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	肺出血	呼吸器、胸郭および縦隔障害	393	48.0H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	肺出血	呼吸器、胸郭および縦隔障害	424	5D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	膵炎	胃腸障害	11	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	3[redacted]/M/C/USA	敗血症	感染症および寄生虫症	76	20D	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/C/USA	無菌性髄膜炎	感染症および寄生虫症	141	4D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	乳び胸	呼吸器、胸郭および縦隔障害	401	9D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	洞結節機能不全	心臓障害	401	9D	Grade 3	Requires or Prolongs Hospitalization	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]	6[redacted]/M/C/USA	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）	400	10D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	大腸炎	胃腸障害	39	15D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	急性冠動脈症候群	心臓障害	41	24.0H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/USA	高カルシウム血症	代謝および栄養障害	61	48.0H	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/USA	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）	100	3D	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/USA	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）	103		Grade 5	Results in Death	NOT RELATED	No	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	バセドウ病	内分泌障害	80	6D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	トランスアミナーゼ上昇	臨床検査	113	15D	Grade 4		RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/M/C/USA	高カルシウム血症	代謝および栄養障害	16	7D	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/USA	肺臓炎	呼吸器、胸郭および縦隔障害	22	22D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/USA	甲状腺炎	内分泌障害	22	21D	Grade 2	Requires or Prolongs Hospitalization	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	9	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	深部静脈血栓症	血管障害	13	6D	Grade 3	Requires or Prolongs Hospitalization	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]/M/C/USA	肺臓炎	呼吸器、胸郭および縦隔障害	8	30D	Grade 2	Requires or Prolongs Hospitalization	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	19	9D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	イレウス	胃腸障害	51	48.0H	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	血尿	腎および尿路障害	409	3D	Grade 1	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	腹痛	胃腸障害	72	48.0H	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	胸痛	一般・全身障害および投与部位の状態	72	48.0H	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	咳嗽	呼吸器、胸郭および縦隔障害	64	48.0H	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/C/USA	心房細動	心臓障害	48	4D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/USA	甲状腺機能亢進症	内分泌障害	22	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/M/C/USA	胆嚢障害	肝胆道系障害	151	48.0H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	肺出血	呼吸器、胸郭および縦隔障害	91	48.0H	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	トランスアミナーゼ上昇	臨床検査	12	4D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/USA	斑状丘疹状皮疹	皮膚および皮下組織障害	80	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/CZE	喉頭炎	感染症および寄生虫症	8	3D	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]	7[redacted]/M/C/CZE	塞栓症	血管障害	85		Grade 5	Results in Death	NOT RELATED	No	DRUG WITHDRAWN	FATAL
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/CZE	急性腎障害	腎および尿路障害	85		Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE DELAYED	NOT RECOVERED/ NOT RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/CZE	下痢	胃腸障害	82	4D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/ RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/CZE	急性腎障害	腎および尿路障害	95	12D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/ RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/CZE	貧血	血液およびリンパ系障害	25	4D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/ RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/CZE	皮下出血	皮膚および皮下組織障害	43	8D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/ RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/CZE	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）	62		Grade 4	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]	5[redacted]/M/C/CZE	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）	67		Grade 5	Results in Death	NOT RELATED	No	DOSE NOT CHANGED	FATAL
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/CZE	発熱	一般・全身障害および投与部位の状態	10	12D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/CZE	高血糖	代謝および栄養障害	175	8D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/CZE	鼡径部痛	筋骨格系および結合組織障害	150	15D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/CZE	関節脱臼	傷害、中毒および処置合併症	182	22D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/CZE	甲状腺機能亢進症	内分泌障害	25	13D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/CZE	肺炎	感染症および寄生虫症	407	4D	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]	7[redacted]/M/C/CZE	肺炎	感染症および寄生虫症	411		Grade 5	Results in Death	NOT RELATED	No	DOSE NOT CHANGED	FATAL
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/CZE	呼吸不全	呼吸器、胸郭および縦隔障害	31		Grade 2	Results in Death, Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE NOT CHANGED	FATAL
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/CZE	関節痛	筋骨格系および結合組織障害	157		Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/CZE	脱水	代謝および栄養障害	28	16D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/ RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/CZE	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）	175		Grade 5	Results in Death	NOT RELATED	No	DOSE NOT CHANGED	FATAL
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/CZE	インフルエンザ様疾患	一般・全身障害および投与部位の状態	96	4D	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]	7[redacted]/M/C/CZE	不全対麻痺	神経系障害	204		Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/CZE	糖尿病	代謝および栄養障害	183	17D	Grade 4	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/CZE	甲状腺機能低下症	内分泌障害	84	23D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/CZE	アラニンアミノトランスフェラーゼ増加	臨床検査	22	10D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/CZE	副腎機能不全	内分泌障害	91	5D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/USA	失神	神経系障害	260	2D	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/C/USA	高血糖	代謝および栄養障害	664		Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERING/RESOLVING
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/B/USA	尿路感染	感染症および寄生虫症	298	5D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/M/C/FRA	発熱	一般・全身障害および投与部位の状態	104	24.0H	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/M/C/FRA	腎機能障害	腎および尿路障害	104	4D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/FRA	発熱	一般・全身障害および投与部位の状態	36	9D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/FRA	関節痛	筋骨格系および結合組織障害	149	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/FRA	筋肉痛	筋骨格系および結合組織障害	36	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]	7[redacted]/F/C/FRA	下痢	胃腸障害	100	7D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/C/FRA	多発ニューロパチー	神経系障害	47	48.0H	Grade 3	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/F/C/FRA	下痢	胃腸障害	16	14D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/F/C/FRA	発熱	一般・全身障害および投与部位の状態	16	14D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/C/FRA	四肢痛	筋骨格系および結合組織障害	63	10D	Grade 3	Requires or Prolongs Hospitalization	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]/F/C/FRA	自己免疫障害	免疫系障害	12	5D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/FRA	中枢神経系病変	神経系障害	188	4D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/F/C/FRA	脳出血	神経系障害	241	8D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/F/O/USA	低血圧	血管障害	67	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/FRA	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	106	48.0H	Grade 3	Requires or Prolongs Hospitalization, 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]	6[redacted]/M/C/FRA	アラニンアミノトランスフェラーゼ増加	臨床検査	106	24D	Grade 3	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/M/C/FRA	発熱	一般・全身障害および投与部位の状態	59	9D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/FRA	肺塞栓症	呼吸器、胸郭および縦隔障害	195		Grade 5	Results in Death	NOT RELATED	No	DRUG WITHDRAWN	FATAL
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/FRA	脳梗塞	神経系障害	378	2D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/FRA	甲状腺腫	内分泌障害	124	198D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/FRA	薬剤誤投与	傷害、中毒および処置合併症	141	33M		Other Medically Important Serious Event	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]	4[redacted]/M/C/FRA	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）	203	8D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/F/O/FRA	鎖骨下静脈閉塞	血管障害	27	22D	Grade 2	Other Medically Important Serious Event	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/ITA	静脈血栓症	血管障害	153	12D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/C/FRA	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）	691	19D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/C/FRA	嘔吐	胃腸障害	123	5D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	8[redacted]/F/C/FRA	倦怠感	一般・全身障害および投与部位の状態	55	3D	Grade 2	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]	8[redacted]/F/C/FRA	倦怠感	一般・全身障害および投与部位の状態	64	29D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/FRA	食欲減退	代謝および栄養障害	57	13D	Grade 3	Requires or Prolongs Hospitalization	RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/FRA	錯乱状態	精神障害	81	18D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	No	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	低血圧	血管障害	108	48.0H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	腎不全	腎および尿路障害	108	5D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	腹痛	胃腸障害	54	14D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	肺炎	感染症および寄生虫症	53	16D	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/USA	背部痛	筋骨格系および結合組織障害	53	30D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/USA	胸水	呼吸器、胸郭および縦隔障害	71	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	悪心	胃腸障害	32	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	大腸炎	胃腸障害	32	4D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	高血糖	代謝および栄養障害	99	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/M/C/USA	横紋筋融解症	筋骨格系および結合組織障害	98	57D	Grade 3	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	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/USA	下垂体炎	内分泌障害	98	5D	Grade 3	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/USA	ショック	血管障害	248	12D	Grade 4	Requires or Prolongs Hospitalization, Is Life Threatening	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/USA	脱水	代謝および栄養障害	157	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/USA	低血糖	代謝および栄養障害	258	48.0H	Grade 4	Requires or Prolongs Hospitalization, Is Life Threatening	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/USA	悪性胸水	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）	85	14D	Grade 3	Requires or Prolongs Hospitalization	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]	6[redacted]/M/C/USA	リパーゼ増加	臨床検査	27	106D	Grade 2	Other Medically Important Serious Event	RELATED	No	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	血中クレアチニン増加	臨床検査	27	7D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/USA	呼吸困難	呼吸器、胸郭および縦隔障害	368	4D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/C/USA	低ナトリウム血症	代謝および栄養障害	55	4D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	基底細胞癌	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）	221	24.0H	Grade 2	Involves Cancer	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/AUS	大腸炎	胃腸障害	55	10D	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]	7[redacted]/F/C/AUS	発熱	一般・全身障害および投与部位の状態	30	23D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/F/C/AUS	肺敗血症	感染症および寄生虫症	2	19D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/C/AUS	肺炎	感染症および寄生虫症	73	4D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/AUS	下痢	胃腸障害	6	8D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/AUS	側腹部痛	筋骨格系および結合組織障害	319	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/AUS	肺炎	感染症および寄生虫症	561	9D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/F/C/AUS	下垂体炎	内分泌障害	128		Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	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
79 / 150

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/AUS	脱水	代謝および栄養障害	88	35.0H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/A/AUS	急性肝炎	肝胆道系障害	20	10D	Grade 4	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/C/AUS	背部痛	筋骨格系および結合組織障害	8	16D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/M/C/AUS	急性副腎皮質機能不全	内分泌障害	326	2D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/M/C/AUS	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）	229	5D	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
80 / 150

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/AUS	疲労	一般・全身障害および投与部位の状態	158	8D	Grade 3	Requires or Prolongs Hospitalization	RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/AUS	痙攣発作	神経系障害	158	24.0H	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/AUS	低ナトリウム血症	代謝および栄養障害	159	19.2H	Grade 4	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/AUS	下垂体炎	内分泌障害	158	8D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/AUS	尿路性敗血症	感染症および寄生虫症	238	16D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/AUS	瘻孔	筋骨格系および結合組織障害	261	5D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/AUS	血尿	腎および尿路障害	233	5D	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/C/AUS	尿閉	腎および尿路障害	169	5D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	8[redacted]/M/C/AUS	起立性低血圧	血管障害	102	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	8[redacted]/M/C/AUS	気胸	呼吸器、胸郭および縦隔障害	604	2D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	8[redacted]/M/C/AUS	不整脈	心臓障害	420	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE DELAYED	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	8[redacted]/M/C/AUS	塞栓性脳梗塞	神経系障害	59		Grade 3	Other Medically Important Serious Event	NOT RELATED	No	DOSE NOT CHANGED	RECOVERING/RESOLVING
NIVOLUMAB+IPILIMUMAB	[redacted]	8[redacted]/M/C/AUS	失神	神経系障害	164	24.0H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	8[redacted]/M/C/AUS	失神	神経系障害	214	24.0H	Grade 2	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]	8[redacted]/M/C/AUS	失神	神経系障害	781	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/AUS	ＲＳウイルス感染	感染症および寄生虫症	363	11D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/AUS	悪心	胃腸障害	279	4D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/AUS	滑膜炎	筋骨格系および結合組織障害	7	4D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/AUS	多尿	腎および尿路障害	261	2D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/GBR	下痢	胃腸障害	51	8D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/GBR	下痢	胃腸障害	65	15D	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]	5[redacted]/M/C/GBR	下痢	胃腸障害	377	9D	Grade 1	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/GBR	肺塞栓症	呼吸器、胸郭および縦隔障害	170	10D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/GBR	トランスアミナーゼ上昇	臨床検査	141	21D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/GBR	敗血症	感染症および寄生虫症	108	48.0H	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/GBR	急性腎障害	腎および尿路障害	10	4D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/B/GBR	直腸出血	胃腸障害	294	48.0H	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/B/GBR	直腸出血	胃腸障害	356	7D	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/B/GBR	膵炎	胃腸障害	86	7D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/B/GBR	膵炎	胃腸障害	103	4D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/B/GBR	発熱	一般・全身障害および投与部位の状態	559	39D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/B/GBR	尿路感染	感染症および寄生虫症	79	4D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/B/GBR	錯乱状態	精神障害	80	3D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/B/GBR	低血糖	代謝および栄養障害	556	3D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/F/C/ITA	自己免疫性好中球減少症	血液およびリンパ系障害	99	38D	Grade 4	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]	7[redacted]/M/C/USA	低ナトリウム血症	代謝および栄養障害	383	28.8H	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	病的骨折	筋骨格系および結合組織障害	14	23D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	静脈破裂	血管障害	315	5D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	大腸炎	胃腸障害	9	16D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/USA	大腸炎	胃腸障害	38	4D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/ESP	胃腸炎	感染症および寄生虫症	310	5D	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/C/ESP	気道感染	感染症および寄生虫症	315		Grade 3	Requires or Prolongs Hospitalization, Other Medically Important Serious Event, Persist or Signif Disability/Incapacity	NOT RELATED	Yes	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/ESP	脳梗塞	神経系障害	315		Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/ESP	脳梗塞	神経系障害	320		Grade 5	Results in Death	NOT RELATED	No	DOSE NOT CHANGED	FATAL
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/F/C/ESP	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）	63	25D	Grade 2	Requires or Prolongs Hospitalization	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]	6[redacted]/F/C/ESP	無菌性髄膜炎	感染症および寄生虫症	20	11D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/ESP	化学性肺炎	傷害、中毒および処置合併症	96	5D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/F/C/ESP	下垂体炎	内分泌障害	58	7D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/ESP	肺臓炎	呼吸器、胸郭および縦隔障害	34	19D	Grade 3	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/ESP	糖尿病	代謝および栄養障害	19	3D	Grade 4	Other Medically Important Serious Event	RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	5[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	49	39D	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/GBR	頭痛	神経系障害	97	25.3H	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED WITH SEQUELAE
NIVOLUMAB+IPILIMUMAB	[redacted]	4[redacted]/M/C/ESP	中毒性肝炎	肝胆道系障害	22	8D	Grade 4	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/POL	呼吸困難	呼吸器、胸郭および縦隔障害	93	8D	Grade 3	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	7[redacted]/M/C/POL	脊髄圧迫	神経系障害	16	21D	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]	5[redacted]/M/C/POL	気管支閉塞	呼吸器、胸郭および縦隔障害	188	15D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/M/C/POL	気管支閉塞	呼吸器、胸郭および縦隔障害	200	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]/F/C/ARG	肺炎	感染症および寄生虫症	12	32D	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE DELAYED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	5[redacted]/F/C/ARG	虚血性脳卒中	神経系障害	12	32D	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/ARG	関節痛	筋骨格系および結合組織障害	111	5D	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
90 / 150

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	インフルエンザ	感染症および寄生虫症	742	4D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
NIVOLUMAB+IPILIMUMAB	[redacted]	6[redacted]/M/C/ARG	副腎機能不全	内分泌障害	120	48.0H	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
SUNITINIB	[redacted]	6[redacted]/M/C/USA	高血圧	血管障害	491	48.0H	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/F/C/USA	扁平上皮癌	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）	36	24.0H	Grade 2	Involves Cancer	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/F/C/USA	肺炎	感染症および寄生虫症	14	6D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/M/C/USA	感染	感染症および寄生虫症	16	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/M/C/USA	疲労	一般・全身障害および投与部位の状態	15	8D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/M/C/USA	歩行障害	一般・全身障害および投与部位の状態	15	8D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/M/C/USA	肺炎	感染症および寄生虫症	15	8D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	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
SUNITINIB	[redacted]	7[redacted]/M/C/USA	脱水	代謝および栄養障害	15	8D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/USA	倦怠感	一般・全身障害および投与部位の状態	10	4D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/USA	発熱	一般・全身障害および投与部位の状態	10	4D	Grade 1	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE REDUCED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/USA	胸痛	一般・全身障害および投与部位の状態	547		Grade 2	Requires or Prolongs Hospitalization	RELATED	No	DRUG WITHDRAWN	RECOVERING/RESOLVING
SUNITINIB	[redacted]	5[redacted]/M/C/USA	塞栓症	血管障害	489	48.0H	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/USA	心筋梗塞	心臓障害	548	24.0H	Grade 2	Requires or Prolongs Hospitalization	RELATED	No	DRUG WITHDRAWN	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/F/C/GBR	尿路性敗血症	感染症および寄生虫症	13	7D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	No	DRUG INTERRUPTED	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
SUNITINIB	[redacted]	6[redacted]/F/C/GBR	尿路性敗血症	感染症および寄生虫症	53	6D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/GBR	肺炎	感染症および寄生虫症	309	9D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/F/C/GBR	胆嚢炎	肝胆道系障害	15	6D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/GBR	呼吸困難	呼吸器、胸郭および縦隔障害	191	48.0H	Grade 2	Requires or Prolongs Hospitalization	RELATED	No	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/M/C/ARG	うっ血性心不全	心臓障害	45	4D	Grade 3	Requires or Prolongs Hospitalization	RELATED	No	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/ARG	胸水	呼吸器、胸郭および縦隔障害	45	3D	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/CHL	直腸膿瘍	感染症および寄生虫症	97	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	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
SUNITINIB	[redacted]	5[redacted]/M/C/CHL	頚髄圧迫	神経系障害	230	24.8H	Grade 4	Results in Death, Requires or Prolongs Hospitalization	NOT RELATED	No	DRUG WITHDRAWN	FATAL
SUNITINIB	[redacted]	7[redacted]/M/C/CHL	急性腎障害	腎および尿路障害	9	15D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/CHL	深部静脈血栓症	血管障害	124	4D	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/CHL	全身健康状態低下	一般・全身障害および投与部位の状態	19	6D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/CHL	粘膜の炎症	一般・全身障害および投与部位の状態	19	6D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/CHL	無力症	一般・全身障害および投与部位の状態	19	6D	Grade 3	Requires or Prolongs Hospitalization	RELATED	No	DRUG INTERRUPTED	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
SUNITINIB	[redacted]	5[redacted]/M/C/CHL	黄疸	肝胆道系障害	19	6D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/CHL	血尿	腎および尿路障害	53	48.0H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE REDUCED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/CHL	鼻出血	呼吸器、胸郭および縦隔障害	64	10D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE REDUCED	RECOVERED/RESOLVED
SUNITINIB	CA209214-101-746	6[redacted]/M/C/CHL	喀血	呼吸器、胸郭および縦隔障害	203	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/F/C/CHL	全身健康状態低下	一般・全身障害および投与部位の状態	122	55D	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/POL	肺炎	感染症および寄生虫症	173		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
SUNITINIB	[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）	211		Grade 5	Results in Death	NOT RELATED	No	DOSE NOT CHANGED	FATAL
SUNITINIB	[redacted]	5[redacted]/F/C/POL	胆道仙痛	肝胆道系障害	25	16D	Grade 3	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/F/C/POL	胆道仙痛	肝胆道系障害	163	6D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/F/C/POL	深部静脈血栓症	血管障害	56		Grade 3	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	NOT RELATED	Yes	DOSE REDUCED	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
SUNITINIB	[redacted]	5[redacted]/F/C/POL	呼吸困難	呼吸器、胸郭および縦隔障害	471		Grade 4	Requires or Prolongs Hospitalization, Is Life Threatening	NOT RELATED	Yes	DRUG INTERRUPTED	NOT RECOVERED/ NOT RESOLVED
SUNITINIB	[redacted]	5[redacted]/F/C/POL	呼吸困難	呼吸器、胸郭および縦隔障害	492		Grade 5	Results in Death	NOT RELATED	Yes	DRUG WITHDRAWN	FATAL
SUNITINIB	[redacted]	6[redacted]/M/C/AUT	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）	672	18D	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/ RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/AUT	胆石症	肝胆道系障害	719	48.0H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/ RESOLVED
SUNITINIB	[redacted]	5[redacted]/F/C/AUT	発熱	一般・全身障害および投与部位の状態	198	7D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/ RESOLVED
SUNITINIB	[redacted]	5[redacted]/F/C/AUT	疲労	一般・全身障害および投与部位の状態	159	9D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	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
SUNITINIB	[redacted]	5[redacted]/F/C/AUT	呼吸困難	呼吸器、胸郭および縦隔障害	293	9D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/F/C/AUT	不整脈	心臓障害	124	15D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/F/C/AUT	低血糖	代謝および栄養障害	225	48.0H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/F/C/AUT	低血糖	代謝および栄養障害	261	12D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/GBR	低ナトリウム血症	代謝および栄養障害	242	12D	Grade 4	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/USA	上腹部痛	胃腸障害	38	5D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/USA	疼痛	一般・全身障害および投与部位の状態	38	5D	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
SUNITINIB	[redacted]	6[redacted]/M/C/USA	呼吸困難	呼吸器、胸郭および縦隔障害	38		Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERING/RESOLVING
SUNITINIB	[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）	204		Grade 5	Results in Death	NOT RELATED	No	DRUG WITHDRAWN	FATAL
SUNITINIB	[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）	38		Grade 5	Results in Death	NOT RELATED	No	DOSE NOT CHANGED	FATAL
SUNITINIB	[redacted]	5[redacted]/M/C/TUR	膵炎	胃腸障害	87	28D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/TUR	胸水	呼吸器、胸郭および縦隔障害	3	6D	Grade 2	Requires or Prolongs Hospitalization, 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
SUNITINIB	[redacted]	6[redacted]/M/C/TUR	甲状腺機能低下症	内分泌障害	113	15D	Grade 2	Other Medically Important Serious Event	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/F/C/TUR	痔出血	胃腸障害	64	12D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/F/C/TUR	疲労	一般・全身障害および投与部位の状態	64		Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	NOT RECOVERED/NOT RESOLVED
SUNITINIB	[redacted]	7[redacted]/F/C/TUR	低ナトリウム血症	代謝および栄養障害	64	18.4H	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/F/C/TUR	血小板数減少	臨床検査	64	4D	Grade 4	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/TUR	深部静脈血栓症	血管障害	79	8D	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
SUNITINIB	[redacted]	6[redacted]/M/C/TUR	血中クレアチニン増加	臨床検査	91	23D	Grade 1	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	4[redacted]/M/C/ISR	疼痛	一般・全身障害および投与部位の状態	28	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	4[redacted]/M/C/ISR	精巣上体炎	感染症および寄生虫症	40	4D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/F/C/ISR	高血圧	血管障害	34	4D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/GBR	感染	感染症および寄生虫症	18	4D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE REDUCED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/GBR	一過性脳虚血発作	神経系障害	169	48.0H	Grade 2	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
SUNITINIB	[redacted]	6[redacted]/M/C/GBR	血尿	腎および尿路障害	18	4D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE REDUCED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/GBR	血尿	腎および尿路障害	26	48.0H	Grade 1	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/F/C/GBR	胸水	呼吸器、胸郭および縦隔障害	167	8D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/ISR	無力症	一般・全身障害および投与部位の状態	36	4D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/ISR	血尿	腎および尿路障害	71		Grade 1	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
SUNITINIB	[redacted]	3[redacted]/M/C/ISR	妊娠	妊娠、産褥および周産期の状態					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
SUNITINIB	[redacted]	5[redacted]/F/C/ISR	呼吸困難	呼吸器、胸郭および縦隔障害	141	12D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE
SUNITINIB	[redacted]	6[redacted]/M/C/ISR	呼吸困難	呼吸器、胸郭および縦隔障害	599	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[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	49		Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
SUNITINIB	[redacted]	6[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）	67		Grade 5	Results in Death	NOT RELATED	Yes	DOSE NOT CHANGED	FATAL
SUNITINIB	[redacted]	7[redacted]/F/C/DEU	顎骨壊死	筋骨格系および結合組織障害	437	6D	Grade 3	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	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
SUNITINIB	[redacted]	7[redacted]/F/C/DEU	顎骨壊死	筋骨格系および結合組織障害	491	8D	Grade 3	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED WITH SEQUELAE
SUNITINIB	[redacted]	7[redacted]/F/C/DEU	喉頭浮腫	呼吸器、胸郭および縦隔障害	199	5D	Grade 1	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/F/C/DEU	傾眠	神経系障害	598	3D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/F/C/DEU	うつ病	精神障害	214	116D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
SUNITINIB	[redacted]	7[redacted]/F/C/DEU	うつ病	精神障害	338	14D	Grade 2	Requires or Prolongs Hospitalization	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
105 / 150

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
SUNITINIB	[redacted]	7[redacted]/F/C/DEU	うつ病	精神障害	416	22D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
SUNITINIB	[redacted]	7[redacted]/F/C/DEU	うつ病	精神障害	442	15D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
SUNITINIB	[redacted]	7[redacted]/F/C/DEU	うつ病	精神障害	505	91D	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/F/C/DEU	うつ病	精神障害	600	13D	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/F/C/CAN	血腫	血管障害	728	11D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/F/C/CAN	上部消化管出血	胃腸障害	193	12.6H	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	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
SUNITINIB	[redacted]	7[redacted]/M/C/CAN	後腹膜出血	胃腸障害	228	6D	Grade 3	Other Medically Important Serious Event	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/M/C/CAN	貧血	血液およびリンパ系障害	227	8D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/M/C/CAN	活性化部分トロンボプラスチン時間延長	臨床検査	227	104D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	4[redacted]/M/C/CAN	腎不全	腎および尿路障害	126	11D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	No	DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE
SUNITINIB	[redacted]	4[redacted]/M/C/CAN	尿細管間質性腎炎	腎および尿路障害	134	48.0H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/CAN	嘔吐	胃腸障害	101	14D	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
SUNITINIB	[redacted]	5[redacted]/M/C/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）	17	9D	Grade 3	Involves Cancer, Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
SUNITINIB	[redacted]	5[redacted]/M/C/CAN	血尿	腎および尿路障害	26	5D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/F/C/DNK	扁桃周囲膿瘍	感染症および寄生虫症	27	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/DNK	前立腺癌	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）	555	15D	Grade 1	Involves Cancer	NOT RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/USA	急性腎障害	腎および尿路障害	17	10D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/F/C/USA	疲労	一般・全身障害および投与部位の状態	17	4D	Grade 2	Requires or Prolongs Hospitalization	RELATED	No	DRUG INTERRUPTED	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
SUNITINIB	[redacted]	7[redacted]/F/C/USA	筋力低下	筋骨格系および結合組織障害	87	33D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/F/C/USA	貧血	血液およびリンパ系障害	22	11D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/F/C/USA	呼吸困難	呼吸器、胸郭および縦隔障害	115	6D	Grade 2	Requires or Prolongs Hospitalization	RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/F/C/ARG	骨壊死	筋骨格系および結合組織障害	524	7D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/AUS	基底細胞癌	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）	75	0S	Grade 2	Involves Cancer	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/AUS	基底細胞癌	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）	384	24.0H	Grade 2	Involves Cancer	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
SUNITINIB	[redacted]	7[redacted]/F/C/DEU	腰椎骨折	傷害、中毒および処置合併症	178	69D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
SUNITINIB	[redacted]	7[redacted]/M/C/DEU	急性腎障害	腎および尿路障害	168	13D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/CHL	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）	31		Grade 5	Results in Death	NOT RELATED	No	DOSE NOT CHANGED	FATAL
SUNITINIB	[redacted]	5[redacted]/M/C/CHL	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）	2	19D	Grade 3	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/DEU	背部痛	筋骨格系および結合組織障害	304	6D	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
SUNITINIB	[redacted]	6[redacted]/M/C/CAN	発熱	一般・全身障害および投与部位の状態	273	24.0H	Grade 1	Requires or Prolongs Hospitalization	NOT RELATED	No	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/CAN	心停止	心臓障害	452		Grade 5	Results in Death	RELATED	Yes	DRUG WITHDRAWN	FATAL
SUNITINIB	[redacted]	6[redacted]/M/C/CAN	譫妄	精神障害	273	24.0H	Grade 1	Requires or Prolongs Hospitalization	NOT RELATED	No	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/CAN	高カルシウム血症	代謝および栄養障害	610	7D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/CAN	基底細胞癌	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）	72	24.0H	Grade 1	Involves Cancer	NOT RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/CAN	基底細胞癌	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）	118	24.0H	Grade 1	Involves Cancer	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
SUNITINIB	[redacted]	6[redacted]/M/C/BRA	背部痛	筋骨格系および結合組織障害	82	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/BRA	呼吸困難	呼吸器、胸郭および縦隔障害	242	48.0H	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/BRA	呼吸困難	呼吸器、胸郭および縦隔障害	294	10D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/F/C/BRA	脳血管発作	神経系障害	28	3D	Grade 1	Other Medically Important Serious Event	RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/F/C/BRA	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）	87	16D	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	No	DRUG WITHDRAWN	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/M/C/BRA	感染性皮膚潰瘍	感染症および寄生虫症	115		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
SUNITINIB	[redacted]	7[redacted]/M/C/BRA	敗血症	感染症および寄生虫症	121		Grade 5	Results in Death	NOT RELATED	No	DRUG WITHDRAWN	FATAL
SUNITINIB	[redacted]	7[redacted]/M/C/BRA	脳血管発作	神経系障害	167	8D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/BRA	腸管穿孔	胃腸障害	71	13D	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/BRA	腹部感染	感染症および寄生虫症	117	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/BRA	高カリウム血症	代謝および栄養障害	26	15D	Grade 3	Other Medically Important Serious Event	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/F/O/BRA	うっ血性心不全	心臓障害	180	9D	Grade 4	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/DNK	気管支閉塞	呼吸器、胸郭および縦隔障害	118	2D	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
SUNITINIB	[redacted]	5[redacted]/F/C/DNK	急性冠動脈症候群	心臓障害	86	20.2H	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/F/C/DNK	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）	122		Grade 1	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERING/RESOLVING
SUNITINIB	[redacted]	6[redacted]/M/C/DNK	肺炎	感染症および寄生虫症	17	16.4H	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/DNK	構語障害	神経系障害	105	5.5H	Grade 1	Other Medically Important Serious Event	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
SUNITINIB	[redacted]	3[redacted]/F/C/IRL	発熱	一般・全身障害および投与部位の状態	10	18D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/USA	無力症	一般・全身障害および投与部位の状態	107		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
SUNITINIB	[redacted]	6[redacted]/M/C/USA	低血糖	代謝および栄養障害	26	11D	Grade 4	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/USA	胆嚢炎	肝胆道系障害	280	44.5H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	4[redacted]/M/C/USA	腰部くも膜下槽圧迫	神経系障害	43	50D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	4[redacted]/M/C/USA	高カルシウム血症	代謝および栄養障害	43	1.6H	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/USA	脊髄圧迫	神経系障害	100	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/USA	血尿	腎および尿路障害	28	16D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	No	DRUG INTERRUPTED	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
SUNITINIB	[redacted]	5[redacted]/M/C/USA	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）	63	24.0H	Grade 3	Involves Cancer, Requires or Prolongs Hospitalization, Other Medically Important Serious Event	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/O/USA	無力症	一般・全身障害および投与部位の状態	121	14D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/O/USA	血小板減少症	血液およびリンパ系障害	121	7D	Grade 2	Requires or Prolongs Hospitalization	RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/O/USA	血中ビリルビン増加	臨床検査	121	7D	Grade 2	Requires or Prolongs Hospitalization	RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/USA	糖尿病性足病変	皮膚および皮下組織障害	177	37D	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	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
SUNITINIB	[redacted]	6[redacted]/M/C/USA	基底細胞癌	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）	62	24.0H	Grade 2	Involves Cancer	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	4[redacted]/M/C/USA	逆流性喉頭炎	呼吸器、胸郭および縦隔障害	129	48.0H	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/F/C/USA	呼吸困難	呼吸器、胸郭および縦隔障害	120	6D	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/F/C/MEX	血尿	腎および尿路障害	17	19D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/F/C/MEX	肺出血	呼吸器、胸郭および縦隔障害	500	12D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/MEX	肺炎	感染症および寄生虫症	48		Grade 4	Is Life Threatening	NOT RELATED	Yes	DRUG INTERRUPTED	NOT RECOVERED/NOT RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/MEX	肺炎	感染症および寄生虫症	49		Grade 5	Results in Death	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
SUNITINIB	[redacted]	5[redacted]/M/C/FRA	胆嚢閉塞	肝胆道系障害	95	19D	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
SUNITINIB	[redacted]	6[redacted]/M/C/MEX	手首関節骨折	傷害、中毒および処置合併症	1	31D	Grade 2	Other Medically Important Serious Event	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[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）	292	3D	Grade 4	Other Medically Important Serious Event	NOT RELATED	No	DRUG WITHDRAWN	RECOVERED/RESOLVED
SUNITINIB	[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）	312		Grade 5	Results in Death	NOT RELATED	No	DOSE NOT CHANGED	FATAL
SUNITINIB	[redacted]	5[redacted]/F/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）	40		Grade 5	Results in Death	NOT RELATED	No	DRUG WITHDRAWN	FATAL

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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
SUNITINIB	[redacted]	6[redacted]/M/C/CAN	上部消化管出血	胃腸障害	118	5D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/O/CAN	直腸出血	胃腸障害	114	15D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/CAN	肺炎	感染症および寄生虫症	431	3D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/F/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）	634		Grade 1	Other Medically Important Serious Event	NOT RELATED	No	DRUG INTERRUPTED	NOT RECOVERED/NOT RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/MEX	下痢	胃腸障害	449		Grade 3	Results in Death, Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	FATAL
SUNITINIB	[redacted]	2[redacted]/M/A/KOR	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）	210	7D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED

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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
SUNITINIB	[redacted]	2[redacted]/M/A/KOR	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）	218	22D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/M/A/KOR	口内炎	胃腸障害	22	5D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/M/A/KOR	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）	605		Grade 1	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERING/RESOLVING
SUNITINIB	[redacted]	4[redacted]/F/C/IRL	下気道感染	感染症および寄生虫症	39	9D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	4[redacted]/F/C/IRL	肺臓炎	呼吸器、胸郭および縦隔障害	82	17D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
SUNITINIB	[redacted]	7[redacted]/M/C/IRL	胸痛	一般・全身障害および投与部位の状態	74		Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERING/RESOLVING

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Race (A:Asian, B:Black/African American, C:White, I:American Indian/Alaska Native, O:Other, P:Native Hawaiian/Other Pacific Islander)
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