表 2.7.6-補遺 2-8　重篤な有害事象の一覧（PR-30-5020-C 試験、本剤群）

Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted] 2[redacted]/Female/Black or African American	20[redacted]	20[redacted]	-4/-2	腹痛 Abdominal pain	NOT APPLICABLE	UNRELATED	3	RECOVERED/RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	130/152	自殺念慮 Suicidal ideation	DOSE NOT CHANGED	UNLIKELY TO BE RELATED	2	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	3/4	悪心 Nausea	DRUG INTERRUPTED	LIKELY RELATED	2	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	3/4	嘔吐 Vomiting	DRUG INTERRUPTED	LIKELY RELATED	2	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	22/23	血小板減少症 Thrombocytopenia	DRUG WITHDRAWN	RELATED	4	RECOVERED/RESOLVED WITH SEQUELAE
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	1/2	腹痛 Abdominal pain	NOT APPLICABLE	UNRELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	18/19	血小板数減少 Platelet count decreased	NOT APPLICABLE	LIKELY RELATED	2	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	19/20	血小板数減少 Platelet count decreased	NOT APPLICABLE	RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	15/24	小腸閉塞 Small intestinal obstruction	DRUG INTERRUPTED DRUG WITHDRAWN	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	20/21	血小板数減少 Platelet count decreased	NOT APPLICABLE	RELATED	4	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	32/34	小腸閉塞 Small intestinal obstruction	NOT APPLICABLE	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/Asian	20[redacted]	20[redacted]	250/252	小腸閉塞 Small intestinal obstruction	DRUG INTERRUPTED	LIKELY RELATED	3	RECOVERED/RESOLVED

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a' ・事象の発現日又は消失日が初回投与前の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし「-」（マイナス）符号を付けて表示した。
・事象の発現日又は消失日が投与期間中（初回投与後から最終投与の間）の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし符号なしとした。
・事象の発現日又は消失日が最終投与後の場合、そのRel Dayは最終投与日を起点として事象の発現日又は消失日までの日数をカウントし「+」（プラス）符号を付けて表示した。

*情報公開時に追記

Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	6/11	小腸閉塞 Small intestinal obstruction	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	21/21	網膜裂孔 Retinal tear	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	21/21	硝子体出血 Vitreous haemorrhage	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	19/23	貧血 Anaemia	DRUG INTERRUPTED	LIKELY RELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	23/27	貧血 Anaemia	DRUG INTERRUPTED DOSE REDUCED	LIKELY RELATED	2	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	55/58	小腸閉塞 Small intestinal obstruction	DRUG INTERRUPTED DOSE REDUCED	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	7/16	小腸閉塞 Small intestinal obstruction	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	3/15	嘔吐 Vomiting	DRUG WITHDRAWN	UNLIKELY TO BE RELATED	3	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	ongoing	28/	再発乳癌 Breast cancer recurrent	NOT APPLICABLE	UNRELATED	3	NOT RECOVERED/NOT RESOLVED
	20[redacted]	20[redacted]	51/65	汎血球減少症 Pancytopenia	DRUG WITHDRAWN	RELATED	4	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/Asian	20[redacted]	20[redacted]	27/33	血小板減少症 Thrombocytopenia	DOSE REDUCED	RELATED	4	RECOVERED/RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	88/89	腎結石症 Nephrolithiasis	DOSE NOT CHANGED	UNRELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	422/423	肺塞栓症 Pulmonary embolism	DOSE NOT CHANGED	UNRELATED	3	RECOVERED/RESOLVED

*
a'・事象の発現日又は消失日が初回投与前の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし「-」（マイナス）符号を付けて表示した。
・事象の発現日又は消失日が投与期間中（初回投与後から最終投与の間）の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし符号なしとした。
・事象の発現日又は消失日が最終投与後の場合、そのRel Dayは最終投与日を起点として事象の発現日又は消失日までの日数をカウントし「+」（プラス）符号を付けて表示した。

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Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	16/24	血尿 Haematuria	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	16/25	血小板減少症 Thrombocytopenia	DRUG WITHDRAWN	RELATED	4	RECOVERED/RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	20/28	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	LIKELY RELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	50/52	発熱 Pyrexia	DOSE NOT CHANGED	UNRELATED	1	RECOVERED/ RESOLVED
[redacted] 4[redacted]/Female/White	20[redacted]	20[redacted]	-4/-3	腎結石症 Nephrolithiasis	NOT APPLICABLE	UNRELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	8/15	血中クレアチニン増加 Blood creatinine increased	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	15/20	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	LIKELY RELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	53/70	血小板減少症 Thrombocytopenia	DRUG WITHDRAWN	LIKELY RELATED	4	RECOVERED/ RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	18/21	便秘 Constipation	DRUG INTERRUPTED	RELATED	3	RECOVERED/ RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	6/11	悪心 Nausea	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/ RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	39/44	胃閉塞 Obstruction gastric	NOT APPLICABLE	UNLIKELY TO BE RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	40/40	心筋梗塞 Myocardial infarction	NOT APPLICABLE	LIKELY RELATED	3	RECOVERED/ RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	74/77	胆道障害 Biliary tract disorder	NOT APPLICABLE	UNRELATED	3	RECOVERED/ RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	29/31	胸水 Pleural effusion	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/ RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	39/39	敗血症 Sepsis	NOT APPLICABLE	UNRELATED	5	FATAL

*
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Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted] 8[redacted]/Female/White	20[redacted]	20[redacted]	22/23	血小板減少症 Thrombocytopenia	NOT APPLICABLE	RELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	22/23	貧血 Anaemia	NOT APPLICABLE	RELATED	3	RECOVERED/ RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	ongoing	13/	骨髄炎 Osteomyelitis	DRUG WITHDRAWN	UNRELATED	3	NOT RECOVERED/ NOT RESOLVED
	20[redacted]	20[redacted]	41/43	脱水 Dehydration	NOT APPLICABLE	UNRELATED	3	RECOVERED/ RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	42/45	胃炎 Gastritis	NOT APPLICABLE	LIKELY RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	50/52	嘔吐 Vomiting	DOSE NOT CHANGED	LIKELY RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	70/72	嘔吐 Vomiting	NOT APPLICABLE	LIKELY RELATED	3	RECOVERED/ RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	-7/-1	便秘 Constipation	NOT APPLICABLE	UNRELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	10/13	食道炎 Oesophagitis	DRUG WITHDRAWN	LIKELY RELATED	3	RECOVERED/ RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	6/6	直腸出血 Rectal haemorrhage	NOT APPLICABLE	UNRELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	6/8	胸水 Pleural effusion	NOT APPLICABLE	UNRELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	37/40	悪性胸水 Malignant pleural effusion	DOSE NOT CHANGED	UNRELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	68/70	気胸 Pneumothorax	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	82/90	呼吸困難 Dyspnoea	NOT APPLICABLE	UNRELATED	3	RECOVERED/ RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	6/8	上室性頻脈 Supraventricular tachycardia	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	25/33	大腸閉塞 Large intestinal obstruction	NOT APPLICABLE	UNRELATED	3	RECOVERED/ RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	10/12	胸痛 Chest pain	DOSE NOT CHANGED	UNLIKELY TO BE RELATED	2	RECOVERED/ RESOLVED

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Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	45/46	呼吸困難 Dyspnoea	DOSE NOT CHANGED	UNRELATED	2	RECOVERED/ RESOLVED WITH SEQUELAE
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	53/61	便秘 Constipation	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/ RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	18/19	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	22/23	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	LIKELY RELATED	3	RECOVERED/RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	22/24	直腸出血 Rectal haemorrhage	DRUG INTERRUPTED	LIKELY RELATED	3	RECOVERED/RESOLVED WITH SEQUELAE
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	9/60	びらん性食道炎 Erosive oesophagitis	DRUG WITHDRAWN	UNRELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	6/60	嘔吐 Vomiting	DRUG WITHDRAWN DRUG INTERRUPTED	UNRELATED	3	ECOVERED/RESOLVED WITH SEQUELAE
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	80/83	便秘 Constipation	NOT APPLICABLE	UNRELATED	3	RECOVERED/ RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	4/20	下痢 Diarrhoea	DRUG INTERRUPTED	LIKELY RELATED	2	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	36/41	小腸閉塞 Small intestinal obstruction	DRUG WITHDRAWN	UNRELATED	3	RECOVERED/ RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	425/426	背部痛 Back pain	DRUG WITHDRAWN	UNRELATED	2	RECOVERED/ RESOLVED

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Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	19/21	血小板数減少 Platelet count decreased	DRUG INTERRUPTED	RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	19/28	小腸閉塞 Small intestinal obstruction	DRUG WITHDRAWN	UNRELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	21/24	血小板減少症 Thrombocytopenia	NOT APPLICABLE	LIKELY RELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	24/28	血小板減少症 Thrombocytopenia	NOT APPLICABLE	LIKELY RELATED	2	RECOVERED/ RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	53/56	過量投与 Overdose	DRUG INTERRUPTED	UNRELATED	-	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	260/261	絞扼性ヘルニア Strangulated hernia	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	264/277	小腸閉塞 Small intestinal obstruction	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/ RESOLVED WITH SEQUELAE
[redacted] 6[redacted]/Female/Black or African American	20[redacted]	20[redacted]	162/169	小腸閉塞 Small intestinal obstruction	DRUG WITHDRAWN	UNRELATED	2	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	184/187	小腸閉塞 Small intestinal obstruction	NOT APPLICABLE	UNRELATED	1	RECOVERED/ RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	6/13	小腸閉塞 Small intestinal obstruction	DRUG WITHDRAWN	UNRELATED	3	RECOVERED/ RESOLVED
[redacted] 7[redacted]/Female/Unknown	20[redacted]	20[redacted]	219/222	腹水 Ascites	NOT APPLICABLE	UNRELATED	2	RECOVERED/ RESOLVED
[redacted] 5[redacted]/Female/Unknown	20[redacted]	20[redacted]	70/78	大腸閉塞 Large intestinal obstruction	NOT APPLICABLE	UNRELATED	4	RECOVERED/ RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	23/25	小腸閉塞 Small intestinal obstruction	NOT APPLICABLE	UNRELATED	3	RECOVERED/ RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	134/136	貧血 Anaemia	DOSE REDUCED DRUG INTERRUPTED	LIKELY RELATED	3	RECOVERED/ RESOLVED

*

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Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	3/10	小腸閉塞 Small intestinal obstruction	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	13/26	腸閉塞 Intestinal obstruction	DRUG WITHDRAWN DRUG INTERRUPTED	UNRELATED	3	RECOVERED/ RESOLVED WITH SEQUELAE
[redacted] 4[redacted]/Female/White	20[redacted]	20[redacted]	26/33	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/ RESOLVED WITH SEQUELAE
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	40/41	悪心 Nausea	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	3	RECOVERED/ RESOLVED
[redacted] 5[redacted]/Female/Black or African American	20[redacted]	20[redacted]	81/84	嘔吐 Vomiting	DOSE NOT CHANGED	UNLIKELY TO BE RELATED	3	RECOVERED/ RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	12/15	心電図QT延長 Electrocardiogram QT prolonged	DRUG INTERRUPTED	LIKELY RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	14/17	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	3	RECOVERED/ RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	17/18	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/ RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	17/24	貧血 Anaemia	DRUG INTERRUPTED	RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	18/22	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	3	RECOVERED/ RESOLVED WITH SEQUELAE
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	43/45	嚥下障害 Dysphagia	DRUG INTERRUPTED	UNRELATED	2	RECOVERED/ RESOLVED WITH SEQUELAE

*

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Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	17/20	血小板減少症 Thrombocytopenia	DRUG WITHDRAWN	RELATED	4	RECOVERED/ RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	20/22	血小板減少症 Thrombocytopenia	DRUG WITHDRAWN	RELATED	3	RECOVERED/ RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	22/23	血小板減少症 Thrombocytopenia	DRUG WITHDRAWN	RELATED	2	RECOVERED/ RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	23/25	血小板減少症 Thrombocytopenia	DRUG WITHDRAWN	RELATED	3	RECOVERED/ RESOLVED WITH SEQUELAE
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	57/59	腹痛 Abdominal pain	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	3	RECOVERED/ RESOLVED
[redacted] 5[redacted]/Female/Asian	20[redacted]	20[redacted]	1/15	敗血症 Sepsis	DRUG INTERRUPTED	UNRELATED	4	RECOVERED/ RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	35/36	血小板数減少 Platelet count decreased	NOT APPLICABLE	RELATED	4	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	36/37	血小板数減少 Platelet count decreased	DRUG WITHDRAWN	RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	37/40	血小板数減少 Platelet count decreased	DRUG WITHDRAWN	RELATED	2	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	39/43	敗血症 Sepsis	DOSE REDUCED	LIKELY RELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	40/41	血小板数減少 Platelet count decreased	DRUG WITHDRAWN	RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	41/42	血小板数減少 Platelet count decreased	DOSE NOT CHANGED	RELATED	2	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	48/57	腹痛 Abdominal pain	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/ RESOLVED

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a' ・事象の発現日又は消失日が初回投与前の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし「-」（マイナス）符号を付けて表示した。
・事象の発現日又は消失日が投与期間中（初回投与後から最終投与の間）の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし符号なしとした。
・事象の発現日又は消失日が最終投与後の場合、そのRel Dayは最終投与日を起点として事象の発現日又は消失日までの日数をカウントし「+」（プラス）符号を付けて表示した。

*情報公開時に追記

Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted] 6[redacted]/Female/Unknown	20[redacted]	20[redacted]	-21/-20	胸水 Pleural effusion	NOT APPLICABLE	UNRELATED	3	RECOVERED/ RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	-21/-20	呼吸困難 Dyspnoea	NOT APPLICABLE	UNRELATED	3	RECOVERED/ RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	-11/-6	悪心 Nausea	NOT APPLICABLE	UNRELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	-11/-6	嘔吐 Vomiting	NOT APPLICABLE	UNRELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	2/13	悪心 Nausea	DRUG WITHDRAWN	LIKELY RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	2/13	嘔吐 Vomiting	DRUG WITHDRAWN	LIKELY RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	24/29	敗血症 Sepsis	NOT APPLICABLE	UNRELATED	4	RECOVERED/RESOLVED WITH SEQUELAE
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	-9/-8	腹痛 Abdominal pain	NOT APPLICABLE	UNRELATED	3	RECOVERED/ RESOLVED

a' ・事象の発現日又は消失日が初回投与前の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし「-」（マイナス）符号を付けて表示した。
・事象の発現日又は消失日が投与期間中（初回投与後から最終投与の間）の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし符号なしとした。
・事象の発現日又は消失日が最終投与後の場合、そのRel Dayは最終投与日を起点として事象の発現日又は消失日までの日数をカウントし「+」（プラス）符号を付けて表示した。

*情報公開時に追記

Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted]-[redacted] 7[redacted]/Female/White	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	17/18	血小板数減少 Platelet count decreased	DRUG INTERRUPTED	RELATED	4	RECOVERED/ RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	18/24	血小板数減少 Platelet count decreased	DOSE REDUCED	RELATED	2	RECOVERED/ RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	22/24	好中球数減少 Neutrophil count decreased	DRUG INTERRUPTED	RELATED	3	RECOVERED/ RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	50/51	血小板数減少 Platelet count decreased	DRUG INTERRUPTED	RELATED	4	RECOVERED/ RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	51/52	貧血 Anaemia	DRUG INTERRUPTED	RELATED	3	RECOVERED/ RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	51/55	血小板数減少 Platelet count decreased	DRUG INTERRUPTED	RELATED	2	RECOVERED/ RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	55/57	血小板数減少 Platelet count decreased	DRUG INTERRUPTED	RELATED	4	RECOVERED/ RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	57/58	血小板数減少 Platelet count decreased	DRUG INTERRUPTED	RELATED	2	RECOVERED/ RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	58/62	好中球数減少 Neutrophil count decreased	DRUG INTERRUPTED	RELATED	3	RECOVERED/ RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	58/62	血小板数減少 Platelet count decreased	DRUG INTERRUPTED	RELATED	3	RECOVERED/ RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	59/64	血中クレアチニン増加 Blood creatinine increased	DRUG INTERRUPTED	UNRELATED	2	RECOVERED/ RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	62/70	血小板数減少 Platelet count decreased	DRUG INTERRUPTED	RELATED	1	RECOVERED/ RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	72/76	血中クレアチニン増加 Blood creatinine increased	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/ RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	155/160	急性腎障害 Acute kidney injury	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/ RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	229/232	腹痛 Abdominal pain	NOT APPLICABLE	UNRELATED	3	RECOVERED/ RESOLVED
[redacted]-[redacted] 7[redacted]/Female/White	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	26/27	一過性全健忘 Transient global amnesia	NOT APPLICABLE	UNRELATED	3	RECOVERED/ RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	26/27	上室性不整脈 Arrhythmia supraventricular	NOT APPLICABLE	LIKELY RELATED	2	RECOVERED/ RESOLVED

a' ・事象の発現日又は消失日が初回投与前の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし「-」（マイナス）符号を付けて表示した。
・事象の発現日又は消失日が投与期間中（初回投与後から最終投与の間）の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし符号なしとした。
・事象の発現日又は消失日が最終投与後の場合、そのRel Dayは最終投与日を起点として事象の発現日又は消失日までの日数をカウントし「+」（プラス）符号を付けて表示した。

*情報公開時に追記

Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted]-[redacted] 5[redacted]/Female/Other	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	56/60	転移部痛 Metastatic pain	DOSE NOT CHANGED	UNLIKELY TO BE RELATED	3	RECOVERED/ RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	147/154	深部静脈血栓症 Deep vein thrombosis	NOT APPLICABLE	UNLIKELY TO BE RELATED	2	RECOVERED/ RESOLVED
[redacted]-[redacted] 6[redacted]/Female/White	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	19/19	貧血 Anaemia	DRUG INTERRUPTED	LIKELY RELATED	2	RECOVERED/ RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	19/19	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	LIKELY RELATED	4	RECOVERED/ RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	19/38	悪心 Nausea	DRUG INTERRUPTED	LIKELY RELATED	3	RECOVERED/ RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	20/20	好中球減少症 Neutropenia	DRUG INTERRUPTED	LIKELY RELATED	1	RECOVERED/ RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	20/20	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	LIKELY RELATED	2	RECOVERED/ RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	20/21	貧血 Anaemia	DRUG INTERRUPTED	LIKELY RELATED	3	RECOVERED/ RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	20/21	白血球減少症 Leukopenia	DRUG INTERRUPTED	LIKELY RELATED	2	RECOVERED/ RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	21/21	好中球減少症 Neutropenia	DRUG INTERRUPTED	LIKELY RELATED	2	RECOVERED/ RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	21/21	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	LIKELY RELATED	3	RECOVERED/ RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	22/22	好中球減少症 Neutropenia	DRUG INTERRUPTED	LIKELY RELATED	3	RECOVERED/ RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	22/23	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	LIKELY RELATED	4	RECOVERED/ RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	22/24	白血球減少症 Leukopenia	DRUG INTERRUPTED	LIKELY RELATED	3	RECOVERED/ RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	22/26	貧血 Anaemia	DRUG INTERRUPTED	LIKELY RELATED	2	RECOVERED/ RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	23/30	好中球減少症 Neutropenia	DRUG INTERRUPTED	LIKELY RELATED	4	RECOVERED/ RESOLVED

*

a' ・事象の発現日又は消失日が初回投与前の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし「-」（マイナス）符号を付けて表示した。
・事象の発現日又は消失日が投与期間中（初回投与後から最終投与の間）の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし符号なしとした。
・事象の発現日又は消失日が最終投与後の場合、そのRel Dayは最終投与日を起点として事象の発現日又は消失日までの日数をカウントし「+」（プラス）符号を付けて表示した。

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Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
	20[redacted]	20[redacted]	24/25	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	2	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	25/25	白血球減少症 Leukopenia	DRUG INTERRUPTED	LIKELY RELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	26/26	白血球減少症 Leukopenia	DRUG INTERRUPTED	LIKELY RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	26/27	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	27/27	貧血 Anaemia	DRUG INTERRUPTED	LIKELY RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	27/28	白血球減少症 Leukopenia	DRUG INTERRUPTED	LIKELY RELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	28/28	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	28/31	貧血 Anaemia	DRUG INTERRUPTED	LIKELY RELATED	2	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	29/32	白血球減少症 Leukopenia	DRUG INTERRUPTED	LIKELY RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	29/34	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	31/32	好中球減少症 Neutropenia	DRUG INTERRUPTED	LIKELY RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	32/34	貧血 Anaemia	DRUG INTERRUPTED	LIKELY RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	33/33	白血球減少症 Leukopenia	DRUG INTERRUPTED	LIKELY RELATED	1	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	35/35	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	2	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	36/62	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	1	RECOVERED/ RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	185/196	小腸閉塞 Small intestinal obstruction	DRUG INTERRUPTED	UNRELATED	4	RECOVERED/ RESOLVED

*

a' ・事象の発現日又は消失日が初回投与前の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし「-」（マイナス）符号を付けて表示した。
・事象の発現日又は消失日が投与期間中（初回投与後から最終投与の間）の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし符号なしとした。
・事象の発現日又は消失日が最終投与後の場合、そのRel Dayは最終投与日を起点として事象の発現日又は消失日までの日数をカウントし「+」（プラス）符号を付けて表示した。

*情報公開時に追記

Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted]-[redacted] 7[redacted]/Female/White	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	-11/-7	便秘 Constipation	NOT APPLICABLE	UNRELATED	3	RECOVERED/ RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	100/103	小腸閉塞 Small intestinal obstruction	DRUG WITHDRAWN	UNRELATED	4	RECOVERED/ RESOLVED
[redacted]-[redacted] 5[redacted]/Female/White	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	45/55	便秘 Constipation	DOSE REDUCED	UNLIKELY TO BE RELATED	3	RECOVERED/ RESOLVED
	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	61/65	腹痛 Abdominal pain	NOT APPLICABLE	UNRELATED	3	RECOVERED/ RESOLVED
[redacted]-[redacted] 5[redacted]/Female/White	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	59/60	発熱 Pyrexia	DRUG INTERRUPTED	UNRELATED	2	RECOVERED/ RESOLVED
[redacted]-[redacted] 6[redacted]/Female/White	20[redacted]-[redacted]-[redacted]	20[redacted]-[redacted]-[redacted]	12/22	小腸閉塞 Small intestinal obstruction	NOT APPLICABLE	UNRELATED	3	UNKNOWN

*

a' ・事象の発現日又は消失日が初回投与前の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし「-」（マイナス）符号を付けて表示した。
・事象の発現日又は消失日が投与期間中（初回投与後から最終投与の間）の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし符号なしとした。
・事象の発現日又は消失日が最終投与後の場合、そのRel Dayは最終投与日を起点として事象の発現日又は消失日までの日数をカウントし「+」（プラス）符号を付けて表示した。

*情報公開時に追記

Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	19/19	血小板減少症 Thrombocytopenia	NOT APPLICABLE	RELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	19/29	粘膜の炎症 Mucosal inflammation	NOT APPLICABLE	RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	19/29	発熱 Pyrexia	NOT APPLICABLE	RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	19/29	脱水 Dehydration	DRUG INTERRUPTED	RELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	20/20	好中球減少症 Neutropenia	NOT APPLICABLE	RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	20/20	血小板減少症 Thrombocytopenia	NOT APPLICABLE	RELATED	1	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	21/23	血小板減少症 Thrombocytopenia	NOT APPLICABLE	RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	21/29	好中球減少症 Neutropenia	NOT APPLICABLE	RELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	24/24	血小板減少症 Thrombocytopenia	NOT APPLICABLE	RELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	24/24	血小板減少症 Thrombocytopenia	NOT APPLICABLE	RELATED	2	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	25/26	血小板減少症 Thrombocytopenia	NOT APPLICABLE	RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	27/27	血小板減少症 Thrombocytopenia	NOT APPLICABLE	RELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	28/35	血小板減少症 Thrombocytopenia	NOT APPLICABLE	RELATED	3	RECOVERED/ RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	14/16	小腸閉塞 Small intestinal obstruction	DRUG INTERRUPTED	UNRELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	67/68	腹痛 Abdominal pain	DRUG INTERRUPTED	LIKELY RELATED	3	RECOVERED/ RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	11/12	痙攣発作 Seizure	DRUG WITHDRAWN	UNRELATED	2	RECOVERED/ RESOLVED

*
a' ・事象の発現日又は消失日が初回投与前の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし「-」（マイナス）符号を付けて表示した。
・事象の発現日又は消失日が投与期間中（初回投与後から最終投与の間）の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし符号なしとした。
・事象の発現日又は消失日が最終投与後の場合、そのRel Dayは最終投与日を起点として事象の発現日又は消失日までの日数をカウントし「+」（プラス）符号を付けて表示した。

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Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	391/593	乳癌 Breast cancer	DRUG WITHDRAWN DRUG INTERRUPTED	UNRELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	27/28	小腸閉塞 Small intestinal obstruction	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	154/156	小腸閉塞 Small intestinal obstruction	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	3	RECOVERED/ RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	17/18	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	LIKELY RELATED	4	RECOVERED/ RESOLVED WITH SEQUELAE
	20[redacted]	20[redacted]	18/29	血小板減少症 Thrombocytopenia	DOSE REDUCED	LIKELY RELATED	2	RECOVERED/ RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	142/142	疲労 Fatigue	NOT APPLICABLE	UNLIKELY TO BE RELATED	3	RECOVERED/ RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	95/98	水腎症 Hydronephrosis	DOSE NOT CHANGED	UNRELATED	3	RECOVERED/ RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	16/18	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	18/23	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	23/23	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	26/32	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	23/38	白血球減少症 Leukopenia	DRUG INTERRUPTED	LIKELY RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	26/32	好中球減少症 Neutropenia	NOT APPLICABLE	LIKELY RELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	32/38	好中球減少症 Neutropenia	DRUG INTERRUPTED	LIKELY RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	92/101	血小板減少症 Thrombocytopenia	DOSE REDUCED	LIKELY RELATED	3	RECOVERED/ RESOLVED

a' ・事象の発現日又は消失日が初回投与前の場合、そのRel Dayは初回投与日を起点として事象の発現日又は消失日までの日数をカウントし「-」（マイナス）符号を付けて表示した。
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*情報公開時に追記

Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted] 4[redacted]/Female/White	20[redacted]	20[redacted]	8/11	肺炎 Pneumonia	DOSE NOT CHANGED	UNLIKELY TO BE RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	69/73	側腹部痛 Flank pain	NOT APPLICABLE	UNLIKELY TO BE RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	69/73	胸水 Pleural effusion	NOT APPLICABLE	UNLIKELY TO BE RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	79/79	胸水 Pleural effusion	NOT APPLICABLE	UNRELATED	3	RECOVERED/ RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	50/52	小腸閉塞 Small intestinal obstruction	DOSE NOT CHANGED	UNLIKELY TO BE RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	50/52	腹痛 Abdominal pain	DOSE NOT CHANGED	UNLIKELY TO BE RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	97/101	てんかん重積状態 Status epilepticus	DRUG WITHDRAWN	UNLIKELY TO BE RELATED	3	RECOVERED/ RESOLVED
[redacted] 6[redacted]/Female/Unknown	20[redacted]	20[redacted]	19/22	血小板減少症 Thrombocytopenia	NOT APPLICABLE	LIKELY RELATED	4	RECOVERED/ RESOLVED
[redacted] 5[redacted]/Female/Black or African American	20[redacted]	20[redacted]	86/93	ヘモグロビン減少 Haemoglobin decreased	DOSE REDUCED DRUG INTERRUPTED	RELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	150/156	貧血 Anaemia	DOSE REDUCED DRUG INTERRUPTED	RELATED	3	RECOVERED/ RESOLVED

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Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	22/27	血小板減少症 Thrombocytopenia	DOSE REDUCED	RELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	27/36	血小板減少症 Thrombocytopenia	DRUG INTERRUPTED	RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	32/36	好中球減少症 Neutropenia	DOSE REDUCED	RELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	85/99	血小板減少症 Thrombocytopenia	DOSE REDUCED	RELATED	2	RECOVERED/ RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	ongoing	29/	口内炎 Stomatitis	DRUG WITHDRAWN	UNLIKELY TO BE RELATED	3	NOT RECOVERED/ NOT RESOLVED
	20[redacted]	20[redacted]	29/31	血小板減少症 Thrombocytopenia	DRUG WITHDRAWN	RELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	29/34	心肺不全 Cardiopulmonary failure	DRUG WITHDRAWN	UNRELATED	5	FATAL
	20[redacted]	ongoing	31/	好中球減少症 Neutropenia	NOT APPLICABLE	RELATED	4	NOT RECOVERED/ NOT RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	6/6	呼吸困難 Dyspnoea	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	2	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	6/6	胸痛 Chest pain	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	2	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	26/36	貧血 Anaemia	DRUG WITHDRAWN	RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	26/36	好中球減少症 Neutropenia	DRUG WITHDRAWN	RELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	26/36	血小板減少症 Thrombocytopenia	DRUG WITHDRAWN	RELATED	4	RECOVERED/ RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	76/78	小腸閉塞 Small intestinal obstruction	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	3	RECOVERED/ RESOLVED

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Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	36/43	好中球減少症 Neutropenia	DOSE REDUCED DRUG INTERRUPTED	RELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	124/126	小腸閉塞 Small intestinal obstruction	DRUG WITHDRAWN	UNRELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	128/152	創傷感染 Wound infection	NOT APPLICABLE	UNRELATED	3	RECOVERED/ RESOLVED
[redacted] 5[redacted]/Female/Asian	20[redacted]	20[redacted]	4/6	頭痛 Headache	DRUG INTERRUPTED	RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	4/6	高血圧 Hypertension	DRUG INTERRUPTED	UNRELATED	3	RECOVERED/ RESOLVED
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	245/247	急性呼吸不全 Acute respiratory failure	NOT APPLICABLE	UNRELATED	3	RECOVERED/ RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	11/13	胆管炎 Cholangitis	DOSE NOT CHANGED	UNLIKELY TO BE RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	12/13	敗血症 Sepsis	DOSE NOT CHANGED	UNRELATED	4	RECOVERED/ RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	7/9	低ナトリウム血症 Hyponatraemia	DRUG INTERRUPTED	LIKELY RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	ongoing	44/	深部静脈血栓症 Deep vein thrombosis	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	2	NOT RECOVERED/NOT RESOLVED
	20[redacted]	20[redacted]	116/120	低ナトリウム血症 Hyponatraemia	NOT APPLICABLE	UNLIKELY TO BE RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	116/123	尿路感染 Urinary tract infection	NOT APPLICABLE	UNRELATED	4	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	116/123	低カリウム血症 Hypokalaemia	NOT APPLICABLE	UNLIKELY TO BE RELATED	4	RECOVERED/ RESOLVED

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Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	15/18	便秘 Constipation	NOT APPLICABLE	LIKELY RELATED	2	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	22/24	胸水 Pleural effusion	NOT APPLICABLE	UNRELATED	2	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	27/33	腹水 Ascites	NOT APPLICABLE	UNRELATED	2	RECOVERED/ RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	20[redacted]	54/62	悪心 Nausea	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	54/62	嘔吐 Vomiting	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	54/62	腹痛 Abdominal pain	DRUG INTERRUPTED	UNLIKELY TO BE RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	58/62	胸水 Pleural effusion	NOT APPLICABLE	UNRELATED	3	RECOVERED/ RESOLVED
[redacted] 4[redacted]/Female/White	20[redacted]	20[redacted]	63/65	嚥下障害 Dysphagia	DRUG INTERRUPTED	LIKELY RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	63/65	嘔吐 Vomiting	DRUG INTERRUPTED	LIKELY RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	97/99	嘔吐 Vomiting	DRUG WITHDRAWN	UNLIKELY TO BE RELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	125/126	呼吸不全 Respiratory failure	NOT APPLICABLE	UNRELATED	5	FATAL
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	22/23	血小板数減少 Platelet count decreased	DRUG INTERRUPTED	RELATED	4	RECOVERED/ RESOLVED
[redacted] 4[redacted]/Female/Black or African American	20[redacted]	20[redacted]	10/14	高血圧 Hypertension	NOT APPLICABLE	LIKELY RELATED	3	RECOVERED/ RESOLVED

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Subject ID Age/Sex/Race	AE Start Date	AE End Date	Rel day[a]	MedDRA Preferred Term	Action Taken	Treatment Related	Intensity	Outcome
[redacted] 6[redacted]/Female/White	20[redacted]	ongoing	59/	血小板数減少 Platelet count decreased	NOT APPLICABLE	LIKELY RELATED	4	NOT RECOVERED/ NOT RESOLVED
	20[redacted]	ongoing	65/	急性骨髄性白血病 Acute myeloid leukemia	NOT APPLICABLE	RELATED	4	NOT RECOVERED/ NOT RESOLVED
	20[redacted]	ongoing	65/	骨髄異形成症候群 Myelodysplastic syndrome	NOT APPLICABLE	RELATED	4	NOT RECOVERED/ NOT RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	39/41	発熱 Pyrexia	DRUG INTERRUPTED	UNRELATED	2	RECOVERED/ RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	9/13	肝不全 Hepatic failure	DRUG WITHDRAWN DRUG INTERRUPTED	UNRELATED	4	RECOVERED/RESOLVED WITH SEQUELAE
[redacted] 7[redacted]/Female/White	20[redacted]	20[redacted]	22/23	血小板数減少 Platelet count decreased	DOSE REDUCED	RELATED	4	RECOVERED/ RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	49/52	腎盂腎炎 Pyelonephritis	DOSE NOT CHANGED	UNRELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	49/52	菌血症 Bacteraemia	DOSE NOT CHANGED	UNRELATED	3	RECOVERED/ RESOLVED
	20[redacted]	20[redacted]	49/52	大腸菌性尿路感染 Escherichia urinary tract infection	DOSE NOT CHANGED	UNRELATED	3	RECOVERED/ RESOLVED
[redacted] 5[redacted]/Female/White	20[redacted]	ongoing	18/	嘔吐 Vomiting	DOSE REDUCED	LIKELY RELATED	3	NOT RECOVERED/ NOT RESOLVED
[redacted] 6[redacted]/Female/White	20[redacted]	20[redacted]	-5/-1	肺塞栓症 Pulmonary embolism	NOT APPLICABLE	UNRELATED	3	RECOVERED/RESOLVED
	20[redacted]	20[redacted]	-5/-1	深部静脈血栓症 Deep vein thrombosis	NOT APPLICABLE	UNRELATED	3	RECOVERED/RESOLVED

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