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/A/TWN	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）	258	7D		Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	3[redacted]/M/A/TWN	遠隔転移を伴う腎細胞癌	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	23		Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/CAN	上腕骨骨折	傷害、中毒および処置合併症	100		Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
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）	93		Grade 4	Results in Death	NOT RELATED	Yes	DOSE NOT CHANGED	FATAL
SUNITINIB	[redacted]	6[redacted]/M/C/CAN	アナフィラキシー反応	免疫系障害	120	24.0H	Grade 3	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/CAN	トロポニン増加	臨床検査	3	37D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/F/C/HUN	急性膵炎	胃腸障害	512	10D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/A/JPN	血小板数減少	臨床検査	13	17D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/F/A/JPN	倦怠感	一般・全身障害および投与部位の状態	399	3D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/F/A/JPN	回転性めまい	耳および迷路障害	533	48.0H	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/F/A/JPN	脱水	代謝および栄養障害	71	9D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE REDUCED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	4[redacted]/F/A/JPN	痔瘻	胃腸障害	136	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]	7[redacted]/F/A/JPN	敗血症	感染症および寄生虫症	15	12D	Grade 4	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/F/A/JPN	多形紅斑	皮膚および皮下組織障害	15	12D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/F/A/JPN	出血性胃潰瘍	胃腸障害	108	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/F/A/JPN	出血性胃潰瘍	胃腸障害	110	5D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/F/A/JPN	出血性胃潰瘍	胃腸障害	117	4D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/F/A/JPN	出血性胃潰瘍	胃腸障害	120	9D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/F/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）	478	48D	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/A/JPN	大腿骨骨折	傷害、中毒および処置合併症	69	51D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[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）	89	31D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/A/JPN	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）	144	56D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/M/A/JPN	感染性胆嚢炎	感染症および寄生虫症	168	46D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/M/A/JPN	胃腸出血	胃腸障害	123	21D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/M/A/JPN	発熱	一般・全身障害および投与部位の状態	15	48.0H	Grade 1	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/A/JPN	発熱	一般・全身障害および投与部位の状態	16	48.0H	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/M/A/JPN	汎血球減少症	血液およびリンパ系障害	123	21D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/M/A/JPN	腎機能障害	腎および尿路障害	15	6D	Grade 1	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/M/A/JPN	血小板数減少	臨床検査	15	8D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/M/A/JPN	血小板数減少	臨床検査	22	3D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/M/A/JPN	血小板数減少	臨床検査	24	4D	Grade 1	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/GBR	くも膜下出血	傷害、中毒および処置合併症	71	17D	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/GBR	胆汁うっ滞性黄疸	肝胆道系障害	317	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/F/C/GBR	インフルエンザ	感染症および寄生虫症	296	24.0H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	No	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/GBR	胸水	呼吸器、胸郭および縦隔障害	141	4D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/GBR	右室不全	心臓障害	162	25D	Grade 4	Results in Death, Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	FATAL
SUNITINIB	[redacted]	5[redacted]/M/C/GBR	血尿	腎および尿路障害	23	5D	Grade 1	Requires or Prolongs Hospitalization	RELATED	No	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/A/GBR	胆道仙痛	肝胆道系障害	487	10D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	4[redacted]/M/C/ITA	脾臓病変	血液およびリンパ系障害	681	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
SUNITINIB	[redacted]	6[redacted]/M/C/ITA	血尿	腎および尿路障害	47	10D	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[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）	92		Grade 5	Results in Death	NOT RELATED	No	DOSE NOT CHANGED	FATAL
SUNITINIB	[redacted]	7[redacted]/M/C/ITA	肺炎	感染症および寄生虫症	157	17D	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/M/C/ITA	頭蓋内動脈瘤	神経系障害	65	6D	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/F/C/FIN	肺塞栓症	呼吸器、胸郭および縦隔障害	29	5D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED WITH SEQUELAE
SUNITINIB	[redacted]	6[redacted]/M/C/NLD	発熱	一般・全身障害および投与部位の状態	216	10D	Grade 1	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/NLD	低酸素症	呼吸器、胸郭および縦隔障害	207	48.0H	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	4[redacted]/M/C/USA	悪心	胃腸障害	11	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
SUNITINIB	[redacted]	4[redacted]/M/C/USA	悪心	胃腸障害	20	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	4[redacted]/M/C/USA	肺感染	感染症および寄生虫症	27	48.0H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	3[redacted]/F/C/USA	頭蓋内出血	神経系障害	75		Grade 5	Results in Death	NOT RELATED	Yes	DRUG WITHDRAWN	FATAL
SUNITINIB	[redacted]	3[redacted]/F/C/USA	発熱	一般・全身障害および投与部位の状態	54	48.0H	Grade 1	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	3[redacted]/F/C/USA	低血圧	血管障害	54	48.0H	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]	3[redacted]/F/C/USA	胸水	呼吸器、胸郭および縦隔障害	45	7D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED WITH SEQUELAE
SUNITINIB	[redacted]	3[redacted]/F/C/USA	頻脈	心臓障害	54	48.0H	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
SUNITINIB	[redacted]	5[redacted]/M/C/USA	狭心症	心臓障害	148	3D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/F/C/USA	突然死	一般・全身障害および投与部位の状態	17		Grade 5	Results in Death	NOT RELATED	No	DOSE NOT CHANGED	FATAL
SUNITINIB	[redacted]	6[redacted]/F/C/USA	脱水	代謝および栄養障害	15		Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERING/RESOLVING
SUNITINIB	[redacted]	5[redacted]/F/C/USA	頚部痛	筋骨格系および結合組織障害	163	7D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/USA	貧血	血液およびリンパ系障害	42	5D	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]	5[redacted]/M/C/USA	膵炎	胃腸障害	114	5D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/USA	悪心	胃腸障害	25	7D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/USA	嘔吐	胃腸障害	25	7D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/USA	脱水	代謝および栄養障害	25	7D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	4[redacted]/F/C/USA	腹痛	胃腸障害	109	4D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/M/C/USA	上腕骨骨折	傷害、中毒および処置合併症	24	6D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/F/C/USA	腹痛	胃腸障害	34	14D	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]	6[redacted]/F/C/USA	低血圧	血管障害	6	8D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/F/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）	35		Grade 3	Results in Death	NOT RELATED	No	DOSE NOT CHANGED	FATAL
SUNITINIB	[redacted]	7[redacted]/M/C/USA	低マグネシウム血症	代謝および栄養障害	20	6D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/M/C/USA	低マグネシウム血症	代謝および栄養障害	43	4D	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
SUNITINIB	[redacted]	6[redacted]/F/C/USA	喘息	呼吸器、胸郭および縦隔障害	568	48.0H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
SUNITINIB	[redacted]	6[redacted]/F/C/USA	心不全	心臓障害	554	48.0H	Grade 4	Requires or Prolongs Hospitalization, Is Life Threatening	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
SUNITINIB	[redacted]	6[redacted]/F/C/USA	低ナトリウム血症	代謝および栄養障害	142	3D	Grade 4	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/F/C/USA	膵炎	胃腸障害	29	3D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED WITH SEQUELAE
SUNITINIB	[redacted]	5[redacted]/F/C/USA	貧血	血液およびリンパ系障害	71	48.0H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/USA	高血圧	血管障害	20	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/F/C/USA	急性腎障害	腎および尿路障害	379	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE REDUCED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/A/USA	高カリウム血症	代謝および栄養障害	638	6.2H	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/A/USA	高血糖	代謝および栄養障害	334	18.6H	Grade 3	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]	5[redacted]/M/A/USA	脱水	代謝および栄養障害	638	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/F/C/USA	下痢	胃腸障害	29	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/F/C/USA	脱水	代謝および栄養障害	309	42.9H	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/NLD	後天性横隔膜性内臓転位	呼吸器、胸郭および縦隔障害	94	38.5H	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/USA	腹痛	胃腸障害	715	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/USA	心停止	心臓障害	59		Grade 5	Results in Death	RELATED	Yes	DRUG WITHDRAWN	FATAL
SUNITINIB	[redacted]	5[redacted]/M/C/USA	失神	神経系障害	13	48.0H	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
SUNITINIB	[redacted]	5[redacted]/M/O/USA	インフルエンザ	感染症および寄生虫症	194	35.9H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/USA	損傷	傷害、中毒および処置合併症	455	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
SUNITINIB	[redacted]	6[redacted]/M/C/USA	発熱	一般・全身障害および投与部位の状態	15	4D	Grade 1	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/USA	敗血症	感染症および寄生虫症	87	4D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[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）	91	10D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	4[redacted]/M/B/USA	虫垂炎	感染症および寄生虫症	108	48.0H	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]	6[redacted]/F/C/USA	遠隔転移を伴う新生物	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）	232	7D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/F/C/USA	卵巣嚢胞	生殖系および乳房障害	189	48.0H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/CZE	急性胆管炎	肝胆道系障害	19	11D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[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）	74	10D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/CZE	急性腎障害	腎および尿路障害	127	4D	Grade 4	Other Medically Important Serious Event	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/CZE	急性腎障害	腎および尿路障害	158	10D	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]/F/C/CZE	子宮出血	生殖系および乳房障害	38	48.0H	Grade 1	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	4[redacted]/M/C/CZE	高カルシウム血症	代謝および栄養障害	358		Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
SUNITINIB	[redacted]	4[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）	362		Grade 5	Results in Death	NOT RELATED	Yes	DOSE NOT CHANGED	FATAL
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）	83	48.0H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/FRA	肺塞栓症	呼吸器、胸郭および縦隔障害	65	27D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/FRA	喀血	呼吸器、胸郭および縦隔障害	65	9D	Grade 4	Requires or Prolongs Hospitalization, Is Life Threatening	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]	6[redacted]/F/C/FRA	背部痛	筋骨格系および結合組織障害	143	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/ RESOLVED
SUNITINIB	[redacted]	5[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）	107	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	No	DRUG INTERRUPTED	RECOVERED/ RESOLVED
SUNITINIB	[redacted]	7[redacted]/M/C/FRA	胆汁うっ滞性黄疸	肝胆道系障害	85	15D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/ RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/FRA	胸水	呼吸器、胸郭および縦隔障害	171	5D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/ RESOLVED
SUNITINIB	[redacted]	7[redacted]/M/C/FRA	頚部痛	筋骨格系および結合組織障害	1	7D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/ RESOLVED
SUNITINIB	[redacted]	7[redacted]/M/C/FRA	股関節部骨折	傷害、中毒および処置合併症	33		Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
SUNITINIB	[redacted]	7[redacted]/M/C/FRA	頭痛	神経系障害	15	19D	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/USA	胃腸出血	胃腸障害	51	3D	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	51	3D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/FRA	腎不全	腎および尿路障害	116	4D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/FRA	腎腫瘤	腎および尿路障害	588	24.0H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/FRA	腎不全	腎および尿路障害	246	10D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/FRA	大腸穿孔	胃腸障害	148		Grade 4	Results in Death, Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	FATAL
SUNITINIB	[redacted]	6[redacted]/M/C/FRA	貧血	血液およびリンパ系障害	145	3D	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]	3[redacted]/M/C/FRA	嘔吐	胃腸障害	61	19D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	3[redacted]/M/C/FRA	肝臓痛	肝胆道系障害	39	12D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/ITA	肺膿瘍	感染症および寄生虫症	463	235D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/ITA	低ナトリウム血症	代謝および栄養障害	32	11D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/F/C/FRA	急性腎障害	腎および尿路障害	212	9D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	No	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/F/C/FRA	胆管炎	肝胆道系障害	76	11D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	8[redacted]/M/C/FRA	肺塞栓症	呼吸器、胸郭および縦隔障害	422		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]/F/C/FRA	胆嚢炎	肝胆道系障害	47	10D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	No	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/F/O/USA	憩室穿孔	胃腸障害	30	10D	Grade 4	Requires or Prolongs Hospitalization, Is Life Threatening	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/F/O/USA	小腸閉塞	胃腸障害	46	7D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/USA	骨折	傷害、中毒および処置合併症	704		Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERING/RESOLVING
SUNITINIB	[redacted]	6[redacted]/M/C/USA	転倒	傷害、中毒および処置合併症	704	14D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/USA	喀血	呼吸器、胸郭および縦隔障害	34	4D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/USA	低ナトリウム血症	代謝および栄養障害	15	8D	Grade 4	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]	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）	42		Grade 5	Results in Death	NOT RELATED	No	DOSE NOT CHANGED	FATAL
SUNITINIB	[redacted]	6[redacted]/F/C/USA	うっ血性心不全	心臓障害	164	7D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE
SUNITINIB	[redacted]	6[redacted]/F/C/USA	うっ血性心不全	心臓障害	177	6D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
SUNITINIB	[redacted]	6[redacted]/F/C/AUS	口内炎	胃腸障害	22	4D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/F/C/AUS	嘔吐	胃腸障害	31	7D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/F/C/AUS	脱水	代謝および栄養障害	43		Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	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]/F/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）	43		Grade 4	Results in Death, Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	FATAL
SUNITINIB	[redacted]	6[redacted]/M/C/AUS	下気道感染	感染症および寄生虫症	178	4D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/M/C/AUS	発熱	一般・全身障害および投与部位の状態	16	7D	Grade 1	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/F/C/AUS	敗血症	感染症および寄生虫症	17	21D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/F/C/AUS	胸水	呼吸器、胸郭および縦隔障害	26	12D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/F/C/AUS	脱水	代謝および栄養障害	25	15D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/F/C/AUS	脱水	代謝および栄養障害	85	11D	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]	5[redacted]/F/C/AUS	脱水	代謝および栄養障害	109	10D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/AUS	胸水	呼吸器、胸郭および縦隔障害	38		Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
SUNITINIB	[redacted]	6[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）	38		Grade 4	Results in Death	NOT RELATED	Yes	DRUG WITHDRAWN	FATAL
SUNITINIB	[redacted]	6[redacted]/M/C/AUS	鼻出血	呼吸器、胸郭および縦隔障害	69	4D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/AUS	腎機能障害	腎および尿路障害	69	7D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/F/C/AUS	胃腸炎	感染症および寄生虫症	76	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)
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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/AUS	筋骨格痛	筋骨格系および結合組織障害	9		Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
SUNITINIB	[redacted]	5[redacted]/F/C/AUS	低血糖	代謝および栄養障害	13	24.0H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/F/C/AUS	低血糖	代謝および栄養障害	31	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE REDUCED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/AUS	直腸出血	胃腸障害	16	7D	Grade 1	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/AUS	疲労	一般・全身障害および投与部位の状態	19	4D	Grade 3	Requires or Prolongs Hospitalization	RELATED	No	DRUG WITHDRAWN	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/AUS	血小板数減少	臨床検査	19	3D	Grade 3	Requires or Prolongs Hospitalization	RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/AUS	腸重積症	胃腸障害	126	5D	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)
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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/AUS	腹痛	胃腸障害	66	26.0H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	No	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/M/C/AUS	背部痛	筋骨格系および結合組織障害	32	8D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	3[redacted]/F/C/GBR	敗血症	感染症および寄生虫症	11	5D	Grade 2	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	3[redacted]/F/C/GBR	胸水	呼吸器、胸郭および縦隔障害	76	13D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
SUNITINIB	[redacted]	3[redacted]/F/C/GBR	胸水	呼吸器、胸郭および縦隔障害	93		Grade 3	Results in Death, Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	FATAL
SUNITINIB	[redacted]	7[redacted]/M/A/GBR	胃腸出血	胃腸障害	258	6D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/GBR	十二指腸潰瘍	胃腸障害	544	6D	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)
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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	末梢性浮腫	一般・全身障害および投与部位の状態	574	13D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/GBR	上肢骨折	傷害、中毒および処置合併症	20	7D	Grade 3	Requires or Prolongs Hospitalization, Other Medically Important Serious Event	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/GBR	急性腎障害	腎および尿路障害	574	13D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/GBR	血中カリウム増加	臨床検査	574	13D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/ITA	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）	110	10D	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE
SUNITINIB	[redacted]	7[redacted]/M/C/USA	下痢	胃腸障害	63	9D	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)
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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/O/COL	胃腸出血	胃腸障害	84		Grade 3	Results in Death, Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	FATAL
SUNITINIB	[redacted]	4[redacted]/M/O/COL	起坐呼吸	呼吸器、胸郭および縦隔障害	36	10D	Grade 1	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	4[redacted]/M/O/COL	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）	178		Grade 5	Results in Death	NOT RELATED	Yes	DOSE NOT CHANGED	FATAL
SUNITINIB	[redacted]	5[redacted]/M/C/HUN	胸水症	呼吸器、胸郭および縦隔障害	8	13D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	5[redacted]/M/C/HUN	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）	26		Grade 4	Results in Death	NOT RELATED	Yes	DOSE NOT CHANGED	FATAL
SUNITINIB	[redacted]	4[redacted]/F/C/HUN	貧血	血液およびリンパ系障害	255	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)
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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]	4[redacted]/F/C/HUN	貧血	血液およびリンパ系障害	338	2D	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	4[redacted]/F/C/HUN	貧血	血液およびリンパ系障害	380	7D	Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/M/C/HUN	鼻出血	呼吸器、胸郭および縦隔障害	128	24.0H	Grade 1	Requires or Prolongs Hospitalization	RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	3[redacted]/F/C/HUN	膵炎	胃腸障害	19	30D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/F/C/ESP	胃出血	胃腸障害	32	15D	Grade 3	Requires or Prolongs Hospitalization	RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
SUNITINIB	[redacted]	4[redacted]/M/C/ESP	漿液腫	傷害、中毒および処置合併症	46	23.9H	Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG INTERRUPTED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/F/C/ESP	低マグネシウム血症	代謝および栄養障害	22	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)
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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/ESP	敗血症	感染症および寄生虫症	29	28D	Grade 4	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	RECOVERED/RESOLVED
SUNITINIB	[redacted]	6[redacted]/M/C/GBR	視野欠損	神経系障害	161		Grade 2	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERING/RESOLVING
SUNITINIB	[redacted]	6[redacted]/F/C/POL	全身健康状態低下	一般・全身障害および投与部位の状態	94		Grade 3	Results in Death, Requires or Prolongs Hospitalization	NOT RELATED	Yes	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）	424		Grade 3	Requires or Prolongs Hospitalization	NOT RELATED	Yes	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
SUNITINIB	[redacted]	8[redacted]/F/C/ARG	胃炎	胃腸障害	30	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)
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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]	8[redacted]/F/C/ARG	大腸穿孔	胃腸障害	35	10D	Grade 3	Requires or Prolongs Hospitalization, Is Life Threatening	NOT RELATED	Yes	DOSE NOT CHANGED	RECOVERED/RESOLVED
SUNITINIB	[redacted]	7[redacted]/M/C/ARG	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）	131		Grade 3	Results in Death, Requires or Prolongs Hospitalization	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)
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表 2.7.4.7-5　留意すべき有害事象の定義（016 試験，16/214 試験）

カテゴリー		サブカテゴリー		PT名	
ENDOCRINE ADVERSE EVENT	内分泌障害	ADRENAL DISORDER	副腎障害	ADRENAL INSUFFICIENCY	副腎機能不全
				ADRENAL SUPPRESSION	副腎抑制
				ADRENOCORTICAL INSUFFICIENCY ACUTE	急性副腎皮質機能不全
				BLOOD CORTICOTROPHIN DECREASED	血中コルチコトロピン減少
				BLOOD CORTICOTROPHIN INCREASED	血中コルチコトロピン増加
				HYPOTHALAMIC PITUITARY ADRENAL AXIS SUPPRESSION	視床下部－下垂体－副腎系抑制
				PRIMARY ADRENAL INSUFFICIENCY	原発性副腎機能不全
				SECONDARY ADRENOCORTICAL INSUFFICIENCY	続発性副腎皮質機能不全
		DIABETES	糖尿病	DIABETES MELLITUS	糖尿病
				DIABETIC KETOACIDOSIS	糖尿病性ケトアシドーシス
				FULMINANT TYPE 1 DIABETES MELLITUS	劇症1 型糖尿病
				LATENT AUTOIMMUNE DIABETES IN ADULTS	成人潜在性自己免疫性糖尿病
				TYPE 1 DIABETES MELLITUS	1 型糖尿病
		PITUITARY DISORDER	下垂体障害	HYPOPHYSITIS	下垂体炎
				HYPOPITUITARISM	下垂体機能低下症
				LYMPHOCYTIC HYPOPHYSITIS	リンパ球性下垂体炎
		THYROID DISORDER	甲状腺障害	ATROPHIC THYROIDITIS	萎縮性甲状腺炎

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表 2.7.4.7-5　留意すべき有害事象の定義（016 試験，16/214 試験）（続き 1）

カテゴリー	サブカテゴリー	PT名	
		AUTOIMMUNE HYPOTHYROIDISM	自己免疫性甲状腺機能低下症
		AUTOIMMUNE THYROIDITIS	自己免疫性甲状腺炎
		BASEDOW'S DISEASE	バセドウ病
		BLOOD THYROID STIMULATING HORMONE DECREASED	血中甲状腺刺激ホルモン減少
		BLOOD THYROID STIMULATING HORMONE INCREASED	血中甲状腺刺激ホルモン増加
		HYPERTHYROIDISM	甲状腺機能亢進症
		HYPOTHYROIDISM	甲状腺機能低下症
		PRIMARY HYPERTHYROIDISM	原発性甲状腺機能亢進症
		PRIMARY HYPOTHYROIDISM	原発性甲状腺機能低下症
		SILENT THYROIDITIS	無痛性甲状腺炎
		THYROID FUNCTION TEST ABNORMAL	甲状腺機能検査異常
		THYROID HORMONES DECREASED	甲状腺ホルモン減少
		THYROID HORMONES INCREASED	甲状腺ホルモン増加
		THYROIDITIS	甲状腺炎
		THYROIDITIS ACUTE	急性甲状腺炎
		THYROXINE DECREASED	サイロキシン減少
		THYROXINE FREE DECREASED	遊離サイロキシン減少

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表 2.7.4.7-5　留意すべき有害事象の定義（016 試験，16/214 試験）（続き 2）

カテゴリー	サブカテゴリー	PT名	
		THYROXINE FREE INCREASED	遊離サイロキシン増加
		THYROXINE INCREASED	サイロキシン増加
		TRI-IODOTHYRONINE UPTAKE INCREASED	トリヨードチロニン摂取増加
GASTROINTESTINAL ADVERSE EVENT	胃腸毒性	AUTOIMMUNE COLITIS	自己免疫性大腸炎
		COLITIS	大腸炎
		COLITIS ULCERATIVE	潰瘍性大腸炎
		DIARRHOEA	下痢
		ENTERITIS	小腸炎
		ENTEROCOLITIS	腸炎
		FREQUENT BOWEL MOVEMENTS	排便回数増加
		GASTROINTESTINAL PERFORATION	消化管穿孔
		LOWER GASTROINTESTINAL PERFORATION	下部消化管穿孔
		UPPER GASTROINTESTINAL PERFORATION	上部消化管穿孔
HEPATIC ADVERSE EVENT	肝毒性	ACUTE HEPATIC FAILURE	急性肝不全
		ACUTE ON CHRONIC LIVER FAILURE	慢性肝不全の急性増悪
		ALANINE AMINOTRANSFERASE INCREASED	アラニンアミノトランスフェラーゼ増加
		ASPARTATE AMINOTRANSFERASE INCREASED	アスパラギン酸アミノトランスフェラーゼ増加

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表 2.7.4.7-5　留意すべき有害事象の定義（016 試験，16/214 試験）（続き 3）

カテゴリー	サブカテゴリー	PT名	
		AUTOIMMUNE HEPATITIS	自己免疫性肝炎
		BILIRUBIN CONJUGATED INCREASED	抱合ビリルビン増加
		BLOOD ALKALINE PHOSPHATASE INCREASED	血中アルカリホスファターゼ増加
		BLOOD BILIRUBIN INCREASED	血中ビリルビン増加
		DRUG-INDUCED LIVER INJURY	薬物性肝障害
		GAMMA-GLUTAMYLTRANSFERASE INCREASED	γ－グルタミルトランスフェラーゼ増加
		HEPATIC ENZYME INCREASED	肝酵素上昇
		HEPATIC FAILURE	肝不全
		HEPATITIS	肝炎
		HEPATITIS ACUTE	急性肝炎
		HEPATOTOXICITY	肝毒性
		HYPERBILIRUBINAEMIA	高ビリルビン血症
		LIVER DISORDER	肝障害
		LIVER FUNCTION TEST ABNORMAL	肝機能検査異常
		LIVER FUNCTION TEST INCREASED	肝機能検査値上昇
		LIVER INJURY	肝損傷
		TRANSAMINASES INCREASED	トランスアミナーゼ上昇

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表 2.7.4.7-5　留意すべき有害事象の定義（016 試験，16/214 試験）（続き 4）

カテゴリー	サブカテゴリー	PT名	
PULMONARY ADVERSE EVENT	肺毒性	ACUTE RESPIRATORY DISTRESS SYNDROME	急性呼吸窮迫症候群
		ACUTE RESPIRATORY FAILURE	急性呼吸不全
		IDIOPATHIC INTERSTITIAL PNEUMONIA	特発性間質性肺炎
		INTERSTITIAL LUNG DISEASE	間質性肺疾患
		LUNG INFILTRATION	肺浸潤
		PNEUMONITIS	肺臓炎
RENAL ADVERSE EVENT	腎毒性	ACUTE KIDNEY INJURY	急性腎障害
		AUTOIMMUNE NEPHRITIS	自己免疫性腎炎
		BLOOD CREATININE INCREASED	血中クレアチニン増加
		BLOOD UREA INCREASED	血中尿素増加
		CREATININE RENAL CLEARANCE DECREASED	腎クレアチニン・クリアランス減少
		HYPERCREATININAEMIA	高クレアチニン血症
		NEPHRITIS	腎炎
		NEPHRITIS ALLERGIC	アレルギー性腎炎
		PARANEOPLASTIC GLOMERULONEPHRITIS	腫瘍随伴性糸球体腎炎
		RENAL FAILURE	腎不全
		RENAL TUBULAR NECROSIS	腎尿細管壊死

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表 2.7.4.7-5　留意すべき有害事象の定義（016 試験，16/214 試験）（続き 5）

カテゴリー	サブカテゴリー	PT名	
		TUBULOINTERSTITIAL NEPHRITIS	尿細管間質性腎炎
		URINE OUTPUT DECREASED	尿量減少
SKIN ADVERSE EVENT	皮膚毒性	AUTOIMMUNE DERMATITIS	自己免疫性皮膚炎
		BLISTER	水疱
		DERMATITIS	皮膚炎
		DERMATITIS ALLERGIC	アレルギー性皮膚炎
		DERMATITIS EXFOLIATIVE	剥脱性皮膚炎
		DRUG ERUPTION	薬疹
		ECZEMA	湿疹
		ERYTHEMA	紅斑
		ERYTHEMA MULTIFORME	多形紅斑
		EXFOLIATIVE RASH	剥脱性発疹
		FIXED ERUPTION	固定疹
		NODULAR RASH	結節性発疹
		PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME	手掌・足底発赤知覚不全症候群
		PEMPHIGOID	類天疱瘡
		PHOTOSENSITIVITY REACTION	光線過敏性反応

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表 2.7.4.7-5　留意すべき有害事象の定義（016 試験，16/214 試験）（続き 6）

カテゴリー	サブカテゴリー	PT名	
		PRURITUS	そう痒症
		PRURITUS ALLERGIC	アレルギー性そう痒症
		PRURITUS GENERALISED	全身性そう痒症
		PSORIASIS	乾癬
		RASH	発疹
		RASH ERYTHEMATOUS	紅斑性皮疹
		RASH GENERALISED	全身性皮疹
		RASH MACULAR	斑状皮疹
		RASH MACULO-PAPULAR	斑状丘疹状皮疹
		RASH MORBILLIFORM	麻疹様発疹
		RASH PAPULAR	丘疹性皮疹
		RASH PRURITIC	そう痒性皮疹
		RASH VESICULAR	小水疱性皮疹
		SKIN EXFOLIATION	皮膚剥脱
		SKIN HYPOPIGMENTATION	皮膚色素減少
		SKIN IRRITATION	皮膚刺激
		STEVENS-JOHNSON SYNDROME	スティーブンス・ジョンソン症候群

MedDRA ver 20.0J

表 2.7.4.7-5　留意すべき有害事象の定義（016 試験，16/214 試験）（続き 7）

カテゴリー	サブカテゴリー	PT名	
		TOXIC EPIDERMAL NECROLYSIS	中毒性表皮壊死融解症
		TOXIC SKIN ERUPTION	中毒性皮疹
		URTICARIA	蕁麻疹
		VITILIGO	尋常性白斑
HYPERSENSITIVITY/INFUSION REACTION	過敏症／Infusion reaction	ANAPHYLACTIC REACTION	アナフィラキシー反応
		ANAPHYLACTIC SHOCK	アナフィラキシーショック
		BRONCHOSPASM	気管支痙攣
		HYPERSENSITIVITY	過敏症
		INFUSION RELATED REACTION	注入に伴う 反応

MedDRA ver 20.0J

表 2.7.4.7-6　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（016 試験）

解析対象集団：All Treated Subjects

Treatment Group: IPI1 + NIV3 N = 47

		Worst Toxicity Grade						
Lab Test Description	Baseline	GRADE 0	GRADE 1	GRADE 2	GRADE 3	GRADE 4	NOT REPORTED	Total
HEMOGLOBIN	GRADE 0	11 (44.0)	12 (48.0)	1 (4.0)	1 (4.0)	N.A.	0	25
	GRADE 1	0	12 (63.2)	7 (36.8)	0	N.A.	0	19
	GRADE 2	0	0	1 (33.3)	2 (66.7)	N.A.	0	3
	GRADE 3	0	0	0	0	N.A.	0	0
	GRADE 4	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
	NOT REPORTED	0	0	0	0	N.A.	0	0
PLATELET COUNT	GRADE 0	30 (65.2)	11 (23.9)	3 (6.5)	2 (4.3)	0	0	46
	GRADE 1	1 (100.0)	0	0	0	0	0	1
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
LEUKOCYTES	GRADE 0	29 (64.4)	10 (22.2)	4 (8.9)	2 (4.4)	0	0	45
	GRADE 1	1 (50.0)	1 (50.0)	0	0	0	0	2
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
LYMPHOCYTES (ABSOLUTE)	GRADE 0	9 (31.0)	15 (51.7)	2 (6.9)	3 (10.3)	0	0	29
	GRADE 1	1 (8.3)	5 (41.7)	5 (41.7)	1 (8.3)	0	0	12
	GRADE 2	0	0	4 (66.7)	2 (33.3)	0	0	6
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0

Treatment: SUN=Sunitinib; PAZ=Pazopanib; IPI=Ipilimumab; NIV=Nivolumab;
Toxicity Scale: NCI CTCAE version 4.0

出典［総括報告書 5.3.5.1-1（016 試験）Table S.7.1B.1 を改変］

表 2.7.4.7-6　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（016 試験）（続き 1）

解析対象集団：All Treated Subjects

Treatment Group: IPI1 + NIV3 N = 47

Lab Test Description	Baseline	Worst Toxicity Grade						
		GRADE 0	GRADE 1	GRADE 2	GRADE 3	GRADE 4	NOT REPORTED	Total
ABSOLUTE NEUTROPHIL COUNT	GRADE 0	36 (76.6)	6 (12.8)	3 (6.4)	2 (4.3)	0	0	47
	GRADE 1	0	0	0	0	0	0	0
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
ALKALINE PHOSPHATASE	GRADE 0	27 (62.8)	13 (30.2)	3 (7.0)	0	0	0	43
	GRADE 1	0	3 (75.0)	1 (25.0)	0	0	0	4
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
ASPARTATE AMINOTRANSFERASE	GRADE 0	19 (41.3)	20 (43.5)	5 (10.9)	1 (2.2)	1 (2.2)	0	46
	GRADE 1	0	1 (100.0)	0	0	0	0	1
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
ALANINE AMINOTRANSFERASE	GRADE 0	23 (51.1)	17 (37.8)	3 (6.7)	1 (2.2)	1 (2.2)	0	45
	GRADE 1	0	1 (50.0)	0	1 (50.0)	0	0	2
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0

Treatment: SUN=Sunitinib; PAZ=Pazopanib; IPI=Ipilimumab; NIV=Nivolumab;
Toxicity Scale: NCI CTCAE version 4.0

出典［総括報告書 5.3.5.1-1（016 試験）Table S.7.1B.1 を改変］

表 2.7.4.7-6　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（016 試験）（続き 2）

解析対象集団：All Treated Subjects

Treatment Group: IPI1 + NIV3 N = 47

Lab Test Description	Baseline	Worst Toxicity Grade						
		GRADE 0	GRADE 1	GRADE 2	GRADE 3	GRADE 4	NOT REPORTED	Total
BILIRUBIN, TOTAL	GRADE 0	38 (80.9)	7 (14.9)	2 (4.3)	0	0	0	47
	GRADE 1	0	0	0	0	0	0	0
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
CREATININE	GRADE 0	12 (41.4)	14 (48.3)	2 (6.9)	1 (3.4)	0	0	29
	GRADE 1	0	10 (58.8)	6 (35.3)	1 (5.9)	0	0	17
	GRADE 2	0	0	1 (100.0)	0	0	0	1
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
LIPASE, TOTAL	GRADE 0	22 (55.0)	5 (12.5)	2 (5.0)	8 (20.0)	3 (7.5)	0	40
	GRADE 1	1 (20.0)	1 (20.0)	1 (20.0)	2 (40.0)	0	0	5
	GRADE 2	0	0	0	1 (100.0)	0	0	1
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	1 (100.0)	0	0	0	0	0	1
HYPERNATREMIA	GRADE 0	43 (91.5)	4 (8.5)	0	0	0	0	47
	GRADE 1	0	0	0	0	0	0	0
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0

Treatment: SUN=Sunitiniib; PAZ=Pazopanib; IPI=Ipilimumab; NIV=Nivolumab;
Toxicity Scale: NCI CTCAE version 4.0

出典［総括報告書 5.3.5.1-1（016 試験）Table S.7.1B.1 を改変］

表 2.7.4.7-6　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（016 試験）（続き 3）

解析対象集団：All Treated Subjects

Treatment Group: IPI1 + NIV3 N = 47

Lab Test Description	Baseline	Worst Toxicity Grade						
		GRADE 0	GRADE 1	GRADE 2	GRADE 3	GRADE 4	NOT REPORTED	Total
HYPONATREMIA	GRADE 0	20 (44.4)	18 (40.0)	0	7 (15.6)	0	0	45
	GRADE 1	0	2 (100.0)	0	0	0	0	2
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
HYPERKALEMIA	GRADE 0	27 (61.4)	10 (22.7)	4 (9.1)	3 (6.8)	0	0	44
	GRADE 1	1 (100.0)	0	0	0	0	0	1
	GRADE 2	0	2 (100.0)	0	0	0	0	2
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
HYPOKALEMIA	GRADE 0	42 (91.3)	3 (6.5)	0	1 (2.2)	0	0	46
	GRADE 1	1 (100.0)	0	0	0	0	0	1
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
HYPERCALCEMIA	GRADE 0	39 (84.8)	5 (10.9)	1 (2.2)	1 (2.2)	0	0	46
	GRADE 1	0	0	0	0	1 (100.0)	0	1
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0

Treatment: SUN=Sunitiniib; PAZ=Pazopanib; IPI=Ipilimumab; NIV=Nivolumab;
Toxicity Scale: NCI CTCAE version 4.0

出典［総括報告書 5.3.5.1-1（016 試験）Table S.7.1B.1 を改変］

表 2.7.4.7-6　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（016 試験）（続き 4）

解析対象集団：All Treated Subjects

Treatment Group: IPI1 + NIV3 N = 47

Lab Test Description	Baseline	Worst Toxicity Grade						
		GRADE 0	GRADE 1	GRADE 2	GRADE 3	GRADE 4	NOT REPORTED	Total
HYPOCALCEMIA	GRADE 0	36 (80.0)	6 (13.3)	3 (6.7)	0	0	0	45
	GRADE 1	0	2 (100.0)	0	0	0	0	2
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
HYPERMAGNESEMIA	GRADE 0	42 (91.3)	4 (8.7)	0	0	0	0	46
	GRADE 1	1 (100.0)	0	0	0	0	0	1
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
HYPOMAGNESEMIA	GRADE 0	41 (87.2)	6 (12.8)	0	0	0	0	47
	GRADE 1	0	0	0	0	0	0	0
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
HYPERGLYCEMIA	GRADE 0	3 (42.9)	1 (14.3)	0	0	0	3 (42.9)	7
	GRADE 1	0	0	0	0	0	0	0
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	6 (66.7)	3 (33.3)	0	0	0	0	9

Treatment: SUN=Sunitiniib; PAZ=Pazopanib; IPI=Ipilimumab; NIV=Nivolumab;
Toxicity Scale: NCI CTCAE version 4.0

出典［総括報告書 5.3.5.1-1（016 試験）Table S.7.1B.1 を改変］

表 2.7.4.7-6　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（016 試験）（続き 5）

解析対象集団：All Treated Subjects

Treatment Group: IPI1 + NIV3 N = 47

Lab Test Description	Baseline	Worst Toxicity Grade						
		GRADE 0	GRADE 1	GRADE 2	GRADE 3	GRADE 4	NOT REPORTED	Total
HYPOGLYCEMIA	GRADE 0	3 (42.9)	1 (14.3)	0	0	0	3 (42.9)	7
	GRADE 1	0	0	0	0	0	0	0
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	7 (77.8)	2 (22.2)	0	0	0	0	9

Treatment: SUN=Sunitinib; PAZ=Pazopanib; IPI=Ipilimumab; NIV=Nivolumab;
Toxicity Scale: NCI CTCAE version 4.0

出典［総括報告書 5.3.5.1-1（016 試験）Table S.7.1B.1 を改変］

表 2.7.4.7-6　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（016 試験）（続き 6）

解析対象集団：All Treated Subjects

Treatment Group: IPI3 + NIV1 N = 47

Lab Test Description	Baseline	Worst Toxicity Grade						
		GRADE 0	GRADE 1	GRADE 2	GRADE 3	GRADE 4	NOT REPORTED	Total
HEMOGLOBIN	GRADE 0	10 (43.5)	11 (47.8)	2 (8.7)	0	N.A.	0	23
	GRADE 1	0	16 (72.7)	4 (18.2)	2 (9.1)	N.A.	0	22
	GRADE 2	0	0	1 (100.0)	0	N.A.	0	1
	GRADE 3	0	0	1 (100.0)	0	N.A.	0	1
	GRADE 4	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
	NOT REPORTED	0	0	0	0	N.A.	0	0
PLATELET COUNT	GRADE 0	36 (78.3)	10 (21.7)	0	0	0	0	46
	GRADE 1	1 (100.0)	0	0	0	0	0	1
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
LEUKOCYTES	GRADE 0	35 (76.1)	8 (17.4)	2 (4.3)	1 (2.2)	0	0	46
	GRADE 1	1 (100.0)	0	0	0	0	0	1
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0

Treatment: SUN=Sunitiniib; PAZ=Pazopanib; IPI=Ipilimumab; NIV=Nivolumab;
Toxicity Scale: NCI CTCAE version 4.0

出典［総括報告書 5.3.5.1-1（016 試験）Table S.7.1B.1 を改変］

表 2.7.4.7-6　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（016 試験）（続き 7）

解析対象集団：All Treated Subjects

Treatment Group: IPI3 + NIV1 N = 47

Lab Test Description	Baseline	Worst Toxicity Grade						
		GRADE 0	GRADE 1	GRADE 2	GRADE 3	GRADE 4	NOT REPORTED	Total
LYMPHOCYTES (ABSOLUTE)	GRADE 0	12 (54.5)	7 (31.8)	1 (4.5)	2 (9.1)	0	0	22
	GRADE 1	0	8 (42.1)	7 (36.8)	3 (15.8)	1 (5.3)	0	19
	GRADE 2	0	0	3 (50.0)	3 (50.0)	0	0	6
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
ABSOLUTE NEUTROPHIL COUNT	GRADE 0	41 (89.1)	3 (6.5)	1 (2.2)	0	1 (2.2)	0	46
	GRADE 1	1 (100.0)	0	0	0	0	0	1
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
ALKALINE PHOSPHATASE	GRADE 0	22 (56.4)	15 (38.5)	1 (2.6)	1 (2.6)	0	0	39
	GRADE 1	0	5 (83.3)	1 (16.7)	0	0	0	6
	GRADE 2	0	0	2 (100.0)	0	0	0	2
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
ASPARTATE AMINOTRANSFERASE	GRADE 0	19 (45.2)	13 (31.0)	4 (9.5)	4 (9.5)	2 (4.8)	0	42
	GRADE 1	1 (20.0)	2 (40.0)	1 (20.0)	1 (20.0)	0	0	5
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0

Treatment: SUN=Sunitiniib; PAZ=Pazopanib; IPI=Ipilimumab; NIV=Nivolumab;
Toxicity Scale: NCI CTCAE version 4.0

出典［総括報告書 5.3.5.1-1（016 試験）Table S.7.1B.1 を改変］

表 2.7.4.7-6　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（016 試験）（続き 8）

解析対象集団：All Treated Subjects

Treatment Group: IPI3 + NIV1 N = 47

Lab Test Description	Baseline	Worst Toxicity Grade						
		GRADE 0	GRADE 1	GRADE 2	GRADE 3	GRADE 4	NOT REPORTED	Total
ALANINE AMINOTRANSFERASE	GRADE 0	21 (53.8)	9 (23.1)	2 (5.1)	5 (12.8)	2 (5.1)	0	39
	GRADE 1	0	3 (37.5)	2 (25.0)	2 (25.0)	1 (12.5)	0	8
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
BILIRUBIN, TOTAL	GRADE 0	41 (91.1)	2 (4.4)	1 (2.2)	1 (2.2)	0	0	45
	GRADE 1	0	1 (100.0)	0	0	0	0	1
	GRADE 2	0	0	1 (100.0)	0	0	0	1
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
CREATININE	GRADE 0	11 (35.5)	16 (51.6)	3 (9.7)	1 (3.2)	0	0	31
	GRADE 1	1 (6.7)	10 (66.7)	4 (26.7)	0	0	0	15
	GRADE 2	0	0	1 (100.0)	0	0	0	1
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
LIPASE, TOTAL	GRADE 0	13 (38.2)	5 (14.7)	3 (8.8)	12 (35.3)	1 (2.9)	0	34
	GRADE 1	0	1 (20.0)	0	1 (20.0)	3 (60.0)	0	5
	GRADE 2	0	0	0	1 (100.0)	0	0	1
	GRADE 3	0	0	1 (33.3)	2 (66.7)	0	0	3
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	1 (25.0)	1 (25.0)	1 (25.0)	1 (25.0)	0	4

Treatment: SUN=Sunitinib; PAZ=Pazopanib; IPI=Ipilimumab; NIV=Nivolumab;
Toxicity Scale: NCI CTCAE version 4.0

出典［総括報告書 5.3.5.1-1（016 試験）Table S.7.1B.1 を改変］

表 2.7.4.7-6　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（016 試験）（続き 9）

解析対象集団：All Treated Subjects

Treatment Group: IPI3 + NIV1 N = 47

Lab Test Description	Baseline	Worst Toxicity Grade						
		GRADE 0	GRADE 1	GRADE 2	GRADE 3	GRADE 4	NOT REPORTED	Total
HYPERNATREMIA	GRADE 0	39 (86.7)	5 (11.1)	1 (2.2)	0	0	0	45
	GRADE 1	0	0	1 (100.0)	0	0	0	1
	GRADE 2	0	0	1 (100.0)	0	0	0	1
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
HYPONATREMIA	GRADE 0	21 (47.7)	19 (43.2)	0	4 (9.1)	0	0	44
	GRADE 1	0	1 (100.0)	0	0	0	0	1
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	1 (50.0)	0	1 (50.0)	0	0	2
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
HYPERKALEMIA	GRADE 0	29 (61.7)	10 (21.3)	7 (14.9)	1 (2.1)	0	0	47
	GRADE 1	0	0	0	0	0	0	0
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
HYPOKALEMIA	GRADE 0	32 (69.6)	10 (21.7)	0	4 (8.7)	0	0	46
	GRADE 1	0	0	0	1 (100.0)	0	0	1
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0

Treatment: SUN=Sunitiniib; PAZ=Pazopanib; IPI=Ipilimumab; NIV=Nivolumab;
Toxicity Scale: NCI CTCAE version 4.0

出典［総括報告書 5.3.5.1-1（016 試験）Table S.7.1B.1 を改変］

表 2.7.4.7-6　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（016 試験）（続き 10）

解析対象集団：All Treated Subjects

Treatment Group: IPI3 + NIV1 N = 47

Lab Test Description	Baseline	Worst Toxicity Grade						
		GRADE 0	GRADE 1	GRADE 2	GRADE 3	GRADE 4	NOT REPORTED	Total
HYPERCALCEMIA	GRADE 0	34 (77.3)	8 (18.2)	1 (2.3)	0	1 (2.3)	0	44
	GRADE 1	3 (100.0)	0	0	0	0	0	3
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
HYPOCALCEMIA	GRADE 0	30 (68.2)	11 (25.0)	2 (4.5)	0	1 (2.3)	0	44
	GRADE 1	0	0	1 (33.3)	2 (66.7)	0	0	3
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
HYPERMAGNESEMIA	GRADE 0	43 (91.5)	4 (8.5)	0	0	0	0	47
	GRADE 1	0	0	0	0	0	0	0
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
HYPOMAGNESEMIA	GRADE 0	39 (84.8)	6 (13.0)	1 (2.2)	0	0	0	46
	GRADE 1	0	1 (100.0)	0	0	0	0	1
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0

Treatment: SUN=Sunitiniib; PAZ=Pazopanib; IPI=Ipilimumab; NIV=Nivolumab;
Toxicity Scale: NCI CTCAE version 4.0

出典［総括報告書 5.3.5.1-1（016 試験）Table S.7.1B.1 を改変］

表 2.7.4.7-6　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（016 試験）（続き 11）

解析対象集団：All Treated Subjects

Treatment Group: IPI3 + NIV1 N = 47

Lab Test Description	Baseline	Worst Toxicity Grade						
		GRADE 0	GRADE 1	GRADE 2	GRADE 3	GRADE 4	NOT REPORTED	Total
HYPERGLYCEMIA	GRADE 0	0	0	0	0	0	2 (100.0)	2
	GRADE 1	0	0	0	0	0	0	0
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	1 (16.7)	5 (83.3)	0	0	0	0	6
HYPOGLYCEMIA	GRADE 0	0	0	0	0	0	2 (100.0)	2
	GRADE 1	0	0	0	0	0	0	0
	GRADE 2	0	0	1 (100.0)	0	0	0	1
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	5 (71.4)	0	2 (28.6)	0	0	0	7

Treatment: SUN=Sunitiniib; PAZ=Pazopanib; IPI=Ipilimumab; NIV=Nivolumab;
Toxicity Scale: NCI CTCAE version 4.0

出典［総括報告書 5.3.5.1-1（016 試験）Table S.7.1B.1 を改変］

表 2.7.4.7-6　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（016 試験）（続き 12）

解析対象集団：All Treated Subjects

Treatment Group: IPI3 + NIV3 N = 6

Lab Test Description	Baseline	Worst Toxicity Grade						
		GRADE 0	GRADE 1	GRADE 2	GRADE 3	GRADE 4	NOT REPORTED	Total
HEMOGLOBIN	GRADE 0	3 (50.0)	2 (33.3)	1 (16.7)	0	N.A.	0	6
	GRADE 1	0	0	0	0	N.A.	0	0
	GRADE 2	0	0	0	0	N.A.	0	0
	GRADE 3	0	0	0	0	N.A.	0	0
	GRADE 4	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
	NOT REPORTED	0	0	0	0	N.A.	0	0
PLATELET COUNT	GRADE 0	3 (60.0)	1 (20.0)	0	1 (20.0)	0	0	5
	GRADE 1	0	1 (100.0)	0	0	0	0	1
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0

Treatment: SUN=Sunitinib; PAZ=Pazopanib; IPI=Ipilimumab; NIV=Nivolumab;
Toxicity Scale: NCI CTCAE version 4.0

出典［総括報告書 5.3.5.1-1（016 試験）Table S.7.1B.1 を改変］

表 2.7.4.7-6　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（016 試験）（続き 13）

解析対象集団：All Treated Subjects

Treatment Group: IPI3 + NIV3 N = 6

Lab Test Description	Baseline	Worst Toxicity Grade						
		GRADE 0	GRADE 1	GRADE 2	GRADE 3	GRADE 4	NOT REPORTED	Total
LEUKOCYTES	GRADE 0	3 (50.0)	2 (33.3)	0	1 (16.7)	0	0	6
	GRADE 1	0	0	0	0	0	0	0
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
LYMPHOCYTES (ABSOLUTE)	GRADE 0	1 (20.0)	2 (40.0)	1 (20.0)	1 (20.0)	0	0	5
	GRADE 1	0	0	0	0	1 (100.0)	0	1
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
ABSOLUTE NEUTROPHIL COUNT	GRADE 0	4 (66.7)	1 (16.7)	1 (16.7)	0	0	0	6
	GRADE 1	0	0	0	0	0	0	0
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
ALKALINE PHOSPHATASE	GRADE 0	5 (100.0)	0	0	0	0	0	5
	GRADE 1	0	1 (100.0)	0	0	0	0	1
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0

Treatment: SUN=Sunitiniib; PAZ=Pazopanib; IPI=Ipilimumab; NIV=Nivolumab;
Toxicity Scale: NCI CTCAE version 4.0

出典［総括報告書 5.3.5.1-1（016 試験）Table S.7.1B.1 を改変］

表 2.7.4.7-6　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（016 試験）（続き 14）

解析対象集団：All Treated Subjects

Treatment Group: IPI3 + NIV3 N = 6

		Worst Toxicity Grade						
Lab Test Description	Baseline	GRADE 0	GRADE 1	GRADE 2	GRADE 3	GRADE 4	NOT REPORTED	Total
ASPARTATE AMINOTRANSFERASE	GRADE 0	3 (50.0)	2 (33.3)	1 (16.7)	0	0	0	6
	GRADE 1	0	0	0	0	0	0	0
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
ALANINE AMINOTRANSFERASE	GRADE 0	2 (40.0)	2 (40.0)	1 (20.0)	0	0	0	5
	GRADE 1	0	1 (100.0)	0	0	0	0	1
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
BILIRUBIN, TOTAL	GRADE 0	4 (66.7)	0	1 (16.7)	1 (16.7)	0	0	6
	GRADE 1	0	0	0	0	0	0	0
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
CREATININE	GRADE 0	2 (40.0)	0	2 (40.0)	0	1 (20.0)	0	5
	GRADE 1	0	1 (100.0)	0	0	0	0	1
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0

Treatment: SUN=Sunitiniib; PAZ=Pazopanib; IPI=Ipilimumab; NIV=Nivolumab;
Toxicity Scale: NCI CTCAE version 4.0

出典［総括報告書 5.3.5.1-1（016 試験）Table S.7.1B.1 を改変］

表 2.7.4.7-6　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（016 試験）（続き 15）

解析対象集団：All Treated Subjects

Treatment Group: IPI3 + NIV3 N = 6

Lab Test Description	Baseline	Worst Toxicity Grade						
		GRADE 0	GRADE 1	GRADE 2	GRADE 3	GRADE 4	NOT REPORTED	Total
LIPASE, TOTAL	GRADE 0	1 (16.7)	2 (33.3)	1 (16.7)	0	2 (33.3)	0	6
	GRADE 1	0	0	0	0	0	0	0
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
HYPERNATREMIA	GRADE 0	6 (100.0)	0	0	0	0	0	6
	GRADE 1	0	0	0	0	0	0	0
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
HYPONATREMIA	GRADE 0	3 (50.0)	3 (50.0)	0	0	0	0	6
	GRADE 1	0	0	0	0	0	0	0
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
HYPERKALEMIA	GRADE 0	3 (50.0)	3 (50.0)	0	0	0	0	6
	GRADE 1	0	0	0	0	0	0	0
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0

Treatment: SUN=Sunitiniib; PAZ=Pazopanib; IPI=Ipilimumab; NIV=Nivolumab;
Toxicity Scale: NCI CTCAE version 4.0

出典［総括報告書 5.3.5.1-1（016 試験）Table S.7.1B.1 を改変］

表 2.7.4.7-6　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（016 試験）（続き 16）

解析対象集団：All Treated Subjects

Treatment Group: IPI3 + NIV3 N = 6

Lab Test Description	Baseline	Worst Toxicity Grade						
		GRADE 0	GRADE 1	GRADE 2	GRADE 3	GRADE 4	NOT REPORTED	Total
HYPOKALEMIA	GRADE 0	4 (66.7)	2 (33.3)	0	0	0	0	6
	GRADE 1	0	0	0	0	0	0	0
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
HYPERCALCEMIA	GRADE 0	6 (100.0)	0	0	0	0	0	6
	GRADE 1	0	0	0	0	0	0	0
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
HYPOCALCEMIA	GRADE 0	2 (40.0)	1 (20.0)	2 (40.0)	0	0	0	5
	GRADE 1	1 (100.0)	0	0	0	0	0	1
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
HYPERMAGNESEMIA	GRADE 0	6 (100.0)	0	0	0	0	0	6
	GRADE 1	0	0	0	0	0	0	0
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0

Treatment: SUN=Sunitinib; PAZ=Pazopanib; IPI=Ipilimumab; NIV=Nivolumab;
Toxicity Scale: NCI CTCAE version 4.0

出典［総括報告書 5.3.5.1-1（016 試験）Table S.7.1B.1 を改変］

表 2.7.4.7-6　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（016 試験）（続き 17）

解析対象集団：All Treated Subjects

Treatment Group: IPI3 + NIV3 N = 6

Lab Test Description	Baseline	Worst Toxicity Grade						
		GRADE 0	GRADE 1	GRADE 2	GRADE 3	GRADE 4	NOT REPORTED	Total
HYPOMAGNESEMIA	GRADE 0	4 (66.7)	2 (33.3)	0	0	0	0	6
	GRADE 1	0	0	0	0	0	0	0
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
HYPERGLYCEMIA	GRADE 0	0	0	0	0	0	0	0
	GRADE 1	0	0	0	0	0	0	0
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	1 (100.0)	0	0	0	0	1
HYPOGLYCEMIA	GRADE 0	0	0	0	0	0	0	0
	GRADE 1	0	0	0	0	0	0	0
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	1 (100.0)	0	0	0	0	0	1

Treatment: SUN=Sunitinib; PAZ=Pazopanib; IPI=Ipilimumab; NIV=Nivolumab;
Toxicity Scale: NCI CTCAE version 4.0

出典［総括報告書 5.3.5.1-1（016 試験）Table S.7.1B.1 を改変］

表 2.7.4.7-7　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（16/214 試験，全体）

解析対象集団：All Treated Subjects

Treatment Group: Nivolumab + Ipilimumab N = 547

Lab Test Description	Baseline	Worst Toxicity Grade						
		Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Not Reported	Total
HEMOGLOBIN (A)	GRADE 0	140 (43.5)	162 (50.3)	15 (4.7)	0	N.A.	5 (1.6)	322
	GRADE 1	5 (2.7)	132 (71.4)	37 (20.0)	9 (4.9)	N.A.	2 (1.1)	185
	GRADE 2	0	7 (21.9)	17 (53.1)	7 (21.9)	N.A.	1 (3.1)	32
	GRADE 3	0	0	1 (14.3)	5 (71.4)	N.A.	1 (14.3)	7
	GRADE 4	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
	NOT REPORTED	0	0	0	0	N.A.	1 (100.0)	1
PLATELET COUNT	GRADE 0	439 (82.7)	78 (14.7)	1 (0.2)	3 (0.6)	1 (0.2)	9 (1.7)	531
	GRADE 1	1 (6.7)	14 (93.3)	0	0	0	0	15
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	1 (100.0)	1
LEUKOCYTES	GRADE 0	452 (84.2)	65 (12.1)	10 (1.9)	0	2 (0.4)	8 (1.5)	537
	GRADE 1	1 (12.5)	5 (62.5)	1 (12.5)	0	0	1 (12.5)	8
	GRADE 2	0	0	0	1 (100.0)	0	0	1
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	1 (100.0)	1
LYMPHOCYTES (ABSOLUTE)	GRADE 0	244 (63.0)	94 (24.3)	34 (8.8)	7 (1.8)	0	8 (2.1)	387
	GRADE 1	12 (8.8)	69 (50.4)	36 (26.3)	17 (12.4)	0	3 (2.2)	137
	GRADE 2	4 (20.0)	3 (15.0)	9 (45.0)	3 (15.0)	0	1 (5.0)	20
	GRADE 3	0	0	1 (50.0)	1 (50.0)	0	0	2
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	1 (100.0)	1

Toxicity Scale: CTC Version 4.0
Includes laboratory results reported after the first dose and within 30 days of last dose of study therapy.
(A) Per Anemia criteria in CTC version 4.0 there is no grade 4 for hemoglobin. N.A.: not applicable.

出典［総括報告書 5.3.5.1-2.1（16/214 試験）Table S.7.3-SI］

表 2.7.4.7-7　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（16/214 試験，全体）（続き 1）

解析対象集団：All Treated Subjects

Treatment Group: Nivolumab + Ipilimumab N = 547

Lab Test Description	Baseline	Worst Toxicity Grade						
		Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Not Reported	Total
ABSOLUTE NEUTROPHIL COUNT	GRADE 0	466 (86.3)	48 (8.9)	9 (1.7)	4 (0.7)	2 (0.4)	11 (2.0)	540
	GRADE 1	1 (16.7)	3 (50.0)	2 (33.3)	0	0	0	6
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	1 (100.0)	1
ALKALINE PHOSPHATASE	GRADE 0	312 (68.9)	116 (25.6)	13 (2.9)	7 (1.5)	0	5 (1.1)	453
	GRADE 1	2 (2.5)	59 (74.7)	14 (17.7)	3 (3.8)	0	1 (1.3)	79
	GRADE 2	0	6 (54.5)	2 (18.2)	1 (9.1)	0	2 (18.2)	11
	GRADE 3	0	0	1 (33.3)	2 (66.7)	0	0	3
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	1 (100.0)	1
ASPARTATE AMINOTRANSFERASE	GRADE 0	297 (58.0)	164 (32.0)	20 (3.9)	20 (3.9)	4 (0.8)	7 (1.4)	512
	GRADE 1	2 (6.3)	23 (71.9)	5 (15.6)	1 (3.1)	1 (3.1)	0	32
	GRADE 2	0	0	0	0	0	1 (100.0)	1
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	1 (50.0)	0	0	0	0	1 (50.0)	2
ALANINE AMINOTRANSFERASE	GRADE 0	280 (56.1)	162 (32.5)	20 (4.0)	24 (4.8)	7 (1.4)	6 (1.2)	499
	GRADE 1	9 (19.6)	26 (56.5)	6 (13.0)	2 (4.3)	2 (4.3)	1 (2.2)	46
	GRADE 2	0	0	0	0	0	1 (100.0)	1
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	1 (100.0)	1

Toxicity Scale: CTC Version 4.0
Includes laboratory results reported after the first dose and within 30 days of last dose of study therapy.
(A) Per Anemia criteria in CTC version 4.0 there is no grade 4 for hemoglobin. N.A.: not applicable.

出典［総括報告書 5.3.5.1-2.1（16/214 試験）Table S.7.3-SI］

表 2.7.4.7-7　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（16/214 試験，全体）（続き 2）

解析対象集団：All Treated Subjects

Treatment Group: Nivolumab + Ipilimumab N = 547

Lab Test Description	Baseline	Worst Toxicity Grade						
		Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Not Reported	Total
BILIRUBIN, TOTAL	GRADE 0	459 (86.8)	42 (7.9)	12 (2.3)	5 (0.9)	1 (0.2)	10 (1.9)	529
	GRADE 1	3 (20.0)	5 (33.3)	6 (40.0)	0	0	1 (6.7)	15
	GRADE 2	0	1 (50.0)	1 (50.0)	0	0	0	2
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	1 (100.0)	1
CREATININE	GRADE 0	144 (47.5)	135 (44.6)	13 (4.3)	3 (1.0)	2 (0.7)	6 (2.0)	303
	GRADE 1	4 (1.8)	147 (64.5)	70 (30.7)	5 (2.2)	0	2 (0.9)	228
	GRADE 2	0	1 (7.1)	11 (78.6)	1 (7.1)	0	1 (7.1)	14
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	1 (50.0)	0	0	0	0	1 (50.0)	2
AMYLASE, TOTAL	GRADE 0	269 (62.3)	91 (21.1)	22 (5.1)	32 (7.4)	3 (0.7)	15 (3.5)	432
	GRADE 1	4 (6.9)	19 (32.8)	17 (29.3)	16 (27.6)	2 (3.4)	0	58
	GRADE 2	1 (7.7)	3 (23.1)	2 (15.4)	6 (46.2)	1 (7.7)	0	13
	GRADE 3	0	0	1 (50.0)	1 (50.0)	0	0	2
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	7 (16.7)	3 (7.1)	1 (2.4)	1 (2.4)	0	30 (71.4)	42
LIPASE, TOTAL	GRADE 0	234 (50.8)	97 (21.0)	32 (6.9)	56 (12.1)	25 (5.4)	17 (3.7)	461
	GRADE 1	6 (12.0)	13 (26.0)	13 (26.0)	12 (24.0)	6 (12.0)	0	50
	GRADE 2	1 (11.1)	2 (22.2)	2 (22.2)	3 (33.3)	1 (11.1)	0	9
	GRADE 3	2 (16.7)	1 (8.3)	1 (8.3)	7 (58.3)	1 (8.3)	0	12
	GRADE 4	0	0	0	1 (50.0)	1 (50.0)	0	2
	NOT REPORTED	9 (69.2)	1 (7.7)	0	1 (7.7)	1 (7.7)	1 (7.7)	13

Toxicity Scale: CTC Version 4.0
Includes laboratory results reported after the first dose and within 30 days of last dose of study therapy.
(A) Per Anemia criteria in CTC version 4.0 there is no grade 4 for hemoglobin. N.A.: not applicable.

出典［総括報告書 5.3.5.1-2.1（16/214 試験）Table S.7.3-SI］

表 2.7.4.7-7　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（16/214 試験，全体）（続き 3）

解析対象集団：All Treated Subjects

Treatment Group: Nivolumab + Ipilimumab N = 547

Lab Test Description	Baseline	Worst Toxicity Grade						
		Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Not Reported	Total
HYPERNATREMIA	GRADE 0	485 (89.5)	47 (8.7)	1 (0.2)	0	0	9 (1.7)	542
	GRADE 1	1 (100.0)	0	0	0	0	0	1
	GRADE 2	1 (100.0)	0	0	0	0	0	1
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	2 (66.7)	0	0	0	0	1 (33.3)	3
HYPONATREMIA	GRADE 0	291 (58.7)	158 (31.9)	0	32 (6.5)	8 (1.6)	7 (1.4)	496
	GRADE 1	7 (15.6)	24 (53.3)	0	11 (24.4)	2 (4.4)	1 (2.2)	45
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	2 (66.7)	0	0	0	1 (33.3)	3
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	1 (33.3)	1 (33.3)	0	0	0	1 (33.3)	3
HYPERKALEMIA	GRADE 0	333 (68.2)	111 (22.7)	27 (5.5)	5 (1.0)	3 (0.6)	9 (1.8)	488
	GRADE 1	14 (30.4)	24 (52.2)	4 (8.7)	4 (8.7)	0	0	46
	GRADE 2	2 (22.2)	2 (22.2)	4 (44.4)	1 (11.1)	0	0	9
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	2 (50.0)	1 (25.0)	0	0	0	1 (25.0)	4
HYPOKALEMIA	GRADE 0	470 (88.2)	47 (8.8)	0	6 (1.1)	1 (0.2)	9 (1.7)	533
	GRADE 1	2 (25.0)	3 (37.5)	0	3 (37.5)	0	0	8
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	1 (50.0)	0	1 (50.0)	0	0	2
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	3 (75.0)	0	0	0	0	1 (25.0)	4

Toxicity Scale: CTC Version 4.0
Includes laboratory results reported after the first dose and within 30 days of last dose of study therapy.
(A) Per Anemia criteria in CTC version 4.0 there is no grade 4 for hemoglobin. N.A.: not applicable.

出典［総括報告書 5.3.5.1-2.1（16/214 試験）Table S.7.3-SI］

表 2.7.4.7-7　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（16/214 試験，全体）（続き 4）

解析対象集団：All Treated Subjects

Treatment Group: Nivolumab + Ipilimumab N = 547

Lab Test Description	Baseline	Worst Toxicity Grade						
		Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Not Reported	Total
HYPERCALCEMIA	GRADE 0	431 (84.7)	57 (11.2)	6 (1.2)	2 (0.4)	3 (0.6)	10 (2.0)	509
	GRADE 1	9 (34.6)	13 (50.0)	2 (7.7)	2 (7.7)	0	0	26
	GRADE 2	1 (100.0)	0	0	0	0	0	1
	GRADE 3	0	1 (33.3)	1 (33.3)	0	0	1 (33.3)	3
	GRADE 4	0	0	0	0	1 (100.0)	0	1
	NOT REPORTED	3 (42.9)	0	0	0	0	4 (57.1)	7
HYPOCALCEMIA	GRADE 0	403 (76.9)	84 (16.0)	24 (4.6)	2 (0.4)	0	11 (2.1)	524
	GRADE 1	3 (20.0)	7 (46.7)	5 (33.3)	0	0	0	15
	GRADE 2	0	0	1 (100.0)	0	0	0	1
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	2 (28.6)	1 (14.3)	0	0	0	4 (57.1)	7
HYPERMAGNESEMIA	GRADE 0	489 (90.9)	29 (5.4)	0	6 (1.1)	0	14 (2.6)	538
	GRADE 1	0	4 (100.0)	0	0	0	0	4
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	4 (80.0)	0	0	0	0	1 (20.0)	5
HYPOMAGNESEMIA	GRADE 0	399 (78.9)	93 (18.4)	2 (0.4)	0	1 (0.2)	11 (2.2)	506
	GRADE 1	4 (11.4)	24 (68.6)	3 (8.6)	0	1 (2.9)	3 (8.6)	35
	GRADE 2	1 (100.0)	0	0	0	0	0	1
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	4 (80.0)	0	0	0	0	1 (20.0)	5

Toxicity Scale: CTC Version 4.0
Includes laboratory results reported after the first dose and within 30 days of last dose of study therapy.
(A) Per Anemia criteria in CTC version 4.0 there is no grade 4 for hemoglobin. N.A.: not applicable.

出典［総括報告書 5.3.5.1-2.1（16/214 試験）Table S.7.3-SI］

表 2.7.4.7-7　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（16/214 試験，全体）（続き 5）

解析対象集団：All Treated Subjects

Treatment Group: Nivolumab + Ipilimumab N = 547

Lab Test Description	Baseline	Worst Toxicity Grade						
		Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Not Reported	Total
HYPERGLYCEMIA	GRADE 0	65 (41.1)	62 (39.2)	9 (5.7)	5 (3.2)	1 (0.6)	16 (10.1)	158
	GRADE 1	5 (7.6)	36 (54.5)	16 (24.2)	7 (10.6)	0	2 (3.0)	66
	GRADE 2	1 (7.1)	2 (14.3)	8 (57.1)	3 (21.4)	0	0	14
	GRADE 3	0	0	0	2 (100.0)	0	0	2
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	24 (7.8)	23 (7.5)	6 (2.0)	3 (1.0)	2 (0.7)	249 (81.1)	307
HYPOGLYCEMIA	GRADE 0	182 (78.4)	18 (7.8)	12 (5.2)	3 (1.3)	1 (0.4)	16 (6.9)	232
	GRADE 1	3 (37.5)	4 (50.0)	0	0	0	1 (12.5)	8
	GRADE 2	0	0	0	0	0	1 (100.0)	1
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	53 (17.3)	4 (1.3)	5 (1.6)	0	2 (0.7)	242 (79.1)	306

Toxicity Scale: CTC Version 4.0
Includes laboratory results reported after the first dose and within 30 days of last dose of study therapy.
(A) Per Anemia criteria in CTC version 4.0 there is no grade 4 for hemoglobin. N.A.: not applicable.

出典［総括報告書 5.3.5.1-2.1（16/214 試験）Table S.7.3-SI］

表 2.7.4.7-7　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（16/214 試験，全体）（続き 6）

解析対象集団：All Treated Subjects

Treatment Group: Sunitinib N = 535

Lab Test Description	Baseline	Worst Toxicity Grade						
		Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Not Reported	Total
HEMOGLOBIN (A)	GRADE 0	66 (23.0)	172 (59.9)	42 (14.6)	5 (1.7)	N.A.	2 (0.7)	287
	GRADE 1	6 (3.1)	86 (43.9)	76 (38.8)	21 (10.7)	N.A.	7 (3.6)	196
	GRADE 2	1 (2.3)	4 (9.1)	18 (40.9)	20 (45.5)	N.A.	1 (2.3)	44
	GRADE 3	1 (16.7)	0	3 (50.0)	1 (16.7)	N.A.	1 (16.7)	6
	GRADE 4	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
	NOT REPORTED	0	0	2 (100.0)	0	N.A.	0	2
PLATELET COUNT	GRADE 0	110 (21.4)	242 (47.0)	88 (17.1)	58 (11.3)	7 (1.4)	10 (1.9)	515
	GRADE 1	0	5 (27.8)	5 (27.8)	6 (33.3)	1 (5.6)	1 (5.6)	18
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	2 (100.0)	0	0	0	0	0	2
LEUKOCYTES	GRADE 0	104 (19.8)	176 (33.6)	212 (40.5)	21 (4.0)	0	11 (2.1)	524
	GRADE 1	0	1 (12.5)	4 (50.0)	3 (37.5)	0	0	8
	GRADE 2	0	0	0	1 (100.0)	0	0	1
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	2 (100.0)	0	0	0	0	0	2
LYMPHOCYTES (ABSOLUTE)	GRADE 0	143 (37.3)	126 (32.9)	76 (19.8)	30 (7.8)	3 (0.8)	5 (1.3)	383
	GRADE 1	3 (2.5)	32 (27.1)	52 (44.1)	27 (22.9)	1 (0.8)	3 (2.5)	118
	GRADE 2	2 (7.4)	2 (7.4)	6 (22.2)	10 (37.0)	2 (7.4)	5 (18.5)	27
	GRADE 3	0	1 (25.0)	0	2 (50.0)	1 (25.0)	0	4
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	1 (33.3)	2 (66.7)	0	0	0	0	3

Toxicity Scale: CTC Version 4.0
Includes laboratory results reported after the first dose and within 30 days of last dose of study therapy.
(A) Per Anemia criteria in CTC version 4.0 there is no grade 4 for hemoglobin. N.A.: not applicable.

出典［総括報告書 5.3.5.1-2.1（16/214 試験）Table S.7.3-SI］

表 2.7.4.7-7　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（16/214 試験，全体）（続き 7）

解析対象集団：All Treated Subjects

Treatment Group: Sunitinib N = 535

Lab Test Description	Baseline	Worst Toxicity Grade					Not Reported	Total
		Grade 0	Grade 1	Grade 2	Grade 3	Grade 4		
ABSOLUTE NEUTROPHIL COUNT	GRADE 0	116 (22.2)	121 (23.1)	176 (33.7)	93 (17.8)	5 (1.0)	12 (2.3)	523
	GRADE 1	0	0	1 (12.5)	7 (87.5)	0	0	8
	GRADE 2	0	0	0	1 (100.0)	0	0	1
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	2 (66.7)	1 (33.3)	0	0	0	0	3
ALKALINE PHOSPHATASE	GRADE 0	269 (63.3)	135 (31.8)	15 (3.5)	2 (0.5)	0	4 (0.9)	425
	GRADE 1	8 (9.0)	65 (73.0)	11 (12.4)	1 (1.1)	0	4 (4.5)	89
	GRADE 2	0	2 (22.2)	5 (55.6)	2 (22.2)	0	0	9
	GRADE 3	0	0	2 (28.6)	5 (71.4)	0	0	7
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	2 (40.0)	1 (20.0)	1 (20.0)	0	0	1 (20.0)	5
ASPARTATE AMINOTRANSFERASE	GRADE 0	186 (36.9)	283 (56.2)	16 (3.2)	10 (2.0)	0	9 (1.8)	504
	GRADE 1	1 (4.0)	19 (76.0)	5 (20.0)	0	0	0	25
	GRADE 2	0	2 (66.7)	0	1 (33.3)	0	0	3
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	2 (66.7)	0	0	0	1 (33.3)	3
ALANINE AMINOTRANSFERASE	GRADE 0	261 (52.6)	195 (39.3)	19 (3.8)	12 (2.4)	0	9 (1.8)	496
	GRADE 1	9 (25.0)	21 (58.3)	4 (11.1)	2 (5.6)	0	0	36
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	1 (33.3)	1 (33.3)	0	0	1 (33.3)	3

Toxicity Scale: CTC Version 4.0
Includes laboratory results reported after the first dose and within 30 days of last dose of study therapy.
(A) Per Anemia criteria in CTC version 4.0 there is no grade 4 for hemoglobin. N.A.: not applicable.

出典［総括報告書 5.3.5.1-2.1（16/214 試験）Table S.7.3-SI］

表 2.7.4.7-7　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（16/214 試験，全体）（続き 8）

解析対象集団：All Treated Subjects

Treatment Group: Sunitinib N = 535

Lab Test Description	Baseline	Worst Toxicity Grade						
		Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Not Reported	Total
BILIRUBIN, TOTAL	GRADE 0	409 (78.4)	69 (13.2)	25 (4.8)	8 (1.5)	1 (0.2)	10 (1.9)	522
	GRADE 1	2 (20.0)	2 (20.0)	6 (60.0)	0	0	0	10
	GRADE 2	0	0	1 (100.0)	0	0	0	1
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	1 (50.0)	0	0	0	0	1 (50.0)	2
CREATININE	GRADE 0	114 (41.0)	137 (49.3)	19 (6.8)	1 (0.4)	0	7 (2.5)	278
	GRADE 1	5 (2.1)	150 (62.8)	75 (31.4)	6 (2.5)	1 (0.4)	2 (0.8)	239
	GRADE 2	0	0	15 (93.8)	0	0	1 (6.3)	16
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	1 (50.0)	0	1 (50.0)	0	0	0	2
AMYLASE, TOTAL	GRADE 0	292 (65.8)	87 (19.6)	29 (6.5)	20 (4.5)	2 (0.5)	14 (3.2)	444
	GRADE 1	3 (6.1)	28 (57.1)	9 (18.4)	8 (16.3)	0	1 (2.0)	49
	GRADE 2	0	0	1 (16.7)	5 (83.3)	0	0	6
	GRADE 3	0	0	0	1 (100.0)	0	0	1
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	7 (20.0)	2 (5.7)	1 (2.9)	1 (2.9)	0	24 (68.6)	35
LIPASE, TOTAL	GRADE 0	229 (49.4)	94 (20.3)	55 (11.9)	61 (13.1)	12 (2.6)	13 (2.8)	464
	GRADE 1	4 (10.5)	6 (15.8)	9 (23.7)	14 (36.8)	5 (13.2)	0	38
	GRADE 2	2 (15.4)	1 (7.7)	1 (7.7)	6 (46.2)	3 (23.1)	0	13
	GRADE 3	0	2 (28.6)	1 (14.3)	2 (28.6)	2 (28.6)	0	7
	GRADE 4	0	1 (100.0)	0	0	0	0	1
	NOT REPORTED	5 (41.7)	3 (25.0)	0	1 (8.3)	0	3 (25.0)	12

Toxicity Scale: CTC Version 4.0
Includes laboratory results reported after the first dose and within 30 days of last dose of study therapy.
(A) Per Anemia criteria in CTC version 4.0 there is no grade 4 for hemoglobin. N.A.: not applicable.

出典［総括報告書 5.3.5.1-2.1（16/214 試験）Table S.7.3-SI］

表 2.7.4.7-7　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（16/214 試験，全体）（続き 9）

解析対象集団：All Treated Subjects

Treatment Group: Sunitinib N = 535

Lab Test Description	Baseline	Worst Toxicity Grade						
		Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Not Reported	Total
HYPERNATREMIA	GRADE 0	473 (89.1)	46 (8.7)	1 (0.2)	1 (0.2)	0	10 (1.9)	531
	GRADE 1	0	2 (100.0)	0	0	0	0	2
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	1 (50.0)	0	0	0	0	1 (50.0)	2
HYPONATREMIA	GRADE 0	293 (61.8)	152 (32.1)	0	22 (4.6)	1 (0.2)	6 (1.3)	474
	GRADE 1	5 (9.4)	30 (56.6)	0	11 (20.8)	3 (5.7)	4 (7.5)	53
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	2 (33.3)	0	3 (50.0)	1 (16.7)	0	6
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	1 (50.0)	0	0	0	1 (50.0)	2
HYPERKALEMIA	GRADE 0	326 (69.7)	95 (20.3)	26 (5.6)	8 (1.7)	2 (0.4)	11 (2.4)	468
	GRADE 1	15 (26.8)	27 (48.2)	9 (16.1)	4 (7.1)	0	1 (1.8)	56
	GRADE 2	0	4 (57.1)	2 (28.6)	0	1 (14.3)	0	7
	GRADE 3	1 (100.0)	0	0	0	0	0	1
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	1 (33.3)	1 (33.3)	0	0	0	1 (33.3)	3
HYPOKALEMIA	GRADE 0	463 (87.5)	49 (9.3)	0	5 (0.9)	0	12 (2.3)	529
	GRADE 1	2 (66.7)	1 (33.3)	0	0	0	0	3
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	2 (66.7)	0	0	0	0	1 (33.3)	3

Toxicity Scale: CTC Version 4.0
Includes laboratory results reported after the first dose and within 30 days of last dose of study therapy.
(A) Per Anemia criteria in CTC version 4.0 there is no grade 4 for hemoglobin. N.A.: not applicable.

出典［総括報告書 5.3.5.1-2.1（16/214 試験）Table S.7.3-SI］

表 2.7.4.7-7　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（16/214 試験，全体）（続き 10）

解析対象集団：All Treated Subjects

Treatment Group: Sunitinib N = 535

Lab Test Description	Baseline	Worst Toxicity Grade						
		Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Not Reported	Total
HYPERCALCEMIA	GRADE 0	433 (88.0)	42 (8.5)	0	1 (0.2)	2 (0.4)	14 (2.8)	492
	GRADE 1	17 (56.7)	12 (40.0)	0	1 (3.3)	0	0	30
	GRADE 2	0	2 (50.0)	2 (50.0)	0	0	0	4
	GRADE 3	1 (33.3)	0	0	2 (66.7)	0	0	3
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	2 (33.3)	1 (16.7)	0	0	0	3 (50.0)	6
HYPOCALCEMIA	GRADE 0	320 (62.3)	130 (25.3)	50 (9.7)	2 (0.4)	1 (0.2)	11 (2.1)	514
	GRADE 1	1 (9.1)	5 (45.5)	3 (27.3)	0	0	2 (18.2)	11
	GRADE 2	1 (33.3)	0	1 (33.3)	0	0	1 (33.3)	3
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	1 (100.0)	0	1
	NOT REPORTED	1 (16.7)	2 (33.3)	0	0	0	3 (50.0)	6
HYPERMAGNESEMIA	GRADE 0	455 (88.9)	37 (7.2)	0	6 (1.2)	0	14 (2.7)	512
	GRADE 1	3 (27.3)	8 (72.7)	0	0	0	0	11
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	1 (100.0)	0	0	1
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	8 (72.7)	1 (9.1)	0	0	0	2 (18.2)	11
HYPOMAGNESEMIA	GRADE 0	347 (69.8)	125 (25.2)	7 (1.4)	2 (0.4)	2 (0.4)	14 (2.8)	497
	GRADE 1	3 (11.5)	15 (57.7)	4 (15.4)	2 (7.7)	2 (7.7)	0	26
	GRADE 2	0	0	0	0	1 (100.0)	0	1
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	5 (45.5)	3 (27.3)	0	1 (9.1)	0	2 (18.2)	11

Toxicity Scale: CTC Version 4.0
Includes laboratory results reported after the first dose and within 30 days of last dose of study therapy.
(A) Per Anemia criteria in CTC version 4.0 there is no grade 4 for hemoglobin. N.A.: not applicable.

出典［総括報告書 5.3.5.1-2.1（16/214 試験）Table S.7.3-SI］

表 2.7.4.7-7　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（16/214 試験，全体）（続き 11）

解析対象集団：All Treated Subjects

Treatment Group: Sunitinib N = 535

Lab Test Description	Baseline	Worst Toxicity Grade						
		Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Not Reported	Total
HYPERGLYCEMIA	GRADE 0	51 (35.4)	76 (52.8)	5 (3.5)	0	0	12 (8.3)	144
	GRADE 1	7 (10.8)	41 (63.1)	7 (10.8)	0	0	10 (15.4)	65
	GRADE 2	0	1 (16.7)	2 (33.3)	1 (16.7)	0	2 (33.3)	6
	GRADE 3	0	0	1 (50.0)	1 (50.0)	0	0	2
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	28 (8.8)	28 (8.8)	2 (0.6)	1 (0.3)	0	259 (81.4)	318
HYPOGLYCEMIA	GRADE 0	172 (80.8)	16 (7.5)	1 (0.5)	0	0	24 (11.3)	213
	GRADE 1	2 (50.0)	1 (25.0)	1 (25.0)	0	0	0	4
	GRADE 2	0	0	0	0	0	1 (100.0)	1
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	55 (17.4)	3 (0.9)	4 (1.3)	0	1 (0.3)	254 (80.1)	317

Toxicity Scale: CTC Version 4.0
Includes laboratory results reported after the first dose and within 30 days of last dose of study therapy.
(A) Per Anemia criteria in CTC version 4.0 there is no grade 4 for hemoglobin. N.A.: not applicable.

出典［総括報告書 5.3.5.1-2.1（16/214 試験）Table S.7.3-SI］

表 2.7.4.7-8　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（16/214 試験，日本人）

解析対象集団：All Treated Subjects

Treatment Group: Nivolumab + Ipilimumab N = 38

		Worst Toxicity Grade						
Lab Test Description	Baseline	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Not Reported	Total
HEMOGLOBIN (A)	GRADE 0	6 (35.3)	11 (64.7)	0	0	N.A.	0	17
	GRADE 1	0	11 (64.7)	5 (29.4)	0	N.A.	1 (5.9)	17
	GRADE 2	0	0	2 (100.0)	0	N.A.	0	2
	GRADE 3	0	0	1 (50.0)	1 (50.0)	N.A.	0	2
	GRADE 4	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
	NOT REPORTED	0	0	0	0	N.A.	0	0
PLATELET COUNT	GRADE 0	24 (64.9)	11 (29.7)	0	0	1 (2.7)	1 (2.7)	37
	GRADE 1	0	1 (100.0)	0	0	0	0	1
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
LEUKOCYTES	GRADE 0	28 (75.7)	4 (10.8)	3 (8.1)	0	1 (2.7)	1 (2.7)	37
	GRADE 1	0	1 (100.0)	0	0	0	0	1
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
LYMPHOCYTES (ABSOLUTE)	GRADE 0	8 (38.1)	10 (47.6)	3 (14.3)	0	0	0	21
	GRADE 1	0	7 (46.7)	6 (40.0)	2 (13.3)	0	0	15
	GRADE 2	0	0	0	1 (50.0)	0	1 (50.0)	2
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0

Toxicity Scale: CTC Version 4.0
Includes laboratory results reported after the first dose and within 30 days of last dose of study therapy.
(A) Per Anemia criteria in CTC version 4.0 there is no grade 4 for hemoglobin. N.A.: not applicable.

出典［5.3.5.1-2.2（16/214 試験）Table S.7.3-SI］

表 2.7.4.7-8　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（16/214 試験，日本人）（続き 1）

解析対象集団：All Treated Subjects

Treatment Group: Nivolumab + Ipilimumab N = 38

Lab Test Description	Baseline	Worst Toxicity Grade						
		Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Not Reported	Total
ABSOLUTE NEUTROPHIL COUNT	GRADE 0	27 (77.1)	3 (8.6)	2 (5.7)	1 (2.9)	1 (2.9)	1 (2.9)	35
	GRADE 1	1 (33.3)	2 (66.7)	0	0	0	0	3
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
ALKALINE PHOSPHATASE	GRADE 0	21 (65.6)	9 (28.1)	2 (6.3)	0	0	0	32
	GRADE 1	0	2 (50.0)	1 (25.0)	1 (25.0)	0	0	4
	GRADE 2	0	1 (100.0)	0	0	0	0	1
	GRADE 3	0	0	1 (100.0)	0	0	0	1
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
ASPARTATE AMINOTRANSFERASE	GRADE 0	18 (51.4)	12 (34.3)	1 (2.9)	4 (11.4)	0	0	35
	GRADE 1	0	2 (66.7)	1 (33.3)	0	0	0	3
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
ALANINE AMINOTRANSFERASE	GRADE 0	17 (48.6)	12 (34.3)	1 (2.9)	5 (14.3)	0	0	35
	GRADE 1	1 (33.3)	1 (33.3)	0	1 (33.3)	0	0	3
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0

Toxicity Scale: CTC Version 4.0
Includes laboratory results reported after the first dose and within 30 days of last dose of study therapy.
(A) Per Anemia criteria in CTC version 4.0 there is no grade 4 for hemoglobin. N.A.: not applicable.

出典［5.3.5.1-2.2（16/214 試験）Table S.7.3-SI］

表 2.7.4.7-8　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（16/214 試験，日本人）（続き 2）

解析対象集団：All Treated Subjects

Treatment Group: Nivolumab + Ipilimumab N = 38

Lab Test Description	Baseline	Worst Toxicity Grade						
		Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Not Reported	Total
BILIRUBIN, TOTAL	GRADE 0	33 (86.8)	2 (5.3)	0	1 (2.6)	1 (2.6)	1 (2.6)	38
	GRADE 1	0	0	0	0	0	0	0
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
CREATININE	GRADE 0	6 (28.6)	12 (57.1)	3 (14.3)	0	0	0	21
	GRADE 1	0	11 (64.7)	5 (29.4)	0	0	1 (5.9)	17
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
AMYLASE, TOTAL	GRADE 0	18 (54.5)	10 (30.3)	2 (6.1)	2 (6.1)	0	1 (3.0)	33
	GRADE 1	0	1 (20.0)	2 (40.0)	2 (40.0)	0	0	5
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
LIPASE, TOTAL	GRADE 0	14 (45.2)	7 (22.6)	3 (9.7)	5 (16.1)	1 (3.2)	1 (3.2)	31
	GRADE 1	1 (16.7)	1 (16.7)	3 (50.0)	0	1 (16.7)	0	6
	GRADE 2	0	0	0	1 (100.0)	0	0	1
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0

Toxicity Scale: CTC Version 4.0
Includes laboratory results reported after the first dose and within 30 days of last dose of study therapy.
(A) Per Anemia criteria in CTC version 4.0 there is no grade 4 for hemoglobin. N.A.: not applicable.

出典［5.3.5.1-2.2（16/214 試験）Table S.7.3-SI］

表 2.7.4.7-8　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（16/214 試験，日本人）（続き 3）

解析対象集団：All Treated Subjects

Treatment Group: Nivolumab + Ipilimumab N = 38

		Worst Toxicity Grade						
Lab Test Description	Baseline	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Not Reported	Total
HYPERNATREMIA	GRADE 0	35 (92.1)	1 (2.6)	1 (2.6)	0	0	1 (2.6)	38
	GRADE 1	0	0	0	0	0	0	0
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
HYPONATREMIA	GRADE 0	15 (48.4)	14 (45.2)	0	2 (6.5)	0	0	31
	GRADE 1	0	3 (50.0)	0	2 (33.3)	1 (16.7)	0	6
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	1 (100.0)	1
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
HYPERKALEMIA	GRADE 0	22 (66.7)	8 (24.2)	0	1 (3.0)	1 (3.0)	1 (3.0)	33
	GRADE 1	0	4 (80.0)	0	1 (20.0)	0	0	5
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
HYPOKALEMIA	GRADE 0	30 (81.1)	6 (16.2)	0	0	0	1 (2.7)	37
	GRADE 1	1 (100.0)	0	0	0	0	0	1
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0

Toxicity Scale: CTC Version 4.0
Includes laboratory results reported after the first dose and within 30 days of last dose of study therapy.
(A) Per Anemia criteria in CTC version 4.0 there is no grade 4 for hemoglobin. N.A.: not applicable.

出典［5.3.5.1-2.2（16/214 試験）Table S.7.3-SI］

表 2.7.4.7-8　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（16/214 試験，日本人）（続き 4）

解析対象集団：All Treated Subjects

Treatment Group: Nivolumab + Ipilimumab N = 38

Lab Test Description	Baseline	Worst Toxicity Grade						
		Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Not Reported	Total
HYPERCALCEMIA	GRADE 0	32 (86.5)	4 (10.8)	0	0	0	1 (2.7)	37
	GRADE 1	0	1 (100.0)	0	0	0	0	1
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
HYPOCALCEMIA	GRADE 0	24 (70.6)	6 (17.6)	2 (5.9)	1 (2.9)	0	1 (2.9)	34
	GRADE 1	0	3 (75.0)	1 (25.0)	0	0	0	4
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
HYPERMAGNESEMIA	GRADE 0	32 (88.9)	2 (5.6)	0	1 (2.8)	0	1 (2.8)	36
	GRADE 1	0	2 (100.0)	0	0	0	0	2
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
HYPOMAGNESEMIA	GRADE 0	26 (74.3)	7 (20.0)	1 (2.9)	0	0	1 (2.9)	35
	GRADE 1	0	3 (100.0)	0	0	0	0	3
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0

Toxicity Scale: CTC Version 4.0
Includes laboratory results reported after the first dose and within 30 days of last dose of study therapy.
(A) Per Anemia criteria in CTC version 4.0 there is no grade 4 for hemoglobin. N.A.: not applicable.

出典［5.3.5.1-2.2（16/214 試験）Table S.7.3-SI］

表 2.7.4.7-8　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（16/214 試験，日本人）（続き 5）

解析対象集団：All Treated Subjects

Treatment Group: Nivolumab + Ipilimumab N = 38

Lab Test Description	Baseline	Worst Toxicity Grade						
		Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Not Reported	Total
HYPERGLYCEMIA	GRADE 0	6 (42.9)	4 (28.6)	2 (14.3)	1 (7.1)	0	1 (7.1)	14
	GRADE 1	1 (14.3)	5 (71.4)	1 (14.3)	0	0	0	7
	GRADE 2	0	0	1 (100.0)	0	0	0	1
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	2 (12.5)	4 (25.0)	1 (6.3)	0	1 (6.3)	8 (50.0)	16
HYPOGLYCEMIA	GRADE 0	20 (90.9)	0	1 (4.5)	0	0	1 (4.5)	22
	GRADE 1	0	0	0	0	0	0	0
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	8 (50.0)	0	0	0	0	8 (50.0)	16

Toxicity Scale: CTC Version 4.0
Includes laboratory results reported after the first dose and within 30 days of last dose of study therapy.
(A) Per Anemia criteria in CTC version 4.0 there is no grade 4 for hemoglobin. N.A.: not applicable.

出典［5.3.5.1-2.2（16/214 試験）Table S.7.3-SI］

表 2.7.4.7-8　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（16/214 試験，日本人）（続き 6）

解析対象集団：All Treated Subjects

Treatment Group: Sunitinib N = 34

Lab Test Description	Baseline	Worst Toxicity Grade					Not Reported	Total
		Grade 0	Grade 1	Grade 2	Grade 3	Grade 4		
HEMOGLOBIN (A)	GRADE 0	0	13 (86.7)	1 (6.7)	1 (6.7)	N.A.	0	15
	GRADE 1	0	8 (50.0)	6 (37.5)	2 (12.5)	N.A.	0	16
	GRADE 2	0	0	1 (33.3)	2 (66.7)	N.A.	0	3
	GRADE 3	0	0	0	0	N.A.	0	0
	GRADE 4	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
	NOT REPORTED	0	0	0	0	N.A.	0	0
PLATELET COUNT	GRADE 0	0	6 (18.8)	8 (25.0)	16 (50.0)	2 (6.3)	0	32
	GRADE 1	0	0	0	2 (100.0)	0	0	2
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
LEUKOCYTES	GRADE 0	4 (12.1)	5 (15.2)	19 (57.6)	5 (15.2)	0	0	33
	GRADE 1	0	0	0	0	0	0	0
	GRADE 2	0	0	0	1 (100.0)	0	0	1
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
LYMPHOCYTES (ABSOLUTE)	GRADE 0	2 (10.5)	7 (36.8)	5 (26.3)	5 (26.3)	0	0	19
	GRADE 1	0	1 (7.7)	4 (30.8)	7 (53.8)	1 (7.7)	0	13
	GRADE 2	0	0	0	0	1 (100.0)	0	1
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	1 (100.0)	0	0	0	0	1

Toxicity Scale: CTC Version 4.0
Includes laboratory results reported after the first dose and within 30 days of last dose of study therapy.
(A) Per Anemia criteria in CTC version 4.0 there is no grade 4 for hemoglobin. N.A.: not applicable.

出典［5.3.5.1-2.2（16/214 試験）Table S.7.3-SI］

表 2.7.4.7-8　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（16/214 試験，日本人）（続き 7）

解析対象集団：All Treated Subjects

Treatment Group: Sunitinib N = 34

Lab Test Description	Baseline	Worst Toxicity Grade						
		Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Not Reported	Total
ABSOLUTE NEUTROPHIL COUNT	GRADE 0	1 (3.2)	4 (12.9)	12 (38.7)	13 (41.9)	1 (3.2)	0	31
	GRADE 1	0	0	0	2 (100.0)	0	0	2
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	1 (100.0)	0	0	0	0	0	1
ALKALINE PHOSPHATASE	GRADE 0	15 (51.7)	12 (41.4)	2 (6.9)	0	0	0	29
	GRADE 1	0	3 (60.0)	2 (40.0)	0	0	0	5
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
ASPARTATE AMINOTRANSFERASE	GRADE 0	2 (6.1)	27 (81.8)	2 (6.1)	2 (6.1)	0	0	33
	GRADE 1	0	0	1 (100.0)	0	0	0	1
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
ALANINE AMINOTRANSFERASE	GRADE 0	10 (30.3)	19 (57.6)	3 (9.1)	1 (3.0)	0	0	33
	GRADE 1	0	0	1 (100.0)	0	0	0	1
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0

Toxicity Scale: CTC Version 4.0
Includes laboratory results reported after the first dose and within 30 days of last dose of study therapy.
(A) Per Anemia criteria in CTC version 4.0 there is no grade 4 for hemoglobin. N.A.: not applicable.

出典［5.3.5.1-2.2（16/214 試験）Table S.7.3-SI］

表 2.7.4.7-8　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（16/214 試験，日本人）（続き 8）

解析対象集団：All Treated Subjects

Treatment Group: Sunitinib N = 34

		Worst Toxicity Grade						
Lab Test Description	Baseline	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Not Reported	Total
BILIRUBIN, TOTAL	GRADE 0	27 (84.4)	3 (9.4)	2 (6.3)	0	0	0	32
	GRADE 1	0	0	2 (100.0)	0	0	0	2
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
CREATININE	GRADE 0	5 (55.6)	4 (44.4)	0	0	0	0	9
	GRADE 1	0	10 (41.7)	14 (58.3)	0	0	0	24
	GRADE 2	0	0	1 (100.0)	0	0	0	1
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
AMYLASE, TOTAL	GRADE 0	16 (55.2)	7 (24.1)	1 (3.4)	5 (17.2)	0	0	29
	GRADE 1	1 (25.0)	2 (50.0)	0	1 (25.0)	0	0	4
	GRADE 2	0	0	0	1 (100.0)	0	0	1
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
LIPASE, TOTAL	GRADE 0	7 (29.2)	3 (12.5)	4 (16.7)	9 (37.5)	1 (4.2)	0	24
	GRADE 1	0	2 (28.6)	1 (14.3)	2 (28.6)	2 (28.6)	0	7
	GRADE 2	0	0	0	1 (100.0)	0	0	1
	GRADE 3	0	0	1 (50.0)	0	1 (50.0)	0	2
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0

Toxicity Scale: CTC Version 4.0
Includes laboratory results reported after the first dose and within 30 days of last dose of study therapy.
(A) Per Anemia criteria in CTC version 4.0 there is no grade 4 for hemoglobin. N.A.: not applicable.

出典［5.3.5.1-2.2（16/214 試験）Table S.7.3-SI］

表 2.7.4.7-8　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（16/214 試験，日本人）（続き 9）

解析対象集団：All Treated Subjects

Treatment Group: Sunitinib N = 34

Lab Test Description	Baseline	Worst Toxicity Grade						
		Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Not Reported	Total
HYPERNATREMIA	GRADE 0	29 (85.3)	5 (14.7)	0	0	0	0	34
	GRADE 1	0	0	0	0	0	0	0
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
HYPONATREMIA	GRADE 0	11 (35.5)	18 (58.1)	0	2 (6.5)	0	0	31
	GRADE 1	0	2 (66.7)	0	1 (33.3)	0	0	3
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
HYPERKALEMIA	GRADE 0	19 (63.3)	8 (26.7)	2 (6.7)	1 (3.3)	0	0	30
	GRADE 1	0	3 (75.0)	1 (25.0)	0	0	0	4
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
HYPOKALEMIA	GRADE 0	28 (82.4)	5 (14.7)	0	1 (2.9)	0	0	34
	GRADE 1	0	0	0	0	0	0	0
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0

Toxicity Scale: CTC Version 4.0
Includes laboratory results reported after the first dose and within 30 days of last dose of study therapy.
(A) Per Anemia criteria in CTC version 4.0 there is no grade 4 for hemoglobin. N.A.: not applicable.

出典［5.3.5.1-2.2（16/214 試験）Table S.7.3-SI］

表 2.7.4.7-8　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（16/214 試験，日本人）（続き 10）

解析対象集団：All Treated Subjects

Treatment Group: Sunitinib N = 34

Lab Test Description	Baseline	Worst Toxicity Grade						
		Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Not Reported	Total
HYPERCALCEMIA	GRADE 0	33 (97.1)	1 (2.9)	0	0	0	0	34
	GRADE 1	0	0	0	0	0	0	0
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
HYPOCALCEMIA	GRADE 0	5 (15.6)	17 (53.1)	10 (31.3)	0	0	0	32
	GRADE 1	0	0	2 (100.0)	0	0	0	2
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
HYPERMAGNESEMIA	GRADE 0	26 (83.9)	4 (12.9)	0	1 (3.2)	0	0	31
	GRADE 1	1 (33.3)	2 (66.7)	0	0	0	0	3
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0
HYPOMAGNESEMIA	GRADE 0	23 (74.2)	8 (25.8)	0	0	0	0	31
	GRADE 1	0	3 (100.0)	0	0	0	0	3
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	0	0	0	0	0	0	0

Toxicity Scale: CTC Version 4.0
Includes laboratory results reported after the first dose and within 30 days of last dose of study therapy.
(A) Per Anemia criteria in CTC version 4.0 there is no grade 4 for hemoglobin. N.A.: not applicable.

出典［5.3.5.1-2.2（16/214 試験）Table S.7.3-SI］

表 2.7.4.7-8　臨床検査値のベースラインに対する投与開始後の Grade（最悪値）のシフトテーブル（16/214 試験，日本人）（続き 11）

解析対象集団：All Treated Subjects

Treatment Group: Sunitinib N = 34

		Worst Toxicity Grade						
Lab Test Description	Baseline	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Not Reported	Total
HYPERGLYCEMIA	GRADE 0	2 (22.2)	5 (55.6)	0	0	0	2 (22.2)	9
	GRADE 1	1 (16.7)	4 (66.7)	1 (16.7)	0	0	0	6
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	5 (26.3)	9 (47.4)	0	0	0	5 (26.3)	19
HYPOGLYCEMIA	GRADE 0	12 (80.0)	1 (6.7)	0	0	0	2 (13.3)	15
	GRADE 1	0	0	0	0	0	0	0
	GRADE 2	0	0	0	0	0	0	0
	GRADE 3	0	0	0	0	0	0	0
	GRADE 4	0	0	0	0	0	0	0
	NOT REPORTED	13 (68.4)	1 (5.3)	0	0	0	5 (26.3)	19

Toxicity Scale: CTC Version 4.0
Includes laboratory results reported after the first dose and within 30 days of last dose of study therapy.
(A) Per Anemia criteria in CTC version 4.0 there is no grade 4 for hemoglobin. N.A.: not applicable.

出典［5.3.5.1-2.2（16/214 試験）Table S.7.3-SI］