表 2.7.4.7-12　重篤な有害事象の一覧表（ONO-4538-15 試験）
解析対象集団：SAF

被験者識別コード	性別・年齢	有害事象名（医師記載）[MedDRA基本語]	発現時期[投与開始●日目]	程度	重篤度*	治験薬の投与継続の判断	処置	治験薬との因果関係	経過	持続期間
4162-001	Male 75	Hyponatremia [低ナトリウム血症]	111 115	Grade 1 Grade 4	Serious③	Interruption	Sodium chloride 3% Sodium chloride Metoclopramide Serenace Atarax-P Risperdal Primperan	Related	Recovered/Resolved	62日間
4162-001	Male 75	Interstitial pneumonia [間質性肺疾患]	129	Grade 3	Serious③	Withdrawal	Methylprednisolone Prednisolone Oxygen administration	Related	Recovering/Resolving	53日間

*:①Results in death　②Is life-threatening　③Requires inpatient hospitalization or results in prolongation of existing hospitalization　④Results in persistent or significant disability/incapacity　⑤Results in a congenital anomaly or birth defect　⑥Occurrence of new cancer　⑦Other medically important events
事象名：MedDRA/J ver18.1

表 2.7.4.7-13　重篤な有害事象の一覧表（CA209039 試験）
解析対象集団：All Treated cHL Subjects
cHL: ASCT-Bren Failed

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209039-2-12 (24/M/C)	NIV 2.9 MG/KG TREATMENT CYCLE 2	[redacted]20[redacted]/15:00 [redacted]20[redacted]/15:48 36	24.8H 14D SAE	血液およびリンパ系障害 リンパ節痛 L GROIN LYMPH NODE PAIN	6 2	1 1
CA209039-2-35 (42/F/C)	NIV 3.0 MG/KG TREATMENT CYCLE 10	[redacted]20[redacted] [redacted]20[redacted] 136	48.0H 4D SAE	呼吸器、胸郭および縦隔障害 喀血 HEMOPTYSIS	5 3	1 1
CA209039-2-63 (26/M/C)	NIV 3.0 MG/KG TREATMENT CYCLE 8	[redacted]20[redacted] [redacted]20[redacted] 121	3D 11D SAE	感染症および寄生虫症 皮膚感染 SKIN INFECTION	5 3	1 1

REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
Race:A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
MedDRA Version: 18.0
CTC Version 4.0
Current treatment is set to "ENDED TREATMENT" for event with an onset date after the last date of study therapy and a corresponding TRD value within 100D indicates that this event occurred within 100 days after last dose of study therapy.

出典［総括報告書 5.3.3.2-3（CA209039 試験）Table S6.26 を改変］

表 2.7.4.7-13　重篤な有害事象の一覧表（CA209039 試験）（続き 1）
解析対象集団：All Treated cHL Subjects
cHL: ASCT-Bren Failed

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209039-2-96	ENDED TREATMENT	[redacted]20[redacted]	5D	胃腸障害	6	1
(42/M/C)	30 DAYS FOLLOW-UP	[redacted]20[redacted]	14D	膵炎	3	6
	CYCLE 18	263	SAE	PANCREATITIS		
CA209039-4-27	ENDED TREATMENT	[redacted]20[redacted]		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）	6	0
(37/M/C)	30 DAYS FOLLOW-UP	CONTINUE	25D	骨髄異形成症候群	3	6
	CYCLE 12	208	SAE	MDS		

REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
Race:A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
MedDRA Version: 18.0
CTC Version 4.0
Current treatment is set to "ENDED TREATMENT" for event with an onset date after the last date of study therapy and
a corresponding TRD value within 100D indicates that this event occurred within 100 days after last dose of study therapy.

出典［総括報告書 5.3.3.2-3（CA209039 試験）Table S6.26 を改変］

表 2.7.4.7-13　重篤な有害事象の一覧表（CA209039 試験）（続き 2）
解析対象集団：All Treated cHL Subjects
cHL: ASCT-Bren Failed

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209039-4-27 (37/M/C)	ENDED TREATMENT	[redacted]20	4D	血液およびリンパ系障害	5	1
	30-100 DAYS FOLLOW-UP	[redacted]20	94D	発熱性好中球減少症	3	1
	OFF-TREATMENT	277	SAE	FEBRILE NEUTROPENIA		
CA209039-5-95 (33/M/O)	NIV 3.0 MG/KG	[redacted]20	8D	感染症および寄生虫症	5	1
	TREATMENT	[redacted]20	0D	マイコプラズマ性肺炎	3	1
	CYCLE 1	1	SAE	MYCOPLASMA PNEUMONIA		
	ENDED TREATMENT	[redacted]20		免疫系障害	5	1
	30-100 DAYS FOLLOW-UP	CONTINUE	58D	移植片対宿主病	2	1
	OFF-TREATMENT	138	SAE	GRAFT VERSUS HOST DISEASE		

REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
Race:A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
MedDRA Version: 18.0
CTC Version 4.0
Current treatment is set to "ENDED TREATMENT" for event with an onset date after the last date of study therapy and a corresponding TRD value within 100D indicates that this event occurred within 100 days after last dose of study therapy.

出典［総括報告書 5.3.3.2-3（CA209039 試験）Table S6.26 を改変］

表 2.7.4.7-13　重篤な有害事象の一覧表（CA209039 試験）（続き 3）
解析対象集団：All Treated cHL Subjects
cHL: ASCT-Bren Failed

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209039-5-95 (33/M/O)	ENDED TREATMENT	[redacted]20[redacted]	7D	傷害、中毒および処置合併症	5	1
	30-100 DAYS FOLLOW-UP	[redacted]20[redacted]	63D	術後発熱	1	1
	OFF-TREATMENT	143	SAE	POST AUTOLOGOUS TANDEM TRANSPLANT FEVER		
	ENDED TREATMENT	[redacted]20[redacted]		感染症および寄生虫症	5	1
	POST 100 DAYS FOLLOW-UP	CONTINUE	375D	肺感染	4	1
	SURVIVAL FOLLOW-UP 1	455	SAE	PULMONARY INFECTION		

REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
Race:A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
MedDRA Version: 18.0
CTC Version 4.0
Current treatment is set to "ENDED TREATMENT" for event with an onset date after the last date of study therapy and a corresponding TRD value within 100D indicates that this event occurred within 100 days after last dose of study therapy.

出典［総括報告書 5.3.3.2-3（CA209039 試験）Table S6.26 を改変］

表 2.7.4.7-13　重篤な有害事象の一覧表（CA209039 試験）（続き 4）
解析対象集団：All Treated cHL Subjects
cHL: Other

Subject ID (Age/Gender/Race)	Current Trt / Period / Visit	Onset D/T / Resolution D/T / Study Day	Dur / TRD / Type	System Organ Class / Preferred Term / Reported Term	REL CTC	TRT ACT
CA209039-1-49 (23/F/C)	NIV 3.0 MG/KG / TREATMENT / CYCLE 1	[redacted]20 / [redacted]20 / 15	48.0H / 14D / SAE	胃腸障害 / 小腸閉塞 / SMALL INTESTINAL OBSTRUCTION	5 / 3	1 / 1
	ENDED TREATMENT / 30 DAYS FOLLOW-UP / CYCLE 35	[redacted]20 / [redacted]20 / 576	4D / 9D / SAE	臨床検査 / 肝機能検査異常 / ELEVATED LFT LABS	5 / 4	0 / 1
CA209039-9-29 (28/F/C)	ENDED TREATMENT / 30 DAYS FOLLOW-UP / OFF-TREATMENT	[redacted]20 / [redacted]20 / 129	7D / 23D / SAE	血液およびリンパ系障害 / 発熱性好中球減少症 / FEBRILE NEUTROPENIA	5 / 3	1 / 1

REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
Race:A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
MedDRA Version: 18.0
CTC Version 4.0
Current treatment is set to "ENDED TREATMENT" for event with an onset date after the last date of study therapy and a corresponding TRD value within 100D indicates that this event occurred within 100 days after last dose of study therapy.

出典［総括報告書 5.3.3.2-3（CA209039 試験）Table S6.26 を改変］

表 2.7.4.7-13　重篤な有害事象の一覧表（CA209039 試験）（続き 5）
解析対象集団：All Treated cHL Subjects
cHL: Other

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209039-9-29	ENDED TREATMENT	[redacted]20[redacted]		免疫系障害	5	1
(28/F/C)	30-100 DAYS FOLLOW-UP	CONTINUE	42D	移植片対宿主病	3	1
	OFF-TREATMENT	148	SAE	GRAFT VERSUS HOST DISEASE		
	ENDED TREATMENT	[redacted]20[redacted]	16D	感染症および寄生虫症	5	1
	30-100 DAYS FOLLOW-UP	[redacted]20[redacted]	52D	脳炎	3	1
	OFF-TREATMENT	158	SAE	ENCEPHALITIS		
	ENDED TREATMENT	[redacted]20[redacted]		腎および尿路障害	5	1
	30-100 DAYS FOLLOW-UP	CONTINUE	81D	急性腎不全	4	1
	OFF-TREATMENT	187	SAE	ACUTE RENAL FAILURE		

REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
Race:A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
MedDRA Version: 18.0
CTC Version 4.0
Current treatment is set to "ENDED TREATMENT" for event with an onset date after the last date of study therapy and
a corresponding TRD value within 100D indicates that this event occurred within 100 days after last dose of study therapy.

出典［総括報告書 5.3.3.2-3（CA209039 試験）Table S6.26 を改変］

表 2.7.4.7-13　重篤な有害事象の一覧表（CA209039 試験）（続き 6）
解析対象集団：All Treated cHL Subjects
cHL: Other

Subject ID (Age/Gender/Race)	Current Trt / Period / Visit	Onset D/T / Resolution D/T / Study Day	Dur / TRD / Type	System Organ Class / Preferred Term / Reported Term	REL / CTC	TRT / ACT
CA209039-9-29 (28/F/C)	ENDED TREATMENT	[redacted]20[redacted]		感染症および寄生虫症	5	1
	30-100 DAYS FOLLOW-UP	CONTINUE	81D	菌血症	4	1
	OFF-TREATMENT	187	SAE	BACTEREMIA		
	ENDED TREATMENT	[redacted]20[redacted]		血液およびリンパ系障害	5	1
	30-100 DAYS FOLLOW-UP	CONTINUE	81D	血栓性微小血管症	4	1
	OFF-TREATMENT	187	SAE	THROMBOTIC MICROANGIOPATHY		
	ENDED TREATMENT	[redacted]20[redacted]		免疫系障害	5	1
	POST 100 DAYS FOLLOW-UP	CONTINUE	117D	移植片対宿主病	5	1
	OFF-TREATMENT	223	SAE	GRAFT VERSUS HOST DISEASE		

REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
Race:A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
MedDRA Version: 18.0
CTC Version 4.0
Current treatment is set to "ENDED TREATMENT" for event with an onset date after the last date of study therapy and a corresponding TRD value within 100D indicates that this event occurred within 100 days after last dose of study therapy.
出典［総括報告書 5.3.3.2-3（CA209039 試験）Table S6.26 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）
解析対象集団：All Enrolled Subjects
Treatment Group: Enrolled but not Treated

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-3-78	NEVER TREATED	[redacted]20[redacted]		呼吸器、胸郭および縦隔障害	5	1
(40/F/O)	SCREENING	CONTINUE		呼吸不全	5	1
	SCREENING	.	SAE	RESPIRATORY FAILURE		
	NEVER TREATED	[redacted]20[redacted]		感染症および寄生虫症	5	1
	SCREENING	CONTINUE		敗血症	5	1
	SCREENING	.	SAE	SEPSIS		
CA209205-33-222	NEVER TREATED	[redacted]20[redacted]	4D	感染症および寄生虫症	5	0
(43/M/C)	SCREENING	[redacted]20[redacted]		敗血症性ショック	5	1
	SCREENING	.	SAE	PNEUMOGENIC SEPTIC COMA		

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.

出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 1）
解析対象集団：All Enrolled Subjects
Treatment Group: Enrolled but not Treated

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-34-207 (31/M/C)	NEVER TREATED SCREENING SCREENING	[redacted]20[redacted] CONTINUE .	SAE	感染症および寄生虫症 肺炎 PNEUMONIA	5 5	1 1
CA209205-35-270 (25/F/C)	NEVER TREATED SCREENING SCREENING	[redacted]20[redacted]/19:52 [redacted]20[redacted]/00:00 .	6D SAE	感染症および寄生虫症 肺炎 PNEUMONIA	5 3	1 1
CA209205-37-208 (72/M/C)	NEVER TREATED SCREENING SCREENING	[redacted]20[redacted]/20:00 [redacted]20[redacted]/06:00 .	10.0H SAE	皮膚および皮下組織障害 薬疹 ALLERGIC EXANTHEMA AFTER MEDICATION WITH XYLONEST	5 2	0 1

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.

出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 2）
解析対象集団：All Enrolled Subjects
Treatment Group: Enrolled but not Treated

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-37-208 (72/M/C)	NEVER TREATED	[redacted]20[redacted]/00:30		傷害、中毒および処置合併症	5	1
	SCREENING	CONTINUE		上腕骨骨折	3	1
	SCREENING	.	SAE	HUMERUS FRACTURE		
CA209205-7-259 (57/M/C)	NEVER TREATED	[redacted]20[redacted]/03:56	21D	精神障害	5	1
	SCREENING	[redacted]20[redacted]		精神状態変化	3	1
	SCREENING	.	SAE	ALTERED MENTAL STATUS		
	NEVER TREATED	[redacted]20[redacted]/03:56	21D	肝胆道系障害	5	1
	SCREENING	[redacted]20[redacted]		肝硬変	3	1
	SCREENING	.	SAE	CIRRHOSIS		

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.

出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 3）
解析対象集団：All Enrolled Subjects
Treatment Group: Enrolled but not Treated

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-7-259 (57/M/C)	NEVER TREATED	[redacted]20[redacted]/03:56	21D	肝胆道系障害	5	1
	SCREENING	[redacted]20[redacted]		肝胆道系疾患	3	1
	SCREENING	.	SAE	HEPATOBILIARY DISORDER		
	NEVER TREATED	[redacted]20[redacted]/03:56	21D	代謝および栄養障害	5	1
	SCREENING	[redacted]20[redacted]		低ナトリウム血症	5	1
	SCREENING	.	SAE	HYPONATREMIA		
	NEVER TREATED	[redacted]20[redacted]	10D	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	5	0
	SCREENING	[redacted]20[redacted]		悪性新生物進行	5	1
	SCREENING	.	SAE	MALIGNANT NEOPLASM PROGRESSION		

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.
出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 4）
解析対象集団：All Enrolled Subjects
Treatment Group: Enrolled but not Treated

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-7-259 (57/M/C)	NEVER TREATED	[redacted]20[redacted]/02:46	10D	胃腸障害	5	1
	SCREENING	[redacted]20[redacted]		腹痛	5	1
	SCREENING	.	SAE	ABDOMINAL PAIN		
	NEVER TREATED	[redacted]20[redacted]/14:46	5.0H	一般・全身障害および投与部位の状態	5	1
	SCREENING	[redacted]20[redacted]/19:45		発熱	1	1
	SCREENING	.	SAE	NON NEUTROPENIC FEVER		

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.

出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 5）
解析対象集団：All Enrolled Subjects
Treatment Group: COHORT A

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-13-117 (61/F/C)	NIV 3.0 MG/KG TREATMENT CYCLE 2	[redacted]20 [redacted]20 27	4D 5D SAE	胃腸障害 下痢 DIARRHEA	6 2	1 1
	ENDED TREATMENT 30 DAYS FOLLOW-UP CYCLE 3	[redacted]20 CONTINUE 49	13D SAE	胃腸障害 下痢 DIARRHOEA	6 3	1 1
	ENDED TREATMENT 30-100 DAYS FOLLOW-UP CYCLE 3	[redacted]20 [redacted]20 88	48.0H 52D SAE	胃腸障害 下痢 DIARRHOEA	6 3	1 1

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.
出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 6）
解析対象集団：All Enrolled Subjects
Treatment Group: COHORT A

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-22-81 (64/M/C)	PRE-TREATMENT SCREENING SCREENING	[redacted]20[redacted] [redacted]20[redacted] -8	18D SAE	一般・全身障害および投与部位の状態 発熱 FEVER	5 1	1 1
CA209205-33-128 (20/F/C)	PRE-TREATMENT SCREENING SCREENING	[redacted]20[redacted]/12:54 [redacted]20[redacted] -24	11D SAE	感染症および寄生虫症 肺感染 PULMONARY INFECTION	5 2	1 1
	NIV 3.0 MG/KG TREATMENT CYCLE 1	[redacted]20[redacted]/18:08 [redacted]20[redacted]/13:00 1	4D 6.1H SAE	傷害、中毒および処置合併症 注入に伴う反応 INFUSION REACTION	6 2	1 1

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.
出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 7）
解析対象集団：All Enrolled Subjects
Treatment Group: COHORT A

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-34-213	NIV 3.0 MG/KG	[redacted]20	10D	感染症および寄生虫症	5	1
(31/M/C)	TREATMENT	[redacted]20	11D	ニューモシスチス・イロベチイ肺炎	3	4
	CYCLE 3	43	SAE	PNEUMOCYSTIS JIROVECI PNEUMONIA		
	NIV 3.0 MG/KG	[redacted]20		呼吸器、胸郭および縦隔障害	6	1
	TREATMENT	CONTINUE	15D	肺臓炎	2	5
	CYCLE 7	124	SAE	PNEUMONITIS		
CA209205-35-240	NIV 2.9 MG/KG	[redacted]20	6D	呼吸器、胸郭および縦隔障害	5	1
(43/M/C)	TREATMENT	[redacted]20	15D	胸水	2	1
	CYCLE 4	58	SAE	PLEURAL EFFUSION		

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.

出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 8）
解析対象集団：All Enrolled Subjects
Treatment Group: COHORT A

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-44-221	ENDED TREATMENT	[redacted]20[redacted]		感染症および寄生虫症	6	1
(40/M/C)	30 DAYS FOLLOW-UP	CONTINUE	12D	異型肺炎	5	6
	CYCLE 1	13	SAE	ATYPICAL BILATERAL PNEUMONIA		

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.

REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED

CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5

TRT (TREATMENT REQUIRED): 0 = NO 1 = YES

ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN

DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS

TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS

MedDRA Version: 18.0, CTC Version 4.0

Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.

出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 9）
解析対象集団：All Enrolled Subjects
Treatment Group: COHORT B

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-1-28 (29/F/C)	NIV 3.0 MG/KG TREATMENT CYCLE 3	[redacted]20 [redacted]20 34	7D 5D SAE	神経系障害 失神 SYNCOPE	5 3	1 4
	ENDED TREATMENT 30 DAYS FOLLOW-UP CYCLE 13	[redacted]20 [redacted]20 200	8D 3D SAE	感染症および寄生虫症 髄膜炎 MENINGITIS	5 3	1 1
	ENDED TREATMENT 30 DAYS FOLLOW-UP CYCLE 13	[redacted]20 CONTINUE 212	15D SAE	皮膚および皮下組織障害 斑状丘疹状皮疹 RASH MACULO-PAPULAR	5 3	1 1

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.
出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 10）
解析対象集団：All Enrolled Subjects
Treatment Group: COHORT B

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-19-36	ENDED TREATMENT	[redacted]20[redacted]		良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	5	1
(29/M/C)	30 DAYS FOLLOW-UP	CONTINUE	24.0H	悪性新生物進行	4	1
	CYCLE 4	59	SAE	MALIGNANT NEOPLASM PROGRESSION		
CA209205-19-37	NIV 3.0 MG/KG	[redacted]20[redacted]	5D	心臓障害	5	1
(32/F/C)	TREATMENT	[redacted]20[redacted]	6D	心不全	3	1
	CYCLE 4	50	SAE	HEART FAILURE		
	NIV 2.9 MG/KG	[redacted]20[redacted]	10D	筋骨格系および結合組織障害	5	1
	TREATMENT	[redacted]20[redacted]	10D	骨壊死	3	4
	CYCLE 14	230	SAE	FEMORAL NECROSIS		

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.
出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 11）
解析対象集団：All Enrolled Subjects
Treatment Group: COHORT B

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-19-88	NIV 2.9 MG/KG	[redacted]20[redacted]	11D	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	5	1
(64/F/C)	TREATMENT CYCLE 11	[redacted]20[redacted] 148	6D SAE	消化管間質性腫瘍 GIST	3	4
CA209205-26-86	NIV 2.8 MG/KG	[redacted]20[redacted]/14:00	2D	一般・全身障害および投与部位の状態	5	1
(18/M/A)	TREATMENT CYCLE 7	[redacted]20[redacted]/20:22 86	25.2H SAE	発熱 PYREXIA; POSSIBLE LOWER RESPIRATORY TRACT INFECTION. NOT NEUTROPENIC	3	1

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.

出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 12）
解析対象集団：All Enrolled Subjects
Treatment Group: COHORT B

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-26-86 (18/M/A)	ENDED TREATMENT	[redacted]20[redacted]/13:27	3D	一般・全身障害および投与部位の状態	5	1
	30 DAYS FOLLOW-UP	[redacted]20[redacted]/16:45	8D	発熱	3	1
	CYCLE 11	149	SAE	FEVER		
	ENDED TREATMENT	[redacted]20[redacted]/13:27	3D	臨床検査	5	1
	30 DAYS FOLLOW-UP	[redacted]20[redacted]/16:45	8D	血小板数減少	3	1
	CYCLE 11	149	SAE	LOW PLATELETS		
	ENDED TREATMENT	[redacted]20[redacted]/13:30	3D	皮膚および皮下組織障害	5	1
	30 DAYS FOLLOW-UP	[redacted]20[redacted]/16:45	8D	発疹	3	1
	CYCLE 11	149	SAE	RASH		

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.
出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 13）
解析対象集団：All Enrolled Subjects
Treatment Group: COHORT B

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-26-86 (18/M/A)	ENDED TREATMENT 30-100 DAYS FOLLOW-UP FOLLOW-UP 1	[redacted]20 CONTINUE 210	69D SAE	感染症および寄生虫症 気道感染 RESPIRATORY TRACT INFECTION.	5 3	1 1
CA209205-3-73 (19/M/O)	NIV 3.0 MG/KG TREATMENT CYCLE 1	[redacted]20 [redacted]20 7	48.0H 6D SAE	感染症および寄生虫症 インフルエンザ INFECTIONS AND INFESTATIONS; UPPER RESPIRATORY INFECTION (INFLUENZA A)	5 2	1 1
CA209205-33-104 (26/M/C)	NIV 2.9 MG/KG TREATMENT CYCLE 3	[redacted]20 [redacted]20 40	4D 11D SAE	感染症および寄生虫症 気管支肺炎 BRONCHOPNEUMONIA	5 2	1 4

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.

出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 14）
解析対象集団：All Enrolled Subjects
Treatment Group: COHORT B

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-33-104	NIV DELAY	[redacted]20[redacted]		感染症および寄生虫症	5	1
(26/M/C)	TREATMENT	CONTINUE	33D	感染	2	1
	CYCLE 16	252	SAE	INFECTION		
CA209205-33-16	ENDED TREATMENT	[redacted]20[redacted]	8D	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	5	1
(23/M/C)	30 DAYS FOLLOW-UP	[redacted]20[redacted]	7D	悪性新生物進行	3	1
	CYCLE 4	50	SAE	MALIGNANT NEOPLASM PROGRESSION		
	ENDED TREATMENT	[redacted]20[redacted]	21D	感染症および寄生虫症	5	1
	30-100 DAYS FOLLOW-UP	[redacted]20[redacted]	91D	肺炎	3	1
	CYCLE 4	134	SAE	PNEUMONIA		

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.
出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 15）
解析対象集団：All Enrolled Subjects
Treatment Group: COHORT B

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-33-22 (27/M/C)	NIV 3.0 MG/KG TREATMENT CYCLE 6	[redacted]20[redacted]/12:06 [redacted]20[redacted] 78	12D 7D SAE	血液およびリンパ系障害 発熱性好中球減少症 NEUTROPENIC FEVER	5 3	1 4
CA209205-33-26 (26/M/C)	NIV 3.0 MG/KG TREATMENT CYCLE 3	[redacted]20[redacted]/13:30 [redacted]20[redacted] 29	34.5H 33M SAE	傷害、中毒および処置合併症 注入に伴う反応 INFUSION REACTION	6 2	1 5
CA209205-33-35 (52/M/C)	NIV 2.8 MG/KG TREATMENT CYCLE 20	[redacted]20[redacted] [redacted]20[redacted] 279	48.0H 12D SAE	心臓障害 不整脈 CARDIAC ARRHYTHMIA	5 2	1 1

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.
出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 16）
解析対象集団：All Enrolled Subjects
Treatment Group: COHORT B

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-34-110	PRE-TREATMENT	[redacted]20[redacted]/08:00	15D	一般・全身障害および投与部位の状態	5	1
(48/M/C)	SCREENING	[redacted]20[redacted]/14:00		全身健康状態低下	2	1
	SCREENING	1	SAE	WORSENING IN PHYSICAL CONDITION		
CA209205-35-61	ENDED TREATMENT	[redacted]20[redacted]	23D	神経系障害	5	1
(22/F/C)	30-100 DAYS FOLLOW-UP	[redacted]20[redacted]	83D	可逆性後白質脳症症候群	3	1
	FOLLOW-UP 1	202	SAE	REVERSIBLE POSTERIOR LEUKOENCEPHALOPATHY SYNDROME		
CA209205-40-109	NIV 3.0 MG/KG	[redacted]20[redacted]	6D	心臓障害	5	1
(54/M/C)	TREATMENT	[redacted]20[redacted]	9D	不整脈	3	4
	CYCLE 5	73	SAE	ARRHYTHMIA		

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.
出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 17）
解析対象集団：All Enrolled Subjects
Treatment Group: COHORT B

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-40-109 (54/M/C)	NIV 3.0 MG/KG TREATMENT CYCLE 5	[redacted]20 [redacted]20 73	6D 9D SAE	血管障害 塞栓症 THROMBOEMBOLIC EVENT	5 3	1 4
	NIV DELAY TREATMENT CYCLE 5	[redacted]20 [redacted]20 85	7D 21D SAE	心臓障害 心嚢液貯留 PERICARDIAL EFFUSION	5 4	1 4
	NIV 3.0 MG/KG TREATMENT CYCLE 9	[redacted]20 CONTINUE 137	24.0H SAE	感染症および寄生虫症 肺感染 LUNG INFECTION	5 3	1 1

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.
出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 18）
解析対象集団：All Enrolled Subjects
Treatment Group: COHORT B

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-40-109 (54/M/C)	NIV 3.0 MG/KG TREATMENT CYCLE 9	[redacted]20 [redacted]20 148	4D 12D SAE	一般・全身障害および投与部位の状態 全身性浮腫 ANASARCA	5 2	1 4
	ENDED TREATMENT 30-100 DAYS FOLLOW-UP OFF-TREATMENT	[redacted]20 CONTINUE 236	37D SAE	感染症および寄生虫症 敗血症 SEPSIS	5 4	1 1
CA209205-40-3 (26/M/O)	NIV 3.0 MG/KG TREATMENT CYCLE 1	[redacted]20 [redacted]20 1	48.0H 0D SAE	一般・全身障害および投与部位の状態 発熱 FEVER	6 1	1 1

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.
出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 19）
解析対象集団：All Enrolled Subjects
Treatment Group: COHORT B

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-40-7 (40/F/C)	NIV 1.0 MG/KG TREATMENT CYCLE 1	[redacted]20 [redacted]20 8	32D 7D SAE	感染症および寄生虫症 髄膜炎 MENINGITIS	6 2	1 4
	NIV 1.0 MG/KG TREATMENT CYCLE 1	[redacted]20 [redacted]20 8	33D 7D SAE	感染症および寄生虫症 肺炎 PNEUMONIA	5 3	1 4
	NIV 3.2 MG/KG TREATMENT CYCLE 3	[redacted]20 [redacted]20 68	3D 11D SAE	代謝および栄養障害 高カルシウム血症 HYPERCALCEMIA	5 4	1 4

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.

出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 20）
解析対象集団：All Enrolled Subjects
Treatment Group: COHORT B

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-40-95 (41/M/B)	NIV 3.0 MG/KG TREATMENT CYCLE 3	[redacted]20 [redacted]20 46	4D 14D SAE	感染症および寄生虫症 肺炎 PNEUMONIA	5 2	1 4
CA209205-40-96 (62/M/C)	PRE-TREATMENT SCREENING SCREENING	[redacted]20 [redacted]20 -13	5D SAE	感染症および寄生虫症 ウイルス性胃腸炎 VIRAL GASTROENTERITIS	5 3	1 1
	ENDED TREATMENT 30 DAYS FOLLOW-UP CYCLE 14	[redacted]20 CONTINUE 190	3D SAE	一般・全身障害および投与部位の状態 多臓器不全 MULTI SYSTEM ORGAN FAILURE	6 5	1 6

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.
出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 21）
解析対象集団：All Enrolled Subjects
Treatment Group: COHORT B

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-41-54	NIV 3.0 MG/KG	[redacted]20[redacted]/18:00	30.0H	傷害、中毒および処置合併症	6	1
(46/F/B)	TREATMENT	[redacted]20[redacted]	1.3H	注入に伴う反応	2	1
	CYCLE 1	1	SAE	INFUSION RELATED REACTION		
CA209205-5-107	NIV 2.7 MG/KG	[redacted]20[redacted]/04:50	4D	感染症および寄生虫症	5	1
(25/M/O)	TREATMENT	[redacted]20[redacted]	6D	パラインフルエンザウイルス感染	2	4
	CYCLE 6	77	SAE	PARAINFLUENZA		
CA209205-8-14	ENDED TREATMENT	[redacted]20[redacted]		筋骨格系および結合組織障害	5	1
(43/M/C)	30-100 DAYS FOLLOW-UP	CONTINUE	72D	背部痛	3	1
	CYCLE 7	157	SAE	BACK PAIN		

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.
出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 22）
解析対象集団：All Enrolled Subjects
Treatment Group: COHORT B

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-8-14	ENDED TREATMENT	[redacted]20[redacted]		筋骨格系および結合組織障害	5	1
(43/M/C)	30-100 DAYS FOLLOW-UP	CONTINUE	77D	骨痛	3	1
	CYCLE 7	162	SAE	CLAVICAL PAIN		
	ENDED TREATMENT	[redacted]20[redacted]		感染症および寄生虫症	5	1
	POST 100 DAYS FOLLOW-UP	CONTINUE	175D	骨髄炎	3	6
	CYCLE 7	260	SAE	OSTEOMYELITIS		
CA209205-9-5	ENDED TREATMENT	[redacted]20[redacted]	26D	呼吸器、胸郭および縦隔障害	5	1
(54/M/C)	30 DAYS FOLLOW-UP	[redacted]20[redacted]	17D	呼吸困難	3	1
	CYCLE 3	50	SAE	SHORTNESS OF BREATH		

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.
出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 23）
解析対象集団：All Enrolled Subjects
Treatment Group: COHORT B

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-9-5	ENDED TREATMENT	[redacted]20[redacted]	5D	呼吸器、胸郭および縦隔障害	6	1
(54/M/C)	30-100 DAYS FOLLOW-UP	[redacted]20[redacted]	50D	肺臓炎	3	1
	FOLLOW-UP 1	83	SAE	PNEUMONITIS		
CA209205-9-9	NIV 2.8 MG/KG	[redacted]20[redacted]	8D	一般・全身障害および投与部位の状態	5	1
(61/M/C)	TREATMENT	[redacted]20[redacted]	14D	発熱	2	4
	CYCLE 9	127	SAE	FEVERS		

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.
出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 24）
解析対象集団：All Enrolled Subjects
Treatment Group: COHORT C

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-1-190	NIV 3.0 MG/KG	[redacted]20[redacted]	48.0H	神経系障害	5	1
(27/F/C)	TREATMENT	[redacted]20[redacted]	11D	痙攣発作	2	1
	CYCLE 1	12	SAE	SEIZURE		
CA209205-12-277	NIV DELAY	[redacted]20[redacted]		皮膚および皮下組織障害	6	1
(53/F/A)	TREATMENT	CONTINUE	18D	発疹	3	1
	CYCLE 1	19	SAE	RASH GRADE 3		
CA209205-19-199	PRE-TREATMENT	[redacted]20[redacted]	33D	一般・全身障害および投与部位の状態	5	1
(23/F/C)	SCREENING	[redacted]20[redacted]		疼痛	4	1
	SCREENING	-2	SAE	UNCONTROLLED PAIN		

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.
出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 25）
解析対象集団：All Enrolled Subjects
Treatment Group: COHORT C

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-19-199	ENDED TREATMENT	[redacted]20[redacted]		良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	5	1
(23/F/C)	30 DAYS FOLLOW-UP	CONTINUE	9D	悪性新生物進行	4	1
	CYCLE 3	39	SAE	MALIGNANT NEOPLASM PROGRESSION		
CA209205-2-185	NIV 3.0 MG/KG	[redacted]20[redacted]	3D	代謝および栄養障害	6	1
(33/F/C)	TREATMENT	[redacted]20[redacted]	16D	耐糖能障害	4	4
	CYCLE 1	17	SAE	GLUCOSE INTOLERANCE		

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.

出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 26）
解析対象集団：All Enrolled Subjects
Treatment Group: COHORT C

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-20-234 (50/M/C)	NIV DELAY TREATMENT CYCLE 1	[redacted]20[redacted] CONTINUE 27	26D SAE	呼吸器、胸郭および縦隔障害 肺障害 RESPIRATORY ISUFFICIENCY DUE TO LUNG PROGRESSIVE DISEASE	5 4	0 5
CA209205-26-139 (32/F/C)	NIV 3.0 MG/KG TREATMENT CYCLE 1	[redacted]20[redacted]/20:00 [redacted]20[redacted] 8	35D 7D SAE	代謝および栄養障害 脱水 DEHYDRATION	5 3	1 1
CA209205-26-219 (24/M/C)	NIV 3.0 MG/KG TREATMENT CYCLE 1	[redacted]20[redacted]/18:44 [redacted]20[redacted]/18:30 1	23.8H 2.7H SAE	胃腸障害 腹痛 ABDOMINAL PAIN	6 1	1 1

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.
出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 27）
解析対象集団：All Enrolled Subjects
Treatment Group: COHORT C

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-26-219 (24/M/C)	NIV 3.0 MG/KG TREATMENT CYCLE 1	[redacted]20[redacted]/18:44 [redacted]20[redacted]/18:30 1	23.8H 2.7H SAE	一般・全身障害および投与部位の状態 発熱 FEVER	6 1	1 1
	NIV 3.0 MG/KG TREATMENT CYCLE 1	[redacted]20[redacted]/18:44 [redacted]20[redacted]/18:30 1	23.8H 2.7H SAE	胃腸障害 悪心 NAUSEA	6 1	1 1
	NIV 3.0 MG/KG TREATMENT CYCLE 1	[redacted]20[redacted]/18:44 [redacted]20[redacted]/18:30 1	23.8H 2.7H SAE	胃腸障害 嘔吐 VOMITTING	6 1	1 1

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.
出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 28）
解析対象集団：All Enrolled Subjects
Treatment Group: COHORT C

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-27-145 (30/M/C)	NIV 3.1 MG/KG TREATMENT CYCLE 4	[redacted]20[redacted]/12:26 [redacted]20[redacted]/19:49 59	5D 16D SAE	呼吸器、胸郭および縦隔障害 肺臓炎 PNEUMONITIS	6 2	1 4
CA209205-27-176 (35/F/C)	NIV 2.9 MG/KG TREATMENT CYCLE 4	[redacted]20[redacted]/11:39 [redacted]20[redacted]/09:53 57	46.2H 14D SAE	臨床検査 アラニンアミノトランスフェラーゼ増加 ALANINE AMINOTRANSFERASE INCREASED	6 3	1 4

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.
出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 29）
解析対象集団：All Enrolled Subjects
Treatment Group: COHORT C

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-27-176 (35/F/C)	NIV DELAY TREATMENT CYCLE 4	[redacted]20[redacted] [redacted]20[redacted] 61	12D 18D SAE	臨床検査 アラニンアミノトランスフェラーゼ増加 ALANINE AMINOTRANSFERASE INCREASED	6 3	1 4
CA209205-30-275 (21/M/C)	NIV 3.1 MG/KG TREATMENT CYCLE 1	[redacted]20[redacted] [redacted]20[redacted] 3	24.0H 2D SAE	神経系障害 痙攣発作 SEIZURE	6 2	1 1
CA209205-32-132 (30/F/C)	NIV 2.9 MG/KG TREATMENT CYCLE 1	[redacted]20[redacted]/12:49 [redacted]20[redacted]/00:00 4	10D 3D SAE	感染症および寄生虫症 気道感染 RESPIRATORY INFECTION	5 3	1 1

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.
出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 30）
解析対象集団：All Enrolled Subjects
Treatment Group: COHORT C

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-32-132 (30/F/C)	NIV 3.0 MG/KG TREATMENT CYCLE 9	[redacted]20 [redacted]20 123	48.0H 11D SAE	外科および内科処置 人工流産 PREGNANCY TERMINATION	5 3	1 5
	NIV DELAY TREATMENT CYCLE 12	[redacted]20 CONTINUE 209	41D SAE	感染症および寄生虫症 腎盂腎炎 PYELONEPHRITIC	. 3	1 4
CA209205-33-250 (19/M/C)	NIV 3.0 MG/KG TREATMENT CYCLE 1	[redacted]20 [redacted]20 11	5D 10D SAE	胃腸障害 膵炎 PANCREATITIS	6 2	1 4

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.
出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 31）
解析対象集団：All Enrolled Subjects
Treatment Group: COHORT C

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-33-267 (22/M/C)	NIV 3.0 MG/KG TREATMENT CYCLE 1	[redacted]20[redacted] [redacted]20[redacted] 4	5D 3D SAE	傷害、中毒および処置合併症 注入に伴う反応 DRUG RELATED INFUSION-ASSOCIATED REACTION AND FEVER	6 2	1 1
CA209205-34-151 (53/F/C)	PRE-TREATMENT SCREENING SCREENING	[redacted]20[redacted] [redacted]20[redacted] -3	5D SAE	一般・全身障害および投与部位の状態 発熱 FEVER	5 1	1 1
	NIV 3.0 MG/KG TREATMENT CYCLE 1	[redacted]20[redacted]/17:00 [redacted]20[redacted] 1	10D 30M SAE	感染症および寄生虫症 菌血症 BACTEREMIA	5 2	1 1

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.
出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 32）
解析対象集団：All Enrolled Subjects
Treatment Group: COHORT C

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-34-151 (53/F/C)	NIV 3.0 MG/KG TREATMENT CYCLE 8	[redacted]20 [redacted]20 114	9D 12D SAE	感染症および寄生虫症 丹毒 ERYSIPELAS	5 3	1 4
CA209205-35-212 (32/F/C)	PRE-TREATMENT SCREENING SCREENING	[redacted]20 [redacted]20 -20	15D SAE	呼吸器、胸郭および縦隔障害 肺臓炎 PNEUMONITIS	5 2	1 1
CA209205-35-226 (24/M/I)	NIV 2.9 MG/KG TREATMENT CYCLE 2	[redacted]20 [redacted]/15:59 [redacted]20 22	11D 6D SAE	呼吸器、胸郭および縦隔障害 肺臓炎 PNEUMONITIS	6 2	1 1

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.
出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 33）
解析対象集団：All Enrolled Subjects
Treatment Group: COHORT C

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-35-264 (24/M/C)	NIV 3.0 MG/KG TREATMENT CYCLE 1	[redacted]20[redacted]/12:30 [redacted]20[redacted]/15:16 1	26.8H 1.4H SAE	傷害、中毒および処置合併症 注入に伴う反応 INFUSION RELATED REACTION	6 3	1 1
CA209205-40-118 (22/F/C)	NIV 2.8 MG/KG TREATMENT CYCLE 8	[redacted]20[redacted] [redacted]20[redacted] 113	48.0H 7D SAE	感染症および寄生虫症 パラインフルエンザウイルス感染 PARAINFLUENZA INFECTION	5 3	1 1
CA209205-44-179 (23/M/C)	NIV 3.0 MG/KG TREATMENT CYCLE 2	[redacted]20[redacted] [redacted]20[redacted] 28	4D 13D SAE	先天性、家族性および遺伝性障害 気管食道瘻 TRACHEOESOPHAGEAL FISTULA	5 3	1 4

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.
出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 34）
解析対象集団：All Enrolled Subjects
Treatment Group: COHORT C

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-46-164	ENDED TREATMENT	[redacted]20[redacted]		一般・全身障害および投与部位の状態	5	1
(50/M/C)	30-100 DAYS FOLLOW-UP	CONTINUE	52D	疾患進行	4	1
	FOLLOW-UP 1	123	SAE	WORSENING DISEASE PROGRESSION		
CA209205-46-233	NIV 3.0 MG/KG	[redacted]20[redacted]		呼吸器、胸郭および縦隔障害	5	1
(22/M/A)	TREATMENT	CONTINUE	12D	気胸	2	4
	CYCLE 2	27	SAE	PNEUMOTHORAX		
	NIV 3.0 MG/KG	[redacted]20[redacted]		呼吸器、胸郭および縦隔障害	5	1
	TREATMENT	CONTINUE	13D	気胸	3	4
	CYCLE 3	68	SAE	PNEUMOTHORAX		

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.
出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 35）
解析対象集団：All Enrolled Subjects
Treatment Group: COHORT C

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-5-124	NIV 3.2 MG/KG	[redacted]20[redacted]	4D	呼吸器、胸郭および縦隔障害	5	1
(47/M/C)	TREATMENT	[redacted]20[redacted]	11D	胸水	3	1
	CYCLE 11	151	SAE	RIGHT PLEURAL EFFUSION		
	ENDED TREATMENT	[redacted]20[redacted]	4D	呼吸器、胸郭および縦隔障害	6	1
	30 DAYS FOLLOW-UP	[redacted]20[redacted]	17D	呼吸困難	5	1
	OFF-TREATMENT	185	SAE	DYSPNEA		
CA209205-7-248	ENDED TREATMENT	[redacted]20[redacted]/16:15	10D	呼吸器、胸郭および縦隔障害	6	1
(28/M/C)	30 DAYS FOLLOW-UP	[redacted]20[redacted]/17:45	18.8H	胸水	2	6
	CYCLE 1	2	SAE	BILATERAL PLEURAL EFFUSION		

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.
出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 36）
解析対象集団：All Enrolled Subjects
Treatment Group: COHORT C

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-7-248 (28/M/C)	ENDED TREATMENT	[redacted]20[redacted]/16:15	10D	心臓障害	6	1
	30 DAYS FOLLOW-UP	[redacted]20[redacted]/17:45	18.8H	心嚢液貯留	4	6
	CYCLE 1	2	SAE	LARGE PERICARDIAL EFFUSION		
	ENDED TREATMENT	[redacted]20[redacted]/16:15	10D	感染症および寄生虫症	6	1
	30 DAYS FOLLOW-UP	[redacted]20[redacted]/17:45	18.8H	肺炎	3	6
	CYCLE 1	2	SAE	PNEUMONIA (RIGHT LUNG)		
CA209205-7-257 (25/M/B)	NIV 3.0 MG/KG	[redacted]20[redacted]/20:36	4D	筋骨格系および結合組織障害	5	1
	TREATMENT	[redacted]20[redacted]/13:59	26.7H	四肢痛	3	1
	CYCLE 1	2	SAE	LEFT ARM PAIN		

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.
出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］

表 2.7.4.7-14　重篤な有害事象の一覧表（CA209205 試験）（続き 37）
解析対象集団：All Enrolled Subjects
Treatment Group: COHORT C

Subject ID (Age/Gender/Race)	Current Trt Period Visit	Onset D/T Resolution D/T Study Day	Dur TRD Type	System Organ Class Preferred Term Reported Term	REL CTC	TRT ACT
CA209205-7-257 (25/M/B)	NIV 3.0 MG/KG TREATMENT CYCLE 1	[redacted]20[redacted]/20:36 [redacted]20[redacted]/13:59 2	4D 26.7H SAE	感染症および寄生虫症 肺炎 PNEUMONIA	5 3	1 1
	NIV 3.0 MG/KG TREATMENT CYCLE 1	[redacted]20[redacted]/20:36 [redacted]20[redacted]/13:59 2	4D 26.7H SAE	呼吸器、胸郭および縦隔障害 胸水 WORSENING PLEURAL EFFUSION	6 2	1 1

A=Asian; B=Black/African American; C=White; I=American Indian/Alaska Native; O=Other; P=Native Hawaiian/Other Pacific Islander.
REL (RELATIONSHIP): 5 = NOT RELATED 6 = RELATED
CTC (COMMON TERMINOLOGY CRITERIA): 1 = GRADE 1 2 = GRADE 2 3 = GRADE 3 4 = GRADE 4 5 = GRADE 5
TRT (TREATMENT REQUIRED): 0 = NO 1 = YES
ACT (ACTION): 1 = DOSE NOT CHANGED 2 = DOSE REDUCED 3 = DOSE INCREASED 4 = DOSE DELAYED 5 = DRUG INTERRUPTED 6 = DRUG WITHDRAWN
DUR (DURATION OF EVENT): D = DAYS H = HOURS M = MINUTES S = SECONDS
TRD (TIME RELATIVE TO MOST RECENT DOSE): D = DAYS H = HOURS M = MINUTES S = SECONDS
MedDRA Version: 18.0, CTC Version 4.0
Current treatment is set to ENDED TREATMENT for event with an onset date after the last date of study therapy and a corresponding TRD value between 30 and 100 indicates that this event occurred during extended follow-up.
出典［総括報告書 5.3.5.2-2（CA209205 試験）Table S6.73 を改変］