daily oral CD/LD tablets = 28 or 0.91 < flow rate <= 0.94 mL/hr	0	0
Daily oral CD/LD tablets = 29 or 0.94 < flow rate <= 0.98 mL/hr	0	2 (2.7)
Daily oral CD/LD tablets = 30 or 0.98 < flow rate <= 1.00 mL/hr	0	0
Daily oral CD/LD tablets >= 31 or 1.00 < flow rate <= 1.04 mL/hr	0	0

Program Source Code: [redacted]

表7　二重盲検期のLDの1日あたりの投与量（安全性解析対象集団）：M15-736試験

[redacted]20[redacted] 19:30 <[redacted]>
ABBV-951
STUDY M15-736
R&D/20/1640 - CLINICAL/STATISTICAL

TABLE 14.1__8.1

Daily Levodopa Dose during Double-Blind Treatment Period from Dosing Diary
(Safety Analysis Set)

	Oral CD/LD			ABBV-951				
Days	Oral Encapsulated CD/LD	Rescue Dose	Total	Loading Dose	Continuous Infusion	ABBV-951 Total	Rescue Dose	Total
1 - 7								
n	46	12	46	0	58	58	19	58
Mean	1037.0	187.5	1085.9		1587.6	1587.6	174.6	1644.8
SD	616.09	104.23	648.42		773.53	773.53	102.49	778.14
Median	816.7	150.0	816.7		1379.2	1379.2	150.0	1488.9
Min	100.0	100.0	400.0		641.5	641.5	100.0	641.5
Max	2700.0	366.7	2866.7		4069.0	4069.0	466.7	4069.0
8 - 14								
n	51	14	51	0	53	53	23	53
Mean	1088.2	266.7	1159.5		1595.7	1595.7	221.0	1691.6
SD	602.00	193.92	681.24		704.25	704.25	159.09	758.95
Median	1000.0	200.0	1000.0		1477.5	1477.5	166.7	1626.9
Min	200.0	100.0	200.0		634.0	634.0	100.0	634.0
Max	2666.7	700.0	3066.7		3721.6	3721.6	600.0	3821.6
15 - 21								
n	43	16	43	0	51	51	22	51
Mean	998.4	207.3	1075.6		1634.5	1634.5	217.4	1728.3
SD	610.63	143.11	664.52		683.03	683.03	147.42	750.06
Median	866.7	133.3	900.0		1516.3	1516.3	166.7	1743.0
Min	200.0	100.0	200.0		640.1	640.1	100.0	640.1
Max	2500.0	500.0	2900.0		3694.0	3694.0	700.0	3927.3

Note: LDP doses from ABBV-951 are converted to levodopa dose using molecular weight conversion 100 mg LDP = 71 mg levodopa.
Data of 3 closest valid dosing diary day to visits day 8, 15, 22, 29, 57, 85, and final visit was used.

Program Source Code: [redacted]

TABLE 14.1 8.1

Daily Levodopa Dose during Double-Blind Treatment Period from Dosing Diary
(Safety Analysis Set)

	Oral CD/LD			ABBV-951				
Days	Oral Encapsulated CD/LD	Rescue Dose	Total	Loading Dose	Continuous Infusion	ABBV-951 Total	Rescue Dose	Total
22 - 28								
n	52	18	52	0	45	45	24	45
Mean	1139.7	240.7	1223.1		1690.1	1690.1	204.9	1799.4
SD	645.01	186.93	713.63		762.75	762.75	127.17	794.34
Median	1000.0	150.0	1025.0		1479.6	1479.6	166.7	1766.8
Min	200.0	100.0	200.0		644.8	644.8	100.0	644.8
Max	2633.3	700.0	3066.7		3910.1	3910.1	566.7	4043.4
29 - 56								
n	53	16	53	0	38	38	22	38
Mean	1099.4	252.1	1175.5		1777.1	1777.1	187.9	1885.9
SD	630.51	180.52	675.40		799.98	799.98	111.17	851.37
Median	933.3	200.0	933.3		1630.7	1630.7	158.3	1774.2
Min	200.0	100.0	200.0		643.7	643.7	100.0	643.7
Max	2600.0	733.3	2833.3		3880.5	3880.5	566.7	4180.5
>= 57								
n	50	15	50	0	38	38	18	38
Mean	1169.7	287.8	1256.0		1762.0	1762.0	168.5	1841.8
SD	597.27	191.33	659.59		771.11	771.11	98.67	814.19
Median	1000.0	200.0	1050.0		1609.0	1609.0	116.7	1737.3
Min	400.0	100.0	400.0		678.3	678.3	100.0	678.3
Max	2600.0	700.0	2966.7		3978.1	3978.1	466.7	4272.0

Note: LDP doses from ABBV-951 are converted to levodopa dose using molecular weight conversion 100 mg LDP = 71 mg levodopa.
Data of 3 closest valid dosing diary day to visits day 8, 15, 22, 29, 57, 85, and final visit was used.

Program Source Code: [redacted]

TABLE 14.1 8.1

Daily Levodopa Dose during Double-Blind Treatment Period from Dosing Diary
(Safety Analysis Set)

	Oral CD/LD			ABBV-951				
Days	Oral Encapsulated CD/LD	Rescue Dose	Total	Loading Dose	Continuous Infusion	ABBV-951 Total	Rescue Dose	Total
Final								
n	58	17	58	0	61	61	28	61
Mean	1131.9	277.5	1213.2		1703.7	1703.7	195.2	1793.3
SD	577.83	184.74	631.43		749.48	749.48	117.14	790.57
Median	1000.0	200.0	1050.0		1613.6	1613.6	166.7	1729.6
Min	400.0	100.0	400.0		643.7	643.7	100.0	643.7
Max	2600.0	700.0	2966.7		3978.1	3978.1	466.7	4272.0

Note: LDP doses from ABBV-951 are converted to levodopa dose using molecular weight conversion 100 mg LDP = 71 mg levodopa.
Data of 3 closest valid dosing diary day to visits day 8, 15, 22, 29, 57, 85, and final visit was used.

Program Source Code: [redacted]

表8　二重盲検期の救済薬投与（安全性解析対象集団）：M15-736試験

[redacted]20[redacted] 19:30 <[redacted]>
ABBV-951
STUDY M15-736
R&D/20/1640 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 4

TABLE 14.1__9

Rescue Dose during 12-Week Double-Blind Treatment Period
(Safety Analysis Set)

Days		Oral CD/LD Low Dose	Oral CD/LD High Dose	Oral CD/LD All	ABBV-951 Low Dose	ABBV-951 High Dose	ABBV-951 All
1 - 7	N*	56	11	67	45	29	74
	0 Time	42 (75.0)	5 (45.5)	47 (70.1)	30 (66.7)	19 (65.5)	49 (66.2)
	1 Time	5 (8.9)	1 (9.1)	6 (9.0)	3 (6.7)	4 (13.8)	7 (9.5)
	2 Times	3 (5.4)	0	3 (4.5)	3 (6.7)	0	3 (4.1)
	>= 3 Times	6 (10.7)	5 (45.5)	11 (16.4)	9 (20.0)	6 (20.7)	15 (20.3)
	n/m#	14/61	6/69	20/130	15/94	10/69	25/163
	Mean	4.4	11.5	6.5	6.3	6.9	6.5
	(SD)	(4.57)	(10.35)	(7.33)	(7.50)	(7.88)	(7.50)
	Median	2.0	11.0	3.0	3.0	4.5	4.0
	Min/Max	1/15	1/30	1/30	1/28	1/26	1/28
8 - 14	N*	51	11	62	39	26	65
	0 Time	40 (78.4)	6 (54.5)	46 (74.2)	22 (56.4)	10 (38.5)	32 (49.2)
	1 Time	2 (3.9)	0	2 (3.2)	4 (10.3)	2 (7.7)	6 (9.2)
	2 Times	4 (7.8)	0	4 (6.5)	3 (7.7)	6 (23.1)	9 (13.8)
	>= 3 Times	5 (9.8)	5 (45.5)	10 (16.1)	10 (25.6)	8 (30.8)	18 (27.7)
	n/m#	11/79	5/152	16/231	17/134	16/147	33/281
	Mean	7.2	30.4	14.4	7.9	9.2	8.5
	(SD)	(8.21)	(25.81)	(18.60)	(9.05)	(10.84)	(9.82)
	Median	2.0	19.0	10.0	3.0	2.5	3.0
	Min/Max	1/27	12/75	1/75	1/33	1/32	1/33

*N is the number of subjects in the study at the current visit with dosing diary data.
#n is number of subjects with at least one occurrence, m is total number of occurrences. The summary statistics are for n.

Program Source Code: [redacted]

TABLE 14.1 9

Rescue Dose during 12-Week Double-Blind Treatment Period
(Safety Analysis Set)

Days		Oral CD/LD Low Dose	Oral CD/LD High Dose	Oral CD/LD All	ABBV-951 Low Dose	ABBV-951 High Dose	ABBV-951 All
15 - 21	N*	47	11	58	33	23	56
	0 Time	34 (72.3)	6 (54.5)	40 (69.0)	21 (63.6)	9 (39.1)	30 (53.6)
	1 Time	2 (4.3)	0	2 (3.4)	2 (6.1)	1 (4.3)	3 (5.4)
	2 Times	2 (4.3)	0	2 (3.4)	0	1 (4.3)	1 (1.8)
	>= 3 Times	9 (19.1)	5 (45.5)	14 (24.1)	10 (30.3)	12 (52.2)	22 (39.3)
	n/m#	13/76	5/107	18/183	12/94	14/121	26/215
	Mean	5.8	21.4	10.2	7.8	8.6	8.3
	(SD)	(6.34)	(17.85)	(12.44)	(7.77)	(6.82)	(7.14)
	Median	4.0	22.0	4.5	4.5	7.0	6.0
	Min/Max	1/25	4/45	1/45	1/25	1/25	1/25
22 - 28	N*	49	11	60	29	21	50
	0 Time	34 (69.4)	6 (54.5)	40 (66.7)	17 (58.6)	7 (33.3)	24 (48.0)
	1 Time	3 (6.1)	0	3 (5.0)	0	1 (4.8)	1 (2.0)
	2 Times	2 (4.1)	0	2 (3.3)	2 (6.9)	2 (9.5)	4 (8.0)
	>= 3 Times	10 (20.4)	5 (45.5)	15 (25.0)	10 (34.5)	11 (52.4)	21 (42.0)
	n/m#	15/139	5/133	20/272	12/132	14/118	26/250
	Mean	9.3	26.6	13.6	11.0	8.4	9.6
	(SD)	(12.30)	(23.07)	(16.82)	(9.52)	(7.30)	(8.32)
	Median	3.0	21.0	7.0	6.5	7.5	7.0
	Min/Max	1/42	10/67	1/67	2/28	1/30	1/30

*N is the number of subjects in the study at the current visit with dosing diary data.
#n is number of subjects with at least one occurrence, m is total number of occurrences. The summary statistics are for n.

Program Source Code: [redacted]

TABLE 14.1 9

Rescue Dose during 12-Week Double-Blind Treatment Period
(Safety Analysis Set)

Days		Oral CD/LD Low Dose	Oral CD/LD High Dose	Oral CD/LD All	ABBV-951 Low Dose	ABBV-951 High Dose	ABBV-951 All
29 - 56	N*	50	11	61	26	23	49
	0 Time	27 (54.0)	6 (54.5)	33 (54.1)	12 (46.2)	6 (26.1)	18 (36.7)
	1 Time	6 (12.0)	0	6 (9.8)	2 (7.7)	2 (8.7)	4 (8.2)
	2 Times	4 (8.0)	0	4 (6.6)	1 (3.8)	1 (4.3)	2 (4.1)
	>= 3 Times	13 (26.0)	5 (45.5)	18 (29.5)	11 (42.3)	14 (60.9)	25 (51.0)
	n/m#	23/693	5/346	28/1039	14/234	17/495	31/729
	Mean	30.1	69.2	37.1	16.7	29.1	23.5
	(SD)	(47.28)	(66.63)	(52.07)	(20.06)	(29.55)	(26.07)
	Median	6.0	68.0	7.5	10.5	17.0	13.0
	Min/Max	1/170	6/176	1/176	1/66	1/99	1/99
>= 57	N*	49	11	60	24	20	44
	0 Time	28 (57.1)	6 (54.5)	34 (56.7)	13 (54.2)	7 (35.0)	20 (45.5)
	1 Time	2 (4.1)	0	2 (3.3)	1 (4.2)	1 (5.0)	2 (4.5)
	2 Times	3 (6.1)	0	3 (5.0)	1 (4.2)	0	1 (2.3)
	>= 3 Times	16 (32.7)	5 (45.5)	21 (35.0)	9 (37.5)	12 (60.0)	21 (47.7)
	n/m#	21/644	5/445	26/1089	11/221	13/424	24/645
	Mean	30.7	89.0	41.9	20.1	32.6	26.9
	(SD)	(41.71)	(64.76)	(51.11)	(25.15)	(31.76)	(29.01)
	Median	12.0	100.0	13.5	11.0	18.0	15.5
	Min/Max	1/151	13/183	1/183	1/89	1/99	1/99

*N is the number of subjects in the study at the current visit with dosing diary data.
#n is number of subjects with at least one occurrence, m is total number of occurrences. The summary statistics are for n.

Program Source Code: [redacted]

TABLE 14.1 9

Rescue Dose during 12-Week Double-Blind Treatment Period
(Safety Analysis Set)

Days		Oral CD/LD Low Dose	Oral CD/LD High Dose	Oral CD/LD All	ABBV-951 Low Dose	ABBV-951 High Dose	ABBV-951 All
Overall	N*	56	11	67	45	29	74
	0 Time	24 (42.9)	5 (45.5)	29 (43.3)	18 (40.0)	5 (17.2)	23 (31.1)
	1 Time	1 (1.8)	0	1 (1.5)	1 (2.2)	1 (3.4)	2 (2.7)
	2 Times	5 (8.9)	0	5 (7.5)	3 (6.7)	1 (3.4)	4 (5.4)
	>= 3 Times	26 (46.4)	6 (54.5)	32 (47.8)	23 (51.1)	22 (75.9)	45 (60.8)
	n/m#	32/1692	6/1252	38/2944	27/909	24/1374	51/2283
	Mean	52.9	208.7	77.5	33.7	57.3	44.8
	(SD)	(91.82)	(200.62)	(125.77)	(45.84)	(57.45)	(52.46)
	Median	11.0	192.5	15.5	11.0	38.5	19.0
	Min/Max	1/329	3/553	1/553	1/175	1/176	1/176

*N is the number of subjects in the study at the current visit with dosing diary data.
#n is number of subjects with at least one occurrence, m is total number of occurrences. The summary statistics are for n.

Program Source Code: [redacted]

表9　二重盲検期の治験薬曝露期間（安全性解析対象集団）：M15-736試験

[redacted]20[redacted] 19:30 <[redacted]>
ABBV-951
STUDY M15-736
R&D/20/1640 - CLINICAL/STATISTICAL

TABLE 14.1__10

Duration of Study Drug Exposure during 12-Week Double-Blind Treatment Period
(Safety Analysis Set)

	Oral CD/LD			ABBV-951		
	Low Dose (N=56)	High Dose (N=11)	All (N=67)	Low Dose (N=45)	High Dose (N=29)	All (N=74)
Duration of study drug exposure (days)						
n	56	11	67	45	29	74
Mean (SD)	80.5 (20.59)	86.5 (3.21)	81.5 (18.97)	59.7 (32.53)	66.4 (29.11)	62.4 (31.20)
Median	85.0	85.0	85.0	83.0	85.0	84.0
Min, Max	3, 106	83, 94	3, 106	3, 89	8, 92	3, 92
By time intervals - n(%)						
Day 1 - 7	1 (1.8)	0	1 (1.5)	4 (8.9)	0	4 (5.4)
Day 8 - 14	2 (3.6)	0	2 (3.0)	3 (6.7)	2 (6.9)	5 (6.8)
Day 15 - 21	1 (1.8)	0	1 (1.5)	2 (4.4)	2 (6.9)	4 (5.4)
Day 22 - 28	0	0	0	5 (11.1)	0	5 (6.8)
Day 29 - 57	0	0	0	3 (6.7)	5 (17.2)	8 (10.8)
Day >= 58	52 (92.9)	11 (100)	63 (94.0)	28 (62.2)	20 (69.0)	48 (64.9)
Patient-years of exposure	12.3	2.6	14.9	7.4	5.3	12.6

Note: Blinded drug solution for ABBV-951 and blinded drug capsules for oral CD/LD.

Program Source Code: [redacted]

TABLE 14.1 10

Duration of Study Drug Exposure during 12-Week Double-Blind Treatment Period
(Safety Analysis Set)

	Oral CD/LD			ABBV-951		
	Low Dose (N=56)	High Dose (N=11)	All (N=67)	Low Dose (N=45)	High Dose (N=29)	All (N=74)
Duration of study drug interruption (days)						
n	16	3	19	15	7	22
Mean (SD)	2.8 (6.74)	0.7 (0.60)	2.5 (6.21)	3.9 (6.62)	7.0 (7.98)	4.9 (7.03)
Median	0.5	0.6	0.6	0.9	4.8	1.7
Min, Max	0, 27	0, 1	0, 27	0, 20	0, 23	0, 23
By time intervals - n(%)						
< 1 Day	11 (68.8)	2 (66.7)	13 (68.4)	8 (53.3)	2 (28.6)	10 (45.5)
1 -< 2 Days	2 (12.5)	1 (33.3)	3 (15.8)	1 (6.7)	0	1 (4.5)
2 -< 3 Days	0	0	0	1 (6.7)	1 (14.3)	2 (9.1)
3 -< 4 Days	1 (6.3)	0	1 (5.3)	1 (6.7)	0	1 (4.5)
4 -< 5 Days	0	0	0	1 (6.7)	1 (14.3)	2 (9.1)
5 -< 10 Days	1 (6.3)	0	1 (5.3)	1 (6.7)	1 (14.3)	2 (9.1)
>= 10 Days	1 (6.3)	0	1 (5.3)	2 (13.3)	2 (28.6)	4 (18.2)
Missing	40	8	48	30	22	52

Note: Blinded drug solution for ABBV-951 and blinded drug capsules for oral CD/LD.

Program Source Code: [redacted]

表10　パーキンソン病日誌に基づく，標準化した1日あたりの平均オフ時間及びオン時間の要約（FAS）：M15-736試験

[redacted]20[redacted] 19:31 <[redacted]>
ABBV-951
STUDY M15-736
R&D/20/1640 - CLINICAL/STATISTICAL

TABLE 14.2__2.1

Repeated-Measure Analysis of Change from Baseline to Post-Baseline Visits in Normalized Time (Hours) Assessed by PD Diary
(Full Analysis Set)

Status / Visit / Treatment	Summary Statistics N	Summary Statistics Mean (SD)	Summary Statistics Min	Summary Statistics Max	Model-Based Statistics@ LS Mean (SE)	Model-Based Statistics@ Within Group P-Value	Treatment Difference between Groups — LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia									
Baseline									
Oral CD/LD	67	9.49 (2.62)	0.0	13.5					
ABBV-951	73	9.20 (2.42)	0.0	13.3					
Change to Day 8									
Oral CD/LD	65	0.62 (2.51)	-4.9	7.7	0.79 (0.44)	0.0746			
ABBV-951	70	1.90 (3.55)	-8.0	10.3	1.87 (0.42)	<=0.001***	1.08 (0.52)	(0.05, 2.12)	0.0393*
Change to Day 15									
Oral CD/LD	63	0.72 (2.38)	-3.7	8.1	0.89 (0.46)	0.0528			
ABBV-951	66	1.94 (3.98)	-8.1	11.3	2.00 (0.44)	<=0.001***	1.11 (0.55)	(0.01, 2.20)	0.0474*
Change to Day 22									
Oral CD/LD	39	1.63 (2.91)	-3.1	8.1	1.46 (0.50)	0.0039**			
ABBV-951	39	1.92 (4.09)	-7.0	11.3	2.32 (0.48)	<=0.001***	0.86 (0.62)	(-0.37, 2.09)	0.1712
Change to Day 29									
Oral CD/LD	62	0.94 (2.48)	-4.9	8.1	1.16 (0.42)	0.0073**			
ABBV-951	54	2.77 (3.46)	-5.7	9.3	2.64 (0.42)	<=0.001***	1.49 (0.51)	(0.47, 2.50)	0.0044**
Change to Day 57									
Oral CD/LD	62	0.96 (3.10)	-7.0	8.1	1.07 (0.48)	0.0269*			
ABBV-951	47	3.76 (3.86)	-6.5	15.7	2.91 (0.49)	<=0.001***	1.84 (0.61)	(0.63, 3.06)	0.0032**
Change to Day 85									
Oral CD/LD	62	0.85 (3.46)	-10.0	8.4	0.97 (0.50)	0.0574			
ABBV-951	47	3.36 (3.62)	-6.7	11.1	2.72 (0.52)	<=0.001***	1.75 (0.65)	(0.46, 3.05)	0.0083**

Note: @ The repeated measures model: change = treatment country visit baseline treatment*visit treatment*baseline.
The unstructured variance-covariance structure is used.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 2.1

Repeated-Measure Analysis of Change from Baseline to Post-Baseline Visits in Normalized Time (Hours) Assessed by PD Diary
(Full Analysis Set)

Status / Visit / Treatment	Summary Statistics N	Mean (SD)	Min	Max	Model-Based Statistics@ LS Mean (SE)	Within Group P-Value	Treatment Difference between Groups: LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
Average Daily Normalized 'Off' Time									
Baseline									
Oral CD/LD	67	5.91 (1.88)	2.5	10.3					
ABBV-951	73	6.34 (2.27)	2.7	14.0					
Change to Day 8									
Oral CD/LD	65	-0.59 (2.41)	-6.4	5.1	-0.67 (0.44)	0.1295			
ABBV-951	70	-2.17 (3.70)	-13.0	8.0	-2.00 (0.41)	<=0.001***	-1.32 (0.52)	(-2.36, -0.29)	0.0124*
Change to Day 15									
Oral CD/LD	63	-0.66 (2.43)	-6.5	3.7	-0.74 (0.45)	0.1004			
ABBV-951	66	-2.08 (3.86)	-11.3	9.1	-2.03 (0.43)	<=0.001***	-1.29 (0.54)	(-2.36, -0.23)	0.0177*
Change to Day 22									
Oral CD/LD	39	-1.35 (2.92)	-6.5	3.6	-1.15 (0.48)	0.0186*			
ABBV-951	39	-1.82 (3.95)	-11.3	7.0	-2.18 (0.47)	<=0.001***	-1.03 (0.60)	(-2.22, 0.17)	0.0909
Change to Day 29									
Oral CD/LD	62	-0.89 (2.58)	-6.4	3.9	-1.02 (0.42)	0.0167*			
ABBV-951	54	-2.69 (3.25)	-9.3	5.7	-2.50 (0.41)	<=0.001***	-1.48 (0.51)	(-2.48, -0.48)	0.0039**
Change to Day 57									
Oral CD/LD	62	-0.95 (2.88)	-6.5	5.9	-0.97 (0.46)	0.0347*			
ABBV-951	47	-3.79 (3.63)	-12.7	6.3	-2.89 (0.46)	<=0.001***	-1.92 (0.58)	(-3.06, -0.78)	0.0011**
Change to Day 85									
Oral CD/LD	62	-0.93 (3.31)	-8.4	10.0	-0.96 (0.49)	0.0518			
ABBV-951	47	-3.41 (3.76)	-12.3	6.7	-2.75 (0.50)	<=0.001***	-1.79 (0.63)	(-3.03, -0.54)	0.0054**

Note: @ The repeated measures model: change = treatment country visit baseline treatment*visit treatment*baseline.
The unstructured variance-covariance structure is used.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 2.1

Repeated-Measure Analysis of Change from Baseline to Post-Baseline Visits in Normalized Time (Hours) Assessed by PD Diary
(Full Analysis Set)

Status / Visit / Treatment	N	Summary Statistics: Mean (SD)	Min	Max	Model-Based Statistics@: LS Mean (SE)	Within Group P-Value	Treatment Difference between Groups: LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
Average Daily Normalized 'On' Time Without Dyskinesia									
Baseline									
Oral CD/LD	67	7.47 (3.72)	0.0	13.5					
ABBV-951	73	7.23 (3.14)	0.0	13.2					
Change to Day 8									
Oral CD/LD	65	0.74 (2.36)	-5.4	5.7	0.93 (0.44)	0.0344*			
ABBV-951	70	2.13 (3.43)	-8.0	9.4	2.17 (0.41)	<=0.001***	1.24 (0.51)	(0.22, 2.25)	0.0170*
Change to Day 15									
Oral CD/LD	63	0.90 (2.76)	-4.6	11.7	1.10 (0.47)	0.0203*			
ABBV-951	66	2.33 (3.74)	-5.0	13.0	2.48 (0.45)	<=0.001***	1.38 (0.57)	(0.27, 2.50)	0.0157*
Change to Day 22									
Oral CD/LD	39	1.84 (3.13)	-3.4	11.7	1.68 (0.52)	0.0014**			
ABBV-951	39	2.28 (4.01)	-7.0	13.0	2.79 (0.50)	<=0.001***	1.11 (0.65)	(-0.17, 2.39)	0.0889
Change to Day 29									
Oral CD/LD	62	1.03 (2.72)	-5.1	11.7	1.29 (0.47)	0.0068**			
ABBV-951	54	2.98 (3.77)	-6.2	13.0	2.87 (0.46)	<=0.001***	1.58 (0.58)	(0.44, 2.73)	0.0069**
Change to Day 57									
Oral CD/LD	62	1.30 (3.50)	-6.4	11.7	1.45 (0.54)	0.0078**			
ABBV-951	47	4.07 (4.02)	-6.5	14.0	3.11 (0.55)	<=0.001***	1.66 (0.70)	(0.28, 3.04)	0.0188*
Change to Day 85									
Oral CD/LD	62	1.15 (3.63)	-10.4	11.7	1.32 (0.53)	0.0130*			
ABBV-951	47	3.96 (3.77)	-4.3	14.0	3.13 (0.54)	<=0.001***	1.81 (0.68)	(0.46, 3.16)	0.0091**

Note: @ The repeated measures model: change = treatment country visit baseline treatment*visit treatment*baseline.
The unstructured variance-covariance structure is used.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 2.1

Repeated-Measure Analysis of Change from Baseline to Post-Baseline Visits in Normalized Time (Hours) Assessed by PD Diary
(Full Analysis Set)

Status / Visit / Treatment	N	Summary Statistics: Mean (SD)	Min	Max	Model-Based Statistics@: LS Mean (SE)	Within Group P-Value	Treatment Difference between Groups: LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
Average Daily Normalized 'On' Time With Non-troublesome Dyskinesia									
Baseline									
Oral CD/LD	67	2.02 (2.75)	0.0	9.8					
ABBV-951	73	1.97 (2.46)	0.0	9.7					
Change to Day 8									
Oral CD/LD	65	-0.12 (1.49)	-3.6	6.2	-0.13 (0.25)	0.5998			
ABBV-951	70	-0.22 (2.17)	-5.4	8.6	-0.23 (0.24)	0.3415	-0.09 (0.31)	(-0.70, 0.51)	0.7569
Change to Day 15									
Oral CD/LD	63	-0.18 (1.50)	-5.8	4.2	-0.20 (0.25)	0.4224			
ABBV-951	66	-0.39 (2.29)	-6.9	6.6	-0.45 (0.24)	0.0645	-0.24 (0.31)	(-0.85, 0.36)	0.4250
Change to Day 22									
Oral CD/LD	39	-0.21 (1.85)	-8.0	3.4	-0.23 (0.27)	0.3835			
ABBV-951	39	-0.37 (1.87)	-4.6	4.7	-0.40 (0.26)	0.1217	-0.17 (0.33)	(-0.82, 0.49)	0.6168
Change to Day 29									
Oral CD/LD	62	-0.09 (1.62)	-8.0	4.9	-0.13 (0.30)	0.6613			
ABBV-951	54	-0.22 (2.95)	-6.9	7.2	-0.27 (0.30)	0.3727	-0.14 (0.39)	(-0.91, 0.63)	0.7249
Change to Day 57									
Oral CD/LD	62	-0.34 (2.15)	-8.0	7.2	-0.38 (0.32)	0.2287			
ABBV-951	47	-0.32 (3.09)	-7.2	9.6	-0.29 (0.33)	0.3808	0.09 (0.43)	(-0.76, 0.94)	0.8343
Change to Day 85									
Oral CD/LD	62	-0.30 (1.88)	-8.0	6.1	-0.36 (0.28)	0.2109			
ABBV-951	47	-0.59 (2.46)	-6.9	6.4	-0.41 (0.29)	0.1660	-0.05 (0.37)	(-0.79, 0.69)	0.8864

Note: @ The repeated measures model: change = treatment country visit baseline treatment*visit treatment*baseline.
The unstructured variance-covariance structure is used.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 2.1

Repeated-Measure Analysis of Change from Baseline to Post-Baseline Visits in Normalized Time (Hours) Assessed by PD Diary
(Full Analysis Set)

Status / Visit / Treatment	N	Summary Statistics: Mean (SD)	Min	Max	Model-Based Statistics@: LS Mean (SE)	Within Group P-Value	Treatment Difference between Groups: LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
Average Daily Normalized 'On' Time With Troublesome Dyskinesia									
Baseline									
Oral CD/LD	67	0.60 (1.46)	0.0	6.7					
ABBV-951	73	0.46 (0.86)	0.0	4.6					
Change to Day 8									
Oral CD/LD	65	-0.03 (0.61)	-2.2	1.7	-0.13 (0.14)	0.3673			
ABBV-951	70	0.27 (1.41)	-1.8	8.0	0.16 (0.14)	0.2453	0.29 (0.19)	(-0.08, 0.66)	0.1243
Change to Day 15									
Oral CD/LD	63	-0.06 (0.74)	-3.1	2.2	-0.16 (0.14)	0.2338			
ABBV-951	66	0.14 (1.23)	-1.9	5.9	0.08 (0.13)	0.5430	0.24 (0.18)	(-0.11, 0.59)	0.1737
Change to Day 22									
Oral CD/LD	39	-0.28 (0.59)	-2.0	0.5	-0.31 (0.10)	0.0027**			
ABBV-951	39	-0.10 (0.77)	-3.0	2.3	-0.16 (0.10)	0.1129	0.15 (0.13)	(-0.10, 0.41)	0.2294
Change to Day 29									
Oral CD/LD	62	-0.05 (0.98)	-3.9	3.2	-0.15 (0.12)	0.2123			
ABBV-951	54	-0.08 (0.80)	-2.2	3.2	-0.12 (0.12)	0.3236	0.03 (0.16)	(-0.29, 0.35)	0.8507
Change to Day 57									
Oral CD/LD	62	-0.01 (1.07)	-2.7	6.2	-0.11 (0.15)	0.4519			
ABBV-951	47	0.04 (1.07)	-3.0	4.4	0.07 (0.15)	0.6620	0.18 (0.20)	(-0.22, 0.58)	0.3798
Change to Day 85									
Oral CD/LD	62	0.08 (1.13)	-2.2	6.4	-0.02 (0.16)	0.9232			
ABBV-951	47	0.05 (1.06)	-1.7	5.8	-0.03 (0.17)	0.8554	-0.02 (0.23)	(-0.46, 0.43)	0.9424

Note: @ The repeated measures model: change = treatment country visit baseline treatment*visit treatment*baseline.
The unstructured variance-covariance structure is used.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

表11　MDS-UPDRSスコア（FAS）：M15-736試験

[redacted]20[redacted] 19:30 <[redacted]>
ABBV-951
STUDY M15-736
R&D/20/1640 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 12

TABLE 14.2__3

Repeated-Measure Analysis of Change from Baseline to Post-Baseline Visits in MDS-UPDRS Scores
(Full Analysis Set)

Status / Visit / Treatment	N	Summary Statistics: Mean (SD)	Min	Max	Model-Based Statistics@: LS Mean (SE)	Within Group P-Value	Treatment Difference between Groups: LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Total Score of Part I-III									
Baseline									
Oral CD/LD	67	50.88 (19.84)	16.0	106.0					
ABBV-951	74	55.84 (22.24)	18.0	118.0					
Change to Day 2									
Oral CD/LD	65	-3.96 (11.21)	-29.0	29.0	-4.94 (1.82)	0.0076**			
ABBV-951	73	-5.75 (14.27)	-42.0	34.0	-5.76 (1.71)	0.0010**	-0.82 (2.13)	(-5.04, 3.40)	0.7026
Change to Day 8									
Oral CD/LD	60	-6.46 (12.46)	-38.0	25.0	-6.81 (2.14)	0.0019**			
ABBV-951	64	-5.22 (18.66)	-65.0	52.0	-4.93 (2.05)	0.0175*	1.88 (2.65)	(-3.37, 7.13)	0.4797
Change to Day 15									
Oral CD/LD	59	-7.78 (16.94)	-49.0	28.0	-8.31 (2.45)	<=0.001***			
ABBV-951	58	-3.44 (19.24)	-39.0	56.0	-4.09 (2.38)	0.0877	4.22 (3.14)	(-2.00, 10.44)	0.1815

Note: @ The repeated measures model: change = treatment country visit baseline treatment*visit treatment*baseline.
The unstructured variance-covariance structure is used.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 3

Repeated-Measure Analysis of Change from Baseline to Post-Baseline Visits in MDS-UPDRS Scores
(Full Analysis Set)

Status / Visit / Treatment	N	Summary Statistics: Mean (SD)	Min	Max	Model-Based Statistics@: LS Mean (SE)	Within Group P-Value	Treatment Difference between Groups: LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Total Score of Part I-III									
Change to Day 22									
Oral CD/LD	17	-11.17 (12.57)	-39.0	6.0	-9.54 (2.99)	0.0018**			
ABBV-951	23	0.33 (22.96)	-70.5	50.0	-2.17 (2.75)	0.4311	7.36 (3.85)	(-0.24, 14.97)	0.0575
Change to Day 29									
Oral CD/LD	59	-6.12 (15.56)	-47.0	48.0	-7.67 (2.24)	<=0.001***			
ABBV-951	53	-5.12 (16.91)	-52.0	38.0	-3.93 (2.22)	0.0790	3.74 (2.87)	(-1.93, 9.41)	0.1943
Change to Day 57									
Oral CD/LD	60	-5.99 (15.48)	-47.0	25.6	-7.35 (2.32)	0.0019**			
ABBV-951	45	-9.59 (18.32)	-62.0	34.0	-5.65 (2.35)	0.0174*	1.70 (3.03)	(-4.29, 7.69)	0.5757
Change to Day 85									
Oral CD/LD	62	-5.40 (16.38)	-57.0	30.0	-6.52 (2.36)	0.0066**			
ABBV-951	46	-11.08 (19.02)	-75.0	23.3	-8.12 (2.48)	0.0014**	-1.60 (3.16)	(-7.86, 4.65)	0.6132

Note: @ The repeated measures model: change = treatment country visit baseline treatment*visit treatment*baseline.
The unstructured variance-covariance structure is used.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 3

Repeated-Measure Analysis of Change from Baseline to Post-Baseline Visits in MDS-UPDRS Scores
(Full Analysis Set)

Status / Visit / Treatment	N	Summary Statistics: Mean (SD)	Min	Max	Model-Based Statistics@: LS Mean (SE)	Within Group P-Value	Treatment Difference between Groups: LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part I Score									
Baseline									
Oral CD/LD	67	9.37 (5.18)	1.0	24.0					
ABBV-951	74	11.35 (6.37)	0.0	31.0					
Change to Day 2									
Oral CD/LD	65	-1.09 (4.40)	-18.0	9.0	-1.68 (0.59)	0.0050**			
ABBV-951	73	-1.63 (5.25)	-24.0	12.0	-1.09 (0.55)	0.0498*	0.59 (0.69)	(-0.77, 1.95)	0.3918
Change to Day 8									
Oral CD/LD	60	-1.13 (5.84)	-18.0	14.0	-1.31 (0.68)	0.0580			
ABBV-951	65	-2.55 (5.61)	-24.0	8.0	-2.02 (0.65)	0.0023**	-0.72 (0.84)	(-2.38, 0.95)	0.3965
Change to Day 15									
Oral CD/LD	59	-1.58 (5.47)	-17.0	9.0	-1.87 (0.72)	0.0108*			
ABBV-951	58	-0.98 (5.35)	-11.0	19.0	-0.84 (0.70)	0.2357	1.03 (0.92)	(-0.78, 2.84)	0.2623

Note: @ The repeated measures model: change = treatment country visit baseline treatment*visit treatment*baseline.
The unstructured variance-covariance structure is used.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 3

Repeated-Measure Analysis of Change from Baseline to Post-Baseline Visits in MDS-UPDRS Scores
(Full Analysis Set)

Status / Visit / Treatment	N	Summary Statistics: Mean (SD)	Min	Max	Model-Based Statistics@: LS Mean (SE)	Within Group P-Value	Treatment Difference between Groups: LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part I Score									
Change to Day 22									
Oral CD/LD	17	-4.24 (4.56)	-17.0	2.0	-2.23 (0.85)	0.0096**			
ABBV-951	23	-1.30 (7.70)	-26.0	10.0	-0.06 (0.79)	0.9392	2.17 (1.08)	(0.03, 4.30)	0.0473*
Change to Day 29									
Oral CD/LD	61	-1.23 (5.55)	-19.0	11.0	-1.60 (0.70)	0.0248*			
ABBV-951	53	-1.18 (5.53)	-25.0	7.0	-0.32 (0.70)	0.6437	1.27 (0.90)	(-0.51, 3.05)	0.1593
Change to Day 57									
Oral CD/LD	62	-0.98 (5.79)	-15.0	18.0	-1.58 (0.75)	0.0363*			
ABBV-951	47	-2.19 (5.94)	-25.0	12.0	-0.83 (0.77)	0.2806	0.75 (0.99)	(-1.20, 2.70)	0.4472
Change to Day 85									
Oral CD/LD	62	-0.82 (5.91)	-16.0	14.0	-1.22 (0.75)	0.1029			
ABBV-951	46	-2.63 (6.93)	-26.0	12.0	-1.22 (0.77)	0.1156	0.00 (0.99)	(-1.95, 1.95)	>0.999

Note: @ The repeated measures model: change = treatment country visit baseline treatment*visit treatment*baseline.
The unstructured variance-covariance structure is used.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 3

Repeated-Measure Analysis of Change from Baseline to Post-Baseline Visits in MDS-UPDRS Scores
(Full Analysis Set)

Status / Visit / Treatment	N	Summary Statistics: Mean (SD)	Min	Max	Model-Based Statistics@: LS Mean (SE)	Within Group P-Value	Treatment Difference between Groups: LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part II Score									
Baseline									
Oral CD/LD	67	13.27 (6.37)	0.0	30.0					
ABBV-951	74	15.31 (6.93)	3.0	33.0					
Change to Day 2									
Oral CD/LD	65	-0.66 (3.92)	-9.0	10.0	-1.16 (0.61)	0.0587			
ABBV-951	73	-1.14 (4.56)	-16.0	10.0	-1.30 (0.57)	0.0251*	-0.14 (0.71)	(-1.54, 1.27)	0.8457
Change to Day 8									
Oral CD/LD	60	-1.15 (4.58)	-11.0	12.0	-1.49 (0.75)	0.0490*			
ABBV-951	65	-1.48 (6.19)	-22.0	14.0	-1.89 (0.72)	0.0093**	-0.40 (0.94)	(-2.26, 1.45)	0.6684
Change to Day 15									
Oral CD/LD	59	-1.49 (5.17)	-15.0	10.0	-2.04 (0.78)	0.0100*			
ABBV-951	58	-1.76 (6.14)	-16.0	18.0	-1.77 (0.76)	0.0213*	0.28 (0.99)	(-1.69, 2.24)	0.7814

Note: @ The repeated measures model: change = treatment country visit baseline treatment*visit treatment*baseline.
The unstructured variance-covariance structure is used.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 3

Repeated-Measure Analysis of Change from Baseline to Post-Baseline Visits in MDS-UPDRS Scores
(Full Analysis Set)

Status / Visit / Treatment	N	Summary Statistics: Mean (SD)	Min	Max	Model-Based Statistics@: LS Mean (SE)	Within Group P-Value	Treatment Difference between Groups: LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part II Score									
Change to Day 22									
Oral CD/LD	17	-3.29 (4.50)	-10.0	3.0	-1.57 (0.94)	0.0970			
ABBV-951	23	0.78 (7.24)	-14.0	13.0	-0.64 (0.89)	0.4754	0.93 (1.22)	(-1.48, 3.34)	0.4468
Change to Day 29									
Oral CD/LD	61	-0.97 (4.60)	-12.0	12.0	-1.55 (0.76)	0.0440*			
ABBV-951	53	-2.32 (6.44)	-22.0	11.0	-2.08 (0.76)	0.0070**	-0.53 (0.98)	(-2.47, 1.42)	0.5929
Change to Day 57									
Oral CD/LD	62	-0.77 (5.53)	-17.0	12.0	-1.36 (0.83)	0.1030			
ABBV-951	47	-3.36 (6.72)	-21.0	11.0	-2.32 (0.84)	0.0069**	-0.95 (1.09)	(-3.12, 1.21)	0.3844
Change to Day 85									
Oral CD/LD	62	-0.48 (4.91)	-12.0	14.0	-1.06 (0.79)	0.1809			
ABBV-951	46	-3.76 (6.98)	-21.0	7.0	-2.65 (0.82)	0.0015**	-1.58 (1.05)	(-3.65, 0.48)	0.1318

Note: @ The repeated measures model: change = treatment country visit baseline treatment*visit treatment*baseline.
The unstructured variance-covariance structure is used.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 3

Repeated-Measure Analysis of Change from Baseline to Post-Baseline Visits in MDS-UPDRS Scores
(Full Analysis Set)

Status / Visit / Treatment	N	Summary Statistics: Mean (SD)	Min	Max	Model-Based Statistics@: LS Mean (SE)	Within Group P-Value	Treatment Difference between Groups: LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part III Score									
Baseline									
Oral CD/LD	67	28.23 (13.76)	3.0	66.0					
ABBV-951	73	29.47 (14.97)	6.0	78.0					
Change to Day 2									
Oral CD/LD	65	-2.22 (8.97)	-27.0	23.0	-2.43 (1.36)	0.0757			
ABBV-951	71	-3.18 (10.72)	-29.0	22.0	-3.29 (1.30)	0.0126*	-0.86 (1.61)	(-4.04, 2.33)	0.5955
Change to Day 8									
Oral CD/LD	59	-4.01 (9.03)	-31.0	12.0	-4.48 (1.47)	0.0029**			
ABBV-951	61	-1.38 (12.46)	-29.0	37.0	-1.21 (1.43)	0.3990	3.26 (1.80)	(-0.31, 6.83)	0.0728
Change to Day 15									
Oral CD/LD	59	-4.69 (11.25)	-34.0	22.0	-4.75 (1.59)	0.0033**			
ABBV-951	57	-0.79 (12.71)	-27.0	39.0	-1.11 (1.57)	0.4801	3.64 (2.00)	(-0.32, 7.60)	0.0711

Note: @ The repeated measures model: change = treatment country visit baseline treatment*visit treatment*baseline.
The unstructured variance-covariance structure is used.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 3

Repeated-Measure Analysis of Change from Baseline to Post-Baseline Visits in MDS-UPDRS Scores
(Full Analysis Set)

Status / Visit / Treatment	N	Summary Statistics: Mean (SD)	Min	Max	Model-Based Statistics@: LS Mean (SE)	Within Group P-Value	Treatment Difference between Groups: LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part III Score									
Change to Day 22									
Oral CD/LD	17	-3.57 (10.19)	-26.0	12.0	-5.70 (2.20)	0.0105*			
ABBV-951	23	0.85 (13.43)	-30.5	32.0	-0.75 (1.99)	0.7066	4.95 (2.80)	(-0.59, 10.49)	0.0793
Change to Day 29									
Oral CD/LD	58	-4.03 (11.20)	-32.0	29.0	-4.68 (1.54)	0.0029**			
ABBV-951	52	-1.65 (11.28)	-24.0	31.0	-1.38 (1.55)	0.3733	3.30 (1.95)	(-0.56, 7.15)	0.0933
Change to Day 57									
Oral CD/LD	58	-4.08 (9.54)	-24.0	17.4	-4.53 (1.47)	0.0025**			
ABBV-951	45	-4.00 (11.63)	-28.0	29.0	-3.30 (1.51)	0.0302*	1.23 (1.86)	(-2.44, 4.90)	0.5090
Change to Day 85									
Oral CD/LD	62	-4.07 (11.34)	-36.0	31.7	-4.57 (1.51)	0.0029**			
ABBV-951	45	-4.77 (10.97)	-33.0	19.0	-4.25 (1.63)	0.0102*	0.32 (1.99)	(-3.62, 4.26)	0.8731

Note: @ The repeated measures model: change = treatment country visit baseline treatment*visit treatment*baseline.
The unstructured variance-covariance structure is used.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 3

Repeated-Measure Analysis of Change from Baseline to Post-Baseline Visits in MDS-UPDRS Scores
(Full Analysis Set)

Status / Visit / Treatment	N	Summary Statistics: Mean (SD)	Min	Max	Model-Based Statistics@: LS Mean (SE)	Within Group P-Value	Treatment Difference between Groups: LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part IV Score									
Baseline									
Oral CD/LD	67	7.73 (3.14)	0.0	16.0					
ABBV-951	74	8.91 (3.33)	3.0	18.0					
Change to Day 2									
Oral CD/LD	65	0.23 (2.44)	-5.0	9.0	0.23 (0.39)	0.5521			
ABBV-951	73	-0.34 (3.23)	-13.0	9.0	-0.04 (0.37)	0.9095	-0.28 (0.48)	(-1.22, 0.67)	0.5651
Change to Day 8									
Oral CD/LD	60	0.03 (2.36)	-6.0	10.0	-0.02 (0.43)	0.9666			
ABBV-951	65	-1.85 (3.91)	-16.0	7.0	-1.41 (0.41)	<=0.001***	-1.40 (0.53)	(-2.45, -0.34)	0.0100**
Change to Day 15									
Oral CD/LD	59	-0.32 (2.60)	-6.0	8.0	-0.46 (0.40)	0.2573			
ABBV-951	58	-1.74 (3.14)	-11.0	3.0	-1.33 (0.40)	0.0011**	-0.87 (0.51)	(-1.88, 0.14)	0.0911

Note: @ The repeated measures model: change = treatment country visit baseline treatment*visit treatment*baseline.
The unstructured variance-covariance structure is used.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 3

Repeated-Measure Analysis of Change from Baseline to Post-Baseline Visits in MDS-UPDRS Scores
(Full Analysis Set)

Status / Visit / Treatment	Summary Statistics: N	Mean (SD)	Min	Max	Model-Based Statistics@: LS Mean (SE)	Within Group P-Value	Treatment Difference between Groups: LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part IV Score									
Change to Day 22									
Oral CD/LD	17	-0.24 (2.49)	-5.0	4.0	-0.45 (0.60)	0.4566			
ABBV-951	23	-1.43 (3.41)	-12.0	2.0	-1.69 (0.56)	0.0029**	-1.24 (0.78)	(-2.78, 0.30)	0.1128
Change to Day 29									
Oral CD/LD	61	-0.34 (2.33)	-8.0	5.0	-0.44 (0.42)	0.2968			
ABBV-951	52	-2.06 (3.86)	-12.0	3.0	-1.28 (0.44)	0.0039**	-0.84 (0.56)	(-1.94, 0.26)	0.1329
Change to Day 57									
Oral CD/LD	62	-0.35 (2.88)	-8.0	5.0	-0.41 (0.47)	0.3897			
ABBV-951	45	-3.33 (4.38)	-16.0	4.0	-2.62 (0.51)	<=0.001***	-2.21 (0.65)	(-3.49, -0.93)	<=0.001***
Change to Day 85									
Oral CD/LD	62	0.13 (2.53)	-6.0	7.0	0.08 (0.43)	0.8489			
ABBV-951	46	-2.83 (3.90)	-13.0	4.0	-2.14 (0.46)	<=0.001***	-2.22 (0.58)	(-3.36, -1.08)	<=0.001***

Note: @ The repeated measures model: change = treatment country visit baseline treatment*visit treatment*baseline.
The unstructured variance-covariance structure is used.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 3

Repeated-Measure Analysis of Change from Baseline to Post-Baseline Visits in MDS-UPDRS Scores
(Full Analysis Set)

Status / Visit / Treatment	N	Summary Statistics: Mean (SD)	Min	Max	Model-Based Statistics@: LS Mean (SE)	Within Group P-Value	Treatment Difference between Groups: LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Hoehn and Yahr Stage									
Baseline									
Oral CD/LD	67	2.22 (0.73)	0.0	5.0					
ABBV-951	74	2.20 (0.68)	1.0	4.0					
Change to Day 2									
Oral CD/LD	65	-0.11 (0.59)	-2.0	1.0	-0.06 (0.08)	0.4787			
ABBV-951	73	-0.05 (0.62)	-3.0	1.0	-0.04 (0.08)	0.6124	0.02 (0.10)	(-0.18, 0.22)	0.8481
Change to Day 8									
Oral CD/LD	60	-0.13 (0.47)	-2.0	1.0	-0.11 (0.08)	0.1969			
ABBV-951	64	-0.13 (0.68)	-3.0	2.0	-0.09 (0.08)	0.2608	0.02 (0.10)	(-0.18, 0.22)	0.8615
Change to Day 15									
Oral CD/LD	59	-0.12 (0.59)	-2.0	1.0	-0.13 (0.09)	0.1553			
ABBV-951	58	-0.09 (0.71)	-3.0	1.0	-0.10 (0.09)	0.2663	0.03 (0.11)	(-0.19, 0.25)	0.7860

Note: @ The repeated measures model: change = treatment country visit baseline treatment*visit treatment*baseline.
The unstructured variance-covariance structure is used.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 3

Repeated-Measure Analysis of Change from Baseline to Post-Baseline Visits in MDS-UPDRS Scores
(Full Analysis Set)

Status / Visit / Treatment	N	Summary Statistics: Mean (SD)	Min	Max	Model-Based Statistics@: LS Mean (SE)	Within Group P-Value	Treatment Difference between Groups: LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Hoehn and Yahr Stage									
Change to Day 22									
Oral CD/LD	17	-0.18 (0.39)	-1.0	0.0	-0.21 (0.10)	0.0387*			
ABBV-951	23	0.22 (0.67)	-1.0	2.0	0.14 (0.10)	0.1432	0.35 (0.13)	(0.10, 0.60)	0.0070**
Change to Day 29									
Oral CD/LD	58	-0.10 (0.61)	-2.0	1.0	-0.09 (0.09)	0.2680			
ABBV-951	53	-0.11 (0.58)	-1.0	1.0	-0.04 (0.09)	0.6422	0.06 (0.11)	(-0.16, 0.27)	0.6065
Change to Day 57									
Oral CD/LD	59	-0.15 (0.66)	-2.0	1.0	-0.13 (0.09)	0.1619			
ABBV-951	45	-0.18 (0.58)	-1.0	1.0	-0.01 (0.09)	0.8804	0.11 (0.11)	(-0.12, 0.34)	0.3322
Change to Day 85									
Oral CD/LD	62	-0.11 (0.66)	-2.0	2.0	-0.09 (0.09)	0.3148			
ABBV-951	45	-0.04 (0.67)	-1.0	1.0	0.06 (0.10)	0.5374	0.15 (0.12)	(-0.09, 0.39)	0.2130

Note: @ The repeated measures model: change = treatment country visit baseline treatment*visit treatment*baseline.
The unstructured variance-covariance structure is used.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

表12　朝の無動（FAS）：M15-736試験

[redacted]20[redacted] 19:30 <[redacted]>
ABBV-951
STUDY M15-736
R&D/20/1640 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 1

TABLE 14.2 4.2

Repeated-Measure Analysis of Early Morning 'Off' Status at Post-Baseline Visits
(Full Analysis Set)

Visit / Treatment	Summary Statistics: N	Summary Statistics: n (%)	Model-Based Statistics@: Odds Ratio between Groups: LS Mean of Odds Ratio (SE)	95% CI	Two-Sided P-Value
Baseline					
Oral CD/LD	67	51 (76.1)			
ABBV-951	71	56 (78.9)			
Day 8					
Oral CD/LD	64	37 (57.8)			
ABBV-951	71	27 (38.0)	0.41 (0.36)	(0.20, 0.85)	0.0168*
Day 15					
Oral CD/LD	62	38 (61.3)			
ABBV-951	64	21 (32.8)	0.28 (0.38)	(0.13, 0.59)	<=0.001***
Day 22					
Oral CD/LD	38	22 (57.9)			
ABBV-951	39	13 (33.3)	0.34 (0.46)	(0.14, 0.85)	0.0210*
Day 29					
Oral CD/LD	61	39 (63.9)			
ABBV-951	54	15 (27.8)	0.24 (0.41)	(0.11, 0.53)	<=0.001***
Day 57					
Oral CD/LD	61	39 (63.9)			
ABBV-951	47	10 (21.3)	0.17 (0.45)	(0.07, 0.40)	<=0.001***
Day 85					
Oral CD/LD	60	38 (63.3)			
ABBV-951	47	8 (17.0)	0.12 (0.49)	(0.04, 0.31)	<=0.001***

Note: @ The generalized linear mixed model: status = treatment country visit baseline treatment*visit.
The unstructured variance-covariance structure is used.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

表13　パーキンソン病日誌に基づく，早朝覚醒時状態の分布（FAS）：M15-736試験

[redacted]20[redacted] 19:31 <[redacted]>
ABBV-951
STUDY M15-736
R&D/20/1640 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 1

TABLE 14.2__4.1

Distribution of Early Morning First Non-Sleep Symptom Assessed by PD Diary
(Full Analysis Set)

Visit / Treatment	N	Off	On without Dyskinesia	On with Non-Troublesome Dyskinesia	On with Troublesome Dyskinesia
		n (%)	n (%)	n (%)	n (%)
Baseline					
Oral CD/LD	67	51 (76.1)	15 (22.4)	0	1 (1.5)
ABBV-951	71	56 (78.9)	11 (15.5)	3 (4.2)	1 (1.4)
Day 8					
Oral CD/LD	64	37 (57.8)	21 (32.8)	3 (4.7)	3 (4.7)
ABBV-951	71	27 (38.0)	38 (53.5)	4 (5.6)	2 (2.8)
Day 15					
Oral CD/LD	62	38 (61.3)	21 (33.9)	2 (3.2)	1 (1.6)
ABBV-951	64	21 (32.8)	39 (60.9)	4 (6.3)	0
Day 22					
Oral CD/LD	38	22 (57.9)	16 (42.1)	0	0
ABBV-951	39	13 (33.3)	24 (61.5)	2 (5.1)	0
Day 29					
Oral CD/LD	61	39 (63.9)	19 (31.1)	2 (3.3)	1 (1.6)
ABBV-951	54	15 (27.8)	36 (66.7)	2 (3.7)	1 (1.9)
Day 57					
Oral CD/LD	61	39 (63.9)	22 (36.1)	0	0
ABBV-951	47	10 (21.3)	32 (68.1)	5 (10.6)	0
Day 85					
Oral CD/LD	60	38 (63.3)	22 (36.7)	0	0
ABBV-951	47	8 (17.0)	33 (70.2)	4 (8.5)	2 (4.3)

Note: Baseline is the last non-missing value prior to the beginning of the treatment period.

Program Source Code: [redacted]

表14　PDSS-2スコア（FAS）：M15-736試験

[redacted]20[redacted] 19:30 <[redacted]>
ABBV-951
STUDY M15-736
R&D/20/1640 - CLINICAL/STATISTICAL

TABLE 14.2__5

ANCOVA of Change from Baseline to Final Visit in PDSS-2 Scores
(Full Analysis Set)

Status / Visit / Treatment	N	Summary Statistics: Mean (SD)	Min	Max	Within Group P-Value#	Model-Based Statistics@: LS Mean (SE)	Treatment Difference between Groups: LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
Parkinson's Disease Sleep Scale-2 (PDSS-2) Total Score									
Baseline									
Oral CD/LD	59	18.71 (8.77)	2.0	47.0					
ABBV-951	44	21.70 (9.04)	7.0	42.0					
Final									
Oral CD/LD	59	17.07 (8.29)	4.0	38.0					
ABBV-951	44	13.36 (8.27)	0.0	36.0					
Change to final									
Oral CD/LD	59	-1.64 (6.22)	-12.0	19.0	0.0469*	-2.52 (1.12)			
ABBV-951	44	-8.34 (8.86)	-40.0	3.0	<=0.001***	-7.92 (1.18)	-5.40 (1.32)	(-8.03, -2.78)	<=0.001***

Note: @ ANCOVA model including effects for treatment, country and baseline.
From one-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 5

ANCOVA of Change from Baseline to Final Visit in PDSS-2 Scores
(Full Analysis Set)

Status / Visit / Treatment	N	Mean (SD)	Min	Max	Within Group P-Value#	LS Mean (SE)	Treatment Difference between Groups -- LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
		Summary Statistics			Model-Based Statistics@				
Parkinson's Disease Sleep Scale-2 (PDSS-2) Moto Symptoms at Night Domain Score									
Baseline									
Oral CD/LD	59	5.19 (4.05)	0.0	18.0					
ABBV-951	44	6.00 (3.92)	0.0	16.0					
Final									
Oral CD/LD	59	4.42 (3.85)	0.0	17.0					
ABBV-951	44	2.91 (2.95)	0.0	12.0					
Change to final									
Oral CD/LD	59	-0.76 (3.15)	-7.0	8.0	0.0683	-0.96 (0.46)			
ABBV-951	44	-3.09 (3.18)	-12.0	1.0	<=0.001***	-2.93 (0.48)	-1.97 (0.54)	(-3.04, -0.90)	<=0.001***

Note: @ ANCOVA model including effects for treatment, country and baseline.
From one-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 5

ANCOVA of Change from Baseline to Final Visit in PDSS-2 Scores
(Full Analysis Set)

Status / Visit / Treatment	N	Summary Statistics: Mean (SD)	Min	Max	Within Group P-Value#	Model-Based Statistics@: LS Mean (SE)	Treatment Difference between Groups: LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
Parkinson's Disease Sleep Scale-2 (PDSS-2) PD Symptoms at Night Domain Score									
Baseline									
Oral CD/LD	59	3.83 (2.90)	0.0	12.0					
ABBV-951	44	4.70 (3.24)	0.0	12.0					
Final									
Oral CD/LD	59	3.19 (2.94)	0.0	14.0					
ABBV-951	44	2.86 (2.79)	0.0	11.0					
Change to final									
Oral CD/LD	59	-0.64 (2.20)	-4.0	7.0	0.0280*	-0.96 (0.40)			
ABBV-951	44	-1.84 (3.32)	-12.0	5.0	<=0.001***	-1.74 (0.43)	-0.78 (0.48)	(-1.73, 0.16)	0.1039

Note: @ ANCOVA model including effects for treatment, country and baseline.
From one-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 5

ANCOVA of Change from Baseline to Final Visit in PDSS-2 Scores
(Full Analysis Set)

Status / Visit / Treatment	N	Mean (SD)	Min	Max	Within Group P-Value#	LS Mean (SE)	LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
	------ Summary Statistics -------					---------- Model-Based Statistics@ ---------- -- Treatment Difference between Groups --			
Parkinson's Disease Sleep Scale-2 (PDSS-2) Disturbed Sleep Domain Score									
Baseline									
Oral CD/LD	59	9.69 (3.98)	1.0	19.0					
ABBV-951	44	11.00 (4.02)	3.0	20.0					
Final									
Oral CD/LD	59	9.46 (4.11)	2.0	18.0					
ABBV-951	44	7.59 (4.00)	0.0	17.0					
Change to final									
Oral CD/LD	59	-0.24 (3.03)	-6.0	9.0	0.5499	-0.61 (0.57)			
ABBV-951	44	-3.41 (4.40)	-16.0	5.0	<=0.001***	-3.24 (0.60)	-2.62 (0.67)	(-3.96, -1.29)	<=0.001***

Note: @ ANCOVA model including effects for treatment, country and baseline.
From one-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

表15　PDQ-39 スコア（FAS）：M15-736試験

[redacted]20[redacted] 19:30 <[redacted]>
ABBV-951
STUDY M15-736
R&D/20/1640 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 9

TABLE 14.2__6

ANCOVA of Change from Baseline to Final Visit in PDQ-39 Scores
(Full Analysis Set)

Status / Visit / Treatment	Summary Statistics N	Mean (SD)	Min	Max	Within Group P-Value#	Model-Based Statistics@ LS Mean (SE)	Treatment Difference between Groups LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
Parkinson's Disease Questionnaie-39 Item (PDQ-39) Summary Index									
Baseline									
Oral CD/LD	59	26.52 (13.89)	3.8	75.0					
ABBV-951	45	29.31 (15.84)	3.2	69.7					
Final									
Oral CD/LD	59	25.96 (15.19)	2.6	70.4					
ABBV-951	45	23.65 (13.35)	3.2	59.6					
Change to final									
Oral CD/LD	59	-0.57 (8.79)	-19.2	26.3	0.6233	-2.28 (1.75)			
ABBV-951	45	-5.66 (13.71)	-47.4	15.4	0.0082**	-6.38 (1.83)	-4.10 (2.04)	(-8.14, -0.05)	0.0470*

Note: @ ANCOVA model including effects for treatment, country and baseline.
From one-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 6

ANCOVA of Change from Baseline to Final Visit in PDQ-39 Scores
(Full Analysis Set)

Status / Visit / Treatment	N	Summary Statistics: Mean (SD)	Min	Max	Within Group P-Value#	Model-Based Statistics@: LS Mean (SE)	Treatment Difference between Groups: LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
Parkinson's Disease Questionnaie-39 Item (PDQ-39) Mobility Domain Score									
Baseline									
Oral CD/LD	59	33.86 (23.64)	0.0	100.0					
ABBV-951	45	36.50 (23.25)	0.0	92.5					
Final									
Oral CD/LD	59	33.56 (25.39)	0.0	92.5					
ABBV-951	45	28.50 (20.63)	0.0	72.5					
Change to final									
Oral CD/LD	59	-0.30 (15.71)	-37.5	42.5	0.8852	-3.80 (2.66)			
ABBV-951	45	-8.00 (18.19)	-72.5	17.5	0.0051**	-10.50 (2.79)	-6.70 (3.09)	(-12.84, -0.56)	0.0327*

Note: @ ANCOVA model including effects for treatment, country and baseline.
From one-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 6

ANCOVA of Change from Baseline to Final Visit in PDQ-39 Scores
(Full Analysis Set)

Status / Visit / Treatment	N	Summary Statistics: Mean (SD)	Min	Max	Within Group P-Value#	Model-Based Statistics@: LS Mean (SE)	Treatment Difference between Groups: LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
Parkinson's Disease Questionnaie-39 Item (PDQ-39) Activities of Daily Living Domain Score									
Baseline									
Oral CD/LD	59	31.14 (22.03)	0.0	95.8					
ABBV-951	45	37.31 (21.60)	0.0	79.2					
Final									
Oral CD/LD	59	27.75 (22.54)	0.0	95.8					
ABBV-951	45	28.33 (21.44)	0.0	83.3					
Change to final									
Oral CD/LD	59	-3.39 (13.37)	-33.3	25.0	0.0563	-4.74 (2.77)			
ABBV-951	45	-8.98 (21.36)	-70.8	41.7	0.0072**	-8.40 (2.89)	-3.66 (3.23)	(-10.07, 2.74)	0.2591

Note: @ ANCOVA model including effects for treatment, country and baseline.
From one-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 6

ANCOVA of Change from Baseline to Final Visit in PDQ-39 Scores
(Full Analysis Set)

Status / Visit / Treatment	N	Summary Statistics: Mean (SD)	Min	Max	Within Group P-Value#	Model-Based Statistics@: LS Mean (SE)	Treatment Difference between Groups: LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
Parkinson's Disease Questionnaie-39 Item (PDQ-39) Emotional Well-Being Domain Score									
Baseline									
Oral CD/LD	59	21.89 (17.70)	0.0	62.5					
ABBV-951	45	22.22 (15.67)	0.0	58.3					
Final									
Oral CD/LD	59	20.62 (16.98)	0.0	70.8					
ABBV-951	45	21.48 (15.33)	0.0	62.5					
Change to final									
Oral CD/LD	59	-1.27 (9.83)	-33.3	29.2	0.3245	-1.81 (1.93)			
ABBV-951	45	-0.74 (15.03)	-37.5	33.3	0.7425	-1.13 (2.03)	0.68 (2.25)	(-3.79, 5.14)	0.7641

Note: @ ANCOVA model including effects for treatment, country and baseline.
From one-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 6

ANCOVA of Change from Baseline to Final Visit in PDQ-39 Scores
(Full Analysis Set)

Status / Visit / Treatment	N	Summary Statistics: Mean (SD)	Min	Max	Within Group P-Value#	Model-Based Statistics@: LS Mean (SE)	Treatment Difference between Groups: LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
Parkinson's Disease Questionnaie-39 Item (PDQ-39) Stigma Domain Score									
Baseline									
Oral CD/LD	59	18.22 (19.47)	0.0	81.3					
ABBV-951	45	25.00 (25.46)	0.0	93.8					
Final									
Oral CD/LD	59	17.58 (19.09)	0.0	81.3					
ABBV-951	45	15.97 (16.08)	0.0	75.0					
Change to final									
Oral CD/LD	59	-0.64 (12.10)	-25.0	37.5	0.6881	-2.97 (2.22)			
ABBV-951	45	-9.03 (20.58)	-75.0	31.3	0.0052**	-8.25 (2.35)	-5.28 (2.61)	(-10.46, -0.10)	0.0458*

Note: @ ANCOVA model including effects for treatment, country and baseline.
From one-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 6

ANCOVA of Change from Baseline to Final Visit in PDQ-39 Scores
(Full Analysis Set)

Status / Visit / Treatment	N	Mean (SD)	Min	Max	Within Group P-Value#	LS Mean (SE)	LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
		Summary Statistics				Model-Based Statistics@	Treatment Difference between Groups		
Parkinson's Disease Questionnaie-39 Item (PDQ-39) Social Support Domain Score									
Baseline									
Oral CD/LD	47	7.80 (11.18)	0.0	41.7					
ABBV-951	42	10.71 (13.44)	0.0	50.0					
Final									
Oral CD/LD	47	11.35 (16.34)	0.0	58.3					
ABBV-951	42	9.72 (11.92)	0.0	41.7					
Change to final									
Oral CD/LD	47	3.55 (10.53)	-16.7	33.3	0.0255*	4.58 (2.06)			
ABBV-951	42	-0.99 (12.51)	-41.7	25.0	0.6101	0.61 (2.05)	-3.97 (2.39)	(-8.71, 0.78)	0.1003

Note: @ ANCOVA model including effects for treatment, country and baseline.
From one-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 6

ANCOVA of Change from Baseline to Final Visit in PDQ-39 Scores
(Full Analysis Set)

Status / Visit / Treatment	N	Mean (SD)	Min	Max	Within Group P-Value#	LS Mean (SE)	LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
		Summary Statistics				Model-Based Statistics@	Treatment Difference between Groups		
Parkinson's Disease Questionnaie-39 Item (PDQ-39) Cognition Domain Score									
Baseline									
Oral CD/LD	59	20.13 (13.69)	0.0	68.8					
ABBV-951	45	25.00 (18.42)	0.0	81.3					
Final									
Oral CD/LD	59	20.87 (15.90)	0.0	62.5					
ABBV-951	45	21.94 (16.30)	0.0	62.5					
Change to final									
Oral CD/LD	59	0.74 (11.44)	-25.0	31.3	0.6203	0.05 (2.10)			
ABBV-951	45	-3.06 (15.46)	-37.5	31.3	0.1918	-2.10 (2.22)	-2.14 (2.46)	(-7.03, 2.75)	0.3870

Note: @ ANCOVA model including effects for treatment, country and baseline.
From one-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 6

ANCOVA of Change from Baseline to Final Visit in PDQ-39 Scores
(Full Analysis Set)

Status / Visit / Treatment	N	Mean (SD)	Min	Max	Within Group P-Value#	LS Mean (SE)	Treatment Difference between Groups -- LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
Parkinson's Disease Questionnaie-39 Item (PDQ-39) Communication Domain Score									
Baseline									
Oral CD/LD	59	25.00 (17.16)	0.0	66.7					
ABBV-951	45	26.67 (19.18)	0.0	66.7					
Final									
Oral CD/LD	59	25.85 (19.86)	0.0	75.0					
ABBV-951	45	23.52 (19.49)	0.0	66.7					
Change to final									
Oral CD/LD	59	0.85 (16.57)	-33.3	41.7	0.6959	-1.23 (2.73)			
ABBV-951	45	-3.15 (17.79)	-41.7	33.3	0.2416	-4.44 (2.86)	-3.21 (3.16)	(-9.49, 3.07)	0.3129

Note: @ ANCOVA model including effects for treatment, country and baseline.
From one-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 6

ANCOVA of Change from Baseline to Final Visit in PDQ-39 Scores
(Full Analysis Set)

Status / Visit / Treatment	N	Summary Statistics: Mean (SD)	Min	Max	Within Group P-Value#	Model-Based Statistics@: LS Mean (SE)	Treatment Difference between Groups: LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
Parkinson's Disease Questionnaie-39 Item (PDQ-39) Bodily Discomfort Domain Score									
Baseline									
Oral CD/LD	59	38.98 (24.00)	0.0	91.7					
ABBV-951	45	35.37 (20.50)	0.0	75.0					
Final									
Oral CD/LD	59	36.86 (22.49)	0.0	83.3					
ABBV-951	45	28.70 (20.91)	0.0	75.0					
Change to final									
Oral CD/LD	59	-2.12 (18.61)	-41.7	33.3	0.3854	-4.23 (2.84)			
ABBV-951	45	-6.67 (18.51)	-50.0	41.7	0.0199*	-9.81 (2.97)	-5.58 (3.30)	(-12.12, 0.96)	0.0937

Note: @ ANCOVA model including effects for treatment, country and baseline.
From one-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

表16　EQ-5D-5Lスコア（FAS）：M15-736試験

[redacted]20[redacted] 19:30 <[redacted]>
ABBV-951
STUDY M15-736
R&D/20/1640 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 7

TABLE 14.2__7

ANCOVA of Change from Baseline to Final Visit in EQ-5D-5L
(Full Analysis Set)

Status / Visit / Treatment	N	Mean (SD)	Min	Max	Within Group P-Value#	LS Mean (SE)	LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
		Summary Statistics				Model-Based Statistics@	Treatment Difference between Groups		
EuroQol 5-Dimension 5-Level (EQ-5D-5L) Summary Index Score Based on USA									
Baseline									
Oral CD/LD	59	0.747 (0.125)	0.308	1.000					
ABBV-951	44	0.748 (0.131)	0.393	1.000					
Final									
Oral CD/LD	59	0.761 (0.143)	0.249	1.000					
ABBV-951	44	0.809 (0.135)	0.485	1.000					
Change to final									
Oral CD/LD	59	0.014 (0.128)	-0.560	0.316	0.4147	0.002 (0.021)			
ABBV-951	44	0.061 (0.164)	-0.473	0.545	0.0179*	0.051 (0.022)	0.049 (0.025)	(-0.001, 0.100)	0.0566

Note: @ ANCOVA model including effects for treatment, country and baseline.
From one-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 7

ANCOVA of Change from Baseline to Final Visit in EQ-5D-5L
(Full Analysis Set)

Status / Visit / Treatment	N	Summary Statistics: Mean (SD)	Min	Max	Within Group P-Value#	Model-Based Statistics@: LS Mean (SE)	Treatment Difference between Groups: LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
EuroQol 5-Dimension 5-Level (EQ-5D-5L) Mobility									
Baseline									
Oral CD/LD	59	2.169 (0.834)	1.000	4.000					
ABBV-951	44	2.227 (0.859)	1.000	4.000					
Final									
Oral CD/LD	59	2.000 (0.965)	1.000	4.000					
ABBV-951	44	1.705 (0.765)	1.000	4.000					
Change to final									
Oral CD/LD	59	-0.169 (1.053)	-3.000	3.000	0.2213	-0.187 (0.137)			
ABBV-951	44	-0.523 (0.876)	-2.000	1.000	<=0.001***	-0.504 (0.145)	-0.317 (0.167)	(-0.648, 0.014)	0.0605

Note: @ ANCOVA model including effects for treatment, country and baseline.
From one-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 7

ANCOVA of Change from Baseline to Final Visit in EQ-5D-5L
(Full Analysis Set)

Status / Visit / Treatment	N	Summary Statistics: Mean (SD)	Min	Max	Within Group P-Value#	Model-Based Statistics@: LS Mean (SE)	Treatment Difference between Groups: LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
EuroQol 5-Dimension 5-Level (EQ-5D-5L) Self-Care									
Baseline									
Oral CD/LD	59	1.610 (0.743)	1.000	4.000					
ABBV-951	44	1.750 (0.811)	1.000	4.000					
Final									
Oral CD/LD	59	1.678 (0.730)	1.000	3.000					
ABBV-951	44	1.545 (0.663)	1.000	4.000					
Change to final									
Oral CD/LD	59	0.068 (0.612)	-1.000	2.000	0.3984	0.051 (0.102)			
ABBV-951	44	-0.205 (0.904)	-3.000	1.000	0.1408	-0.146 (0.108)	-0.196 (0.124)	(-0.443, 0.050)	0.1172

Note: @ ANCOVA model including effects for treatment, country and baseline.
From one-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 7

ANCOVA of Change from Baseline to Final Visit in EQ-5D-5L
(Full Analysis Set)

Status / Visit / Treatment	N	Summary Statistics: Mean (SD)	Min	Max	Within Group P-Value#	Model-Based Statistics@: LS Mean (SE)	Treatment Difference between Groups: LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
EuroQol 5-Dimension 5-Level (EQ-5D-5L) Usual Activities									
Baseline									
Oral CD/LD	59	2.085 (0.934)	1.000	4.000					
ABBV-951	44	2.091 (0.936)	1.000	4.000					
Final									
Oral CD/LD	59	1.983 (0.956)	1.000	4.000					
ABBV-951	44	1.682 (0.740)	1.000	4.000					
Change to final									
Oral CD/LD	59	-0.102 (0.904)	-2.000	3.000	0.3911	-0.063 (0.130)			
ABBV-951	44	-0.409 (1.041)	-2.000	2.000	0.0125*	-0.372 (0.138)	-0.309 (0.158)	(-0.623, 0.005)	0.0538

Note: @ ANCOVA model including effects for treatment, country and baseline.
From one-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 7

ANCOVA of Change from Baseline to Final Visit in EQ-5D-5L
(Full Analysis Set)

Status / Visit / Treatment	N	Summary Statistics: Mean (SD)	Min	Max	Within Group P-Value#	Model-Based Statistics@: LS Mean (SE)	Treatment Difference between Groups: LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
EuroQol 5-Dimension 5-Level (EQ-5D-5L) Pain/Discomfort									
Baseline									
Oral CD/LD	59	2.169 (0.854)	1.000	5.000					
ABBV-951	44	2.000 (0.807)	1.000	4.000					
Final									
Oral CD/LD	59	2.034 (0.964)	1.000	5.000					
ABBV-951	44	1.750 (0.892)	1.000	4.000					
Change to final									
Oral CD/LD	59	-0.136 (0.955)	-2.000	3.000	0.2800	0.019 (0.141)			
ABBV-951	44	-0.250 (1.014)	-3.000	3.000	0.1094	-0.203 (0.151)	-0.222 (0.173)	(-0.565, 0.121)	0.2017

Note: @ ANCOVA model including effects for treatment, country and baseline.
From one-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 7

ANCOVA of Change from Baseline to Final Visit in EQ-5D-5L
(Full Analysis Set)

Status / Visit / Treatment	N	Summary Statistics: Mean (SD)	Min	Max	Within Group P-Value#	Model-Based Statistics@: LS Mean (SE)	Treatment Difference between Groups: LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
EuroQol 5-Dimension 5-Level (EQ-5D-5L) Anxiety/Depression									
Baseline									
Oral CD/LD	59	1.576 (0.835)	1.000	5.000					
ABBV-951	44	1.591 (0.816)	1.000	5.000					
Final									
Oral CD/LD	59	1.610 (0.851)	1.000	4.000					
ABBV-951	44	1.477 (0.628)	1.000	3.000					
Change to final									
Oral CD/LD	59	0.034 (0.850)	-3.000	2.000	0.7605	0.096 (0.108)			
ABBV-951	44	-0.114 (0.689)	-2.000	1.000	0.2803	-0.052 (0.115)	-0.148 (0.131)	(-0.409, 0.113)	0.2621

Note: @ ANCOVA model including effects for treatment, country and baseline.
From one-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 7

ANCOVA of Change from Baseline to Final Visit in EQ-5D-5L
(Full Analysis Set)

Status / Visit / Treatment	N	Summary Statistics: Mean (SD)	Min	Max	Within Group P-Value#	Model-Based Statistics@: LS Mean (SE)	Treatment Difference between Groups: LS Mean of Difference (SE)	95% CI	Two-Sided P-Value
EuroQol 5-Dimension 5-Level (EQ-5D-5L) Visual Analogue Scale (VAS) Score									
Baseline									
Oral CD/LD	59	74.593 (12.755)	31.000	95.000					
ABBV-951	44	72.273 (16.103)	30.000	100.000					
Final									
Oral CD/LD	59	73.915 (16.576)	31.000	97.000					
ABBV-951	44	78.773 (15.367)	30.000	100.000					
Change to final									
Oral CD/LD	59	-0.678 (16.198)	-58.000	31.000	0.7490	-1.501 (2.443)			
ABBV-951	44	6.500 (17.743)	-30.000	48.000	0.0193*	4.513 (2.611)	6.014 (2.983)	(0.095, 11.933)	0.0465*

Note: @ ANCOVA model including effects for treatment, country and baseline.
From one-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

表17　二重盲検期に発現した有害事象の概要（安全性解析対象集団）：M15-736試験

[redacted]20[redacted] 19:32 <[redacted]>
ABBV-951
STUDY M15-736
R&D/20/1640 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 8

TABLE 14.3__1.1.2

Overview of Treatment-Emergent Adverse Events during Double-Blind Treatment Period by Time Interval
(Safety Analysis Set)

	Oral CD/LD			ABBV-951			
	Low Dose (N=56) n (%)	High Dose (N=11) n (%)	All (N=67) n (%)	Low Dose (N=45) n (%)	High Dose (N=29) n (%)	All (N=74) n (%)	Total (N=141) n (%)
Double-blind treatment period	N=56	N=11	N=67	N=45	N=29	N=74	N=141
Subjects with:							
Any TEAE	35 (62.5)	7 (63.6)	42 (62.7)	39 (86.7)	24 (82.8)	63 (85.1)	105 (74.5)
Any TEAE that is							
Mild	31 (55.4)	6 (54.5)	37 (55.2)	33 (73.3)	19 (65.5)	52 (70.3)	89 (63.1)
Moderate	9 (16.1)	3 (27.3)	12 (17.9)	25 (55.6)	17 (58.6)	42 (56.8)	54 (38.3)
Severe	1 (1.8)	0	1 (1.5)	2 (4.4)	5 (17.2)	7 (9.5)	8 (5.7)
Any TEAE considered related with study drug$	12 (21.4)	3 (27.3)	15 (22.4)	32 (71.1)	20 (69.0)	52 (70.3)	67 (47.5)
Any TEAE associated with any product complaint$	7 (12.5)	1 (9.1)	8 (11.9)	29 (64.4)	17 (58.6)	46 (62.2)	54 (38.3)
ABBV-951 or Placebo solution*	1 (1.8)	1 (9.1)	2 (3.0)	20 (44.4)	8 (27.6)	28 (37.8)	30 (21.3)
CD/LD IR or Placebo capsules	0	0	0	0	0	0	0
Open label CD/LD IR tablets	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Infusion pump	1 (1.8)	0	1 (1.5)	5 (11.1)	2 (6.9)	7 (9.5)	8 (5.7)
Vial adapter	0	0	0	0	0	0	0
Syringes	0	0	0	0	0	0	0
Neria guard infusion set 6 mm	1 (1.8)	0	1 (1.5)	5 (11.1)	2 (6.9)	7 (9.5)	8 (5.7)
Neria guard infusion set 9 mm	4 (7.1)	0	4 (6.0)	10 (22.2)	10 (34.5)	20 (27.0)	24 (17.0)
[redacted]	1 (1.8)	0	1 (1.5)	1 (2.2)	0	1 (1.4)	2 (1.4)
Any TEAE considered associated with COVID-19 infection	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
Any TEAE leading to premature discontinuation of study drug	1 (1.8)	0	1 (1.5)	12 (26.7)	4 (13.8)	16 (21.6)	17 (12.1)
Any TEAE leading to death	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
Any serious TEAE	3 (5.4)	1 (9.1)	4 (6.0)	3 (6.7)	3 (10.3)	6 (8.1)	10 (7.1)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
$ As assessed by investigator.
* ABBV-951 or placebo solution associates with ABBV-951 for ABBV-951 group, associates with placebo solution for Oral CD/LD group.

Program Source Code: [redacted]

TABLE 14.3 1.1.2

Overview of Treatment-Emergent Adverse Events during Double-Blind Treatment Period by Time Interval
(Safety Analysis Set)

	Oral CD/LD			ABBV-951			
	Low Dose (N=56) n (%)	High Dose (N=11) n (%)	All (N=67) n (%)	Low Dose (N=45) n (%)	High Dose (N=29) n (%)	All (N=74) n (%)	Total (N=141) n (%)
Any SAE considered related with infusion pump$	0	0	0	1 (2.2)	2 (6.9)	3 (4.1)	3 (2.1)
Possible	0	0	0	0	0	0	0
Probable	0	0	0	0	2 (6.9)	2 (2.7)	2 (1.4)
Causal relationship	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
All deaths#	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
Deaths related to COVID-19	0	0	0	0	0	0	0
AESI: Any AESI	21 (37.5)	4 (36.4)	25 (37.3)	39 (86.7)	20 (69.0)	59 (79.7)	84 (59.6)
AESI: Infusion Related Infections	2 (3.6)	0	2 (3.0)	14 (31.1)	7 (24.1)	21 (28.4)	23 (16.3)
AESI: Infusion Related Reactions	5 (8.9)	0	5 (7.5)	31 (68.9)	15 (51.7)	46 (62.2)	51 (36.2)
AESI: Hallucinations/psychosis	1 (1.8)	1 (9.1)	2 (3.0)	5 (11.1)	6 (20.7)	11 (14.9)	13 (9.2)
AESI: Polyneuropathy	2 (3.6)	0	2 (3.0)	2 (4.4)	0	2 (2.7)	4 (2.8)
AESI: Somnolence	1 (1.8)	0	1 (1.5)	1 (2.2)	0	1 (1.4)	2 (1.4)
AESI: Falls and associated injuries	13 (23.2)	4 (36.4)	17 (25.4)	8 (17.8)	5 (17.2)	13 (17.6)	30 (21.3)
AESI: Weight loss	1 (1.8)	0	1 (1.5)	1 (2.2)	0	1 (1.4)	2 (1.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
$ As assessed by investigator.
# Includes non treatment-emergent deaths. Same subject with the death on 14.3_1.1.1.

Program Source Code: [redacted]

TABLE 14.3 1.1.2

Overview of Treatment-Emergent Adverse Events during Double-Blind Treatment Period by Time Interval
(Safety Analysis Set)

	Oral CD/LD			ABBV-951			
	Low Dose (N=56) n (%)	High Dose (N=11) n (%)	All (N=67) n (%)	Low Dose (N=45) n (%)	High Dose (N=29) n (%)	All (N=74) n (%)	Total (N=141) n (%)
CSCI optimization phase	N=56	N=11	N=67	N=45	N=29	N=74	N=141
Subjects with:							
Any TEAE	24 (42.9)	4 (36.4)	28 (41.8)	36 (80.0)	19 (65.5)	55 (74.3)	83 (58.9)
Any TEAE that is							
Mild	20 (35.7)	3 (27.3)	23 (34.3)	29 (64.4)	15 (51.7)	44 (59.5)	67 (47.5)
Moderate	7 (12.5)	3 (27.3)	10 (14.9)	20 (44.4)	11 (37.9)	31 (41.9)	41 (29.1)
Severe	0	0	0	2 (4.4)	3 (10.3)	5 (6.8)	5 (3.5)
Any TEAE considered related with study drug$	10 (17.9)	2 (18.2)	12 (17.9)	28 (62.2)	15 (51.7)	43 (58.1)	55 (39.0)
Any TEAE associated with any product complaint$	5 (8.9)	1 (9.1)	6 (9.0)	25 (55.6)	15 (51.7)	40 (54.1)	46 (32.6)
ABBV-951 or Placebo solution*	0	1 (9.1)	1 (1.5)	17 (37.8)	6 (20.7)	23 (31.1)	24 (17.0)
CD/LD IR or Placebo capsules	0	0	0	0	0	0	0
Open label CD/LD IR tablets	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Infusion pump	0	0	0	4 (8.9)	2 (6.9)	6 (8.1)	6 (4.3)
Vial adapter	0	0	0	0	0	0	0
Syringes	0	0	0	0	0	0	0
Neria guard infusion set 6 mm	1 (1.8)	0	1 (1.5)	5 (11.1)	2 (6.9)	7 (9.5)	8 (5.7)
Neria guard infusion set 9 mm	3 (5.4)	0	3 (4.5)	8 (17.8)	8 (27.6)	16 (21.6)	19 (13.5)
[redacted]	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
Any TEAE considered associated with COVID-19 infection	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
Any TEAE leading to premature discontinuation of study drug	0	0	0	9 (20.0)	3 (10.3)	12 (16.2)	12 (8.5)
Any TEAE leading to death	0	0	0	0	0	0	0
Any serious TEAE	1 (1.8)	1 (9.1)	2 (3.0)	2 (4.4)	1 (3.4)	3 (4.1)	5 (3.5)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
$ As assessed by investigator.
* ABBV-951 or placebo solution associates with ABBV-951 for ABBV-951 group, associates with placebo solution for Oral CD/LD group.

Program Source Code: [redacted]

TABLE 14.3 1.1.2

Overview of Treatment-Emergent Adverse Events during Double-Blind Treatment Period by Time Interval
(Safety Analysis Set)

	Oral CD/LD			ABBV-951			
	Low Dose (N=56) n (%)	High Dose (N=11) n (%)	All (N=67) n (%)	Low Dose (N=45) n (%)	High Dose (N=29) n (%)	All (N=74) n (%)	Total (N=141) n (%)
Any SAE considered related with infusion pump$	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
Possible	0	0	0	0	0	0	0
Probable	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
Causal relationship	0	0	0	0	0	0	0
All deaths#	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
Deaths related to COVID-19	0	0	0	0	0	0	0
AESI: Any AESI	12 (21.4)	2 (18.2)	14 (20.9)	34 (75.6)	17 (58.6)	51 (68.9)	65 (46.1)
AESI: Infusion Related Infections	1 (1.8)	0	1 (1.5)	7 (15.6)	3 (10.3)	10 (13.5)	11 (7.8)
AESI: Infusion Related Reactions	4 (7.1)	0	4 (6.0)	27 (60.0)	13 (44.8)	40 (54.1)	44 (31.2)
AESI: Hallucinations/psychosis	1 (1.8)	1 (9.1)	2 (3.0)	4 (8.9)	4 (13.8)	8 (10.8)	10 (7.1)
AESI: Polyneuropathy	1 (1.8)	0	1 (1.5)	2 (4.4)	0	2 (2.7)	3 (2.1)
AESI: Somnolence	0	0	0	0	0	0	0
AESI: Falls and associated injuries	6 (10.7)	2 (18.2)	8 (11.9)	6 (13.3)	4 (13.8)	10 (13.5)	18 (12.8)
AESI: Weight loss	0	0	0	0	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.
# Includes non treatment-emergent deaths. Same subject with the death on 14.3_1.1.1.

Program Source Code: [redacted]

TABLE 14.3 1.1.2

Overview of Treatment-Emergent Adverse Events during Double-Blind Treatment Period by Time Interval
(Safety Analysis Set)

	Oral CD/LD			ABBV-951			
	Low Dose (N=56) n (%)	High Dose (N=11) n (%)	All (N=67) n (%)	Low Dose (N=45) n (%)	High Dose (N=29) n (%)	All (N=74) n (%)	Total (N=141) n (%)
Maintenance phase	N=52	N=11	N=63	N=31	N=25	N=56	N=119
Subjects with:							
Any TEAE	20 (38.5)	6 (54.5)	26 (41.3)	22 (71.0)	16 (64.0)	38 (67.9)	64 (53.8)
Any TEAE that is							
Mild	19 (36.5)	5 (45.5)	24 (38.1)	18 (58.1)	10 (40.0)	28 (50.0)	52 (43.7)
Moderate	3 (5.8)	1 (9.1)	4 (6.3)	13 (41.9)	8 (32.0)	21 (37.5)	25 (21.0)
Severe	1 (1.9)	0	1 (1.6)	0	3 (12.0)	3 (5.4)	4 (3.4)
Any TEAE considered related with study drug$	3 (5.8)	2 (18.2)	5 (7.9)	17 (54.8)	14 (56.0)	31 (55.4)	36 (30.3)
Any TEAE associated with any product complaint$	2 (3.8)	1 (9.1)	3 (4.8)	12 (38.7)	8 (32.0)	20 (35.7)	23 (19.3)
ABBV-951 or Placebo solution*	1 (1.9)	1 (9.1)	2 (3.2)	8 (25.8)	5 (20.0)	13 (23.2)	15 (12.6)
CD/LD IR or Placebo capsules	0	0	0	0	0	0	0
Open label CD/LD IR tablets	0	0	0	0	0	0	0
Infusion pump	1 (1.9)	0	1 (1.6)	1 (3.2)	0	1 (1.8)	2 (1.7)
Vial adapter	0	0	0	0	0	0	0
Syringes	0	0	0	0	0	0	0
Neria guard infusion set 6 mm	0	0	0	1 (3.2)	0	1 (1.8)	1 (0.8)
Neria guard infusion set 9 mm	1 (1.9)	0	1 (1.6)	3 (9.7)	3 (12.0)	6 (10.7)	7 (5.9)
[redacted]	0	0	0	1 (3.2)	0	1 (1.8)	1 (0.8)
Any TEAE considered associated with COVID-19 infection	0	0	0	0	0	0	0
Any TEAE leading to premature discontinuation of study drug	1 (1.9)	0	1 (1.6)	3 (9.7)	1 (4.0)	4 (7.1)	5 (4.2)
Any TEAE leading to death	1 (1.9)	0	1 (1.6)	0	0	0	1 (0.8)
Any serious TEAE	2 (3.8)	0	2 (3.2)	1 (3.2)	2 (8.0)	3 (5.4)	5 (4.2)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
$ As assessed by investigator.
* ABBV-951 or placebo solution associates with ABBV-951 for ABBV-951 group, associates with placebo solution for Oral CD/LD group.

Program Source Code: [redacted]

TABLE 14.3 1.1.2

Overview of Treatment-Emergent Adverse Events during Double-Blind Treatment Period by Time Interval
(Safety Analysis Set)

	Oral CD/LD			ABBV-951			
	Low Dose (N=56) n (%)	High Dose (N=11) n (%)	All (N=67) n (%)	Low Dose (N=45) n (%)	High Dose (N=29) n (%)	All (N=74) n (%)	Total (N=141) n (%)
Any SAE considered related with infusion pump$	0	0	0	1 (3.2)	1 (4.0)	2 (3.6)	2 (1.7)
Possible	0	0	0	0	0	0	0
Probable	0	0	0	0	1 (4.0)	1 (1.8)	1 (0.8)
Causal relationship	0	0	0	1 (3.2)	0	1 (1.8)	1 (0.8)
All deaths#	1 (1.9)	0	1 (1.6)	0	0	0	1 (0.8)
Deaths related to COVID-19	0	0	0	0	0	0	0
AESI: Any AESI	12 (23.1)	3 (27.3)	15 (23.8)	19 (61.3)	13 (52.0)	32 (57.1)	47 (39.5)
AESI: Infusion Related Infections	1 (1.9)	0	1 (1.6)	7 (22.6)	5 (20.0)	12 (21.4)	13 (10.9)
AESI: Infusion Related Reactions	1 (1.9)	0	1 (1.6)	13 (41.9)	8 (32.0)	21 (37.5)	22 (18.5)
AESI: Hallucinations/psychosis	0	0	0	1 (3.2)	5 (20.0)	6 (10.7)	6 (5.0)
AESI: Polyneuropathy	1 (1.9)	0	1 (1.6)	0	0	0	1 (0.8)
AESI: Somnolence	1 (1.9)	0	1 (1.6)	1 (3.2)	0	1 (1.8)	2 (1.7)
AESI: Falls and associated injuries	8 (15.4)	3 (27.3)	11 (17.5)	4 (12.9)	1 (4.0)	5 (8.9)	16 (13.4)
AESI: Weight loss	1 (1.9)	0	1 (1.6)	1 (3.2)	0	1 (1.8)	2 (1.7)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
$ As assessed by investigator.
# Includes non treatment-emergent deaths. Same subject with the death on 14.3_1.1.1.

Program Source Code: [redacted]

TABLE 14.3 1.1.2

Overview of Treatment-Emergent Adverse Events during Double-Blind Treatment Period by Time Interval
(Safety Analysis Set)

	Oral CD/LD			ABBV-951			
	Low Dose (N=56) n (%)	High Dose (N=11) n (%)	All (N=67) n (%)	Low Dose (N=45) n (%)	High Dose (N=29) n (%)	All (N=74) n (%)	Total (N=141) n (%)
Persistent from CSCI optimization phase to maintenance phase	N=52	N=11	N=63	N=31	N=25	N=56	N=119
Subjects with:							
Any TEAE	12 (23.1)	1 (9.1)	13 (20.6)	19 (61.3)	11 (44.0)	30 (53.6)	43 (36.1)
Any TEAE that is							
Mild	7 (13.5)	1 (9.1)	8 (12.7)	16 (51.6)	8 (32.0)	24 (42.9)	32 (26.9)
Moderate	5 (9.6)	0	5 (7.9)	9 (29.0)	4 (16.0)	13 (23.2)	18 (15.1)
Severe	0	0	0	0	2 (8.0)	2 (3.6)	2 (1.7)
Any TEAE considered related with study drug$	4 (7.7)	1 (9.1)	5 (7.9)	15 (48.4)	10 (40.0)	25 (44.6)	30 (25.2)
Any TEAE associated with any product complaint$	0	0	0	11 (35.5)	9 (36.0)	20 (35.7)	20 (16.8)
ABBV-951 or Placebo solution*	0	0	0	6 (19.4)	4 (16.0)	10 (17.9)	10 (8.4)
CD/LD IR or Placebo capsules	0	0	0	0	0	0	0
Open label CD/LD IR tablets	0	0	0	0	0	0	0
Infusion pump	0	0	0	0	1 (4.0)	1 (1.8)	1 (0.8)
Vial adapter	0	0	0	0	0	0	0
Syringes	0	0	0	0	0	0	0
Neria guard infusion set 6 mm	0	0	0	1 (3.2)	1 (4.0)	2 (3.6)	2 (1.7)
Neria guard infusion set 9 mm	0	0	0	5 (16.1)	3 (12.0)	8 (14.3)	8 (6.7)
[redacted]	0	0	0	0	0	0	0
Any TEAE considered associated with COVID-19 infection	0	0	0	0	0	0	0
Any TEAE leading to premature discontinuation of study drug	0	0	0	1 (3.2)	1 (4.0)	2 (3.6)	2 (1.7)
Any TEAE leading to death	0	0	0	0	0	0	0
Any serious TEAE	0	0	0	0	1 (4.0)	1 (1.8)	1 (0.8)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
$ As assessed by investigator.
* ABBV-951 or placebo solution associates with ABBV-951 for ABBV-951 group, associates with placebo solution for Oral CD/LD group.

Program Source Code: [redacted]

TABLE 14.3 1.1.2

Overview of Treatment-Emergent Adverse Events during Double-Blind Treatment Period by Time Interval
(Safety Analysis Set)

	Oral CD/LD			ABBV-951			
	Low Dose (N=56) n (%)	High Dose (N=11) n (%)	All (N=67) n (%)	Low Dose (N=45) n (%)	High Dose (N=29) n (%)	All (N=74) n (%)	Total (N=141) n (%)
Any SAE considered related with infusion pump$	0	0	0	0	1 (4.0)	1 (1.8)	1 (0.8)
Possible	0	0	0	0	0	0	0
Probable	0	0	0	0	1 (4.0)	1 (1.8)	1 (0.8)
Causal relationship	0	0	0	0	0	0	0
All deaths#	1 (1.9)	0	1 (1.6)	0	0	0	1 (0.8)
Deaths related to COVID-19	0	0	0	0	0	0	0
AESI: Any AESI	6 (11.5)	1 (9.1)	7 (11.1)	15 (48.4)	10 (40.0)	25 (44.6)	32 (26.9)
AESI: Infusion Related Infections	0	0	0	4 (12.9)	1 (4.0)	5 (8.9)	5 (4.2)
AESI: Infusion Related Reactions	0	0	0	12 (38.7)	8 (32.0)	20 (35.7)	20 (16.8)
AESI: Hallucinations/psychosis	1 (1.9)	1 (9.1)	2 (3.2)	0	4 (16.0)	4 (7.1)	6 (5.0)
AESI: Polyneuropathy	1 (1.9)	0	1 (1.6)	1 (3.2)	0	1 (1.8)	2 (1.7)
AESI: Somnolence	0	0	0	0	0	0	0
AESI: Falls and associated injuries	4 (7.7)	0	4 (6.3)	1 (3.2)	2 (8.0)	3 (5.4)	7 (5.9)
AESI: Weight loss	0	0	0	0	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.
# Includes non treatment-emergent deaths. Same subject with the death on 14.3_1.1.1.

Program Source Code: [redacted]

表18　二重盲検期に発現したすべての有害事象（安全性解析対象集団）：M15-736試験

[redacted]20[redacted] 19:32 <[redacted]>
ABBV-951
STUDY M15-736
R&D/20/1640 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 12

TABLE 14.3__1.3.1.1

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

	Oral CD/LD			ABBV-951			
System Organ Class MedDRA 24.0 Preferred Term	Low Dose (N=56) n (%)	High Dose (N=11) n (%)	All (N=67) n (%)	Low Dose (N=45) n (%)	High Dose (N=29) n (%)	All (N=74) n (%)	Total (N=141) n (%)
Any adverse event	35 (62.5)	7 (63.6)	42 (62.7)	39 (86.7)	24 (82.8)	63 (85.1)	105 (74.5)
心臓障害	2 (3.6)	0	2 (3.0)	0	0	0	2 (1.4)
徐脈	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
心室性期外収縮	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
耳および迷路障害	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
回転性めまい	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
眼障害	2 (3.6)	1 (9.1)	3 (4.5)	2 (4.4)	0	2 (2.7)	5 (3.5)
白内障	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
複視	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
眼刺激	2 (3.6)	0	2 (3.0)	0	0	0	2 (1.4)
硝子体浮遊物	0	1 (9.1)	1 (1.5)	1 (2.2)	0	1 (1.4)	2 (1.4)
胃腸障害	5 (8.9)	2 (18.2)	7 (10.4)	7 (15.6)	2 (6.9)	9 (12.2)	16 (11.3)
腹部不快感	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
便秘	0	0	0	3 (6.7)	1 (3.4)	4 (5.4)	4 (2.8)
齲歯	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
下痢	2 (3.6)	0	2 (3.0)	1 (2.2)	0	1 (1.4)	3 (2.1)

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

Program Source Code: [redacted]

TABLE 14.3 1.3.1.1

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

System Organ Class MedDRA 24.0 Preferred Term	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
胃腸障害 (Cont.)							
口内乾燥	0	1 (9.1)	1 (1.5)	1 (2.2)	0	1 (1.4)	2 (1.4)
おくび	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
鼓腸	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
胃食道逆流性疾患	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
悪心	2 (3.6)	0	2 (3.0)	2 (4.4)	1 (3.4)	3 (4.1)	5 (3.5)
食道食物嵌入	0	1 (9.1)	1 (1.5)	0	0	0	1 (0.7)
一般・全身障害および投与部位の状態	8 (14.3)	1 (9.1)	9 (13.4)	33 (73.3)	16 (55.2)	49 (66.2)	58 (41.1)
無力症	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
カテーテル留置部位内出血	1 (1.8)	0	1 (1.5)	2 (4.4)	0	2 (2.7)	3 (2.1)
カテーテル留置部位紅斑	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
カテーテル留置部位出血	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
カテーテル留置部位硬結	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
カテーテル留置部位疼痛	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
カテーテル留置部位小水疱	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
疲労	2 (3.6)	0	2 (3.0)	1 (2.2)	0	1 (1.4)	3 (2.1)
熱感	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)

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

Program Source Code: [redacted]

TABLE 14.3 1.3.1.1

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

System Organ Class MedDRA 24.0 Preferred Term	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
一般・全身障害および投与部位の状態 (Cont.)							
体温変動感	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
歩行障害	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
インフルエンザ様疾患	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
注入部位内出血	2 (3.6)	0	2 (3.0)	4 (8.9)	2 (6.9)	6 (8.1)	8 (5.7)
注入部位紅斑	1 (1.8)	0	1 (1.5)	14 (31.1)	6 (20.7)	20 (27.0)	21 (14.9)
注入部位血管外漏出	0	0	0	2 (4.4)	0	2 (2.7)	2 (1.4)
注入部位血腫	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
注入部位出血	0	0	0	5 (11.1)	1 (3.4)	6 (8.1)	6 (4.3)
注入部位硬結	0	0	0	2 (4.4)	2 (6.9)	4 (5.4)	4 (2.8)
注入部位炎症	0	0	0	1 (2.2)	1 (3.4)	2 (2.7)	2 (1.4)
注入部位腫瘤	0	0	0	1 (2.2)	1 (3.4)	2 (2.7)	2 (1.4)
注入部位結節	0	0	0	4 (8.9)	2 (6.9)	6 (8.1)	6 (4.3)
注入部位浮腫	0	0	0	8 (17.8)	1 (3.4)	9 (12.2)	9 (6.4)
注入部位疼痛	1 (1.8)	0	1 (1.5)	13 (28.9)	6 (20.7)	19 (25.7)	20 (14.2)
注入部位蒼白	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
注入部位丘疹	0	0	0	2 (4.4)	1 (3.4)	3 (4.1)	3 (2.1)
注入部位そう痒感	0	0	0	4 (8.9)	0	4 (5.4)	4 (2.8)
注入部位発疹	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
注入部位反応	0	0	0	1 (2.2)	2 (6.9)	3 (4.1)	3 (2.1)
注入部位腫脹	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)

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

Program Source Code: [redacted]

TABLE 14.3 1.3.1.1

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

System Organ Class MedDRA 24.0 Preferred Term	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
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	2 (4.4)	0	2 (2.7)	2 (1.4)
注射部位内出血	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
注射部位紅斑	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
注射部位漏出	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
注射部位硬結	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
注射部位炎症	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
注射部位疼痛	0	0	0	2 (4.4)	1 (3.4)	3 (4.1)	3 (2.1)
倦怠感	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
医療機器使用部位そう痒感	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
末梢性浮腫	0	1 (9.1)	1 (1.5)	0	1 (3.4)	1 (1.4)	2 (1.4)
末梢腫脹	0	0	0	3 (6.7)	1 (3.4)	4 (5.4)	4 (2.8)
穿刺部位内出血	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
穿刺部位出血	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
免疫系障害	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
薬物過敏症	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)

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

Program Source Code: [redacted]

TABLE 14.3 1.3.1.1

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

System Organ Class MedDRA 24.0 Preferred Term	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
感染症および寄生虫症	8 (14.3)	0	8 (11.9)	15 (33.3)	7 (24.1)	22 (29.7)	30 (21.3)
肛門カンジダ症	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
COVID-19肺炎	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
カンジダ感染	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
カテーテル留置部位蜂巣炎	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
蜂巣炎	2 (3.6)	0	2 (3.0)	1 (2.2)	0	1 (1.4)	3 (2.1)
真菌感染	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
消化管内細菌過剰増殖	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
消化器カンジダ症	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
麦粒腫	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
注入部位膿瘍	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
注入部位蜂巣炎	0	0	0	10 (22.2)	4 (13.8)	14 (18.9)	14 (9.9)
注入部位感染	0	0	0	1 (2.2)	3 (10.3)	4 (5.4)	4 (2.8)
注射部位蜂巣炎	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
副鼻腔炎	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
尿路感染	2 (3.6)	0	2 (3.0)	1 (2.2)	0	1 (1.4)	3 (2.1)
外陰部腟カンジダ症	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)

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

Program Source Code: [redacted]

TABLE 14.3 1.3.1.1

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

System Organ Class MedDRA 24.0 Preferred Term	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
傷害、中毒および処置合併症	11 (19.6)	4 (36.4)	15 (22.4)	7 (15.6)	4 (13.8)	11 (14.9)	26 (18.4)
動物による引っかき傷	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
節足動物咬傷	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
挫傷	1 (1.8)	0	1 (1.5)	1 (2.2)	1 (3.4)	2 (2.7)	3 (2.1)
転倒	8 (14.3)	4 (36.4)	12 (17.9)	3 (6.7)	3 (10.3)	6 (8.1)	18 (12.8)
関節損傷	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
靭帯捻挫	2 (3.6)	0	2 (3.0)	0	0	0	2 (1.4)
四肢損傷	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
半月板損傷	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
筋骨格内異物	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
引っかき傷	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
皮膚擦過傷	0	1 (9.1)	1 (1.5)	1 (2.2)	0	1 (1.4)	2 (1.4)
皮膚裂傷	1 (1.8)	0	1 (1.5)	1 (2.2)	1 (3.4)	2 (2.7)	3 (2.1)
臨床検査	2 (3.6)	1 (9.1)	3 (4.5)	3 (6.7)	0	3 (4.1)	6 (4.3)
血中アルカリホスファターゼ増加	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
血中ホモシステイン増加	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
血圧上昇	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
血中トリグリセリド増加	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
眼圧上昇	0	1 (9.1)	1 (1.5)	0	0	0	1 (0.7)
ビタミンB6減少	1 (1.8)	0	1 (1.5)	1 (2.2)	0	1 (1.4)	2 (1.4)
体重減少	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)

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

Program Source Code: [redacted]

TABLE 14.3 1.3.1.1

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

System Organ Class MedDRA 24.0 Preferred Term	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
代謝および栄養障害	1 (1.8)	0	1 (1.5)	2 (4.4)	0	2 (2.7)	3 (2.1)
食欲減退	1 (1.8)	0	1 (1.5)	1 (2.2)	0	1 (1.4)	2 (1.4)
脱水	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
筋骨格系および結合組織障害	1 (1.8)	0	1 (1.5)	7 (15.6)	5 (17.2)	12 (16.2)	13 (9.2)
関節痛	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
背部痛	0	0	0	2 (4.4)	0	2 (2.7)	2 (1.4)
骨嚢腫	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
骨腫脹	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
滑液包炎	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
四肢不快感	0	0	0	2 (4.4)	0	2 (2.7)	2 (1.4)
運動性低下	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
筋痙縮	0	0	0	2 (4.4)	0	2 (2.7)	2 (1.4)
筋骨格系胸痛	0	0	0	1 (2.2)	1 (3.4)	2 (2.7)	2 (1.4)
四肢痛	0	0	0	0	2 (6.9)	2 (2.7)	2 (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 1.3.1.1

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

System Organ Class MedDRA 24.0 Preferred Term	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
神経系障害	13 (23.2)	3 (27.3)	16 (23.9)	12 (26.7)	11 (37.9)	23 (31.1)	39 (27.7)
動作時振戦	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
平衡障害	0	0	0	4 (8.9)	0	4 (5.4)	4 (2.8)
運動緩慢	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
手根管症候群	1 (1.8)	0	1 (1.5)	0	1 (3.4)	1 (1.4)	2 (1.4)
頚髄神経根障害	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
認知障害	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
振動覚低下	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
注意力障害	1 (1.8)	0	1 (1.5)	1 (2.2)	0	1 (1.4)	2 (1.4)
浮動性めまい	2 (3.6)	1 (9.1)	3 (4.5)	2 (4.4)	1 (3.4)	3 (4.1)	6 (4.3)
体位性めまい	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
異常感覚	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
味覚不全	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
ジスキネジア	3 (5.4)	1 (9.1)	4 (6.0)	4 (8.9)	4 (13.8)	8 (10.8)	12 (8.5)
ジストニア	1 (1.8)	0	1 (1.5)	1 (2.2)	0	1 (1.4)	2 (1.4)
すくみ現象	0	0	0	1 (2.2)	1 (3.4)	2 (2.7)	2 (1.4)
頭痛	2 (3.6)	1 (9.1)	3 (4.5)	0	1 (3.4)	1 (1.4)	4 (2.8)
感覚鈍麻	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
運動低下	0	0	0	1 (2.2)	1 (3.4)	2 (2.7)	2 (1.4)
嗜眠	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)

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

Program Source Code: [redacted]

TABLE 14.3 1.3.1.1

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

System Organ Class MedDRA 24.0 Preferred Term	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
神経系障害 (Cont.)							
片頭痛	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
オンオフ現象	0	0	0	2 (4.4)	4 (13.8)	6 (8.1)	6 (4.3)
錯感覚	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
パーキンソン病	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
パーキンソニズム	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
下肢静止不能症候群	1 (1.8)	0	1 (1.5)	1 (2.2)	0	1 (1.4)	2 (1.4)
傾眠	1 (1.8)	0	1 (1.5)	1 (2.2)	0	1 (1.4)	2 (1.4)
失神	0	1 (9.1)	1 (1.5)	0	0	0	1 (0.7)
振戦	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
精神障害	8 (14.3)	2 (18.2)	10 (14.9)	8 (17.8)	7 (24.1)	15 (20.3)	25 (17.7)
激越	0	1 (9.1)	1 (1.5)	2 (4.4)	1 (3.4)	3 (4.1)	4 (2.8)
怒り	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
不安	3 (5.4)	0	3 (4.5)	2 (4.4)	1 (3.4)	3 (4.1)	6 (4.3)
無感情	2 (3.6)	0	2 (3.0)	0	0	0	2 (1.4)
妄想	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
うつ病	2 (3.6)	0	2 (3.0)	0	0	0	2 (1.4)
不快気分	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
感情的苦悩	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
幻覚	0	1 (9.1)	1 (1.5)	3 (6.7)	2 (6.9)	5 (6.8)	6 (4.3)

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

Program Source Code: [redacted]

TABLE 14.3 1.3.1.1

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

System Organ Class MedDRA 24.0 Preferred Term	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
精神障害 (Cont.)							
幻嗅	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
幻視	0	0	0	1 (2.2)	3 (10.3)	4 (5.4)	4 (2.8)
不眠症	1 (1.8)	0	1 (1.5)	2 (4.4)	1 (3.4)	3 (4.1)	4 (2.8)
易刺激性	0	1 (9.1)	1 (1.5)	0	0	0	1 (0.7)
中期不眠症	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
悪夢	1 (1.8)	0	1 (1.5)	1 (2.2)	0	1 (1.4)	2 (1.4)
パニック発作	0	0	0	2 (4.4)	0	2 (2.7)	2 (1.4)
妄想症	1 (1.8)	0	1 (1.5)	0	1 (3.4)	1 (1.4)	2 (1.4)
精神病性障害	0	0	0	1 (2.2)	2 (6.9)	3 (4.1)	3 (2.1)
思考異常	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
腎および尿路障害	4 (7.1)	1 (9.1)	5 (7.5)	2 (4.4)	0	2 (2.7)	7 (5.0)
腎結石症	0	1 (9.1)	1 (1.5)	0	0	0	1 (0.7)
頻尿	2 (3.6)	0	2 (3.0)	0	0	0	2 (1.4)
尿管結石症	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
尿失禁	2 (3.6)	0	2 (3.0)	1 (2.2)	0	1 (1.4)	3 (2.1)
生殖系および乳房障害	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
前立腺腫大	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
呼吸器、胸郭および縦隔障害	2 (3.6)	0	2 (3.0)	4 (8.9)	3 (10.3)	7 (9.5)	9 (6.4)
急性呼吸不全	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
咳嗽	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
横隔膜筋力低下	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
発声障害	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)

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

Program Source Code: [redacted]

TABLE 14.3 1.3.1.1

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

System Organ Class MedDRA 24.0 Preferred Term	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)							
呼吸困難	0	0	0	2 (4.4)	1 (3.4)	3 (4.1)	3 (2.1)
頻呼吸	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
上気道咳症候群	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
皮膚および皮下組織障害	3 (5.4)	0	3 (4.5)	5 (11.1)	1 (3.4)	6 (8.1)	9 (6.4)
脱毛症	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
接触皮膚炎	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
紅斑	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
発疹	2 (3.6)	0	2 (3.0)	2 (4.4)	1 (3.4)	3 (4.1)	5 (3.5)
尋常性白斑	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
社会環境	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
日常活動における個人の自立の喪失	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
血管障害	2 (3.6)	0	2 (3.0)	4 (8.9)	1 (3.4)	5 (6.8)	7 (5.0)
潮紅	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
出血	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
高血圧	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
不安定血圧	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)

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

Program Source Code: [redacted]

TABLE 14.3 1.3.1.1

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

	Oral CD/LD			ABBV-951			
System Organ Class MedDRA 24.0 Preferred Term	Low Dose (N=56) n (%)	High Dose (N=11) n (%)	All (N=67) n (%)	Low Dose (N=45) n (%)	High Dose (N=29) n (%)	All (N=74) n (%)	Total (N=141) n (%)
血管障害 (Cont.)							
起立性低血圧	2 (3.6)	0	2 (3.0)	1 (2.2)	0	1 (1.4)	3 (2.1)
静脈瘤	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)

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

Program Source Code: [redacted]

表19　二重盲検期に発現した治験薬との因果関係別の有害事象（安全性解析対象集団）：M15-736試験

[redacted]20[redacted] 19:32 <[redacted]>
ABBV-951
STUDY M15-736
R&D/20/1640 - CLINICAL/STATISTICAL

TABLE 14.3__1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
Any adverse event	35 (62.5)	7 (63.6)	42 (62.7)	39 (86.7)	24 (82.8)	63 (85.1)	105 (74.5)
No reasonable possibility	23 (41.1)	4 (36.4)	27 (40.3)	7 (15.6)	4 (13.8)	11 (14.9)	38 (27.0)
Reasonable possibility	12 (21.4)	3 (27.3)	15 (22.4)	32 (71.1)	20 (69.0)	52 (70.3)	67 (47.5)
心臓障害	2 (3.6)	0	2 (3.0)	0	0	0	2 (1.4)
No reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
Reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
徐脈	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
Reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
心室性期外収縮	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
No reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
耳および迷路障害	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
耳および迷路障害 (Cont.)							
回転性めまい	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
眼障害	2 (3.6)	1 (9.1)	3 (4.5)	2 (4.4)	0	2 (2.7)	5 (3.5)
No reasonable possibility	2 (3.6)	1 (9.1)	3 (4.5)	2 (4.4)	0	2 (2.7)	5 (3.5)
白内障	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
複視	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
No reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
眼刺激	2 (3.6)	0	2 (3.0)	0	0	0	2 (1.4)
No reasonable possibility	2 (3.6)	0	2 (3.0)	0	0	0	2 (1.4)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
眼障害 (Cont.)							
硝子体浮遊物	0	1 (9.1)	1 (1.5)	1 (2.2)	0	1 (1.4)	2 (1.4)
No reasonable possibility	0	1 (9.1)	1 (1.5)	1 (2.2)	0	1 (1.4)	2 (1.4)
胃腸障害	5 (8.9)	2 (18.2)	7 (10.4)	7 (15.6)	2 (6.9)	9 (12.2)	16 (11.3)
No reasonable possibility	3 (5.4)	1 (9.1)	4 (6.0)	4 (8.9)	0	4 (5.4)	8 (5.7)
Reasonable possibility	2 (3.6)	1 (9.1)	3 (4.5)	3 (6.7)	2 (6.9)	5 (6.8)	8 (5.7)
腹部不快感	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
No reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
便秘	0	0	0	3 (6.7)	1 (3.4)	4 (5.4)	4 (2.8)
No reasonable possibility	0	0	0	2 (4.4)	0	2 (2.7)	2 (1.4)
Reasonable possibility	0	0	0	1 (2.2)	1 (3.4)	2 (2.7)	2 (1.4)
齲歯	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
No reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
胃腸障害 (Cont.)							
下痢	2 (3.6)	0	2 (3.0)	1 (2.2)	0	1 (1.4)	3 (2.1)
No reasonable possibility	2 (3.6)	0	2 (3.0)	1 (2.2)	0	1 (1.4)	3 (2.1)
口内乾燥	0	1 (9.1)	1 (1.5)	1 (2.2)	0	1 (1.4)	2 (1.4)
Reasonable possibility	0	1 (9.1)	1 (1.5)	1 (2.2)	0	1 (1.4)	2 (1.4)
おくび	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
Reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
鼓腸	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
No reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
胃食道逆流性疾患	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
胃腸障害 (Cont.)							
悪心	2 (3.6)	0	2 (3.0)	2 (4.4)	1 (3.4)	3 (4.1)	5 (3.5)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	2 (3.6)	0	2 (3.0)	1 (2.2)	1 (3.4)	2 (2.7)	4 (2.8)
食道食物嵌入	0	1 (9.1)	1 (1.5)	0	0	0	1 (0.7)
No reasonable possibility	0	1 (9.1)	1 (1.5)	0	0	0	1 (0.7)
一般・全身障害および投与部位の状態	8 (14.3)	1 (9.1)	9 (13.4)	33 (73.3)	16 (55.2)	49 (66.2)	58 (41.1)
No reasonable possibility	4 (7.1)	1 (9.1)	5 (7.5)	8 (17.8)	5 (17.2)	13 (17.6)	18 (12.8)
Reasonable possibility	4 (7.1)	0	4 (6.0)	25 (55.6)	11 (37.9)	36 (48.6)	40 (28.4)
無力症	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
カテーテル留置部位内出血	1 (1.8)	0	1 (1.5)	2 (4.4)	0	2 (2.7)	3 (2.1)
Reasonable possibility	1 (1.8)	0	1 (1.5)	2 (4.4)	0	2 (2.7)	3 (2.1)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
一般・全身障害および投与部位の状態 (Cont.)							
カテーテル留置部位紅斑	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
カテーテル留置部位出血	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
カテーテル留置部位硬結	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
カテーテル留置部位疼痛	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
カテーテル留置部位小水疱	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
一般・全身障害および投与部位の状態 (Cont.)							
疲労	2 (3.6)	0	2 (3.0)	1 (2.2)	0	1 (1.4)	3 (2.1)
No reasonable possibility	2 (3.6)	0	2 (3.0)	0	0	0	2 (1.4)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
熱感	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
体温変動感	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
No reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
歩行障害	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
No reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
インフルエンザ様疾患	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
一般・全身障害および投与部位の状態 (Cont.)							
注入部位内出血	2 (3.6)	0	2 (3.0)	4 (8.9)	2 (6.9)	6 (8.1)	8 (5.7)
No reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
Reasonable possibility	1 (1.8)	0	1 (1.5)	4 (8.9)	2 (6.9)	6 (8.1)	7 (5.0)
注入部位紅斑	1 (1.8)	0	1 (1.5)	14 (31.1)	6 (20.7)	20 (27.0)	21 (14.9)
No reasonable possibility	0	0	0	3 (6.7)	1 (3.4)	4 (5.4)	4 (2.8)
Reasonable possibility	1 (1.8)	0	1 (1.5)	11 (24.4)	5 (17.2)	16 (21.6)	17 (12.1)
注入部位血管外漏出	0	0	0	2 (4.4)	0	2 (2.7)	2 (1.4)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
注入部位血腫	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
注入部位出血	0	0	0	5 (11.1)	1 (3.4)	6 (8.1)	6 (4.3)
No reasonable possibility	0	0	0	1 (2.2)	1 (3.4)	2 (2.7)	2 (1.4)
Reasonable possibility	0	0	0	4 (8.9)	0	4 (5.4)	4 (2.8)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
一般・全身障害および投与部位の状態 (Cont.)							
注入部位硬結	0	0	0	2 (4.4)	2 (6.9)	4 (5.4)	4 (2.8)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	2 (6.9)	3 (4.1)	3 (2.1)
注入部位炎症	0	0	0	1 (2.2)	1 (3.4)	2 (2.7)	2 (1.4)
Reasonable possibility	0	0	0	1 (2.2)	1 (3.4)	2 (2.7)	2 (1.4)
注入部位腫瘤	0	0	0	1 (2.2)	1 (3.4)	2 (2.7)	2 (1.4)
Reasonable possibility	0	0	0	1 (2.2)	1 (3.4)	2 (2.7)	2 (1.4)
注入部位結節	0	0	0	4 (8.9)	2 (6.9)	6 (8.1)	6 (4.3)
No reasonable possibility	0	0	0	2 (4.4)	0	2 (2.7)	2 (1.4)
Reasonable possibility	0	0	0	2 (4.4)	2 (6.9)	4 (5.4)	4 (2.8)
注入部位浮腫	0	0	0	8 (17.8)	1 (3.4)	9 (12.2)	9 (6.4)
No reasonable possibility	0	0	0	3 (6.7)	0	3 (4.1)	3 (2.1)
Reasonable possibility	0	0	0	5 (11.1)	1 (3.4)	6 (8.1)	6 (4.3)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
一般・全身障害および投与部位の状態 (Cont.)							
注入部位疼痛	1 (1.8)	0	1 (1.5)	13 (28.9)	6 (20.7)	19 (25.7)	20 (14.2)
No reasonable possibility	0	0	0	4 (8.9)	1 (3.4)	5 (6.8)	5 (3.5)
Reasonable possibility	1 (1.8)	0	1 (1.5)	9 (20.0)	5 (17.2)	14 (18.9)	15 (10.6)
注入部位蒼白	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
注入部位丘疹	0	0	0	2 (4.4)	1 (3.4)	3 (4.1)	3 (2.1)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	1 (3.4)	2 (2.7)	2 (1.4)
注入部位そう痒感	0	0	0	4 (8.9)	0	4 (5.4)	4 (2.8)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	3 (6.7)	0	3 (4.1)	3 (2.1)
注入部位発疹	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
一般・全身障害および投与部位の状態 (Cont.)							
注入部位反応	0	0	0	1 (2.2)	2 (6.9)	3 (4.1)	3 (2.1)
Reasonable possibility	0	0	0	1 (2.2)	2 (6.9)	3 (4.1)	3 (2.1)
注入部位腫脹	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
注入部位熱感	0	0	0	2 (4.4)	0	2 (2.7)	2 (1.4)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
注射部位内出血	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
注射部位紅斑	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
一般・全身障害および投与部位の状態 (Cont.)							
注射部位漏出	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
注射部位硬結	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
注射部位炎症	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
注射部位疼痛	0	0	0	2 (4.4)	1 (3.4)	3 (4.1)	3 (2.1)
No reasonable possibility	0	0	0	1 (2.2)	1 (3.4)	2 (2.7)	2 (1.4)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
倦怠感	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
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	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
末梢性浮腫	0	1 (9.1)	1 (1.5)	0	1 (3.4)	1 (1.4)	2 (1.4)
No reasonable possibility	0	1 (9.1)	1 (1.5)	0	1 (3.4)	1 (1.4)	2 (1.4)
末梢腫脹	0	0	0	3 (6.7)	1 (3.4)	4 (5.4)	4 (2.8)
No reasonable possibility	0	0	0	2 (4.4)	1 (3.4)	3 (4.1)	3 (2.1)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
穿刺部位内出血	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
穿刺部位出血	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
免疫系障害	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
薬物過敏症	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
感染症および寄生虫症	8 (14.3)	0	8 (11.9)	15 (33.3)	7 (24.1)	22 (29.7)	30 (21.3)
No reasonable possibility	8 (14.3)	0	8 (11.9)	5 (11.1)	0	5 (6.8)	13 (9.2)
Reasonable possibility	0	0	0	10 (22.2)	7 (24.1)	17 (23.0)	17 (12.1)
肛門カンジダ症	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
COVID-19肺炎	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
No reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
感染症および寄生虫症 (Cont.)							
カンジダ感染	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
カテーテル留置部位蜂巣炎	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
蜂巣炎	2 (3.6)	0	2 (3.0)	1 (2.2)	0	1 (1.4)	3 (2.1)
No reasonable possibility	2 (3.6)	0	2 (3.0)	1 (2.2)	0	1 (1.4)	3 (2.1)
真菌感染	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
No reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
消化管内細菌過剰増殖	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
感染症および寄生虫症 (Cont.)							
消化器カンジダ症	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
麦粒腫	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
No reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
注入部位膿瘍	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
注入部位蜂巣炎	0	0	0	10 (22.2)	4 (13.8)	14 (18.9)	14 (9.9)
No reasonable possibility	0	0	0	2 (4.4)	0	2 (2.7)	2 (1.4)
Reasonable possibility	0	0	0	8 (17.8)	4 (13.8)	12 (16.2)	12 (8.5)
注入部位感染	0	0	0	1 (2.2)	3 (10.3)	4 (5.4)	4 (2.8)
Reasonable possibility	0	0	0	1 (2.2)	3 (10.3)	4 (5.4)	4 (2.8)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
感染症および寄生虫症 (Cont.)							
注射部位蜂巣炎	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
副鼻腔炎	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
No reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
尿路感染	2 (3.6)	0	2 (3.0)	1 (2.2)	0	1 (1.4)	3 (2.1)
No reasonable possibility	2 (3.6)	0	2 (3.0)	1 (2.2)	0	1 (1.4)	3 (2.1)
外陰部腟カンジダ症	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
傷害、中毒および処置合併症	11 (19.6)	4 (36.4)	15 (22.4)	7 (15.6)	4 (13.8)	11 (14.9)	26 (18.4)
No reasonable possibility	10 (17.9)	4 (36.4)	14 (20.9)	5 (11.1)	4 (13.8)	9 (12.2)	23 (16.3)
Reasonable possibility	1 (1.8)	0	1 (1.5)	2 (4.4)	0	2 (2.7)	3 (2.1)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
傷害、中毒および処置合併症 (Cont.)							
動物による引っかき傷	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
節足動物咬傷	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
挫傷	1 (1.8)	0	1 (1.5)	1 (2.2)	1 (3.4)	2 (2.7)	3 (2.1)
No reasonable possibility	1 (1.8)	0	1 (1.5)	1 (2.2)	1 (3.4)	2 (2.7)	3 (2.1)
転倒	8 (14.3)	4 (36.4)	12 (17.9)	3 (6.7)	3 (10.3)	6 (8.1)	18 (12.8)
No reasonable possibility	7 (12.5)	4 (36.4)	11 (16.4)	2 (4.4)	3 (10.3)	5 (6.8)	16 (11.3)
Reasonable possibility	1 (1.8)	0	1 (1.5)	1 (2.2)	0	1 (1.4)	2 (1.4)
関節損傷	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
No reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
傷害、中毒および処置合併症 (Cont.)							
靭帯捻挫	2 (3.6)	0	2 (3.0)	0	0	0	2 (1.4)
No reasonable possibility	2 (3.6)	0	2 (3.0)	0	0	0	2 (1.4)
四肢損傷	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
No reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
半月板損傷	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
筋骨格内異物	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
引っかき傷	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
No reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
傷害、中毒および処置合併症 (Cont.)							
皮膚擦過傷	0	1 (9.1)	1 (1.5)	1 (2.2)	0	1 (1.4)	2 (1.4)
No reasonable possibility	0	1 (9.1)	1 (1.5)	0	0	0	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
皮膚裂傷	1 (1.8)	0	1 (1.5)	1 (2.2)	1 (3.4)	2 (2.7)	3 (2.1)
No reasonable possibility	1 (1.8)	0	1 (1.5)	1 (2.2)	1 (3.4)	2 (2.7)	3 (2.1)
臨床検査	2 (3.6)	1 (9.1)	3 (4.5)	3 (6.7)	0	3 (4.1)	6 (4.3)
No reasonable possibility	2 (3.6)	1 (9.1)	3 (4.5)	0	0	0	3 (2.1)
Reasonable possibility	0	0	0	3 (6.7)	0	3 (4.1)	3 (2.1)
血中アルカリホスファターゼ増加	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
血中ホモシステイン増加	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
臨床検査 (Cont.)							
血圧上昇	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
No reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
血中トリグリセリド増加	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
眼圧上昇	0	1 (9.1)	1 (1.5)	0	0	0	1 (0.7)
No reasonable possibility	0	1 (9.1)	1 (1.5)	0	0	0	1 (0.7)
ビタミンB6減少	1 (1.8)	0	1 (1.5)	1 (2.2)	0	1 (1.4)	2 (1.4)
No reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
体重減少	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
代謝および栄養障害	1 (1.8)	0	1 (1.5)	2 (4.4)	0	2 (2.7)	3 (2.1)
No reasonable possibility	1 (1.8)	0	1 (1.5)	2 (4.4)	0	2 (2.7)	3 (2.1)
食欲減退	1 (1.8)	0	1 (1.5)	1 (2.2)	0	1 (1.4)	2 (1.4)
No reasonable possibility	1 (1.8)	0	1 (1.5)	1 (2.2)	0	1 (1.4)	2 (1.4)
脱水	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
筋骨格系および結合組織障害	1 (1.8)	0	1 (1.5)	7 (15.6)	5 (17.2)	12 (16.2)	13 (9.2)
No reasonable possibility	1 (1.8)	0	1 (1.5)	5 (11.1)	5 (17.2)	10 (13.5)	11 (7.8)
Reasonable possibility	0	0	0	2 (4.4)	0	2 (2.7)	2 (1.4)
関節痛	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
筋骨格系および結合組織障害 (Cont.)							
背部痛	0	0	0	2 (4.4)	0	2 (2.7)	2 (1.4)
No reasonable possibility	0	0	0	2 (4.4)	0	2 (2.7)	2 (1.4)
骨嚢腫	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
No reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
骨腫脹	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
滑液包炎	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
四肢不快感	0	0	0	2 (4.4)	0	2 (2.7)	2 (1.4)
No reasonable possibility	0	0	0	2 (4.4)	0	2 (2.7)	2 (1.4)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
筋骨格系および結合組織障害 (Cont.)							
運動性低下	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
筋痙縮	0	0	0	2 (4.4)	0	2 (2.7)	2 (1.4)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
筋骨格系胸痛	0	0	0	1 (2.2)	1 (3.4)	2 (2.7)	2 (1.4)
No reasonable possibility	0	0	0	1 (2.2)	1 (3.4)	2 (2.7)	2 (1.4)
四肢痛	0	0	0	0	2 (6.9)	2 (2.7)	2 (1.4)
No reasonable possibility	0	0	0	0	2 (6.9)	2 (2.7)	2 (1.4)
神経系障害	13 (23.2)	3 (27.3)	16 (23.9)	12 (26.7)	11 (37.9)	23 (31.1)	39 (27.7)
No reasonable possibility	8 (14.3)	2 (18.2)	10 (14.9)	3 (6.7)	5 (17.2)	8 (10.8)	18 (12.8)
Reasonable possibility	5 (8.9)	1 (9.1)	6 (9.0)	9 (20.0)	6 (20.7)	15 (20.3)	21 (14.9)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
神経系障害 (Cont.)							
動作時振戦	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
No reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
平衡障害	0	0	0	4 (8.9)	0	4 (5.4)	4 (2.8)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	3 (6.7)	0	3 (4.1)	3 (2.1)
運動緩慢	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
手根管症候群	1 (1.8)	0	1 (1.5)	0	1 (3.4)	1 (1.4)	2 (1.4)
No reasonable possibility	1 (1.8)	0	1 (1.5)	0	1 (3.4)	1 (1.4)	2 (1.4)
頚髄神経根障害	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
No reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
神経系障害 (Cont.)							
認知障害	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
振動覚低下	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
No reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
注意力障害	1 (1.8)	0	1 (1.5)	1 (2.2)	0	1 (1.4)	2 (1.4)
No reasonable possibility	1 (1.8)	0	1 (1.5)	1 (2.2)	0	1 (1.4)	2 (1.4)
浮動性めまい	2 (3.6)	1 (9.1)	3 (4.5)	2 (4.4)	1 (3.4)	3 (4.1)	6 (4.3)
No reasonable possibility	1 (1.8)	1 (9.1)	2 (3.0)	1 (2.2)	0	1 (1.4)	3 (2.1)
Reasonable possibility	1 (1.8)	0	1 (1.5)	1 (2.2)	1 (3.4)	2 (2.7)	3 (2.1)
体位性めまい	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
神経系障害 (Cont.)							
異常感覚	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
味覚不全	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
ジスキネジア	3 (5.4)	1 (9.1)	4 (6.0)	4 (8.9)	4 (13.8)	8 (10.8)	12 (8.5)
No reasonable possibility	1 (1.8)	0	1 (1.5)	1 (2.2)	1 (3.4)	2 (2.7)	3 (2.1)
Reasonable possibility	2 (3.6)	1 (9.1)	3 (4.5)	3 (6.7)	3 (10.3)	6 (8.1)	9 (6.4)
ジストニア	1 (1.8)	0	1 (1.5)	1 (2.2)	0	1 (1.4)	2 (1.4)
No reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
すくみ現象	0	0	0	1 (2.2)	1 (3.4)	2 (2.7)	2 (1.4)
Reasonable possibility	0	0	0	1 (2.2)	1 (3.4)	2 (2.7)	2 (1.4)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
神経系障害 (Cont.)							
頭痛	2 (3.6)	1 (9.1)	3 (4.5)	0	1 (3.4)	1 (1.4)	4 (2.8)
No reasonable possibility	2 (3.6)	1 (9.1)	3 (4.5)	0	1 (3.4)	1 (1.4)	4 (2.8)
感覚鈍麻	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
運動低下	0	0	0	1 (2.2)	1 (3.4)	2 (2.7)	2 (1.4)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
嗜眠	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
No reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
片頭痛	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
神経系障害 (Cont.)							
オンオフ現象	0	0	0	2 (4.4)	4 (13.8)	6 (8.1)	6 (4.3)
No reasonable possibility	0	0	0	0	2 (6.9)	2 (2.7)	2 (1.4)
Reasonable possibility	0	0	0	2 (4.4)	2 (6.9)	4 (5.4)	4 (2.8)
錯感覚	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
Reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
パーキンソン病	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
パーキンソニズム	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
下肢静止不能症候群	1 (1.8)	0	1 (1.5)	1 (2.2)	0	1 (1.4)	2 (1.4)
Reasonable possibility	1 (1.8)	0	1 (1.5)	1 (2.2)	0	1 (1.4)	2 (1.4)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
神経系障害 (Cont.)							
傾眠	1 (1.8)	0	1 (1.5)	1 (2.2)	0	1 (1.4)	2 (1.4)
No reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
失神	0	1 (9.1)	1 (1.5)	0	0	0	1 (0.7)
No reasonable possibility	0	1 (9.1)	1 (1.5)	0	0	0	1 (0.7)
振戦	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
No reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
精神障害	8 (14.3)	2 (18.2)	10 (14.9)	8 (17.8)	7 (24.1)	15 (20.3)	25 (17.7)
No reasonable possibility	3 (5.4)	0	3 (4.5)	2 (4.4)	1 (3.4)	3 (4.1)	6 (4.3)
Reasonable possibility	5 (8.9)	2 (18.2)	7 (10.4)	6 (13.3)	6 (20.7)	12 (16.2)	19 (13.5)
激越	0	1 (9.1)	1 (1.5)	2 (4.4)	1 (3.4)	3 (4.1)	4 (2.8)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	1 (9.1)	1 (1.5)	1 (2.2)	1 (3.4)	2 (2.7)	3 (2.1)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
精神障害 (Cont.)							
怒り	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
不安	3 (5.4)	0	3 (4.5)	2 (4.4)	1 (3.4)	3 (4.1)	6 (4.3)
No reasonable possibility	2 (3.6)	0	2 (3.0)	0	0	0	2 (1.4)
Reasonable possibility	1 (1.8)	0	1 (1.5)	2 (4.4)	1 (3.4)	3 (4.1)	4 (2.8)
無感情	2 (3.6)	0	2 (3.0)	0	0	0	2 (1.4)
No reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
Reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
妄想	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
うつ病	2 (3.6)	0	2 (3.0)	0	0	0	2 (1.4)
No reasonable possibility	2 (3.6)	0	2 (3.0)	0	0	0	2 (1.4)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
精神障害 (Cont.)							
不快気分	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
感情的苦悩	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
幻覚	0	1 (9.1)	1 (1.5)	3 (6.7)	2 (6.9)	5 (6.8)	6 (4.3)
No reasonable possibility	0	0	0	1 (2.2)	1 (3.4)	2 (2.7)	2 (1.4)
Reasonable possibility	0	1 (9.1)	1 (1.5)	2 (4.4)	1 (3.4)	3 (4.1)	4 (2.8)
幻嗅	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
幻視	0	0	0	1 (2.2)	3 (10.3)	4 (5.4)	4 (2.8)
Reasonable possibility	0	0	0	1 (2.2)	3 (10.3)	4 (5.4)	4 (2.8)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
精神障害 (Cont.)							
不眠症	1 (1.8)	0	1 (1.5)	2 (4.4)	1 (3.4)	3 (4.1)	4 (2.8)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	1 (1.8)	0	1 (1.5)	1 (2.2)	1 (3.4)	2 (2.7)	3 (2.1)
易刺激性	0	1 (9.1)	1 (1.5)	0	0	0	1 (0.7)
Reasonable possibility	0	1 (9.1)	1 (1.5)	0	0	0	1 (0.7)
中期不眠症	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
悪夢	1 (1.8)	0	1 (1.5)	1 (2.2)	0	1 (1.4)	2 (1.4)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
パニック発作	0	0	0	2 (4.4)	0	2 (2.7)	2 (1.4)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
精神障害 (Cont.)							
妄想症	1 (1.8)	0	1 (1.5)	0	1 (3.4)	1 (1.4)	2 (1.4)
Reasonable possibility	1 (1.8)	0	1 (1.5)	0	1 (3.4)	1 (1.4)	2 (1.4)
精神病性障害	0	0	0	1 (2.2)	2 (6.9)	3 (4.1)	3 (2.1)
No reasonable possibility	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	1 (3.4)	2 (2.7)	2 (1.4)
思考異常	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
Reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
腎および尿路障害	4 (7.1)	1 (9.1)	5 (7.5)	2 (4.4)	0	2 (2.7)	7 (5.0)
No reasonable possibility	4 (7.1)	1 (9.1)	5 (7.5)	2 (4.4)	0	2 (2.7)	7 (5.0)
腎結石症	0	1 (9.1)	1 (1.5)	0	0	0	1 (0.7)
No reasonable possibility	0	1 (9.1)	1 (1.5)	0	0	0	1 (0.7)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
腎および尿路障害 (Cont.)							
頻尿	2 (3.6)	0	2 (3.0)	0	0	0	2 (1.4)
No reasonable possibility	2 (3.6)	0	2 (3.0)	0	0	0	2 (1.4)
尿管結石症	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
尿失禁	2 (3.6)	0	2 (3.0)	1 (2.2)	0	1 (1.4)	3 (2.1)
No reasonable possibility	2 (3.6)	0	2 (3.0)	1 (2.2)	0	1 (1.4)	3 (2.1)
生殖系および乳房障害	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
前立腺腫大	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
呼吸器、胸郭および縦隔障害	2 (3.6)	0	2 (3.0)	4 (8.9)	3 (10.3)	7 (9.5)	9 (6.4)
No reasonable possibility	2 (3.6)	0	2 (3.0)	2 (4.4)	2 (6.9)	4 (5.4)	6 (4.3)
Reasonable possibility	0	0	0	2 (4.4)	1 (3.4)	3 (4.1)	3 (2.1)
急性呼吸不全	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
No reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
咳嗽	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
No reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
横隔膜筋力低下	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
発声障害	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)							
呼吸困難	0	0	0	2 (4.4)	1 (3.4)	3 (4.1)	3 (2.1)
No reasonable possibility	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	2 (4.4)	0	2 (2.7)	2 (1.4)
頻呼吸	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
上気道咳症候群	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
皮膚および皮下組織障害	3 (5.4)	0	3 (4.5)	5 (11.1)	1 (3.4)	6 (8.1)	9 (6.4)
No reasonable possibility	3 (5.4)	0	3 (4.5)	3 (6.7)	1 (3.4)	4 (5.4)	7 (5.0)
Reasonable possibility	0	0	0	2 (4.4)	0	2 (2.7)	2 (1.4)
脱毛症	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
皮膚および皮下組織障害 (Cont.)							
接触皮膚炎	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
紅斑	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
No reasonable possibility	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
発疹	2 (3.6)	0	2 (3.0)	2 (4.4)	1 (3.4)	3 (4.1)	5 (3.5)
No reasonable possibility	2 (3.6)	0	2 (3.0)	2 (4.4)	1 (3.4)	3 (4.1)	5 (3.5)
尋常性白斑	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
社会環境	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
社会環境 (Cont.)							
日常活動における個人の自立の喪失	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
血管障害	2 (3.6)	0	2 (3.0)	4 (8.9)	1 (3.4)	5 (6.8)	7 (5.0)
No reasonable possibility	0	0	0	2 (4.4)	0	2 (2.7)	2 (1.4)
Reasonable possibility	2 (3.6)	0	2 (3.0)	2 (4.4)	1 (3.4)	3 (4.1)	5 (3.5)
潮紅	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
出血	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)

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 1.5

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

System Organ Class MedDRA 24.0 Preferred Term Relationship	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
血管障害 (Cont.)							
高血圧	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
不安定血圧	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
Reasonable possibility	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
起立性低血圧	2 (3.6)	0	2 (3.0)	1 (2.2)	0	1 (1.4)	3 (2.1)
Reasonable possibility	2 (3.6)	0	2 (3.0)	1 (2.2)	0	1 (1.4)	3 (2.1)
静脈瘤	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
No reasonable possibility	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)

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]

表20　死亡した被験者一覧：M15-736試験

[redacted]20[redacted] 19:32 <[redacted]>
ABBV-951
STUDY M15-736
R&D/20/1640 - CLINICAL/STATISTICAL

TABLE 14.3__2.1

Listing of All Deaths
(All Subjects Screened)

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: Open-Label CD/LD IR* R2: Study Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with Study Drug from 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: ORAL CD/LD LOW DOSE								
[redacted]# Age: 8[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg Country: UNITED STATES								
	TRT	1 TO 70	68	68	R: CELLULITIS OF THE RIGHT LEG S: 感染症および寄生虫症 P: 蜂巣炎 L: Cellulitis of leg	O: Yes	S: SEVERE R1: NO REASONABLE POSSIBILITY R2: NO REASONABLE POSSIBILITY R4: No A1: DRUG WITHDRAWN O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED	S: Yes, Hospitalization or prolonged hospitalization R: NOT RELATED O: SUBJECT BUMPED HER KNEE RESULTING IN INFECTION A: NO REASONABLE POSSIBILITY

* from oral stablization period.
\# Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.1

Listing of All Deaths
(All Subjects Screened)

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: Open-Label CD/LD IR* R2: Study Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with Study Drug from 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: ORAL CD/LD LOW DOSE								
[redacted]# Age: 8[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg Country: UNITED STATES								
	FU	71 TO 21	91		R: ACUTE RESPIRATORY FAILURE S: 呼吸器、胸郭および縦隔障害 P: 急性呼吸不全 L: Acute respiratory failure	E: 98 L: 8 DAYS	S: SEVERE R1: NO REASONABLE POSSIBILITY R2: NO REASONABLE POSSIBILITY R4: No A1: Other: SUBJECT HAD PREVIOUSLY STOPPED STUDY DRUG, ORAL AND ABBV-951 AT PREVIOUS HOSPITAL STAY O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED	S: Yes, Life threatening, Death of subject, Hospitalization or prolonged hospitalization R: NOT RELATED O: SEPSIS A: NO REASONABLE POSSIBILITY

* from oral stablization period.
\# Subject prematurely discontinued.

Program Source Code: [redacted]

表21　二重盲検期に発現した重篤な有害事象（安全性解析対象集団）：M15-736試験

[redacted]20[redacted] 19:32 <[redacted]>
ABBV-951
STUDY M15-736
R&D/20/1640 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 2

TABLE 14.3__1.3.2.1

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

	Oral CD/LD			ABBV-951			
System Organ Class MedDRA 24.0 Preferred Term	Low Dose (N=56) n (%)	High Dose (N=11) n (%)	All (N=67) n (%)	Low Dose (N=45) n (%)	High Dose (N=29) n (%)	All (N=74) n (%)	Total (N=141) n (%)
Any adverse event	3 (5.4)	1 (9.1)	4 (6.0)	3 (6.7)	3 (10.3)	6 (8.1)	10 (7.1)
感染症および寄生虫症	2 (3.6)	0	2 (3.0)	1 (2.2)	1 (3.4)	2 (2.7)	4 (2.8)
COVID-19肺炎	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
カテーテル留置部位蜂巣炎	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
蜂巣炎	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
注入部位蜂巣炎	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
傷害、中毒および処置合併症	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
挫傷	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
転倒	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
代謝および栄養障害	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
脱水	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
神経系障害	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
片頭痛	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
精神障害	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
妄想	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
妄想症	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
精神病性障害	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)

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

Program Source Code: [redacted]

TABLE 14.3 1.3.2.1

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

System Organ Class MedDRA 24.0 Preferred Term	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
腎および尿路障害	0	1 (9.1)	1 (1.5)	0	0	0	1 (0.7)
腎結石症	0	1 (9.1)	1 (1.5)	0	0	0	1 (0.7)
生殖系および乳房障害	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
前立腺腫大	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
呼吸器、胸郭および縦隔障害	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
急性呼吸不全	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)

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

Program Source Code: [redacted]

表22　二重盲検期に発現した中止に至った有害事象（安全性解析対象集団）：M15-736試験

[redacted]20[redacted] 19:32 <[redacted]>
ABBV-951
STUDY M15-736
R&D/20/1640 - CLINICAL/STATISTICAL

TABLE 14.3__1.3.3.1

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

System Organ Class MedDRA 24.0 Preferred Term	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
Any adverse event	1 (1.8)	0	1 (1.5)	12 (26.7)	4 (13.8)	16 (21.6)	17 (12.1)
一般・全身障害および投与部位の状態	0	0	0	8 (17.8)	0	8 (10.8)	8 (5.7)
無力症	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
注入部位内出血	0	0	0	2 (4.4)	0	2 (2.7)	2 (1.4)
注入部位紅斑	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
注入部位出血	0	0	0	2 (4.4)	0	2 (2.7)	2 (1.4)
注入部位結節	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
注入部位浮腫	0	0	0	2 (4.4)	0	2 (2.7)	2 (1.4)
注入部位疼痛	0	0	0	3 (6.7)	0	3 (4.1)	3 (2.1)
感染症および寄生虫症	1 (1.8)	0	1 (1.5)	3 (6.7)	1 (3.4)	4 (5.4)	5 (3.5)
蜂巣炎	1 (1.8)	0	1 (1.5)	0	0	0	1 (0.7)
注入部位蜂巣炎	0	0	0	3 (6.7)	1 (3.4)	4 (5.4)	4 (2.8)
筋骨格系および結合組織障害	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
運動性低下	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)

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

Program Source Code: [redacted]

TABLE 14.3 1.3.3.1

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

System Organ Class MedDRA 24.0 Preferred Term	Oral CD/LD Low Dose (N=56) n (%)	Oral CD/LD High Dose (N=11) n (%)	Oral CD/LD All (N=67) n (%)	ABBV-951 Low Dose (N=45) n (%)	ABBV-951 High Dose (N=29) n (%)	ABBV-951 All (N=74) n (%)	Total (N=141) n (%)
神経系障害	0	0	0	0	2 (6.9)	2 (2.7)	2 (1.4)
体位性めまい	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
運動低下	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
精神障害	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
幻覚	0	0	0	1 (2.2)	0	1 (1.4)	1 (0.7)
呼吸器、胸郭および縦隔障害	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)
横隔膜筋力低下	0	0	0	0	1 (3.4)	1 (1.4)	1 (0.7)

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			X

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	5[redacted]	MALE	WHITE

Medical History	Onset Year
ALLERGY FISH	19[redacted]
PYLORIC STENOSIS	19[redacted]
MUMPS	19[redacted]
CHICKEN POX	19[redacted]
SEVERED MUSCLE LEFT FOOT (HALLICIS LONGUS)	19[redacted]
CHRONIC TONSILLITIS	19[redacted]
SLIGHT HEARING LOSS LEFT EAR	19[redacted]
DISLOCATION RIGHT ELBOW	19[redacted]
FRACTURED HUMEROUS	19[redacted]
DEPRESSION	20[redacted]
SPIRAL FRACTURE 5TH FINGER RIGHT HAND	20[redacted]
ROSS RIVER VIRUS	20[redacted]
ARTHRITIS LEFT HIP	20[redacted]
SEVERE DEPRESSION	20[redacted]
CELLULITIS WRIST	20[redacted]
COMMINUTED FRACTURE OF DISTAL RADIUS (WRIST)	20[redacted]
HEAD TRAUMA	20[redacted]
MAXILLARY FRACTURES	20[redacted]
MULTIPLE ORBITAL FRACTURE	20[redacted]
ARTHRITIS RIGHT ELBOW, FINGERS, RIGHT FOOT	20[redacted]
LIPODERMATOSCLEROSIS	20[redacted]
VARICOSE ECZEMA	20[redacted]
VARICOSE VEINS LEFT LEG	20[redacted]
BURSITIS METATARSAL HEADS RIGHT FOOT	20[redacted]
MIILD CONSTIPATION	20[redacted]

CHRONIC MICRO HAEMORRAGES BRAIN	20[redacted]
VENOUS ULCERS	20[redacted]
ANXIETY	20[redacted]
CHRONIC VENOUS INSUFFICIENCY LEFT LEG	20[redacted]
LOW SERUM VITAMIN B12	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
REPAIR FLEXOR HALLLICIS LONGUS LEFT FOOT	19[redacted]
RIGHT WRIST FRACTURE REPAIR - CORTICAL PLATE WITH SCREW FIXATION	20[redacted]
REMOVAL SCREWS RIGHT WRIST	20[redacted]
DISTAL RADIO-ULNAR OSTEOTOMIES	20[redacted]
MRI	20[redacted]
TOTAL HIP REPLACEMENT LEFT HIP	20[redacted]
ARTHROSCOPY AND DEBRIDEMENT RIGHT ELBOW	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	1 CIGARETTE	3	19[redacted]
CIGARS	FORMER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

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

Study Drug Prescription

Study Drug	New Quadrant for Pump Infusion	Continuous Flow Rate (mL/h)	Infusion Loading Dose Volume (mL)	Oral study drug dose (CAPSULE)	Dose Date/Day
ABBV-951	SITE A9				[redacted]20[redacted]/ 1
ABBV-951		0.57	1.6		[redacted]20[redacted]/ 1
ABBV-951	SITE A2				[redacted]20[redacted]/ 3

ABBV-951	SITE A12			[redacted] / 6
ABBV-951		0.62	0.0	[redacted] / 6
ABBV-951	SITE A10			[redacted] / 8
ABBV-951		0.7	0.0	[redacted] / 15
ABBV-951	SITE A1			[redacted] / 17
ABBV-951	SITE A4			[redacted] / 20
ABBV-951	SITE B5			[redacted] / 23
ABBV-951	SITE A2			[redacted] / 26
ABBV-951		0.78	0.0	[redacted] / 29
ABBV-951	SITE A3			[redacted] / 55
ABBV-951	SITE A3			[redacted] / 76
ABBV-951	SITE A9			[redacted] / 79
ABBV-951	SITE A12			[redacted] / 82

Daily Dose by Molecular Weight

Study Drug	CSCI Infusion (mg LD)	Total Oral Dose (mg)	Route (Subcutaneous) / Frequency (Times per Day)	First Dose Date/Day	Last Dose Date/Day
ABBV-951 Loading dose	273.2		SC / CONTINUOUS	[redacted] / 1	
Placebo ORAL CD/LD			ORAL / 2	[redacted] / 1	
ABBV-951	1273.04		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951	2287.19		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951	2237.55		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951	2259.94		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951	2303.74		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951	2332.42		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951	2471.94		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951	2461.36		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
Placebo ORAL CD/LD			ORAL / 1	[redacted] / 9	
ABBV-951	2441.24		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
Placebo ORAL CD/LD			ORAL / 6	[redacted] / 10	
ABBV-951	2474.06		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
Placebo ORAL CD/LD			ORAL / 6	[redacted] / 11	
ABBV-951	2420.07		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
Placebo ORAL CD/LD			ORAL / 6	[redacted] / 12	
ABBV-951	2493.12		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
Placebo ORAL CD/LD			ORAL / 6	[redacted] / 13	
ABBV-951	2452.89		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13

Placebo ORAL CD/LD		ORAL / 6	[redacted]20[redacted] / 14	
ABBV-951	2519.58	SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
Placebo ORAL CD/LD		ORAL / 6	[redacted]20[redacted] / 15	
ABBV-951	2470.88	SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
Placebo ORAL CD/LD		ORAL / 6	[redacted]20[redacted] / 16	
ABBV-951	2716.80	SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
Placebo ORAL CD/LD		ORAL / 6	[redacted]20[redacted] / 17	
ABBV-951	2800.47	SC / CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
Placebo ORAL CD/LD		ORAL / 6	[redacted]20[redacted] / 18	
ABBV-951	2771.78	SC / CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
Placebo ORAL CD/LD		ORAL / 6	[redacted]20[redacted] / 19	
ABBV-951	2805.25	SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
Placebo ORAL CD/LD		ORAL / 6	[redacted]20[redacted] / 20	
ABBV-951	2818.39	SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
Placebo ORAL CD/LD		ORAL / 6	[redacted]20[redacted] / 21	
ABBV-951	2781.34	SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
Placebo ORAL CD/LD		ORAL / 6	[redacted]20[redacted] / 22	
ABBV-951	2805.25	SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
Placebo ORAL CD/LD		ORAL / 6	[redacted]20[redacted] / 23	
ABBV-951	2801.66	SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
Placebo ORAL CD/LD		ORAL / 6	[redacted]20[redacted] / 24	
ABBV-951	2783.73	SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
Placebo ORAL CD/LD		ORAL / 8	[redacted]20[redacted] / 25	
ABBV-951	2735.92	SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
Placebo ORAL CD/LD		ORAL / 6	[redacted]20[redacted] / 26	
ABBV-951	2857.84	SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
Placebo ORAL CD/LD		ORAL / 6	[redacted]20[redacted] / 27	
ABBV-951	2800.47	SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
Placebo ORAL CD/LD		ORAL / 6	[redacted]20[redacted] / 28	
ABBV-951	2848.28	SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
Placebo ORAL CD/LD		ORAL / 2	[redacted]20[redacted] / 29	
ABBV-951	2817.20	SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34

ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
Placebo ORAL CD/LD		ORAL / 7	[redacted]20[redacted] / 54	
ABBV-951	3177.79	SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
Placebo ORAL CD/LD		ORAL / 6	[redacted]20[redacted] / 55	
ABBV-951	3168.47	SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
INTERRUPTION			[redacted]20[redacted] / 55	[redacted]20[redacted] / 56
Placebo ORAL CD/LD		ORAL / 6	[redacted]20[redacted] / 56	
ABBV-951	3085.89	SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
INTERRUPTION			[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
Placebo ORAL CD/LD		ORAL / 2	[redacted]20[redacted] / 57	
ABBV-951	3140.50	SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65

ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 74	[redacted]20[redacted] / 74
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 76
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 77
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 78	[redacted]20[redacted] / 78
ABBV-951	3196.44	SC / CONTINUOUS	[redacted]20[redacted] / 79	[redacted]20[redacted] / 79
Placebo ORAL CD/LD		ORAL / 6	[redacted]20[redacted] / 80	
ABBV-951	3113.86	SC / CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 80
Placebo ORAL CD/LD		ORAL / 6	[redacted]20[redacted] / 81	
ABBV-951	3169.80	SC / CONTINUOUS	[redacted]20[redacted] / 81	[redacted]20[redacted] / 81
Placebo ORAL CD/LD		ORAL / 6	[redacted]20[redacted] / 82	
ABBV-951	3051.26	SC / CONTINUOUS	[redacted]20[redacted] / 82	[redacted]20[redacted] / 82
Placebo ORAL CD/LD		ORAL / 7	[redacted]20[redacted] / 83	
ABBV-951	3121.85	SC / CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
Placebo ORAL CD/LD		ORAL / 1	[redacted]20[redacted] / 84	
ABBV-951	1668.80	SC / CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
SERTRALINE	100 mg	QD	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	250.000 mg	QID	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	100.000 mg	QID	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	50.000 mg	QID	Y-M: 20[redacted]
ENTACAPONE	200.000 mg	QID	Y-M: 20[redacted]
CANNABIDIOL	100 mg	QD	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	200.000 mg	QD	Y-M: 20[redacted] / -175
COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19)	NOT REPORTED	ONCE	Y-M: 20[redacted]-[redacted] / -98
INFLUENZA VACCINE	1 INJECTION mg	OTHER: ANNUAL	Y-M: 20[redacted]-[redacted] / -56

COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19)	NOT REPORTED	ONCE	Y-M: 20[redacted] / -24
ROTIGOTINE	6.000 mg	QD	Y-M: 20[redacted] / -24
HYDROXOCOBALAMIN	1 mL	OTHER: WEEKLY	Y-M: 20[redacted] / -17

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
SERTRALINE	100 mg	QD	Y-M: 20[redacted]	ONGOING
CANNABIDIOL	100 mg	QD	Y-M: 20[redacted]	ONGOING
COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19)		ONCE	Y-M: 20[redacted] / -98	NOT REPORTED
COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19)		ONCE	Y-M: 20[redacted] / -24	NOT REPORTED
HYDROXOCOBALAMIN	1 mL	OTHER: WEEKLY	Y-M: 20[redacted] / -17	ONGOING
CODEINE PHOSPHATE;PARACETAMOL	500/30 mg	PRN	Y-M: 20[redacted] / 17	ONGOING
FLUCLOXACILLIN	1000 mg	QID	Y-M: 20[redacted] / 17	Y-M: 20[redacted] / 21
OXYCODONE	10 mg	OTHER: STAT	Y-M: 20[redacted] / 21	Y-M: 20[redacted] / 21
VANCOMYCIN	2500 mg	OTHER: STAT	Y-M: 20[redacted] / 21	Y-M: 20[redacted] / 21
VANCOMYCIN	1500 mg	BID	Y-M: 20[redacted] / 22	Y-M: 20[redacted] / 22
CEFALEXIN	500 mg	QID	Y-M: 20[redacted] / 23	Y-M: 20[redacted] / 32
CORTICOSTEROID NOS	1 INJECTION mL	OTHER: STAT	Y-M: 20[redacted] / 64	Y-M: 20[redacted] / 64
FLUCLOXACILLIN	1000 mg	QID	Y-M: 20[redacted] / 81	ONGOING

Event #1: Serious Adverse Event, 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] / 17
Age at AE Onset	5[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 21): ALANINE AMINOTRANSFERASE: 6 [0 - 55] U/L; ALBUMIN: 35 [34 - 48] G/L; ALKALINE PHOSPHATASE: 88 [30 - 110] U/L; ASPARTATE AMINOTRANSFERASE: 28 [0 - 45] U/L; BASOPHILS: 0.02 [NOT REPORTED - 0.1] 10^9/L; BASOPHILS/LEUKOCYTES: 0 [0 - 2] %; BILIRUBIN: 11 [2 - 24] UMOL/L; CALCIUM: 2.26 [2.1 - 2.6] MMOL/L; CREATININE: 56 [60 - 110] UMOL/L; EOSINOPHILS: 0.02 [0.02 - 0.5] 10^9/L; EOSINOPHILS/LEUKOCYTES: 0 [1 - 4] %; ERYTHROCYTES: 4.3 [4.5 - 6] 10^12/L; GLUCOSE: 5.6 [3.2 - 5.5] MMOL/L; HEMOGLOBIN: 132 [135 - 175] G/L; LEUKOCYTES: 7.6 [4 - 11] 10^9/L; LYMPHOCYTES: 0.73 [1.1 - 3.5] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 10 [20 - 44] %; MONOCYTES: 0.43 [0.2 - 0.8] 10^9/L; MONOCYTES/LEUKOCYTES: 6 [2 - 9] %; NPTST004-ANION GAP: 16 [7 - 17] MMOL/L; NPTST009-BICARBONATE: 23 [22 - 32] MMOL/L; NPTST012-C-REACTIVE PROTEIN: 75.3 [0 - 8] MG/L; NPTST015-

CHLORIDE: 103 [95 - 110] MMOL/L; NPTST017-CLC.IONISED CALCIUM: 1.19 [1.1 - 1.3] MMOL/L; NPTST025-ESTIMATED GFR: >90 [60 - NOT REPORTED] ML/MIN/1.73M2; NPTST027-GAMMA GLUTAMYL TRANS: 22 [0 - 60] U/L; NPTST029-GLOBULINS: 36 [21 - 41] G/L; NPTST036-LACTATE DEHYDROGENASE: 172 [120 - 250] U/L; NPTST045-MEAN CELL HB CONCENTRATION: 340 [310 - 360] G/L; NPTST046-MEAN CELL VOLUME: 89.9 [80 - 98] FL; NPTST047-MEAN CORPUSCULAR HEMOGLOBIN: 31 [27 - 33] PG; NPTST048-MEAN PLATELET VOLUME: 10 [9.5 - 13] FL; NPTST055-PACKED CELL VOLUME: 0.39 [0.4 - 0.5] L/L; NPTST058-PHOSPHATE: 1.04 [0.75 - 1.5] MMOL/L; NPTST065-RED CELL DISTRIBUTION: 12.2 [12 - 15] %; NPTST068-URATE: 0.27 [0.2 - 0.4] MMOL/L; NPTST069-UREA: 3.8 [2.7 - 8] MMOL/L; NEUTROPHILS: 6.42 [1.8 - 7.5] 10^9/L; NEUTROPHILS/LEUKOCYTES: 84 [50 - 70] %; PLATELETS: 253 [150 - 450] 10^9/L; POTASSIUM: 4 [3.5 - 5.2] MMOL/L; PROTEIN: 71 [60 - 80] G/L; SODIUM: 138 [135 - 145] MMOL/L

Microbiology

[redacted]20[redacted] (RX DAY 21): BLOOD BLOOD CULTURE: NEGATIVE

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 21): ULTRASOUND ABDOMEN:TARGETED SCANNING OF THE ANTERIOR ABDOMINAL WALL IN THE REGION. THERE WAS INCREASED FAT ECHOGENICITY AND HYPERAEMIA COMPATIBLE WITH CELLULITIS. THIS WAS INTERSPACED WITH SMALL HYPO ECHOIC POCKET LIKEL Y OEDEMA IN SETTING OF CELLULITIS. NO DRAINABLE COLLECTION.

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	PROBABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Pump	[redacted] INFUSION SET 9 MM
Other Cause of Event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #2: 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] / 80
Age at AE Onset	5[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	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 Pump	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Generated: [redacted]20[redacted]:10:27

Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-736

治験責任医師からの報告。本被験者はオーストラリアの 5[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で盲検下にて治験薬及びカルビドパ / レボドパ（以下「CD/LD」）が投与され，注入部位蜂巣炎を発現した。

Event 1 の臨床経過：

関連する病歴は，手首の蜂巣炎，静脈瘤性湿疹，左下肢の静脈瘤，パーキンソン病，静脈性潰瘍，左下肢の慢性静脈不全，元喫煙者（紙巻きタバコ 1 日 1 本を 3 年間），葉巻きの元喫煙者，及び現飲酒者（1 日 2 杯未満）であった。

ランダム化に先立ち，本被験者は 20[redacted] 年 [redacted] 月 [redacted] 日から 20[redacted] 年 [redacted] 月 [redacted] 日まで本治験の安定化期にて CD/LD を経口投与された。20[redacted] 年 [redacted] 月 [redacted] 日，本被験者はランダム化され，本治験の二重盲検最適化期を開始した。当該事象は本治験の二重盲検最適化期に発現した。

投与 17 日目，被験者は注入部位蜂巣炎を発現した。

投与 21 日目，被験者は抗生物質を 4 日間経口投与したにも関わらず蜂巣炎が悪化したため入院した。症状及び徴候には進行性紅斑，前腹壁部の圧痛，注入部位紅斑，疼痛，及び浮腫が挙げられた。被験者は抗生物質を静脈内投与された。投与 22 日目，被験者は退院した。

治験責任医師によると，皮下注入がリスク因子に含まれた。

被験者にオキシコドン，フルクロキサシリン，アセトアミノフェン／コデイン，バンコマイシン，及びセファレキシンが投与された。

The patient's past medications include:

SINEMET CR for PARKINSON'S DISEASE (20[redacted] - [redacted] 20[redacted], 20[redacted] - [redacted] 20[redacted])

ENTACAPONE for PARKINSON'S DISEASE (20[redacted] - [redacted] 20[redacted])

MADOPAR for PARKINSON'S DISEASE (20[redacted] - [redacted] 20[redacted], 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Blinded)

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1) Infusion site cellulitis (10065455) (Infusion site cellulitis (10065455)) [v.24.0] [10065455]

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

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Not Applicable

Causality for CARBIDOPA/LEVODOPA (Open Label)

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1) Infusion site cellulitis (10065455) (Infusion site cellulitis (10065455)) [v.24.0] [10065455]

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

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

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Blinded)

Event of INFUSION SITE CELLULITIS

- Investigator: Not applicable

- AbbVie: Not applicable

Alternative Etiology for CARBIDOPA/LEVODOPA (Open Label)

Event of INFUSION SITE CELLULITIS

- Investigator: More likely related to blinded ABBV-951.

- AbbVie: Temporally implausible as event occurred 3 weeks after administration of last dose of oral levodopa/carbidopa.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BILIRUBIN:** 11 umol/L (normal 2 to 24)

[redacted] **20[redacted] BLOOD CULTURE:** Negative

[redacted] **20[redacted] CREATININE:** 56 umol/l (normal 60 to 110)

[redacted] **20[redacted] ESTIMATED GFR:** .90 (099¥¥mL/min/1.73m2)

[redacted] **20[redacted] MEAN CELL VOLUME:** 89.9 fL (normal 80.0 to 98.0)

[redacted] **20[redacted] MEAN CORPUSCULAR HEMOGLOBIN:** 31 PG (normal 27 to 33)

Unknown date MEAN PLATELET VOLUME: 10 fL (normal 9.5 to 13.0)

[redacted] **20[redacted] PACKED CELL VOLUME:** 0.39 L/L (normal 0.40 to 0.50)

[redacted] **20[redacted] ULTRASOUND ABDOMEN:** Targeted scanning of the anterior abdominal wall in the region. There was increased fat echogenicity and hyperaemia compatible with cellulitis. This was interspaced with small hypo echoic pocket likely oedema in setting of cellulitis. No drainable collection