表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	発熱	一般・全身障害および投与部位の状態	265	4D	Grade 1	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	播種性帯状疱疹	感染症および寄生虫症	148	48.0H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	眼痛	眼障害	281	6D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	涙道の炎症	眼障害	281	6D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	尿意切迫	腎および尿路障害	260	4D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	前立腺炎	生殖系および乳房障害	265	4D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	腹痛	胃腸障害	23	4D	Grade 1	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	血中クレアチニン増加	臨床検査	23	4D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/USA	下痢	胃腸障害	52	3D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/USA	下痢	胃腸障害	65	5D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/USA	心房細動	心臓障害	56	28.5H	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/C/USA	錯感覚	神経系障害	96	10D	Grade 1	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/C/USA	錯感覚	神経系障害	106	6D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	発熱	一般・全身障害および投与部位の状態	21		Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	NOT RECOVERED/NOT RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	敗血症	感染症および寄生虫症	21	6D	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	肺炎	感染症および寄生虫症	76	4D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	低血圧	血管障害	21		Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	NOT RECOVERED/NOT RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/USA	虫垂炎	感染症および寄生虫症	594	5D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/USA	血管障害	血管障害	513	19D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/USA	呼吸困難	呼吸器、胸郭および縦隔障害	600	3D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/USA	肺障害	呼吸器、胸郭および縦隔障害	588	34.8H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	発熱	一般・全身障害および投与部位の状態	317	5D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	低血圧	血管障害	14	48.0H	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	痙攣発作	神経系障害	65	3D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	脳新生物	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）	83	24.0H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/F/C/USA	胃炎	胃腸障害	374	3D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/F/C/USA	胸水	呼吸器、胸郭および縦隔障害	23	42D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/F/C/USA	頭痛	神経系障害	81	12D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/F/C/USA	下垂体炎	内分泌障害	81	24D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	顔面不全麻痺	神経系障害	104	4D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	急性腎障害	腎および尿路障害	104	4D	Grade 1	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/C/USA	そう痒症	皮膚および皮下組織障害	85	7D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/C/USA	斑状丘疹状皮疹	皮膚および皮下組織障害	85	7D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/USA	アスパラギン酸アミノトランスフェラーゼ増加	臨床検査	99	15D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/USA	アラニンアミノトランスフェラーゼ増加	臨床検査	99	36D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	血中クレアチニン増加	臨床検査	15	5D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/B/USA	発熱	一般・全身障害および投与部位の状態	52	7D	Grade 1	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	アラニンアミノトランスフェラーゼ増加	臨床検査	57	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	悪心	胃腸障害	139	11D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	下痢	胃腸障害	85	5D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	下痢	胃腸障害	139	11D	Grade 1	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	倦怠感	一般・全身障害および投与部位の状態	139	11D	Grade 2	Requires or Prolongs Hospitalization	RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	アシドーシス	代謝および栄養障害	320	4D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	糖尿病性ケトアシドーシス	代謝および栄養障害	320	4D	Grade 4	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/ARG	尿路感染	感染症および寄生虫症	78	17D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/ARG	尿路閉塞	腎および尿路障害	74	5D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/F/C/CHL	心停止	心臓障害	38	30D	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/CHL	肝毒性	肝胆道系障害	20	53D	Grade 3	Other Medically Important Serious Event	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/CHL	病的骨折	筋骨格系および結合組織障害	818	4D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE DELAYED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/CHL	胸水	呼吸器、胸郭および縦隔障害	60	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/CHL	脊髄圧迫	神経系障害	264	8D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/CHL	肺炎	感染症および寄生虫症	269	2D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/CHL	気管支炎	感染症および寄生虫症	655	6D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/CHL	譫妄	精神障害	131	7D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/CHL	急性副腎皮質機能不全	内分泌障害	680	24D	Grade 3	Other Medically Important Serious Event	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/CHL	下垂体炎	内分泌障害	126	9D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/CHL	頭蓋内圧上昇	神経系障害	813		Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/C/CHL	発疹	皮膚および皮下組織障害	67	9D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/CHL	急性心筋梗塞	心臓障害	84	14D	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/CHL	急性腎障害	腎および尿路障害	63	26D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/POL	失語症	神経系障害	486	6D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/POL	悪性新生物進行	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）	478		Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/POL	胃腸出血	胃腸障害	359	6D	Grade 4	Is Life Threatening	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/POL	末梢性浮腫	一般・全身障害および投与部位の状態	58	8D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/POL	貧血	血液およびリンパ系障害	359	6D	Grade 4	Is Life Threatening	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/POL	呼吸困難	呼吸器、胸郭および縦隔障害	344	8D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/POL	肺塞栓症	呼吸器、胸郭および縦隔障害	372	4D	Grade 4	Requires or Prolongs Hospitalization, Is Life Threatening	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/POL	心肺不全	心臓障害	376		Grade 5	Results in Death	NOT RELATED	No	DOSE NOT CHANGED	FATAL
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/POL	貧血	血液およびリンパ系障害	23		Grade 4	Requires or Prolongs Hospitalization, Is Life Threatening	NOT RELATED	Yes	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/POL	心停止	心臓障害	24		Grade 5	Results in Death	NOT RELATED	Yes	DRUG WITHDRAWN	FATAL
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/POL	低カリウム血症	代謝および栄養障害	23		Grade 4	Requires or Prolongs Hospitalization, Is Life Threatening	NOT RELATED	Yes	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/POL	悪性新生物進行	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）	24		Grade 5	Results in Death	NOT RELATED	Yes	DRUG WITHDRAWN	FATAL
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/AUT	胸部不快感	一般・全身障害および投与部位の状態	230	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/GBR	下痢	胃腸障害	51	6D	Grade 1	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/GBR	下痢	胃腸障害	63	10D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/M/C/GBR	顔面麻痺	神経系障害	45		Grade 2	Other Medically Important Serious Event	RELATED	Yes	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/GBR	第３脳神経麻痺	神経系障害	61	19D	Grade 1	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/GBR	下垂体機能低下症	内分泌障害	65	52D	Grade 2	Other Medically Important Serious Event	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/GBR	呼吸困難	呼吸器、胸郭および縦隔障害	9		Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/GBR	悪性新生物進行	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）	48	29D	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	No	DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/GBR	重症筋無力症	神経系障害	38	62D	Grade 4	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/F/C/GBR	錯乱状態	精神障害	43	10D	Grade 1	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/C/GBR	運動不能	社会環境	59	8D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/O/USA	錯乱状態	精神障害	43	3D	Grade 1	Involves Cancer, Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/O/USA	高カルシウム血症	代謝および栄養障害	43	7D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/C/USA	呼吸困難	呼吸器、胸郭および縦隔障害	35	4D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/F/C/POL	血中クレアチニン増加	臨床検査	289	62D	Grade 3	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/F/C/POL	血中クレアチニン増加	臨床検査	339	17D	Grade 4	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/TUR	嚥下障害	胃腸障害	51	8D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/TUR	呼吸困難	呼吸器、胸郭および縦隔障害	51	8D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/TUR	会話障害	神経系障害	51	8D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/TUR	肝炎	肝胆道系障害	93	81D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/TUR	急性心筋梗塞	心臓障害	32		Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERING/RESOLVING
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/TUR	心停止	心臓障害	35		Grade 5	Results in Death	NOT RELATED	Yes	DRUG WITHDRAWN	FATAL

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/TUR	疲労	一般・全身障害および投与部位の状態	37		Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERING/RESOLVING
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/TUR	門脈血栓症	肝胆道系障害	35		Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERING/RESOLVING
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/TUR	食欲減退	代謝および栄養障害	37		Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/M/C/TUR	術後ヘルニア	傷害、中毒および処置合併症	658	10D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/M/C/TUR	自己免疫性甲状腺機能低下症	内分泌障害	101		Grade 2	Other Medically Important Serious Event	RELATED	Yes	DOSE NOT CHANGED	RECOVERING/RESOLVING
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/ISR	下垂体炎	内分泌障害	71	6D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/ISR	十二指腸閉塞	胃腸障害	20	19D	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/ISR	肺炎	感染症および寄生虫症	253		Grade 4	Results in Death, Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	FATAL
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/ISR	小腸腺癌	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）	22		Grade 3	Involves Cancer	NOT RELATED	Yes	DOSE DELAYED	NOT RECOVERED/ NOT RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/ISR	胃腸炎	感染症および寄生虫症	68	14D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/ RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/ISR	気管支炎	感染症および寄生虫症	80		Grade 4	Results in Death, Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	FATAL
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/ISR	敗血症性ショック	感染症および寄生虫症	82		Grade 4	Results in Death, Is Life Threatening	NOT RELATED	Yes	DOSE NOT CHANGED	FATAL
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/ISR	自己免疫性大腸炎	胃腸障害	283	5D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/ RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/ISR	食道炎	胃腸障害	65	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/ISR	急性腎障害	腎および尿路障害	62	3D	Grade 1	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/GBR	膵炎	胃腸障害	252		Grade 2		RELATED	No	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/GBR	下気道感染	感染症および寄生虫症	64	38.0H	Grade 1	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/GBR	下気道感染	感染症および寄生虫症	249		Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/GBR	敗血症	感染症および寄生虫症	253		Grade 4	Results in Death, Is Life Threatening	NOT RELATED	No	DRUG WITHDRAWN	FATAL

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/GBR	胸水	呼吸器、胸郭および縦隔障害	7	6D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/GBR	自己免疫性腎炎	腎および尿路障害	253		Grade 4	Is Life Threatening	RELATED	Yes	DOSE DELAYED	NOT RECOVERED/NOT RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/GBR	骨転移	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）	239	7D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/ISR	下痢	胃腸障害	116	4D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/ISR	慢性閉塞性肺疾患	呼吸器、胸郭および縦隔障害	281	2D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/ISR	心筋梗塞	心臓障害	295	4D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/ISR	肺炎	感染症および寄生虫症	54	9D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/ISR	頭蓋内出血	神経系障害	84	15D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/F/C/ISR	低ナトリウム血症	代謝および栄養障害	57	48.0H	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/ISR	脳炎	感染症および寄生虫症	144	24D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/M/C/DEU	腹痛	胃腸障害	10		Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/M/C/DEU	悪性新生物進行	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）	14		Grade 5	Results in Death	NOT RELATED	No	DOSE NOT CHANGED	FATAL
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/C/DEU	全身健康状態低下	一般・全身障害および投与部位の状態	288	10D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/C/DEU	尿路感染	感染症および寄生虫症	85	2D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/C/DEU	低血糖	代謝および栄養障害	323	13.0H	Grade 2	Other Medically Important Serious Event	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/DEU	胸水	呼吸器、胸郭および縦隔障害	133	12D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/DEU	胸水	呼吸器、胸郭および縦隔障害	152	3D	Grade 3	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/DEU	胸水	呼吸器、胸郭および縦隔障害	177	4D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/DEU	関節炎	筋骨格系および結合組織障害	104	8D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED WITH SEQUELAE

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/DEU	関節炎	筋骨格系および結合組織障害	181	5D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/DEU	心筋梗塞	心臓障害	156	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/DEU	全身健康状態低下	一般・全身障害および投与部位の状態	10	5D	Grade 3	Is Life Threatening	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/DEU	全身健康状態低下	一般・全身障害および投与部位の状態	16		Grade 5	Results in Death	NOT RELATED	No	DOSE NOT CHANGED	FATAL
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/DEU	悪性新生物進行	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）	16		Grade 5	Results in Death, Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE NOT CHANGED	FATAL
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/DEU	肺臓炎	呼吸器、胸郭および縦隔障害	74	6D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/DEU	咳嗽	呼吸器、胸郭および縦隔障害	161	3D	Grade 1	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/DEU	咳嗽	呼吸器、胸郭および縦隔障害	260	48.0H	Grade 1	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	8[redacted]/M/C/DEU	血性下痢	胃腸障害	64	12D	Grade 3	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/DEU	癒痕ヘルニア	傷害、中毒および処置合併症	519	7D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/M/C/DEU	貧血	血液およびリンパ系障害	540	48.0H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/M/C/DEU	貧血	血液およびリンパ系障害	540	48.0H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/M/C/DEU	悪性新生物進行	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）	526	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/M/C/DEU	血中クレアチニン増加	臨床検査	56	5D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/CAN	脱水	代謝および栄養障害	214	5D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/CAN	低ナトリウム血症	代謝および栄養障害	214	5D	Grade 4	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/DEU	脱水	代謝および栄養障害	281	16D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/DEU	低カリウム血症	代謝および栄養障害	281	15D	Grade 4	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/CAN	発熱	一般・全身障害および投与部位の状態	47	4D	Grade 1	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/CAN	背部痛	筋骨格系および結合組織障害	20	4D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/CAN	癌疼痛	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）	105	18D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/C/CAN	骨溶解	筋骨格系および結合組織障害	74	33.5H	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/CAN	下垂体炎	内分泌障害	54	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/M/C/CAN	下痢	胃腸障害	52	9D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/SWE	副腎機能不全	内分泌障害	302	16.7H	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/DNK	肺臓炎	呼吸器、胸郭および縦隔障害	99	7D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/DNK	甲状腺炎	内分泌障害	29	3D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/DNK	造影剤アレルギー	免疫系障害	100	2D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/DNK	慢性閉塞性肺疾患	呼吸器、胸郭および縦隔障害	145	44.0H	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/DNK	水分過負荷	代謝および栄養障害	129	27.5H	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/DNK	脱水	代謝および栄養障害	19	42.7H	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/DNK	造影剤アレルギー	免疫系障害	167	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/DNK	造影剤反応	免疫系障害	125	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/DNK	急性腎障害	腎および尿路障害	36	12D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/DNK	肺感染	感染症および寄生虫症	3	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/DNK	造影剤アレルギー	免疫系障害	217	25.2H	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/DNK	造影剤反応	免疫系障害	125	4D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/DNK	腎損傷	腎および尿路障害	49	2D	Grade 1	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/DNK	腎炎	腎および尿路障害	15	10D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/DNK	腎炎	腎および尿路障害	261	3D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/DNK	腎損傷	腎および尿路障害	181	4D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/C/DNK	気管支炎	感染症および寄生虫症	131	9D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	悪心	胃腸障害	71	24.0H	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	下痢	胃腸障害	71	24.0H	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	嘔吐	胃腸障害	59	13D	Grade 1	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	アスパラギン酸アミノトランスフェラーゼ増加	臨床検査	71	73D	Grade 2		RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	アラニンアミノトランスフェラーゼ増加	臨床検査	71	101D	Grade 3		RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/ARG	発熱	一般・全身障害および投与部位の状態	55	5D	Grade 1	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/ARG	肺臓炎	呼吸器、胸郭および縦隔障害	92	8D	Grade 2	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/ARG	肺臓炎	呼吸器、胸郭および縦隔障害	325	6D	Grade 3	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/ARG	末梢性運動ニューロパチー	神経系障害	33	50D	Grade 2	Other Medically Important Serious Event	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	8[redacted]/F/C/ARG	軟部組織感染	感染症および寄生虫症	108	9D	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	8[redacted]/F/C/ARG	敗血症性ショック	感染症および寄生虫症	69	11D	Grade 4	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	8[redacted]/F/C/ARG	蜂巣炎	感染症および寄生虫症	125	8D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	8[redacted]/F/C/ARG	脳症	神経系障害	245	30D	Grade 3	Other Medically Important Serious Event	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	8[redacted]/F/C/ARG	末梢性運動ニューロパチー	神経系障害	40	29D	Grade 2	Other Medically Important Serious Event	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	8[redacted]/F/C/ARG	脱水	代謝および栄養障害	231	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/DEU	複視	眼障害	155	22D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/DEU	敗血症	感染症および寄生虫症	119	5D	Grade 4	Is Life Threatening	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/DEU	アラニンアミノトランスフェラーゼ増加	臨床検査	81	27D	Grade 4	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/M/C/DEU	胸水	呼吸器、胸郭および縦隔障害	78		Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/DEU	脳出血	神経系障害	89	6D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/DEU	中枢神経系転移	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）	50	48.0H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/DEU	肺炎	感染症および寄生虫症	206	7D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/DEU	肺臓炎	呼吸器、胸郭および縦隔障害	224	9D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/DEU	肺炎	感染症および寄生虫症	711	5D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/DEU	心筋梗塞	心臓障害	685	14D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/DEU	一過性脳虚血発作	神経系障害	55	7D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/M//CAN	悪性新生物進行	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）	24		Grade 3	Results in Death, Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	FATAL
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/CAN	下痢	胃腸障害	77	8D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/CAN	肺塞栓症	呼吸器、胸郭および縦隔障害	92	5D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/CAN	下部消化管出血	胃腸障害	420	4D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/CAN	尿路感染	感染症および寄生虫症	108	6D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/CAN	呼吸困難	呼吸器、胸郭および縦隔障害	113	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/BRA	腸閉塞	胃腸障害	562	7D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/BRA	劇症１型糖尿病	代謝および栄養障害	66	4D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/BRA	糖尿病性ケトアシドーシス	代謝および栄養障害	450	4D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/BRA	医療機器破損	製品の問題	541	30.3H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/BRA	肺炎	感染症および寄生虫症	610	12D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/BRA	心筋梗塞	心臓障害	315	18D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/BRA	心不全	心臓障害	610	12D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/BRA	肺臓炎	呼吸器、胸郭および縦隔障害	55		Grade 1	Requires or Prolongs Hospitalization	RELATED	No	DOSE DELAYED	RECOVERING/RESOLVING

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/DNK	尿路閉塞	腎および尿路障害	362		Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/DNK	下垂体炎	内分泌障害	49	3D	Grade 1	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/DNK	下痢	胃腸障害	27	5D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/DNK	発熱	一般・全身障害および投与部位の状態	22	23.9H	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/IRL	胸水	呼吸器、胸郭および縦隔障害	22	9D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/IRL	胸水	呼吸器、胸郭および縦隔障害	73	7D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/IRL	下痢	胃腸障害	49	11D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/IRL	下痢	胃腸障害	62	12D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	悪心	胃腸障害	20	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	嘔吐	胃腸障害	20	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	高血糖	代謝および栄養障害	29	8D	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	下垂体炎	内分泌障害	143		Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	副腎機能不全	内分泌障害	143		Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/F/C/USA	蜂巣炎	感染症および寄生虫症	288	6D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/C/USA	ウイルス感染	感染症および寄生虫症	118	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	肺臓炎	呼吸器、胸郭および縦隔障害	28	30D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	急性腎障害	腎および尿路障害	77	7D	Grade 4	Requires or Prolongs Hospitalization, Is Life Threatening	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/MEX	貧血	血液およびリンパ系障害	64		Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/MEX	悪性新生物進行	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）	64	30D	Grade 4	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/F/C/MEX	大腿骨骨折	傷害、中毒および処置合併症	80	14D	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/FRA	コントロール不良の糖尿病	代謝および栄養障害	114	6D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/FRA	コントロール不良の糖尿病	代謝および栄養障害	120	9D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/FRA	副腎機能不全	内分泌障害	100	10D	Grade 4	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/FRA	顔面神経障害	神経系障害	49	51D	Grade 1	Other Medically Important Serious Event	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/FRA	大腸炎	胃腸障害	97	18D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/FRA	関節痛	筋骨格系および結合組織障害	131	4D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/MEX	急性呼吸不全	呼吸器、胸郭および縦隔障害	38		Grade 5	Results in Death	NOT RELATED	No	DRUG WITHDRAWN	FATAL
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/MEX	心血管障害	心臓障害	38		Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/CAN	下痢	胃腸障害	10	19D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/CAN	末梢性ニューロパチー	神経系障害	30	73D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/MEX	心肺停止	心臓障害	156		Grade 4	Results in Death, Is Life Threatening	NOT RELATED	No	DRUG WITHDRAWN	FATAL

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/MEX	尿路感染	感染症および寄生虫症	148	4D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/MEX	創傷	傷害、中毒および処置合併症	167	11D	Grade 1	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/MEX	悪性新生物進行	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）	170		Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/A/KOR	下垂体炎	内分泌障害	63	8D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/A/KOR	下垂体炎	内分泌障害	93	6D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/A/KOR	下垂体炎	内分泌障害	131	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/A/TWN	嘔吐	胃腸障害	86	7D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/A/TWN	副腎機能不全	内分泌障害	97	30D	Grade 3	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/A/JPN	高カリウム血症	代謝および栄養障害	43	48.0H	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/A/JPN	高カリウム血症	代謝および栄養障害	44	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/A/JPN	高カリウム血症	代謝および栄養障害	46	48.0H	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/A/JPN	高カリウム血症	代謝および栄養障害	47	4D	Grade 1	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/A/JPN	高カリウム血症	代謝および栄養障害	50	5D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/A/JPN	薬疹	皮膚および皮下組織障害	152	21D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/M/C/HUN	中枢神経系転移	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）	8	54D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/A/JPN	心筋炎	心臓障害	36	11D	Grade 4	Requires or Prolongs Hospitalization, Is Life Threatening	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/A/JPN	心筋炎	心臓障害	46	33D	Grade 3	Requires or Prolongs Hospitalization, Is Life Threatening	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/M/A/JPN	悪性新生物進行	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）	516	42D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/A/JPN	続発性副腎皮質機能不全	内分泌障害	156	12D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/A/JPN	副腎皮質刺激ホルモン欠損症	内分泌障害	156	12D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/A/JPN	胃腺腫	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）	353	11D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/A/JPN	下痢	胃腸障害	313	3D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/A/JPN	胆汁うっ滞性黄疸	肝胆道系障害	23	19D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/A/JPN	胆汁うっ滞性黄疸	肝胆道系障害	42	50D	Grade 1	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/A/JPN	下垂体機能低下症	内分泌障害	103	59D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/BEL	バセドウ病	内分泌障害	14	8D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/A/JPN	悪性新生物進行	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）	51	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/A/JPN	悪性新生物進行	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）	53	12D	Grade 1	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/A/JPN	下痢	胃腸障害	29	13D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/M/A/JPN	蜂巣炎	感染症および寄生虫症	100	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/A/JPN	大腸炎	胃腸障害	34	10D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/A/JPN	スティーブンス・ジョンソン症候群	皮膚および皮下組織障害	1		Grade 3	Requires or Prolongs Hospitalization, Is Life Threatening	RELATED	Yes	DRUG WITHDRAWN	RECOVERING/RESOLVING
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/A/JPN	脳梗塞	神経系障害	201	33D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/F/A/JPN	肺臓炎	呼吸器、胸郭および縦隔障害	67	33D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/A/JPN	腫瘍疼痛	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）	215	14D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/A/JPN	腫瘍疼痛	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）	258	49D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/A/JPN	肝機能異常	肝胆道系障害	69	10D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/A/JPN	肝機能異常	肝胆道系障害	79	10D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/A/JPN	続発性副腎皮質機能不全	内分泌障害	63	5D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/A/JPN	続発性副腎皮質機能不全	内分泌障害	67	18D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/A/JPN	副腎機能不全	内分泌障害	417	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/A/JPN	悪性新生物進行	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）	20		Grade 3	Results in Death, Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	FATAL
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/A/JPN	劇症１型糖尿病	代謝および栄養障害	177	29D	Grade 4	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/A/JPN	間質性肺疾患	呼吸器、胸郭および縦隔障害	49	8D	Grade 1	Requires or Prolongs Hospitalization	RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/A/JPN	下痢	胃腸障害	9	24.0H	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/A/JPN	下痢	胃腸障害	10	3D	Grade 1	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/A/JPN	疲労	一般・全身障害および投与部位の状態	10	3D	Grade 1	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/A/JPN	悪性新生物進行	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）	410	22D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/A/JPN	上気道感染	感染症および寄生虫症	474	5D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/A/JPN	挫傷	傷害、中毒および処置合併症	76	4D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/A/JPN	ステロイド離脱症候群	内分泌障害	90	10D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/A/JPN	回転性めまい	耳および迷路障害	48	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/A/JPN	回転性めまい	耳および迷路障害	51	3D	Grade 1	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/A/JPN	悪性新生物進行	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）	80		Grade 2	Results in Death, Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	FATAL
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/GBR	下気道感染	感染症および寄生虫症	60	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/GBR	下気道感染	感染症および寄生虫症	71	22D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/GBR	肺炎	感染症および寄生虫症	31	11D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/GBR	心筋梗塞	心臓障害	79	14D	Grade 3	Is Life Threatening	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/GBR	アラニンアミノトランスフェラーゼ増加	臨床検査	31	6D	Grade 2	Requires or Prolongs Hospitalization	RELATED	No	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/F/C/GBR	大腸炎	胃腸障害	41	12D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/ITA	憩室炎	感染症および寄生虫症	384	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/ITA	低ナトリウム血症	代謝および栄養障害	36	22D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/ITA	複視	眼障害	136	69D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	8[redacted]/M/C/ITA	全身健康状態低下	一般・全身障害および投与部位の状態	137		Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	8[redacted]/M/C/ITA	悪性新生物進行	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）	155		Grade 5	Results in Death	NOT RELATED	No	DOSE NOT CHANGED	FATAL
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/F/C/ITA	膵酵素増加	臨床検査	87	89D	Grade 4		RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/ITA	死亡	一般・全身障害および投与部位の状態	152		Grade 5	Results in Death	NOT RELATED	No	DRUG WITHDRAWN	FATAL
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/ITA	胃潰瘍	胃腸障害	278	17D	Grade 2	Other Medically Important Serious Event	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/M/C/ITA	全身健康状態低下	一般・全身障害および投与部位の状態	101	12D	Grade 4	Involves Cancer	NOT RELATED	No	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/ITA	低ナトリウム血症	代謝および栄養障害	63	7D	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/F/B/ITA	腫瘍出血	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）	526	7D	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/ITA	下痢	胃腸障害	584	6D	Grade 3	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/ITA	感染性下痢	感染症および寄生虫症	470	44D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/FIN	痙攣発作	神経系障害	590	12D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/FIN	高血糖	代謝および栄養障害	307	31.0H	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/NLD	背部痛	筋骨格系および結合組織障害	72		Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	UNKNOWN

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/NLD	下垂体炎	内分泌障害	80	4D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/USA	副腎機能不全	内分泌障害	84	4D	Grade 4	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	錯乱状態	精神障害	8	48.0H	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/O/USA	胃腸炎	感染症および寄生虫症	21	5D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/O/USA	肺臓炎	呼吸器、胸郭および縦隔障害	133	7D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	腹痛	胃腸障害	19	9D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	貧血	血液およびリンパ系障害	21	4D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	塞栓症	血管障害	46	5D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	肺臓炎	呼吸器、胸郭および縦隔障害	46	5D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	高カルシウム血症	代謝および栄養障害	45	5D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/F/C/USA	大腸炎	胃腸障害	31	7D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/M/C/USA	下痢	胃腸障害	83	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/USA	アスパラギン酸アミノトランスフェラーゼ増加	臨床検査	59	6D	Grade 4	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/USA	アラニンアミノトランスフェラーゼ増加	臨床検査	59	48.0H	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/C/USA	呼吸困難	呼吸器、胸郭および縦隔障害	68	9D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/C/USA	肺臓炎	呼吸器、胸郭および縦隔障害	32	8D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	悪心	胃腸障害	15	6D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	発熱	一般・全身障害および投与部位の状態	8	3D	Grade 1	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	自殺企図	精神障害	32		Grade 5	Results in Death	NOT RELATED	No	DOSE NOT CHANGED	FATAL
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	発疹	皮膚および皮下組織障害	8	3D	Grade 2	Requires or Prolongs Hospitalization	RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/A/USA	病的骨折	筋骨格系および結合組織障害	63	24.0H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/A/USA	脳浮腫	神経系障害	78	42D	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/USA	下痢	胃腸障害	28	13D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/USA	甲状腺炎	内分泌障害	29	85D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/F/C/USA	甲状腺機能亢進症	内分泌障害	36	5D	Grade 2	Other Medically Important Serious Event	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/M/C/USA	無力症	一般・全身障害および投与部位の状態	18	5D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/M/C/USA	呼吸不全	呼吸器、胸郭および縦隔障害	41		Grade 5	Results in Death	NOT RELATED	Yes	DOSE NOT CHANGED	FATAL

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	悪心	胃腸障害	48	7D	Grade 2	Other Medically Important Serious Event	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	下痢	胃腸障害	48	7D	Grade 2	Other Medically Important Serious Event	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	発熱	一般・全身障害および投与部位の状態	48	5D	Grade 1	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	疲労	一般・全身障害および投与部位の状態	48	7D	Grade 2	Other Medically Important Serious Event	RELATED	No	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	低ナトリウム血症	代謝および栄養障害	48	4D	Grade 3	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	甲状腺機能低下症	内分泌障害	51	14D	Grade 2	Other Medically Important Serious Event	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	視床下部－下垂体障害	内分泌障害	51	4D	Grade 3	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	視床下部－下垂体障害	内分泌障害	55	52D	Grade 2	Other Medically Important Serious Event	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	肺炎	感染症および寄生虫症	245	5D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/USA	低ナトリウム血症	代謝および栄養障害	179	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/USA	副腎機能不全	内分泌障害	183	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/C/USA	潰瘍性食道炎	胃腸障害	61	48.0H	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/C/USA	発熱	一般・全身障害および投与部位の状態	135	4D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/C/USA	狭心症	心臓障害	61	48.0H	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	8[redacted]/M/C/USA	肺感染	感染症および寄生虫症	18	3D	Grade 4	Requires or Prolongs Hospitalization, Is Life Threatening	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	8[redacted]/F/C/USA	筋力低下	筋骨格系および結合組織障害	527	8D	Grade 3	Requires or Prolongs Hospitalization, Persist or Signif Disability/Incapacity	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	高血糖	代謝および栄養障害	26		Grade 4	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERING/RESOLVING
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/M/C/USA	頭痛	神経系障害	245	3D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/M/C/USA	副腎機能不全	内分泌障害	458	4D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	8[redacted]/M/C/USA	肺炎	感染症および寄生虫症	67	6D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	8[redacted]/M/C/USA	心筋梗塞	心臓障害	58	9D	Grade 4	Requires or Prolongs Hospitalization, Is Life Threatening	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	8[redacted]/M/C/USA	下垂体炎	内分泌障害	55	12D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	虫垂炎	感染症および寄生虫症	85	4D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/USA	大腸炎	胃腸障害	47	4D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/C/USA	錯乱状態	精神障害	167	3D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/F/C/USA	悪心	胃腸障害	214	12D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/F/C/USA	嘔吐	胃腸障害	214	12D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/F/C/USA	肺臓炎	呼吸器、胸郭および縦隔障害	219	7D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/M/C/USA	肝炎	肝胆道系障害	57	12D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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表2.7.4.7-4　重篤な有害事象の一覧表（16/214試験）

Arm	Subject ID	Age/Gender/Race/Country	Preferred Term	System Organ Class	Study Relative Day	Duration Event	Common Terminology Criteria	Category of Seriousness	Relationship	Treatment Required	Action	Outcome
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/M/C/USA	下痢	胃腸障害	30	9D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/M/C/USA	大腸炎	胃腸障害	33	9D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/C/USA	発熱	一般・全身障害および投与部位の状態	29	6.1H	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/C/USA	肺臓炎	呼吸器、胸郭および縦隔障害	29	32D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/NLD	腸炎	胃腸障害	176	4D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/NLD	下垂体炎	内分泌障害	163	4D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/F/C/NLD	肝炎	肝胆道系障害	50	36.0H	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE

Gendar (F:Female, M:Male)
Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
MedDRA ver20.0
CTCAE ver4.0
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