2.7.6.1.2.3.9 出血事象

出血事象は、ICAC が判定を行い、ICAC の判定結果を安全性の主解析に用いた。

2.7.6.1.2.3.9.1 安全性主要評価項目

2.7.6.1.2.3.9.1.1 TIMI 分類の「大出血」

本試験では TIMI 分類の「大出血」を安全性主要評価項目とした。

全体集団における On-treatment 期間に認められた TIMI 分類の「大出血」の要約を表 2.7.6.1-22 に示す。

TIMI 分類の「大出血」の発現割合は、リバーロキサバン群で 1.9%（62/3,256 例）、プラセボ群で 1.4%（44/3,248 例）であり、発現率（100 人年あたり）は、それぞれ 0.96 及び 0.67 であった。リバーロキサバン群のプラセボ群に対する HR は 1.43（95%CI：0.97～2.10）であった。

TIMI 分類の「大出血」のカテゴリー別では、「致死的出血」の発現割合は、リバーロキサバン群で 0.2%（6/3,256 例）、プラセボ群で 0.2%（6/3,248 例）であり、発現率（100 人年あたり）は、両投与群共に 0.09 であった。リバーロキサバン群のプラセボ群に対する HR は 1.02（95%CI：0.33～3.15）であった。

「頭蓋内出血」の発現割合は、リバーロキサバン群で 0.4%（13/3,256 例）、プラセボ群で 0.5%（17/3,248 例）であり、発現率（100 人年あたり）は、それぞれ 0.20 及び 0.26 であった。リバーロキサバン群のプラセボ群に対する HR は 0.78（95%CI：0.38～1.61）であった。

「臨床的に明らかな出血の徴候」（5g/dL 以上のヘモグロビン値の低下又は 15%以上のヘマトクリット値の低下）の発現割合は、リバーロキサバン群で 1.4%（46/3,256 例）、プラセボ群で 0.7%（24/3,248 例）であり、発現率（100 人年あたり）は、それぞれ 0.71 及び 0.36 であった。リバーロキサバン群のプラセボ群に対する HR は 1.94（95%CI：1.18～3.17）であった。

リバーロキサバン群におけるこれらの事象はすべて CABG に関連しない出血であった。CABG 関連の非致死的な出血事象が、プラセボ群で血漿の輸血を必要とした 1 例に認められた。

「臨床的に明らかな出血の徴候」の発現がプラセボ群と比較してリバーロキサバン群で数値的に多かったが、「致死的出血」及び「頭蓋内出血」の発現は各投与群で同程度であった。

表 2.7.6.1-22 On-treatment 期間に認められた TIMI 分類の「大出血」（全体集団、SAF）

Bleeding Event	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)		Rivaroxaban Placebo bid + ASA 100 mg od N=3248 (100%)		Rivaroxaban 2.5 mg bid + ASA 100 mg od vs Rivaroxaban Placebo bid+ ASA 100 mg od	
Overall Subcategories	**n (%)**	**n/100 p-yrs (95% CI)**	**n (%)**	**n/100 p-yrs (95% CI)**	**HR (95% CI)**	**P-value**
TIMI major bleeding	62 (1.9%)	0.96 (0.73; 1.23)	44 (1.4%)	0.67 (0.48; 0.90)	1.43 (0.97, 2.10)	0.0695
Fatal bleeding (CABG or non-CABG)	6 (0.2%)	0.09 (0.03; 0.20)	6 (0.2%)	0.09 (0.03; 0.20)	1.02 (0.33, 3.15)	0.9773
Intracranial bleeding (CABG or non-CABG)	13 (0.4%)	0.20 (0.11; 0.34)	17 (0.5%)	0.26 (0.15; 0.41)	0.78 (0.38, 1.61)	0.5020
Non-CABG related TIMI major bleeding	62 (1.9%)	0.96 (0.73; 1.23)	43 (1.3%)	0.65 (0.47; 0.88)	1.46 (0.99, 2.16)	0.0546
Fatal bleeding	6 (0.2%)	0.09 (0.03; 0.20)	6 (0.2%)	0.09 (0.03; 0.20)	1.02 (0.33, 3.15)	0.9773
Any intracranial bleeding	13 (0.4%)	0.20 (0.11; 0.34)	17 (0.5%)	0.26 (0.15; 0.41)	0.78 (0.38, 1.61)	0.5020
Clinically overt signs of hemorrhage associated with a drop in hemoglobin of ≥5 g/dL or drop in Hct of ≥15%	46 (1.4%)	0.71 (0.52; 0.95)	24 (0.7%)	0.36 (0.23; 0.54)	1.94 (1.18, 3.17)	0.0076
CABG-related TIMI major bleeding	0	0 (0.00; 0.06)	1 (<0.1%)	0.02 (0.00; 0.08)	-	-
Fatal bleeding	0	0 (0.00; 0.06)	0	0 (0.00; 0.06)	-	-
Perioperative intracranial bleeding	0	0 (0.00; 0.06)	0	0 (0.00; 0.06)	-	-
Reoperation after closure of the sternotomy incision for the purpose of controlling bleeding	0	0 (0.00; 0.06)	0	0 (0.00; 0.06)	-	-
Transfusion of ≥5 U PRBCs or whole blood within a 48-h period (cell saver transfusion will not be counted in calculations of blood products)	0	0 (0.00; 0.06)	1 (<0.1%)	0.02 (0.00; 0.08)	-	-
Chest tube output >2 L within a 24-h period	0	0 (0.00; 0.06)	0	0 (0.00; 0.06)	-	-

ASA = Acetylsalicylic acid 100 mg once daily, bid = twice daily, od = once daily, Rivaroxaban = Rivaroxaban 2.5 mg twice daily, CABG = Coronary artery bypass graft, TIMI = Thrombolysis in Myocardial Infarction (study group), SAF = safety analysis set,
N = total number of subjects, n = number of subjects with first event, % = 100 * n / N, n/100 p-yrs = ratio of number of subjects with incident events /cumulative at-risk time.

Table displays outcome events meeting the definition as adjudicated by the Independent Clinical Adjudication Committee. The safety analysis set includes all randomized subjects who received at least one dose of study drug (rivaroxaban or rivaroxaban placebo). The on-treatment data scope includes outcome events observed from randomization until 2 days after permanent stop of the study drug.

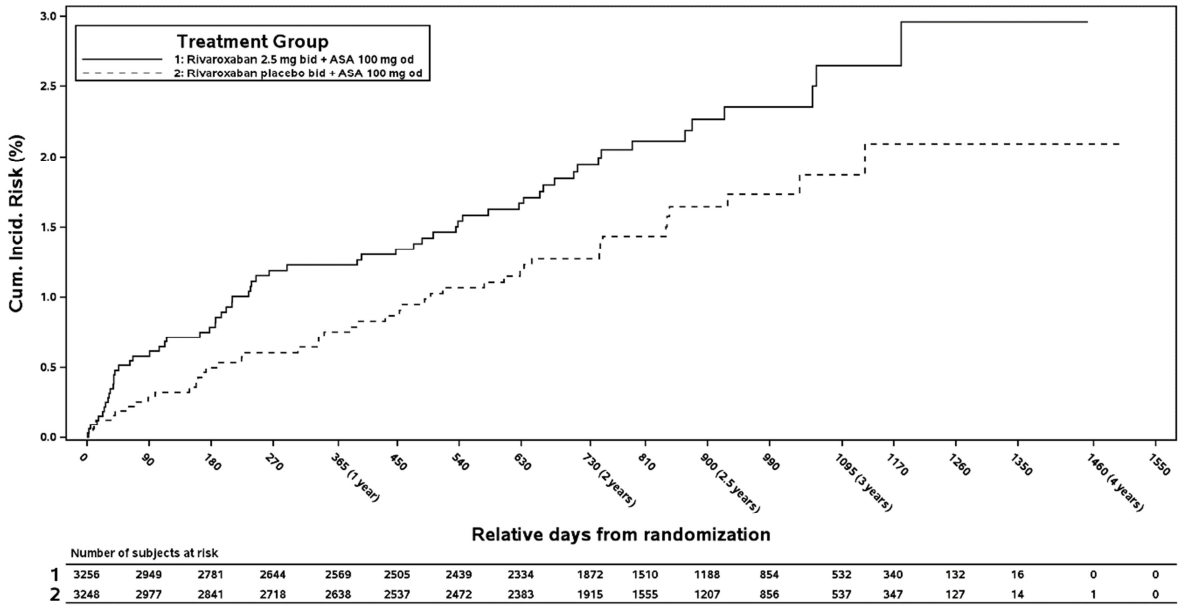
HR (95% CI) is based on the Cox proportional hazards model stratified by type of procedure and clopidogrel use, per IxRS assignment, with treatment as the only covariate. P−value (2-sided) is based on the log rank test stratified by type of procedure and clopidogrel use per IxRS assignment with treatment as a factor.

Source: PH-40164/Table 14.3.1.3/1

On-treatment 期間に認められた TIMI 分類の「大出血」の累積イベント発現率に関する Kaplan-Meier 曲線を図 2.7.6.1-11 に示す。

累積イベント発現率の Kaplan-Meier 曲線において、治験薬投与開始から 30 日以内にリバーロキサバン群とプラセボ群の間に乖離がみられ、プラセボ群と比較してリバーロキサバン群で治験薬投与開始後早期の発現率が高かった。一方、3 年までの累積イベント発現率の差は約 0.5%であり、9 ヵ月以降の群間差はおおむね一定であった。TIMI 分類の「大出血」の累積イベント発現率は、リバーロキサバン群及びプラセボ群で、それぞれ無作為割付けから 30 日後で 0.25%（95%CI：0.13～0.50）及び 0.13%（95%CI：0.05～0.33）、1 年後で 1.23%（95%CI：0.89～1.70）及び 0.75%（95%CI：0.50～1.14）、3 年後で 2.65%（95%CI：2.00～3.50）及び 1.87%（95%CI：1.35～2.59）であった（PH-40164/Table 14.3.1.3/13）。

図 2.7.6.1-11 On-treatment 期間に認められた TIMI 分類の「大出血」の累積イベント発現率の Kaplan-Meier 曲線（全体集団、SAF）



At-risk subject counts were calculated as at end of timepoint.
Figure displays outcome events meeting the definition as adjudicated by Independent Clinical Adjudication Committee (ICAC).
The safety analysis set includes all randomized subjects who received at least one dose of study drug (rivaroxaban or rivaroxaban placebo).
The on-treatment data scope includes outcome events from randomization until 2 days after permanent stop of study drug (rivaroxaban or rivaroxaban placebo).
bid = twice daily, od = once daily, ASA = acetylsalicylic acid
K-M = Kaplan-Meier, Cum. Incid. Risk (%) = K-M estimates of the cumulative incidence for an event, calculated as 100 * (1 minus the K-M estimates of the survival function).
Only the first occurrence of the outcome event under analysis within the data scope from a subject is considered.

Source: PH-40164/Figure 14.3.1.3/4

無作為割付けから ECOD までの TIMI 分類の「大出血」の発現割合は、リバーロキサバン群で 3.0%（97/3,256 例）、プラセボ群で 2.1%（67/3,248 例）（HR：1.45、95%CI：1.06～1.98）、全試験期間の TIMI 分類の「大出血」の発現割合は、3.0%（98 例）及び 2.1%（69 例）（HR：1.43、95%CI：1.05～1.94）であり、On-treatment 期間に認められた TIMI 分類の「大出血」の結果とおおむね一貫していた（PH-40164/Table 14.3.1.3/4、14.3.1.3/7）。

日本人集団の結果は、17454_J_analysis/Table 14.3.1.3/1、14.3.1.3/4、14.3.1.3/7、14.3.1.3/13 及び Figure 14.3.1.3/4 を参照のこと。

2.7.6.1.2.3.9.1.2 TIMI 分類の「大出血」の出血部位別の結果

全体集団における On-treatment 期間に認められた TIMI 分類の「大出血」の出血部位別の結果を表 2.7.6.1-23 に示す。

リバーロキサバン群で TIMI 分類の「大出血」が最も多く発現した部位は消化管－胃であり、リバーロキサバン群で 0.3%（10/3,256 例）、プラセボ群で 0.2%（7/3,248 例）に認められた。次いで、血管－血管処置部位が両投与群共に 0.2%（8 例）、消化管－その他が 0.2%（8 例）及び 0%（0 例）、消化管－大腸/結腸が 0.2%（6 例）及び 0%（0 例）、頭蓋内－脳実質内が 0.2%（5 例）及び 0.2%（7 例）、頭蓋内－硬膜下が 0.2%（5 例）及び 0.1%（4 例）に認められた。

表 2.7.6.1-23 On-treatment 期間に認められた出血部位別の TIMI 分類の「大出血」（全体集団、SAF）

	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban Placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
Bleeding Event			
TIMI Major Bleeding Overall	62 (1.9%)	44 (1.4%)	106 (1.6%)
Site of bleeding			
Missing	0	1 (<0.1%)	1 (<0.1%)
Blood vessel - vascular procedure site	8 (0.2%)	8 (0.2%)	16 (0.2%)
Gastrointestinal tract - duodenal	4 (0.1%)	3 (<0.1%)	7 (0.1%)
Gastrointestinal tract - esophageal	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gastrointestinal tract - gastric	10 (0.3%)	7 (0.2%)	17 (0.3%)
Gastrointestinal tract - large intestine / colon	6 (0.2%)	0	6 (<0.1%)
Gastrointestinal tract - small intestine (jejunum / ileum)	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Gastrointestinal tract - other	8 (0.2%)	0	8 (0.1%)
Intra-abdominal, site unknown	0	1 (<0.1%)	1 (<0.1%)
Intracranial - hemorrhagic transformation of ischemic stroke	0	1 (<0.1%)	1 (<0.1%)
Intracranial - intraparenchymal hemorrhage	5 (0.2%)	7 (0.2%)	12 (0.2%)
Intracranial - intraventricular hemorrhage	1 (<0.1%)	0	1 (<0.1%)
Intracranial - subdural	5 (0.2%)	4 (0.1%)	9 (0.1%)
Intracranial - subarachnoidal	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Intramuscular - with compartment syndrome	2 (<0.1%)	0	2 (<0.1%)
Intramuscular - without compartment syndrome	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Nasal	1 (<0.1%)	0	1 (<0.1%)
Pancreas	0	1 (<0.1%)	1 (<0.1%)
Retroperitoneal	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Skin - other	1 (<0.1%)	0	1 (<0.1%)
Unknown	1 (<0.1%)	0	1 (<0.1%)
Other	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)

ASA = Acetylsalicylic acid, bid = twice daily, od = once daily,
Non-CABG related TIMI major bleeding = Non coronary artery bypass graft related thrombolysis in myocardial infarction bleeding

Table displays outcome events meeting the definition as adjudicated by Independent Clinical Adjudication Committee (ICAC).The safety analysis set includes all randomized subjects who received at least one dose of study drug (rivaroxaban or rivaroxaban placebo). The on-treatment data scope includes outcome events observed from randomization until 2 days after permanent stop of the study drug.
Site of bleeding for TIMI major bleeding other than intracranial, is based on adjudication of bleeding site done for all ISTH major bleedings. Subjects are counted once for each category and can be included in more than one category.

Source: PH-40164/Table 14.3.1.3/41

日本人集団の結果は、17454_J_analysis/Table 14.3.1.3/49 を参照のこと。

2.7.6.1.2.3.9.2 安全性副次評価項目

2.7.6.1.2.3.9.2.1 ISTH 分類の「重大な出血」

全体集団における On-treatment 期間に認められた ISTH 分類の「重大な出血」の要約を表 2.7.6.1-24 に示す。

ISTH 分類の「重大な出血」の発現割合は、リバーロキサバン群で 4.3%（140/3,256 例）、プラセボ群で 3.1%（100/3,248 例）であり、発現率（100 人年あたり）は、それぞれ 2.18 及び 1.53 であった。リバーロキサバン群のプラセボ群に対する HR は 1.42（95%CI：1.10～1.84）であった。

ISTH 分類の「重大な出血」のカテゴリー別では、「致死的出血」の発現割合は、リバーロキサバン群で 0.2%（6/3,256 例）、プラセボ群で 0.2%（8/3,248 例）であり、発現率（100 人年あたり）は、それぞれ 0.09 及び 0.12 であった。リバーロキサバン群のプラセボ群に対する HR は 0.76（95%CI：0.26～2.19）であった。このうち、致死的な頭蓋内出血は、リバーロキサバン群で 0.1%未満（2 例）、プラセボ群で 0.2%（6 例）に認められ、リバーロキサバン群のプラセボ群に対する HR は 0.34（95%CI：0.07～1.67）であった。

「非致死的で重要な臓器出血」は、リバーロキサバン群で 0.9%（29/3,256 例）、プラセボ群で 0.8%（26/3,248 例）であり、発現率（100 人年あたり）は、それぞれ 0.45 及び 0.39 であった。リバーロキサバン群のプラセボ群に対する HR は 1.14（95%CI：0.67～1.93）であった。

「非致死的で重要でない臓器出血」（2g/dL 以上のヘモグロビン値の低下又は 6%以上のヘマトクリット値の低下、2 単位以上の輸血）は、リバーロキサバン群で 3.2%（105/3,256 例）、プラセボ群で 2.1%（69/3,248 例）であり、発現率（100 人年あたり）は、それぞれ 1.63 及び 1.05 であった。リバーロキサバン群のプラセボ群に対する HR は 1.54（95%CI：1.14～2.09）であった。

表 2.7.6.1-24 On-treatment 期間に認められた ISTH 分類の「重大な出血」（全体集団、SAF）

Bleeding Event Overall	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)		Rivaroxaban Placebo bid + ASA 100 mg od N=3248 (100%)		Rivaroxaban 2.5 mg bid + ASA 100 mg od vs Rivaroxaban Placebo bid + ASA 100 mg od	
Subcategories	n (%)	n/100 p-yrs (95% CI)	n (%)	n/100 p-yrs (95% CI)	HR (95% CI)	P-value
ISTH major bleeding	140 (4.3%)	2.18 (1.84; 2.58)	100 (3.1%)	1.53 (1.24; 1.86)	1.42 (1.10, 1.84)	0.0068
ISTH fatal bleeding	6 (0.2%)	0.09 (0.03; 0.20)	8 (0.2%)	0.12 (0.05; 0.24)	0.76 (0.26, 2.19)	0.6126
ISTH fatal intracranial bleeding	2 (<0.1%)	0.03 (0.00; 0.11)	6 (0.2%)	0.09 (0.03; 0.20)	0.34 (0.07, 1.67)	0.1631
ISTH non-fatal critical organ bleeding	29 (0.9%)	0.45 (0.30; 0.64)	26 (0.8%)	0.39 (0.26; 0.58)	1.14 (0.67, 1.93)	0.6298
ISTH non-fatal non critical organ bleeding (fall in Hb ≥ 2g/dl or hematocrit ≥ 6% and/or transfusion ≥ 2 units)	105 (3.2%)	1.63 (1.34; 1.98)	69 (2.1%)	1.05 (0.82; 1.33)	1.54 (1.14, 2.09)	0.0048

ASA = Acetylsalicylic acid 100 mg once daily, bid = twice daily, od = once daily, Rivaroxaban = Rivaroxaban 2.5 mg twice daily, ISTH = International Society on Thrombosis and Haemostasis, SAF = safety analysis set

Table displays outcome events meeting the definition as adjudicated by Independent Clinical Adjudication Committee (ICAC). The safety analysis set includes all randomized subjects who received at least one dose of study drug (rivaroxaban or rivaroxaban placebo). The on-treatment data scope includes outcome events observed from randomization until 2 days after permanent stop of the study drug.

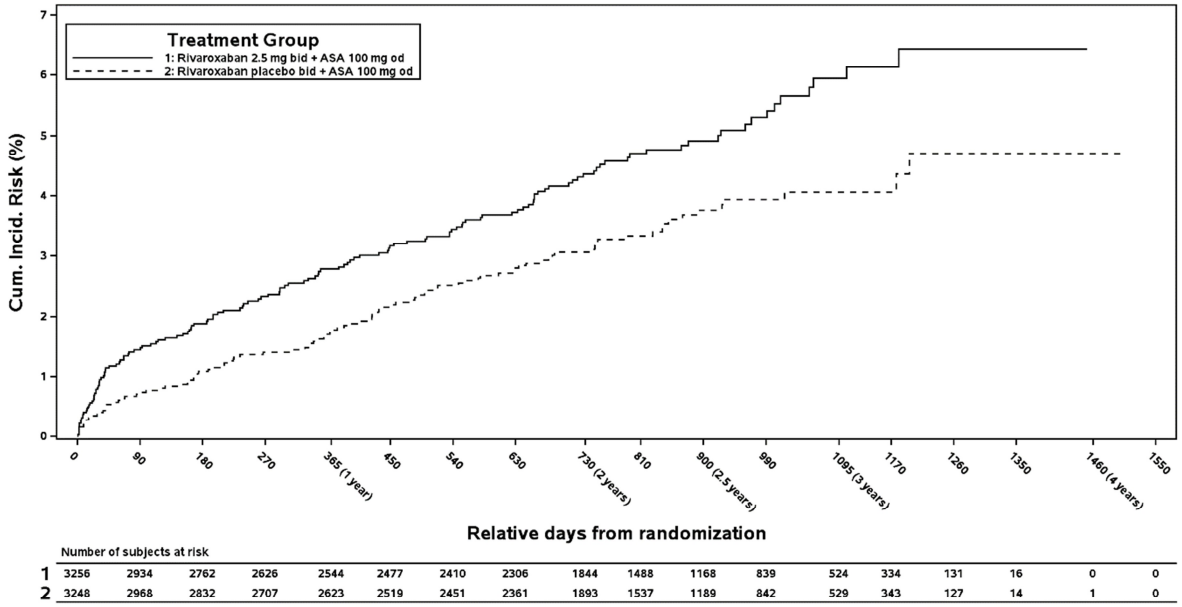
N = total number of subjects, n = number of subjects with first event, % = 100 * n / N, n/100 p-yrs = ratio of number of subjects with incident events /cumulative at-risk time. HR (95% CI): Hazard ratios (95% confidence interval) is based on the Cox proportional hazards model stratified by type of procedure and clopidogrel use (per IxRS), with treatment as the only covariate. P-value (2-sided) is based on the log rank test stratified by type of procedure and clopidogrel use with treatment as a fixed factor.

Source: PH-40164/Table 14.3.1.3/1

On-treatment 期間に認められた ISTH 分類の「重大な出血」の累積イベント発現率に関する Kaplan-Meier 曲線を図 2.7.6.1-12 に示す。

累積イベント発現率の Kaplan-Meier 曲線において、治験薬投与開始から 30 日以内にリバーロキサバン群とプラセボ群の間に乖離がみられ、プラセボ群と比較してリバーロキサバン群で治験薬投与開始後早期の発現率が高かった。一方、3 年までの累積イベント発現率の差は約 1%であり、9 ヵ月以降の群間差はおおむね一定であった。ISTH 分類の「重大な出血」の累積イベント発現率は、リバーロキサバン群及びプラセボ群で、それぞれ無作為割付けから 30 日後で 0.85%（95%CI：0.58～1.24）及び 0.37%（95%CI：0.21～0.66）、1 年後で 2.78%（95%CI：2.24～3.44）及び 1.74%（95%CI：1.32～2.28）、3 年後で 5.94%（95%CI：4.95～7.12）及び 4.06%（95%CI：3.30～4.99）であった（PH-40164/Table 14.3.1.3/22）。

図 2.7.6.1-12 On-treatment 期間に認められた ISTH 分類の「重大な出血」の累積イベント発現率の Kaplan-Meier 曲線（全体集団、SAF）



At-risk subject counts were calculated as at end of timepoint.
Figure displays outcome events meeting the definition as adjudicated by Independent Clinical Adjudication Committee (ICAC).
The safety analysis set includes all randomized subjects who received at least one dose of study drug (rivaroxaban or rivaroxaban placebo).
The on-treatment data scope includes outcome events from randomization until 2 days after permanent stop of study drug (rivaroxaban or rivaroxaban placebo).
bid = twice daily, od = once daily, ASA = acetylsalicylic acid
K-M = Kaplan-Meier, Cum. Incid. Risk (%) = K-M estimates of the cumulative incidence for an event, calculated as 100 * (1 minus the K-M estimates of the survival function).
Only the first occurrence of the outcome event under analysis within the data scope from a subject is considered.

Source: PH-40164/Figure 14.3.1.3/13

無作為割付けから ECOD までの ISTH 分類の「重大な出血」の発現割合は、リバーロキサバン群で 6.2%（201/3,256 例）、プラセボ群で 4.7%（153/3,248 例）（HR：1.33、95%CI：1.08～1.64）、全試験期間の ISTH 分類の「重大な出血」の発現割合は、6.3%（205 例）及び 4.8%（156 例）（HR：1.33、95%CI：1.08～1.64）であり、On-treatment 期間に認められた ISTH 分類の「重大な出血」の結果とおおむね一貫していた（PH-40164/Table 14.3.1.3/4、14.3.1.3/7）。

日本人集団の結果は、17454_J_analysis/Table 14.3.1.3/1、14.3.1.3/4、14.3.1.3/7、14.3.1.3/22 及び Figure 14.3.1.3/13 を参照のこと。

2.7.6.1.2.3.9.2.2 BARC 分類

全体集団における On-treatment 期間に認められた BARC 分類の出血事象の要約を表 2.7.6.1-25 に示す。

BARC 分類 Type 3b 以上の出血事象の発現割合は、リバーロキサバン群で 2.9%（93/3,256 例）、プラセボ群で 2.2%（73/3,248 例）であり、発現率（100 人年あたり）は、それぞれ 1.45 及び 1.11 であった。リバーロキサバン群のプラセボ群に対する HR は 1.29（95%CI：0.95～1.76）であった。

BARC 分類 Type 1～3b に分類される出血事象の発現割合は、プラセボ群と比較してリバーロキサバン群で高かったが、Type 3b を超える重症度の高い出血事象の発現割合はリバーロキサバン群とプラセボ群で同程度であった。

表 2.7.6.1-25 On-treatment 期間に認められた BARC 分類の出血事象（全体集団、SAF）

Bleeding Category	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)		Rivaroxaban Placebo bid + ASA 100 mg od N=3248 (100%)		Rivaroxaban 2.5 mg bid + ASA 100 mg od vs Rivaroxaban Placebo bid + ASA 100 mg od	
	n (%)	n/100p-yrs (95% CI)	n (%)	n/100p-yrs (95% CI)	HR (95% CI)	P-value
BARC type 3b and above	93 (2.9%)	1.45 (1.17; 1.77)	73 (2.2%)	1.11 (0.87; 1.40)	1.29 (0.95, 1.76)	0.0979
BARC type 1 to 3a	422 (13.0%)	7.02 (6.36; 7.72)	257 (7.9%)	4.09 (3.61; 4.63)	1.69 (1.45, 1.98)	<.0001
BARC type 1	173 (5.3%)	2.75 (2.36; 3.20)	109 (3.4%)	1.69 (1.39; 2.04)	1.62 (1.27, 2.05)	<.0001
BARC type 2	242 (7.4%)	3.88 (3.40; 4.40)	135 (4.2%)	2.10 (1.76; 2.48)	1.83 (1.49, 2.26)	<.0001
BARC type 3a	57 (1.8%)	0.88 (0.67; 1.14)	39 (1.2%)	0.59 (0.42; 0.81)	1.48 (0.98, 2.22)	0.0577
BARC type 3b	70 (2.1%)	1.09 (0.85; 1.37)	48 (1.5%)	0.73 (0.54; 0.97)	1.48 (1.02, 2.13)	0.0367
BARC type 3c	17 (0.5%)	0.26 (0.15; 0.42)	17 (0.5%)	0.26 (0.15; 0.41)	1.03 (0.53, 2.02)	0.9316
BARC type 4	0	0 (0.00; 0.06)	1 (<0.1%)	0.02 (0.00; 0.08)	-	-
BARC type 5a	1 (<0.1%)	0.02 (0.00; 0.09)	1 (<0.1%)	0.02 (0.00; 0.08)	1.02 (0.06, 16.34)	0.9876
BARC type 5b	5 (0.2%)	0.08 (0.02; 0.18)	7 (0.2%)	0.11 (0.04; 0.22)	0.72 (0.23, 2.28)	0.5799

ASA = acetylsalicylic acid 100 mg once daily, BARC = Bleeding Academic Research Consortium, bid = twice daily, od = once daily, Rivaroxaban = Rivaroxaban 2.5 mg twice daily, SAF = safety analysis set, N = total number of subjects, n = number of subjects with first event, % = 100 * n / N, n/100 p-yrs = ratio of number of subjects with incident events /cumulative at-risk time. HR (95% CI): Hazard ratios (95% confidence interval) is based on the Cox proportional hazards model stratified by type of procedure and clopidogrel use, with treatment as the only covariate. P-value (2-sided) is based on the log rank test stratified by type of procedure and clopidogrel use with treatment as a fixed factor.

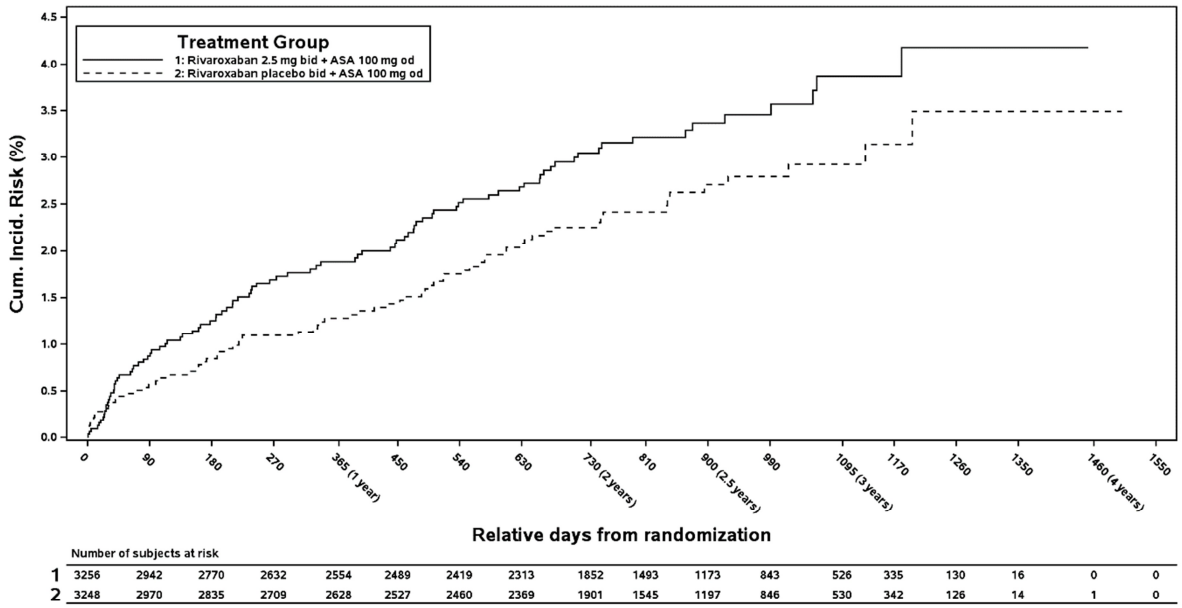
Table displays outcome events meeting the definition as adjudicated by Independent Clinical Adjudication Committee (ICAC). The safety analysis set includes all randomized subjects who received at least one dose of study drug (rivaroxaban or rivaroxaban placebo). The on-treatment data scope includes outcome events observed from randomization until 2 days after permanent stop of the study drug.

Source: PH-40164/Table 14.3.1.3/1

On-treatment 期間に認められた BARC 分類 Type 3b 以上の出血事象の累積イベント発現率に関する Kaplan-Meier 曲線を図 2.7.6.1-13 に示す。

累積イベント発現率の Kaplan-Meier 曲線において、プラセボ群と比較してリバーロキサバン群で治験薬投与開始後 60 日までに発現の増加がみられたが、3 年までの累積イベント発現率の差は約 0.7%であり、1 年以降の群間差はおおむね一定であった。BARC 分類 Type 3b 以上の出血事象の累積イベント発現率は、リバーロキサバン群及びプラセボ群で、それぞれ無作為割付けから 30 日後で 0.38%（95%CI：0.22～0.67）及び 0.34%（95%CI：0.19～0.62）、1 年後で 1.88%（95%CI：1.45～2.45）及び 1.28%（95%CI：0.94～1.76）、3 年後で 3.86%（95%CI：3.09～4.83）及び 2.92%（95%CI：2.28～3.73）であった（PH-40164/Table 14.3.1.3/31）。

図 2.7.6.1-13 On-treatment 期間に認められた BARC 分類 Type 3b 以上の出血事象の累積イベント発現率の Kaplan-Meier 曲線（全体集団、SAF）



At-risk subject counts were calculated as at end of timepoint.
Figure displays outcome events meeting the definition as adjudicated by Independent Clinical Adjudication Committee (ICAC).
The safety analysis set includes all randomized subjects who received at least one dose of study drug (rivaroxaban or rivaroxaban placebo).
The on-treatment data scope includes outcome events from randomization until 2 days after permanent stop of study drug (rivaroxaban or rivaroxaban placebo).
bid = twice daily, od = once daily, ASA = acetylsalicylic acid
K-M = Kaplan-Meier, Cum. Incid. Risk (%) = K-M estimates of the cumulative incidence for an event, calculated as 100 * (1 minus the K-M estimates of the survival function).
Only the first occurrence of the outcome event under analysis within the data scope from a subject is considered.

Source: PH-40164/Figure 14.3.1.3/22

無作為割付けから ECOD までの BARC 分類 Type 3b 以上の出血事象の発現割合は、リバーロキサバン群で 4.2%（138/3,256 例）、プラセボ群で 3.4%（109/3,248 例）（HR：1.27、95%CI：0.99～1.63）、全試験期間の BARC 分類 Type 3b 以上の出血事象の発現割合は、4.3%（140 例）及び 3.4%（112 例）（HR：1.26、95%CI：0.98～1.61）であり、On-treatment 期間に認められた BARC 分類 Type 3b 以上の出血事象の結果とおおむね一貫していた（PH-40164/Table 14.3.1.3/4、14.3.1.3/7）。

日本人集団の結果は、17454_J_analysis/Table 14.3.1.3/1、14.3.1.3/4、14.3.1.3/7、14.3.1.3/31 及び Figure 14.3.1.3/22 を参照のこと。

2.7.6.1.2.3.9.3 出血事象に関する部分集団解析

2.7.6.1.2.3.9.3.1 血行再建術のタイプとクロピドグレルの使用の有無別の TIMI 分類の「大出血」の部分集団解析

全体集団における On-treatment 期間に認められた TIMI 分類の「大出血」について、実際の血行再建術のタイプとクロピドグレルの使用の有無別の部分集団解析の結果を表 2.7.6.1-26 に示す。IxRS による無作為割付け時の層別因子とした血行再建術による部分集団解析の結果については PH-40164/Table 14.3.1.3/2 を参照のこと。

外科的血行再建術、血管内血行再建術でクロピドグレルの使用あり、及び血管内血行再建術でクロピドグレルの使用なしの各部分集団における、TIMI 分類の「大出血」のプラセボ群に対する HR は、それぞれ 0.88（95%CI：0.39～1.95）、1.40（95%CI：0.81～2.42）及び 2.31（95% CI：1.05～5.06）であり、リバーロキサバン群における TIMI 分類の「大出血」の発現リスクは外科的血行再建術で低く、血管内血行再建術のクロピドグレルの使用なしで高かった。一方、TIMI 分類の「大出血」のカテゴリー別において、「致死的出血」の発現リスクはいずれの部分集団においても各投与群で同程度であった。

表 2.7.6.1-26 実際の血行再建術のタイプとクロピドグレルの使用の有無別の On-treatment 期間に認められた TIMI 分類の「大出血」（全体集団、SAF）

Bleeding Event Subgroup	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256		Rivaroxaban Placebo bid + ASA 100 mg od N=3248		Rivaroxaban 2.5 mg bid + ASA 100 mg od vs Rivaroxaban Placebo bid + ASA 100 mg od	
Subcategories	**n (%)**	**n/100 p-yrs (95% CI)**	**n (%)**	**n/100 p-yrs (95% CI)**	**HR (95% CI)**	**P-value**
Surgery	**N = 1072**		**N = 1099**			
TIMI major bleeding	11 (1.0%)	0.51 (0.25; 0.91)	13 (1.2%)	0.58 (0.31; 1.00)	0.88 (0.39, 1.95)	0.7450
Fatal bleeding (CABG or non-CABG)	3 (0.3%)	0.14 (0.03; 0.40)	3 (0.3%)	0.13 (0.03; 0.39)	1.04 (0.21, 5.13)	0.9661
Intracranial bleeding (CABG or non-CABG)	2 (0.2%)	0.09 (0.01; 0.33)	3 (0.3%)	0.13 (0.03; 0.39)	0.69 (0.12, 4.14)	0.6844
Non-CABG related TIMI major bleeding	11 (1.0%)	0.51 (0.25; 0.91)	13 (1.2%)	0.58 (0.31; 1.00)	0.88 (0.39, 1.95)	0.7450
Fatal bleeding	3 (0.3%)	0.14 (0.03; 0.40)	3 (0.3%)	0.13 (0.03; 0.39)	1.04 (0.21, 5.13)	0.9661
Any intracranial bleeding	2 (0.2%)	0.09 (0.01; 0.33)	3 (0.3%)	0.13 (0.03; 0.39)	0.69 (0.12, 4.14)	0.6844
Clinically overt signs of hemorrhage associated with a drop in hemoglobin of ≥ 5 g/dl or drop in Hct of ≥15%	7 (0.7%)	0.32 (0.13; 0.67)	8 (0.7%)	0.36 (0.16; 0.71)	0.91 (0.33, 2.50)	0.8488
CABG-related TIMI major bleeding	0	0 (0.00; 0.17)	0	0 (0.00; 0.16)		

Bleeding Event Subgroup	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256		Rivaroxaban Placebo bid + ASA 100 mg od N=3248		Rivaroxaban 2.5 mg bid + ASA 100 mg od vs Rivaroxaban Placebo bid + ASA 100 mg od	
Subcategories	**n (%)**	**n/100 p-yrs (95% CI)**	**n (%)**	**n/100 p-yrs (95% CI)**	**HR (95% CI)**	**P-value**
Endovascular with clopidogrel						
	N = 1495		**N = 1481**			
TIMI major bleeding	31 (2.1%)	1.05 (0.72; 1.49)	22 (1.5%)	0.75 (0.47; 1.14)	1.40 (0.81, 2.42)	0.2228
Fatal bleeding (CABG or non-CABG)	2 (0.1%)	0.07 (0.01; 0.24)	2 (0.1%)	0.07 (0.01; 0.25)	0.99 (0.14, 7.05)	0.9945
Intracranial bleeding (CABG or non-CABG)	3 (0.2%)	0.10 (0.02; 0.30)	9 (0.6%)	0.31 (0.14; 0.58)	0.33 (0.09, 1.22)	0.0813
Non-CABG related TIMI major bleeding	31 (2.1%)	1.05 (0.72; 1.49)	21 (1.4%)	0.72 (0.44; 1.09)	1.47 (0.84, 2.56)	0.1707
Fatal bleeding	2 (0.1%)	0.07 (0.01; 0.24)	2 (0.1%)	0.07 (0.01; 0.25)	0.99 (0.14, 7.05)	0.9945
Any intracranial bleeding	3 (0.2%)	0.10 (0.02; 0.30)	9 (0.6%)	0.31 (0.14; 0.58)	0.33 (0.09, 1.22)	0.0813
Clinically overt signs of hemorrhage associated with a drop in hemoglobin of ≥ 5 g/dl or drop in Hct of ≥15%	27 (1.8%)	0.92 (0.60; 1.33)	12 (0.8%)	0.41 (0.21; 0.71)	2.24 (1.13, 4.42)	0.0169
CABG-related TIMI major bleeding	0	0 (0.00; 0.12)	1 (<0.1%)	0.03 (0.00; 0.19)		
Fatal bleeding	0	0 (0.00; 0.12)	0	0 (0.00; 0.13)		
Perioperative intracranial bleeding	0	0 (0.00; 0.12)	0	0 (0.00; 0.13)		
Reoperation after closure of the sternotomy incision for the purpose of controlling bleeding	0	0 (0.00; 0.12)	0	0 (0.00; 0.13)		
Transfusion of ≥5U PRBCs or whole blood within a 48-h period (cell saver transfusion will not be counted in blood product calculations)	0	0 (0.00; 0.12)	1 (<0.1%)	0.03 (0.00; 0.19)		
Chest tube output >2 L within a 24-h period	0	0 (0.00; 0.12)	0	0 (0.00; 0.13)		
Endovascular without clopidogrel						
	N = 685		**N = 663**			
TIMI major bleeding	20 (2.9%)	1.47 (0.90; 2.27)	9 (1.4%)	0.63 (0.29; 1.20)	2.31 (1.05, 5.06)	0.0322
Fatal bleeding (CABG or non-CABG)	1 (0.1%)	0.07 (0.00; 0.41)	1 (0.2%)	0.07 (0.00; 0.39)	1.03 (0.06, 16.39)	0.9858
Intracranial bleeding (CABG or non-CABG)	8 (1.2%)	0.59 (0.25; 1.15)	5 (0.8%)	0.35 (0.11; 0.82)	1.65 (0.54, 5.06)	0.3721
Non-CABG related TIMI major bleeding	20 (2.9%)	1.47 (0.90; 2.27)	9 (1.4%)	0.63 (0.29; 1.20)	2.31 (1.05, 5.06)	0.0322
Fatal bleeding	1 (0.1%)	0.07 (0.00; 0.41)	1 (0.2%)	0.07 (0.00; 0.39)	1.03 (0.06, 16.39)	0.9858

Bleeding Event Subgroup	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256		Rivaroxaban Placebo bid + ASA 100 mg od N=3248		Rivaroxaban 2.5 mg bid + ASA 100 mg od vs Rivaroxaban Placebo bid + ASA 100 mg od	
Subcategories	**n (%)**	**n/100 p-yrs (95% CI)**	**n (%)**	**n/100 p-yrs (95% CI)**	**HR (95% CI)**	**P-value**
Any intracranial bleeding	8 (1.2%)	0.59 (0.25; 1.15)	5 (0.8%)	0.35 (0.11; 0.82)	1.65 (0.54, 5.06)	0.3721
Clinically overt signs of hemorrhage associated with a drop in hemoglobin of ≥ 5 g/dl or drop in Hct of ≥15%	12 (1.8%)	0.88 (0.45; 1.54)	4 (0.6%)	0.28 (0.08; 0.72)	3.12 (1.01, 9.67)	0.0378
CABG-related TIMI major bleeding	0	0 (0.00; 0.27)	0	0 (0.00; 0.26)		

ASA = acetylsalicylic acid 100 mg once daily, Rivaroxaban = Rivaroxaban 2.5 mg twice daily, CABG = coronary artery bypass graft, bid = twice daily, od = once daily, TIMI = Thrombolysis in Myocardial Infarction (study group), SAF = safety analysis set; N = total number of subjects, n = number of subjects with first event, % = 100 * n / N, n/100 p-yrs = ratio of number of subjects with incident events /cumulative at-risk time.
Table displays outcome events as adjudicated by Independent Clinical Adjudication Committee (ICAC).
The safety analysis set includes all randomized subjects who received at least one dose of study drug (rivaroxaban or rivaroxaban placebo). The on-treatment data scope includes outcome events observed from randomization until 2 days after permanent stop of the study drug. Only the first occurrence of the outcome event under analysis within the data scope from a subject is considered. HR (95% CI) is based on the Cox proportional hazards model with treatment as the only covariate.
P-value is based on the log rank test with treatment as the only covariate.
Source: PH-40164/Table 14.3.1.3/3

日本人集団の結果は、17454_J_analysis/Table 14.3.1.3/2 及び 14.3.1.3/3 を参照のこと。

2.7.6.1.2.3.9.3.2 人口統計学的及びベースラインの特性に関する TIMI 分類の「大出血」の部分集団解析

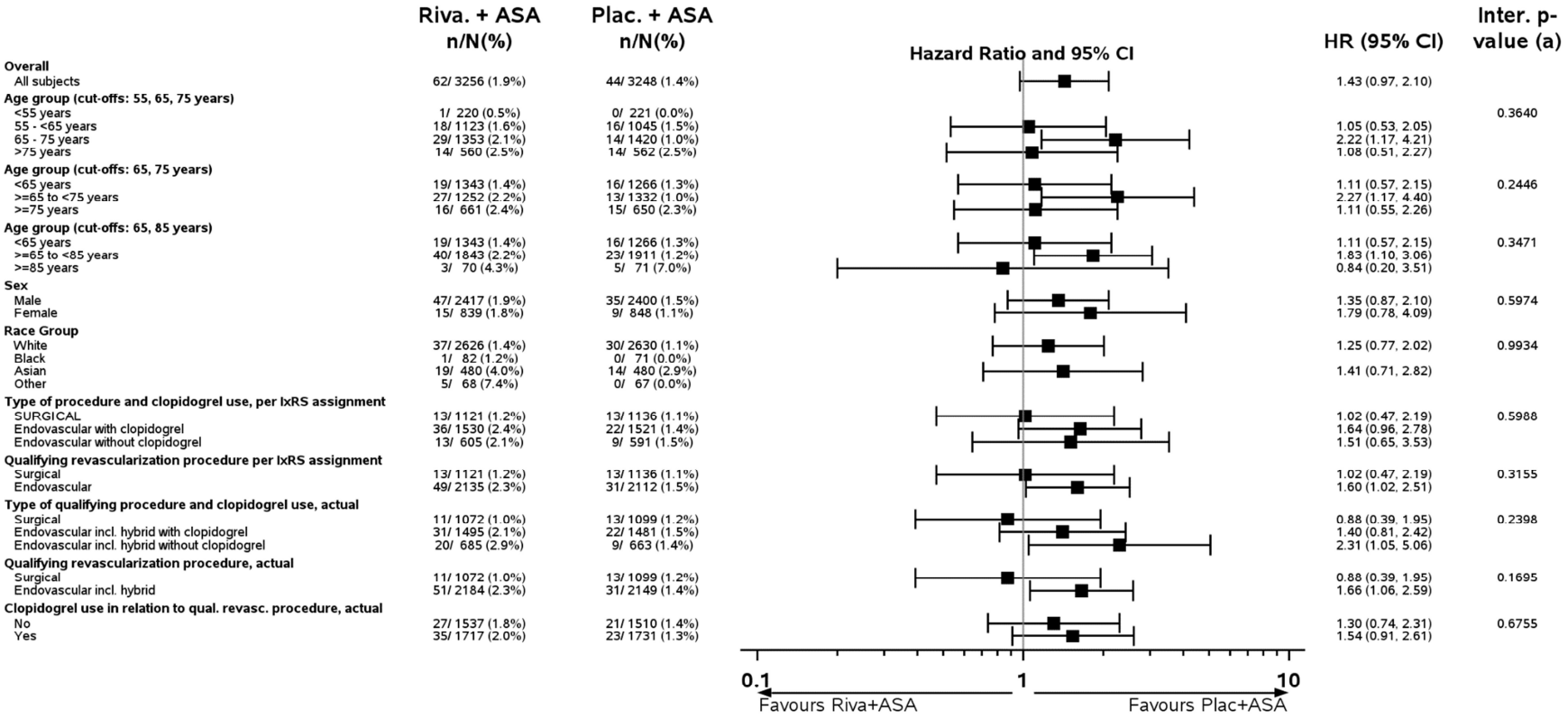
全体集団における TIMI 分類の「大出血」について、人口統計学的及びベースラインの特性による影響を評価するために、Cox 比例ハザードモデルを用いて部分集団解析を実施した。On-treatment 期間に認められた TIMI 分類の「大出血」の部分集団解析の Forest プロットを図 2.7.6.1-14 に示す。

全体的に、これらの部分集団解析の結果は全体集団の結果とおおむね一貫していた。

糖尿病の有無別の部分集団解析において、TIMI 分類の「大出血」のプラセボ群に対する HR は、糖尿病歴のない部分集団で 1.01（95%CI：0.61～1.66）、糖尿病を有する部分集団で 2.45（95%CI：1.28～4.69）であり、交互作用項の p 値が 0.05 を下回ったが（p＝0.0334）、Gail-Simon 検定において質的交互作用の p 値は 0.05 を上回っていた（p＝0.5000）（PH-40164/Table 14.3.1.3/37）。なお、事後解析における ISTH 分類の「重大な出血」の部分集団解析では、いずれの部分集団においても交互作用項の p 値が 0.05 を上回り、糖尿病の有無による影響は示唆されなかった（PH-40164/Post-hoc Table 14.3.7.2.1/10、Figure 14.3.7.2.1/1）。

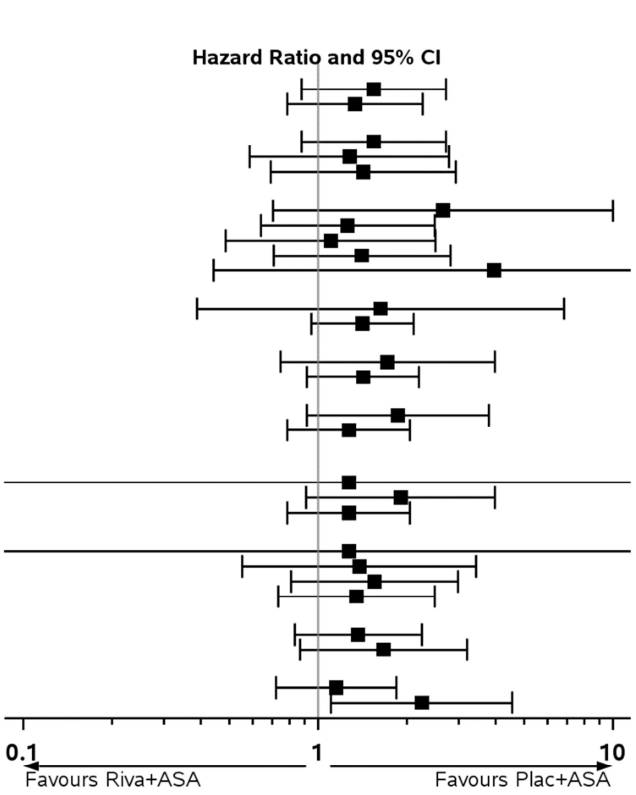
日本人集団の結果は、17454_J_analysis/Table 14.3.1.3/40 及び Figure 14.3.1.3/61 を参照のこと。

図 2.7.6.1-14 人口統計学的特性及びベースラインの疾患特性別の On-treatment 期間に認められた TIMI 分類の「大出血」の Forest プロット（全体集団、SAF）



(continued)

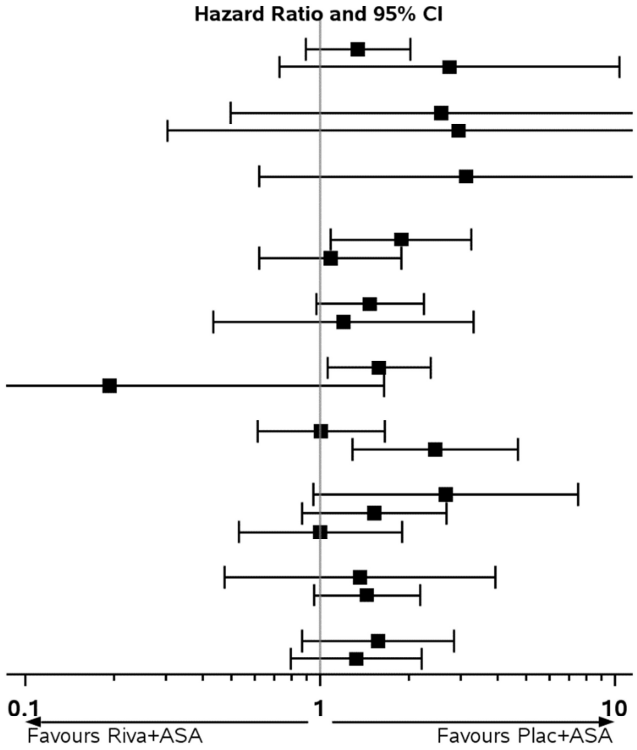
	Riva. + ASA n/N(%)	Plac. + ASA n/N(%)	HR (95% CI)	Inter. p-value (a)
Clopidogrel use at the time of randomization				
No	30/ 1603 (1.9%)	20/ 1601 (1.2%)	1.55 (0.88, 2.72)	0.7090
Yes	32/ 1646 (1.9%)	24/ 1637 (1.5%)	1.33 (0.78, 2.26)	
Clopidogrel use continued after randomization (days)				
None	30/ 1603 (1.9%)	20/ 1601 (1.2%)	1.55 (0.88, 2.72)	0.9279
<= 30 days	15/ 983 (1.5%)	11/ 926 (1.2%)	1.28 (0.59, 2.78)	
> 30 days	17/ 642 (2.6%)	13/ 676 (1.9%)	1.42 (0.69, 2.92)	
Geographic Region 1				
North America	8/ 339 (2.4%)	3/ 343 (0.9%)	2.65 (0.70, 9.99)	0.6902
Western Europe	19/ 898 (2.1%)	15/ 891 (1.7%)	1.26 (0.64, 2.48)	
Eastern Europe	12/ 1299 (0.9%)	11/ 1297 (0.8%)	1.10 (0.49, 2.50)	
Asia Pacific	19/ 477 (4.0%)	14/ 478 (2.9%)	1.41 (0.71, 2.81)	
South America	4/ 243 (1.6%)	1/ 239 (0.4%)	3.95 (0.44, 35.38)	
Geographic Region 3				
US	5/ 257 (1.9%)	3/ 258 (1.2%)	1.63 (0.39, 6.81)	0.8448
non-US	57/ 2999 (1.9%)	41/ 2990 (1.4%)	1.41 (0.95, 2.11)	
Weight group (cut-off 60 kg)				
<=60 kg	14/ 529 (2.6%)	9/ 538 (1.7%)	1.72 (0.74, 3.98)	0.7285
>60 kg	48/ 2694 (1.8%)	34/ 2681 (1.3%)	1.42 (0.91, 2.20)	
eGFR (cut-offs: 60 ml/min/1.73m2)				
<60 ml/min/1.73m2	21/ 649 (3.2%)	12/ 657 (1.8%)	1.86 (0.92, 3.79)	0.3726
>=60 ml/min/1.73m2	38/ 2483 (1.5%)	30/ 2474 (1.2%)	1.27 (0.79, 2.05)	
eGFR (cut-offs: 15, 30 and 60 ml/min/1.73m2)				
<15 ml/min/1.73m2	0/ 1 (0.0%)	0/ 0		0.6371
15 - <30 ml/min/1.73m2	1/ 13 (7.7%)	1/ 28 (3.6%)	1.27 (0.08, 20.80)	
30 - <60 ml/min/1.73m2	20/ 635 (3.1%)	11/ 629 (1.7%)	1.90 (0.91, 3.98)	
>=60 ml/min/1.73m2	38/ 2483 (1.5%)	30/ 2474 (1.2%)	1.27 (0.79, 2.05)	
eGFR (cut-offs: 30, 50 and 80 ml/min/1.73m2)				
<30 ml/min/1.73m2	1/ 14 (7.1%)	1/ 28 (3.6%)	1.27 (0.08, 20.80)	0.9818
30 - 50 ml/min/1.73m2	11/ 337 (3.3%)	8/ 303 (2.6%)	1.38 (0.55, 3.44)	
>50 - 80 ml/min/1.73m2	23/ 1355 (1.7%)	15/ 1360 (1.1%)	1.55 (0.81, 2.97)	
>80 ml/min/1.73m2	24/ 1426 (1.7%)	18/ 1440 (1.3%)	1.35 (0.73, 2.48)	
Fragile subjects				
No	37/ 2323 (1.6%)	27/ 2317 (1.2%)	1.37 (0.83, 2.24)	0.6457
Yes	23/ 822 (2.8%)	15/ 826 (1.8%)	1.66 (0.87, 3.19)	
Prior coronary artery disease				
No	37/ 2215 (1.7%)	33/ 2242 (1.5%)	1.15 (0.72, 1.84)	0.1245
Yes	25/ 1041 (2.4%)	11/ 1006 (1.1%)	2.24 (1.10, 4.56)	



(continued)

2.7.6.1

	Riva. + ASA n/N(%)	Plac. + ASA n/N(%)	HR (95% CI)	Inter. p-value (a)
Prior MI				
No	54/ 2896 (1.9%)	41/ 2902 (1.4%)	1.34 (0.90, 2.02)	0.3655
Yes	8/ 360 (2.2%)	3/ 345 (0.9%)	2.75 (0.73, 10.38)	
Prior MI and age <65 years				
No	5/ 220 (2.3%)	2/ 226 (0.9%)	2.57 (0.50, 13.31)	0.9312
Yes	3/ 140 (2.1%)	1/ 119 (0.8%)	2.95 (0.30, 28.68)	
Prior MI and eGFR < 60 mL/min				
No	6/ 258 (2.3%)	2/ 222 (0.9%)	3.13 (0.62, 15.73)	0.9929
Yes	2/ 86 (2.3%)	0/ 102 (0.0%)		
Prior history of limb revascularization				
No	36/ 2084 (1.7%)	20/ 2103 (1.0%)	1.88 (1.09, 3.25)	0.1631
Yes	26/ 1172 (2.2%)	24/ 1144 (2.1%)	1.08 (0.62, 1.89)	
Carotid artery disease history				
No	54/ 2978 (1.8%)	37/ 2958 (1.3%)	1.48 (0.97, 2.25)	0.6854
Yes	8/ 277 (2.9%)	7/ 287 (2.4%)	1.20 (0.44, 3.31)	
History of heart failure				
No	61/ 2988 (2.0%)	39/ 2975 (1.3%)	1.58 (1.06, 2.36)	0.0671
Yes	1/ 267 (0.4%)	5/ 272 (1.8%)	0.19 (0.02, 1.65)	
Diabetes mellitus				
No	31/ 1958 (1.6%)	31/ 1942 (1.6%)	1.01 (0.61, 1.66)	0.0334
Yes	31/ 1298 (2.4%)	13/ 1305 (1.0%)	2.45 (1.28, 4.69)	
Smoking status				
NEVER	13/ 653 (2.0%)	5/ 686 (0.7%)	2.66 (0.95, 7.48)	0.2398
FORMER	30/ 1466 (2.0%)	20/ 1440 (1.4%)	1.53 (0.87, 2.69)	
CURRENT	19/ 1136 (1.7%)	19/ 1122 (1.7%)	1.00 (0.53, 1.89)	
Hypertension				
No	8/ 599 (1.3%)	6/ 610 (1.0%)	1.37 (0.47, 3.94)	0.8885
Yes	54/ 2657 (2.0%)	38/ 2638 (1.4%)	1.44 (0.95, 2.19)	
Hyperlipidemia				
No	28/ 1305 (2.1%)	18/ 1295 (1.4%)	1.57 (0.87, 2.84)	0.6747
Yes	34/ 1950 (1.7%)	26/ 1953 (1.3%)	1.33 (0.80, 2.21)	



(continued)

	Riva. + ASA n/N(%)	Plac. + ASA n/N(%)	HR (95% CI)	Inter. p-value (a)
ABI/TBI categories at baseline (Month 1 vis				
ABI <= 0.80 or TBI <= 0.60	13/ 827 (1.6%)	10/ 787 (1.3%)	1.23 (0.54, 2.80)	0.6836
ABI > 0.80 and/or TBI > 0.60	43/ 2236 (1.9%)	32/ 2283 (1.4%)	1.39 (0.88, 2.20)	
TBI and ABI not done	6/ 193 (3.1%)	2/ 178 (1.1%)	3.10 (0.62, 15.36)	
Atrial fibrillation disease history				
No	59/ 3165 (1.9%)	43/ 3160 (1.4%)	1.39 (0.94, 2.06)	0.4850
Yes	3/ 91 (3.3%)	1/ 87 (1.1%)	3.58 (0.37, 34.50)	
Atrial flutter disease history				
No	61/ 3241 (1.9%)	44/ 3237 (1.4%)	1.41 (0.95, 2.07)	0.9760
Yes	1/ 15 (6.7%)	0/ 10 (0.0%)		
Critical limb ischemia				
No	47/ 2269 (2.1%)	27/ 2285 (1.2%)	1.77 (1.10, 2.84)	0.1089
Yes	15/ 987 (1.5%)	17/ 962 (1.8%)	0.89 (0.44, 1.78)	
Critical leg ischemia categories				
No critical leg ischemia	47/ 2269 (2.1%)	27/ 2285 (1.2%)	1.77 (1.10, 2.84)	0.1142
Critical leg ischemia history	5/ 393 (1.3%)	10/ 386 (2.6%)	0.51 (0.17, 1.50)	
Critical leg ischemia ongoing	10/ 594 (1.7%)	7/ 576 (1.2%)	1.46 (0.55, 3.83)	
Length of target lesion on the index leg				
SHORT (< 5 CM)	10/ 708 (1.4%)	11/ 762 (1.4%)	1.01 (0.43, 2.38)	0.3929
INTERMEDIATE (5 CM TO < 15 CM)	21/ 1325 (1.6%)	10/ 1262 (0.8%)	2.05 (0.96, 4.35)	
LONG (>= 15 CM)	27/ 1114 (2.4%)	22/ 1120 (2.0%)	1.22 (0.69, 2.13)	
Time from qualifying revasc. procedure to				
< Median (Days)	30/ 1590 (1.9%)	23/ 1536 (1.5%)	1.28 (0.74, 2.21)	0.5820
>= Median (Days)	32/ 1666 (1.9%)	21/ 1712 (1.2%)	1.59 (0.92, 2.76)	
Statin use during study				
No	15/ 655 (2.3%)	11/ 612 (1.8%)	1.35 (0.62, 2.95)	0.8591
Yes	47/ 2601 (1.8%)	33/ 2636 (1.3%)	1.45 (0.93, 2.26)	

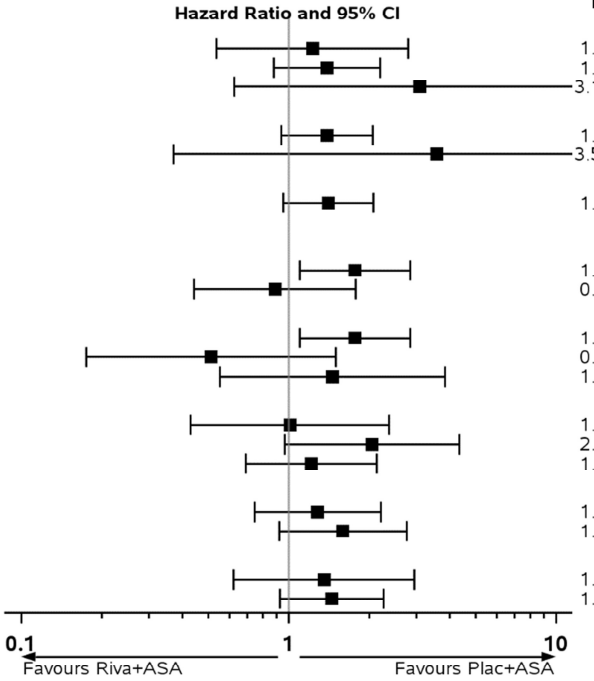


Figure displays outcome events meeting the definition as adjudicated by Independent Clinical Adjudication Committee (ICAC). Subgroup variables from Atrial fibrillation disease history and below are added post-hoc.
The safety analysis set includes all randomized subjects who received at least one dose of study drug (rivaroxaban or rivaroxaban placebo).
The on-treatment data scope includes outcome events from randomization until 2 days after permanent stop of study drug (rivaroxaban or rivaroxaban placebo).
Only the first occurrence of the outcome event under analysis within the data scope from a subject is considered. Subjects will be considered fragile if age >75 years or weight <=50 kg or baseline eGFR <50 mL/min/1.73m2.
bid = twice daily, od = once daily, ASA = acetylsalicylic acid, CI = confidence interval, Riva. + ASA = Rivaroxaban 2.5 mg bid + ASA 100 mg od, Plac. + ASA = Rivaroxaban placebo bid + ASA 100 mg od
n = number of subjects with events, N = number of subjects at risk, % = 100 * n/N. Inter. = Interaction
HR (95% CI) is based on the Cox proportional hazards model stratified by type of procedure and clopidogrel use (per IxRS) (except for subgroups related to qualifying revascularization procedure or clopidogrel use), with treatment as the only covariate.
(a) P-value for interaction is based on the Cox proportional hazards model stratified by type of procedure and clopidogrel use (per IxRS) by adding the corresponding treatment interaction term.

Source: PH-40164/Figure 14.3.1.3/43

2.7.6.1.2.3.9.4 出血事象のその他の解析

2.7.6.1.2.3.9.4.1 致死的出血

本項では、致死的出血に関する結果の詳細について記述する。全体集団における On-treatment 期間に認められた TIMI 分類の「致死的出血」の一覧を表 2.7.6.1-27 に示す。

TIMI 分類の「致死的出血」の発現割合は、リバーロキサバン群で 0.2%（6/3,256 例）、プラセボ群で 0.2%（6/3,248 例）であり、発現率（100 人年あたり）は両投与群共に 0.09 であった（2.7.6.1.2.3.9.1.1）。

リバーロキサバン群における「致死的出血」の出血部位の内訳は、頭蓋内が 2 例（くも膜下、脳実質内が各 1 例）、血管処置部位が 2 例（血管形成術時の動脈破裂、動脈内膜剥離術の縫合不全が各 1 例）、消化管が 2 例（胃、非閉塞性腸管虚血が各 1 例）であった。3 例（血管処置部位の出血の 2 例及び非閉塞性腸管虚血の 1 例）が ISTH 分類における輸血を必要とする出血であった。

プラセボ群における「致死的出血」の出血部位の内訳は、頭蓋内が 4 例（硬膜下 2 例、くも膜下 1 例、脳実質内 1 例）、血管処置部位が 1 例（右下肢）、腹膜が 1 例（腹部大動脈瘤破裂）であった。

ISTH 分類における「致死的出血」は、上述の TIMI 分類による各投与群 6 例の他に、プラセボ群の 2 例（頭蓋内出血と同日に虚血性脳卒中を発現した 1 例、特発性硬膜下出血を発現した 1 例）に報告された。これらの出血事象はいずれも TIMI 分類の「致死的出血」（7 日以内に死亡に至った直接の死因の出血）に該当しないと判定された（PH-40164/Section 10.6.4.1）。

表 2.7.6.1-27 On-treatment 期間に認められた TIMI 分類の「致死的出血」の一覧（全体集団、SAF）

Subject ID	ISTH major bleeding criteria and BARC bleeding classification	Bleeding Event, specify, investigator	Site of bleeding as documented by ICAC	Extent of exposure* (days)	Specific treatment(s) of Bleeding Event, investigator	Brief narrative of the bleeding, per investigator
Rivaroxaban 2.5 mg bid + Aspirin 100 mg od						
[redacted]	Bleeding causing a fall in HB or Hct as defined, or leading to transfusion; fatal bleeding BARC TYPE 5B	Bleeding: Non occlusive mesenteric ischemia; site: Gastrointestinal tract	Gastrointestinal tract, other	16	Plasma (FFP) transfusion	The subject was found falling down in toilet. Taken in the ambulance, and used AED but passed away for idiopathic VF, and significant gastrointestinal bleeding with bloody stools and hematemesis were found.
[redacted]	Fatal bleeding BARC TYPE 5A	Bleeding: Hemorrhagic erosive gastritis; site: Gastrointestinal tract	Gastrointestinal tract – Gastric	238	Remedial systemic drug therapy, including antihemorrhagic agents (cryoprecipitate, prothrombin complex concentrates, antifibrinolytic agents, vasoactive agents, etc.).	There was visible blood. Bleeding was symptom of hemorrhagic erosive gastritis
[redacted]	Bleeding causing a fall in HB or Hct as defined, or leading to transfusion; fatal bleeding BARC TYPE 5B	Bleeding: Artery rupture; site: Blood vessel – vascular procedure site	Blood vessel – vascular procedure site	446	Remedial systemic drug therapy, including antihemorrhagic agents (cryoprecipitate, prothrombin complex concentrates, antifibrinolytic agents, vasoactive agents, etc.).	Artery rupture during angioplasty. Bad evolution, patient died.
[redacted]	Bleeding causing a fall in HB or Hct as defined, or leading to transfusion; fatal bleeding BARC TYPE 5B	Bleeding: Postoperative bleeding because of suture insufficiently; site: Blood vessel – vascular procedure site	Blood vessel – vascular procedure site	11	Major procedure – endovascular/interventional radiology or surgical/open, Required unplanned take back procedure to control bleeding	It was complication of the endarterectomy (qualifying revascularization). Main reason is the insufficiency of arterial suture. After reoperation there was no bleeding and patient went home at [redacted]th [redacted]

2.7.6.1

Subject ID	ISTH major bleeding criteria and BARC bleeding classification	Bleeding Event, specify, investigator	Site of bleeding as documented by ICAC	Extent of exposure* (days)	Specific treatment(s) of Bleeding Event, investigator	Brief narrative of the bleeding, per investigator
[redacted]	Fatal bleeding, Symptomatic bleeding in a critical area or organ BARC TYPE 5B	Bleeding: intracranial hemorrhage (subarachnoid hemorrhage); site: Intracranial	Intracranial – subarachnoidal	545		He visited [redacted] 20[redacted] and had no problems at that time. He collapsed after returning to the home and diagnosed subarachnoid hemorrhage at other hospital. He died on [redacted] 20[redacted]
[redacted]	Fatal bleeding, Symptomatic bleeding in a critical area or organ BARC TYPE 5B	Bleeding: intracranial hemorrhage; frontal temporal parietal; site: Intracranial	Intracranial – Intra-parenchymal hemorrhage	39	Major procedure – endovascular/interventional radiology or surgical/open, Plasma (FFP) transfusion	It was intracranial hemorrhage. Could be related with study medication use.
Rivaroxaban Placebo + Aspirin 100 mg od						
[redacted]	Fatal bleeding, Symptomatic bleeding in a critical area or organ BARC TYPE 5B	Bleeding: Acute subarachnoid hemorrhage; site: Intracranial	Intracranial – subarachnoidal	457	NONE	Fatal due to intracranial hemorrhage
[redacted]	Fatal bleeding, Symptomatic bleeding in a critical area or organ BARC TYPE 5B	Bleeding: Extensive hemorrhagic transformation of the ischemic stroke; site: Intracranial	Intracranial – Intra-parenchymal hemorrhage	431	Major procedure – endovascular/interventional radiology or surgical/open, other	See reports of ischemic stroke made by principal investigator
[redacted]	Fatal bleeding, Symptomatic bleeding in a critical area or organ BARC TYPE 5B	Bleeding: intracranial; site: Intracranial	Intracranial – subdural	157	NONE	The patient was found dead [redacted] 20[redacted] What really happened I do not know, but autopsy showed massive intracranial bleeding.
[redacted]	Fatal bleeding, Symptomatic bleeding in a critical area or organ BARC TYPE 5B	Bleeding: intracranial bleeding after trauma; site: Intracranial	Intracranial – subdural	68	NONE	The patient suffered bleeding in the brain after falling on his head with drunkenness. Bleeding was fatal. The autopsy was done.

Subject ID	ISTH major bleeding criteria and BARC bleeding classification	Bleeding Event, specify, investigator	Site of bleeding as documented by ICAC	Extent of exposure* (days)	Specific treatment(s) of Bleeding Event, investigator	Brief narrative of the bleeding, per investigator
[redacted]	Fatal bleeding BARC TYPE 5A	Bleeding: Bleeding in right leg (exact location unknown); site: Blood vessel – vascular procedure site	Blood vessel – vascular procedure site	9	NONE	As reported by patient´s daughter, the bleeding in right leg (site of qualifying revascularization procedure) was intense and it was necessary to activate the emergency service.
[redacted]	Fatal bleeding, Symptomatic bleeding in a critical area or organ BARC TYPE 5B	Bleeding: Rupture of the aneurysm of the abdominal aorta [redacted] 20[redacted]; site: Peritoneal	Retroperitoneal	306	NONE	The patient´s death came from a rupture of the abdominal aorta (end point).

Rivaroxaban = Rivaroxaban 2.5 mg twice daily, BARC = Bleeding Academic Research Consortium, ID = identification; ISTH = International Society on Thrombosis and Haemostasis, TIMI = Thrombolysis in Myocardial Infarction (study group), HB = hemoglobin, AED = automated external defibrillator, VF = ventricular fibrillation

Table displays outcome events meeting the definition as adjudicated by Independent Clinical Adjudication Committee (ICAC). The on-treatment data scope includes all outcome events observed from randomization until 2 days following permanent discontinuation of the study drug.

*Extent of exposure is a derived variable that includes the time from the first day through the last day of treatment.

Source: PH-40164/Listing 16.2.5/2, 16.2.5/4 (compliance), 16.2.8.2/1 (per ICAC), 16.2.8.2/2 (per investigator), 16.2.8.3/6

2.7.6.1.2.3.9.4.2 重大ではない出血事象

TIMI 分類、ISTH 分類及び BARC 分類に基づき ICAC が評価した、全体集団における On-treatment 期間に認められた重大ではない出血事象を表 2.7.6.1-28 に示す。

重大ではない出血事象として、TIMI 分類では、「小出血」（3g/dL 以上 5g/dL 未満のヘモグロビン値の低下又は 9%以上 15%未満のヘマトクリット値の低下）、「臨床的に注意が必要な出血」（「大出血」及び「小出血」の判定基準に該当しない治療を要する出血）、又は「微出血」（上記判定基準のいずれにも該当しない出血）について評価した。また、ISTH 分類では「重大ではないが臨床的に問題となる出血」及び「臨床的に重要ではない小出血」の定義に該当する事象、BARC 分類では Type 3b 未満（BARC 分類 Type 1、2 及び 3a）に分類される出血事象について評価した。TIMI 分類、ISTH 分類及び BARC 分類に基づく重大ではない出血事象の定義の詳細については PH-40164/Section 16.1.4.3_ICAC Charter version 4.0 を参照のこと。

全体的に、重大ではない出血事象の発現は、プラセボ群と比較してリバーロキサバン群で多く認められた。

表 2.7.6.1-28 On-treatment 期間に認められた重大ではない出血事象の要約（全体集団、SAF）

Bleeding Event	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)		Rivaroxaban Placebo bid + ASA 100 mg od N=3248 (100%)		Rivaroxaban 2.5 mg bid + ASA 100 mg od vs Rivaroxaban Placebo bid + ASA 100 mg od	
Subcategories	n (%)	n/100p-yrs	n (%)	n/100p-yrs	HR (95% CI)	P-value
TIMI minor bleeding	46 (1.4%)	0.71 (0.52; 0.95)	31 (1.0%)	0.47 (0.32; 0.67)	1.50 (0.95, 2.37)	0.0785
TIMI bleeding requiring medical attention	316 (9.7%)	5.11 (4.56; 5.71)	192 (5.9%)	3.00 (2.59; 3.46)	1.69 (1.41, 2.02)	<.0001
TIMI minimal bleeding	138 (4.2%)	2.19 (1.84; 2.59)	91 (2.8%)	1.41 (1.13; 1.73)	1.54 (1.18, 2.01)	0.0012
ISTH clinically relevant non-major bleeding	246 (7.6%)	3.93 (3.45; 4.45)	139 (4.3%)	2.16 (1.81; 2.55)	1.81 (1.47, 2.23)	<.0001
ISTH not clinically relevant minor bleeding	166 (5.1%)	2.65 (2.27; 3.09)	114 (3.5%)	1.77 (1.46; 2.13)	1.48 (1.17, 1.88)	0.0011
BARC Type 1 to 3a	422 (13.0%)	7.02 (6.36; 7.72)	257 (7.9%)	4.09 (3.61; 4.63)	1.69 (1.45, 1.98)	<.0001
BARC Type 1	173 (5.3%)	2.75 (2.36; 3.20)	109 (3.4%)	1.69 (1.39; 2.04)	1.62 (1.27, 2.05)	<.0001
BARC Type 2	242 (7.4%)	3.88 (3.40; 4.40)	135 (4.2%)	2.10 (1.76; 2.48)	1.83 (1.49, 2.26)	<.0001
BARC Type 3a	57 (1.8%)	0.88 (0.67; 1.14)	39 (1.2%)	0.59 (0.42; 0.81)	1.48 (0.98, 2.22)	0.0577

ASA = Acetylsalicylic acid 100 mg once daily, bid = twice daily, od = once daily, Rivaroxaban = Rivaroxaban 2.5 mg twice daily, BARC = Bleeding Academic Research Consortium, CABG = Coronary artery bypass graft, ISTH = International Society on Thrombosis and Haemostasis, TIMI = Thrombolysis in Myocardial Infarction (study group)

Table displays outcome events meeting the definition as adjudicated by Independent Clinical Adjudication Committee (ICAC). The safety analysis set includes all randomized subjects who received at least one dose of study drug (rivaroxaban or rivaroxaban placebo). The on-treatment data scope includes outcome events observed from randomization until 2 days after permanent stop of the study drug.

N = total number of subjects, n = number of subjects with first event, % = 100 * n / N, n/100 p-yrs = ratio of number of subjects with incident events /cumulative at-risk time; HR (95% CI): Hazard ratios (95% confidence interval) is based on the Cox proportional hazards model stratified by type of procedure and clopidogrel use, with treatment as the only covariate. P-value (2-sided) is based on the log rank test stratified by type of procedure and clopidogrel use with treatment as a fixed factor.

Source: PH-40164/Table 14.3.1.3/1

日本人集団の結果は、17454_J_analysis/Table 14.3.1.3/1 を参照のこと。

2.7.6.1.2.3.9.4.3 治験薬投与後に認められた出血事象（事後解析）

全体集団における治験薬投与終了後 3 日目から最終コンタクト日までの TIMI 分類の「大出血」の発現割合は、リバーロキサバン群で 1.2%（38/3,256 例）、プラセボ群で 0.8%（27/3,248 例）であり、発現率（100 人年あたり）はそれぞれ 2.34 及び 1.77 であった（PH-40164/Post-hoc Table 14.3.7.2.1/5）。

日本人集団の結果は、17454_J_posthoc/Table 14.3.7.2.1/1 を参照のこと。

2.7.6.1.2.3.9.4.4 TIMI 分類の「大出血」の発現回数

全体集団における On-treatment 期間に認められた TIMI 分類の「大出血」の発現回数を表 2.7.6.1-29 に示す。

On-treatment 期間に TIMI 分類の「大出血」が認められなかった被験者は、リバーロキサバン群で 98.1%（3,194/3,256 例）、プラセボ群で 98.6%（3,204/3,248 例）であった。TIMI 分類の「大出血」が 1 回発現した被験者は 1.8%（60 例）及び 1.4%（44 例）、2 回発現した被験者はリバーロキサバン群のみに 2 例に認められ、2 例はいずれも血管内血行再建術でクロピドグレルの使用ありの被験者であった（PH-40164/Table 14.3.1.3/46）。

表 2.7.6.1-29 On-treatment 期間に認められた TIMI 分類の「大出血」の発現回数（全体集団、SAF）

	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban Placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
Number of subjects with			
0 Event	3194 (98.1%)	3204 (98.6%)	6398 (98.4%)
1 Event	60 (1.8%)	44 (1.4%)	104 (1.6%)
2 Events	2 (<0.1%)	0	2 (<0.1%)

bid = twice daily, od = once daily, ASA = acetylsalicylic acid 100 mg once daily, Rivaroxaban = Rivaroxaban 2.5 mg twice daily, SAF = safety analysis set

The safety analysis set includes all randomized subjects who received at least one dose of study drug (rivaroxaban or rivaroxaban placebo). The on-treatment data scope includes outcome events observed from randomization until 2 days after permanent stop of the study drug (rivaroxaban or rivaroxaban placebo).

Source: PH-40164/Table 14.3.1.3/44

日本人集団の結果は、17454_J_analysis/Table 14.3.1.3/52 及び 14.3.1.3/54 を参照のこと。

2.7.6.1.2.3.10 バイタルサイン、身体的所見及び安全性に関連する他の観察項目

全体集団における収縮期及び拡張期血圧、並びに脈拍数の平均値は、いずれもベースラインからの変化量は小さく、投与群間で明らかな違いは認められなかった（PH-40164/Table 14.3.4/1～14.3.4/3）。

日本人集団の結果は、17454_J_analysis/Table 14.3.4/1～14.3.4/3 を参照のこと。

2.7.6.1.2.4 その他の評価指標

2.7.6.1.2.4.1 PAD の重症度評価

PAD の重症度は、本試験組入れの根拠とした血行再建術施行前、ベースライン時及び各来院時に評価した。全体集団（ITT）において、重度の跛行が認められた被験者の割合は、ベースライン時にリバーロキサバン群で 53.1%（1,742/3,286 例）、プラセボ群で 52.9%（1,732/3,278 例）であり、1 ヵ月後に両投与群共に 9.3%（267 例）に減少した。1 ヵ月後に無症候性であった被験者の割合は 37.4%（1,075 例）及び 37.8%（1,090 例）であった。この傾向は両投与群共に治験薬投与終了時まで持続した（PH-40164/Table 14.2.7/2）。

日本人集団の結果は、17454_J_analysis/Table 14.2.7/3 を参照のこと。

2.7.6.1.2.4.2 ベネフィット・リスク評価

有効性主要評価項目（MI、虚血性脳卒中、心血管死、ALI、血管系の原因による大切断）と安全性主要評価項目（TIMI 分類の「大出血」）の結果に基づき、リバーロキサバン群のベネフィット・リスク評価を行った。本評価は仮説検定を行ったものではなく、前述の有効性及び安全性の評価を補足するために探索的に評価した。

全体集団の ITT を対象とした ECOD までの期間及び SAF を対象とした On-treatment 期間における、有効性主要評価項目及び安全性主要評価項目の 10,000 人年あたりの発現例数のプラセボ群に対する差に関する Forest プロットを図 2.7.6.1-15 に示す。

ITT を対象とした ECOD までの期間では、有効性主要評価項目の 10,000 人年あたりの発現例数はプラセボ群に対し 120 例減少し、安全性主要評価項目の 10,000 人あたりの発現例数はプラセボ群に対し 40 例増加した。リバーロキサバン群のイベント抑制効果は、主に ALI（99 例）及び MI（22 例）の減少によるものであった。心血管死はプラセボ群に対し 31 例増加した。重大な肢イベント（ALI、血管系の原因による大切断）の複合エンドポイントの減少が、重大な心血管イベント（MI、虚血性脳卒中、心血管死）の複合エンドポイントの減少と比較して顕著であった。

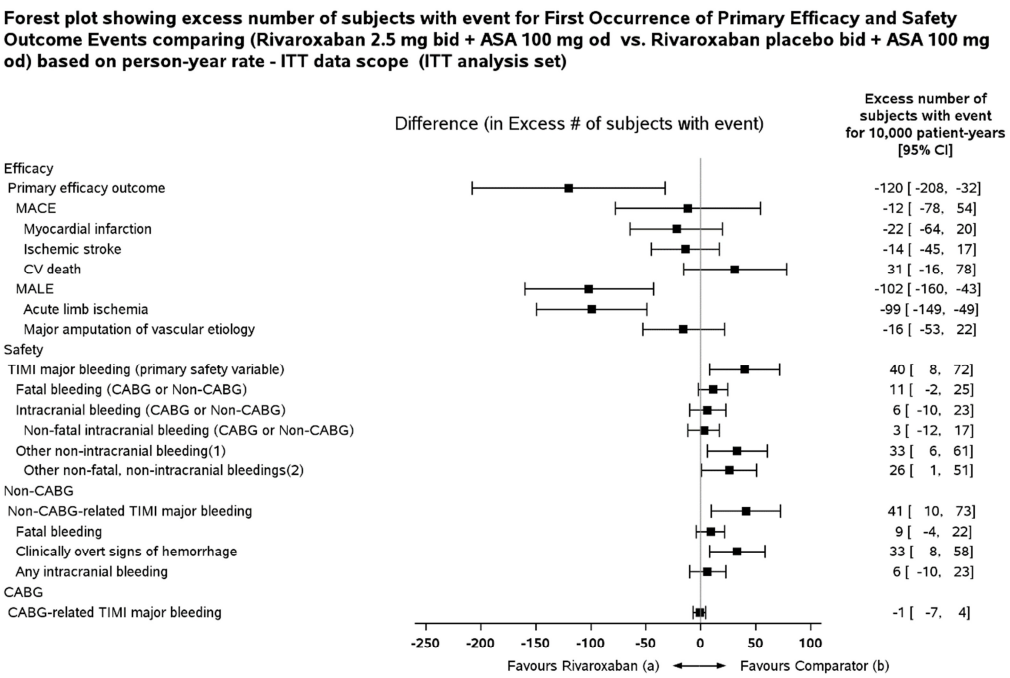
SAF を対象とした On-treatment 期間では、有効性主要評価項目の 10,000 人年あたりの発現例数はプラセボ群に対し 181 例減少し、安全性主要評価項目の発現例数はプラセボ群に対し 29 例増加した。リバーロキサバン群のイベント抑制効果は心血管死を含むすべての構成要素において認められ、ITT の結果と同様に、この効果は主に ALI（110 例）及び MI（42 例）の減少によるものであった。

ITT を対象とした ECOD までの期間及び SAF を対象とした On-treatment 期間における、有効性主要評価項目及び安全性主要評価項目の 10,000 人年あたりの累積イベント発現率に関する Kaplan-Meier 曲線を図 2.7.6.1-16 に示す。

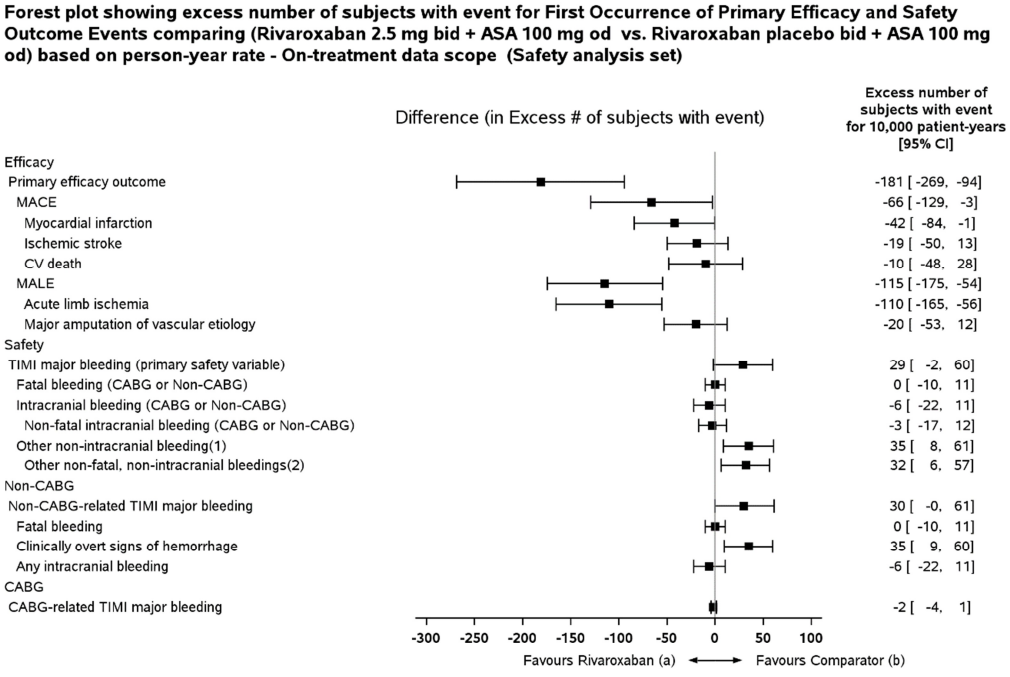
有効性主要評価項目におけるリバーロキサバン群の効果は早期に認められ、その効果は長期にわたり持続した。一方、安全性主要評価項目とした TIMI の「大出血」も早期に発現が認められ

たが、約 9 ヵ月以降は一定に推移し、3 年の評価期間においてリバーロキサバンの良好なベネフィット・リスクプロファイルが示された。

図 2.7.6.1-15 有効性主要評価項目及び安全性主要評価項目における 10,000 人年あたりの発現例数に関する Forest プロット（全体集団、ITT 及び SAF）



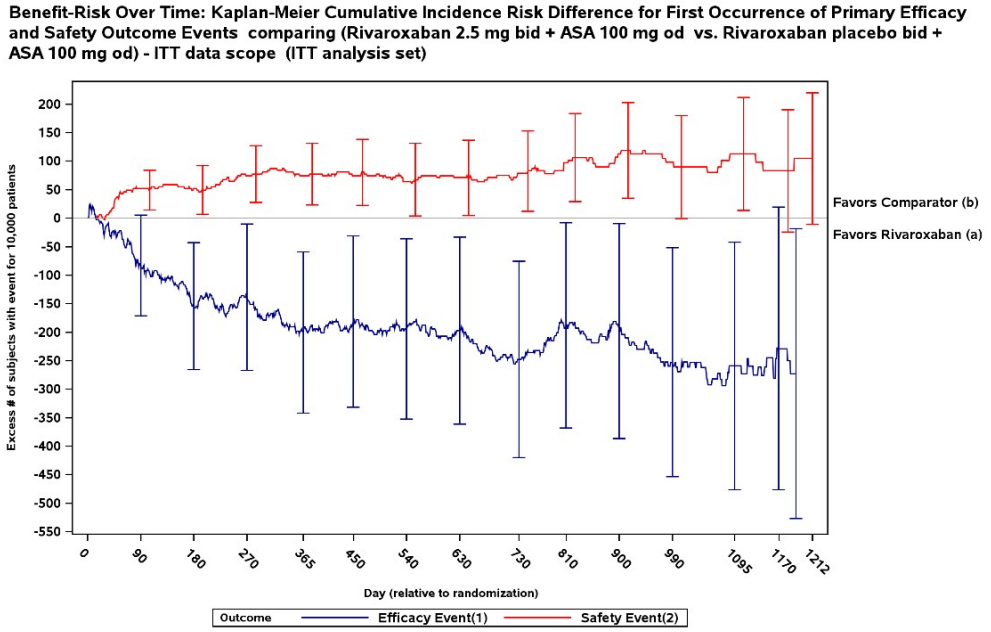
(1): Other non-intracranial TIMI major bleedings (CABG or Non-CABG), (2): Other non-fatal, non-intracranial TIMI major bleedings (CABG or Non-CABG)
Rivaroxaban (a): Rivaroxaban 2.5 mg bid + ASA 100 mg od , Comparator (b): Rivaroxaban placebo bid + ASA 100 mg od
The ITT data scope includes outcome events observed from randomization date until the efficacy cut-off date.



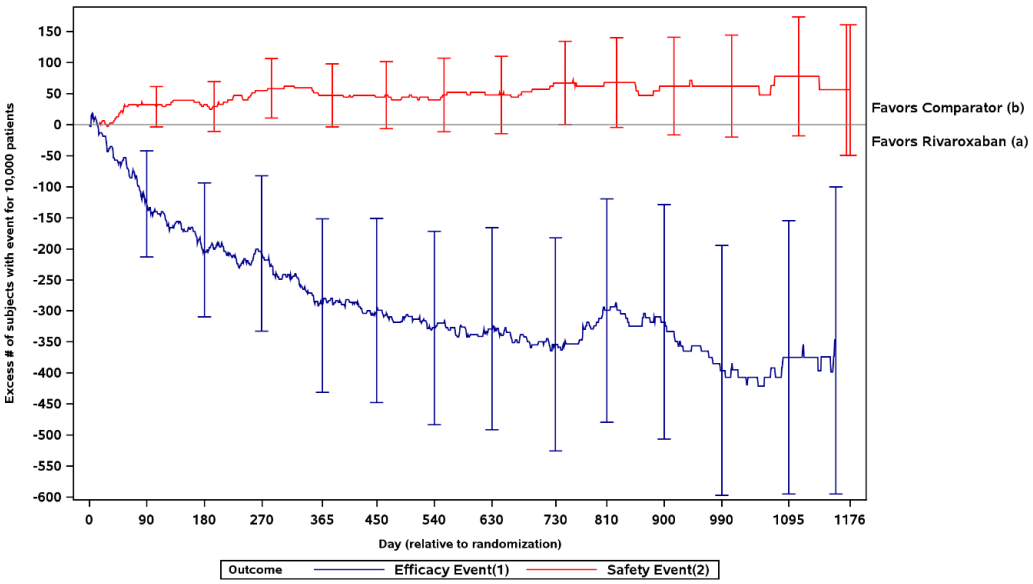
(1): Other non-intracranial TIMI major bleedings (CABG or Non-CABG), (2): Other non-fatal, non-intracranial TIMI major bleedings (CABG or Non-CABG)
Rivaroxaban (a): Rivaroxaban 2.5 mg bid + ASA 100 mg od , Comparator (b): Rivaroxaban placebo bid + ASA 100 mg od
The on-treatment data scope includes all outcome events observed from randomization until 2 days following permanent discontinuation of the study drug.

Source: PH-40164/Figure 14.3.8.1/1, 14.3.8.3/1

図 2.7.6.1-16 有効性主要評価項目及び安全性主要評価項目の累積イベント発現率に関する Kaplan-Meier 曲線（全体集団、ITT 及び SAF）



(1): Primary efficacy outcome, (2): TIMI major bleeding (primary safety variable)
Rivaroxaban (a): Rivaroxaban 2.5 mg bid + ASA 100 mg od , Comparator (b): Rivaroxaban placebo bid + ASA 100 mg od
The ITT data scope includes outcome events observed from randomization date until the efficacy cut-off date.
The x-axis of the Kaplan-Meier figures is restricted to the period in which at least 10% of the analysis set subjects are at risk as suggested by Pocock et al. (2002)



(1): Primary efficacy outcome, (2): TIMI major bleeding (primary safety variable)
Rivaroxaban (a): Rivaroxaban 2.5 mg bid + ASA 100 mg od , Comparator (b): Rivaroxaban placebo bid + ASA 100 mg od
The on-treatment data scope includes all outcome events observed from randomization until 2 days following permanent discontinuation of the study drug.
The x-axis of the Kaplan-Meier figures is restricted to the period in which at least 10% of the analysis set subjects are at risk as suggested by Pocock et al. (2002)

Source: PH-40164/Figure 14.3.8.1/4, 14.3.8.3/4

日本人集団の結果は、17454_J_add1/Figure 14.1.1/1、14.1.1/7、14.2.1/1 及び 14.2.1/7 を参照のこと。

2.7.6.1.3 結論

下肢血行再建術施行後の症候性PAD患者を対象に、リバーロキサバン2.5mg 1日2回とASAを併用投与したときのASA単剤投与に対する有効性及び安全性を検討した結果、以下の結論が得られた。

- 有効性主要評価項目としたMI、虚血性脳卒中、心血管死、ALI、又は血管系の原因による大切断の複合エンドポイントの発現リスクの低減において、プラセボ群に対するリバーロキサバン群の優越性が示された（HR：0.85、95%CI：0.76～0.96）。

- 有効性主要評価項目の5つの構成要素のうち4つの構成要素において、プラセボ群に対するリバーロキサバン群の発現リスクの低減が示され、最大の効果はALIで認められた。
  - MI：HR 0.88（95%CI：0.70～1.12）
  - 虚血性脳卒中：HR 0.87（95%CI：0.63～1.19）
  - ALI：HR 0.67（95%CI：0.55～0.82）
  - 血管系の原因による大切断：HR 0.89（95%CI：0.68～1.16）
- 有効性主要評価項目の構成要素のうち、心血管死については、プラセボ群に対するリバーロキサバン群の発現リスクの数値的な増加が認められた（HR：1.14、95%CI：0.93～1.40）。一方、On-treatment期間における評価では、5つのすべての構成要素でHRの点推定値が1を下回った。

- 有効性副次評価項目において7つの評価項目を階層的な検定手順を用いて評価した結果、5つの評価項目でプラセボ群に対するリバーロキサバン群の統計学的に有意な発現リスクの低減が示された。

- 有効性副次評価項目のうち、全死亡については、プラセボ群に対するリバーロキサバン群の発現リスクの数値的な増加が認められた（HR：1.08、95%CI：0.92～1.27）。一方、On-treatment期間における全死亡についてはHRの点推定値が1を下回った。

- 安全性主要評価項目としたTIMI分類の「大出血」において、リバーロキサバン群のプラセボ群に対するHRは1.43（95%CI：0.97～2.10）であった。これは、「臨床的に明らかな出血の徴候」（5g/dL以上のヘモグロビン値の低下又は15%以上のヘマトクリット値の低下）がプラセボ群と比較してリバーロキサバン群で多く発現したことに起因するものであった。部位別では消化管出血が多かった。

- TIMI分類の「致死的出血」及び「頭蓋内出血」において、プラセボ群に対するリバーロキサバン群の発現リスクの増加は示されなかった。

- 安全性副次評価項目としたISTH分類の「重大な出血」及びBARC分類のType 3b以上の出血事象の評価においても、TIMI分類の出血事象の評価を支持する結果が得られた。

- 本試験で観察された有害事象において、新たな安全性シグナルは確認されなかった。

- 有効性主要評価項目及び安全性主要評価項目の結果に基づくベネフィット・リスク評価において、3年の評価期間におけるリバーロキサバンの良好なベネフィット・リスクプロファイルが示された。

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2.7.6.1.a.1 付表

付表 2.7.6.1.a.1-1 IxRS による血行再建術のタイプとクロピドグレルの使用の有無別の人口統計学的及びベースライン特性（全体集団、ITT）

Categories	Type of procedure and clopidogrel use, per IxRS assignment: SURGICAL			Type of procedure and clopidogrel use, per IxRS assignment: Endovascular with clopidogrel			Type of procedure and clopidogrel use, per IxRS assignment: Endovascular without clopidogrel		
	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=1133 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=1138 (100%)	Total N=2271 (100%)	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=1539 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=1541 (100%)	Total N=3080 (100%)	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=614 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=599 (100%)	Total N=1213 (100%)
Age (years)									
n	1133	1138	2271	1539	1541	3080	614	599	1213
Nmiss	0	0	0	0	0	0	0	0	0
Mean	65.8	66.4	66.1	67.2	67.4	67.3	68.4	67.8	68.1
SD	8.1	8.0	8.1	8.6	8.7	8.6	8.7	8.6	8.7
Min	49	50	49	50	50	50	50	50	50
Q1	60.0	60.0	60.0	61.0	61.0	61.0	61.0	62.0	62.0
Median	65.0	66.0	66.0	67.0	67.0	67.0	69.0	68.0	68.0
Q3	71.0	72.0	71.0	73.0	73.0	73.0	75.0	74.0	74.0
Max	92	91	92	93	95	95	91	95	95
Age group (cut-offs: 55, 65, 75 years)									
<55 years	85 (7.5%)	73 (6.4%)	158 (7.0%)	98 (6.4%)	106 (6.9%)	204 (6.6%)	37 (6.0%)	42 (7.0%)	79 (6.5%)
55 - <65 years	437 (38.6%)	405 (35.6%)	842 (37.1%)	521 (33.9%)	483 (31.3%)	1004 (32.6%)	171 (27.9%)	164 (27.4%)	335 (27.6%)
65 - 75 years	470 (41.5%)	495 (43.5%)	965 (42.5%)	635 (41.3%)	662 (43.0%)	1297 (42.1%)	262 (42.7%)	280 (46.7%)	542 (44.7%)
>75 years	141 (12.4%)	165 (14.5%)	306 (13.5%)	285 (18.5%)	290 (18.8%)	575 (18.7%)	144 (23.5%)	113 (18.9%)	257 (21.2%)
Age group (cut-offs: 65, 75 years)									
<65 years	522 (46.1%)	478 (42.0%)	1000 (44.0%)	619 (40.2%)	589 (38.2%)	1208 (39.2%)	208 (33.9%)	206 (34.4%)	414 (34.1%)
>=65 to <75 years	444 (39.2%)	463 (40.7%)	907 (39.9%)	580 (37.7%)	622 (40.4%)	1202 (39.0%)	240 (39.1%)	263 (43.9%)	503 (41.5%)
>=75 years	167 (14.7%)	197 (17.3%)	364 (16.0%)	340 (22.1%)	330 (21.4%)	670 (21.8%)	166 (27.0%)	130 (21.7%)	296 (24.4%)
Age group (cut-offs: 65, 85 years)									
<65 years	522 (46.1%)	478 (42.0%)	1000 (44.0%)	619 (40.2%)	589 (38.2%)	1208 (39.2%)	208 (33.9%)	206 (34.4%)	414 (34.1%)
>=65 to <85 years	593 (52.3%)	651 (57.2%)	1244 (54.8%)	883 (57.4%)	909 (59.0%)	1792 (58.2%)	391 (63.7%)	374 (62.4%)	765 (63.1%)
>=85 years	18 (1.6%)	9 (0.8%)	27 (1.2%)	37 (2.4%)	43 (2.8%)	80 (2.6%)	15 (2.4%)	19 (3.2%)	34 (2.8%)
Sex									
Male	901 (79.5%)	904 (79.4%)	1805 (79.5%)	1109 (72.1%)	1068 (69.3%)	2177 (70.7%)	429 (69.9%)	449 (75.0%)	878 (72.4%)

2.7.6.1.a 付録 1

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Categories	Type of procedure and clopidogrel use, per IxRS assignment: SURGICAL			Type of procedure and clopidogrel use, per IxRS assignment: Endovascular with clopidogrel			Type of procedure and clopidogrel use, per IxRS assignment: Endovascular without clopidogrel		
	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=1133 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=1138 (100%)	Total N=2271 (100%)	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=1539 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=1541 (100%)	Total N=3080 (100%)	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=614 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=599 (100%)	Total N=1213 (100%)
Female	232 (20.5%)	234 (20.6%)	466 (20.5%)	430 (27.9%)	473 (30.7%)	903 (29.3%)	185 (30.1%)	150 (25.0%)	335 (27.6%)
Race									
WHITE	1008 (89.0%)	1021 (89.7%)	2029 (89.3%)	1209 (78.6%)	1210 (78.5%)	2419 (78.5%)	430 (70.0%)	425 (71.0%)	855 (70.5%)
BLACK OR AFRICAN AMERICAN	13 (1.1%)	4 (0.4%)	17 (0.7%)	55 (3.6%)	55 (3.6%)	110 (3.6%)	16 (2.6%)	12 (2.0%)	28 (2.3%)
ASIAN	88 (7.8%)	86 (7.6%)	174 (7.7%)	243 (15.8%)	245 (15.9%)	488 (15.8%)	153 (24.9%)	151 (25.2%)	304 (25.1%)
AMERICAN INDIAN OR ALASKA NATIVE	0	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)	2 (0.1%)	3 (<0.1%)	0	1 (0.2%)	1 (<0.1%)
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	0	0	0	1 (<0.1%)	1 (<0.1%)	0	0	0
NOT REPORTED	24 (2.1%)	25 (2.2%)	49 (2.2%)	31 (2.0%)	27 (1.8%)	58 (1.9%)	14 (2.3%)	10 (1.7%)	24 (2.0%)
MULTIPLE	0	1 (<0.1%)	1 (<0.1%)	0	1 (<0.1%)	1 (<0.1%)	1 (0.2%)	0	1 (<0.1%)
Race Group									
White	1008 (89.0%)	1021 (89.7%)	2029 (89.3%)	1209 (78.6%)	1210 (78.5%)	2419 (78.5%)	430 (70.0%)	425 (71.0%)	855 (70.5%)
Black	13 (1.1%)	4 (0.4%)	17 (0.7%)	55 (3.6%)	55 (3.6%)	110 (3.6%)	16 (2.6%)	12 (2.0%)	28 (2.3%)
Asian	88 (7.8%)	86 (7.6%)	174 (7.7%)	243 (15.8%)	245 (15.9%)	488 (15.8%)	153 (24.9%)	151 (25.2%)	304 (25.1%)
Other	24 (2.1%)	27 (2.4%)	51 (2.2%)	32 (2.1%)	31 (2.0%)	63 (2.0%)	15 (2.4%)	11 (1.8%)	26 (2.1%)
Days from qualifying revascularization procedure to randomization, actual									
n	1133	1138	2271	1539	1541	3080	614	599	1213
Nmiss	0	0	0	0	0	0	0	0	0
Mean	6.0	6.0	6.0	4.4	4.4	4.4	4.6	4.8	4.7
SD	2.5	2.5	2.5	2.8	2.8	2.8	2.8	2.8	2.8
Min	1	1	1	1	1	1	1	1	1
Q1	4.0	4.0	4.0	2.0	2.0	2.0	2.0	2.0	2.0
Median	6.0	6.0	6.0	4.0	3.0	3.0	4.0	4.0	4.0
Q3	8.0	8.0	8.0	7.0	7.0	7.0	7.0	7.0	7.0
Max	11	23	23	11	12	12	11	13	13

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Categories	Type of procedure and clopidogrel use, per IxRS assignment: SURGICAL			Type of procedure and clopidogrel use, per IxRS assignment: Endovascular with clopidogrel			Type of procedure and clopidogrel use, per IxRS assignment: Endovascular without clopidogrel		
	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=1133 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=1138 (100%)	Total N=2271 (100%)	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=1539 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=1541 (100%)	Total N=3080 (100%)	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=614 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=599 (100%)	Total N=1213 (100%)
Days from qualifying revascularization procedure to start of study drug, actual									
n	1121	1136	2257	1530	1521	3051	605	591	1196
Nmiss	12	2	14	9	20	29	9	8	17
Mean	6.1	6.1	6.1	4.6	4.7	4.7	4.8	5.0	4.9
SD	2.6	2.7	2.7	3.0	3.7	3.4	2.9	3.1	3.0
Min	1	1	1	1	1	1	1	1	1
Q1	4.0	4.0	4.0	2.0	2.0	2.0	2.0	2.0	2.0
Median	6.0	6.0	6.0	4.0	4.0	4.0	4.0	5.0	4.0
Q3	8.0	8.0	8.0	7.0	7.0	7.0	7.0	7.0	7.0
Max	39	44	44	30	62	62	28	36	36
Type of procedure and clopidogrel use, per IxRS assignment									
Endovascular with clopidogrel				1539 (100.0%)	1541 (100.0%)	3080 (100.0%)			
Endovascular without clopidogrel							614 (100.0%)	599 (100.0%)	1213 (100.0%)
SURGICAL	1133 (100.0%)	1138 (100.0%)	2271 (100.0%)						
Qualifying revascularization procedure per IxRS assignment									
Surgical	1133 (100.0%)	1138 (100.0%)	2271 (100.0%)	0	0	0	0	0	0
Endovascular	0	0	0	1539 (100.0%)	1541 (100.0%)	3080 (100.0%)	614 (100.0%)	599 (100.0%)	1213 (100.0%)
Type of qualifying procedure and clopidogrel use, actual									
Surgical	1055 (93.1%)	1074 (94.4%)	2129 (93.7%)	9 (0.6%)	8 (0.5%)	17 (0.6%)	20 (3.3%)	19 (3.2%)	39 (3.2%)
Endovascular incl. hybrid with clopidogrel	27 (2.4%)	27 (2.4%)	54 (2.4%)	1437 (93.4%)	1438 (93.3%)	2875 (93.3%)	41 (6.7%)	34 (5.7%)	75 (6.2%)

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Categories	Type of procedure and clopidogrel use, per IxRS assignment: SURGICAL			Type of procedure and clopidogrel use, per IxRS assignment: Endovascular with clopidogrel			Type of procedure and clopidogrel use, per IxRS assignment: Endovascular without clopidogrel		
	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=1133 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=1138 (100%)	Total N=2271 (100%)	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=1539 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=1541 (100%)	Total N=3080 (100%)	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=614 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=599 (100%)	Total N=1213 (100%)
Endovascular incl. hybrid without clopidogrel	51 (4.5%)	37 (3.3%)	88 (3.9%)	90 (5.8%)	90 (5.8%)	180 (5.8%)	552 (89.9%)	546 (91.2%)	1098 (90.5%)
Endovascular incl. hybrid with unknown clopidogrel use	0	0	0	3 (0.2%)	5 (0.3%)	8 (0.3%)	1 (0.2%)	0	1 (<0.1%)
Actual type of qualifying procedure and clopidogrel use at randomization, detailed									
Endovascular incl. hybrid with clopidogrel	27 (2.4%)	27 (2.4%)	54 (2.4%)	1437 (93.4%)	1438 (93.3%)	2875 (93.3%)	41 (6.7%)	34 (5.7%)	75 (6.2%)
Endovascular incl. hybrid without clopidogrel	51 (4.5%)	37 (3.3%)	88 (3.9%)	90 (5.8%)	90 (5.8%)	180 (5.8%)	552 (89.9%)	546 (91.2%)	1098 (90.5%)
Endovascular incl. hybrid with unknown clopidogrel use	0	0	0	3 (0.2%)	5 (0.3%)	8 (0.3%)	1 (0.2%)	0	1 (<0.1%)
Surgical with clopidogrel	146 (12.9%)	149 (13.1%)	295 (13.0%)	7 (0.5%)	7 (0.5%)	14 (0.5%)	0	0	0
Surgical without clopidogrel	907 (80.1%)	920 (80.8%)	1827 (80.4%)	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)	20 (3.3%)	19 (3.2%)	39 (3.2%)
Surgical with unknown clopidogrel use	2 (0.2%)	5 (0.4%)	7 (0.3%)	1 (<0.1%)	0	1 (<0.1%)	0	0	0
Qualifying revascularization procedure, actual									
Surgical	1055 (93.1%)	1074 (94.4%)	2129 (93.7%)	9 (0.6%)	8 (0.5%)	17 (0.6%)	20 (3.3%)	19 (3.2%)	39 (3.2%)
Endovascular incl. hybrid	78 (6.9%)	64 (5.6%)	142 (6.3%)	1530 (99.4%)	1533 (99.5%)	3063 (99.4%)	594 (96.7%)	580 (96.8%)	1174 (96.8%)

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Categories	Type of procedure and clopidogrel use, per IxRS assignment: SURGICAL			Type of procedure and clopidogrel use, per IxRS assignment: Endovascular with clopidogrel			Type of procedure and clopidogrel use, per IxRS assignment: Endovascular without clopidogrel		
	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=1133 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=1138 (100%)	Total N=2271 (100%)	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=1539 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=1541 (100%)	Total N=3080 (100%)	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=614 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=599 (100%)	Total N=1213 (100%)
Qualifying revascularization procedure, actual (3 groups)									
Surgical	1055 (93.1%)	1074 (94.4%)	2129 (93.7%)	9 (0.6%)	8 (0.5%)	17 (0.6%)	20 (3.3%)	19 (3.2%)	39 (3.2%)
Endovascular	26 (2.3%)	26 (2.3%)	52 (2.3%)	1474 (95.8%)	1479 (96.0%)	2953 (95.9%)	539 (87.8%)	547 (91.3%)	1086 (89.5%)
Hybrid	52 (4.6%)	38 (3.3%)	90 (4.0%)	56 (3.6%)	54 (3.5%)	110 (3.6%)	55 (9.0%)	33 (5.5%)	88 (7.3%)
Clopidogrel use in relation to qualifying revascularization procedure, actual									
No	949 (83.8%)	947 (83.2%)	1896 (83.5%)	79 (5.1%)	59 (3.8%)	138 (4.5%)	527 (85.8%)	514 (85.8%)	1041 (85.8%)
Yes	184 (16.2%)	188 (16.5%)	372 (16.4%)	1458 (94.7%)	1478 (95.9%)	2936 (95.3%)	87 (14.2%)	85 (14.2%)	172 (14.2%)
Unknown	0	3 (0.3%)	3 (0.1%)	2 (0.1%)	4 (0.3%)	6 (0.2%)	0	0	0
Clopidogrel use at the time of randomization									
No	958 (84.6%)	957 (84.1%)	1915 (84.3%)	91 (5.9%)	91 (5.9%)	182 (5.9%)	572 (93.2%)	565 (94.3%)	1137 (93.7%)
Yes	173 (15.3%)	176 (15.5%)	349 (15.4%)	1444 (93.8%)	1445 (93.8%)	2889 (93.8%)	41 (6.7%)	34 (5.7%)	75 (6.2%)
Unknown	2 (0.2%)	5 (0.4%)	7 (0.3%)	4 (0.3%)	5 (0.3%)	9 (0.3%)	1 (0.2%)	0	1 (<0.1%)
Clopidogrel use continued after randomization (days) among clopidogrel user at randomization									
None	958 (84.6%)	957 (84.1%)	1915 (84.3%)	91 (5.9%)	91 (5.9%)	182 (5.9%)	572 (93.2%)	565 (94.3%)	1137 (93.7%)
<= 30 days	135 (11.9%)	138 (12.1%)	273 (12.0%)	833 (54.1%)	780 (50.6%)	1613 (52.4%)	20 (3.3%)	17 (2.8%)	37 (3.1%)
> 30 days	33 (2.9%)	36 (3.2%)	69 (3.0%)	592 (38.5%)	625 (40.6%)	1217 (39.5%)	19 (3.1%)	17 (2.8%)	36 (3.0%)
Unknown	7 (0.6%)	7 (0.6%)	14 (0.6%)	23 (1.5%)	45 (2.9%)	68 (2.2%)	3 (0.5%)	0	3 (0.2%)
Region									
North America	76 (6.7%)	76 (6.7%)	152 (6.7%)	205 (13.3%)	204 (13.2%)	409 (13.3%)	66 (10.7%)	67 (11.2%)	133 (11.0%)
Western Europe	250 (22.1%)	252 (22.1%)	502 (22.1%)	480 (31.2%)	480 (31.1%)	960 (31.2%)	184 (30.0%)	180 (30.1%)	364 (30.0%)
Eastern Europe	640 (56.5%)	643 (56.5%)	1283 (56.5%)	485 (31.5%)	483 (31.3%)	968 (31.4%)	176 (28.7%)	172 (28.7%)	348 (28.7%)
Asia Pacific	87 (7.7%)	87 (7.6%)	174 (7.7%)	240 (15.6%)	243 (15.8%)	483 (15.7%)	154 (25.1%)	150 (25.0%)	304 (25.1%)

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Categories	Type of procedure and clopidogrel use, per IxRS assignment: SURGICAL			Type of procedure and clopidogrel use, per IxRS assignment: Endovascular with clopidogrel			Type of procedure and clopidogrel use, per IxRS assignment: Endovascular without clopidogrel		
	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=1133 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=1138 (100%)	Total N=2271 (100%)	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=1539 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=1541 (100%)	Total N=3080 (100%)	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=614 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=599 (100%)	Total N=1213 (100%)
South America	80 (7.1%)	80 (7.0%)	160 (7.0%)	129 (8.4%)	131 (8.5%)	260 (8.4%)	34 (5.5%)	30 (5.0%)	64 (5.3%)
Region									
US	34 (3.0%)	33 (2.9%)	67 (3.0%)	186 (12.1%)	186 (12.1%)	372 (12.1%)	42 (6.8%)	43 (7.2%)	85 (7.0%)
non-US	1099 (97.0%)	1105 (97.1%)	2204 (97.0%)	1353 (87.9%)	1355 (87.9%)	2708 (87.9%)	572 (93.2%)	556 (92.8%)	1128 (93.0%)
Weight group (cut-off 60 kg)									
missing	8 (0.7%)	14 (1.2%)	22 (1.0%)	17 (1.1%)	11 (0.7%)	28 (0.9%)	11 (1.8%)	6 (1.0%)	17 (1.4%)
<=60 kg	174 (15.4%)	178 (15.6%)	352 (15.5%)	237 (15.4%)	244 (15.8%)	481 (15.6%)	123 (20.0%)	125 (20.9%)	248 (20.4%)
>60 kg	951 (83.9%)	946 (83.1%)	1897 (83.5%)	1285 (83.5%)	1286 (83.5%)	2571 (83.5%)	480 (78.2%)	468 (78.1%)	948 (78.2%)
Baseline Estimated Glomerular Filtration Rate (mL/min/1.73m2)									
n	1094	1092	2186	1477	1491	2968	589	576	1165
Nmiss	39	46	85	62	50	112	25	23	48
Mean	83.722	81.894	82.809	76.355	76.217	76.285	74.692	76.282	75.478
SD	29.244	23.301	26.453	23.120	23.193	23.153	23.772	23.474	23.629
Min	9.31	24.00	9.31	21.00	17.50	17.50	12.13	19.40	12.13
Q1	66.000	65.100	66.000	60.000	60.000	60.000	59.000	60.000	60.000
Median	83.150	83.000	83.000	75.600	75.350	75.470	73.000	75.900	74.200
Q3	96.000	95.585	96.000	90.000	90.000	90.000	90.000	91.000	90.000
Max	619.23	237.00	619.23	198.48	176.00	198.48	158.90	152.00	158.90
eGFR (cut-offs: 60 ml/min/1.73m2)									
missing	39 (3.4%)	46 (4.0%)	85 (3.7%)	62 (4.0%)	50 (3.2%)	112 (3.6%)	25 (4.1%)	23 (3.8%)	48 (4.0%)
<60 ml/min/1.73m2	167 (14.7%)	179 (15.7%)	346 (15.2%)	341 (22.2%)	352 (22.8%)	693 (22.5%)	153 (24.9%)	135 (22.5%)	288 (23.7%)
>=60 ml/min/1.73m2	927 (81.8%)	913 (80.2%)	1840 (81.0%)	1136 (73.8%)	1139 (73.9%)	2275 (73.9%)	436 (71.0%)	441 (73.6%)	877 (72.3%)
eGFR (cut-offs: 15, 30 and 60 ml/min/1.73m2)									
missing	39 (3.4%)	46 (4.0%)	85 (3.7%)	62 (4.0%)	50 (3.2%)	112 (3.6%)	25 (4.1%)	23 (3.8%)	48 (4.0%)
<15 ml/min/1.73m2	1 (<0.1%)	0	1 (<0.1%)	0	0	0	1 (0.2%)	0	1 (<0.1%)
15 - <30 ml/min/1.73m2	0	6 (0.5%)	6 (0.3%)	9 (0.6%)	14 (0.9%)	23 (0.7%)	4 (0.7%)	8 (1.3%)	12 (1.0%)

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Categories	Type of procedure and clopidogrel use, per IxRS assignment: SURGICAL			Type of procedure and clopidogrel use, per IxRS assignment: Endovascular with clopidogrel			Type of procedure and clopidogrel use, per IxRS assignment: Endovascular without clopidogrel		
	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=1133 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=1138 (100%)	Total N=2271 (100%)	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=1539 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=1541 (100%)	Total N=3080 (100%)	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=614 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=599 (100%)	Total N=1213 (100%)
30 - <60 ml/min/1.73m2	166 (14.7%)	173 (15.2%)	339 (14.9%)	332 (21.6%)	338 (21.9%)	670 (21.8%)	148 (24.1%)	127 (21.2%)	275 (22.7%)
>=60 ml/min/1.73m2	927 (81.8%)	913 (80.2%)	1840 (81.0%)	1136 (73.8%)	1139 (73.9%)	2275 (73.9%)	436 (71.0%)	441 (73.6%)	877 (72.3%)
eGFR (cut-offs: 30, 50 and 80 ml/min/1.73m2)									
missing	39 (3.4%)	46 (4.0%)	85 (3.7%)	62 (4.0%)	50 (3.2%)	112 (3.6%)	25 (4.1%)	23 (3.8%)	48 (4.0%)
<30 ml/min/1.73m2	1 (<0.1%)	6 (0.5%)	7 (0.3%)	9 (0.6%)	14 (0.9%)	23 (0.7%)	5 (0.8%)	8 (1.3%)	13 (1.1%)
30 - 50 ml/min/1.73m2	88 (7.8%)	80 (7.0%)	168 (7.4%)	170 (11.0%)	167 (10.8%)	337 (10.9%)	85 (13.8%)	61 (10.2%)	146 (12.0%)
>50 - 80 ml/min/1.73m2	410 (36.2%)	420 (36.9%)	830 (36.5%)	690 (44.8%)	683 (44.3%)	1373 (44.6%)	267 (43.5%)	266 (44.4%)	533 (43.9%)
>80 ml/min/1.73m2	595 (52.5%)	586 (51.5%)	1181 (52.0%)	608 (39.5%)	627 (40.7%)	1235 (40.1%)	232 (37.8%)	241 (40.2%)	473 (39.0%)
Fragile subjects									
missing	37 (3.3%)	42 (3.7%)	79 (3.5%)	56 (3.6%)	45 (2.9%)	101 (3.3%)	20 (3.3%)	20 (3.3%)	40 (3.3%)
No	876 (77.3%)	856 (75.2%)	1732 (76.3%)	1070 (69.5%)	1068 (69.3%)	2138 (69.4%)	392 (63.8%)	408 (68.1%)	800 (66.0%)
Yes	220 (19.4%)	240 (21.1%)	460 (20.3%)	413 (26.8%)	428 (27.8%)	841 (27.3%)	202 (32.9%)	171 (28.5%)	373 (30.8%)
Baseline LDL Cholesterol (mmol/L)									
n	163	178	341	443	431	874	173	142	315
Nmiss	970	960	1930	1096	1110	2206	441	457	898
Mean	100.458	106.565	103.646	102.361	100.968	101.674	101.441	97.269	99.560
SD	40.312	45.210	42.985	41.596	42.093	41.823	40.938	33.881	37.919
Min	16.00	14.00	14.00	29.00	8.00	8.00	21.27	22.00	21.27
Q1	73.473	75.300	74.600	72.000	71.000	72.000	72.000	70.379	71.000
Median	93.195	96.675	96.000	97.000	95.000	95.708	99.769	95.000	97.000
Q3	121.000	134.572	126.451	127.611	125.678	126.838	126.451	119.877	125.000
Max	251.00	303.17	303.17	326.76	270.00	326.76	246.33	177.50	246.33
Smoking status									
missing	1 (<0.1%)	0	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)	0	0	0
NEVER	166 (14.7%)	200 (17.6%)	366 (16.1%)	337 (21.9%)	357 (23.2%)	694 (22.5%)	159 (25.9%)	132 (22.0%)	291 (24.0%)
FORMER	543 (47.9%)	524 (46.0%)	1067 (47.0%)	673 (43.7%)	674 (43.7%)	1347 (43.7%)	259 (42.2%)	258 (43.1%)	517 (42.6%)
CURRENT	423 (37.3%)	414 (36.4%)	837 (36.9%)	528 (34.3%)	509 (33.0%)	1037 (33.7%)	196 (31.9%)	209 (34.9%)	405 (33.4%)

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Categories	Type of procedure and clopidogrel use, per IxRS assignment: SURGICAL			Type of procedure and clopidogrel use, per IxRS assignment: Endovascular with clopidogrel			Type of procedure and clopidogrel use, per IxRS assignment: Endovascular without clopidogrel		
	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=1133 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=1138 (100%)	Total N=2271 (100%)	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=1539 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=1541 (100%)	Total N=3080 (100%)	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=614 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=599 (100%)	Total N=1213 (100%)
Prior coronary artery disease									
missing	1 (<0.1%)	0	1 (<0.1%)	0	0	0	0	0	0
No	778 (68.7%)	812 (71.4%)	1590 (70.0%)	1005 (65.3%)	1028 (66.7%)	2033 (66.0%)	450 (73.3%)	423 (70.6%)	873 (72.0%)
Yes	354 (31.2%)	326 (28.6%)	680 (29.9%)	534 (34.7%)	513 (33.3%)	1047 (34.0%)	164 (26.7%)	176 (29.4%)	340 (28.0%)
Prior MI									
missing	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)	0	0	0	0	0	0
No	999 (88.2%)	1030 (90.5%)	2029 (89.3%)	1368 (88.9%)	1373 (89.1%)	2741 (89.0%)	553 (90.1%)	525 (87.6%)	1078 (88.9%)
Yes	133 (11.7%)	107 (9.4%)	240 (10.6%)	171 (11.1%)	168 (10.9%)	339 (11.0%)	61 (9.9%)	74 (12.4%)	135 (11.1%)
If yes, time of MI <12 months before randomization	6 (0.5%)	5 (0.4%)	11 (0.5%)	10 (0.6%)	11 (0.7%)	21 (0.7%)	2 (0.3%)	3 (0.5%)	5 (0.4%)
Prior MI and eGFR < 60 mL/min									
missing	1006 (88.8%)	1042 (91.6%)	2048 (90.2%)	1375 (89.3%)	1380 (89.6%)	2755 (89.4%)	557 (90.7%)	528 (88.1%)	1085 (89.4%)
No	103 (9.1%)	68 (6.0%)	171 (7.5%)	121 (7.9%)	106 (6.9%)	227 (7.4%)	37 (6.0%)	51 (8.5%)	88 (7.3%)
Yes	24 (2.1%)	28 (2.5%)	52 (2.3%)	43 (2.8%)	55 (3.6%)	98 (3.2%)	20 (3.3%)	20 (3.3%)	40 (3.3%)
Prior MI and age <65 years									
missing	1000 (88.3%)	1031 (90.6%)	2031 (89.4%)	1368 (88.9%)	1373 (89.1%)	2741 (89.0%)	553 (90.1%)	525 (87.6%)	1078 (88.9%)
No	74 (6.5%)	72 (6.3%)	146 (6.4%)	109 (7.1%)	109 (7.1%)	218 (7.1%)	42 (6.8%)	48 (8.0%)	90 (7.4%)
Yes	59 (5.2%)	35 (3.1%)	94 (4.1%)	62 (4.0%)	59 (3.8%)	121 (3.9%)	19 (3.1%)	26 (4.3%)	45 (3.7%)
Prior history of limb revascularization									
missing	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)	0	0	0	0	0	0
No	783 (69.1%)	813 (71.4%)	1596 (70.3%)	934 (60.7%)	907 (58.9%)	1841 (59.8%)	387 (63.0%)	402 (67.1%)	789 (65.0%)
Yes	349 (30.8%)	324 (28.5%)	673 (29.6%)	605 (39.3%)	634 (41.1%)	1239 (40.2%)	227 (37.0%)	197 (32.9%)	424 (35.0%)
Carotid artery disease history									
missing	2 (0.2%)	1 (<0.1%)	3 (0.1%)	0	1 (<0.1%)	1 (<0.1%)	0	1 (0.2%)	1 (<0.1%)
No	1033 (91.2%)	1035 (90.9%)	2068 (91.1%)	1397 (90.8%)	1387 (90.0%)	2784 (90.4%)	572 (93.2%)	560 (93.5%)	1132 (93.3%)

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Categories	Type of procedure and clopidogrel use, per IxRS assignment: SURGICAL			Type of procedure and clopidogrel use, per IxRS assignment: Endovascular with clopidogrel			Type of procedure and clopidogrel use, per IxRS assignment: Endovascular without clopidogrel		
	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=1133 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=1138 (100%)	Total N=2271 (100%)	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=1539 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=1541 (100%)	Total N=3080 (100%)	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=614 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=599 (100%)	Total N=1213 (100%)
Yes	98 (8.6%)	102 (9.0%)	200 (8.8%)	142 (9.2%)	153 (9.9%)	295 (9.6%)	42 (6.8%)	38 (6.3%)	80 (6.6%)
Intermittent claudication present within past 12 months									
missing	1 (<0.1%)	0	1 (<0.1%)	0	0	0	2 (0.3%)	0	2 (0.2%)
No	54 (4.8%)	39 (3.4%)	93 (4.1%)	73 (4.7%)	83 (5.4%)	156 (5.1%)	37 (6.0%)	30 (5.0%)	67 (5.5%)
Yes	1078 (95.1%)	1099 (96.6%)	2177 (95.9%)	1466 (95.3%)	1458 (94.6%)	2924 (94.9%)	575 (93.6%)	569 (95.0%)	1144 (94.3%)
History of heart failure									
missing	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)	1 (<0.1%)	0	1 (<0.1%)	0	0	0
No	1023 (90.3%)	1027 (90.2%)	2050 (90.3%)	1419 (92.2%)	1420 (92.1%)	2839 (92.2%)	575 (93.6%)	558 (93.2%)	1133 (93.4%)
Yes	109 (9.6%)	110 (9.7%)	219 (9.6%)	119 (7.7%)	121 (7.9%)	240 (7.8%)	39 (6.4%)	41 (6.8%)	80 (6.6%)
Diabetes mellitus									
missing	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)	0	0	0	0	0	0
No	762 (67.3%)	798 (70.1%)	1560 (68.7%)	856 (55.6%)	823 (53.4%)	1679 (54.5%)	354 (57.7%)	340 (56.8%)	694 (57.2%)
Yes	370 (32.7%)	339 (29.8%)	709 (31.2%)	683 (44.4%)	718 (46.6%)	1401 (45.5%)	260 (42.3%)	259 (43.2%)	519 (42.8%)
Hypertension									
missing	1 (<0.1%)	0	1 (<0.1%)	0	0	0	0	0	0
No	215 (19.0%)	230 (20.2%)	445 (19.6%)	273 (17.7%)	283 (18.4%)	556 (18.1%)	113 (18.4%)	107 (17.9%)	220 (18.1%)
Yes	917 (80.9%)	908 (79.8%)	1825 (80.4%)	1266 (82.3%)	1258 (81.6%)	2524 (81.9%)	501 (81.6%)	492 (82.1%)	993 (81.9%)
Hyperlipidemia									
missing	2 (0.2%)	0	2 (<0.1%)	0	0	0	0	0	0
No	537 (47.4%)	559 (49.1%)	1096 (48.3%)	526 (34.2%)	526 (34.1%)	1052 (34.2%)	250 (40.7%)	225 (37.6%)	475 (39.2%)
Yes	594 (52.4%)	579 (50.9%)	1173 (51.7%)	1013 (65.8%)	1015 (65.9%)	2028 (65.8%)	364 (59.3%)	374 (62.4%)	738 (60.8%)
Baseline ABI (cut-off: 0.8)									
missing	90 (7.9%)	70 (6.2%)	160 (7.0%)	138 (9.0%)	150 (9.7%)	288 (9.4%)	54 (8.8%)	45 (7.5%)	99 (8.2%)
<= 0.8	376 (33.2%)	352 (30.9%)	728 (32.1%)	285 (18.5%)	281 (18.2%)	566 (18.4%)	135 (22.0%)	119 (19.9%)	254 (20.9%)
> 0.8	667 (58.9%)	716 (62.9%)	1383 (60.9%)	1116 (72.5%)	1110 (72.0%)	2226 (72.3%)	425 (69.2%)	435 (72.6%)	860 (70.9%)

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Categories	Type of procedure and clopidogrel use, per IxRS assignment: SURGICAL			Type of procedure and clopidogrel use, per IxRS assignment: Endovascular with clopidogrel			Type of procedure and clopidogrel use, per IxRS assignment: Endovascular without clopidogrel		
	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=1133 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=1138 (100%)	Total N=2271 (100%)	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=1539 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=1541 (100%)	Total N=3080 (100%)	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=614 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=599 (100%)	Total N=1213 (100%)
Baseline TBI (cut-off: 0.6)									
missing	1117 (98.6%)	1128 (99.1%)	2245 (98.9%)	1500 (97.5%)	1501 (97.4%)	3001 (97.4%)	604 (98.4%)	586 (97.8%)	1190 (98.1%)
<= 0.6	9 (0.8%)	6 (0.5%)	15 (0.7%)	23 (1.5%)	22 (1.4%)	45 (1.5%)	2 (0.3%)	9 (1.5%)	11 (0.9%)
> 0.6	7 (0.6%)	4 (0.4%)	11 (0.5%)	16 (1.0%)	18 (1.2%)	34 (1.1%)	8 (1.3%)	4 (0.7%)	12 (1.0%)
ABI/TBI categories at baseline (Month 1 visit)									
ABI <= 0.80 or TBI <= 0.60	384 (33.9%)	357 (31.4%)	741 (32.6%)	308 (20.0%)	303 (19.7%)	611 (19.8%)	137 (22.3%)	128 (21.4%)	265 (21.8%)
ABI > 0.80 and/or TBI > 0.60	673 (59.4%)	717 (63.0%)	1390 (61.2%)	1132 (73.6%)	1128 (73.2%)	2260 (73.4%)	433 (70.5%)	438 (73.1%)	871 (71.8%)
TBI and ABI not done	76 (6.7%)	64 (5.6%)	140 (6.2%)	99 (6.4%)	110 (7.1%)	209 (6.8%)	44 (7.2%)	33 (5.5%)	77 (6.3%)
Atrial fibrillation disease history									
missing	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)	0	0	0	0	0	0
No	1094 (96.6%)	1107 (97.3%)	2201 (96.9%)	1499 (97.4%)	1501 (97.4%)	3000 (97.4%)	600 (97.7%)	581 (97.0%)	1181 (97.4%)
Yes	38 (3.4%)	30 (2.6%)	68 (3.0%)	40 (2.6%)	40 (2.6%)	80 (2.6%)	14 (2.3%)	18 (3.0%)	32 (2.6%)
Atrial flutter disease history									
missing	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)	0	0	0	0	0	0
No	1128 (99.6%)	1132 (99.5%)	2260 (99.5%)	1529 (99.4%)	1538 (99.8%)	3067 (99.6%)	613 (99.8%)	597 (99.7%)	1210 (99.8%)
Yes	4 (0.4%)	5 (0.4%)	9 (0.4%)	10 (0.6%)	3 (0.2%)	13 (0.4%)	1 (0.2%)	2 (0.3%)	3 (0.2%)
Region									
South America	80 (7.1%)	80 (7.0%)	160 (7.0%)	129 (8.4%)	131 (8.5%)	260 (8.4%)	34 (5.5%)	30 (5.0%)	64 (5.3%)
non-South America	1053 (92.9%)	1058 (93.0%)	2111 (93.0%)	1410 (91.6%)	1410 (91.5%)	2820 (91.6%)	580 (94.5%)	569 (95.0%)	1149 (94.7%)
Critical limb ischemia									
missing	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)	0	0	0	0	0	0
No	663 (58.5%)	695 (61.1%)	1358 (59.8%)	1173 (76.2%)	1171 (76.0%)	2344 (76.1%)	450 (73.3%)	442 (73.8%)	892 (73.5%)
Yes	469 (41.4%)	442 (38.8%)	911 (40.1%)	366 (23.8%)	370 (24.0%)	736 (23.9%)	164 (26.7%)	157 (26.2%)	321 (26.5%)

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Categories	Type of procedure and clopidogrel use, per IxRS assignment: SURGICAL			Type of procedure and clopidogrel use, per IxRS assignment: Endovascular with clopidogrel			Type of procedure and clopidogrel use, per IxRS assignment: Endovascular without clopidogrel		
	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=1133 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=1138 (100%)	Total N=2271 (100%)	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=1539 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=1541 (100%)	Total N=3080 (100%)	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=614 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=599 (100%)	Total N=1213 (100%)
Critical leg ischemia categories									
missing	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)	0	0	0	0	0	0
No critical leg ischemia	663 (58.5%)	695 (61.1%)	1358 (59.8%)	1173 (76.2%)	1171 (76.0%)	2344 (76.1%)	450 (73.3%)	442 (73.8%)	892 (73.5%)
Critical leg ischemia history	190 (16.8%)	188 (16.5%)	378 (16.6%)	151 (9.8%)	145 (9.4%)	296 (9.6%)	55 (9.0%)	54 (9.0%)	109 (9.0%)
Critical leg ischemia ongoing	279 (24.6%)	254 (22.3%)	533 (23.5%)	215 (14.0%)	225 (14.6%)	440 (14.3%)	109 (17.8%)	103 (17.2%)	212 (17.5%)
Length of target lesion on the index leg									
missing	44 (3.9%)	51 (4.5%)	95 (4.2%)	42 (2.7%)	33 (2.1%)	75 (2.4%)	23 (3.7%)	22 (3.7%)	45 (3.7%)
SHORT (< 5 CM)	182 (16.1%)	191 (16.8%)	373 (16.4%)	348 (22.6%)	402 (26.1%)	750 (24.4%)	186 (30.3%)	175 (29.2%)	361 (29.8%)
INTERMEDIATE (5 CM TO < 15 CM)	413 (36.5%)	401 (35.2%)	814 (35.8%)	667 (43.3%)	621 (40.3%)	1288 (41.8%)	256 (41.7%)	255 (42.6%)	511 (42.1%)
LONG (>= 15 CM)	494 (43.6%)	495 (43.5%)	989 (43.5%)	482 (31.3%)	485 (31.5%)	967 (31.4%)	149 (24.3%)	147 (24.5%)	296 (24.4%)
Endovascular qualifying procedure with drug coated devices									
missing	1055 (93.1%)	1074 (94.4%)	2129 (93.7%)	9 (0.6%)	8 (0.5%)	17 (0.6%)	20 (3.3%)	21 (3.5%)	41 (3.4%)
Drug-coated balloon or drug-coated stent	14 (1.2%)	14 (1.2%)	28 (1.2%)	566 (36.8%)	583 (37.8%)	1149 (37.3%)	86 (14.0%)	95 (15.9%)	181 (14.9%)
Not drug-coated devices	59 (5.2%)	50 (4.4%)	109 (4.8%)	957 (62.2%)	940 (61.0%)	1897 (61.6%)	506 (82.4%)	477 (79.6%)	983 (81.0%)
No device	5 (0.4%)	0	5 (0.2%)	7 (0.5%)	10 (0.6%)	17 (0.6%)	2 (0.3%)	6 (1.0%)	8 (0.7%)
Time from qualifying revascularization procedure to randomization, actual (cut-offs: median)									
< Median (Days)	376 (33.2%)	357 (31.4%)	733 (32.3%)	895 (58.2%)	892 (57.9%)	1787 (58.0%)	340 (55.4%)	308 (51.4%)	648 (53.4%)
>= Median (Days)	757 (66.8%)	781 (68.6%)	1538 (67.7%)	644 (41.8%)	649 (42.1%)	1293 (42.0%)	274 (44.6%)	291 (48.6%)	565 (46.6%)
Statin use during study									
No	264 (23.3%)	253 (22.2%)	517 (22.8%)	256 (16.6%)	241 (15.6%)	497 (16.1%)	138 (22.5%)	123 (20.5%)	261 (21.5%)

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Categories	Type of procedure and clopidogrel use, per IxRS assignment: SURGICAL			Type of procedure and clopidogrel use, per IxRS assignment: Endovascular with clopidogrel			Type of procedure and clopidogrel use, per IxRS assignment: Endovascular without clopidogrel		
	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=1133 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=1138 (100%)	Total N=2271 (100%)	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=1539 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=1541 (100%)	Total N=3080 (100%)	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=614 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=599 (100%)	Total N=1213 (100%)
Yes	869 (76.7%)	885 (77.8%)	1754 (77.2%)	1283 (83.4%)	1300 (84.4%)	2583 (83.9%)	476 (77.5%)	476 (79.5%)	952 (78.5%)
Baseline Anemia									
No	1102 (97.3%)	1111 (97.6%)	2213 (97.4%)	1490 (96.8%)	1476 (95.8%)	2966 (96.3%)	589 (95.9%)	578 (96.5%)	1167 (96.2%)
Yes	31 (2.7%)	27 (2.4%)	58 (2.6%)	49 (3.2%)	65 (4.2%)	114 (3.7%)	25 (4.1%)	21 (3.5%)	46 (3.8%)
ACE inhibitors									
No	655 (57.8%)	699 (61.4%)	1354 (59.6%)	927 (60.2%)	968 (62.8%)	1895 (61.5%)	406 (66.1%)	392 (65.4%)	798 (65.8%)
Yes	478 (42.2%)	439 (38.6%)	917 (40.4%)	612 (39.8%)	573 (37.2%)	1185 (38.5%)	208 (33.9%)	207 (34.6%)	415 (34.2%)
Angiotensin II receptor antagonist									
No	886 (78.2%)	908 (79.8%)	1794 (79.0%)	1097 (71.3%)	1069 (69.4%)	2166 (70.3%)	435 (70.8%)	387 (64.6%)	822 (67.8%)
Yes	247 (21.8%)	230 (20.2%)	477 (21.0%)	442 (28.7%)	472 (30.6%)	914 (29.7%)	179 (29.2%)	212 (35.4%)	391 (32.2%)
Prior Ischemic amputation									
No	1079 (95.2%)	1085 (95.3%)	2164 (95.3%)	1454 (94.5%)	1463 (94.9%)	2917 (94.7%)	579 (94.3%)	562 (93.8%)	1141 (94.1%)
Yes	54 (4.8%)	53 (4.7%)	107 (4.7%)	85 (5.5%)	78 (5.1%)	163 (5.3%)	35 (5.7%)	37 (6.2%)	72 (5.9%)
Baseline eGFR imputed (mL/min)									
n	1130	1138	2268	1538	1541	3079	613	598	1211
Nmiss	3	0	3	1	0	1	1	1	2
Mean	84.219	82.404	83.308	77.193	76.803	76.998	75.577	76.660	76.112
SD	29.185	23.558	26.521	23.883	23.598	23.738	24.423	23.843	24.134
Min	9.31	24.00	9.31	21.00	17.50	17.50	12.13	19.40	12.13
Q1	66.000	66.000	66.000	60.000	60.000	60.000	59.400	60.000	60.000
Median	84.000	83.000	83.070	76.000	76.000	76.000	73.700	76.415	75.000
Q3	97.000	96.000	96.000	91.000	90.000	91.000	90.000	91.700	90.000
Max	619.23	237.00	619.23	208.93	176.00	208.93	185.21	153.46	185.21
eGFR imputed (cut-offs: 60ml/min/1.73m2)									
missing	3 (0.3%)	0	3 (0.1%)	1 (<0.1%)	0	1 (<0.1%)	1 (0.2%)	1 (0.2%)	2 (0.2%)
<60 ml/min/1.73m2	168 (14.8%)	181 (15.9%)	349 (15.4%)	349 (22.7%)	356 (23.1%)	705 (22.9%)	154 (25.1%)	139 (23.2%)	293 (24.2%)

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Categories	Type of procedure and clopidogrel use, per IxRS assignment: SURGICAL			Type of procedure and clopidogrel use, per IxRS assignment: Endovascular with clopidogrel			Type of procedure and clopidogrel use, per IxRS assignment: Endovascular without clopidogrel		
	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=1133 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=1138 (100%)	Total N=2271 (100%)	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=1539 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=1541 (100%)	Total N=3080 (100%)	Rivaroxaban 2.5 mg bid + ASA 100 mg od N=614 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=599 (100%)	Total N=1213 (100%)
>=60 ml/min/1.73m2	962 (84.9%)	957 (84.1%)	1919 (84.5%)	1189 (77.3%)	1185 (76.9%)	2374 (77.1%)	459 (74.8%)	459 (76.6%)	918 (75.7%)
ABI prior to procedure									
n	1095	1112	2207	1475	1475	2950	597	577	1174
Nmiss	38	26	64	64	66	130	17	22	39
Mean	0.4692	0.4615	0.4653	0.5755	0.5794	0.5775	0.5570	0.5755	0.5661
SD	0.1891	0.1888	0.1889	0.1867	0.1881	0.1874	0.1849	0.1877	0.1864
Min	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Q1	0.3500	0.3500	0.3500	0.4700	0.4800	0.4800	0.4500	0.4700	0.4600
Median	0.4800	0.4700	0.4800	0.6000	0.6000	0.6000	0.5800	0.6000	0.5900
Q3	0.6000	0.6000	0.6000	0.7000	0.7000	0.7000	0.6800	0.7000	0.7000
Max	1.220	1.050	1.220	1.430	1.280	1.430	1.250	1.280	1.280
TBI prior to procedure									
n	13	7	20	47	47	94	12	13	25
Nmiss	1120	1131	2251	1492	1494	2986	602	586	1188
Mean	0.3569	0.1986	0.3015	0.3515	0.3813	0.3664	0.3933	0.3438	0.3676
SD	0.1752	0.1187	0.1728	0.1900	0.1786	0.1840	0.1746	0.2203	0.1972
Min	0.140	0.000	0.000	0.000	0.000	0.000	0.160	0.000	0.000
Q1	0.2000	0.1100	0.1700	0.2200	0.2700	0.2500	0.2150	0.1600	0.1900
Median	0.4300	0.1900	0.2400	0.3500	0.3700	0.3600	0.4400	0.3000	0.4000
Q3	0.5000	0.2900	0.4750	0.5200	0.5000	0.5100	0.5400	0.5400	0.5400
Max	0.600	0.360	0.600	0.650	0.780	0.780	0.630	0.600	0.630

The ITT analysis set includes all randomized subjects.
The median time from actual qualifying revascularization procedure to randomization is 5 days.
bid = twice daily, od = once daily, ASA = acetylsalicylic acid.
eGFR = estimated glomerular filtration rate, NYHA = New York Heart Association, ABI = ankle brachial index, TBI = toe brachial index, LDL = low-density lipoprotein, MI = myocardial infarction.
Imputation of baseline eGFR uses Cockcroft and Gault formula or if missing weight, but age, gender and race (White or other race includes not reported race) are available, then CKD-EPI formula is used.
Percentages are calculated with the number of subjects in each parameter and treatment group as denominator.
Multiple: Subjects who reported that they belong to more than one race.
Subjects are considered fragile if age >75 years or weight <=50 kg or baseline eGFR <50 mL/min/1.73m2. Subgroup variables from Atrial fibrillation disease history and below are added post-hoc.
Baseline value for ABI and TBI is defined as the measurement at month 1 visit. All other baseline characteristics are defined as the measurement at screening.
Source: 5.3.5.1.1 PH-40164/Post-hoc Table 14.3.5.1.2/1

付表 2.7.6.1.a.1-2 すべての TEAE（全体集団、SAF）

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
Number (%) of subjects with at least one adverse event		1485 (45.6%)	1491 (45.9%)	2976 (45.8%)
Blood and lymphatic system disorders	血液およびリンパ系障害	66 (2.0%)	49 (1.5%)	115 (1.8%)
Anaemia	貧血	43 (1.3%)	32 (1.0%)	75 (1.2%)
Antiphospholipid syndrome	抗リン脂質抗体症候群	0	1 (<0.1%)	1 (<0.1%)
Blood loss anaemia	失血性貧血	1 (<0.1%)	0	1 (<0.1%)
Eosinophilia	好酸球増加症	0	1 (<0.1%)	1 (<0.1%)
Febrile neutropenia	発熱性好中球減少症	1 (<0.1%)	0	1 (<0.1%)
Hypercoagulation	凝固亢進	0	1 (<0.1%)	1 (<0.1%)
Increased tendency to bruise	内出血発生の増加傾向	0	3 (<0.1%)	3 (<0.1%)
Iron deficiency anaemia	鉄欠乏性貧血	10 (0.3%)	4 (0.1%)	14 (0.2%)
Leukocytosis	白血球増加症	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Leukopenia	白血球減少症	1 (<0.1%)	0	1 (<0.1%)
Lymphadenopathy	リンパ節症	0	1 (<0.1%)	1 (<0.1%)
Lymphocytosis	リンパ球増加症	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Microcytic anaemia	小球性貧血	0	1 (<0.1%)	1 (<0.1%)
Nephrogenic anaemia	腎性貧血	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Neutropenia	好中球減少症	1 (<0.1%)	0	1 (<0.1%)
Normochromic normocytic anaemia	正色素性正球性貧血	2 (<0.1%)	0	2 (<0.1%)
Normocytic anaemia	正球性貧血	1 (<0.1%)	0	1 (<0.1%)
Pancytopenia	汎血球減少症	1 (<0.1%)	0	1 (<0.1%)
Polycythaemia	赤血球増加症	2 (<0.1%)	0	2 (<0.1%)
Splenomegaly	脾腫	1 (<0.1%)	0	1 (<0.1%)
Thrombocytopenia	血小板減少症	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Thrombocytosis	血小板増加症	1 (<0.1%)	0	1 (<0.1%)
Thrombotic thrombocytopenic purpura	血栓性血小板減少性紫斑病	1 (<0.1%)	0	1 (<0.1%)
Cardiac disorders	心臓障害	179 (5.5%)	193 (5.9%)	372 (5.7%)
Acute left ventricular failure	急性左室不全	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Acute myocardial infarction	急性心筋梗塞	0	1 (<0.1%)	1 (<0.1%)
Angina pectoris	狭心症	18 (0.6%)	16 (0.5%)	34 (0.5%)
Angina unstable	不安定狭心症	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Aortic valve incompetence	大動脈弁閉鎖不全症	1 (<0.1%)	0	1 (<0.1%)
Aortic valve stenosis	大動脈弁狭窄	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Arrhythmia	不整脈	5 (0.2%)	4 (0.1%)	9 (0.1%)
Arrhythmia supraventricular	上室性不整脈	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Arteriosclerosis coronary artery	冠動脈硬化症	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Atrial fibrillation	心房細動	50 (1.5%)	67 (2.1%)	117 (1.8%)
Atrial flutter	心房粗動	7 (0.2%)	3 (<0.1%)	10 (0.2%)
Atrial tachycardia	心房頻脈	0	1 (<0.1%)	1 (<0.1%)
Atrial thrombosis	心房血栓症	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Atrioventricular block complete	完全房室ブロック	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Atrioventricular block first degree	第一度房室ブロック	0	1 (<0.1%)	1 (<0.1%)
Atrioventricular block second degree	第二度房室ブロック	0	3 (<0.1%)	3 (<0.1%)
Bradycardia	徐脈	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Bundle branch block left	左脚ブロック	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bundle branch block right	右脚ブロック	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cardiac arrest	心停止	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cardiac failure	心不全	15 (0.5%)	20 (0.6%)	35 (0.5%)
Cardiac failure acute	急性心不全	3 (<0.1%)	6 (0.2%)	9 (0.1%)
Cardiac failure chronic	慢性心不全	7 (0.2%)	3 (<0.1%)	10 (0.2%)
Cardiac failure congestive	うっ血性心不全	12 (0.4%)	10 (0.3%)	22 (0.3%)
Cardiac tamponade	心タンポナーデ	1 (<0.1%)	0	1 (<0.1%)
Cardiac valve disease	心臓弁膜疾患	2 (<0.1%)	0	2 (<0.1%)
Cardio-respiratory arrest	心肺停止	2 (<0.1%)	0	2 (<0.1%)
Cardiogenic shock	心原性ショック	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
Cardiopulmonary failure	心肺不全	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cardiovascular disorder	心血管障害	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Cardiovascular insufficiency	心血管不全	1 (<0.1%)	0	1 (<0.1%)
Congestive cardiomyopathy	うっ血性心筋症	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Coronary artery disease	冠動脈疾患	25 (0.8%)	27 (0.8%)	52 (0.8%)
Coronary artery occlusion	冠動脈閉塞	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Coronary artery stenosis	冠動脈狭窄	7 (0.2%)	3 (<0.1%)	10 (0.2%)
Cyanosis	チアノーゼ	2 (<0.1%)	0	2 (<0.1%)
Extrasystoles	期外収縮	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Hypertensive heart disease	高血圧性心疾患	0	2 (<0.1%)	2 (<0.1%)
Ischaemic cardiomyopathy	虚血性心筋症	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Left ventricular dysfunction	左室機能不全	0	2 (<0.1%)	2 (<0.1%)
Left ventricular failure	左室不全	1 (<0.1%)	0	1 (<0.1%)
Left ventricular hypertrophy	左室肥大	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Mitral valve incompetence	僧帽弁閉鎖不全症	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Myocardial fibrosis	心筋線維症	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Myocardial infarction	心筋梗塞	1 (<0.1%)	0	1 (<0.1%)
Myocardial ischaemia	心筋虚血	8 (0.2%)	2 (<0.1%)	10 (0.2%)
Palpitations	動悸	3 (<0.1%)	4 (0.1%)	7 (0.1%)
Pericardial effusion	心嚢液貯留	0	2 (<0.1%)	2 (<0.1%)
Pericardial haemorrhage	心嚢内出血	0	1 (<0.1%)	1 (<0.1%)
Pericarditis	心膜炎	0	1 (<0.1%)	1 (<0.1%)
Right ventricular failure	右室不全	0	2 (<0.1%)	2 (<0.1%)
Sinus arrest	洞停止	1 (<0.1%)	0	1 (<0.1%)
Sinus bradycardia	洞性徐脈	0	1 (<0.1%)	1 (<0.1%)
Sinus node dysfunction	洞結節機能不全	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Sinus tachycardia	洞性頻脈	4 (0.1%)	0	4 (<0.1%)
Stress cardiomyopathy	ストレス心筋症	0	1 (<0.1%)	1 (<0.1%)
Supraventricular extrasystoles	上室性期外収縮	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Supraventricular tachyarrhythmia	上室性頻脈性不整脈	0	1 (<0.1%)	1 (<0.1%)
Supraventricular tachycardia	上室性頻脈	4 (0.1%)	0	4 (<0.1%)
Systolic dysfunction	収縮機能障害	2 (<0.1%)	0	2 (<0.1%)
Tachycardia	頻脈	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Tachycardia paroxysmal	発作性頻脈	1 (<0.1%)	0	1 (<0.1%)
Tricuspid valve incompetence	三尖弁閉鎖不全症	1 (<0.1%)	0	1 (<0.1%)
Ventricular arrhythmia	心室性不整脈	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Ventricular extrasystoles	心室性期外収縮	0	1 (<0.1%)	1 (<0.1%)
Ventricular fibrillation	心室細動	0	2 (<0.1%)	2 (<0.1%)
Ventricular tachycardia	心室性頻脈	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Congenital, familial and genetic disorders	先天性、家族性および遺伝性障害	7 (0.2%)	5 (0.2%)	12 (0.2%)
Adenomatous polyposis coli	大腸腺腫性ポリポーシス	1 (<0.1%)	0	1 (<0.1%)
Atrial septal defect	心房中隔欠損症	1 (<0.1%)	0	1 (<0.1%)
Carbohydrate metabolism disorder	炭水化物代謝障害	0	1 (<0.1%)	1 (<0.1%)
Cerebral palsy	脳性麻痺	1 (<0.1%)	0	1 (<0.1%)
Congenital bladder neck obstruction	先天性膀胱頚部閉塞症	0	1 (<0.1%)	1 (<0.1%)
Factor V Leiden mutation	第Ｖ因子ライデン変異	1 (<0.1%)	0	1 (<0.1%)
Haemophilia	血友病	1 (<0.1%)	0	1 (<0.1%)
Hydrocele	陰嚢水瘤	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Phimosis	包茎	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Ear and labyrinth disorders	耳および迷路障害	18 (0.6%)	25 (0.8%)	43 (0.7%)
Deafness	難聴	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Ear pain	耳痛	0	1 (<0.1%)	1 (<0.1%)
Eustachian tube dysfunction	耳管機能障害	1 (<0.1%)	0	1 (<0.1%)
Hypoacusis	聴力低下	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Otorrhoea	耳漏	0	1 (<0.1%)	1 (<0.1%)
Sudden hearing loss	突発性難聴	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Tinnitus	耳鳴	4 (0.1%)	3 (<0.1%)	7 (0.1%)

2.7.6.1.a 付録 1

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
Vertigo	回転性めまい	7 (0.2%)	13 (0.4%)	20 (0.3%)
Vertigo labyrinthine	迷路性回転性めまい	0	1 (<0.1%)	1 (<0.1%)
Vertigo positional	頭位性回転性めまい	0	1 (<0.1%)	1 (<0.1%)
Endocrine disorders	内分泌障害	10 (0.3%)	9 (0.3%)	19 (0.3%)
Adrenal cyst	副腎嚢胞	0	1 (<0.1%)	1 (<0.1%)
Cushing's syndrome	クッシング症候群	1 (<0.1%)	0	1 (<0.1%)
Goitre	甲状腺腫	3 (<0.1%)	4 (0.1%)	7 (0.1%)
Hyperthyroidism	甲状腺機能亢進症	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Hypothyroidism	甲状腺機能低下症	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Thyroid mass	甲状腺腫瘤	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Eye disorders	眼障害	42 (1.3%)	39 (1.2%)	81 (1.2%)
Age-related macular degeneration	加齢黄斑変性	1 (<0.1%)	0	1 (<0.1%)
Blepharochalasis	眼瞼弛緩症	0	1 (<0.1%)	1 (<0.1%)
Cataract	白内障	20 (0.6%)	16 (0.5%)	36 (0.6%)
Cataract cortical	皮質白内障	1 (<0.1%)	0	1 (<0.1%)
Cataract nuclear	核性白内障	0	1 (<0.1%)	1 (<0.1%)
Cataract subcapsular	嚢下白内障	1 (<0.1%)	0	1 (<0.1%)
Cystoid macular oedema	嚢胞様黄斑浮腫	0	1 (<0.1%)	1 (<0.1%)
Dacryostenosis acquired	後天性涙道狭窄	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Detachment of macular retinal pigment epithelium	黄斑網膜色素上皮剥離	0	1 (<0.1%)	1 (<0.1%)
Diabetic retinal oedema	糖尿病性網膜浮腫	0	1 (<0.1%)	1 (<0.1%)
Diabetic retinopathy	糖尿病網膜症	7 (0.2%)	2 (<0.1%)	9 (0.1%)
Diplopia	複視	0	1 (<0.1%)	1 (<0.1%)
Eye allergy	眼のアレルギー	1 (<0.1%)	0	1 (<0.1%)
Eye disorder	眼の障害	0	2 (<0.1%)	2 (<0.1%)
Eye haemorrhage	眼出血	1 (<0.1%)	0	1 (<0.1%)
Eye movement disorder	眼運動障害	1 (<0.1%)	0	1 (<0.1%)
Eye swelling	眼部腫脹	0	1 (<0.1%)	1 (<0.1%)
Eyelid bleeding	眼瞼出血	1 (<0.1%)	0	1 (<0.1%)
Eyelid ptosis	眼瞼下垂	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Glaucoma	緑内障	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Iridocyclitis	虹彩毛様体炎	0	1 (<0.1%)	1 (<0.1%)
Iritis	虹彩炎	1 (<0.1%)	0	1 (<0.1%)
Macular degeneration	黄斑変性	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Macular detachment	黄斑剥離	0	1 (<0.1%)	1 (<0.1%)
Macular hole	黄斑円孔	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Macular oedema	黄斑浮腫	1 (<0.1%)	0	1 (<0.1%)
Myopia	近視	0	1 (<0.1%)	1 (<0.1%)
Panophthalmitis	全眼球炎	1 (<0.1%)	0	1 (<0.1%)
Retinal artery embolism	網膜動脈塞栓症	0	1 (<0.1%)	1 (<0.1%)
Retinal artery occlusion	網膜動脈閉塞	1 (<0.1%)	0	1 (<0.1%)
Retinal detachment	網膜剥離	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Retinal haemorrhage	網膜出血	0	1 (<0.1%)	1 (<0.1%)
Retinal vascular disorder	網膜血管障害	0	1 (<0.1%)	1 (<0.1%)
Retinopathy	網膜症	0	1 (<0.1%)	1 (<0.1%)
Swelling of eyelid	眼瞼腫脹	1 (<0.1%)	0	1 (<0.1%)
Visual acuity reduced	視力低下	0	1 (<0.1%)	1 (<0.1%)
Visual impairment	視力障害	0	1 (<0.1%)	1 (<0.1%)
Vitreoretinal traction syndrome	硝子体網膜牽引症候群	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vitreous floaters	硝子体浮遊物	0	1 (<0.1%)	1 (<0.1%)
Vitreous haemorrhage	硝子体出血	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal disorders	胃腸障害	198 (6.1%)	187 (5.8%)	385 (5.9%)
Abdominal adhesions	腹部癒着	0	1 (<0.1%)	1 (<0.1%)
Abdominal discomfort	腹部不快感	6 (0.2%)	3 (<0.1%)	9 (0.1%)
Abdominal distension	腹部膨満	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Abdominal hernia	腹部ヘルニア	1 (<0.1%)	0	1 (<0.1%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
Abdominal incarcerated hernia	嵌頓腹部ヘルニア	1 (<0.1%)	0	1 (<0.1%)
Abdominal mass	腹部腫瘤	0	1 (<0.1%)	1 (<0.1%)
Abdominal pain	腹痛	9 (0.3%)	8 (0.2%)	17 (0.3%)
Abdominal pain lower	下腹部痛	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Abdominal pain upper	上腹部痛	19 (0.6%)	16 (0.5%)	35 (0.5%)
Abdominal tenderness	腹部圧痛	0	1 (<0.1%)	1 (<0.1%)
Alcoholic pancreatitis	アルコール性膵炎	1 (<0.1%)	0	1 (<0.1%)
Anal fissure	裂肛	0	2 (<0.1%)	2 (<0.1%)
Anal incontinence	肛門失禁	1 (<0.1%)	0	1 (<0.1%)
Anal stenosis	肛門狭窄	0	1 (<0.1%)	1 (<0.1%)
Ascites	腹水	0	1 (<0.1%)	1 (<0.1%)
Chronic gastritis	慢性胃炎	3 (<0.1%)	4 (0.1%)	7 (0.1%)
Colitis	大腸炎	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Colitis ischaemic	虚血性大腸炎	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Constipation	便秘	12 (0.4%)	13 (0.4%)	25 (0.4%)
Crohn's disease	クローン病	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Dental alveolar anomaly	歯槽異常	0	1 (<0.1%)	1 (<0.1%)
Dental caries	齲歯	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Diaphragmatic hernia	横隔膜ヘルニア	0	1 (<0.1%)	1 (<0.1%)
Diarrhoea	下痢	26 (0.8%)	22 (0.7%)	48 (0.7%)
Diverticulum	憩室	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Diverticulum intestinal	腸憩室	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Diverticulum intestinal haemorrhagic	出血性腸憩室	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Dry mouth	口内乾燥	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Duodenal polyp	十二指腸ポリープ	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Duodenal ulcer	十二指腸潰瘍	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Duodenitis	十二指腸炎	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Dyspepsia	消化不良	15 (0.5%)	8 (0.2%)	23 (0.4%)
Dysphagia	嚥下障害	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Enterocolitis	腸炎	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Enterocutaneous fistula	腸管皮膚瘻	1 (<0.1%)	0	1 (<0.1%)
Enterovesical fistula	腸膀胱瘻	0	1 (<0.1%)	1 (<0.1%)
Erosive duodenitis	びらん性十二指腸炎	0	1 (<0.1%)	1 (<0.1%)
Erosive oesophagitis	びらん性食道炎	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Flatulence	鼓腸	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Food poisoning	食中毒	0	1 (<0.1%)	1 (<0.1%)
Gallstone ileus	胆石性イレウス	0	1 (<0.1%)	1 (<0.1%)
Gastric antral vascular ectasia	胃前庭部毛細血管拡張症	1 (<0.1%)	0	1 (<0.1%)
Gastric disorder	胃障害	1 (<0.1%)	0	1 (<0.1%)
Gastric haemorrhage	胃出血	1 (<0.1%)	0	1 (<0.1%)
Gastric polyps	胃ポリープ	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gastric ulcer	胃潰瘍	6 (0.2%)	6 (0.2%)	12 (0.2%)
Gastric ulcer haemorrhage	出血性胃潰瘍	1 (<0.1%)	0	1 (<0.1%)
Gastritis	胃炎	18 (0.6%)	9 (0.3%)	27 (0.4%)
Gastritis erosive	びらん性胃炎	3 (<0.1%)	6 (0.2%)	9 (0.1%)
Gastrointestinal angiodysplasia	胃腸管血管異形成	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Gastrointestinal disorder	胃腸障害	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Gastrointestinal necrosis	消化管壊死	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal pain	消化器痛	0	1 (<0.1%)	1 (<0.1%)
Gastrooesophageal reflux disease	胃食道逆流性疾患	9 (0.3%)	9 (0.3%)	18 (0.3%)
Gingival bleeding	歯肉出血	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Glossitis	舌炎	1 (<0.1%)	0	1 (<0.1%)
Glycogenic acanthosis	グリコーゲンアカントーシス	1 (<0.1%)	0	1 (<0.1%)
Haematemesis	吐血	1 (<0.1%)	0	1 (<0.1%)
Haemorrhagic erosive gastritis	出血性びらん性胃炎	0	1 (<0.1%)	1 (<0.1%)
Haemorrhoids	痔核	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Hiatus hernia	裂孔ヘルニア	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Ileus	イレウス	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Impaired gastric emptying	胃排出不全	2 (<0.1%)	0	2 (<0.1%)
Inguinal hernia	鼠径ヘルニア	5 (0.2%)	9 (0.3%)	14 (0.2%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
Intestinal angina	腸管アンギナ	0	1 (<0.1%)	1 (<0.1%)
Intestinal ischaemia	腸管虚血	4 (0.1%)	3 (<0.1%)	7 (0.1%)
Intestinal obstruction	腸閉塞	4 (0.1%)	3 (<0.1%)	7 (0.1%)
Intestinal perforation	腸管穿孔	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Intestinal polyp	腸管ポリープ	1 (<0.1%)	0	1 (<0.1%)
Intestinal ulcer	腸潰瘍	0	1 (<0.1%)	1 (<0.1%)
Large intestinal obstruction	大腸閉塞	0	1 (<0.1%)	1 (<0.1%)
Large intestine perforation	大腸穿孔	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Large intestine polyp	大腸ポリープ	13 (0.4%)	7 (0.2%)	20 (0.3%)
Loose tooth	弛緩歯	0	1 (<0.1%)	1 (<0.1%)
Lower gastrointestinal haemorrhage	下部消化管出血	1 (<0.1%)	0	1 (<0.1%)
Mechanical ileus	機械的イレウス	1 (<0.1%)	0	1 (<0.1%)
Melaena	メレナ	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Nausea	悪心	15 (0.5%)	10 (0.3%)	25 (0.4%)
Obstructive pancreatitis	閉塞性膵炎	0	1 (<0.1%)	1 (<0.1%)
Oedematous pancreatitis	浮腫性膵炎	1 (<0.1%)	0	1 (<0.1%)
Oesophagitis	食道炎	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Oral lichen planus	口腔扁平苔癬	0	1 (<0.1%)	1 (<0.1%)
Pancreatic duct stenosis	膵管狭窄	0	1 (<0.1%)	1 (<0.1%)
Pancreatic mass	膵腫瘤	0	1 (<0.1%)	1 (<0.1%)
Pancreatitis	膵炎	6 (0.2%)	1 (<0.1%)	7 (0.1%)
Pancreatitis acute	急性膵炎	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Pancreatitis chronic	慢性膵炎	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Pancreatitis necrotising	壊死性膵炎	1 (<0.1%)	0	1 (<0.1%)
Peptic ulcer perforation	穿孔性消化性潰瘍	0	1 (<0.1%)	1 (<0.1%)
Periodontal disease	歯周病	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Rectal polyp	直腸ポリープ	1 (<0.1%)	0	1 (<0.1%)
Salivary duct obstruction	唾液管閉塞	0	1 (<0.1%)	1 (<0.1%)
Salivary gland calculus	唾液腺結石	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Small intestinal obstruction	小腸閉塞	0	3 (<0.1%)	3 (<0.1%)
Small intestinal perforation	小腸穿孔	1 (<0.1%)	0	1 (<0.1%)
Subileus	亜イレウス	1 (<0.1%)	0	1 (<0.1%)
Tongue blistering	舌水疱形成	1 (<0.1%)	0	1 (<0.1%)
Tooth loss	歯の脱落	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Toothache	歯痛	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Umbilical hernia	臍ヘルニア	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Umbilical hernia, obstructive	閉塞性臍ヘルニア	0	1 (<0.1%)	1 (<0.1%)
Upper gastrointestinal haemorrhage	上部消化管出血	2 (<0.1%)	0	2 (<0.1%)
Volvulus	腸の軸捻転	0	1 (<0.1%)	1 (<0.1%)
Vomiting	嘔吐	7 (0.2%)	15 (0.5%)	22 (0.3%)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	118 (3.6%)	119 (3.7%)	237 (3.6%)
Asthenia	無力症	7 (0.2%)	4 (0.1%)	11 (0.2%)
Catheter site induration	カテーテル留置部位硬結	0	1 (<0.1%)	1 (<0.1%)
Catheter site swelling	カテーテル留置部位腫脹	1 (<0.1%)	0	1 (<0.1%)
Chest discomfort	胸部不快感	6 (0.2%)	2 (<0.1%)	8 (0.1%)
Chest pain	胸痛	15 (0.5%)	19 (0.6%)	34 (0.5%)
Chills	悪寒	1 (<0.1%)	0	1 (<0.1%)
Complication associated with device	医療機器関連合併症	1 (<0.1%)	0	1 (<0.1%)
Crepitations	捻髪音	0	1 (<0.1%)	1 (<0.1%)
Death	死亡	1 (<0.1%)	0	1 (<0.1%)
Discomfort	不快感	0	1 (<0.1%)	1 (<0.1%)
Drug intolerance	薬物不耐性	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Face oedema	顔面浮腫	1 (<0.1%)	0	1 (<0.1%)
Fatigue	疲労	11 (0.3%)	12 (0.4%)	23 (0.4%)
Feeling cold	冷感	1 (<0.1%)	0	1 (<0.1%)
Gait disturbance	歩行障害	5 (0.2%)	3 (<0.1%)	8 (0.1%)
General physical health deterioration	全身健康状態悪化	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Granuloma	肉芽腫	1 (<0.1%)	0	1 (<0.1%)
Hernia	ヘルニア	0	2 (<0.1%)	2 (<0.1%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
Impaired healing	治癒不良	7 (0.2%)	9 (0.3%)	16 (0.2%)
Inflammation	炎症	4 (0.1%)	3 (<0.1%)	7 (0.1%)
Influenza like illness	インフルエンザ様疾患	1 (<0.1%)	0	1 (<0.1%)
Malaise	倦怠感	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Medical device site pain	医療機器使用部位疼痛	1 (<0.1%)	0	1 (<0.1%)
Multiple organ dysfunction syndrome	多臓器機能不全症候群	0	3 (<0.1%)	3 (<0.1%)
Non-cardiac chest pain	非心臓性胸痛	8 (0.2%)	6 (0.2%)	14 (0.2%)
Oedema	浮腫	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Oedema peripheral	末梢性浮腫	17 (0.5%)	21 (0.6%)	38 (0.6%)
Organ failure	臓器不全	1 (<0.1%)	0	1 (<0.1%)
Pain	疼痛	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Peripheral swelling	末梢腫脹	9 (0.3%)	11 (0.3%)	20 (0.3%)
Puncture site haemorrhage	穿刺部位出血	1 (<0.1%)	0	1 (<0.1%)
Pyrexia	発熱	4 (0.1%)	3 (<0.1%)	7 (0.1%)
Secretion discharge	分泌物分泌	0	1 (<0.1%)	1 (<0.1%)
Stent-graft endoleak	ステントグラフトエンドリーク	1 (<0.1%)	0	1 (<0.1%)
Swelling face	顔面腫脹	1 (<0.1%)	0	1 (<0.1%)
Systemic inflammatory response syndrome	全身性炎症反応症候群	1 (<0.1%)	0	1 (<0.1%)
Thirst	口渇	1 (<0.1%)	0	1 (<0.1%)
Vascular device occlusion	血管デバイス閉塞	0	2 (<0.1%)	2 (<0.1%)
Vascular stent occlusion	血管ステント閉塞	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Vascular stent stenosis	血管ステント狭窄	18 (0.6%)	17 (0.5%)	35 (0.5%)
Vascular stent thrombosis	血管ステント血栓症	0	1 (<0.1%)	1 (<0.1%)
Hepatobiliary disorders	肝胆道系障害	29 (0.9%)	38 (1.2%)	67 (1.0%)
Bile duct obstruction	胆管閉塞	0	3 (<0.1%)	3 (<0.1%)
Bile duct stone	胆管結石	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Biliary dyskinesia	胆道ジスキネジア	1 (<0.1%)	0	1 (<0.1%)
Cholangitis	胆管炎	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Cholangitis acute	急性胆管炎	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cholecystitis	胆嚢炎	7 (0.2%)	4 (0.1%)	11 (0.2%)
Cholecystitis acute	急性胆嚢炎	2 (<0.1%)	13 (0.4%)	15 (0.2%)
Cholecystitis chronic	慢性胆嚢炎	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Cholelithiasis	胆石症	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Cholestasis	胆汁うっ滞	0	1 (<0.1%)	1 (<0.1%)
Cirrhosis alcoholic	アルコール性肝硬変	1 (<0.1%)	0	1 (<0.1%)
Hepatic calcification	肝石灰化	0	1 (<0.1%)	1 (<0.1%)
Hepatic cirrhosis	肝硬変	3 (<0.1%)	0	3 (<0.1%)
Hepatic failure	肝不全	0	1 (<0.1%)	1 (<0.1%)
Hepatic function abnormal	肝機能異常	2 (<0.1%)	0	2 (<0.1%)
Hepatic steatosis	脂肪肝	4 (0.1%)	3 (<0.1%)	7 (0.1%)
Hepatomegaly	肝腫大	0	3 (<0.1%)	3 (<0.1%)
Hepatorenal syndrome	肝腎症候群	0	1 (<0.1%)	1 (<0.1%)
Hyperbilirubinaemia	高ビリルビン血症	0	1 (<0.1%)	1 (<0.1%)
Liver disorder	肝障害	1 (<0.1%)	0	1 (<0.1%)
Liver injury	肝損傷	0	1 (<0.1%)	1 (<0.1%)
Portal hypertension	門脈圧亢進症	0	1 (<0.1%)	1 (<0.1%)
Primary biliary cholangitis	原発性胆汁性胆管炎	1 (<0.1%)	0	1 (<0.1%)
Steatohepatitis	脂肪性肝炎	0	2 (<0.1%)	2 (<0.1%)
Immune system disorders	免疫系障害	5 (0.2%)	10 (0.3%)	15 (0.2%)
Allergy to arthropod bite	節足動物咬傷アレルギー	1 (<0.1%)	0	1 (<0.1%)
Allergy to arthropod sting	節足動物刺傷アレルギー	0	1 (<0.1%)	1 (<0.1%)
Anaphylactic reaction	アナフィラキシー反応	0	3 (<0.1%)	3 (<0.1%)
Drug hypersensitivity	薬物過敏症	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hypersensitivity	過敏症	2 (<0.1%)	5 (0.2%)	7 (0.1%)
Multiple allergies	複合アレルギー	0	1 (<0.1%)	1 (<0.1%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
Seasonal allergy	季節性アレルギー	1 (<0.1%)	0	1 (<0.1%)
Infections and infestations	感染症および寄生虫症	380 (11.7%)	378 (11.6%)	758 (11.7%)
Abdominal abscess	腹部膿瘍	0	1 (<0.1%)	1 (<0.1%)
Abdominal infection	腹部感染	1 (<0.1%)	0	1 (<0.1%)
Abscess	膿瘍	2 (<0.1%)	0	2 (<0.1%)
Abscess limb	四肢膿瘍	8 (0.2%)	6 (0.2%)	14 (0.2%)
Acarodermatitis	ダニ皮膚炎	1 (<0.1%)	0	1 (<0.1%)
Acute sinusitis	急性副鼻腔炎	0	2 (<0.1%)	2 (<0.1%)
Anal abscess	肛門膿瘍	1 (<0.1%)	0	1 (<0.1%)
Appendicitis	虫垂炎	4 (0.1%)	5 (0.2%)	9 (0.1%)
Arteriosclerotic gangrene	動脈硬化性壊疽	1 (<0.1%)	0	1 (<0.1%)
Arthritis bacterial	細菌性関節炎	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Arthritis infective	感染性関節炎	1 (<0.1%)	0	1 (<0.1%)
Bacteraemia	菌血症	0	2 (<0.1%)	2 (<0.1%)
Bacterial infection	細菌感染	1 (<0.1%)	0	1 (<0.1%)
Blister infected	感染性水疱	0	1 (<0.1%)	1 (<0.1%)
Bone abscess	骨膿瘍	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Borrelia infection	ボレリア感染	1 (<0.1%)	0	1 (<0.1%)
Bronchiolitis	細気管支炎	0	1 (<0.1%)	1 (<0.1%)
Bronchitis	気管支炎	17 (0.5%)	18 (0.6%)	35 (0.5%)
Bronchitis bacterial	細菌性気管支炎	0	1 (<0.1%)	1 (<0.1%)
Burn infection	熱傷部感染	1 (<0.1%)	0	1 (<0.1%)
Carbuncle	よう	0	1 (<0.1%)	1 (<0.1%)
Cellulitis	蜂巣炎	28 (0.9%)	23 (0.7%)	51 (0.8%)
Cellulitis gangrenous	壊疽性蜂巣炎	0	1 (<0.1%)	1 (<0.1%)
Cholecystitis infective	感染性胆嚢炎	0	2 (<0.1%)	2 (<0.1%)
Chronic hepatitis B	慢性Ｂ型肝炎	1 (<0.1%)	0	1 (<0.1%)
Clostridium difficile colitis	クロストリジウム・ディフィシレ大腸炎	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Clostridium difficile infection	クロストリジウム・ディフィシレ感染	1 (<0.1%)	0	1 (<0.1%)
Complicated appendicitis	合併症を伴う虫垂炎	0	1 (<0.1%)	1 (<0.1%)
Conjunctivitis	結膜炎	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Conjunctivitis viral	ウイルス性結膜炎	1 (<0.1%)	0	1 (<0.1%)
Cystitis	膀胱炎	3 (<0.1%)	4 (0.1%)	7 (0.1%)
Cystitis bacterial	細菌性膀胱炎	1 (<0.1%)	0	1 (<0.1%)
Dermo-hypodermitis	皮膚皮下組織炎	1 (<0.1%)	0	1 (<0.1%)
Device related infection	医療機器関連感染	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Diabetic foot infection	糖尿病性足感染	3 (<0.1%)	6 (0.2%)	9 (0.1%)
Diabetic gangrene	糖尿病性壊疽	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Diarrhoea infectious	感染性下痢	1 (<0.1%)	0	1 (<0.1%)
Diverticulitis	憩室炎	5 (0.2%)	7 (0.2%)	12 (0.2%)
Ear infection	耳感染	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Eczema infected	感染性湿疹	1 (<0.1%)	0	1 (<0.1%)
Endocarditis	心内膜炎	1 (<0.1%)	0	1 (<0.1%)
Endophthalmitis	眼内炎	0	1 (<0.1%)	1 (<0.1%)
Epididymitis	精巣上体炎	0	1 (<0.1%)	1 (<0.1%)
Erysipelas	丹毒	2 (<0.1%)	12 (0.4%)	14 (0.2%)
Escherichia sepsis	大腸菌性敗血症	1 (<0.1%)	0	1 (<0.1%)
Extradural abscess	硬膜外膿瘍	1 (<0.1%)	0	1 (<0.1%)
Fournier's gangrene	フルニエー壊疽	0	1 (<0.1%)	1 (<0.1%)
Fungal cystitis	真菌性膀胱炎	0	1 (<0.1%)	1 (<0.1%)
Fungal skin infection	皮膚真菌感染	4 (0.1%)	0	4 (<0.1%)
Furuncle	せつ	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gangrene	壊疽	21 (0.6%)	22 (0.7%)	43 (0.7%)
Gastric infection	胃感染	0	1 (<0.1%)	1 (<0.1%)
Gastric ulcer helicobacter	ヘリコバクター胃潰瘍	1 (<0.1%)	0	1 (<0.1%)
Gastroenteritis	胃腸炎	5 (0.2%)	5 (0.2%)	10 (0.2%)
Gastroenteritis salmonella	サルモネラ菌性胃腸炎	0	1 (<0.1%)	1 (<0.1%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
Gastroenteritis viral	ウイルス性胃腸炎	5 (0.2%)	1 (<0.1%)	6 (<0.1%)
Genitourinary tract infection	泌尿生殖器感染	1 (<0.1%)	0	1 (<0.1%)
Graft infection	移植片感染	1 (<0.1%)	0	1 (<0.1%)
Groin abscess	鼠径部膿瘍	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Groin infection	鼠径部感染	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Haematoma infection	血腫感染	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Helicobacter gastritis	ヘリコバクター性胃炎	0	1 (<0.1%)	1 (<0.1%)
Hepatitis C	Ｃ型肝炎	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Herpes zoster	帯状疱疹	5 (0.2%)	7 (0.2%)	12 (0.2%)
Hordeolum	麦粒腫	0	1 (<0.1%)	1 (<0.1%)
Infected lymphocele	感染性リンパ嚢腫	2 (<0.1%)	0	2 (<0.1%)
Infected seroma	感染性漿液腫	1 (<0.1%)	0	1 (<0.1%)
Infected skin ulcer	感染性皮膚潰瘍	8 (0.2%)	5 (0.2%)	13 (0.2%)
Infection	感染	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Infectious pleural effusion	感染性胸水	0	1 (<0.1%)	1 (<0.1%)
Infective exacerbation of chronic obstructive airways disease	感染による慢性閉塞性気道疾患の増悪	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Influenza	インフルエンザ	12 (0.4%)	7 (0.2%)	19 (0.3%)
Intervertebral discitis	椎間板炎	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Large intestine infection	大腸感染	0	1 (<0.1%)	1 (<0.1%)
Laryngitis	喉頭炎	0	2 (<0.1%)	2 (<0.1%)
Lice infestation	シラミ寄生	0	1 (<0.1%)	1 (<0.1%)
Localised infection	限局性感染	27 (0.8%)	17 (0.5%)	44 (0.7%)
Lower respiratory tract infection	下気道感染	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Lymph gland infection	リンパ節感染	1 (<0.1%)	0	1 (<0.1%)
Lymphangitis	リンパ管炎	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Mastoiditis	乳様突起炎	1 (<0.1%)	0	1 (<0.1%)
Medical device site infection	医療機器使用部位感染	1 (<0.1%)	0	1 (<0.1%)
Medical device site joint infection	医療機器使用部位関節感染	0	3 (<0.1%)	3 (<0.1%)
Nasopharyngitis	上咽頭炎	21 (0.6%)	30 (0.9%)	51 (0.8%)
Oesophageal candidiasis	食道カンジダ症	1 (<0.1%)	0	1 (<0.1%)
Ophthalmic herpes zoster	眼帯状疱疹	1 (<0.1%)	0	1 (<0.1%)
Oral candidiasis	口腔カンジダ症	1 (<0.1%)	0	1 (<0.1%)
Oral herpes	口腔ヘルペス	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Orchitis	精巣炎	1 (<0.1%)	0	1 (<0.1%)
Osteomyelitis	骨髄炎	14 (0.4%)	13 (0.4%)	27 (0.4%)
Osteomyelitis bacterial	細菌性骨髄炎	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Osteomyelitis chronic	慢性骨髄炎	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Otitis media	中耳炎	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Otitis media acute	急性中耳炎	0	1 (<0.1%)	1 (<0.1%)
Paronychia	爪囲炎	0	2 (<0.1%)	2 (<0.1%)
Parotitis	耳下腺炎	1 (<0.1%)	0	1 (<0.1%)
Perineal abscess	会陰膿瘍	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Perineal cellulitis	会陰蜂巣炎	0	1 (<0.1%)	1 (<0.1%)
Perinephric abscess	腎周囲膿瘍	1 (<0.1%)	0	1 (<0.1%)
Periodontitis	歯周炎	0	2 (<0.1%)	2 (<0.1%)
Peritonitis	腹膜炎	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Periumbilical abscess	臍帯周囲膿瘍	0	1 (<0.1%)	1 (<0.1%)
Pharyngitis	咽頭炎	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Pneumocystis jirovecii pneumonia	ニューモシスチス・イロベチイ肺炎	1 (<0.1%)	0	1 (<0.1%)
Pneumonia	肺炎	48 (1.5%)	57 (1.8%)	105 (1.6%)
Pneumonia bacterial	細菌性肺炎	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Post procedural infection	処置後感染	1 (<0.1%)	0	1 (<0.1%)
Post procedural sepsis	処置後敗血症	0	1 (<0.1%)	1 (<0.1%)
Postoperative wound infection	術後創感染	33 (1.0%)	32 (1.0%)	65 (1.0%)
Pseudomembranous colitis	偽膜性大腸炎	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pulmonary sepsis	肺敗血症	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Pulmonary tuberculosis	肺結核	2 (<0.1%)	0	2 (<0.1%)
Pulpitis dental	歯髄炎	2 (<0.1%)	0	2 (<0.1%)

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Purulent discharge	化膿性分泌物	0	1 (<0.1%)	1 (<0.1%)
Pyelitis	腎盂炎	1 (<0.1%)	0	1 (<0.1%)
Pyelonephritis	腎盂腎炎	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Pyelonephritis acute	急性腎盂腎炎	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pyelonephritis chronic	慢性腎盂腎炎	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pyoderma	膿皮症	0	1 (<0.1%)	1 (<0.1%)
Pyuria	膿尿	0	1 (<0.1%)	1 (<0.1%)
Respiratory tract infection	気道感染	6 (0.2%)	3 (<0.1%)	9 (0.1%)
Respiratory tract infection viral	ウイルス性気道感染	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Rhinitis	鼻炎	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Rotavirus infection	ロタウイルス感染	0	1 (<0.1%)	1 (<0.1%)
Scrotal abscess	陰嚢膿瘍	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Sepsis	敗血症	14 (0.4%)	14 (0.4%)	28 (0.4%)
Septic shock	敗血症性ショック	1 (<0.1%)	5 (0.2%)	6 (<0.1%)
Sialoadenitis	唾液腺炎	0	2 (<0.1%)	2 (<0.1%)
Sinusitis	副鼻腔炎	6 (0.2%)	5 (0.2%)	11 (0.2%)
Sinusitis bacterial	細菌性副鼻腔炎	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Skin infection	皮膚感染	3 (<0.1%)	4 (0.1%)	7 (0.1%)
Soft tissue infection	軟部組織感染	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Streptococcal sepsis	レンサ球菌性敗血症	0	1 (<0.1%)	1 (<0.1%)
Subcutaneous abscess	皮下組織膿瘍	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Superinfection bacterial	細菌重複感染	0	1 (<0.1%)	1 (<0.1%)
Tinea pedis	足部白癬	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Tonsillitis	扁桃炎	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tooth abscess	歯膿瘍	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tooth infection	歯感染	1 (<0.1%)	0	1 (<0.1%)
Tracheobronchitis	気管気管支炎	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Tuberculosis	結核	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Upper respiratory tract infection	上気道感染	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Urinary tract infection	尿路感染	33 (1.0%)	32 (1.0%)	65 (1.0%)
Urosepsis	尿路性敗血症	0	6 (0.2%)	6 (<0.1%)
Varicella zoster virus infection	水痘帯状疱疹ウイルス感染	0	1 (<0.1%)	1 (<0.1%)
Vascular device infection	血管デバイス感染	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Viral infection	ウイルス感染	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Viral upper respiratory tract infection	ウイルス性上気道感染	2 (<0.1%)	0	2 (<0.1%)
Wound infection	創傷感染	25 (0.8%)	19 (0.6%)	44 (0.7%)
Wound infection bacterial	細菌性創感染	1 (<0.1%)	0	1 (<0.1%)
Wound infection fungal	真菌性創感染	1 (<0.1%)	0	1 (<0.1%)
Wound infection pseudomonas	シュードモナス性創感染	1 (<0.1%)	0	1 (<0.1%)
Wound infection staphylococcal	ブドウ球菌性創感染	1 (<0.1%)	0	1 (<0.1%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	195 (6.0%)	207 (6.4%)	402 (6.2%)
Accidental overdose	偶発的過量投与	2 (<0.1%)	0	2 (<0.1%)
Alcohol poisoning	アルコール中毒	2 (<0.1%)	0	2 (<0.1%)
Anastomotic stenosis	吻合部狭窄	0	2 (<0.1%)	2 (<0.1%)
Animal bite	動物咬傷	1 (<0.1%)	0	1 (<0.1%)
Ankle fracture	足関節部骨折	3 (<0.1%)	5 (0.2%)	8 (0.1%)
Arterial bypass occlusion	動脈バイパス閉塞	4 (0.1%)	6 (0.2%)	10 (0.2%)
Arterial bypass stenosis	動脈バイパス狭窄	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Arterial bypass thrombosis	動脈バイパス血栓症	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Arterial restenosis	動脈再狭窄	1 (<0.1%)	0	1 (<0.1%)
Bone contusion	骨挫傷	2 (<0.1%)	0	2 (<0.1%)
Brain herniation	脳ヘルニア	0	1 (<0.1%)	1 (<0.1%)
Carbon monoxide poisoning	一酸化炭素中毒	1 (<0.1%)	0	1 (<0.1%)
Cerebral hyperperfusion syndrome	脳過潅流症候群	1 (<0.1%)	0	1 (<0.1%)
Chemical burn of skin	皮膚化学熱傷	0	1 (<0.1%)	1 (<0.1%)
Chest injury	胸部損傷	0	1 (<0.1%)	1 (<0.1%)
Clavicle fracture	鎖骨骨折	0	1 (<0.1%)	1 (<0.1%)
Compression fracture	圧迫骨折	0	1 (<0.1%)	1 (<0.1%)

2.7.6.1.a 付録 1

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
Concussion	脳振盪	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Contusion	挫傷	10 (0.3%)	10 (0.3%)	20 (0.3%)
Coronary artery restenosis	冠動脈再狭窄	1 (<0.1%)	0	1 (<0.1%)
Craniocerebral injury	頭蓋脳損傷	2 (<0.1%)	0	2 (<0.1%)
Epicondylitis	上顆炎	3 (<0.1%)	0	3 (<0.1%)
Eye contusion	眼挫傷	1 (<0.1%)	0	1 (<0.1%)
Face injury	顔面損傷	0	1 (<0.1%)	1 (<0.1%)
Facial bones fracture	顔面骨骨折	0	2 (<0.1%)	2 (<0.1%)
Failure to anastomose	吻合不全	0	1 (<0.1%)	1 (<0.1%)
Fall	転倒	11 (0.3%)	8 (0.2%)	19 (0.3%)
Femoral neck fracture	大腿骨頚部骨折	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Femur fracture	大腿骨骨折	10 (0.3%)	12 (0.4%)	22 (0.3%)
Fibula fracture	腓骨骨折	3 (<0.1%)	0	3 (<0.1%)
Foot fracture	足骨折	7 (0.2%)	4 (0.1%)	11 (0.2%)
Forearm fracture	前腕骨折	0	1 (<0.1%)	1 (<0.1%)
Foreign body	体内異物	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Foreign body in gastrointestinal tract	消化管内異物	0	1 (<0.1%)	1 (<0.1%)
Fractured sacrum	仙骨骨折	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal anastomotic leak	胃腸吻合部漏出	0	1 (<0.1%)	1 (<0.1%)
Graft thrombosis	移植片血栓症	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hand fracture	手骨折	2 (<0.1%)	0	2 (<0.1%)
Head injury	頭部損傷	2 (<0.1%)	0	2 (<0.1%)
Heat stroke	熱射病	0	1 (<0.1%)	1 (<0.1%)
Hip fracture	股関節部骨折	5 (0.2%)	5 (0.2%)	10 (0.2%)
Humerus fracture	上腕骨骨折	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Incision site erythema	切開部位紅斑	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Incision site inflammation	切開部位炎症	1 (<0.1%)	0	1 (<0.1%)
Incision site swelling	切開部位腫脹	1 (<0.1%)	0	1 (<0.1%)
Incisional hernia	瘢痕ヘルニア	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Inflammation of wound	創部炎症	0	1 (<0.1%)	1 (<0.1%)
Injury	損傷	3 (<0.1%)	0	3 (<0.1%)
Intentional overdose	企図的過量投与	1 (<0.1%)	0	1 (<0.1%)
Intentional product misuse	企図的製品誤用	1 (<0.1%)	0	1 (<0.1%)
Intra-ocular injection complication	眼内注射合併症	1 (<0.1%)	0	1 (<0.1%)
Joint capsule rupture	関節包断裂	1 (<0.1%)	0	1 (<0.1%)
Joint dislocation	関節脱臼	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Joint injury	関節損傷	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Ligament rupture	靭帯断裂	2 (<0.1%)	0	2 (<0.1%)
Ligament sprain	靭帯捻挫	0	5 (0.2%)	5 (<0.1%)
Limb injury	四肢損傷	13 (0.4%)	15 (0.5%)	28 (0.4%)
Lower limb fracture	下肢骨折	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Lumbar vertebral fracture	腰椎骨折	2 (<0.1%)	5 (0.2%)	7 (0.1%)
Meniscus injury	半月板損傷	4 (0.1%)	8 (0.2%)	12 (0.2%)
Multiple injuries	多発性外傷	2 (<0.1%)	0	2 (<0.1%)
Muscle rupture	筋断裂	1 (<0.1%)	0	1 (<0.1%)
Muscle strain	肉離れ	4 (0.1%)	3 (<0.1%)	7 (0.1%)
Nasal injury	鼻部損傷	0	1 (<0.1%)	1 (<0.1%)
Open fracture	開放骨折	0	1 (<0.1%)	1 (<0.1%)
Overdose	過量投与	1 (<0.1%)	0	1 (<0.1%)
Patella fracture	膝蓋骨骨折	1 (<0.1%)	0	1 (<0.1%)
Pelvic fracture	骨盤骨折	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Penetrating abdominal trauma	鋭的腹部外傷	0	1 (<0.1%)	1 (<0.1%)
Peripheral arterial reocclusion	末梢動脈再閉塞	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Peripheral artery restenosis	末梢動脈再狭窄	18 (0.6%)	19 (0.6%)	37 (0.6%)
Periprosthetic fracture	人工関節周囲骨折	0	1 (<0.1%)	1 (<0.1%)
Post angioplasty restenosis	血管形成後再狭窄	0	1 (<0.1%)	1 (<0.1%)
Post laminectomy syndrome	椎弓切除後症候群	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Post procedural bile leak	処置後胆汁漏出	0	1 (<0.1%)	1 (<0.1%)
Post procedural complication	処置後合併症	2 (<0.1%)	0	2 (<0.1%)
Post procedural diarrhoea	処置後下痢	0	1 (<0.1%)	1 (<0.1%)

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Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
Post procedural discharge	処置後分泌物	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Post procedural haematuria	処置後血尿	0	1 (<0.1%)	1 (<0.1%)
Post procedural inflammation	処置後炎症	1 (<0.1%)	0	1 (<0.1%)
Post procedural oedema	処置後浮腫	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Post-traumatic pain	外傷後疼痛	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Postoperative respiratory failure	術後呼吸不全	0	1 (<0.1%)	1 (<0.1%)
Postoperative thoracic procedure complication	術後胸部処置合併症	0	1 (<0.1%)	1 (<0.1%)
Postoperative wound complication	術後創合併症	0	1 (<0.1%)	1 (<0.1%)
Procedural complication	処置合併症	0	1 (<0.1%)	1 (<0.1%)
Procedural intestinal perforation	処置による腸管穿孔	0	1 (<0.1%)	1 (<0.1%)
Procedural pain	処置による疼痛	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Procedural vomiting	処置による嘔吐	0	1 (<0.1%)	1 (<0.1%)
Pseudophakic bullous keratopathy	偽水晶体性水疱性角膜症	1 (<0.1%)	0	1 (<0.1%)
Pubis fracture	恥骨骨折	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Radiation proctitis	放射線性直腸炎	0	1 (<0.1%)	1 (<0.1%)
Radius fracture	橈骨骨折	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Repetitive strain injury	反復性挫傷	1 (<0.1%)	0	1 (<0.1%)
Rib fracture	肋骨骨折	4 (0.1%)	6 (0.2%)	10 (0.2%)
Road traffic accident	交通事故	1 (<0.1%)	0	1 (<0.1%)
Seroma	漿液腫	4 (0.1%)	3 (<0.1%)	7 (0.1%)
Skin abrasion	皮膚擦過傷	2 (<0.1%)	0	2 (<0.1%)
Skin laceration	皮膚裂傷	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Skin scar contracture	皮膚瘢痕拘縮	0	1 (<0.1%)	1 (<0.1%)
Skin wound	皮膚創傷	0	1 (<0.1%)	1 (<0.1%)
Skull fractured base	頭蓋底骨折	1 (<0.1%)	0	1 (<0.1%)
Spinal column injury	脊柱損傷	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Spinal compression fracture	脊椎圧迫骨折	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Spinal fracture	脊椎骨折	0	1 (<0.1%)	1 (<0.1%)
Sternal fracture	胸骨骨折	0	1 (<0.1%)	1 (<0.1%)
Sunburn	サンバーン	1 (<0.1%)	0	1 (<0.1%)
Suture rupture	縫合部離開	0	1 (<0.1%)	1 (<0.1%)
Tendon injury	腱損傷	1 (<0.1%)	0	1 (<0.1%)
Tendon rupture	腱断裂	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Thermal burn	熱傷	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Thoracic vertebral fracture	胸椎骨折	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Tibia fracture	脛骨骨折	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Transplant failure	移植不全	1 (<0.1%)	0	1 (<0.1%)
Traumatic fracture	外傷性骨折	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Traumatic haemorrhage	外傷性出血	0	1 (<0.1%)	1 (<0.1%)
Traumatic haemothorax	外傷性血胸	0	1 (<0.1%)	1 (<0.1%)
Traumatic intracranial haemorrhage	外傷性頭蓋内出血	0	1 (<0.1%)	1 (<0.1%)
Traumatic ulcer	外傷性潰瘍	1 (<0.1%)	0	1 (<0.1%)
Ulna fracture	尺骨骨折	1 (<0.1%)	0	1 (<0.1%)
Underdose	過少量投与	0	1 (<0.1%)	1 (<0.1%)
Upper limb fracture	上肢骨折	1 (<0.1%)	0	1 (<0.1%)
Vascular access site haematoma	血管確保部位血腫	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vascular graft complication	移植血管合併症	6 (0.2%)	3 (<0.1%)	9 (0.1%)
Vascular graft occlusion	移植血管閉塞	3 (<0.1%)	4 (0.1%)	7 (0.1%)
Vascular graft restenosis	移植血管再狭窄	0	2 (<0.1%)	2 (<0.1%)
Vascular graft stenosis	移植血管狭窄	4 (0.1%)	3 (<0.1%)	7 (0.1%)
Vascular graft thrombosis	血管グラフト血栓症	1 (<0.1%)	0	1 (<0.1%)
Vascular procedure complication	血管処置合併症	1 (<0.1%)	0	1 (<0.1%)
Vascular pseudoaneurysm	血管偽動脈瘤	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Wound complication	創合併症	2 (<0.1%)	0	2 (<0.1%)
Wound dehiscence	創離開	6 (0.2%)	4 (0.1%)	10 (0.2%)
Wound haemorrhage	創傷出血	2 (<0.1%)	0	2 (<0.1%)
Wound necrosis	創壊死	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Wrist fracture	手首関節骨折	0	1 (<0.1%)	1 (<0.1%)
Investigations	臨床検査	41 (1.3%)	45 (1.4%)	86 (1.3%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
Angiogram peripheral	末梢血管造影	1 (<0.1%)	0	1 (<0.1%)
Ankle brachial index decreased	足関節上腕血圧比減少	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Aortogram abnormal	大動脈造影異常	1 (<0.1%)	0	1 (<0.1%)
Arteriogram carotid	頚動脈造影	0	1 (<0.1%)	1 (<0.1%)
Aspiration bone marrow	骨髄穿刺	0	1 (<0.1%)	1 (<0.1%)
Biopsy lung	肺生検	1 (<0.1%)	0	1 (<0.1%)
Biopsy prostate	前立腺生検	0	1 (<0.1%)	1 (<0.1%)
Blood bilirubin increased	血中ビリルビン増加	0	1 (<0.1%)	1 (<0.1%)
Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	0	1 (<0.1%)	1 (<0.1%)
Blood creatinine increased	血中クレアチニン増加	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Blood glucose increased	血中ブドウ糖増加	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	0	1 (<0.1%)	1 (<0.1%)
Blood lactic acid increased	血中乳酸増加	0	1 (<0.1%)	1 (<0.1%)
Blood potassium increased	血中カリウム増加	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Blood pressure decreased	血圧低下	1 (<0.1%)	0	1 (<0.1%)
Blood pressure increased	血圧上昇	4 (0.1%)	7 (0.2%)	11 (0.2%)
Blood triglycerides increased	血中トリグリセリド増加	0	1 (<0.1%)	1 (<0.1%)
Blood uric acid increased	血中尿酸増加	0	1 (<0.1%)	1 (<0.1%)
Blood urine present	尿中血陽性	0	1 (<0.1%)	1 (<0.1%)
Carbohydrate antigen 19-9 increased	糖鎖抗原１９－９増加	1 (<0.1%)	0	1 (<0.1%)
Cardiac monitoring abnormal	心モニタリング異常	1 (<0.1%)	0	1 (<0.1%)
Cardiac stress test abnormal	心臓負荷試験異常	0	2 (<0.1%)	2 (<0.1%)
Cardiothoracic ratio increased	心胸郭比増加	0	1 (<0.1%)	1 (<0.1%)
Cardiovascular function test abnormal	心血管機能検査異常	0	1 (<0.1%)	1 (<0.1%)
Coagulation time prolonged	凝固時間延長	1 (<0.1%)	0	1 (<0.1%)
Colonoscopy	結腸内視鏡検査	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Cystoscopy	膀胱鏡検査	1 (<0.1%)	0	1 (<0.1%)
Ejection fraction decreased	駆出率減少	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Glycosylated haemoglobin increased	グリコヘモグロビン増加	0	2 (<0.1%)	2 (<0.1%)
HIV test positive	ＨＩＶ検査陽性	0	1 (<0.1%)	1 (<0.1%)
Haematocrit decreased	ヘマトクリット減少	0	2 (<0.1%)	2 (<0.1%)
Haemoglobin decreased	ヘモグロビン減少	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Heart rate decreased	心拍数減少	1 (<0.1%)	0	1 (<0.1%)
Heart rate increased	心拍数増加	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Heart rate irregular	心拍数不整	1 (<0.1%)	0	1 (<0.1%)
Helicobacter test positive	ヘリコバクター検査陽性	0	1 (<0.1%)	1 (<0.1%)
Hepatic enzyme increased	肝酵素上昇	3 (<0.1%)	0	3 (<0.1%)
Hepatitis B virus test positive	Ｂ型肝炎ウイルス検査陽性	1 (<0.1%)	0	1 (<0.1%)
Immunoglobulins decreased	免疫グロブリン減少	1 (<0.1%)	0	1 (<0.1%)
Laboratory test abnormal	臨床検査異常	0	1 (<0.1%)	1 (<0.1%)
Low density lipoprotein increased	低比重リポ蛋白増加	0	1 (<0.1%)	1 (<0.1%)
Occult blood positive	便潜血陽性	2 (<0.1%)	0	2 (<0.1%)
Oxygen consumption increased	酸素消費量増加	1 (<0.1%)	0	1 (<0.1%)
Platelet count increased	血小板数増加	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Prostatic specific antigen increased	前立腺特異性抗原増加	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Serum ferritin decreased	血清フェリチン減少	0	1 (<0.1%)	1 (<0.1%)
Staphylococcus test positive	ブドウ球菌検査陽性	0	1 (<0.1%)	1 (<0.1%)
Vascular test	血管検査	1 (<0.1%)	0	1 (<0.1%)
Weight decreased	体重減少	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Metabolism and nutrition disorders	代謝および栄養障害	88 (2.7%)	106 (3.3%)	194 (3.0%)
Cachexia	悪液質	0	1 (<0.1%)	1 (<0.1%)
Decreased appetite	食欲減退	6 (0.2%)	5 (0.2%)	11 (0.2%)
Dehydration	脱水	8 (0.2%)	3 (<0.1%)	11 (0.2%)
Diabetes mellitus	糖尿病	11 (0.3%)	20 (0.6%)	31 (0.5%)
Diabetes mellitus inadequate control	コントロール不良の糖尿病	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Diabetic ketoacidosis	糖尿病性ケトアシドーシス	2 (<0.1%)	0	2 (<0.1%)
Diabetic metabolic decompensation	糖尿病性代謝代償不全	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
Dyslipidaemia	脂質異常症	1 (<0.1%)	5 (0.2%)	6 (<0.1%)
Folate deficiency	葉酸欠乏	2 (<0.1%)	0	2 (<0.1%)
Glucose tolerance impaired	耐糖能障害	0	2 (<0.1%)	2 (<0.1%)
Gout	痛風	5 (0.2%)	11 (0.3%)	16 (0.2%)
Hypercholesterolaemia	高コレステロール血症	0	2 (<0.1%)	2 (<0.1%)
Hyperglycaemia	高血糖	4 (0.1%)	5 (0.2%)	9 (0.1%)
Hyperglycaemic hyperosmolar nonketotic syndrome	高血糖性高浸透圧性非ケトン性症候群	0	1 (<0.1%)	1 (<0.1%)
Hyperhomocysteinaemia	高ホモシステイン血症	0	1 (<0.1%)	1 (<0.1%)
Hyperkalaemia	高カリウム血症	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Hyperlipidaemia	高脂血症	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Hypertriglyceridaemia	高トリグリセリド血症	0	2 (<0.1%)	2 (<0.1%)
Hyperuricaemia	高尿酸血症	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Hypoglycaemia	低血糖	4 (0.1%)	8 (0.2%)	12 (0.2%)
Hypokalaemia	低カリウム血症	3 (<0.1%)	4 (0.1%)	7 (0.1%)
Hypomagnesaemia	低マグネシウム血症	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Hyponatraemia	低ナトリウム血症	5 (0.2%)	8 (0.2%)	13 (0.2%)
Hypophagia	過小食	0	2 (<0.1%)	2 (<0.1%)
Hypoproteinaemia	低蛋白血症	1 (<0.1%)	0	1 (<0.1%)
Impaired fasting glucose	空腹時血中ブドウ糖不良	1 (<0.1%)	0	1 (<0.1%)
Iron deficiency	鉄欠乏	3 (<0.1%)	0	3 (<0.1%)
Ketoacidosis	ケトアシドーシス	1 (<0.1%)	0	1 (<0.1%)
Lactic acidosis	乳酸アシドーシス	1 (<0.1%)	0	1 (<0.1%)
Metabolic disorder	代謝障害	0	1 (<0.1%)	1 (<0.1%)
Polydipsia	多飲症	0	1 (<0.1%)	1 (<0.1%)
Type 1 diabetes mellitus	１型糖尿病	0	2 (<0.1%)	2 (<0.1%)
Type 2 diabetes mellitus	２型糖尿病	15 (0.5%)	12 (0.4%)	27 (0.4%)
Type 3 diabetes mellitus	３型糖尿病	0	1 (<0.1%)	1 (<0.1%)
Vitamin B complex deficiency	ビタミンＢ群欠乏	1 (<0.1%)	0	1 (<0.1%)
Vitamin B12 deficiency	ビタミンＢ１２欠乏	0	3 (<0.1%)	3 (<0.1%)
Vitamin D deficiency	ビタミンＤ欠乏	5 (0.2%)	1 (<0.1%)	6 (<0.1%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	202 (6.2%)	220 (6.8%)	422 (6.5%)
Acquired claw toe	後天性鉤爪趾	0	1 (<0.1%)	1 (<0.1%)
Arthralgia	関節痛	18 (0.6%)	32 (1.0%)	50 (0.8%)
Arthritis	関節炎	3 (<0.1%)	4 (0.1%)	7 (0.1%)
Back pain	背部痛	26 (0.8%)	32 (1.0%)	58 (0.9%)
Bone disorder	骨障害	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bone formation increased	骨形成亢進	0	1 (<0.1%)	1 (<0.1%)
Bone loss	骨喪失	1 (<0.1%)	0	1 (<0.1%)
Bone pain	骨痛	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Bone swelling	骨腫脹	0	1 (<0.1%)	1 (<0.1%)
Bursitis	滑液包炎	5 (0.2%)	8 (0.2%)	13 (0.2%)
Cervical spinal stenosis	頚部脊柱管狭窄症	0	1 (<0.1%)	1 (<0.1%)
Compartment syndrome	コンパートメント症候群	0	1 (<0.1%)	1 (<0.1%)
Diffuse idiopathic skeletal hyperostosis	びまん性特発性骨増殖症	0	1 (<0.1%)	1 (<0.1%)
Dupuytren's contracture	デュプイトラン拘縮	1 (<0.1%)	0	1 (<0.1%)
Enthesopathy	腱付着部症	0	1 (<0.1%)	1 (<0.1%)
Fistula	瘻孔	1 (<0.1%)	0	1 (<0.1%)
Flank pain	側腹部痛	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Foot deformity	足変形	0	2 (<0.1%)	2 (<0.1%)
Fracture nonunion	骨折による偽関節	0	1 (<0.1%)	1 (<0.1%)
Gouty arthritis	痛風性関節炎	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Gouty tophus	痛風結節	0	1 (<0.1%)	1 (<0.1%)
Groin pain	鼠径部痛	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Intervertebral disc degeneration	椎間板変性症	3 (<0.1%)	0	3 (<0.1%)
Intervertebral disc disorder	椎間板障害	1 (<0.1%)	0	1 (<0.1%)
Intervertebral disc protrusion	椎間板突出	12 (0.4%)	11 (0.3%)	23 (0.4%)
Jaw cyst	顎骨嚢胞	1 (<0.1%)	0	1 (<0.1%)

2.7.6.1.a 付録 1

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
Joint ankylosis	関節強直	0	1 (<0.1%)	1 (<0.1%)
Joint effusion	関節滲出液	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Joint stiffness	関節硬直	0	1 (<0.1%)	1 (<0.1%)
Joint swelling	関節腫脹	6 (0.2%)	2 (<0.1%)	8 (0.1%)
Knee deformity	膝関節変形	0	1 (<0.1%)	1 (<0.1%)
Ligament disorder	靱帯障害	0	1 (<0.1%)	1 (<0.1%)
Limb discomfort	四肢不快感	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Lumbar spinal stenosis	腰部脊柱管狭窄症	7 (0.2%)	4 (0.1%)	11 (0.2%)
Metatarsalgia	中足骨痛	0	1 (<0.1%)	1 (<0.1%)
Mobility decreased	運動性低下	1 (<0.1%)	0	1 (<0.1%)
Muscle discomfort	筋不快感	1 (<0.1%)	0	1 (<0.1%)
Muscle disorder	筋障害	0	1 (<0.1%)	1 (<0.1%)
Muscle spasms	筋痙縮	13 (0.4%)	13 (0.4%)	26 (0.4%)
Muscle tightness	筋緊張	1 (<0.1%)	0	1 (<0.1%)
Muscle twitching	筋攣縮	1 (<0.1%)	0	1 (<0.1%)
Muscular weakness	筋力低下	5 (0.2%)	5 (0.2%)	10 (0.2%)
Musculoskeletal chest pain	筋骨格系胸痛	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Musculoskeletal discomfort	筋骨格不快感	0	1 (<0.1%)	1 (<0.1%)
Musculoskeletal disorder	筋骨格障害	0	1 (<0.1%)	1 (<0.1%)
Musculoskeletal pain	筋骨格痛	11 (0.3%)	12 (0.4%)	23 (0.4%)
Myalgia	筋肉痛	6 (0.2%)	4 (0.1%)	10 (0.2%)
Myopathy	ミオパチー	0	1 (<0.1%)	1 (<0.1%)
Myosclerosis	筋硬化症	1 (<0.1%)	0	1 (<0.1%)
Myositis	筋炎	1 (<0.1%)	0	1 (<0.1%)
Neck pain	頚部痛	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Osteitis	骨炎	0	1 (<0.1%)	1 (<0.1%)
Osteoarthritis	変形性関節症	24 (0.7%)	27 (0.8%)	51 (0.8%)
Osteochondrosis	骨端症	0	1 (<0.1%)	1 (<0.1%)
Osteonecrosis	骨壊死	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Osteonecrosis of jaw	顎骨壊死	1 (<0.1%)	0	1 (<0.1%)
Osteopenia	骨減少症	1 (<0.1%)	0	1 (<0.1%)
Osteoporosis	骨粗鬆症	0	1 (<0.1%)	1 (<0.1%)
Osteoporotic fracture	骨粗鬆症性骨折	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pain in extremity	四肢痛	52 (1.6%)	64 (2.0%)	116 (1.8%)
Pathological fracture	病的骨折	1 (<0.1%)	0	1 (<0.1%)
Periarthritis	関節周囲炎	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Plantar fascial fibromatosis	足底腱膜線維腫症	1 (<0.1%)	0	1 (<0.1%)
Plantar fasciitis	足底筋膜炎	0	3 (<0.1%)	3 (<0.1%)
Polymyalgia rheumatica	リウマチ性多発筋痛	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Pseudarthrosis	偽関節	0	1 (<0.1%)	1 (<0.1%)
Psoriatic arthropathy	乾癬性関節症	1 (<0.1%)	0	1 (<0.1%)
Rhabdomyolysis	横紋筋融解症	0	1 (<0.1%)	1 (<0.1%)
Rheumatic disorder	リウマチ性障害	0	2 (<0.1%)	2 (<0.1%)
Rheumatoid arthritis	関節リウマチ	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Rotator cuff syndrome	肩回旋筋腱板症候群	4 (0.1%)	5 (0.2%)	9 (0.1%)
Soft tissue disorder	軟部組織障害	1 (<0.1%)	0	1 (<0.1%)
Soft tissue necrosis	軟部組織壊死	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Spinal osteoarthritis	変形性脊椎症	4 (0.1%)	6 (0.2%)	10 (0.2%)
Spinal pain	脊椎痛	1 (<0.1%)	5 (0.2%)	6 (<0.1%)
Spinal stenosis	脊柱管狭窄症	10 (0.3%)	7 (0.2%)	17 (0.3%)
Spondyloarthropathy	脊椎関節障害	1 (<0.1%)	0	1 (<0.1%)
Spondylolisthesis	脊椎すべり症	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Synovial cyst	滑液嚢腫	0	1 (<0.1%)	1 (<0.1%)
Synovitis	滑膜炎	0	1 (<0.1%)	1 (<0.1%)
Systemic scleroderma	全身性強皮症	0	1 (<0.1%)	1 (<0.1%)
Tendon discomfort	腱不快感	1 (<0.1%)	0	1 (<0.1%)
Tendon disorder	腱障害	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tendon pain	腱痛	1 (<0.1%)	0	1 (<0.1%)
Tendonitis	腱炎	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Tenosynovitis	腱鞘炎	0	1 (<0.1%)	1 (<0.1%)

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Tenosynovitis stenosans	狭窄性腱鞘炎	0	1 (<0.1%)	1 (<0.1%)
Trigger finger	弾発指	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vertebral column mass	脊柱腫瘤	1 (<0.1%)	0	1 (<0.1%)
Vertebral foraminal stenosis	椎間孔狭窄	0	1 (<0.1%)	1 (<0.1%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	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）	138 (4.2%)	139 (4.3%)	277 (4.3%)
Acute myeloid leukaemia	急性骨髄性白血病	1 (<0.1%)	0	1 (<0.1%)
Adenocarcinoma	腺癌	0	1 (<0.1%)	1 (<0.1%)
Adenocarcinoma gastric	胃腺癌	0	1 (<0.1%)	1 (<0.1%)
Adenocarcinoma of colon	結腸腺癌	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Adenocarcinoma pancreas	膵腺癌	0	1 (<0.1%)	1 (<0.1%)
Adenolymphoma	腺リンパ腫	0	1 (<0.1%)	1 (<0.1%)
Adrenal neoplasm	副腎新生物	1 (<0.1%)	0	1 (<0.1%)
Anogenital warts	肛門性器疣贅	0	1 (<0.1%)	1 (<0.1%)
B-cell lymphoma	Ｂ細胞性リンパ腫	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Basal cell carcinoma	基底細胞癌	4 (0.1%)	8 (0.2%)	12 (0.2%)
Benign laryngeal neoplasm	喉頭の良性新生物	1 (<0.1%)	0	1 (<0.1%)
Benign neoplasm	良性新生物	1 (<0.1%)	0	1 (<0.1%)
Benign neoplasm of skin	皮膚良性新生物	1 (<0.1%)	0	1 (<0.1%)
Benign ovarian tumour	卵巣良性腫瘍	1 (<0.1%)	0	1 (<0.1%)
Benign salivary gland neoplasm	唾液腺の良性新生物	1 (<0.1%)	0	1 (<0.1%)
Bile duct cancer	胆管癌	0	2 (<0.1%)	2 (<0.1%)
Bladder cancer	膀胱癌	5 (0.2%)	5 (0.2%)	10 (0.2%)
Bladder cancer stage IV	膀胱癌第４期	0	1 (<0.1%)	1 (<0.1%)
Bladder neoplasm	膀胱新生物	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Bladder transitional cell carcinoma	膀胱移行上皮癌	2 (<0.1%)	0	2 (<0.1%)
Bone cancer	骨癌	0	1 (<0.1%)	1 (<0.1%)
Brain neoplasm	脳新生物	0	1 (<0.1%)	1 (<0.1%)
Breast cancer	乳癌	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Bronchial carcinoma	気管支癌	1 (<0.1%)	0	1 (<0.1%)
Central nervous system lymphoma	中枢神経系リンパ腫	1 (<0.1%)	0	1 (<0.1%)
Cervix carcinoma	子宮頚部癌	0	1 (<0.1%)	1 (<0.1%)
Cholangiocarcinoma	胆管細胞癌	2 (<0.1%)	0	2 (<0.1%)
Cholesteatoma	真珠腫	0	1 (<0.1%)	1 (<0.1%)
Chronic lymphocytic leukaemia	慢性リンパ性白血病	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Chronic lymphocytic leukaemia stage 0	慢性リンパ性白血病第０期	1 (<0.1%)	0	1 (<0.1%)
Chronic myeloid leukaemia	慢性骨髄性白血病	0	1 (<0.1%)	1 (<0.1%)
Chronic myelomonocytic leukaemia	慢性骨髄単球性白血病	0	1 (<0.1%)	1 (<0.1%)
Colon adenoma	大腸腺腫	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Colon cancer	結腸癌	5 (0.2%)	4 (0.1%)	9 (0.1%)
Colon cancer stage 0	結腸癌第０期	1 (<0.1%)	0	1 (<0.1%)
Colorectal adenocarcinoma	結腸直腸腺癌	0	1 (<0.1%)	1 (<0.1%)
Colorectal cancer	結腸直腸癌	0	1 (<0.1%)	1 (<0.1%)
Ductal adenocarcinoma of pancreas	膵腺管癌	0	1 (<0.1%)	1 (<0.1%)
Endometrial cancer	子宮内膜癌	1 (<0.1%)	0	1 (<0.1%)
Endometrial cancer metastatic	遠隔転移を伴う子宮内膜癌	0	1 (<0.1%)	1 (<0.1%)
Essential thrombocythaemia	本態性血小板血症	0	1 (<0.1%)	1 (<0.1%)
Follicular thyroid cancer	濾胞性甲状腺癌	1 (<0.1%)	0	1 (<0.1%)
Gallbladder cancer	胆嚢癌	1 (<0.1%)	0	1 (<0.1%)
Gallbladder neoplasm	胆嚢新生物	1 (<0.1%)	0	1 (<0.1%)
Gastric adenoma	胃腺腫	1 (<0.1%)	0	1 (<0.1%)
Gastric cancer	胃癌	5 (0.2%)	6 (0.2%)	11 (0.2%)
Gastric cancer stage I	胃癌第１期	1 (<0.1%)	0	1 (<0.1%)
Gastric cancer stage II	胃癌第２期	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal adenocarcinoma	消化器腺癌	1 (<0.1%)	0	1 (<0.1%)
Gingival cancer	歯肉癌	1 (<0.1%)	0	1 (<0.1%)
Haemangioma	血管腫	1 (<0.1%)	0	1 (<0.1%)
Head and neck cancer	頭頚部癌	1 (<0.1%)	0	1 (<0.1%)
Hepatic cancer	肝癌	0	1 (<0.1%)	1 (<0.1%)

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Hepatocellular carcinoma	肝細胞癌	1 (<0.1%)	0	1 (<0.1%)
Hodgkin's disease	ホジキン病	1 (<0.1%)	0	1 (<0.1%)
Hodgkin's disease stage IV	ホジキン病第４期	1 (<0.1%)	0	1 (<0.1%)
Inflammatory pseudotumour	炎症性偽腫瘍	1 (<0.1%)	0	1 (<0.1%)
Keratoacanthoma	ケラトアカントーマ	0	1 (<0.1%)	1 (<0.1%)
Laryngeal cancer	喉頭癌	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Laryngeal neoplasm	喉頭新生物	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Leiomyosarcoma	平滑筋肉腫	0	1 (<0.1%)	1 (<0.1%)
Lip and/or oral cavity cancer	口唇および口腔内癌	0	1 (<0.1%)	1 (<0.1%)
Lung adenocarcinoma	肺腺癌	4 (0.1%)	4 (0.1%)	8 (0.1%)
Lung adenocarcinoma recurrent	再発肺腺癌	1 (<0.1%)	0	1 (<0.1%)
Lung adenocarcinoma stage IV	肺腺癌第４期	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Lung cancer metastatic	遠隔転移を伴う肺癌	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Lung carcinoma cell type unspecified recurrent	再発肺癌、細胞タイプ不明	1 (<0.1%)	0	1 (<0.1%)
Lung carcinoma cell type unspecified stage IV	肺癌第４期、細胞タイプ不明	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Lung neoplasm	肺新生物	4 (0.1%)	5 (0.2%)	9 (0.1%)
Lung neoplasm malignant	肺の悪性新生物	8 (0.2%)	15 (0.5%)	23 (0.4%)
Lung squamous cell carcinoma metastatic	遠隔転移を伴う肺扁平上皮癌	0	1 (<0.1%)	1 (<0.1%)
Lung squamous cell carcinoma stage IV	肺扁平上皮癌第４期	1 (<0.1%)	0	1 (<0.1%)
Malignant genitourinary tract neoplasm	泌尿生殖器の悪性新生物	1 (<0.1%)	0	1 (<0.1%)
Malignant melanoma	悪性黒色腫	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Malignant neoplasm papilla of Vater	ファーター乳頭部の悪性新生物	0	1 (<0.1%)	1 (<0.1%)
Metastases to central nervous system	中枢神経系転移	0	1 (<0.1%)	1 (<0.1%)
Metastases to liver	肝転移	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Metastases to lung	肺転移	1 (<0.1%)	0	1 (<0.1%)
Metastases to lymph nodes	リンパ節転移	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Metastases to neck	頚部転移	0	1 (<0.1%)	1 (<0.1%)
Metastases to peritoneum	腹膜転移	0	1 (<0.1%)	1 (<0.1%)
Metastatic neoplasm	遠隔転移を伴う新生物	0	1 (<0.1%)	1 (<0.1%)
Metastatic squamous cell carcinoma	遠隔転移を伴う扁平上皮癌	0	1 (<0.1%)	1 (<0.1%)
Myelodysplastic syndrome	骨髄異形成症候群	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Myeloproliferative neoplasm	骨髄増殖性新生物	1 (<0.1%)	0	1 (<0.1%)
Neoplasm malignant	悪性新生物	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Neoplasm skin	皮膚の新生物	0	1 (<0.1%)	1 (<0.1%)
Neuroendocrine carcinoma	神経内分泌癌	1 (<0.1%)	0	1 (<0.1%)
Neuroendocrine carcinoma of the skin	皮膚神経内分泌癌	0	1 (<0.1%)	1 (<0.1%)
Non-small cell lung cancer	非小細胞肺癌	1 (<0.1%)	0	1 (<0.1%)
Non-small cell lung cancer metastatic	遠隔転移を伴う非小細胞肺癌	0	1 (<0.1%)	1 (<0.1%)
Oesophageal adenocarcinoma	食道腺癌	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Oesophageal cancer metastatic	遠隔転移を伴う食道癌	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Oesophageal carcinoma	食道癌	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Oesophageal carcinoma recurrent	再発食道癌	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Oesophageal neoplasm	食道新生物	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Oropharyngeal cancer	中咽頭癌	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Pancreatic carcinoma	膵癌	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Pancreatic carcinoma stage IV	膵癌第４期	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pancreatic neoplasm	膵新生物	0	1 (<0.1%)	1 (<0.1%)
Papillary serous endometrial carcinoma	乳頭状漿液性子宮内膜癌	0	1 (<0.1%)	1 (<0.1%)
Plasma cell myeloma	形質細胞性骨髄腫	1 (<0.1%)	0	1 (<0.1%)
Pleural mesothelioma	胸膜中皮腫	1 (<0.1%)	0	1 (<0.1%)
Polycythaemia vera	真性多血症	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Prostate cancer	前立腺癌	10 (0.3%)	5 (0.2%)	15 (0.2%)
Prostate cancer stage III	前立腺癌第３期	0	1 (<0.1%)	1 (<0.1%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
Prostatic adenoma	前立腺腺腫	0	1 (<0.1%)	1 (<0.1%)
Rectal adenocarcinoma	直腸腺癌	2 (<0.1%)	0	2 (<0.1%)
Rectal adenoma	直腸腺腫	1 (<0.1%)	0	1 (<0.1%)
Rectal cancer	直腸癌	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Rectal cancer stage I	直腸癌第１期	0	1 (<0.1%)	1 (<0.1%)
Rectal cancer stage IV	直腸癌第４期	1 (<0.1%)	0	1 (<0.1%)
Rectal neoplasm	直腸新生物	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Rectosigmoid cancer	直腸Ｓ状結腸癌	0	1 (<0.1%)	1 (<0.1%)
Renal cancer	腎癌	3 (<0.1%)	0	3 (<0.1%)
Renal cell carcinoma	腎細胞癌	0	1 (<0.1%)	1 (<0.1%)
Renal neoplasm	腎新生物	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Respiratory tract neoplasm	気道新生物	0	1 (<0.1%)	1 (<0.1%)
Salivary gland adenoma	唾液腺腫	1 (<0.1%)	0	1 (<0.1%)
Skin cancer	皮膚癌	1 (<0.1%)	0	1 (<0.1%)
Skin papilloma	皮膚乳頭腫	0	1 (<0.1%)	1 (<0.1%)
Skin squamous cell carcinoma recurrent	再発皮膚有棘細胞癌	1 (<0.1%)	0	1 (<0.1%)
Small cell carcinoma	小細胞癌	0	1 (<0.1%)	1 (<0.1%)
Small cell lung cancer	小細胞肺癌	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Spinal meningioma benign	良性脊髄髄膜腫	1 (<0.1%)	0	1 (<0.1%)
Squamous cell carcinoma	扁平上皮癌	0	1 (<0.1%)	1 (<0.1%)
Squamous cell carcinoma of lung	肺扁平上皮癌	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Squamous cell carcinoma of skin	皮膚有棘細胞癌	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Squamous cell carcinoma of the oral cavity	口腔内扁平上皮癌	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Squamous cell carcinoma of the tongue	舌扁平上皮癌	0	2 (<0.1%)	2 (<0.1%)
T-cell lymphoma	Ｔ細胞性リンパ腫	1 (<0.1%)	0	1 (<0.1%)
Thymoma malignant	悪性胸腺腫	1 (<0.1%)	0	1 (<0.1%)
Tongue neoplasm	舌新生物	1 (<0.1%)	0	1 (<0.1%)
Transitional cell carcinoma	移行上皮癌	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Nervous system disorders	神経系障害	164 (5.0%)	200 (6.2%)	364 (5.6%)
Alcoholic seizure	アルコール性痙攣	0	1 (<0.1%)	1 (<0.1%)
Altered state of consciousness	意識変容状態	1 (<0.1%)	0	1 (<0.1%)
Amputation stump pain	断端痛	1 (<0.1%)	0	1 (<0.1%)
Balance disorder	平衡障害	0	1 (<0.1%)	1 (<0.1%)
Brachial plexopathy	腕神経叢障害	1 (<0.1%)	0	1 (<0.1%)
Brain injury	脳損傷	1 (<0.1%)	0	1 (<0.1%)
Burning sensation	灼熱感	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Carotid arteriosclerosis	頚動脈硬化症	0	2 (<0.1%)	2 (<0.1%)
Carotid artery disease	頚動脈疾患	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Carotid artery occlusion	頚動脈閉塞	0	1 (<0.1%)	1 (<0.1%)
Carotid artery stenosis	頚動脈狭窄	22 (0.7%)	30 (0.9%)	52 (0.8%)
Carpal tunnel syndrome	手根管症候群	3 (<0.1%)	8 (0.2%)	11 (0.2%)
Cerebellar atrophy	小脳萎縮	1 (<0.1%)	0	1 (<0.1%)
Cerebral atrophy	大脳萎縮	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Cerebral calcification	大脳石灰化	1 (<0.1%)	0	1 (<0.1%)
Cerebral haemorrhage	脳出血	0	1 (<0.1%)	1 (<0.1%)
Cerebral infarction	脳梗塞	0	2 (<0.1%)	2 (<0.1%)
Cerebral small vessel ischaemic disease	虚血性脳小血管疾患	2 (<0.1%)	0	2 (<0.1%)
Cerebrovascular disorder	脳血管障害	0	1 (<0.1%)	1 (<0.1%)
Cervical radiculopathy	頚髄神経根障害	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Cervicobrachial syndrome	頚腕症候群	1 (<0.1%)	0	1 (<0.1%)
Cervicogenic vertigo	頚原性回転性めまい	0	1 (<0.1%)	1 (<0.1%)
Cognitive disorder	認知障害	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Colloid brain cyst	脳コロイド嚢胞	0	1 (<0.1%)	1 (<0.1%)
Cranial nerve disorder	脳神経障害	0	1 (<0.1%)	1 (<0.1%)
Dementia	認知症	5 (0.2%)	3 (<0.1%)	8 (0.1%)
Dementia Alzheimer's type	アルツハイマー型認知症	0	2 (<0.1%)	2 (<0.1%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
Diabetic neuropathy	糖尿病性ニューロパチー	5 (0.2%)	6 (0.2%)	11 (0.2%)
Dizziness	浮動性めまい	27 (0.8%)	29 (0.9%)	56 (0.9%)
Dizziness postural	体位性めまい	1 (<0.1%)	0	1 (<0.1%)
Drop attacks	転倒発作	0	1 (<0.1%)	1 (<0.1%)
Dysaesthesia	異常感覚	0	1 (<0.1%)	1 (<0.1%)
Dysarthria	構語障害	1 (<0.1%)	0	1 (<0.1%)
Dysgeusia	味覚不全	1 (<0.1%)	0	1 (<0.1%)
Encephalopathy	脳症	0	1 (<0.1%)	1 (<0.1%)
Epilepsy	てんかん	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Facial paralysis	顔面麻痺	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Facial paresis	顔面不全麻痺	1 (<0.1%)	0	1 (<0.1%)
Facial spasm	顔面痙攣	1 (<0.1%)	0	1 (<0.1%)
Guillain-Barre syndrome	ギラン・バレー症候群	0	1 (<0.1%)	1 (<0.1%)
Headache	頭痛	18 (0.6%)	19 (0.6%)	37 (0.6%)
Hemiparaesthesia	片側錯感覚	1 (<0.1%)	0	1 (<0.1%)
Hemiparesis	不全片麻痺	0	1 (<0.1%)	1 (<0.1%)
Horner's syndrome	ホルネル症候群	0	1 (<0.1%)	1 (<0.1%)
Hydrocephalus	水頭症	0	1 (<0.1%)	1 (<0.1%)
Hyperaesthesia	知覚過敏	1 (<0.1%)	0	1 (<0.1%)
Hyperkinesia	運動過多	0	1 (<0.1%)	1 (<0.1%)
Hypertensive encephalopathy	高血圧性脳症	0	1 (<0.1%)	1 (<0.1%)
Hypoaesthesia	感覚鈍麻	6 (0.2%)	8 (0.2%)	14 (0.2%)
Hypotonia	筋緊張低下	1 (<0.1%)	0	1 (<0.1%)
Intercostal neuralgia	肋間神経痛	2 (<0.1%)	0	2 (<0.1%)
Intracranial aneurysm	頭蓋内動脈瘤	0	2 (<0.1%)	2 (<0.1%)
Ischaemic neuropathy	虚血性ニューロパチー	0	2 (<0.1%)	2 (<0.1%)
Ischaemic stroke	虚血性脳卒中	0	1 (<0.1%)	1 (<0.1%)
Loss of consciousness	意識消失	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Lumbar radiculopathy	腰髄神経根障害	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Lumbosacral radiculopathy	腰仙部神経根障害	0	1 (<0.1%)	1 (<0.1%)
Memory impairment	記憶障害	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Mental impairment	精神的機能障害	1 (<0.1%)	0	1 (<0.1%)
Meralgia paraesthetica	感覚異常性大腿神経痛	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Migraine	片頭痛	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Monoparesis	不全単麻痺	0	1 (<0.1%)	1 (<0.1%)
Morton's neuralgia	モートン神経痛	0	1 (<0.1%)	1 (<0.1%)
Motor neurone disease	運動ニューロン疾患	0	1 (<0.1%)	1 (<0.1%)
Myelopathy	脊髄症	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Myoclonus	ミオクローヌス	1 (<0.1%)	0	1 (<0.1%)
Nerve compression	神経圧迫	1 (<0.1%)	0	1 (<0.1%)
Nervous system disorder	神経系障害	1 (<0.1%)	0	1 (<0.1%)
Neuralgia	神経痛	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Neuropathy peripheral	末梢性ニューロパチー	5 (0.2%)	1 (<0.1%)	6 (<0.1%)
Occipital neuralgia	後頭神経痛	1 (<0.1%)	0	1 (<0.1%)
Orthostatic intolerance	起立不耐性	0	1 (<0.1%)	1 (<0.1%)
Paraesthesia	錯感覚	4 (0.1%)	9 (0.3%)	13 (0.2%)
Parkinson's disease	パーキンソン病	4 (0.1%)	3 (<0.1%)	7 (0.1%)
Parkinsonism	パーキンソニズム	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Peripheral nerve lesion	末梢神経病変	0	1 (<0.1%)	1 (<0.1%)
Peripheral nerve paresis	末梢神経不全麻痺	0	1 (<0.1%)	1 (<0.1%)
Peripheral sensorimotor neuropathy	末梢性感覚運動ニューロパチー	1 (<0.1%)	0	1 (<0.1%)
Phantom limb syndrome	幻肢症候群	0	1 (<0.1%)	1 (<0.1%)
Polyneuropathy	多発ニューロパチー	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Poor quality sleep	睡眠の質低下	1 (<0.1%)	0	1 (<0.1%)
Presyncope	失神寸前の状態	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Pseudoradicular syndrome	偽性根症候群	1 (<0.1%)	0	1 (<0.1%)
Putamen haemorrhage	被殻出血	0	1 (<0.1%)	1 (<0.1%)
Radiculopathy	神経根障害	3 (<0.1%)	0	3 (<0.1%)
Restless legs syndrome	下肢静止不能症候群	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Sacral radiculopathy	仙部神経根症	1 (<0.1%)	0	1 (<0.1%)

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Sciatica	坐骨神経痛	8 (0.2%)	17 (0.5%)	25 (0.4%)
Seizure	痙攣発作	0	1 (<0.1%)	1 (<0.1%)
Senile dementia	老年認知症	1 (<0.1%)	0	1 (<0.1%)
Somnolence	傾眠	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Spinal claudication	脊髄性跛行症	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Spinal cord compression	脊髄圧迫	0	1 (<0.1%)	1 (<0.1%)
Status epilepticus	てんかん重積状態	1 (<0.1%)	0	1 (<0.1%)
Subarachnoid haemorrhage	くも膜下出血	0	1 (<0.1%)	1 (<0.1%)
Syncope	失神	12 (0.4%)	20 (0.6%)	32 (0.5%)
Tension headache	緊張性頭痛	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Thermohyperaesthesia	温度覚過敏	1 (<0.1%)	0	1 (<0.1%)
Tonic convulsion	強直性痙攣	1 (<0.1%)	0	1 (<0.1%)
Tremor	振戦	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Trigeminal neuralgia	三叉神経痛	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vascular dementia	血管性認知症	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vascular encephalopathy	血管性脳症	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Vertebral artery stenosis	椎骨動脈狭窄	0	1 (<0.1%)	1 (<0.1%)
Visual field defect	視野欠損	0	1 (<0.1%)	1 (<0.1%)
Product issues	製品の問題	10 (0.3%)	1 (<0.1%)	11 (0.2%)
Device battery issue	医療機器バッテリー問題	1 (<0.1%)	0	1 (<0.1%)
Device breakage	医療機器破損	2 (<0.1%)	0	2 (<0.1%)
Device connection issue	医療機器接続不具合	1 (<0.1%)	0	1 (<0.1%)
Device dislocation	医療機器位置異常	1 (<0.1%)	0	1 (<0.1%)
Device failure	医療機器不具合	1 (<0.1%)	0	1 (<0.1%)
Device loosening	医療機器のゆるみ	2 (<0.1%)	0	2 (<0.1%)
Device material opacification	医療機器材質の混濁	1 (<0.1%)	0	1 (<0.1%)
Device occlusion	医療機器閉塞	0	1 (<0.1%)	1 (<0.1%)
Patient-device incompatibility	患者と医療機器間の不適合	1 (<0.1%)	0	1 (<0.1%)
Psychiatric disorders	精神障害	30 (0.9%)	41 (1.3%)	71 (1.1%)
Acute psychosis	急性精神病	0	1 (<0.1%)	1 (<0.1%)
Adjustment disorder with depressed mood	抑うつ気分を伴う適応障害	0	1 (<0.1%)	1 (<0.1%)
Alcohol abuse	アルコール乱用	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Alcohol withdrawal syndrome	アルコール離脱症候群	0	1 (<0.1%)	1 (<0.1%)
Alcoholism	アルコール症	1 (<0.1%)	0	1 (<0.1%)
Anxiety	不安	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Completed suicide	自殺既遂	4 (0.1%)	0	4 (<0.1%)
Confusional state	錯乱状態	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Delirium	譫妄	0	4 (0.1%)	4 (<0.1%)
Depression	うつ病	12 (0.4%)	18 (0.6%)	30 (0.5%)
Drug abuse	薬物乱用	0	1 (<0.1%)	1 (<0.1%)
Insomnia	不眠症	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Intentional self-injury	故意の自傷行為	1 (<0.1%)	0	1 (<0.1%)
Loss of libido	リビドー消失	1 (<0.1%)	0	1 (<0.1%)
Mental status changes	精神状態変化	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Mood altered	気分変化	0	1 (<0.1%)	1 (<0.1%)
Nervousness	神経過敏	0	1 (<0.1%)	1 (<0.1%)
Organic brain syndrome	器質性脳症候群	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Restlessness	落ち着きのなさ	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Sleep disorder	睡眠障害	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Stress	ストレス	0	1 (<0.1%)	1 (<0.1%)
Transient psychosis	一過性精神病	1 (<0.1%)	0	1 (<0.1%)
Renal and urinary disorders	腎および尿路障害	82 (2.5%)	67 (2.1%)	149 (2.3%)
Acute kidney injury	急性腎障害	15 (0.5%)	21 (0.6%)	36 (0.6%)
Bladder irritation	膀胱刺激症状	1 (<0.1%)	0	1 (<0.1%)
Bladder mass	膀胱腫瘤	1 (<0.1%)	0	1 (<0.1%)
Calculus bladder	膀胱結石	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)

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Calculus urinary	尿路結石	0	1 (<0.1%)	1 (<0.1%)
Chronic kidney disease	慢性腎臓病	13 (0.4%)	3 (<0.1%)	16 (0.2%)
Diabetic nephropathy	糖尿病性腎症	2 (<0.1%)	0	2 (<0.1%)
Dysuria	排尿困難	3 (<0.1%)	4 (0.1%)	7 (0.1%)
End stage renal disease	末期腎疾患	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Haematuria	血尿	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Microalbuminuria	ミクロアルブミン尿	0	1 (<0.1%)	1 (<0.1%)
Nephrolithiasis	腎結石症	4 (0.1%)	3 (<0.1%)	7 (0.1%)
Nephrosclerosis	腎硬化症	0	1 (<0.1%)	1 (<0.1%)
Nocturia	夜間頻尿	0	1 (<0.1%)	1 (<0.1%)
Pelvi-ureteric obstruction	骨盤部尿管閉塞	1 (<0.1%)	0	1 (<0.1%)
Pollakiuria	頻尿	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Polyuria	多尿	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Proteinuria	蛋白尿	1 (<0.1%)	0	1 (<0.1%)
Renal artery stenosis	腎動脈狭窄症	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Renal colic	腎仙痛	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Renal cyst	腎嚢胞	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Renal failure	腎不全	8 (0.2%)	8 (0.2%)	16 (0.2%)
Renal impairment	腎機能障害	6 (0.2%)	8 (0.2%)	14 (0.2%)
Renal injury	腎損傷	0	1 (<0.1%)	1 (<0.1%)
Stress urinary incontinence	腹圧性尿失禁	0	1 (<0.1%)	1 (<0.1%)
Ureteric fistula	尿管瘻	1 (<0.1%)	0	1 (<0.1%)
Ureterolithiasis	尿管結石症	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Urethral stenosis	尿道狭窄	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Urge incontinence	切迫性尿失禁	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Urinary incontinence	尿失禁	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Urinary retention	尿閉	4 (0.1%)	3 (<0.1%)	7 (0.1%)
Urinary tract obstruction	尿路閉塞	2 (<0.1%)	0	2 (<0.1%)
Reproductive system and breast disorders	生殖系および乳房障害	22 (0.7%)	19 (0.6%)	41 (0.6%)
Benign prostatic hyperplasia	良性前立腺肥大症	8 (0.2%)	11 (0.3%)	19 (0.3%)
Cervical polyp	子宮頚管ポリープ	1 (<0.1%)	0	1 (<0.1%)
Erectile dysfunction	勃起不全	0	1 (<0.1%)	1 (<0.1%)
Gynaecomastia	女性化乳房	1 (<0.1%)	0	1 (<0.1%)
Ovarian cyst	卵巣嚢胞	1 (<0.1%)	0	1 (<0.1%)
Pelvic pain	骨盤痛	2 (<0.1%)	0	2 (<0.1%)
Pelvic prolapse	骨盤脱	0	1 (<0.1%)	1 (<0.1%)
Prostatic obstruction	前立腺閉塞	1 (<0.1%)	0	1 (<0.1%)
Prostatism	前立腺症	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Prostatitis	前立腺炎	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Scrotal swelling	陰嚢腫脹	0	1 (<0.1%)	1 (<0.1%)
Sexual dysfunction	性機能不全	0	1 (<0.1%)	1 (<0.1%)
Spermatocele	精液瘤	1 (<0.1%)	0	1 (<0.1%)
Testicular disorder	精巣障害	1 (<0.1%)	0	1 (<0.1%)
Uterine prolapse	子宮脱	2 (<0.1%)	0	2 (<0.1%)
Vulval eczema	外陰部湿疹	0	1 (<0.1%)	1 (<0.1%)
Vulvar dysplasia	外陰異形成	1 (<0.1%)	0	1 (<0.1%)
Vulvovaginal pain	外陰腟痛	0	1 (<0.1%)	1 (<0.1%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	103 (3.2%)	103 (3.2%)	206 (3.2%)
Acute interstitial pneumonitis	急性間質性肺臓炎	0	1 (<0.1%)	1 (<0.1%)
Acute pulmonary oedema	急性肺水腫	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Acute respiratory distress syndrome	急性呼吸窮迫症候群	1 (<0.1%)	0	1 (<0.1%)
Acute respiratory failure	急性呼吸不全	2 (<0.1%)	7 (0.2%)	9 (0.1%)
Allergic cough	アレルギー性咳嗽	0	1 (<0.1%)	1 (<0.1%)
Aspiration	誤嚥	1 (<0.1%)	0	1 (<0.1%)
Aspirin-exacerbated respiratory disease	アスピリン増悪呼吸器疾患	0	1 (<0.1%)	1 (<0.1%)
Asthma	喘息	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
Bronchiectasis	気管支拡張症	2 (<0.1%)	0	2 (<0.1%)
Bronchitis chronic	慢性気管支炎	0	3 (<0.1%)	3 (<0.1%)
Bronchospasm	気管支痙攣	0	1 (<0.1%)	1 (<0.1%)
Catarrh	カタル	0	1 (<0.1%)	1 (<0.1%)
Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	21 (0.6%)	13 (0.4%)	34 (0.5%)
Chronic respiratory disease	慢性呼吸疾患	1 (<0.1%)	0	1 (<0.1%)
Cough	咳嗽	9 (0.3%)	14 (0.4%)	23 (0.4%)
Dyspnoea	呼吸困難	15 (0.5%)	21 (0.6%)	36 (0.6%)
Dyspnoea at rest	安静時呼吸困難	1 (<0.1%)	0	1 (<0.1%)
Dyspnoea exertional	労作性呼吸困難	3 (<0.1%)	5 (0.2%)	8 (0.1%)
Emphysema	肺気腫	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Epistaxis	鼻出血	9 (0.3%)	3 (<0.1%)	12 (0.2%)
Haemoptysis	喀血	0	3 (<0.1%)	3 (<0.1%)
Hypoxia	低酸素症	2 (<0.1%)	0	2 (<0.1%)
Interstitial lung disease	間質性肺疾患	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Lung infiltration	肺浸潤	0	1 (<0.1%)	1 (<0.1%)
Nasal discharge discolouration	鼻汁変色	1 (<0.1%)	0	1 (<0.1%)
Nasal dryness	鼻乾燥	0	1 (<0.1%)	1 (<0.1%)
Nasal obstruction	鼻閉塞	1 (<0.1%)	0	1 (<0.1%)
Nasal polyps	鼻茸	1 (<0.1%)	0	1 (<0.1%)
Nasal septum deviation	鼻中隔弯曲	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Oropharyngeal pain	口腔咽頭痛	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Pharyngeal lesion	咽頭病変	0	1 (<0.1%)	1 (<0.1%)
Pharyngeal swelling	咽頭腫脹	0	1 (<0.1%)	1 (<0.1%)
Pleural effusion	胸水	6 (0.2%)	5 (0.2%)	11 (0.2%)
Pneumonia aspiration	誤嚥性肺炎	5 (0.2%)	6 (0.2%)	11 (0.2%)
Pneumonitis	肺臓炎	0	1 (<0.1%)	1 (<0.1%)
Pneumothorax	気胸	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Pneumothorax spontaneous	自然気胸	1 (<0.1%)	0	1 (<0.1%)
Productive cough	湿性咳嗽	0	1 (<0.1%)	1 (<0.1%)
Pulmonary congestion	肺うっ血	1 (<0.1%)	0	1 (<0.1%)
Pulmonary embolism	肺塞栓症	0	1 (<0.1%)	1 (<0.1%)
Pulmonary fibrosis	肺線維症	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pulmonary hypertension	肺高血圧症	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pulmonary mass	肺腫瘤	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Pulmonary oedema	肺水腫	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Respiratory distress	呼吸窮迫	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Respiratory failure	呼吸不全	5 (0.2%)	4 (0.1%)	9 (0.1%)
Rhinitis allergic	アレルギー性鼻炎	1 (<0.1%)	0	1 (<0.1%)
Rhinorrhoea	鼻漏	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Sinus polyp	副鼻腔ポリープ	1 (<0.1%)	0	1 (<0.1%)
Sleep apnoea syndrome	睡眠時無呼吸症候群	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Sneezing	くしゃみ	0	1 (<0.1%)	1 (<0.1%)
Sputum increased	喀痰増加	0	1 (<0.1%)	1 (<0.1%)
Status asthmaticus	喘息発作重積	0	1 (<0.1%)	1 (<0.1%)
Tonsillar cyst	扁桃嚢胞	0	1 (<0.1%)	1 (<0.1%)
Vocal cord inflammation	声帯の炎症	1 (<0.1%)	0	1 (<0.1%)
Vocal cord polyp	声帯ポリープ	0	1 (<0.1%)	1 (<0.1%)
Wheezing	喘鳴	1 (<0.1%)	0	1 (<0.1%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	115 (3.5%)	123 (3.8%)	238 (3.7%)
Actinic keratosis	光線角化症	1 (<0.1%)	0	1 (<0.1%)
Alopecia	脱毛症	3 (<0.1%)	0	3 (<0.1%)
Angioedema	血管浮腫	0	2 (<0.1%)	2 (<0.1%)
Blister	水疱	0	1 (<0.1%)	1 (<0.1%)
Brow ptosis	眉毛下垂	1 (<0.1%)	0	1 (<0.1%)
Decubitus ulcer	褥瘡性潰瘍	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Dermal cyst	皮膚嚢腫	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Dermatitis	皮膚炎	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Dermatitis allergic	アレルギー性皮膚炎	2 (<0.1%)	4 (0.1%)	6 (<0.1%)

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Dermatitis contact	接触皮膚炎	0	2 (<0.1%)	2 (<0.1%)
Diabetic foot	糖尿病性足病変	14 (0.4%)	10 (0.3%)	24 (0.4%)
Diabetic ulcer	糖尿病性潰瘍	2 (<0.1%)	0	2 (<0.1%)
Drug eruption	薬疹	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Drug reaction with eosinophilia and systemic symptoms	好酸球増加と全身症状を伴う薬物反応	0	1 (<0.1%)	1 (<0.1%)
Dry skin	皮膚乾燥	0	2 (<0.1%)	2 (<0.1%)
Ecchymosis	斑状出血	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Eczema	湿疹	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Erythema	紅斑	2 (<0.1%)	5 (0.2%)	7 (0.1%)
Haemorrhage subcutaneous	皮下出血	0	1 (<0.1%)	1 (<0.1%)
Hair growth abnormal	毛髪成長異常	0	1 (<0.1%)	1 (<0.1%)
Henoch-Schonlein purpura	ヘノッホ・シェーンライン紫斑病	0	1 (<0.1%)	1 (<0.1%)
Hidradenitis	汗腺炎	0	1 (<0.1%)	1 (<0.1%)
Hyperhidrosis	多汗症	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Intertrigo	間擦疹	0	1 (<0.1%)	1 (<0.1%)
Ischaemic skin ulcer	虚血性皮膚潰瘍	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Melanocytic hyperplasia	メラニン細胞過形成	1 (<0.1%)	0	1 (<0.1%)
Myxoid cyst	粘液様嚢胞	1 (<0.1%)	0	1 (<0.1%)
Nail dystrophy	爪ジストロフィー	1 (<0.1%)	0	1 (<0.1%)
Neurodermatitis	神経皮膚炎	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Neuropathic ulcer	神経障害性潰瘍	0	1 (<0.1%)	1 (<0.1%)
Pemphigoid	類天疱瘡	2 (<0.1%)	0	2 (<0.1%)
Pemphigus	天疱瘡	0	1 (<0.1%)	1 (<0.1%)
Petechiae	点状出血	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Precancerous skin lesion	前癌性皮膚病変	0	1 (<0.1%)	1 (<0.1%)
Prurigo	痒疹	1 (<0.1%)	0	1 (<0.1%)
Pruritus	そう痒症	10 (0.3%)	7 (0.2%)	17 (0.3%)
Pruritus allergic	アレルギー性そう痒症	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Psoriasis	乾癬	2 (<0.1%)	0	2 (<0.1%)
Rash	発疹	16 (0.5%)	18 (0.6%)	34 (0.5%)
Rash erythematous	紅斑性皮疹	0	2 (<0.1%)	2 (<0.1%)
Rash macular	斑状皮疹	0	1 (<0.1%)	1 (<0.1%)
Rash papular	丘疹性皮疹	0	1 (<0.1%)	1 (<0.1%)
Rash pruritic	そう痒性皮疹	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Scar pain	瘢痕痛	0	1 (<0.1%)	1 (<0.1%)
Skin discolouration	皮膚変色	1 (<0.1%)	0	1 (<0.1%)
Skin disorder	皮膚障害	2 (<0.1%)	0	2 (<0.1%)
Skin exfoliation	皮膚剥脱	1 (<0.1%)	0	1 (<0.1%)
Skin lesion	皮膚病変	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Skin necrosis	皮膚壊死	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Skin reaction	皮膚反応	0	1 (<0.1%)	1 (<0.1%)
Skin ulcer	皮膚潰瘍	24 (0.7%)	26 (0.8%)	50 (0.8%)
Solar lentigo	日光黒子	1 (<0.1%)	0	1 (<0.1%)
Stasis dermatitis	うっ滞性皮膚炎	1 (<0.1%)	0	1 (<0.1%)
Toxic skin eruption	中毒性皮疹	0	1 (<0.1%)	1 (<0.1%)
Urticaria	蕁麻疹	9 (0.3%)	5 (0.2%)	14 (0.2%)
Urticarial vasculitis	蕁麻疹様血管炎	0	1 (<0.1%)	1 (<0.1%)
Social circumstances	社会環境	0	2 (<0.1%)	2 (<0.1%)
Disease risk factor	疾患の危険因子	0	2 (<0.1%)	2 (<0.1%)
Surgical and medical procedures	外科および内科処置	44 (1.4%)	46 (1.4%)	90 (1.4%)
Amputation	切断	1 (<0.1%)	0	1 (<0.1%)
Angioplasty	血管形成	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Bladder calculus removal	膀胱結石除去	0	1 (<0.1%)	1 (<0.1%)
Bladder neoplasm surgery	膀胱新生物手術	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bladder polypectomy	膀胱ポリープ切除	0	1 (<0.1%)	1 (<0.1%)
Blepharoplasty	眼瞼形成	1 (<0.1%)	0	1 (<0.1%)
Brain tumour operation	脳腫瘍手術	1 (<0.1%)	0	1 (<0.1%)

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Cardioversion	心臓除細動	1 (<0.1%)	0	1 (<0.1%)
Carotid endarterectomy	頚動脈内膜剥離術	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Cataract operation	白内障手術	5 (0.2%)	8 (0.2%)	13 (0.2%)
Cholecystectomy	胆嚢切除	0	1 (<0.1%)	1 (<0.1%)
Cystoprostatectomy	膀胱前立腺摘除	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Debridement	デブリードマン	2 (<0.1%)	0	2 (<0.1%)
Dental care	デンタルケア	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Diabetes mellitus management	糖尿病管理	0	1 (<0.1%)	1 (<0.1%)
Elective surgery	待期的手術	1 (<0.1%)	0	1 (<0.1%)
Eventration repair	脱出臓器還納	0	1 (<0.1%)	1 (<0.1%)
Eyelid operation	眼瞼手術	0	1 (<0.1%)	1 (<0.1%)
Foot amputation	足切断	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Glaucoma surgery	緑内障手術	1 (<0.1%)	0	1 (<0.1%)
Hip arthroplasty	股関節形成	1 (<0.1%)	0	1 (<0.1%)
Inguinal hernia repair	鼠径部ヘルニア修復	1 (<0.1%)	0	1 (<0.1%)
Knee arthroplasty	膝関節形成	0	2 (<0.1%)	2 (<0.1%)
Large intestinal polypectomy	大腸ポリープ切除	0	1 (<0.1%)	1 (<0.1%)
Limb reconstructive surgery	四肢再建手術	0	2 (<0.1%)	2 (<0.1%)
Mole excision	色素性母斑切除	1 (<0.1%)	0	1 (<0.1%)
Neuroprosthesis implantation	神経補綴装置埋込み	1 (<0.1%)	0	1 (<0.1%)
Oral surgery	口腔手術	1 (<0.1%)	0	1 (<0.1%)
Papilloma excision	乳頭腫切除	0	1 (<0.1%)	1 (<0.1%)
Peripheral artery angioplasty	末梢動脈形成	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Peripheral artery bypass	末梢動脈バイパス	0	1 (<0.1%)	1 (<0.1%)
Peripheral artery stent insertion	末梢動脈ステント挿入	1 (<0.1%)	0	1 (<0.1%)
Peripheral endarterectomy	末梢動脈内膜剥離術	0	1 (<0.1%)	1 (<0.1%)
Peripheral revascularisation	末梢血行再建	0	1 (<0.1%)	1 (<0.1%)
Polypectomy	ポリープ切除	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Radical prostatectomy	根治的前立腺摘除	0	1 (<0.1%)	1 (<0.1%)
Rehabilitation therapy	リハビリテーション療法	1 (<0.1%)	0	1 (<0.1%)
Sebaceous cyst excision	皮脂腺嚢胞切除	1 (<0.1%)	0	1 (<0.1%)
Sequestrectomy	腐骨摘出	1 (<0.1%)	0	1 (<0.1%)
Skin graft	植皮	1 (<0.1%)	0	1 (<0.1%)
Skin implant	皮膚内植込み	1 (<0.1%)	0	1 (<0.1%)
Spinal nerve stimulator implantation	脊髄神経刺激装置埋込み	1 (<0.1%)	0	1 (<0.1%)
Strabismus correction	斜視矯正術	1 (<0.1%)	0	1 (<0.1%)
Sympathectomy	交感神経切除	0	2 (<0.1%)	2 (<0.1%)
Synovectomy	滑膜切除	0	1 (<0.1%)	1 (<0.1%)
Tenoplasty	腱形成	1 (<0.1%)	0	1 (<0.1%)
Thyroidectomy	甲状腺摘除	0	1 (<0.1%)	1 (<0.1%)
Toe amputation	足指切断	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Tooth extraction	抜歯	6 (0.2%)	5 (0.2%)	11 (0.2%)
Transurethral bladder resection	経尿道的膀胱切除	0	1 (<0.1%)	1 (<0.1%)
Umbilical hernia repair	臍ヘルニア修復	1 (<0.1%)	0	1 (<0.1%)
Ureteral stent insertion	尿管ステント挿入	1 (<0.1%)	0	1 (<0.1%)
Vitrectomy	硝子体切除	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vascular disorders	血管障害	418 (12.8%)	436 (13.4%)	854 (13.1%)
Angiopathy	血管障害	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Aortic aneurysm	大動脈瘤	3 (<0.1%)	5 (0.2%)	8 (0.1%)
Aortic arteriosclerosis	大動脈硬化症	1 (<0.1%)	0	1 (<0.1%)
Aortic dissection	大動脈解離	2 (<0.1%)	0	2 (<0.1%)
Aortic stenosis	大動脈狭窄	6 (0.2%)	6 (0.2%)	12 (0.2%)
Arterial occlusive disease	動脈閉塞性疾患	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Arteriosclerosis	動脈硬化症	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Arteriovenous fistula	動静脈瘻	0	2 (<0.1%)	2 (<0.1%)
Blood pressure fluctuation	血圧変動	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Blood pressure inadequately controlled	コントロール不良の血圧	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Circulatory collapse	循環虚脱	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Diabetic macroangiopathy	糖尿病性大血管障害	0	2 (<0.1%)	2 (<0.1%)

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Diabetic microangiopathy	糖尿病性微小血管症	0	1 (<0.1%)	1 (<0.1%)
Dry gangrene	乾性壊疽	3 (<0.1%)	7 (0.2%)	10 (0.2%)
Essential hypertension	本態性高血圧症	0	1 (<0.1%)	1 (<0.1%)
Extremity necrosis	四肢壊死	16 (0.5%)	13 (0.4%)	29 (0.4%)
Haematoma	血腫	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Hot flush	ほてり	0	1 (<0.1%)	1 (<0.1%)
Hypertension	高血圧	50 (1.5%)	54 (1.7%)	104 (1.6%)
Hypertensive crisis	高血圧クリーゼ	16 (0.5%)	18 (0.6%)	34 (0.5%)
Hypertensive emergency	高血圧緊急症	1 (<0.1%)	0	1 (<0.1%)
Hypertensive urgency	高血圧切迫症	0	1 (<0.1%)	1 (<0.1%)
Hypotension	低血圧	11 (0.3%)	3 (<0.1%)	14 (0.2%)
Hypovolaemic shock	血液量減少性ショック	1 (<0.1%)	0	1 (<0.1%)
Iliac artery occlusion	腸骨動脈閉塞	1 (<0.1%)	0	1 (<0.1%)
Iliac artery stenosis	腸骨動脈狭窄	4 (0.1%)	4 (0.1%)	8 (0.1%)
Intermittent claudication	間欠性跛行	78 (2.4%)	93 (2.9%)	171 (2.6%)
Ischaemic limb pain	虚血性四肢痛	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Lymphatic fistula	リンパ瘻	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Lymphocele	リンパ嚢腫	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Lymphoedema	リンパ浮腫	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Lymphorrhoea	リンパ漏	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Lymphostasis	リンパうっ滞	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Microangiopathy	微小血管症	0	1 (<0.1%)	1 (<0.1%)
Orthostatic hypotension	起立性低血圧	0	1 (<0.1%)	1 (<0.1%)
Pallor	蒼白	0	1 (<0.1%)	1 (<0.1%)
Penetrating atherosclerotic ulcer	穿通性アテローム動脈硬化性潰瘍	0	1 (<0.1%)	1 (<0.1%)
Peripheral arterial occlusive disease	末梢動脈閉塞性疾患	145 (4.5%)	149 (4.6%)	294 (4.5%)
Peripheral artery aneurysm	末梢動脈瘤	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Peripheral artery dissection	末梢動脈解離	0	1 (<0.1%)	1 (<0.1%)
Peripheral artery occlusion	末梢動脈閉塞	11 (0.3%)	21 (0.6%)	32 (0.5%)
Peripheral artery stenosis	末梢動脈狭窄	36 (1.1%)	23 (0.7%)	59 (0.9%)
Peripheral artery thrombosis	末梢動脈血栓症	3 (<0.1%)	5 (0.2%)	8 (0.1%)
Peripheral coldness	末梢冷感	0	2 (<0.1%)	2 (<0.1%)
Peripheral embolism	末梢血管塞栓症	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Peripheral ischaemia	末梢性虚血	37 (1.1%)	35 (1.1%)	72 (1.1%)
Peripheral vascular disorder	末梢血管障害	8 (0.2%)	8 (0.2%)	16 (0.2%)
Peripheral venous disease	末梢静脈疾患	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Poor peripheral circulation	末梢循環不良	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Raynaud's phenomenon	レイノー現象	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Renovascular hypertension	腎血管性高血圧	1 (<0.1%)	0	1 (<0.1%)
Reperfusion injury	再潅流障害	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Spider vein	くも状静脈	1 (<0.1%)	0	1 (<0.1%)
Subclavian artery stenosis	鎖骨下動脈狭窄	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Subclavian steal syndrome	鎖骨下動脈スチール症候群	1 (<0.1%)	0	1 (<0.1%)
Systolic hypertension	収縮期高血圧	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Temporal arteritis	側頭動脈炎	1 (<0.1%)	0	1 (<0.1%)
Thrombophlebitis	血栓性静脈炎	1 (<0.1%)	0	1 (<0.1%)
Thrombophlebitis superficial	表在性血栓性静脈炎	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Varicose vein	静脈瘤	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Vascular stenosis	血管狭窄	0	1 (<0.1%)	1 (<0.1%)
Vasodilatation	血管拡張	0	1 (<0.1%)	1 (<0.1%)
Venous occlusion	静脈閉塞	1 (<0.1%)	0	1 (<0.1%)

The safety analysis set includes all randomized subjects who received at least one dose of study drug (rivaroxaban or rivaroxaban placebo).
Adverse events are sorted in alphabetical order by primary SOC and preferred term.
A subject is counted only once within each preferred term or any primary SOC.
bid = twice daily, od = once daily, ASA = acetylsalicylic acid
Treatment emergent events are defined as all events with an onset date on or after the date of randomization until 2 days following permanent discontinuation of the study drug (rivaroxaban or rivaroxaban placebo).
Source: 5.3.5.1.1 PH-40164/Table 14.3.1.1/3

付表 2.7.6.1.a.1-3 治験薬と関連のある TEAE（全体集団、SAF）

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
Number (%) of subjects with at least one adverse event		124 (3.8%)	108 (3.3%)	232 (3.6%)
Blood and lymphatic system disorders	血液およびリンパ系障害	19 (0.6%)	11 (0.3%)	30 (0.5%)
Anaemia	貧血	16 (0.5%)	8 (0.2%)	24 (0.4%)
Blood loss anaemia	失血性貧血	1 (<0.1%)	0	1 (<0.1%)
Increased tendency to bruise	内出血発生の増加傾向	0	2 (<0.1%)	2 (<0.1%)
Iron deficiency anaemia	鉄欠乏性貧血	2 (<0.1%)	0	2 (<0.1%)
Nephrogenic anaemia	腎性貧血	0	1 (<0.1%)	1 (<0.1%)
Cardiac disorders	心臓障害	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Cardiovascular disorder	心血管障害	0	1 (<0.1%)	1 (<0.1%)
Coronary artery disease	冠動脈疾患	2 (<0.1%)	0	2 (<0.1%)
Palpitations	動悸	0	1 (<0.1%)	1 (<0.1%)
Pericardial haemorrhage	心嚢内出血	0	1 (<0.1%)	1 (<0.1%)
Tachycardia	頻脈	1 (<0.1%)	0	1 (<0.1%)
Ear and labyrinth disorders	耳および迷路障害	0	2 (<0.1%)	2 (<0.1%)
Otorrhoea	耳漏	0	1 (<0.1%)	1 (<0.1%)
Vertigo	回転性めまい	0	1 (<0.1%)	1 (<0.1%)
Eye disorders	眼障害	2 (<0.1%)	0	2 (<0.1%)
Eye haemorrhage	眼出血	1 (<0.1%)	0	1 (<0.1%)
Vitreous haemorrhage	硝子体出血	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal disorders	胃腸障害	39 (1.2%)	23 (0.7%)	62 (1.0%)
Abdominal discomfort	腹部不快感	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Abdominal distension	腹部膨満	0	1 (<0.1%)	1 (<0.1%)
Abdominal pain	腹痛	1 (<0.1%)	0	1 (<0.1%)
Abdominal pain upper	上腹部痛	5 (0.2%)	4 (0.1%)	9 (0.1%)
Constipation	便秘	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Diarrhoea	下痢	7 (0.2%)	4 (0.1%)	11 (0.2%)
Diverticulum intestinal haemorrhagic	出血性腸憩室	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Dry mouth	口内乾燥	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Dyspepsia	消化不良	5 (0.2%)	4 (0.1%)	9 (0.1%)
Flatulence	鼓腸	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gastric antral vascular ectasia	胃前庭部毛細血管拡張症	1 (<0.1%)	0	1 (<0.1%)
Gastric ulcer	胃潰瘍	2 (<0.1%)	0	2 (<0.1%)
Gastric ulcer haemorrhage	出血性胃潰瘍	1 (<0.1%)	0	1 (<0.1%)
Gastritis	胃炎	3 (<0.1%)	0	3 (<0.1%)
Gastrooesophageal reflux disease	胃食道逆流性疾患	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gingival bleeding	歯肉出血	1 (<0.1%)	0	1 (<0.1%)
Lower gastrointestinal haemorrhage	下部消化管出血	1 (<0.1%)	0	1 (<0.1%)
Melaena	メレナ	2 (<0.1%)	0	2 (<0.1%)
Nausea	悪心	3 (<0.1%)	5 (0.2%)	8 (0.1%)
Pancreatitis	膵炎	0	1 (<0.1%)	1 (<0.1%)
Pancreatitis chronic	慢性膵炎	0	1 (<0.1%)	1 (<0.1%)
Upper gastrointestinal haemorrhage	上部消化管出血	2 (<0.1%)	0	2 (<0.1%)
Vomiting	嘔吐	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	9 (0.3%)	5 (0.2%)	14 (0.2%)
Asthenia	無力症	1 (<0.1%)	0	1 (<0.1%)
Catheter site induration	カテーテル留置部位硬結	0	1 (<0.1%)	1 (<0.1%)
Chest pain	胸痛	1 (<0.1%)	0	1 (<0.1%)
Drug intolerance	薬物不耐性	1 (<0.1%)	0	1 (<0.1%)
Face oedema	顔面浮腫	1 (<0.1%)	0	1 (<0.1%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
Fatigue	疲労	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Malaise	倦怠感	0	1 (<0.1%)	1 (<0.1%)
Non-cardiac chest pain	非心臓性胸痛	0	1 (<0.1%)	1 (<0.1%)
Oedema peripheral	末梢性浮腫	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Peripheral swelling	末梢腫脹	1 (<0.1%)	0	1 (<0.1%)
Puncture site haemorrhage	穿刺部位出血	1 (<0.1%)	0	1 (<0.1%)
Pyrexia	発熱	1 (<0.1%)	0	1 (<0.1%)
Vascular stent stenosis	血管ステント狭窄	2 (<0.1%)	0	2 (<0.1%)
Hepatobiliary disorders	肝胆道系障害	1 (<0.1%)	0	1 (<0.1%)
Hepatic function abnormal	肝機能異常	1 (<0.1%)	0	1 (<0.1%)
Immune system disorders	免疫系障害	0	5 (0.2%)	5 (<0.1%)
Hypersensitivity	過敏症	0	4 (0.1%)	4 (<0.1%)
Multiple allergies	複合アレルギー	0	1 (<0.1%)	1 (<0.1%)
Infections and infestations	感染症および寄生虫症	0	1 (<0.1%)	1 (<0.1%)
Cellulitis	蜂巣炎	0	1 (<0.1%)	1 (<0.1%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	5 (0.2%)	4 (0.1%)	9 (0.1%)
Contusion	挫傷	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Overdose	過量投与	1 (<0.1%)	0	1 (<0.1%)
Skin laceration	皮膚裂傷	1 (<0.1%)	0	1 (<0.1%)
Traumatic intracranial haemorrhage	外傷性頭蓋内出血	0	1 (<0.1%)	1 (<0.1%)
Underdose	過少量投与	0	1 (<0.1%)	1 (<0.1%)
Vascular pseudoaneurysm	血管偽動脈瘤	1 (<0.1%)	0	1 (<0.1%)
Wound haemorrhage	創傷出血	1 (<0.1%)	0	1 (<0.1%)
Investigations	臨床検査	7 (0.2%)	3 (<0.1%)	10 (0.2%)
Blood creatinine increased	血中クレアチニン増加	0	1 (<0.1%)	1 (<0.1%)
Blood pressure increased	血圧上昇	1 (<0.1%)	0	1 (<0.1%)
Blood urine present	尿中血陽性	0	1 (<0.1%)	1 (<0.1%)
Coagulation time prolonged	凝固時間延長	1 (<0.1%)	0	1 (<0.1%)
Haemoglobin decreased	ヘモグロビン減少	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Hepatic enzyme increased	肝酵素上昇	1 (<0.1%)	0	1 (<0.1%)
Occult blood positive	便潜血陽性	2 (<0.1%)	0	2 (<0.1%)
Metabolism and nutrition disorders	代謝および栄養障害	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Decreased appetite	食欲減退	1 (<0.1%)	0	1 (<0.1%)
Gout	痛風	0	1 (<0.1%)	1 (<0.1%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	2 (<0.1%)	5 (0.2%)	7 (0.1%)
Muscle spasms	筋痙縮	0	1 (<0.1%)	1 (<0.1%)
Muscular weakness	筋力低下	0	1 (<0.1%)	1 (<0.1%)
Myalgia	筋肉痛	1 (<0.1%)	0	1 (<0.1%)
Osteoarthritis	変形性関節症	1 (<0.1%)	0	1 (<0.1%)
Pain in extremity	四肢痛	0	3 (<0.1%)	3 (<0.1%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	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）	1 (<0.1%)	0	1 (<0.1%)
Myelodysplastic syndrome	骨髄異形成症候群	1 (<0.1%)	0	1 (<0.1%)
Nervous system disorders	神経系障害	11 (0.3%)	8 (0.2%)	19 (0.3%)
Cerebral haemorrhage	脳出血	0	1 (<0.1%)	1 (<0.1%)
Dizziness	浮動性めまい	5 (0.2%)	4 (0.1%)	9 (0.1%)
Headache	頭痛	5 (0.2%)	1 (<0.1%)	6 (<0.1%)
Putamen haemorrhage	被殻出血	0	1 (<0.1%)	1 (<0.1%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
Subarachnoid haemorrhage	くも膜下出血	0	1 (<0.1%)	1 (<0.1%)
Syncope	失神	1 (<0.1%)	0	1 (<0.1%)
Psychiatric disorders	精神障害	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Anxiety	不安	0	1 (<0.1%)	1 (<0.1%)
Depression	うつ病	0	1 (<0.1%)	1 (<0.1%)
Insomnia	不眠症	1 (<0.1%)	0	1 (<0.1%)
Mood altered	気分変化	0	1 (<0.1%)	1 (<0.1%)
Restlessness	落ち着きのなさ	0	1 (<0.1%)	1 (<0.1%)
Sleep disorder	睡眠障害	1 (<0.1%)	0	1 (<0.1%)
Renal and urinary disorders	腎および尿路障害	5 (0.2%)	5 (0.2%)	10 (0.2%)
Acute kidney injury	急性腎障害	0	1 (<0.1%)	1 (<0.1%)
Haematuria	血尿	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Renal failure	腎不全	1 (<0.1%)	0	1 (<0.1%)
Renal impairment	腎機能障害	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	8 (0.2%)	4 (0.1%)	12 (0.2%)
Dyspnoea	呼吸困難	0	1 (<0.1%)	1 (<0.1%)
Epistaxis	鼻出血	6 (0.2%)	1 (<0.1%)	7 (0.1%)
Haemoptysis	喀血	0	2 (<0.1%)	2 (<0.1%)
Nasal discharge discolouration	鼻汁変色	1 (<0.1%)	0	1 (<0.1%)
Pulmonary fibrosis	肺線維症	1 (<0.1%)	0	1 (<0.1%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	22 (0.7%)	33 (1.0%)	55 (0.8%)
Dermatitis allergic	アレルギー性皮膚炎	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Dermatitis contact	接触皮膚炎	0	1 (<0.1%)	1 (<0.1%)
Drug eruption	薬疹	2 (<0.1%)	0	2 (<0.1%)
Drug reaction with eosinophilia and systemic symptoms	好酸球増加と全身症状を伴う薬物反応	0	1 (<0.1%)	1 (<0.1%)
Dry skin	皮膚乾燥	0	1 (<0.1%)	1 (<0.1%)
Ecchymosis	斑状出血	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Eczema	湿疹	0	1 (<0.1%)	1 (<0.1%)
Erythema	紅斑	0	1 (<0.1%)	1 (<0.1%)
Haemorrhage subcutaneous	皮下出血	0	1 (<0.1%)	1 (<0.1%)
Henoch-Schonlein purpura	ヘノッホ・シェーンライン紫斑病	0	1 (<0.1%)	1 (<0.1%)
Hyperhidrosis	多汗症	0	1 (<0.1%)	1 (<0.1%)
Petechiae	点状出血	0	1 (<0.1%)	1 (<0.1%)
Prurigo	痒疹	1 (<0.1%)	0	1 (<0.1%)
Pruritus	そう痒症	4 (0.1%)	3 (<0.1%)	7 (0.1%)
Pruritus allergic	アレルギー性そう痒症	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Rash	発疹	8 (0.2%)	12 (0.4%)	20 (0.3%)
Rash erythematous	紅斑性皮疹	0	1 (<0.1%)	1 (<0.1%)
Rash pruritic	そう痒性皮疹	0	1 (<0.1%)	1 (<0.1%)
Skin reaction	皮膚反応	0	1 (<0.1%)	1 (<0.1%)
Urticaria	蕁麻疹	4 (0.1%)	3 (<0.1%)	7 (0.1%)
Surgical and medical procedures	外科および内科処置	1 (<0.1%)	0	1 (<0.1%)
Tooth extraction	抜歯	1 (<0.1%)	0	1 (<0.1%)
Vascular disorders	血管障害	8 (0.2%)	5 (0.2%)	13 (0.2%)
Blood pressure fluctuation	血圧変動	1 (<0.1%)	0	1 (<0.1%)
Haematoma	血腫	2 (<0.1%)	0	2 (<0.1%)
Hypertension	高血圧	0	1 (<0.1%)	1 (<0.1%)
Hypotension	低血圧	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
Intermittent claudication	間欠性跛行	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Peripheral arterial occlusive disease	末梢動脈閉塞性疾患	2 (<0.1%)	0	2 (<0.1%)
Peripheral ischaemia	末梢性虚血	0	1 (<0.1%)	1 (<0.1%)
Venous occlusion	静脈閉塞	1 (<0.1%)	0	1 (<0.1%)

The safety analysis set includes all randomized subjects who received at least one dose of study drug (rivaroxaban or rivaroxaban placebo).
Adverse events are sorted in alphabetical order by primary SOC and preferred term.
A subject is counted only once within each preferred term or any primary SOC.
bid = twice daily, od = once daily, ASA = acetylsalicylic acid
Treatment emergent events are defined as all events with an onset date on or after the date of randomization until 2 days following permanent discontinuation of the study drug (rivaroxaban or rivaroxaban placebo).
Source: 5.3.5.1.1 PH-40164/Table 14.3.1.1/5

付表 2.7.6.1.a.1-4 重篤な TEAE（全体集団、SAF）

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
Number (%) of subjects with at least one adverse event		948 (29.1%)	927 (28.5%)	1875 (28.8%)
Blood and lymphatic system disorders	血液およびリンパ系障害	23 (0.7%)	13 (0.4%)	36 (0.6%)
Anaemia	貧血	14 (0.4%)	10 (0.3%)	24 (0.4%)
Blood loss anaemia	失血性貧血	1 (<0.1%)	0	1 (<0.1%)
Iron deficiency anaemia	鉄欠乏性貧血	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Leukocytosis	白血球増加症	1 (<0.1%)	0	1 (<0.1%)
Microcytic anaemia	小球性貧血	0	1 (<0.1%)	1 (<0.1%)
Nephrogenic anaemia	腎性貧血	1 (<0.1%)	0	1 (<0.1%)
Normochromic normocytic anaemia	正色素性正球性貧血	1 (<0.1%)	0	1 (<0.1%)
Normocytic anaemia	正球性貧血	1 (<0.1%)	0	1 (<0.1%)
Thrombocytopenia	血小板減少症	0	1 (<0.1%)	1 (<0.1%)
Thrombocytosis	血小板増加症	1 (<0.1%)	0	1 (<0.1%)
Cardiac disorders	心臓障害	101 (3.1%)	111 (3.4%)	212 (3.3%)
Acute left ventricular failure	急性左室不全	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Acute myocardial infarction	急性心筋梗塞	0	1 (<0.1%)	1 (<0.1%)
Angina pectoris	狭心症	10 (0.3%)	10 (0.3%)	20 (0.3%)
Angina unstable	不安定狭心症	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Aortic valve stenosis	大動脈弁狭窄	2 (<0.1%)	0	2 (<0.1%)
Arrhythmia	不整脈	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Arrhythmia supraventricular	上室性不整脈	0	1 (<0.1%)	1 (<0.1%)
Arteriosclerosis coronary artery	冠動脈硬化症	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Atrial fibrillation	心房細動	19 (0.6%)	20 (0.6%)	39 (0.6%)
Atrial flutter	心房粗動	0	1 (<0.1%)	1 (<0.1%)
Atrioventricular block complete	完全房室ブロック	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Atrioventricular block first degree	第一度房室ブロック	0	1 (<0.1%)	1 (<0.1%)
Atrioventricular block second degree	第二度房室ブロック	0	2 (<0.1%)	2 (<0.1%)
Bradycardia	徐脈	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Cardiac arrest	心停止	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cardiac failure	心不全	14 (0.4%)	14 (0.4%)	28 (0.4%)
Cardiac failure acute	急性心不全	3 (<0.1%)	6 (0.2%)	9 (0.1%)
Cardiac failure chronic	慢性心不全	6 (0.2%)	3 (<0.1%)	9 (0.1%)
Cardiac failure congestive	うっ血性心不全	10 (0.3%)	8 (0.2%)	18 (0.3%)
Cardiac tamponade	心タンポナーデ	1 (<0.1%)	0	1 (<0.1%)
Cardio-respiratory arrest	心肺停止	2 (<0.1%)	0	2 (<0.1%)
Cardiogenic shock	心原性ショック	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cardiopulmonary failure	心肺不全	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Congestive cardiomyopathy	うっ血性心筋症	1 (<0.1%)	0	1 (<0.1%)
Coronary artery disease	冠動脈疾患	15 (0.5%)	21 (0.6%)	36 (0.6%)
Coronary artery occlusion	冠動脈閉塞	1 (<0.1%)	0	1 (<0.1%)
Coronary artery stenosis	冠動脈狭窄	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Cyanosis	チアノーゼ	1 (<0.1%)	0	1 (<0.1%)
Hypertensive heart disease	高血圧性心疾患	0	2 (<0.1%)	2 (<0.1%)
Ischaemic cardiomyopathy	虚血性心筋症	1 (<0.1%)	0	1 (<0.1%)
Myocardial infarction	心筋梗塞	1 (<0.1%)	0	1 (<0.1%)
Myocardial ischaemia	心筋虚血	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Pericardial effusion	心嚢液貯留	0	2 (<0.1%)	2 (<0.1%)
Pericardial haemorrhage	心嚢内出血	0	1 (<0.1%)	1 (<0.1%)
Pericarditis	心膜炎	0	1 (<0.1%)	1 (<0.1%)
Right ventricular failure	右室不全	0	2 (<0.1%)	2 (<0.1%)
Sinus arrest	洞停止	1 (<0.1%)	0	1 (<0.1%)
Sinus bradycardia	洞性徐脈	0	1 (<0.1%)	1 (<0.1%)
Sinus node dysfunction	洞結節機能不全	0	2 (<0.1%)	2 (<0.1%)
Stress cardiomyopathy	ストレス心筋症	0	1 (<0.1%)	1 (<0.1%)
Supraventricular tachyarrhythmia	上室性頻脈性不整脈	0	1 (<0.1%)	1 (<0.1%)
Supraventricular tachycardia	上室性頻脈	3 (<0.1%)	0	3 (<0.1%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
Ventricular arrhythmia	心室性不整脈	0	1 (<0.1%)	1 (<0.1%)
Ventricular fibrillation	心室細動	0	1 (<0.1%)	1 (<0.1%)
Ventricular tachycardia	心室性頻脈	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Congenital, familial and genetic disorders	先天性、家族性および遺伝性障害	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Adenomatous polyposis coli	大腸腺腫性ポリポーシス	1 (<0.1%)	0	1 (<0.1%)
Congenital bladder neck obstruction	先天性膀胱頚部閉塞症	0	1 (<0.1%)	1 (<0.1%)
Hydrocele	陰嚢水瘤	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Phimosis	包茎	0	2 (<0.1%)	2 (<0.1%)
Ear and labyrinth disorders	耳および迷路障害	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Deafness	難聴	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Sudden hearing loss	突発性難聴	2 (<0.1%)	0	2 (<0.1%)
Vertigo	回転性めまい	0	2 (<0.1%)	2 (<0.1%)
Endocrine disorders	内分泌障害	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Goitre	甲状腺腫	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Thyroid mass	甲状腺腫瘤	1 (<0.1%)	0	1 (<0.1%)
Eye disorders	眼障害	16 (0.5%)	17 (0.5%)	33 (0.5%)
Cataract	白内障	8 (0.2%)	8 (0.2%)	16 (0.2%)
Cataract subcapsular	嚢下白内障	1 (<0.1%)	0	1 (<0.1%)
Detachment of macular retinal pigment epithelium	黄斑網膜色素上皮剥離	0	1 (<0.1%)	1 (<0.1%)
Diabetic retinopathy	糖尿病網膜症	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Eyelid ptosis	眼瞼下垂	0	1 (<0.1%)	1 (<0.1%)
Glaucoma	緑内障	2 (<0.1%)	0	2 (<0.1%)
Iridocyclitis	虹彩毛様体炎	0	1 (<0.1%)	1 (<0.1%)
Macular degeneration	黄斑変性	1 (<0.1%)	0	1 (<0.1%)
Macular detachment	黄斑剥離	0	1 (<0.1%)	1 (<0.1%)
Macular hole	黄斑円孔	1 (<0.1%)	0	1 (<0.1%)
Macular oedema	黄斑浮腫	1 (<0.1%)	0	1 (<0.1%)
Myopia	近視	0	1 (<0.1%)	1 (<0.1%)
Retinal detachment	網膜剥離	0	1 (<0.1%)	1 (<0.1%)
Retinal haemorrhage	網膜出血	0	1 (<0.1%)	1 (<0.1%)
Vitreoretinal traction syndrome	硝子体網膜牽引症候群	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vitreous haemorrhage	硝子体出血	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal disorders	胃腸障害	69 (2.1%)	63 (1.9%)	132 (2.0%)
Abdominal adhesions	腹部癒着	0	1 (<0.1%)	1 (<0.1%)
Abdominal incarcerated hernia	嵌頓腹部ヘルニア	1 (<0.1%)	0	1 (<0.1%)
Abdominal mass	腹部腫瘤	0	1 (<0.1%)	1 (<0.1%)
Abdominal pain	腹痛	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Abdominal pain lower	下腹部痛	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Abdominal pain upper	上腹部痛	0	1 (<0.1%)	1 (<0.1%)
Alcoholic pancreatitis	アルコール性膵炎	1 (<0.1%)	0	1 (<0.1%)
Anal fissure	裂肛	0	1 (<0.1%)	1 (<0.1%)
Anal stenosis	肛門狭窄	0	1 (<0.1%)	1 (<0.1%)
Ascites	腹水	0	1 (<0.1%)	1 (<0.1%)
Chronic gastritis	慢性胃炎	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Colitis	大腸炎	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Colitis ischaemic	虚血性大腸炎	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Constipation	便秘	1 (<0.1%)	0	1 (<0.1%)
Crohn's disease	クローン病	2 (<0.1%)	0	2 (<0.1%)
Dental alveolar anomaly	歯槽異常	0	1 (<0.1%)	1 (<0.1%)
Diaphragmatic hernia	横隔膜ヘルニア	0	1 (<0.1%)	1 (<0.1%)
Diarrhoea	下痢	3 (<0.1%)	0	3 (<0.1%)
Diverticulum intestinal haemorrhagic	出血性腸憩室	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
Dry mouth	口内乾燥	0	1 (<0.1%)	1 (<0.1%)
Duodenal ulcer	十二指腸潰瘍	0	1 (<0.1%)	1 (<0.1%)
Dysphagia	嚥下障害	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Enterovesical fistula	腸膀胱瘻	0	1 (<0.1%)	1 (<0.1%)
Gallstone ileus	胆石性イレウス	0	1 (<0.1%)	1 (<0.1%)
Gastric antral vascular ectasia	胃前庭部毛細血管拡張症	1 (<0.1%)	0	1 (<0.1%)
Gastric haemorrhage	胃出血	1 (<0.1%)	0	1 (<0.1%)
Gastric polyps	胃ポリープ	0	1 (<0.1%)	1 (<0.1%)
Gastric ulcer	胃潰瘍	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Gastric ulcer haemorrhage	出血性胃潰瘍	1 (<0.1%)	0	1 (<0.1%)
Gastritis	胃炎	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Gastritis erosive	びらん性胃炎	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gastrointestinal necrosis	消化管壊死	1 (<0.1%)	0	1 (<0.1%)
Gastrooesophageal reflux disease	胃食道逆流性疾患	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Haemorrhoids	痔核	0	1 (<0.1%)	1 (<0.1%)
Hiatus hernia	裂孔ヘルニア	0	1 (<0.1%)	1 (<0.1%)
Ileus	イレウス	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Impaired gastric emptying	胃排出不全	2 (<0.1%)	0	2 (<0.1%)
Inguinal hernia	鼠径ヘルニア	4 (0.1%)	4 (0.1%)	8 (0.1%)
Intestinal angina	腸管アンギナ	0	1 (<0.1%)	1 (<0.1%)
Intestinal ischaemia	腸管虚血	4 (0.1%)	3 (<0.1%)	7 (0.1%)
Intestinal obstruction	腸閉塞	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Intestinal perforation	腸管穿孔	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Intestinal ulcer	腸潰瘍	0	1 (<0.1%)	1 (<0.1%)
Large intestinal obstruction	大腸閉塞	0	1 (<0.1%)	1 (<0.1%)
Large intestine perforation	大腸穿孔	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Large intestine polyp	大腸ポリープ	10 (0.3%)	4 (0.1%)	14 (0.2%)
Lower gastrointestinal haemorrhage	下部消化管出血	1 (<0.1%)	0	1 (<0.1%)
Mechanical ileus	機械的イレウス	1 (<0.1%)	0	1 (<0.1%)
Nausea	悪心	1 (<0.1%)	0	1 (<0.1%)
Obstructive pancreatitis	閉塞性膵炎	0	1 (<0.1%)	1 (<0.1%)
Oedematous pancreatitis	浮腫性膵炎	1 (<0.1%)	0	1 (<0.1%)
Oesophagitis	食道炎	1 (<0.1%)	0	1 (<0.1%)
Pancreatic duct stenosis	膵管狭窄	0	1 (<0.1%)	1 (<0.1%)
Pancreatic mass	膵腫瘤	0	1 (<0.1%)	1 (<0.1%)
Pancreatitis	膵炎	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Pancreatitis acute	急性膵炎	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Pancreatitis chronic	慢性膵炎	0	4 (0.1%)	4 (<0.1%)
Pancreatitis necrotising	壊死性膵炎	1 (<0.1%)	0	1 (<0.1%)
Peptic ulcer perforation	穿孔性消化性潰瘍	0	1 (<0.1%)	1 (<0.1%)
Periodontal disease	歯周病	1 (<0.1%)	0	1 (<0.1%)
Small intestinal obstruction	小腸閉塞	0	3 (<0.1%)	3 (<0.1%)
Small intestinal perforation	小腸穿孔	1 (<0.1%)	0	1 (<0.1%)
Subileus	亜イレウス	1 (<0.1%)	0	1 (<0.1%)
Tooth loss	歯の脱落	0	1 (<0.1%)	1 (<0.1%)
Umbilical hernia	臍ヘルニア	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Umbilical hernia, obstructive	閉塞性臍ヘルニア	0	1 (<0.1%)	1 (<0.1%)
Upper gastrointestinal haemorrhage	上部消化管出血	2 (<0.1%)	0	2 (<0.1%)
Volvulus	腸の軸捻転	0	1 (<0.1%)	1 (<0.1%)
Vomiting	嘔吐	0	2 (<0.1%)	2 (<0.1%)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	35 (1.1%)	38 (1.2%)	73 (1.1%)
Asthenia	無力症	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Chest discomfort	胸部不快感	0	1 (<0.1%)	1 (<0.1%)
Chest pain	胸痛	4 (0.1%)	3 (<0.1%)	7 (0.1%)
Crepitations	捻髪音	0	1 (<0.1%)	1 (<0.1%)
Death	死亡	1 (<0.1%)	0	1 (<0.1%)
Drug intolerance	薬物不耐性	0	1 (<0.1%)	1 (<0.1%)
Gait disturbance	歩行障害	0	1 (<0.1%)	1 (<0.1%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
General physical health deterioration	全身健康状態悪化	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Granuloma	肉芽腫	1 (<0.1%)	0	1 (<0.1%)
Hernia	ヘルニア	0	1 (<0.1%)	1 (<0.1%)
Impaired healing	治癒不良	3 (<0.1%)	7 (0.2%)	10 (0.2%)
Inflammation	炎症	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Multiple organ dysfunction syndrome	多臓器機能不全症候群	0	2 (<0.1%)	2 (<0.1%)
Non-cardiac chest pain	非心臓性胸痛	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Oedema	浮腫	0	1 (<0.1%)	1 (<0.1%)
Oedema peripheral	末梢性浮腫	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Organ failure	臓器不全	1 (<0.1%)	0	1 (<0.1%)
Pain	疼痛	1 (<0.1%)	0	1 (<0.1%)
Peripheral swelling	末梢腫脹	0	2 (<0.1%)	2 (<0.1%)
Puncture site haemorrhage	穿刺部位出血	1 (<0.1%)	0	1 (<0.1%)
Pyrexia	発熱	1 (<0.1%)	0	1 (<0.1%)
Stent-graft endoleak	ステントグラフトエンドリーク	1 (<0.1%)	0	1 (<0.1%)
Systemic inflammatory response syndrome	全身性炎症反応症候群	1 (<0.1%)	0	1 (<0.1%)
Vascular device occlusion	血管デバイス閉塞	0	1 (<0.1%)	1 (<0.1%)
Vascular stent occlusion	血管ステント閉塞	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Vascular stent stenosis	血管ステント狭窄	11 (0.3%)	8 (0.2%)	19 (0.3%)
Vascular stent thrombosis	血管ステント血栓症	0	1 (<0.1%)	1 (<0.1%)
Hepatobiliary disorders	肝胆道系障害	22 (0.7%)	27 (0.8%)	49 (0.8%)
Bile duct obstruction	胆管閉塞	0	3 (<0.1%)	3 (<0.1%)
Bile duct stone	胆管結石	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Biliary dyskinesia	胆道ジスキネジア	1 (<0.1%)	0	1 (<0.1%)
Cholangitis	胆管炎	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Cholangitis acute	急性胆管炎	1 (<0.1%)	0	1 (<0.1%)
Cholecystitis	胆嚢炎	7 (0.2%)	3 (<0.1%)	10 (0.2%)
Cholecystitis acute	急性胆嚢炎	2 (<0.1%)	12 (0.4%)	14 (0.2%)
Cholelithiasis	胆石症	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Cholestasis	胆汁うっ滞	0	1 (<0.1%)	1 (<0.1%)
Cirrhosis alcoholic	アルコール性肝硬変	1 (<0.1%)	0	1 (<0.1%)
Hepatic cirrhosis	肝硬変	3 (<0.1%)	0	3 (<0.1%)
Hepatic failure	肝不全	0	1 (<0.1%)	1 (<0.1%)
Hepatic function abnormal	肝機能異常	2 (<0.1%)	0	2 (<0.1%)
Hepatic steatosis	脂肪肝	0	1 (<0.1%)	1 (<0.1%)
Hepatorenal syndrome	肝腎症候群	0	1 (<0.1%)	1 (<0.1%)
Primary biliary cholangitis	原発性胆汁性胆管炎	1 (<0.1%)	0	1 (<0.1%)
Steatohepatitis	脂肪性肝炎	0	1 (<0.1%)	1 (<0.1%)
Immune system disorders	免疫系障害	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Anaphylactic reaction	アナフィラキシー反応	0	2 (<0.1%)	2 (<0.1%)
Hypersensitivity	過敏症	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Infections and infestations	感染症および寄生虫症	236 (7.2%)	231 (7.1%)	467 (7.2%)
Abdominal infection	腹部感染	1 (<0.1%)	0	1 (<0.1%)
Abscess	膿瘍	1 (<0.1%)	0	1 (<0.1%)
Abscess limb	四肢膿瘍	6 (0.2%)	5 (0.2%)	11 (0.2%)
Acute sinusitis	急性副鼻腔炎	0	1 (<0.1%)	1 (<0.1%)
Appendicitis	虫垂炎	4 (0.1%)	5 (0.2%)	9 (0.1%)
Arteriosclerotic gangrene	動脈硬化性壊疽	1 (<0.1%)	0	1 (<0.1%)
Arthritis bacterial	細菌性関節炎	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Arthritis infective	感染性関節炎	1 (<0.1%)	0	1 (<0.1%)
Bacteraemia	菌血症	0	1 (<0.1%)	1 (<0.1%)
Blister infected	感染性水疱	0	1 (<0.1%)	1 (<0.1%)
Bone abscess	骨膿瘍	1 (<0.1%)	0	1 (<0.1%)
Bronchiolitis	細気管支炎	0	1 (<0.1%)	1 (<0.1%)
Bronchitis	気管支炎	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
Burn infection	熱傷部感染	1 (<0.1%)	0	1 (<0.1%)
Carbuncle	よう	0	1 (<0.1%)	1 (<0.1%)
Cellulitis	蜂巣炎	19 (0.6%)	18 (0.6%)	37 (0.6%)
Cellulitis gangrenous	壊疽性蜂巣炎	0	1 (<0.1%)	1 (<0.1%)
Cholecystitis infective	感染性胆嚢炎	0	1 (<0.1%)	1 (<0.1%)
Clostridium difficile colitis	クロストリジウム・ディフィシレ大腸炎	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Complicated appendicitis	合併症を伴う虫垂炎	0	1 (<0.1%)	1 (<0.1%)
Cystitis	膀胱炎	0	1 (<0.1%)	1 (<0.1%)
Cystitis bacterial	細菌性膀胱炎	1 (<0.1%)	0	1 (<0.1%)
Dermo-hypodermitis	皮膚皮下組織炎	1 (<0.1%)	0	1 (<0.1%)
Device related infection	医療機器関連感染	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Diabetic foot infection	糖尿病性足感染	1 (<0.1%)	6 (0.2%)	7 (0.1%)
Diabetic gangrene	糖尿病性壊疽	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Diarrhoea infectious	感染性下痢	1 (<0.1%)	0	1 (<0.1%)
Diverticulitis	憩室炎	4 (0.1%)	5 (0.2%)	9 (0.1%)
Ear infection	耳感染	0	1 (<0.1%)	1 (<0.1%)
Eczema infected	感染性湿疹	1 (<0.1%)	0	1 (<0.1%)
Endocarditis	心内膜炎	1 (<0.1%)	0	1 (<0.1%)
Epididymitis	精巣上体炎	0	1 (<0.1%)	1 (<0.1%)
Erysipelas	丹毒	1 (<0.1%)	10 (0.3%)	11 (0.2%)
Escherichia sepsis	大腸菌性敗血症	1 (<0.1%)	0	1 (<0.1%)
Extradural abscess	硬膜外膿瘍	1 (<0.1%)	0	1 (<0.1%)
Fournier's gangrene	フルニエ壊疽	0	1 (<0.1%)	1 (<0.1%)
Fungal cystitis	真菌性膀胱炎	0	1 (<0.1%)	1 (<0.1%)
Fungal skin infection	皮膚真菌感染	1 (<0.1%)	0	1 (<0.1%)
Gangrene	壊疽	16 (0.5%)	20 (0.6%)	36 (0.6%)
Gastric infection	胃感染	0	1 (<0.1%)	1 (<0.1%)
Gastroenteritis	胃腸炎	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Gastroenteritis salmonella	サルモネラ菌性胃腸炎	0	1 (<0.1%)	1 (<0.1%)
Gastroenteritis viral	ウイルス性胃腸炎	2 (<0.1%)	0	2 (<0.1%)
Graft infection	移植片感染	1 (<0.1%)	0	1 (<0.1%)
Groin abscess	鼠径部膿瘍	3 (<0.1%)	0	3 (<0.1%)
Groin infection	鼠径部感染	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Haematoma infection	血腫感染	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Infected lymphocele	感染性リンパ嚢腫	2 (<0.1%)	0	2 (<0.1%)
Infected seroma	感染性漿液腫	1 (<0.1%)	0	1 (<0.1%)
Infected skin ulcer	感染性皮膚潰瘍	6 (0.2%)	4 (0.1%)	10 (0.2%)
Infectious pleural effusion	感染性胸水	0	1 (<0.1%)	1 (<0.1%)
Infective exacerbation of chronic obstructive airways disease	感染による慢性閉塞性気道疾患の増悪	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Influenza	インフルエンザ	2 (<0.1%)	0	2 (<0.1%)
Intervertebral discitis	椎間板炎	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Large intestine infection	大腸感染	0	1 (<0.1%)	1 (<0.1%)
Localised infection	限局性感染	19 (0.6%)	11 (0.3%)	30 (0.5%)
Lower respiratory tract infection	下気道感染	0	2 (<0.1%)	2 (<0.1%)
Lymph gland infection	リンパ節感染	1 (<0.1%)	0	1 (<0.1%)
Lymphangitis	リンパ管炎	1 (<0.1%)	0	1 (<0.1%)
Mastoiditis	乳様突起炎	1 (<0.1%)	0	1 (<0.1%)
Medical device site infection	医療機器使用部位感染	1 (<0.1%)	0	1 (<0.1%)
Medical device site joint infection	医療機器使用部位関節感染	0	3 (<0.1%)	3 (<0.1%)
Oesophageal candidiasis	食道カンジダ症	1 (<0.1%)	0	1 (<0.1%)
Ophthalmic herpes zoster	眼帯状疱疹	1 (<0.1%)	0	1 (<0.1%)
Orchitis	精巣炎	1 (<0.1%)	0	1 (<0.1%)
Osteomyelitis	骨髄炎	11 (0.3%)	12 (0.4%)	23 (0.4%)
Osteomyelitis bacterial	細菌性骨髄炎	0	1 (<0.1%)	1 (<0.1%)
Osteomyelitis chronic	慢性骨髄炎	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Otitis media	中耳炎	0	1 (<0.1%)	1 (<0.1%)
Perineal abscess	会陰膿瘍	2 (<0.1%)	0	2 (<0.1%)
Perineal cellulitis	会陰蜂巣炎	0	1 (<0.1%)	1 (<0.1%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
Perinephric abscess	腎周囲膿瘍	1 (<0.1%)	0	1 (<0.1%)
Periodontitis	歯周炎	0	1 (<0.1%)	1 (<0.1%)
Peritonitis	腹膜炎	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Periumbilical abscess	臍帯周囲膿瘍	0	1 (<0.1%)	1 (<0.1%)
Pharyngitis	咽頭炎	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pneumocystis jirovecii pneumonia	ニューモシスチス・イロベチイ肺炎	1 (<0.1%)	0	1 (<0.1%)
Pneumonia	肺炎	40 (1.2%)	45 (1.4%)	85 (1.3%)
Pneumonia bacterial	細菌性肺炎	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Post procedural infection	処置後感染	1 (<0.1%)	0	1 (<0.1%)
Post procedural sepsis	処置後敗血症	0	1 (<0.1%)	1 (<0.1%)
Postoperative wound infection	術後創感染	27 (0.8%)	25 (0.8%)	52 (0.8%)
Pseudomembranous colitis	偽膜性大腸炎	1 (<0.1%)	0	1 (<0.1%)
Pulmonary sepsis	肺敗血症	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Pulmonary tuberculosis	肺結核	2 (<0.1%)	0	2 (<0.1%)
Pyelonephritis	腎盂腎炎	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Pyelonephritis acute	急性腎盂腎炎	1 (<0.1%)	0	1 (<0.1%)
Respiratory tract infection	気道感染	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Scrotal abscess	陰嚢膿瘍	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Sepsis	敗血症	12 (0.4%)	13 (0.4%)	25 (0.4%)
Septic shock	敗血症性ショック	1 (<0.1%)	5 (0.2%)	6 (<0.1%)
Sinusitis	副鼻腔炎	0	2 (<0.1%)	2 (<0.1%)
Skin infection	皮膚感染	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Soft tissue infection	軟部組織感染	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Streptococcal sepsis	レンサ球菌性敗血症	0	1 (<0.1%)	1 (<0.1%)
Subcutaneous abscess	皮下組織膿瘍	1 (<0.1%)	0	1 (<0.1%)
Superinfection bacterial	細菌重複感染	0	1 (<0.1%)	1 (<0.1%)
Tonsillitis	扁桃炎	1 (<0.1%)	0	1 (<0.1%)
Tuberculosis	結核	0	1 (<0.1%)	1 (<0.1%)
Urinary tract infection	尿路感染	13 (0.4%)	11 (0.3%)	24 (0.4%)
Urosepsis	尿路性敗血症	0	5 (0.2%)	5 (<0.1%)
Vascular device infection	血管デバイス感染	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Wound infection	創傷感染	17 (0.5%)	15 (0.5%)	32 (0.5%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	109 (3.3%)	114 (3.5%)	223 (3.4%)
Accidental overdose	偶発的過量投与	1 (<0.1%)	0	1 (<0.1%)
Alcohol poisoning	アルコール中毒	2 (<0.1%)	0	2 (<0.1%)
Anastomotic stenosis	吻合部狭窄	0	1 (<0.1%)	1 (<0.1%)
Ankle fracture	足関節部骨折	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Arterial bypass occlusion	動脈バイパス閉塞	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Arterial bypass stenosis	動脈バイパス狭窄	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Arterial bypass thrombosis	動脈バイパス血栓症	0	1 (<0.1%)	1 (<0.1%)
Bone contusion	骨挫傷	1 (<0.1%)	0	1 (<0.1%)
Brain herniation	脳ヘルニア	0	1 (<0.1%)	1 (<0.1%)
Carbon monoxide poisoning	一酸化炭素中毒	1 (<0.1%)	0	1 (<0.1%)
Cerebral hyperperfusion syndrome	脳過潅流症候群	1 (<0.1%)	0	1 (<0.1%)
Chemical burn of skin	皮膚化学熱傷	0	1 (<0.1%)	1 (<0.1%)
Chest injury	胸部損傷	0	1 (<0.1%)	1 (<0.1%)
Compression fracture	圧迫骨折	0	1 (<0.1%)	1 (<0.1%)
Concussion	脳振盪	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Contusion	挫傷	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Coronary artery restenosis	冠動脈再狭窄	1 (<0.1%)	0	1 (<0.1%)
Craniocerebral injury	頭蓋脳損傷	2 (<0.1%)	0	2 (<0.1%)
Facial bones fracture	顔面骨骨折	0	2 (<0.1%)	2 (<0.1%)
Failure to anastomose	吻合不全	0	1 (<0.1%)	1 (<0.1%)
Fall	転倒	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Femoral neck fracture	大腿骨頚部骨折	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Femur fracture	大腿骨骨折	10 (0.3%)	12 (0.4%)	22 (0.3%)
Fibula fracture	腓骨骨折	3 (<0.1%)	0	3 (<0.1%)
Foot fracture	足骨折	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
Forearm fracture	前腕骨折	0	1 (<0.1%)	1 (<0.1%)
Foreign body in gastrointestinal tract	消化管内異物	0	1 (<0.1%)	1 (<0.1%)
Fractured sacrum	仙骨骨折	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal anastomotic leak	胃腸吻合部漏出	0	1 (<0.1%)	1 (<0.1%)
Graft thrombosis	移植片血栓症	1 (<0.1%)	0	1 (<0.1%)
Head injury	頭部損傷	2 (<0.1%)	0	2 (<0.1%)
Hip fracture	股関節部骨折	5 (0.2%)	5 (0.2%)	10 (0.2%)
Humerus fracture	上腕骨骨折	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Incisional hernia	瘢痕ヘルニア	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Injury	損傷	2 (<0.1%)	0	2 (<0.1%)
Intentional overdose	企図的過量投与	1 (<0.1%)	0	1 (<0.1%)
Joint dislocation	関節脱臼	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Limb injury	四肢損傷	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Lower limb fracture	下肢骨折	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Lumbar vertebral fracture	腰椎骨折	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Meniscus injury	半月板損傷	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Multiple injuries	多発性外傷	1 (<0.1%)	0	1 (<0.1%)
Open fracture	開放骨折	0	1 (<0.1%)	1 (<0.1%)
Patella fracture	膝蓋骨骨折	1 (<0.1%)	0	1 (<0.1%)
Pelvic fracture	骨盤骨折	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Penetrating abdominal trauma	鋭的腹部外傷	0	1 (<0.1%)	1 (<0.1%)
Peripheral arterial reocclusion	末梢動脈再閉塞	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Peripheral artery restenosis	末梢動脈再狭窄	16 (0.5%)	15 (0.5%)	31 (0.5%)
Periprosthetic fracture	人工関節周囲骨折	0	1 (<0.1%)	1 (<0.1%)
Post laminectomy syndrome	椎弓切除後症候群	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Post procedural bile leak	処置後胆汁漏出	0	1 (<0.1%)	1 (<0.1%)
Post procedural complication	処置後合併症	1 (<0.1%)	0	1 (<0.1%)
Post procedural discharge	処置後分泌物	0	1 (<0.1%)	1 (<0.1%)
Post procedural oedema	処置後浮腫	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Postoperative thoracic procedure complication	術後胸部処置合併症	0	1 (<0.1%)	1 (<0.1%)
Procedural complication	処置合併症	0	1 (<0.1%)	1 (<0.1%)
Procedural intestinal perforation	処置による腸管穿孔	0	1 (<0.1%)	1 (<0.1%)
Pubis fracture	恥骨骨折	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Radius fracture	橈骨骨折	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Rib fracture	肋骨骨折	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Road traffic accident	交通事故	1 (<0.1%)	0	1 (<0.1%)
Seroma	漿液腫	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Skin laceration	皮膚裂傷	0	1 (<0.1%)	1 (<0.1%)
Skin scar contracture	皮膚瘢痕拘縮	0	1 (<0.1%)	1 (<0.1%)
Skull fractured base	頭蓋底骨折	1 (<0.1%)	0	1 (<0.1%)
Spinal column injury	脊柱損傷	0	1 (<0.1%)	1 (<0.1%)
Spinal compression fracture	脊椎圧迫骨折	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Spinal fracture	脊椎骨折	0	1 (<0.1%)	1 (<0.1%)
Tendon rupture	腱断裂	1 (<0.1%)	0	1 (<0.1%)
Thermal burn	熱傷	1 (<0.1%)	0	1 (<0.1%)
Thoracic vertebral fracture	胸椎骨折	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Tibia fracture	脛骨骨折	3 (<0.1%)	0	3 (<0.1%)
Traumatic fracture	外傷性骨折	0	1 (<0.1%)	1 (<0.1%)
Traumatic intracranial haemorrhage	外傷性頭蓋内出血	0	1 (<0.1%)	1 (<0.1%)
Traumatic ulcer	外傷性潰瘍	1 (<0.1%)	0	1 (<0.1%)
Underdose	過少量投与	0	1 (<0.1%)	1 (<0.1%)
Upper limb fracture	上肢骨折	1 (<0.1%)	0	1 (<0.1%)
Vascular access site haematoma	血管確保部位血腫	1 (<0.1%)	0	1 (<0.1%)
Vascular graft complication	移植血管合併症	5 (0.2%)	1 (<0.1%)	6 (<0.1%)
Vascular graft occlusion	移植血管閉塞	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Vascular graft restenosis	移植血管再狭窄	0	2 (<0.1%)	2 (<0.1%)
Vascular graft stenosis	移植血管狭窄	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Vascular graft thrombosis	血管グラフト血栓症	1 (<0.1%)	0	1 (<0.1%)
Vascular procedure complication	血管処置合併症	1 (<0.1%)	0	1 (<0.1%)

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Vascular pseudoaneurysm	血管偽動脈瘤	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Wound complication	創合併症	1 (<0.1%)	0	1 (<0.1%)
Wound dehiscence	創離開	4 (0.1%)	3 (<0.1%)	7 (0.1%)
Wound necrosis	創壊死	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Investigations	臨床検査	6 (0.2%)	6 (0.2%)	12 (0.2%)
Blood creatinine increased	血中クレアチニン増加	0	1 (<0.1%)	1 (<0.1%)
Blood glucose increased	血中ブドウ糖増加	0	1 (<0.1%)	1 (<0.1%)
Blood potassium increased	血中カリウム増加	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Blood pressure increased	血圧上昇	0	1 (<0.1%)	1 (<0.1%)
Carbohydrate antigen 19-9 increased	糖鎖抗原１９－９増加	1 (<0.1%)	0	1 (<0.1%)
Cardiac stress test abnormal	心臓負荷試験異常	0	1 (<0.1%)	1 (<0.1%)
Cardiovascular function test abnormal	心血管機能検査異常	0	1 (<0.1%)	1 (<0.1%)
Cystoscopy	膀胱鏡検査	1 (<0.1%)	0	1 (<0.1%)
Hepatic enzyme increased	肝酵素上昇	1 (<0.1%)	0	1 (<0.1%)
Immunoglobulins decreased	免疫グロブリン減少	1 (<0.1%)	0	1 (<0.1%)
Vascular test	血管検査	1 (<0.1%)	0	1 (<0.1%)
Metabolism and nutrition disorders	代謝および栄養障害	29 (0.9%)	36 (1.1%)	65 (1.0%)
Decreased appetite	食欲減退	0	1 (<0.1%)	1 (<0.1%)
Dehydration	脱水	6 (0.2%)	1 (<0.1%)	7 (0.1%)
Diabetes mellitus	糖尿病	6 (0.2%)	8 (0.2%)	14 (0.2%)
Diabetes mellitus inadequate control	コントロール不良の糖尿病	2 (<0.1%)	0	2 (<0.1%)
Diabetic ketoacidosis	糖尿病性ケトアシドーシス	2 (<0.1%)	0	2 (<0.1%)
Diabetic metabolic decompensation	糖尿病性代謝代償不全	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hyperglycaemia	高血糖	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Hyperglycaemic hyperosmolar nonketotic syndrome	高血糖性高浸透圧性非ケトン性症候群	0	1 (<0.1%)	1 (<0.1%)
Hyperkalaemia	高カリウム血症	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hypoglycaemia	低血糖	3 (<0.1%)	6 (0.2%)	9 (0.1%)
Hypokalaemia	低カリウム血症	0	1 (<0.1%)	1 (<0.1%)
Hyponatraemia	低ナトリウム血症	3 (<0.1%)	5 (0.2%)	8 (0.1%)
Hypophagia	過小食	0	1 (<0.1%)	1 (<0.1%)
Ketoacidosis	ケトアシドーシス	1 (<0.1%)	0	1 (<0.1%)
Lactic acidosis	乳酸アシドーシス	1 (<0.1%)	0	1 (<0.1%)
Metabolic disorder	代謝障害	0	1 (<0.1%)	1 (<0.1%)
Type 1 diabetes mellitus	１型糖尿病	0	2 (<0.1%)	2 (<0.1%)
Type 2 diabetes mellitus	２型糖尿病	3 (<0.1%)	5 (0.2%)	8 (0.1%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	54 (1.7%)	66 (2.0%)	120 (1.8%)
Acquired claw toe	後天性鉤爪趾	0	1 (<0.1%)	1 (<0.1%)
Arthritis	関節炎	0	1 (<0.1%)	1 (<0.1%)
Back pain	背部痛	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Bone disorder	骨障害	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bone formation increased	骨形成亢進	0	1 (<0.1%)	1 (<0.1%)
Bone loss	骨喪失	1 (<0.1%)	0	1 (<0.1%)
Bursitis	滑液包炎	0	1 (<0.1%)	1 (<0.1%)
Cervical spinal stenosis	頚部脊柱管狭窄症	0	1 (<0.1%)	1 (<0.1%)
Compartment syndrome	コンパートメント症候群	0	1 (<0.1%)	1 (<0.1%)
Foot deformity	足変形	0	1 (<0.1%)	1 (<0.1%)
Fracture nonunion	骨折による偽関節	0	1 (<0.1%)	1 (<0.1%)
Gouty arthritis	痛風性関節炎	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Intervertebral disc disorder	椎間板障害	1 (<0.1%)	0	1 (<0.1%)
Intervertebral disc protrusion	椎間板突出	6 (0.2%)	6 (0.2%)	12 (0.2%)
Jaw cyst	顎骨嚢胞	1 (<0.1%)	0	1 (<0.1%)
Ligament disorder	靭帯障害	0	1 (<0.1%)	1 (<0.1%)
Lumbar spinal stenosis	腰部脊柱管狭窄症	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Metatarsalgia	中足骨痛	0	1 (<0.1%)	1 (<0.1%)

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Muscle disorder	筋障害	0	1 (<0.1%)	1 (<0.1%)
Muscle spasms	筋痙縮	1 (<0.1%)	0	1 (<0.1%)
Muscular weakness	筋力低下	1 (<0.1%)	0	1 (<0.1%)
Musculoskeletal chest pain	筋骨格系胸痛	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Musculoskeletal pain	筋骨格痛	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Osteitis	骨炎	0	1 (<0.1%)	1 (<0.1%)
Osteoarthritis	変形性関節症	14 (0.4%)	13 (0.4%)	27 (0.4%)
Osteonecrosis	骨壊死	1 (<0.1%)	0	1 (<0.1%)
Osteoporotic fracture	骨粗鬆症性骨折	0	1 (<0.1%)	1 (<0.1%)
Pain in extremity	四肢痛	6 (0.2%)	14 (0.4%)	20 (0.3%)
Pathological fracture	病的骨折	1 (<0.1%)	0	1 (<0.1%)
Polymyalgia rheumatica	リウマチ性多発筋痛	1 (<0.1%)	0	1 (<0.1%)
Pseudarthrosis	偽関節	0	1 (<0.1%)	1 (<0.1%)
Rhabdomyolysis	横紋筋融解症	0	1 (<0.1%)	1 (<0.1%)
Rotator cuff syndrome	肩回旋筋腱板症候群	0	4 (0.1%)	4 (<0.1%)
Soft tissue disorder	軟部組織障害	1 (<0.1%)	0	1 (<0.1%)
Soft tissue necrosis	軟部組織壊死	0	1 (<0.1%)	1 (<0.1%)
Spinal osteoarthritis	変形性脊椎症	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Spinal pain	脊椎痛	0	1 (<0.1%)	1 (<0.1%)
Spinal stenosis	脊柱管狭窄症	6 (0.2%)	2 (<0.1%)	8 (0.1%)
Spondyloarthropathy	脊椎関節障害	1 (<0.1%)	0	1 (<0.1%)
Spondylolisthesis	脊椎すべり症	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Synovial cyst	滑液嚢腫	0	1 (<0.1%)	1 (<0.1%)
Systemic scleroderma	全身性強皮症	0	1 (<0.1%)	1 (<0.1%)
Tendon disorder	腱障害	0	1 (<0.1%)	1 (<0.1%)
Vertebral column mass	脊柱腫瘤	1 (<0.1%)	0	1 (<0.1%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	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）	119 (3.7%)	119 (3.7%)	238 (3.7%)
Acute myeloid leukaemia	急性骨髄性白血病	1 (<0.1%)	0	1 (<0.1%)
Adenocarcinoma	腺癌	0	1 (<0.1%)	1 (<0.1%)
Adenocarcinoma gastric	胃腺癌	0	1 (<0.1%)	1 (<0.1%)
Adenocarcinoma of colon	結腸腺癌	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Adenocarcinoma pancreas	膵腺癌	0	1 (<0.1%)	1 (<0.1%)
Adenolymphoma	腺リンパ腫	0	1 (<0.1%)	1 (<0.1%)
Adrenal neoplasm	副腎新生物	1 (<0.1%)	0	1 (<0.1%)
B-cell lymphoma	Ｂ細胞性リンパ腫	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Basal cell carcinoma	基底細胞癌	3 (<0.1%)	7 (0.2%)	10 (0.2%)
Benign laryngeal neoplasm	喉頭の良性新生物	1 (<0.1%)	0	1 (<0.1%)
Benign neoplasm of skin	皮膚良性新生物	1 (<0.1%)	0	1 (<0.1%)
Benign ovarian tumour	卵巣良性腫瘍	1 (<0.1%)	0	1 (<0.1%)
Bile duct cancer	胆管癌	0	2 (<0.1%)	2 (<0.1%)
Bladder cancer	膀胱癌	4 (0.1%)	4 (0.1%)	8 (0.1%)
Bladder cancer stage IV	膀胱癌第４期	0	1 (<0.1%)	1 (<0.1%)
Bladder neoplasm	膀胱新生物	0	1 (<0.1%)	1 (<0.1%)
Bladder transitional cell carcinoma	膀胱移行上皮癌	2 (<0.1%)	0	2 (<0.1%)
Bone cancer	骨癌	0	1 (<0.1%)	1 (<0.1%)
Brain neoplasm	脳新生物	0	1 (<0.1%)	1 (<0.1%)
Breast cancer	乳癌	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Bronchial carcinoma	気管支癌	1 (<0.1%)	0	1 (<0.1%)
Central nervous system lymphoma	中枢神経系リンパ腫	1 (<0.1%)	0	1 (<0.1%)
Cervix carcinoma	子宮頚部癌	0	1 (<0.1%)	1 (<0.1%)
Cholangiocarcinoma	胆管細胞癌	2 (<0.1%)	0	2 (<0.1%)
Cholesteatoma	真珠腫	0	1 (<0.1%)	1 (<0.1%)
Chronic myeloid leukaemia	慢性骨髄性白血病	0	1 (<0.1%)	1 (<0.1%)
Chronic myelomonocytic leukaemia	慢性骨髄単球性白血病	0	1 (<0.1%)	1 (<0.1%)
Colon adenoma	大腸腺腫	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Colon cancer	結腸癌	5 (0.2%)	4 (0.1%)	9 (0.1%)
Colorectal adenocarcinoma	結腸直腸腺癌	0	1 (<0.1%)	1 (<0.1%)
Colorectal cancer	結腸直腸癌	0	1 (<0.1%)	1 (<0.1%)

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Ductal adenocarcinoma of pancreas	膵腺管癌	0	1 (<0.1%)	1 (<0.1%)
Endometrial cancer	子宮内膜癌	1 (<0.1%)	0	1 (<0.1%)
Follicular thyroid cancer	濾胞性甲状腺癌	1 (<0.1%)	0	1 (<0.1%)
Gallbladder cancer	胆嚢癌	1 (<0.1%)	0	1 (<0.1%)
Gastric cancer	胃癌	5 (0.2%)	4 (0.1%)	9 (0.1%)
Gastric cancer stage I	胃癌第１期	1 (<0.1%)	0	1 (<0.1%)
Gastric cancer stage II	胃癌第２期	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal adenocarcinoma	消化器腺癌	1 (<0.1%)	0	1 (<0.1%)
Gingival cancer	歯肉癌	1 (<0.1%)	0	1 (<0.1%)
Head and neck cancer	頭頚部癌	1 (<0.1%)	0	1 (<0.1%)
Hepatic cancer	肝癌	0	1 (<0.1%)	1 (<0.1%)
Hepatocellular carcinoma	肝細胞癌	1 (<0.1%)	0	1 (<0.1%)
Hodgkin's disease	ホジキン病	1 (<0.1%)	0	1 (<0.1%)
Hodgkin's disease stage IV	ホジキン病第４期	1 (<0.1%)	0	1 (<0.1%)
Inflammatory pseudotumour	炎症性偽腫瘍	1 (<0.1%)	0	1 (<0.1%)
Laryngeal cancer	喉頭癌	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Laryngeal neoplasm	喉頭新生物	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Lip and/or oral cavity cancer	口唇および口腔内癌	0	1 (<0.1%)	1 (<0.1%)
Lung adenocarcinoma	肺腺癌	4 (0.1%)	3 (<0.1%)	7 (0.1%)
Lung adenocarcinoma recurrent	再発肺腺癌	1 (<0.1%)	0	1 (<0.1%)
Lung adenocarcinoma stage IV	肺腺癌第４期	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Lung cancer metastatic	遠隔転移を伴う肺癌	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Lung carcinoma cell type unspecified recurrent	再発肺癌、細胞タイプ不明	1 (<0.1%)	0	1 (<0.1%)
Lung carcinoma cell type unspecified stage IV	肺癌第４期、細胞タイプ不明	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Lung neoplasm	肺新生物	4 (0.1%)	4 (0.1%)	8 (0.1%)
Lung neoplasm malignant	肺の悪性新生物	8 (0.2%)	14 (0.4%)	22 (0.3%)
Lung squamous cell carcinoma metastatic	遠隔転移を伴う肺扁平上皮癌	0	1 (<0.1%)	1 (<0.1%)
Lung squamous cell carcinoma stage IV	肺扁平上皮癌第４期	1 (<0.1%)	0	1 (<0.1%)
Malignant genitourinary tract neoplasm	泌尿生殖器の悪性新生物	1 (<0.1%)	0	1 (<0.1%)
Malignant melanoma	悪性黒色腫	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Malignant neoplasm papilla of Vater	ファーター乳頭部の悪性新生物	0	1 (<0.1%)	1 (<0.1%)
Metastases to central nervous system	中枢神経系転移	0	1 (<0.1%)	1 (<0.1%)
Metastases to liver	肝転移	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Metastases to lung	肺転移	1 (<0.1%)	0	1 (<0.1%)
Metastases to lymph nodes	リンパ節転移	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Metastases to neck	頚部転移	0	1 (<0.1%)	1 (<0.1%)
Metastases to peritoneum	腹膜転移	0	1 (<0.1%)	1 (<0.1%)
Metastatic neoplasm	遠隔転移を伴う新生物	0	1 (<0.1%)	1 (<0.1%)
Metastatic squamous cell carcinoma	遠隔転移を伴う扁平上皮癌	0	1 (<0.1%)	1 (<0.1%)
Myelodysplastic syndrome	骨髄異形成症候群	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Neoplasm malignant	悪性新生物	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Neoplasm skin	皮膚の新生物	0	1 (<0.1%)	1 (<0.1%)
Neuroendocrine carcinoma	神経内分泌癌	1 (<0.1%)	0	1 (<0.1%)
Non-small cell lung cancer	非小細胞肺癌	1 (<0.1%)	0	1 (<0.1%)
Non-small cell lung cancer metastatic	遠隔転移を伴う非小細胞肺癌	0	1 (<0.1%)	1 (<0.1%)
Oesophageal adenocarcinoma	食道腺癌	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Oesophageal cancer metastatic	遠隔転移を伴う食道癌	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Oesophageal carcinoma	食道癌	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Oesophageal carcinoma recurrent	再発食道癌	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Oesophageal neoplasm	食道新生物	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Oropharyngeal cancer	中咽頭癌	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pancreatic carcinoma	膵癌	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Pancreatic carcinoma stage IV	膵癌第４期	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pancreatic neoplasm	膵新生物	0	1 (<0.1%)	1 (<0.1%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
Papillary serous endometrial carcinoma	乳頭状漿液性子宮内膜癌	0	1 (<0.1%)	1 (<0.1%)
Plasma cell myeloma	形質細胞性骨髄腫	1 (<0.1%)	0	1 (<0.1%)
Pleural mesothelioma	胸膜中皮腫	1 (<0.1%)	0	1 (<0.1%)
Prostate cancer	前立腺癌	9 (0.3%)	2 (<0.1%)	11 (0.2%)
Prostate cancer stage III	前立腺癌第３期	0	1 (<0.1%)	1 (<0.1%)
Rectal adenocarcinoma	直腸腺癌	2 (<0.1%)	0	2 (<0.1%)
Rectal adenoma	直腸腺腫	1 (<0.1%)	0	1 (<0.1%)
Rectal cancer	直腸癌	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Rectal cancer stage I	直腸癌第１期	0	1 (<0.1%)	1 (<0.1%)
Rectal cancer stage IV	直腸癌第４期	1 (<0.1%)	0	1 (<0.1%)
Rectal neoplasm	直腸新生物	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Rectosigmoid cancer	直腸Ｓ状結腸癌	0	1 (<0.1%)	1 (<0.1%)
Renal cancer	腎癌	3 (<0.1%)	0	3 (<0.1%)
Renal cell carcinoma	腎細胞癌	0	1 (<0.1%)	1 (<0.1%)
Renal neoplasm	腎新生物	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Respiratory tract neoplasm	気道新生物	0	1 (<0.1%)	1 (<0.1%)
Salivary gland adenoma	唾液腺腫	1 (<0.1%)	0	1 (<0.1%)
Skin squamous cell carcinoma recurrent	再発皮膚有棘細胞癌	1 (<0.1%)	0	1 (<0.1%)
Small cell carcinoma	小細胞癌	0	1 (<0.1%)	1 (<0.1%)
Small cell lung cancer	小細胞肺癌	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Squamous cell carcinoma	扁平上皮癌	0	1 (<0.1%)	1 (<0.1%)
Squamous cell carcinoma of lung	肺扁平上皮癌	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Squamous cell carcinoma of skin	皮膚有棘細胞癌	0	1 (<0.1%)	1 (<0.1%)
Squamous cell carcinoma of the oral cavity	口腔内扁平上皮癌	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Squamous cell carcinoma of the tongue	舌扁平上皮癌	0	2 (<0.1%)	2 (<0.1%)
T-cell lymphoma	Ｔ細胞性リンパ腫	1 (<0.1%)	0	1 (<0.1%)
Thymoma malignant	悪性胸腺腫	1 (<0.1%)	0	1 (<0.1%)
Transitional cell carcinoma	移行上皮癌	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Nervous system disorders	神経系障害	62 (1.9%)	74 (2.3%)	136 (2.1%)
Brain injury	脳損傷	1 (<0.1%)	0	1 (<0.1%)
Carotid artery disease	頚動脈疾患	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Carotid artery occlusion	頚動脈閉塞	0	1 (<0.1%)	1 (<0.1%)
Carotid artery stenosis	頚動脈狭窄	22 (0.7%)	24 (0.7%)	46 (0.7%)
Carpal tunnel syndrome	手根管症候群	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Cerebral atrophy	大脳萎縮	0	1 (<0.1%)	1 (<0.1%)
Cerebral haemorrhage	脳出血	0	1 (<0.1%)	1 (<0.1%)
Cerebral infarction	脳梗塞	0	1 (<0.1%)	1 (<0.1%)
Cervical radiculopathy	頚髄神経根障害	0	1 (<0.1%)	1 (<0.1%)
Colloid brain cyst	脳コロイド嚢胞	0	1 (<0.1%)	1 (<0.1%)
Cranial nerve disorder	脳神経障害	0	1 (<0.1%)	1 (<0.1%)
Dementia	認知症	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Diabetic neuropathy	糖尿病性ニューロパチー	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Dizziness	浮動性めまい	5 (0.2%)	3 (<0.1%)	8 (0.1%)
Dizziness postural	体位性めまい	1 (<0.1%)	0	1 (<0.1%)
Drop attacks	転倒発作	0	1 (<0.1%)	1 (<0.1%)
Epilepsy	てんかん	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Facial paresis	顔面不全麻痺	1 (<0.1%)	0	1 (<0.1%)
Guillain-Barre syndrome	ギラン・バレー症候群	0	1 (<0.1%)	1 (<0.1%)
Hemiparesis	不全片麻痺	0	1 (<0.1%)	1 (<0.1%)
Hydrocephalus	水頭症	0	1 (<0.1%)	1 (<0.1%)
Intracranial aneurysm	頭蓋内動脈瘤	0	1 (<0.1%)	1 (<0.1%)
Ischaemic neuropathy	虚血性ニューロパチー	0	1 (<0.1%)	1 (<0.1%)
Ischaemic stroke	虚血性脳卒中	0	1 (<0.1%)	1 (<0.1%)
Lumbar radiculopathy	腰髄神経根障害	1 (<0.1%)	0	1 (<0.1%)
Mental impairment	精神的機能障害	1 (<0.1%)	0	1 (<0.1%)
Myelopathy	脊髄症	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
Nerve compression	神経圧迫	1 (<0.1%)	0	1 (<0.1%)
Neuralgia	神経痛	0	2 (<0.1%)	2 (<0.1%)
Parkinson's disease	パーキンソン病	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Parkinsonism	パーキンソニズム	0	1 (<0.1%)	1 (<0.1%)
Polyneuropathy	多発ニューロパチー	0	1 (<0.1%)	1 (<0.1%)
Presyncope	失神寸前の状態	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Pseudoradicular syndrome	偽性根症候群	1 (<0.1%)	0	1 (<0.1%)
Putamen haemorrhage	被殻出血	0	1 (<0.1%)	1 (<0.1%)
Restless legs syndrome	下肢静止不能症候群	1 (<0.1%)	0	1 (<0.1%)
Sacral radiculopathy	仙部神経根症	1 (<0.1%)	0	1 (<0.1%)
Sciatica	坐骨神経痛	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Somnolence	傾眠	0	1 (<0.1%)	1 (<0.1%)
Spinal claudication	脊髄性跛行症	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Status epilepticus	てんかん重積状態	1 (<0.1%)	0	1 (<0.1%)
Subarachnoid haemorrhage	くも膜下出血	0	1 (<0.1%)	1 (<0.1%)
Syncope	失神	9 (0.3%)	11 (0.3%)	20 (0.3%)
Tension headache	緊張性頭痛	1 (<0.1%)	0	1 (<0.1%)
Tonic convulsion	強直性痙攣	1 (<0.1%)	0	1 (<0.1%)
Vascular encephalopathy	血管性脳症	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vertebral artery stenosis	椎骨動脈狭窄	0	1 (<0.1%)	1 (<0.1%)
Product issues	製品の問題	5 (0.2%)	1 (<0.1%)	6 (<0.1%)
Device battery issue	医療機器バッテリー問題	1 (<0.1%)	0	1 (<0.1%)
Device breakage	医療機器破損	2 (<0.1%)	0	2 (<0.1%)
Device dislocation	医療機器位置異常	1 (<0.1%)	0	1 (<0.1%)
Device occlusion	医療機器閉塞	0	1 (<0.1%)	1 (<0.1%)
Patient-device incompatibility	患者と医療機器間の不適合	1 (<0.1%)	0	1 (<0.1%)
Psychiatric disorders	精神障害	12 (0.4%)	13 (0.4%)	25 (0.4%)
Acute psychosis	急性精神病	0	1 (<0.1%)	1 (<0.1%)
Alcohol abuse	アルコール乱用	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Alcohol withdrawal syndrome	アルコール離脱症候群	0	1 (<0.1%)	1 (<0.1%)
Alcoholism	アルコール症	1 (<0.1%)	0	1 (<0.1%)
Completed suicide	自殺既遂	4 (0.1%)	0	4 (<0.1%)
Depression	うつ病	3 (<0.1%)	5 (0.2%)	8 (0.1%)
Drug abuse	薬物乱用	0	1 (<0.1%)	1 (<0.1%)
Intentional self-injury	故意の自傷行為	1 (<0.1%)	0	1 (<0.1%)
Mental status changes	精神状態変化	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Organic brain syndrome	器質性脳症候群	0	1 (<0.1%)	1 (<0.1%)
Transient psychosis	一過性精神病	1 (<0.1%)	0	1 (<0.1%)
Renal and urinary disorders	腎および尿路障害	38 (1.2%)	33 (1.0%)	71 (1.1%)
Acute kidney injury	急性腎障害	9 (0.3%)	17 (0.5%)	26 (0.4%)
Calculus bladder	膀胱結石	3 (<0.1%)	0	3 (<0.1%)
Calculus urinary	尿路結石	0	1 (<0.1%)	1 (<0.1%)
Chronic kidney disease	慢性腎臓病	5 (0.2%)	2 (<0.1%)	7 (0.1%)
End stage renal disease	末期腎疾患	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Nephrolithiasis	腎結石症	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Pelvi-ureteric obstruction	骨盤部尿管閉塞	1 (<0.1%)	0	1 (<0.1%)
Renal artery stenosis	腎動脈狭窄症	0	1 (<0.1%)	1 (<0.1%)
Renal colic	腎仙痛	4 (0.1%)	0	4 (<0.1%)
Renal failure	腎不全	6 (0.2%)	3 (<0.1%)	9 (0.1%)
Renal impairment	腎機能障害	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Ureteric fistula	尿管瘻	1 (<0.1%)	0	1 (<0.1%)
Ureterolithiasis	尿管結石症	0	1 (<0.1%)	1 (<0.1%)
Urethral stenosis	尿道狭窄	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Urinary incontinence	尿失禁	1 (<0.1%)	0	1 (<0.1%)
Urinary retention	尿閉	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Urinary tract obstruction	尿路閉塞	1 (<0.1%)	0	1 (<0.1%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
Reproductive system and breast disorders	生殖系および乳房障害	9 (0.3%)	4 (0.1%)	13 (0.2%)
Benign prostatic hyperplasia	良性前立腺肥大症	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Cervical polyp	子宮頚管ポリープ	1 (<0.1%)	0	1 (<0.1%)
Pelvic prolapse	骨盤脱	0	1 (<0.1%)	1 (<0.1%)
Prostatic obstruction	前立腺閉塞	1 (<0.1%)	0	1 (<0.1%)
Spermatocele	精液瘤	1 (<0.1%)	0	1 (<0.1%)
Uterine prolapse	子宮脱	2 (<0.1%)	0	2 (<0.1%)
Vulval eczema	外陰部湿疹	0	1 (<0.1%)	1 (<0.1%)
Vulvar dysplasia	外陰異形成	1 (<0.1%)	0	1 (<0.1%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	53 (1.6%)	46 (1.4%)	99 (1.5%)
Acute interstitial pneumonitis	急性間質性肺臓炎	0	1 (<0.1%)	1 (<0.1%)
Acute pulmonary oedema	急性肺水腫	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Acute respiratory distress syndrome	急性呼吸窮迫症候群	1 (<0.1%)	0	1 (<0.1%)
Acute respiratory failure	急性呼吸不全	2 (<0.1%)	5 (0.2%)	7 (0.1%)
Aspiration	誤嚥	1 (<0.1%)	0	1 (<0.1%)
Asthma	喘息	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	16 (0.5%)	9 (0.3%)	25 (0.4%)
Chronic respiratory disease	慢性呼吸疾患	1 (<0.1%)	0	1 (<0.1%)
Cough	咳嗽	1 (<0.1%)	0	1 (<0.1%)
Dyspnoea	呼吸困難	4 (0.1%)	6 (0.2%)	10 (0.2%)
Emphysema	肺気腫	0	1 (<0.1%)	1 (<0.1%)
Hypoxia	低酸素症	1 (<0.1%)	0	1 (<0.1%)
Interstitial lung disease	間質性肺疾患	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Nasal polyps	鼻茸	1 (<0.1%)	0	1 (<0.1%)
Nasal septum deviation	鼻中隔弯曲	1 (<0.1%)	0	1 (<0.1%)
Pharyngeal lesion	咽頭病変	0	1 (<0.1%)	1 (<0.1%)
Pleural effusion	胸水	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Pneumonia aspiration	誤嚥性肺炎	5 (0.2%)	6 (0.2%)	11 (0.2%)
Pneumothorax	気胸	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Pneumothorax spontaneous	自然気胸	1 (<0.1%)	0	1 (<0.1%)
Pulmonary congestion	肺うっ血	1 (<0.1%)	0	1 (<0.1%)
Pulmonary embolism	肺塞栓症	0	1 (<0.1%)	1 (<0.1%)
Pulmonary fibrosis	肺線維症	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pulmonary hypertension	肺高血圧症	0	1 (<0.1%)	1 (<0.1%)
Pulmonary mass	肺腫瘤	1 (<0.1%)	0	1 (<0.1%)
Pulmonary oedema	肺水腫	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Respiratory distress	呼吸窮迫	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Respiratory failure	呼吸不全	5 (0.2%)	4 (0.1%)	9 (0.1%)
Sinus polyp	副鼻腔ポリープ	1 (<0.1%)	0	1 (<0.1%)
Tonsillar cyst	扁桃嚢胞	0	1 (<0.1%)	1 (<0.1%)
Vocal cord polyp	声帯ポリープ	0	1 (<0.1%)	1 (<0.1%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	32 (1.0%)	36 (1.1%)	68 (1.0%)
Angioedema	血管浮腫	0	2 (<0.1%)	2 (<0.1%)
Decubitus ulcer	褥瘡性潰瘍	0	2 (<0.1%)	2 (<0.1%)
Dermal cyst	皮膚嚢腫	1 (<0.1%)	0	1 (<0.1%)
Dermatitis	皮膚炎	2 (<0.1%)	0	2 (<0.1%)
Dermatitis allergic	アレルギー性皮膚炎	1 (<0.1%)	0	1 (<0.1%)
Dermatitis contact	接触皮膚炎	0	1 (<0.1%)	1 (<0.1%)
Diabetic foot	糖尿病性足病変	9 (0.3%)	9 (0.3%)	18 (0.3%)
Diabetic ulcer	糖尿病性潰瘍	1 (<0.1%)	0	1 (<0.1%)
Drug reaction with eosinophilia and systemic symptoms	好酸球増加と全身症状を伴う薬物反応	0	1 (<0.1%)	1 (<0.1%)
Haemorrhage subcutaneous	皮下出血	0	1 (<0.1%)	1 (<0.1%)
Hidradenitis	汗腺炎	0	1 (<0.1%)	1 (<0.1%)
Ischaemic skin ulcer	虚血性皮膚潰瘍	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Myxoid cyst	粘液様嚢胞	1 (<0.1%)	0	1 (<0.1%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
Pemphigoid	類天疱瘡	2 (<0.1%)	0	2 (<0.1%)
Pemphigus	天疱瘡	0	1 (<0.1%)	1 (<0.1%)
Skin exfoliation	皮膚剥脱	1 (<0.1%)	0	1 (<0.1%)
Skin lesion	皮膚病変	0	1 (<0.1%)	1 (<0.1%)
Skin necrosis	皮膚壊死	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Skin ulcer	皮膚潰瘍	10 (0.3%)	12 (0.4%)	22 (0.3%)
Toxic skin eruption	中毒性皮疹	0	1 (<0.1%)	1 (<0.1%)
Urticaria	蕁麻疹	2 (<0.1%)	0	2 (<0.1%)
Social circumstances	社会環境	0	1 (<0.1%)	1 (<0.1%)
Disease risk factor	疾患の危険因子	0	1 (<0.1%)	1 (<0.1%)
Surgical and medical procedures	外科および内科処置	9 (0.3%)	14 (0.4%)	23 (0.4%)
Amputation	切断	1 (<0.1%)	0	1 (<0.1%)
Bladder calculus removal	膀胱結石除去	0	1 (<0.1%)	1 (<0.1%)
Bladder neoplasm surgery	膀胱新生物手術	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bladder polypectomy	膀胱ポリープ切除	0	1 (<0.1%)	1 (<0.1%)
Blepharoplasty	眼瞼形成	1 (<0.1%)	0	1 (<0.1%)
Brain tumour operation	脳腫瘍手術	1 (<0.1%)	0	1 (<0.1%)
Carotid endarterectomy	頚動脈内膜剥離術	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cystoprostatectomy	膀胱前立腺摘除	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Diabetes mellitus management	糖尿病管理	0	1 (<0.1%)	1 (<0.1%)
Eventration repair	脱出臓器還納	0	1 (<0.1%)	1 (<0.1%)
Foot amputation	足切断	1 (<0.1%)	0	1 (<0.1%)
Knee arthroplasty	膝関節形成	0	2 (<0.1%)	2 (<0.1%)
Limb reconstructive surgery	四肢再建手術	0	1 (<0.1%)	1 (<0.1%)
Peripheral artery angioplasty	末梢動脈形成	1 (<0.1%)	0	1 (<0.1%)
Peripheral artery bypass	末梢動脈バイパス	0	1 (<0.1%)	1 (<0.1%)
Peripheral artery stent insertion	末梢動脈ステント挿入	1 (<0.1%)	0	1 (<0.1%)
Peripheral revascularisation	末梢血行再建	0	1 (<0.1%)	1 (<0.1%)
Radical prostatectomy	根治的前立腺摘除	0	1 (<0.1%)	1 (<0.1%)
Transurethral bladder resection	経尿道的膀胱切除	0	1 (<0.1%)	1 (<0.1%)
Umbilical hernia repair	臍ヘルニア修復	1 (<0.1%)	0	1 (<0.1%)
Vitrectomy	硝子体切除	0	1 (<0.1%)	1 (<0.1%)
Vascular disorders	血管障害	270 (8.3%)	272 (8.4%)	542 (8.3%)
Angiopathy	血管障害	1 (<0.1%)	0	1 (<0.1%)
Aortic aneurysm	大動脈瘤	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Aortic dissection	大動脈解離	1 (<0.1%)	0	1 (<0.1%)
Aortic stenosis	大動脈狭窄	6 (0.2%)	3 (<0.1%)	9 (0.1%)
Arterial occlusive disease	動脈閉塞性疾患	0	1 (<0.1%)	1 (<0.1%)
Arteriovenous fistula	動静脈瘻	0	1 (<0.1%)	1 (<0.1%)
Circulatory collapse	循環虚脱	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Dry gangrene	乾性壊疽	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Extremity necrosis	四肢壊死	12 (0.4%)	8 (0.2%)	20 (0.3%)
Haematoma	血腫	1 (<0.1%)	0	1 (<0.1%)
Hypertension	高血圧	1 (<0.1%)	5 (0.2%)	6 (<0.1%)
Hypertensive crisis	高血圧クリーゼ	5 (0.2%)	6 (0.2%)	11 (0.2%)
Hypertensive emergency	高血圧緊急症	1 (<0.1%)	0	1 (<0.1%)
Hypertensive urgency	高血圧切迫症	0	1 (<0.1%)	1 (<0.1%)
Hypotension	低血圧	4 (0.1%)	0	4 (<0.1%)
Hypovolaemic shock	血液量減少性ショック	1 (<0.1%)	0	1 (<0.1%)
Iliac artery stenosis	腸骨動脈狭窄	4 (0.1%)	3 (<0.1%)	7 (0.1%)
Intermittent claudication	間欠性跛行	43 (1.3%)	52 (1.6%)	95 (1.5%)
Ischaemic limb pain	虚血性四肢痛	0	1 (<0.1%)	1 (<0.1%)
Lymphatic fistula	リンパ瘻	0	3 (<0.1%)	3 (<0.1%)
Lymphocele	リンパ嚢腫	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Lymphoedema	リンパ浮腫	0	1 (<0.1%)	1 (<0.1%)
Lymphorrhoea	リンパ漏	2 (<0.1%)	0	2 (<0.1%)
Orthostatic hypotension	起立性低血圧	0	1 (<0.1%)	1 (<0.1%)

2.7.6.1.a 付録 1

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
Peripheral arterial occlusive disease	末梢動脈閉塞性疾患	125 (3.8%)	130 (4.0%)	255 (3.9%)
Peripheral artery aneurysm	末梢動脈瘤	0	1 (<0.1%)	1 (<0.1%)
Peripheral artery occlusion	末梢動脈閉塞	7 (0.2%)	9 (0.3%)	16 (0.2%)
Peripheral artery stenosis	末梢動脈狭窄	25 (0.8%)	14 (0.4%)	39 (0.6%)
Peripheral artery thrombosis	末梢動脈血栓症	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Peripheral coldness	末梢冷感	0	1 (<0.1%)	1 (<0.1%)
Peripheral embolism	末梢血管塞栓症	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Peripheral ischaemia	末梢性虚血	34 (1.0%)	29 (0.9%)	63 (1.0%)
Peripheral vascular disorder	末梢血管障害	3 (<0.1%)	5 (0.2%)	8 (0.1%)
Peripheral venous disease	末梢静脈疾患	1 (<0.1%)	0	1 (<0.1%)
Poor peripheral circulation	末梢循環不良	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Renovascular hypertension	腎血管性高血圧	1 (<0.1%)	0	1 (<0.1%)
Subclavian artery stenosis	鎖骨下動脈狭窄	0	1 (<0.1%)	1 (<0.1%)
Temporal arteritis	側頭動脈炎	1 (<0.1%)	0	1 (<0.1%)
Thrombophlebitis superficial	表在性血栓性静脈炎	0	1 (<0.1%)	1 (<0.1%)
Varicose vein	静脈瘤	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Vascular stenosis	血管狭窄	0	1 (<0.1%)	1 (<0.1%)
Venous occlusion	静脈閉塞	1 (<0.1%)	0	1 (<0.1%)

The safety analysis set includes all randomized subjects who received at least one dose of study drug (rivaroxaban or rivaroxaban placebo).
Adverse events are sorted in alphabetical order by primary SOC and preferred term.
A subject is counted only once within each preferred term or any primary SOC.
bid = twice daily, od = once daily, ASA = acetylsalicylic acid
Treatment emergent events are defined as all events with an onset date on or after the date of randomization until 2 days following permanent discontinuation of the study drug (rivaroxaban or rivaroxaban placebo).
Source: 5.3.5.1.1 PH-40164/Table 14.3.1.1/4

付表 2.7.6.1.a.1-5 治験薬の投与中止に至った TEAE（全体集団、SAF）

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
Number (%) of subjects with at least one adverse event		20 (0.6%)	18 (0.6%)	38 (0.6%)
Blood and lymphatic system disorders	血液およびリンパ系障害	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Anaemia	貧血	1 (<0.1%)	0	1 (<0.1%)
Antiphospholipid syndrome	抗リン脂質抗体症候群	0	1 (<0.1%)	1 (<0.1%)
Cardiac disorders	心臓障害	4 (0.1%)	4 (0.1%)	8 (0.1%)
Atrial fibrillation	心房細動	3 (<0.1%)	4 (0.1%)	7 (0.1%)
Atrial thrombosis	心房血栓症	1 (<0.1%)	0	1 (<0.1%)
Gastrointestinal disorders	胃腸障害	4 (0.1%)	0	4 (<0.1%)
Abdominal discomfort	腹部不快感	1 (<0.1%)	0	1 (<0.1%)
Flatulence	鼓腸	2 (<0.1%)	0	2 (<0.1%)
Upper gastrointestinal haemorrhage	上部消化管出血	1 (<0.1%)	0	1 (<0.1%)
Vomiting	嘔吐	1 (<0.1%)	0	1 (<0.1%)
Infections and infestations	感染症および寄生虫症	0	2 (<0.1%)	2 (<0.1%)
Medical device site joint infection	医療機器使用部位関節感染	0	1 (<0.1%)	1 (<0.1%)
Streptococcal sepsis	レンサ球菌性敗血症	0	1 (<0.1%)	1 (<0.1%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	1 (<0.1%)	0	1 (<0.1%)
Multiple injuries	多発性外傷	1 (<0.1%)	0	1 (<0.1%)
Metabolism and nutrition disorders	代謝および栄養障害	1 (<0.1%)	0	1 (<0.1%)
Decreased appetite	食欲減退	1 (<0.1%)	0	1 (<0.1%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	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）	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Cholangiocarcinoma	胆管細胞癌	1 (<0.1%)	0	1 (<0.1%)
Lung adenocarcinoma stage IV	肺腺癌第４期	0	1 (<0.1%)	1 (<0.1%)
Lung neoplasm malignant	肺の悪性新生物	2 (<0.1%)	0	2 (<0.1%)
Lung squamous cell carcinoma stage IV	肺扁平上皮癌第４期	1 (<0.1%)	0	1 (<0.1%)
Metastatic neoplasm	遠隔転移を伴う新生物	0	1 (<0.1%)	1 (<0.1%)
Nervous system disorders	神経系障害	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Carotid artery stenosis	頚動脈狭窄	0	1 (<0.1%)	1 (<0.1%)
Dementia	認知症	1 (<0.1%)	0	1 (<0.1%)
Dementia Alzheimer's type	アルツハイマー型認知症	0	1 (<0.1%)	1 (<0.1%)
Dizziness	浮動性めまい	1 (<0.1%)	0	1 (<0.1%)
Subarachnoid haemorrhage	くも膜下出血	0	1 (<0.1%)	1 (<0.1%)
Vascular dementia	血管性認知症	0	1 (<0.1%)	1 (<0.1%)
Psychiatric disorders	精神障害	1 (<0.1%)	0	1 (<0.1%)
Sleep disorder	睡眠障害	1 (<0.1%)	0	1 (<0.1%)
Renal and urinary disorders	腎および尿路障害	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Chronic kidney disease	慢性腎臓病	1 (<0.1%)	0	1 (<0.1%)
Renal failure	腎不全	0	1 (<0.1%)	1 (<0.1%)
Renal impairment	腎機能障害	0	1 (<0.1%)	1 (<0.1%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	0	1 (<0.1%)	1 (<0.1%)
Aspirin-exacerbated respiratory disease	アスピリン増悪呼吸器疾患	0	1 (<0.1%)	1 (<0.1%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3256 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3248 (100%)	Total N=6504 (100%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Drug eruption	薬疹	1 (<0.1%)	0	1 (<0.1%)
Drug reaction with eosinophilia and systemic symptoms	好酸球増加と全身症状を伴う薬物反応	0	1 (<0.1%)	1 (<0.1%)
Vascular disorders	血管障害	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Haematoma	血腫	1 (<0.1%)	0	1 (<0.1%)
Peripheral ischaemia	末梢性虚血	0	1 (<0.1%)	1 (<0.1%)

The safety analysis set includes all randomized subjects who received at least one dose of study drug (rivaroxaban or rivaroxaban placebo).
Adverse events are sorted in alphabetical order by primary SOC and preferred term.
A subject is counted only once within each preferred term or any primary SOC.
bid = twice daily, od = once daily, ASA = acetylsalicylic acid
Treatment emergent events are defined as all events with an onset date on or after the date of randomization until 2 days following permanent discontinuation of the study drug (rivaroxaban or rivaroxaban placebo). Adverse events with action taken drug withdrawn were considered.
Source: 5.3.5.1.1 PH-40164/Table 14.3.1.1/8

付表 2.7.6.1.a.1-6 すべての TEAE 及び治験薬と関連のある TEAE（外国人集団、SAF）

Primary system organ class Preferred term MedDRA version 22.1	Primary system organ class Preferred term MedDRA version 22.1	Treatment-emergent Rivaroxaban 2.5 mg bid, Aspirin 100mg od N=3027 (100%)	Treatment-emergent Rivaroxaban Placebo, Aspirin 100 mg od N=3019 (100%)	Study drug-related Rivaroxaban 2.5 mg bid, Aspirin 100mg od N=3027 (100%)	Study drug-related Rivaroxaban Placebo, Aspirin 100 mg od N=3019 (100%)
Number of subjects (%) with at least one adverse event	Number of subjects (%) with at least one adverse event	1331 (44.0%)	1352 (44.8%)	109 (3.6%)	93 (3.1%)
Blood and lymphatic system disorders	血液およびリンパ系障害	55 (1.8%)	46 (1.5%)	15 (0.5%)	9 (0.3%)
Anaemia	貧血	37 (1.2%)	29 (1.0%)	13 (0.4%)	6 (0.2%)
Antiphospholipid syndrome	抗リン脂質抗体症候群	0	1 (<0.1%)	0	0
Blood loss anaemia	失血性貧血	1 (<0.1%)	0	1 (<0.1%)	0
Eosinophilia	好酸球増加症	0	1 (<0.1%)	0	0
Febrile neutropenia	発熱性好中球減少症	1 (<0.1%)	0	0	0
Hypercoagulation	凝固亢進	0	1 (<0.1%)	0	0
Increased tendency to bruise	内出血発生の増加傾向	0	3 (<0.1%)	0	2 (<0.1%)
Iron deficiency anaemia	鉄欠乏性貧血	6 (0.2%)	4 (0.1%)	1 (<0.1%)	0
Leukocytosis	白血球増加症	2 (<0.1%)	3 (<0.1%)	0	0
Leukopenia	白血球減少症	1 (<0.1%)	0	0	0
Lymphadenopathy	リンパ節症	0	1 (<0.1%)	0	0
Lymphocytosis	リンパ球増加症	1 (<0.1%)	1 (<0.1%)	0	0
Microcytic anaemia	小球性貧血	0	1 (<0.1%)	0	0
Nephrogenic anaemia	腎性貧血	0	1 (<0.1%)	0	1 (<0.1%)
Neutropenia	好中球減少症	1 (<0.1%)	0	0	0
Normochromic normocytic anaemia	正色素性正球性貧血	2 (<0.1%)	0	0	0
Normocytic anaemia	正球性貧血	1 (<0.1%)	0	0	0
Pancytopenia	汎血球減少症	1 (<0.1%)	0	0	0
Polycythaemia	赤血球増加症	2 (<0.1%)	0	0	0
Splenomegaly	脾腫	1 (<0.1%)	0	0	0
Thrombocytopenia	血小板減少症	2 (<0.1%)	1 (<0.1%)	0	0
Thrombocytosis	血小板増加症	1 (<0.1%)	0	0	0
Thrombotic thrombocytopenic purpura	血栓性血小板減少性紫斑病	1 (<0.1%)	0	0	0
Cardiac disorders	心臓障害	154 (5.1%)	176 (5.8%)	3 (<0.1%)	2 (<0.1%)
Acute left ventricular failure	急性左室不全	2 (<0.1%)	1 (<0.1%)	0	0
Acute myocardial infarction	急性心筋梗塞	0	1 (<0.1%)	0	0
Angina pectoris	狭心症	16 (0.5%)	12 (0.4%)	0	0
Angina unstable	不安定狭心症	1 (<0.1%)	1 (<0.1%)	0	0
Aortic valve incompetence	大動脈弁閉鎖不全症	1 (<0.1%)	0	0	0
Aortic valve stenosis	大動脈弁狭窄	1 (<0.1%)	2 (<0.1%)	0	0
Arrhythmia	不整脈	5 (0.2%)	4 (0.1%)	0	0
Arrhythmia supraventricular	上室性不整脈	1 (<0.1%)	1 (<0.1%)	0	0
Arteriosclerosis coronary artery	冠動脈硬化症	2 (<0.1%)	1 (<0.1%)	0	0
Atrial fibrillation	心房細動	45 (1.5%)	61 (2.0%)	0	0
Atrial flutter	心房粗動	5 (0.2%)	3 (<0.1%)	0	0
Atrial tachycardia	心房頻脈	0	1 (<0.1%)	0	0
Atrial thrombosis	心房血栓症	1 (<0.1%)	1 (<0.1%)	0	0
Atrioventricular block complete	完全房室ブロック	3 (<0.1%)	2 (<0.1%)	0	0
Atrioventricular block first degree	第一度房室ブロック	0	1 (<0.1%)	0	0
Atrioventricular block second degree	第二度房室ブロック	0	3 (<0.1%)	0	0
Bradycardia	徐脈	1 (<0.1%)	4 (0.1%)	0	0

Primary system organ class Preferred term MedDRA version 22.1	Primary system organ class Preferred term MedDRA version 22.1	Treatment-emergent Rivaroxaban 2.5 mg bid, Aspirin 100mg od N=3027 (100%)	Treatment-emergent Rivaroxaban Placebo, Aspirin 100 mg od N=3019 (100%)	Study drug-related Rivaroxaban 2.5 mg bid, Aspirin 100mg od N=3027 (100%)	Study drug-related Rivaroxaban Placebo, Aspirin 100 mg od N=3019 (100%)
Bundle branch block left	左脚ブロック	1 (<0.1%)	1 (<0.1%)	0	0
Bundle branch block right	右脚ブロック	1 (<0.1%)	1 (<0.1%)	0	0
Cardiac arrest	心停止	1 (<0.1%)	1 (<0.1%)	0	0
Cardiac failure	心不全	13 (0.4%)	18 (0.6%)	0	0
Cardiac failure acute	急性心不全	2 (<0.1%)	6 (0.2%)	0	0
Cardiac failure chronic	慢性心不全	5 (0.2%)	3 (<0.1%)	0	0
Cardiac failure congestive	うっ血性心不全	11 (0.4%)	9 (0.3%)	0	0
Cardiac tamponade	心タンポナーデ	1 (<0.1%)	0	0	0
Cardiac valve disease	心臓弁膜疾患	1 (<0.1%)	0	0	0
Cardio-respiratory arrest	心肺停止	2 (<0.1%)	0	0	0
Cardiogenic shock	心原性ショック	1 (<0.1%)	1 (<0.1%)	0	0
Cardiopulmonary failure	心肺不全	1 (<0.1%)	1 (<0.1%)	0	0
Cardiovascular disorder	心血管障害	1 (<0.1%)	2 (<0.1%)	0	1 (<0.1%)
Cardiovascular insufficiency	心血管不全	1 (<0.1%)	0	0	0
Congestive cardiomyopathy	うっ血性心筋症	1 (<0.1%)	1 (<0.1%)	0	0
Coronary artery disease	冠動脈疾患	24 (0.8%)	27 (0.9%)	2 (<0.1%)	0
Coronary artery occlusion	冠動脈閉塞	1 (<0.1%)	1 (<0.1%)	0	0
Coronary artery stenosis	冠動脈狭窄	4 (0.1%)	3 (<0.1%)	0	0
Cyanosis	チアノーゼ	2 (<0.1%)	0	0	0
Extrasystoles	期外収縮	1 (<0.1%)	2 (<0.1%)	0	0
Hypertensive heart disease	高血圧性心疾患	0	2 (<0.1%)	0	0
Ischaemic cardiomyopathy	虚血性心筋症	1 (<0.1%)	1 (<0.1%)	0	0
Left ventricular dysfunction	左室機能不全	0	2 (<0.1%)	0	0
Left ventricular failure	左室不全	1 (<0.1%)	0	0	0
Left ventricular hypertrophy	左室肥大	1 (<0.1%)	2 (<0.1%)	0	0
Mitral valve incompetence	僧帽弁閉鎖不全症	2 (<0.1%)	1 (<0.1%)	0	0
Myocardial fibrosis	心筋線維症	2 (<0.1%)	1 (<0.1%)	0	0
Myocardial infarction	心筋梗塞	1 (<0.1%)	0	0	0
Myocardial ischaemia	心筋虚血	6 (0.2%)	2 (<0.1%)	0	0
Palpitations	動悸	3 (<0.1%)	4 (0.1%)	0	1 (<0.1%)
Pericardial effusion	心嚢液貯留	0	1 (<0.1%)	0	0
Pericarditis	心膜炎	0	1 (<0.1%)	0	0
Right ventricular failure	右室不全	0	1 (<0.1%)	0	0
Sinus arrest	洞停止	1 (<0.1%)	0	0	0
Sinus bradycardia	洞性徐脈	0	1 (<0.1%)	0	0
Sinus node dysfunction	洞結節機能不全	1 (<0.1%)	3 (<0.1%)	0	0
Sinus tachycardia	洞性頻脈	4 (0.1%)	0	0	0
Supraventricular extrasystoles	上室性期外収縮	2 (<0.1%)	1 (<0.1%)	0	0
Supraventricular tachyarrhythmia	上室性頻脈性不整脈	0	1 (<0.1%)	0	0
Supraventricular tachycardia	上室性頻脈	2 (<0.1%)	0	0	0
Systolic dysfunction	収縮機能障害	2 (<0.1%)	0	0	0
Tachycardia	頻脈	2 (<0.1%)	2 (<0.1%)	1 (<0.1%)	0
Tachycardia paroxysmal	発作性頻脈	1 (<0.1%)	0	0	0
Tricuspid valve incompetence	三尖弁閉鎖不全症	1 (<0.1%)	0	0	0
Ventricular arrhythmia	心室性不整脈	1 (<0.1%)	1 (<0.1%)	0	0
Ventricular extrasystoles	心室性期外収縮	0	1 (<0.1%)	0	0
Ventricular fibrillation	心室細動	0	2 (<0.1%)	0	0

Primary system organ class Preferred term MedDRA version 22.1	Primary system organ class Preferred term MedDRA version 22.1	Treatment-emergent Rivaroxaban 2.5 mg bid, Aspirin 100mg od N=3027 (100%)	Treatment-emergent Rivaroxaban Placebo, Aspirin 100 mg od N=3019 (100%)	Study drug-related Rivaroxaban 2.5 mg bid, Aspirin 100mg od N=3027 (100%)	Study drug-related Rivaroxaban Placebo, Aspirin 100 mg od N=3019 (100%)
Ventricular tachycardia	心室性頻脈	1 (<0.1%)	2 (<0.1%)	0	0
Congenital, familial and genetic disorders	先天性、家族性および遺伝性障害	7 (0.2%)	5 (0.2%)	0	0
Adenomatous polyposis coli	大腸腺腫性ポリポーシス	1 (<0.1%)	0	0	0
Atrial septal defect	心房中隔欠損症	1 (<0.1%)	0	0	0
Carbohydrate metabolism disorder	炭水化物代謝障害	0	1 (<0.1%)	0	0
Cerebral palsy	脳性麻痺	1 (<0.1%)	0	0	0
Congenital bladder neck obstruction	先天性膀胱頚部閉塞症	0	1 (<0.1%)	0	0
Factor V Leiden mutation	第Ⅴ因子ライデン変異	1 (<0.1%)	0	0	0
Haemophilia	血友病	1 (<0.1%)	0	0	0
Hydrocele	陰嚢水瘤	1 (<0.1%)	1 (<0.1%)	0	0
Phimosis	包茎	1 (<0.1%)	2 (<0.1%)	0	0
Ear and labyrinth disorders	耳および迷路障害	17 (0.6%)	24 (0.8%)	0	2 (<0.1%)
Deafness	難聴	3 (<0.1%)	3 (<0.1%)	0	0
Ear pain	耳痛	0	1 (<0.1%)	0	0
Eustachian tube dysfunction	耳管機能障害	1 (<0.1%)	0	0	0
Hypoacusis	聴力低下	2 (<0.1%)	1 (<0.1%)	0	0
Otorrhoea	耳漏	0	1 (<0.1%)	0	1 (<0.1%)
Sudden hearing loss	突発性難聴	2 (<0.1%)	1 (<0.1%)	0	0
Tinnitus	耳鳴	4 (0.1%)	3 (<0.1%)	0	0
Vertigo	回転性めまい	7 (0.2%)	12 (0.4%)	0	1 (<0.1%)
Vertigo labyrinthine	迷路性回転性めまい	0	1 (<0.1%)	0	0
Vertigo positional	頭位性回転性めまい	0	1 (<0.1%)	0	0
Endocrine disorders	内分泌障害	10 (0.3%)	9 (0.3%)	0	0
Adrenal cyst	副腎嚢胞	0	1 (<0.1%)	0	0
Cushing's syndrome	クッシング症候群	1 (<0.1%)	0	0	0
Goitre	甲状腺腫	3 (<0.1%)	4 (0.1%)	0	0
Hyperthyroidism	甲状腺機能亢進症	2 (<0.1%)	3 (<0.1%)	0	0
Hypothyroidism	甲状腺機能低下症	3 (<0.1%)	1 (<0.1%)	0	0
Thyroid mass	甲状腺腫瘤	1 (<0.1%)	1 (<0.1%)	0	0
Eye disorders	眼障害	35 (1.2%)	31 (1.0%)	1 (<0.1%)	0
Age-related macular degeneration	加齢黄斑変性	1 (<0.1%)	0	0	0
Blepharochalasis	眼瞼弛緩症	0	1 (<0.1%)	0	0
Cataract	白内障	16 (0.5%)	11 (0.4%)	0	0
Cataract cortical	皮質白内障	1 (<0.1%)	0	0	0
Cataract nuclear	核性白内障	0	1 (<0.1%)	0	0
Cystoid macular oedema	嚢胞様黄斑浮腫	0	1 (<0.1%)	0	0
Dacryostenosis acquired	後天性涙道狭窄	1 (<0.1%)	1 (<0.1%)	0	0
Detachment of macular retinal pigment epithelium	黄斑網膜色素上皮剥離	0	1 (<0.1%)	0	0
Diabetic retinal oedema	糖尿病性網膜浮腫	0	1 (<0.1%)	0	0
Diabetic retinopathy	糖尿病網膜症	7 (0.2%)	1 (<0.1%)	0	0
Diplopia	複視	0	1 (<0.1%)	0	0
Eye allergy	眼のアレルギー	1 (<0.1%)	0	0	0
Eye disorder	眼の障害	0	2 (<0.1%)	0	0
Eye haemorrhage	眼出血	1 (<0.1%)	0	1 (<0.1%)	0
Eye movement disorder	眼運動障害	1 (<0.1%)	0	0	0
Eye swelling	眼部腫脹	0	1 (<0.1%)	0	0
Eyelid bleeding	眼瞼出血	1 (<0.1%)	0	0	0

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Eyelid ptosis	眼瞼下垂	2 (<0.1%)	0	0	0
Glaucoma	緑内障	3 (<0.1%)	2 (<0.1%)	0	0
Iridocyclitis	虹彩毛様体炎	0	1 (<0.1%)	0	0
Iritis	虹彩炎	1 (<0.1%)	0	0	0
Macular degeneration	黄斑変性	2 (<0.1%)	1 (<0.1%)	0	0
Macular detachment	黄斑剥離	0	1 (<0.1%)	0	0
Macular hole	黄斑円孔	0	1 (<0.1%)	0	0
Macular oedema	黄斑浮腫	1 (<0.1%)	0	0	0
Myopia	近視	0	1 (<0.1%)	0	0
Panophthalmitis	全眼球炎	1 (<0.1%)	0	0	0
Retinal artery embolism	網膜動脈塞栓症	0	1 (<0.1%)	0	0
Retinal artery occlusion	網膜動脈閉塞	1 (<0.1%)	0	0	0
Retinal detachment	網膜剥離	1 (<0.1%)	2 (<0.1%)	0	0
Retinal vascular disorder	網膜血管障害	0	1 (<0.1%)	0	0
Retinopathy	網膜症	0	1 (<0.1%)	0	0
Swelling of eyelid	眼瞼腫脹	1 (<0.1%)	0	0	0
Visual acuity reduced	視力低下	0	1 (<0.1%)	0	0
Visual impairment	視力障害	0	1 (<0.1%)	0	0
Vitreoretinal traction syndrome	硝子体網膜牽引症候群	0	1 (<0.1%)	0	0
Vitreous floaters	硝子体浮遊物	0	1 (<0.1%)	0	0
Gastrointestinal disorders	胃腸障害	177 (5.8%)	173 (5.7%)	32 (1.1%)	21 (0.7%)
Abdominal adhesions	腹部癒着	0	1 (<0.1%)	0	0
Abdominal discomfort	腹部不快感	6 (0.2%)	3 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Abdominal distension	腹部膨満	1 (<0.1%)	1 (<0.1%)	0	1 (<0.1%)
Abdominal hernia	腹部ヘルニア	1 (<0.1%)	0	0	0
Abdominal incarcerated hernia	嵌頓腹部ヘルニア	1 (<0.1%)	0	0	0
Abdominal mass	腹部腫瘤	0	1 (<0.1%)	0	0
Abdominal pain	腹痛	9 (0.3%)	7 (0.2%)	1 (<0.1%)	0
Abdominal pain lower	下腹部痛	3 (<0.1%)	1 (<0.1%)	0	0
Abdominal pain upper	上腹部痛	17 (0.6%)	16 (0.5%)	5 (0.2%)	4 (0.1%)
Abdominal tenderness	腹部圧痛	0	1 (<0.1%)	0	0
Alcoholic pancreatitis	アルコール性膵炎	1 (<0.1%)	0	0	0
Anal fissure	裂肛	0	2 (<0.1%)	0	0
Anal incontinence	肛門失禁	1 (<0.1%)	0	0	0
Ascites	腹水	0	1 (<0.1%)	0	0
Chronic gastritis	慢性胃炎	3 (<0.1%)	4 (0.1%)	0	0
Colitis	大腸炎	1 (<0.1%)	3 (<0.1%)	0	0
Colitis ischaemic	虚血性大腸炎	2 (<0.1%)	1 (<0.1%)	0	0
Constipation	便秘	12 (0.4%)	13 (0.4%)	1 (<0.1%)	1 (<0.1%)
Crohn's disease	クローン病	2 (<0.1%)	1 (<0.1%)	0	0
Dental alveolar anomaly	歯槽異常	0	1 (<0.1%)	0	0
Dental caries	齲歯	1 (<0.1%)	1 (<0.1%)	0	0
Diaphragmatic hernia	横隔膜ヘルニア	0	1 (<0.1%)	0	0
Diarrhoea	下痢	26 (0.9%)	22 (0.7%)	7 (0.2%)	4 (0.1%)
Diverticulum	憩室	2 (<0.1%)	1 (<0.1%)	0	0
Diverticulum intestinal	腸憩室	1 (<0.1%)	4 (0.1%)	0	0
Dry mouth	口内乾燥	3 (<0.1%)	2 (<0.1%)	1 (<0.1%)	1 (<0.1%)
Duodenal polyp	十二指腸ポリープ	1 (<0.1%)	1 (<0.1%)	0	0
Duodenal ulcer	十二指腸潰瘍	4 (0.1%)	1 (<0.1%)	0	0
Duodenitis	十二指腸炎	2 (<0.1%)	3 (<0.1%)	0	0
Dyspepsia	消化不良	15 (0.5%)	8 (0.3%)	5 (0.2%)	4 (0.1%)
Dysphagia	嚥下障害	3 (<0.1%)	1 (<0.1%)	0	0
Enterocolitis	腸炎	1 (<0.1%)	1 (<0.1%)	0	0
Enterocutaneous fistula	腸管皮膚瘻	1 (<0.1%)	0	0	0
Enterovesical fistula	腸膀胱瘻	0	1 (<0.1%)	0	0
Erosive duodenitis	びらん性十二指腸炎	0	1 (<0.1%)	0	0

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Erosive oesophagitis	びらん性食道炎	1 (<0.1%)	1 (<0.1%)	0	0
Flatulence	鼓腸	3 (<0.1%)	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)
Food poisoning	食中毒	0	1 (<0.1%)	0	0
Gallstone ileus	胆石性イレウス	0	1 (<0.1%)	0	0
Gastric antral vascular ectasia	胃前庭部毛細血管拡張症	1 (<0.1%)	0	1 (<0.1%)	0
Gastric disorder	胃障害	1 (<0.1%)	0	0	0
Gastric polyps	胃ポリープ	1 (<0.1%)	1 (<0.1%)	0	0
Gastric ulcer	胃潰瘍	4 (0.1%)	5 (0.2%)	1 (<0.1%)	0
Gastritis	胃炎	17 (0.6%)	9 (0.3%)	3 (<0.1%)	0
Gastritis erosive	びらん性胃炎	3 (<0.1%)	6 (0.2%)	0	0
Gastrointestinal angiodysplasia	胃腸管血管異形成	1 (<0.1%)	2 (<0.1%)	0	0
Gastrointestinal disorder	胃腸障害	1 (<0.1%)	2 (<0.1%)	0	0
Gastrointestinal necrosis	消化管壊死	1 (<0.1%)	0	0	0
Gastrointestinal pain	消化器痛	0	1 (<0.1%)	0	0
Gastrooesophageal reflux disease	胃食道逆流性疾患	9 (0.3%)	8 (0.3%)	1 (<0.1%)	1 (<0.1%)
Gingival bleeding	歯肉出血	2 (<0.1%)	1 (<0.1%)	1 (<0.1%)	0
Glycogenic acanthosis	グリコーゲンアカントーシス	1 (<0.1%)	0	0	0
Haematemesis	吐血	1 (<0.1%)	0	0	0
Haemorrhagic erosive gastritis	出血性びらん性胃炎	0	1 (<0.1%)	0	0
Haemorrhoids	痔核	1 (<0.1%)	3 (<0.1%)	0	0
Hiatus hernia	裂孔ヘルニア	4 (0.1%)	2 (<0.1%)	0	0
Ileus	イレウス	1 (<0.1%)	1 (<0.1%)	0	0
Impaired gastric emptying	胃排出不全	2 (<0.1%)	0	0	0
Inguinal hernia	鼠径ヘルニア	4 (0.1%)	9 (0.3%)	0	0
Intestinal angina	腸管アンギナ	0	1 (<0.1%)	0	0
Intestinal ischaemia	腸管虚血	3 (<0.1%)	3 (<0.1%)	0	0
Intestinal obstruction	腸閉塞	4 (0.1%)	3 (<0.1%)	0	0
Intestinal perforation	腸管穿孔	1 (<0.1%)	1 (<0.1%)	0	0
Intestinal polyp	腸管ポリープ	1 (<0.1%)	0	0	0
Intestinal ulcer	腸潰瘍	0	1 (<0.1%)	0	0
Large intestinal obstruction	大腸閉塞	0	1 (<0.1%)	0	0
Large intestine perforation	大腸穿孔	2 (<0.1%)	1 (<0.1%)	0	0
Large intestine polyp	大腸ポリープ	6 (0.2%)	3 (<0.1%)	0	0
Loose tooth	弛緩歯	0	1 (<0.1%)	0	0
Mechanical ileus	機械的イレウス	1 (<0.1%)	0	0	0
Melaena	メレナ	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)	0
Nausea	悪心	15 (0.5%)	10 (0.3%)	3 (<0.1%)	5 (0.2%)
Obstructive pancreatitis	閉塞性膵炎	0	1 (<0.1%)	0	0
Oedematous pancreatitis	浮腫性膵炎	1 (<0.1%)	0	0	0
Oesophagitis	食道炎	1 (<0.1%)	1 (<0.1%)	0	0
Oral lichen planus	口腔扁平苔癬	0	1 (<0.1%)	0	0
Pancreatic duct stenosis	膵管狭窄	0	1 (<0.1%)	0	0
Pancreatic mass	膵腫瘤	0	1 (<0.1%)	0	0
Pancreatitis	膵炎	5 (0.2%)	0	0	0
Pancreatitis acute	急性膵炎	1 (<0.1%)	3 (<0.1%)	0	0
Pancreatitis chronic	慢性膵炎	1 (<0.1%)	3 (<0.1%)	0	0
Pancreatitis necrotising	壊死性膵炎	1 (<0.1%)	0	0	0
Peptic ulcer perforation	穿孔性消化性潰瘍	0	1 (<0.1%)	0	0
Periodontal disease	歯周病	0	1 (<0.1%)	0	0
Rectal polyp	直腸ポリープ	1 (<0.1%)	0	0	0
Salivary duct obstruction	唾液管閉塞	0	1 (<0.1%)	0	0
Salivary gland calculus	唾液腺結石	1 (<0.1%)	1 (<0.1%)	0	0

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Small intestinal obstruction	小腸閉塞	0	3 (<0.1%)	0	0
Small intestinal perforation	小腸穿孔	1 (<0.1%)	0	0	0
Subileus	亜イレウス	1 (<0.1%)	0	0	0
Tongue blistering	舌水疱形成	1 (<0.1%)	0	0	0
Tooth loss	歯の脱落	1 (<0.1%)	0	0	0
Toothache	歯痛	1 (<0.1%)	3 (<0.1%)	0	0
Umbilical hernia	臍ヘルニア	2 (<0.1%)	3 (<0.1%)	0	0
Umbilical hernia, obstructive	閉塞性臍ヘルニア	0	1 (<0.1%)	0	0
Vomiting	嘔吐	7 (0.2%)	15 (0.5%)	3 (<0.1%)	3 (<0.1%)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	109 (3.6%)	108 (3.6%)	8 (0.3%)	4 (0.1%)
Asthenia	無力症	7 (0.2%)	4 (0.1%)	1 (<0.1%)	0
Catheter site induration	カテーテル留置部位硬結	0	1 (<0.1%)	0	1 (<0.1%)
Catheter site swelling	カテーテル留置部位腫脹	1 (<0.1%)	0	0	0
Chest discomfort	胸部不快感	6 (0.2%)	2 (<0.1%)	0	0
Chest pain	胸痛	11 (0.4%)	17 (0.6%)	1 (<0.1%)	0
Chills	悪寒	1 (<0.1%)	0	0	0
Complication associated with device	医療機器関連合併症	1 (<0.1%)	0	0	0
Crepitations	捻髪音	0	1 (<0.1%)	0	0
Death	死亡	1 (<0.1%)	0	0	0
Discomfort	不快感	0	1 (<0.1%)	0	0
Drug intolerance	薬物不耐性	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)	0
Face oedema	顔面浮腫	1 (<0.1%)	0	1 (<0.1%)	0
Fatigue	疲労	11 (0.4%)	12 (0.4%)	1 (<0.1%)	1 (<0.1%)
Feeling cold	冷感	1 (<0.1%)	0	0	0
Gait disturbance	歩行障害	5 (0.2%)	3 (<0.1%)	0	0
General physical health deterioration	全身健康状態悪化	2 (<0.1%)	3 (<0.1%)	0	0
Granuloma	肉芽腫	1 (<0.1%)	0	0	0
Hernia	ヘルニア	0	2 (<0.1%)	0	0
Impaired healing	治癒不良	7 (0.2%)	9 (0.3%)	0	0
Inflammation	炎症	4 (0.1%)	3 (<0.1%)	0	0
Influenza like illness	インフルエンザ様疾患	1 (<0.1%)	0	0	0
Malaise	倦怠感	2 (<0.1%)	1 (<0.1%)	0	1 (<0.1%)
Medical device site pain	医療機器使用部位疼痛	1 (<0.1%)	0	0	0
Multiple organ dysfunction syndrome	多臓器機能不全症候群	0	3 (<0.1%)	0	0
Non-cardiac chest pain	非心臓性胸痛	8 (0.3%)	6 (0.2%)	0	1 (<0.1%)
Oedema	浮腫	1 (<0.1%)	2 (<0.1%)	0	0
Oedema peripheral	末梢性浮腫	17 (0.6%)	19 (0.6%)	1 (<0.1%)	0
Organ failure	臓器不全	1 (<0.1%)	0	0	0
Pain	疼痛	3 (<0.1%)	1 (<0.1%)	0	0
Peripheral swelling	末梢腫脹	9 (0.3%)	11 (0.4%)	1 (<0.1%)	0
Pyrexia	発熱	4 (0.1%)	3 (<0.1%)	1 (<0.1%)	0
Secretion discharge	分泌物分泌	0	1 (<0.1%)	0	0
Stent-graft endoleak	ステントグラフトエンドリーク	1 (<0.1%)	0	0	0
Swelling face	顔面腫脹	1 (<0.1%)	0	0	0
Systemic inflammatory response syndrome	全身性炎症反応症候群	1 (<0.1%)	0	0	0
Thirst	口渇	1 (<0.1%)	0	0	0
Vascular device occlusion	血管デバイス閉塞	0	2 (<0.1%)	0	0

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Vascular stent occlusion	血管ステント閉塞	4 (0.1%)	2 (<0.1%)	0	0
Vascular stent stenosis	血管ステント狭窄	14 (0.5%)	11 (0.4%)	2 (<0.1%)	0
Hepatobiliary disorders	肝胆道系障害	26 (0.9%)	33 (1.1%)	1 (<0.1%)	0
Bile duct obstruction	胆管閉塞	0	3 (<0.1%)	0	0
Bile duct stone	胆管結石	2 (<0.1%)	2 (<0.1%)	0	0
Biliary dyskinesia	胆道ジスキネジア	1 (<0.1%)	0	0	0
Cholangitis acute	急性胆管炎	1 (<0.1%)	1 (<0.1%)	0	0
Cholecystitis	胆嚢炎	7 (0.2%)	4 (0.1%)	0	0
Cholecystitis acute	急性胆嚢炎	2 (<0.1%)	12 (0.4%)	0	0
Cholecystitis chronic	慢性胆嚢炎	1 (<0.1%)	2 (<0.1%)	0	0
Cholelithiasis	胆石症	2 (<0.1%)	3 (<0.1%)	0	0
Cholestasis	胆汁うっ滞	0	1 (<0.1%)	0	0
Cirrhosis alcoholic	アルコール性肝硬変	1 (<0.1%)	0	0	0
Hepatic calcification	肝石灰化	0	1 (<0.1%)	0	0
Hepatic cirrhosis	肝硬変	3 (<0.1%)	0	0	0
Hepatic failure	肝不全	0	1 (<0.1%)	0	0
Hepatic function abnormal	肝機能異常	2 (<0.1%)	0	1 (<0.1%)	0
Hepatic steatosis	脂肪肝	4 (0.1%)	3 (<0.1%)	0	0
Hepatomegaly	肝腫大	0	3 (<0.1%)	0	0
Hepatorenal syndrome	肝腎症候群	0	1 (<0.1%)	0	0
Hyperbilirubinaemia	高ビリルビン血症	0	1 (<0.1%)	0	0
Liver disorder	肝障害	1 (<0.1%)	0	0	0
Liver injury	肝損傷	0	1 (<0.1%)	0	0
Portal hypertension	門脈圧亢進症	0	1 (<0.1%)	0	0
Primary biliary cholangitis	原発性胆汁性胆管炎	1 (<0.1%)	0	0	0
Steatohepatitis	脂肪性肝炎	0	2 (<0.1%)	0	0
Immune system disorders	免疫系障害	4 (0.1%)	10 (0.3%)	0	5 (0.2%)
Allergy to arthropod bite	節足動物咬傷アレルギー	1 (<0.1%)	0	0	0
Allergy to arthropod sting	節足動物刺傷アレルギー	0	1 (<0.1%)	0	0
Anaphylactic reaction	アナフィラキシー反応	0	3 (<0.1%)	0	0
Drug hypersensitivity	薬物過敏症	1 (<0.1%)	1 (<0.1%)	0	0
Hypersensitivity	過敏症	1 (<0.1%)	5 (0.2%)	0	4 (0.1%)
Multiple allergies	複合アレルギー	0	1 (<0.1%)	0	1 (<0.1%)
Seasonal allergy	季節性アレルギー	1 (<0.1%)	0	0	0
Infections and infestations	感染症および寄生虫症	362 (12.0%)	361 (12.0%)	0	1 (<0.1%)
Abdominal abscess	腹部膿瘍	0	1 (<0.1%)	0	0
Abdominal infection	腹部感染	1 (<0.1%)	0	0	0
Abscess	膿瘍	2 (<0.1%)	0	0	0
Abscess limb	四肢膿瘍	8 (0.3%)	6 (0.2%)	0	0
Acarodermatitis	ダニ皮膚炎	1 (<0.1%)	0	0	0
Acute sinusitis	急性副鼻腔炎	0	2 (<0.1%)	0	0
Anal abscess	肛門膿瘍	1 (<0.1%)	0	0	0
Appendicitis	虫垂炎	4 (0.1%)	5 (0.2%)	0	0
Arteriosclerotic gangrene	動脈硬化性壊疽	1 (<0.1%)	0	0	0
Arthritis bacterial	細菌性関節炎	1 (<0.1%)	2 (<0.1%)	0	0
Arthritis infective	感染性関節炎	1 (<0.1%)	0	0	0
Bacteraemia	菌血症	0	2 (<0.1%)	0	0
Bacterial infection	細菌感染	1 (<0.1%)	0	0	0
Blister infected	感染性水疱	0	1 (<0.1%)	0	0
Bone abscess	骨膿瘍	1 (<0.1%)	1 (<0.1%)	0	0
Borrelia infection	ボレリア感染	1 (<0.1%)	0	0	0
Bronchiolitis	細気管支炎	0	1 (<0.1%)	0	0

2.7.6.1.a 付録 1

Primary system organ class Preferred term MedDRA version 22.1	Primary system organ class Preferred term MedDRA version 22.1	Treatment-emergent Rivaroxaban 2.5 mg bid, Aspirin 100mg od N=3027 (100%)	Treatment-emergent Rivaroxaban Placebo, Aspirin 100 mg od N=3019 (100%)	Study drug-related Rivaroxaban 2.5 mg bid, Aspirin 100mg od N=3027 (100%)	Study drug-related Rivaroxaban Placebo, Aspirin 100 mg od N=3019 (100%)
Bronchitis	気管支炎	17 (0.6%)	18 (0.6%)	0	0
Bronchitis bacterial	細菌性気管支炎	0	1 (<0.1%)	0	0
Burn infection	熱傷部感染	1 (<0.1%)	0	0	0
Carbuncle	よう	0	1 (<0.1%)	0	0
Cellulitis	蜂巣炎	24 (0.8%)	22 (0.7%)	0	1 (<0.1%)
Cellulitis gangrenous	壊疽性蜂巣炎	0	1 (<0.1%)	0	0
Cholecystitis infective	感染性胆嚢炎	0	2 (<0.1%)	0	0
Chronic hepatitis B	慢性Ｂ型肝炎	1 (<0.1%)	0	0	0
Clostridium difficile colitis	クロストリジウム・ディフィシレ大腸炎	2 (<0.1%)	2 (<0.1%)	0	0
Clostridium difficile infection	クロストリジウム・ディフィシレ感染	1 (<0.1%)	0	0	0
Complicated appendicitis	合併症を伴う虫垂炎	0	1 (<0.1%)	0	0
Conjunctivitis	結膜炎	2 (<0.1%)	2 (<0.1%)	0	0
Conjunctivitis viral	ウイルス性結膜炎	1 (<0.1%)	0	0	0
Cystitis	膀胱炎	3 (<0.1%)	4 (0.1%)	0	0
Cystitis bacterial	細菌性膀胱炎	1 (<0.1%)	0	0	0
Dermo-hypodermitis	皮膚皮下組織炎	1 (<0.1%)	0	0	0
Device related infection	医療機器関連感染	2 (<0.1%)	2 (<0.1%)	0	0
Diabetic foot infection	糖尿病性足感染	3 (<0.1%)	6 (0.2%)	0	0
Diabetic gangrene	糖尿病性壊疽	3 (<0.1%)	2 (<0.1%)	0	0
Diarrhoea infectious	感染性下痢	1 (<0.1%)	0	0	0
Diverticulitis	憩室炎	5 (0.2%)	6 (0.2%)	0	0
Ear infection	耳感染	2 (<0.1%)	3 (<0.1%)	0	0
Eczema infected	感染性湿疹	1 (<0.1%)	0	0	0
Endocarditis	心内膜炎	1 (<0.1%)	0	0	0
Endophthalmitis	眼内炎	0	1 (<0.1%)	0	0
Epididymitis	精巣上体炎	0	1 (<0.1%)	0	0
Erysipelas	丹毒	2 (<0.1%)	12 (0.4%)	0	0
Escherichia sepsis	大腸菌性敗血症	1 (<0.1%)	0	0	0
Extradural abscess	硬膜外膿瘍	1 (<0.1%)	0	0	0
Fournier's gangrene	フルニエー壊疽	0	1 (<0.1%)	0	0
Fungal cystitis	真菌性膀胱炎	0	1 (<0.1%)	0	0
Fungal skin infection	皮膚真菌感染	4 (0.1%)	0	0	0
Furuncle	せつ	1 (<0.1%)	1 (<0.1%)	0	0
Gangrene	壊疽	21 (0.7%)	22 (0.7%)	0	0
Gastric infection	胃感染	0	1 (<0.1%)	0	0
Gastric ulcer helicobacter	ヘリコバクター胃潰瘍	1 (<0.1%)	0	0	0
Gastroenteritis	胃腸炎	5 (0.2%)	3 (<0.1%)	0	0
Gastroenteritis viral	ウイルス性胃腸炎	5 (0.2%)	1 (<0.1%)	0	0
Genitourinary tract infection	泌尿生殖器感染	1 (<0.1%)	0	0	0
Graft infection	移植片感染	1 (<0.1%)	0	0	0
Groin abscess	鼠径部膿瘍	3 (<0.1%)	1 (<0.1%)	0	0
Groin infection	鼠径部感染	1 (<0.1%)	1 (<0.1%)	0	0
Haematoma infection	血腫感染	1 (<0.1%)	1 (<0.1%)	0	0
Helicobacter gastritis	ヘリコバクター性胃炎	0	1 (<0.1%)	0	0
Hepatitis C	Ｃ型肝炎	2 (<0.1%)	1 (<0.1%)	0	0
Herpes zoster	帯状疱疹	4 (0.1%)	6 (0.2%)	0	0
Hordeolum	麦粒腫	0	1 (<0.1%)	0	0
Infected lymphocele	感染性リンパ嚢腫	2 (<0.1%)	0	0	0
Infected seroma	感染性漿液腫	1 (<0.1%)	0	0	0
Infected skin ulcer	感染性皮膚潰瘍	8 (0.3%)	5 (0.2%)	0	0
Infection	感染	1 (<0.1%)	2 (<0.1%)	0	0
Infectious pleural effusion	感染性胸水	0	1 (<0.1%)	0	0
Infective exacerbation of chronic obstructive airways disease	感染による慢性閉塞性気道疾患の増悪	3 (<0.1%)	2 (<0.1%)	0	0

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Influenza	インフルエンザ	12 (0.4%)	7 (0.2%)	0	0
Intervertebral discitis	椎間板炎	1 (<0.1%)	1 (<0.1%)	0	0
Large intestine infection	大腸感染	0	1 (<0.1%)	0	0
Laryngitis	喉頭炎	0	2 (<0.1%)	0	0
Lice infestation	シラミ寄生	0	1 (<0.1%)	0	0
Localised infection	限局性感染	27 (0.9%)	17 (0.6%)	0	0
Lower respiratory tract infection	下気道感染	1 (<0.1%)	3 (<0.1%)	0	0
Lymph gland infection	リンパ節感染	1 (<0.1%)	0	0	0
Lymphangitis	リンパ管炎	1 (<0.1%)	1 (<0.1%)	0	0
Mastoiditis	乳様突起炎	1 (<0.1%)	0	0	0
Medical device site infection	医療機器使用部位感染	1 (<0.1%)	0	0	0
Medical device site joint infection	医療機器使用部位関節感染	0	3 (<0.1%)	0	0
Nasopharyngitis	上咽頭炎	21 (0.7%)	28 (0.9%)	0	0
Oesophageal candidiasis	食道カンジダ症	1 (<0.1%)	0	0	0
Ophthalmic herpes zoster	眼帯状疱疹	1 (<0.1%)	0	0	0
Oral candidiasis	口腔カンジダ症	1 (<0.1%)	0	0	0
Oral herpes	口腔ヘルペス	2 (<0.1%)	0	0	0
Orchitis	精巣炎	1 (<0.1%)	0	0	0
Osteomyelitis	骨髄炎	14 (0.5%)	12 (0.4%)	0	0
Osteomyelitis bacterial	細菌性骨髄炎	1 (<0.1%)	0	0	0
Osteomyelitis chronic	慢性骨髄炎	4 (0.1%)	2 (<0.1%)	0	0
Otitis media	中耳炎	1 (<0.1%)	1 (<0.1%)	0	0
Otitis media acute	急性中耳炎	0	1 (<0.1%)	0	0
Paronychia	爪囲炎	0	2 (<0.1%)	0	0
Parotitis	耳下腺炎	1 (<0.1%)	0	0	0
Perineal abscess	会陰膿瘍	2 (<0.1%)	1 (<0.1%)	0	0
Perineal cellulitis	会陰蜂巣炎	0	1 (<0.1%)	0	0
Perinephric abscess	腎周囲膿瘍	1 (<0.1%)	0	0	0
Periodontitis	歯周炎	0	1 (<0.1%)	0	0
Peritonitis	腹膜炎	1 (<0.1%)	1 (<0.1%)	0	0
Periumbilical abscess	臍帯周囲膿瘍	0	1 (<0.1%)	0	0
Pharyngitis	咽頭炎	1 (<0.1%)	2 (<0.1%)	0	0
Pneumocystis jirovecii pneumonia	ニューモシスチス・イロベチイ肺炎	1 (<0.1%)	0	0	0
Pneumonia	肺炎	40 (1.3%)	54 (1.8%)	0	0
Pneumonia bacterial	細菌性肺炎	2 (<0.1%)	1 (<0.1%)	0	0
Post procedural infection	処置後感染	1 (<0.1%)	0	0	0
Post procedural sepsis	処置後敗血症	0	1 (<0.1%)	0	0
Postoperative wound infection	術後創感染	32 (1.1%)	31 (1.0%)	0	0
Pseudomembranous colitis	偽膜性大腸炎	1 (<0.1%)	1 (<0.1%)	0	0
Pulmonary sepsis	肺敗血症	1 (<0.1%)	2 (<0.1%)	0	0
Pulmonary tuberculosis	肺結核	2 (<0.1%)	0	0	0
Pulpitis dental	歯髄炎	2 (<0.1%)	0	0	0
Purulent discharge	化膿性分泌物	0	1 (<0.1%)	0	0
Pyelitis	腎盂炎	1 (<0.1%)	0	0	0
Pyelonephritis	腎盂腎炎	1 (<0.1%)	2 (<0.1%)	0	0
Pyelonephritis acute	急性腎盂腎炎	1 (<0.1%)	1 (<0.1%)	0	0
Pyelonephritis chronic	慢性腎盂腎炎	1 (<0.1%)	1 (<0.1%)	0	0
Pyoderma	膿皮症	0	1 (<0.1%)	0	0
Pyuria	膿尿	0	1 (<0.1%)	0	0
Respiratory tract infection	気道感染	6 (0.2%)	3 (<0.1%)	0	0
Respiratory tract infection viral	ウイルス性気道感染	2 (<0.1%)	4 (0.1%)	0	0
Rhinitis	鼻炎	1 (<0.1%)	2 (<0.1%)	0	0

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Rotavirus infection	ロタウイルス感染	0	1 (<0.1%)	0	0
Scrotal abscess	陰嚢膿瘍	1 (<0.1%)	1 (<0.1%)	0	0
Sepsis	敗血症	14 (0.5%)	13 (0.4%)	0	0
Septic shock	敗血症性ショック	1 (<0.1%)	5 (0.2%)	0	0
Sialoadenitis	唾液腺炎	0	2 (<0.1%)	0	0
Sinusitis	副鼻腔炎	6 (0.2%)	5 (0.2%)	0	0
Sinusitis bacterial	細菌性副鼻腔炎	1 (<0.1%)	1 (<0.1%)	0	0
Skin infection	皮膚感染	3 (<0.1%)	4 (0.1%)	0	0
Soft tissue infection	軟部組織感染	3 (<0.1%)	3 (<0.1%)	0	0
Subcutaneous abscess	皮下組織膿瘍	4 (0.1%)	1 (<0.1%)	0	0
Superinfection bacterial	細菌重複感染	0	1 (<0.1%)	0	0
Tinea pedis	足部白癬	2 (<0.1%)	1 (<0.1%)	0	0
Tonsillitis	扁桃炎	1 (<0.1%)	1 (<0.1%)	0	0
Tooth abscess	歯膿瘍	1 (<0.1%)	1 (<0.1%)	0	0
Tooth infection	歯感染	1 (<0.1%)	0	0	0
Tracheobronchitis	気管気管支炎	2 (<0.1%)	1 (<0.1%)	0	0
Tuberculosis	結核	1 (<0.1%)	1 (<0.1%)	0	0
Upper respiratory tract infection	上気道感染	4 (0.1%)	2 (<0.1%)	0	0
Urinary tract infection	尿路感染	31 (1.0%)	31 (1.0%)	0	0
Urosepsis	尿路性敗血症	0	6 (0.2%)	0	0
Varicella zoster virus infection	水痘帯状疱疹ウイルス感染	0	1 (<0.1%)	0	0
Vascular device infection	血管デバイス感染	2 (<0.1%)	2 (<0.1%)	0	0
Viral infection	ウイルス感染	2 (<0.1%)	1 (<0.1%)	0	0
Viral upper respiratory tract infection	ウイルス性上気道感染	2 (<0.1%)	0	0	0
Wound infection	創傷感染	23 (0.8%)	19 (0.6%)	0	0
Wound infection bacterial	細菌性創感染	1 (<0.1%)	0	0	0
Wound infection fungal	真菌性創感染	1 (<0.1%)	0	0	0
Wound infection pseudomonas	シュードモナス性創感染	1 (<0.1%)	0	0	0
Wound infection staphylococcal	ブドウ球菌性創感染	1 (<0.1%)	0	0	0
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	169 (5.6%)	190 (6.3%)	5 (0.2%)	3 (<0.1%)
Accidental overdose	偶発的過量投与	2 (<0.1%)	0	0	0
Alcohol poisoning	アルコール中毒	2 (<0.1%)	0	0	0
Anastomotic stenosis	吻合部狭窄	0	1 (<0.1%)	0	0
Animal bite	動物咬傷	1 (<0.1%)	0	0	0
Ankle fracture	足関節部骨折	3 (<0.1%)	5 (0.2%)	0	0
Arterial bypass occlusion	動脈バイパス閉塞	4 (0.1%)	6 (0.2%)	0	0
Arterial bypass stenosis	動脈バイパス狭窄	3 (<0.1%)	2 (<0.1%)	0	0
Arterial bypass thrombosis	動脈バイパス血栓症	2 (<0.1%)	1 (<0.1%)	0	0
Arterial restenosis	動脈再狭窄	1 (<0.1%)	0	0	0
Bone contusion	骨挫傷	2 (<0.1%)	0	0	0
Carbon monoxide poisoning	一酸化炭素中毒	1 (<0.1%)	0	0	0
Chemical burn of skin	皮膚化学熱傷	0	1 (<0.1%)	0	0
Chest injury	胸部損傷	0	1 (<0.1%)	0	0
Clavicle fracture	鎖骨骨折	0	1 (<0.1%)	0	0
Compression fracture	圧迫骨折	0	1 (<0.1%)	0	0
Concussion	脳振盪	2 (<0.1%)	3 (<0.1%)	0	0
Contusion	挫傷	10 (0.3%)	9 (0.3%)	1 (<0.1%)	2 (<0.1%)
Craniocerebral injury	頭蓋脳損傷	2 (<0.1%)	0	0	0
Epicondylitis	上顆炎	3 (<0.1%)	0	0	0
Eye contusion	眼挫傷	1 (<0.1%)	0	0	0

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Face injury	顔面損傷	0	1 (<0.1%)	0	0
Facial bones fracture	顔面骨骨折	0	1 (<0.1%)	0	0
Failure to anastomose	吻合不全	0	1 (<0.1%)	0	0
Fall	転倒	11 (0.4%)	8 (0.3%)	0	0
Femoral neck fracture	大腿骨頚部骨折	4 (0.1%)	1 (<0.1%)	0	0
Femur fracture	大腿骨骨折	8 (0.3%)	11 (0.4%)	0	0
Fibula fracture	腓骨骨折	3 (<0.1%)	0	0	0
Foot fracture	足骨折	7 (0.2%)	3 (<0.1%)	0	0
Forearm fracture	前腕骨折	0	1 (<0.1%)	0	0
Foreign body	体内異物	1 (<0.1%)	1 (<0.1%)	0	0
Foreign body in gastrointestinal tract	消化管内異物	0	1 (<0.1%)	0	0
Gastrointestinal anastomotic leak	胃腸吻合部漏出	0	1 (<0.1%)	0	0
Graft thrombosis	移植片血栓症	1 (<0.1%)	1 (<0.1%)	0	0
Hand fracture	手骨折	2 (<0.1%)	0	0	0
Head injury	頭部損傷	2 (<0.1%)	0	0	0
Heat stroke	熱射病	0	1 (<0.1%)	0	0
Hip fracture	股関節部骨折	5 (0.2%)	5 (0.2%)	0	0
Humerus fracture	上腕骨骨折	1 (<0.1%)	3 (<0.1%)	0	0
Incision site erythema	切開部位紅斑	2 (<0.1%)	1 (<0.1%)	0	0
Incision site inflammation	切開部位炎症	1 (<0.1%)	0	0	0
Incision site swelling	切開部位腫脹	1 (<0.1%)	0	0	0
Incisional hernia	瘢痕ヘルニア	1 (<0.1%)	0	0	0
Inflammation of wound	創部炎症	0	1 (<0.1%)	0	0
Injury	損傷	3 (<0.1%)	0	0	0
Intentional overdose	企図的過量投与	1 (<0.1%)	0	0	0
Intentional product misuse	企図的製品誤用	1 (<0.1%)	0	0	0
Intra-ocular injection complication	眼内注射合併症	1 (<0.1%)	0	0	0
Joint capsule rupture	関節包断裂	1 (<0.1%)	0	0	0
Joint dislocation	関節脱臼	2 (<0.1%)	2 (<0.1%)	0	0
Joint injury	関節損傷	1 (<0.1%)	2 (<0.1%)	0	0
Ligament rupture	靭帯断裂	2 (<0.1%)	0	0	0
Ligament sprain	靭帯捻挫	0	5 (0.2%)	0	0
Limb injury	四肢損傷	13 (0.4%)	15 (0.5%)	0	0
Lower limb fracture	下肢骨折	2 (<0.1%)	3 (<0.1%)	0	0
Lumbar vertebral fracture	腰椎骨折	2 (<0.1%)	5 (0.2%)	0	0
Meniscus injury	半月板損傷	4 (0.1%)	7 (0.2%)	0	0
Multiple injuries	多発性外傷	1 (<0.1%)	0	0	0
Muscle rupture	筋断裂	1 (<0.1%)	0	0	0
Muscle strain	肉離れ	4 (0.1%)	3 (<0.1%)	0	0
Nasal injury	鼻部損傷	0	1 (<0.1%)	0	0
Open fracture	開放骨折	0	1 (<0.1%)	0	0
Overdose	過量投与	1 (<0.1%)	0	1 (<0.1%)	0
Patella fracture	膝蓋骨骨折	1 (<0.1%)	0	0	0
Pelvic fracture	骨盤骨折	1 (<0.1%)	2 (<0.1%)	0	0
Penetrating abdominal trauma	鋭的腹部外傷	0	1 (<0.1%)	0	0
Peripheral artery restenosis	末梢動脈再狭窄	6 (0.2%)	12 (0.4%)	0	0
Periprosthetic fracture	人工関節周囲骨折	0	1 (<0.1%)	0	0
Post angioplasty restenosis	血管形成後再狭窄	0	1 (<0.1%)	0	0
Post laminectomy syndrome	椎弓切除後症候群	1 (<0.1%)	1 (<0.1%)	0	0
Post procedural bile leak	処置後胆汁漏出	0	1 (<0.1%)	0	0

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Post procedural complication	処置後合併症	2 (<0.1%)	0	0	0
Post procedural diarrhoea	処置後下痢	0	1 (<0.1%)	0	0
Post procedural discharge	処置後分泌物	1 (<0.1%)	3 (<0.1%)	0	0
Post procedural haematuria	処置後血尿	0	1 (<0.1%)	0	0
Post procedural inflammation	処置後炎症	1 (<0.1%)	0	0	0
Post procedural oedema	処置後浮腫	2 (<0.1%)	2 (<0.1%)	0	0
Post-traumatic pain	外傷後疼痛	1 (<0.1%)	1 (<0.1%)	0	0
Postoperative respiratory failure	術後呼吸不全	0	1 (<0.1%)	0	0
Postoperative thoracic procedure complication	術後胸部処置合併症	0	1 (<0.1%)	0	0
Postoperative wound complication	術後創合併症	0	1 (<0.1%)	0	0
Procedural complication	処置合併症	0	1 (<0.1%)	0	0
Procedural intestinal perforation	処置による腸管穿孔	0	1 (<0.1%)	0	0
Procedural pain	処置による疼痛	0	2 (<0.1%)	0	0
Procedural vomiting	処置による嘔吐	0	1 (<0.1%)	0	0
Pseudophakic bullous keratopathy	偽水晶体性水疱性角膜症	1 (<0.1%)	0	0	0
Pubis fracture	恥骨骨折	1 (<0.1%)	1 (<0.1%)	0	0
Radiation proctitis	放射線性直腸炎	0	1 (<0.1%)	0	0
Radius fracture	橈骨骨折	3 (<0.1%)	2 (<0.1%)	0	0
Repetitive strain injury	反復性挫傷	1 (<0.1%)	0	0	0
Rib fracture	肋骨骨折	3 (<0.1%)	6 (0.2%)	0	0
Road traffic accident	交通事故	1 (<0.1%)	0	0	0
Seroma	漿液腫	4 (0.1%)	3 (<0.1%)	0	0
Skin abrasion	皮膚擦過傷	2 (<0.1%)	0	0	0
Skin laceration	皮膚裂傷	1 (<0.1%)	4 (0.1%)	1 (<0.1%)	0
Skin scar contracture	皮膚瘢痕拘縮	0	1 (<0.1%)	0	0
Skin wound	皮膚創傷	0	1 (<0.1%)	0	0
Skull fractured base	頭蓋底骨折	1 (<0.1%)	0	0	0
Spinal column injury	脊柱損傷	1 (<0.1%)	2 (<0.1%)	0	0
Spinal compression fracture	脊椎圧迫骨折	0	4 (0.1%)	0	0
Spinal fracture	脊椎骨折	0	1 (<0.1%)	0	0
Sternal fracture	胸骨骨折	0	1 (<0.1%)	0	0
Sunburn	サンバーン	1 (<0.1%)	0	0	0
Suture rupture	縫合部離開	0	1 (<0.1%)	0	0
Tendon injury	腱損傷	1 (<0.1%)	0	0	0
Tendon rupture	腱断裂	1 (<0.1%)	1 (<0.1%)	0	0
Thermal burn	熱傷	1 (<0.1%)	1 (<0.1%)	0	0
Thoracic vertebral fracture	胸椎骨折	1 (<0.1%)	2 (<0.1%)	0	0
Tibia fracture	脛骨骨折	3 (<0.1%)	1 (<0.1%)	0	0
Transplant failure	移植不全	1 (<0.1%)	0	0	0
Traumatic fracture	外傷性骨折	1 (<0.1%)	1 (<0.1%)	0	0
Traumatic haemorrhage	外傷性出血	0	1 (<0.1%)	0	0
Traumatic haemothorax	外傷性血胸	0	1 (<0.1%)	0	0
Traumatic ulcer	外傷性潰瘍	1 (<0.1%)	0	0	0
Ulna fracture	尺骨骨折	1 (<0.1%)	0	0	0
Underdose	過少量投与	0	1 (<0.1%)	0	1 (<0.1%)
Upper limb fracture	上肢骨折	1 (<0.1%)	0	0	0
Vascular access site haematoma	血管確保部位血腫	0	1 (<0.1%)	0	0
Vascular graft complication	移植血管合併症	6 (0.2%)	3 (<0.1%)	0	0

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Vascular graft occlusion	移植血管閉塞	3 (<0.1%)	4 (0.1%)	0	0
Vascular graft restenosis	移植血管再狭窄	0	1 (<0.1%)	0	0
Vascular graft stenosis	移植血管狭窄	4 (0.1%)	3 (<0.1%)	0	0
Vascular graft thrombosis	血管グラフト血栓症	1 (<0.1%)	0	0	0
Vascular procedure complication	血管処置合併症	1 (<0.1%)	0	0	0
Vascular pseudoaneurysm	血管偽動脈瘤	2 (<0.1%)	1 (<0.1%)	1 (<0.1%)	0
Wound complication	創合併症	2 (<0.1%)	0	0	0
Wound dehiscence	創離開	6 (0.2%)	4 (0.1%)	0	0
Wound haemorrhage	創傷出血	2 (<0.1%)	0	1 (<0.1%)	0
Wound necrosis	創壊死	1 (<0.1%)	3 (<0.1%)	0	0
Wrist fracture	手首関節骨折	0	1 (<0.1%)	0	0
Investigations	臨床検査	39 (1.3%)	44 (1.5%)	7 (0.2%)	3 (<0.1%)
Angiogram peripheral	末梢血管造影	1 (<0.1%)	0	0	0
Ankle brachial index decreased	足関節上腕血圧比減少	1 (<0.1%)	2 (<0.1%)	0	0
Aortogram abnormal	大動脈造影異常	1 (<0.1%)	0	0	0
Arteriogram carotid	頚動脈造影	0	1 (<0.1%)	0	0
Aspiration bone marrow	骨髄穿刺	0	1 (<0.1%)	0	0
Biopsy lung	肺生検	1 (<0.1%)	0	0	0
Biopsy prostate	前立腺生検	0	1 (<0.1%)	0	0
Blood bilirubin increased	血中ビリルビン増加	0	1 (<0.1%)	0	0
Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	0	1 (<0.1%)	0	0
Blood creatinine increased	血中クレアチニン増加	1 (<0.1%)	2 (<0.1%)	0	1 (<0.1%)
Blood glucose increased	血中ブドウ糖増加	2 (<0.1%)	1 (<0.1%)	0	0
Blood lactate dehydrogenase increased	血中乳酸脱水素酵素増加	0	1 (<0.1%)	0	0
Blood lactic acid increased	血中乳酸増加	0	1 (<0.1%)	0	0
Blood potassium increased	血中カリウム増加	0	1 (<0.1%)	0	0
Blood pressure decreased	血圧低下	1 (<0.1%)	0	0	0
Blood pressure increased	血圧上昇	4 (0.1%)	7 (0.2%)	1 (<0.1%)	0
Blood triglycerides increased	血中トリグリセリド増加	0	1 (<0.1%)	0	0
Blood uric acid increased	血中尿酸増加	0	1 (<0.1%)	0	0
Blood urine present	尿中血陽性	0	1 (<0.1%)	0	1 (<0.1%)
Cardiac monitoring abnormal	心モニタリング異常	1 (<0.1%)	0	0	0
Cardiac stress test abnormal	心臓負荷試験異常	0	2 (<0.1%)	0	0
Cardiovascular function test abnormal	心血管機能検査異常	0	1 (<0.1%)	0	0
Coagulation time prolonged	凝固時間延長	1 (<0.1%)	0	1 (<0.1%)	0
Colonoscopy	結腸内視鏡検査	1 (<0.1%)	2 (<0.1%)	0	0
Cystoscopy	膀胱鏡検査	1 (<0.1%)	0	0	0
Ejection fraction decreased	駆出率減少	1 (<0.1%)	2 (<0.1%)	0	0
Glycosylated haemoglobin increased	グリコヘモグロビン増加	0	2 (<0.1%)	0	0
HIV test positive	ＨＩＶ検査陽性	0	1 (<0.1%)	0	0
Haematocrit decreased	ヘマトクリット減少	0	2 (<0.1%)	0	0
Haemoglobin decreased	ヘモグロビン減少	5 (0.2%)	2 (<0.1%)	2 (<0.1%)	1 (<0.1%)
Heart rate decreased	心拍数減少	1 (<0.1%)	0	0	0
Heart rate increased	心拍数増加	1 (<0.1%)	2 (<0.1%)	0	0

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Heart rate irregular	心拍数不整	1 (<0.1%)	0	0	0
Helicobacter test positive	ヘリコバクター検査陽性	0	1 (<0.1%)	0	0
Hepatic enzyme increased	肝酵素上昇	3 (<0.1%)	0	1 (<0.1%)	0
Hepatitis B virus test positive	Ｂ型肝炎ウイルス検査陽性	1 (<0.1%)	0	0	0
Immunoglobulins decreased	免疫グロブリン減少	1 (<0.1%)	0	0	0
Laboratory test abnormal	臨床検査異常	0	1 (<0.1%)	0	0
Low density lipoprotein increased	低比重リポ蛋白増加	0	1 (<0.1%)	0	0
Occult blood positive	便潜血陽性	2 (<0.1%)	0	2 (<0.1%)	0
Oxygen consumption increased	酸素消費量増加	1 (<0.1%)	0	0	0
Platelet count increased	血小板数増加	1 (<0.1%)	2 (<0.1%)	0	0
Prostatic specific antigen increased	前立腺特異性抗原増加	2 (<0.1%)	1 (<0.1%)	0	0
Serum ferritin decreased	血清フェリチン減少	0	1 (<0.1%)	0	0
Staphylococcus test positive	ブドウ球菌検査陽性	0	1 (<0.1%)	0	0
Vascular test	血管検査	1 (<0.1%)	0	0	0
Weight decreased	体重減少	3 (<0.1%)	2 (<0.1%)	0	0
Metabolism and nutrition disorders	代謝および栄養障害	82 (2.7%)	98 (3.2%)	1 (<0.1%)	1 (<0.1%)
Cachexia	悪液質	0	1 (<0.1%)	0	0
Decreased appetite	食欲減退	5 (0.2%)	5 (0.2%)	1 (<0.1%)	0
Dehydration	脱水	8 (0.3%)	3 (<0.1%)	0	0
Diabetes mellitus	糖尿病	8 (0.3%)	16 (0.5%)	0	0
Diabetes mellitus inadequate control	コントロール不良の糖尿病	3 (<0.1%)	3 (<0.1%)	0	0
Diabetic ketoacidosis	糖尿病性ケトアシドーシス	2 (<0.1%)	0	0	0
Diabetic metabolic decompensation	糖尿病性代謝代償不全	1 (<0.1%)	1 (<0.1%)	0	0
Dyslipidaemia	脂質異常症	1 (<0.1%)	4 (0.1%)	0	0
Folate deficiency	葉酸欠乏	2 (<0.1%)	0	0	0
Glucose tolerance impaired	耐糖能障害	0	2 (<0.1%)	0	0
Gout	痛風	5 (0.2%)	11 (0.4%)	0	1 (<0.1%)
Hypercholesterolaemia	高コレステロール血症	0	2 (<0.1%)	0	0
Hyperglycaemia	高血糖	4 (0.1%)	5 (0.2%)	0	0
Hyperglycaemic hyperosmolar nonketotic syndrome	高血糖性高浸透圧性非ケトン性症候群	0	1 (<0.1%)	0	0
Hyperhomocysteinaemia	高ホモシステイン血症	0	1 (<0.1%)	0	0
Hyperkalaemia	高カリウム血症	1 (<0.1%)	4 (0.1%)	0	0
Hyperlipidaemia	高脂血症	3 (<0.1%)	1 (<0.1%)	0	0
Hypertriglyceridaemia	高トリグリセリド血症	0	2 (<0.1%)	0	0
Hyperuricaemia	高尿酸血症	3 (<0.1%)	2 (<0.1%)	0	0
Hypoglycaemia	低血糖	3 (<0.1%)	7 (0.2%)	0	0
Hypokalaemia	低カリウム血症	2 (<0.1%)	4 (0.1%)	0	0
Hypomagnesaemia	低マグネシウム血症	1 (<0.1%)	2 (<0.1%)	0	0
Hyponatraemia	低ナトリウム血症	5 (0.2%)	7 (0.2%)	0	0
Hypophagia	過小食	0	1 (<0.1%)	0	0
Hypoproteinaemia	低蛋白血症	1 (<0.1%)	0	0	0
Impaired fasting glucose	空腹時血中ブドウ糖不良	1 (<0.1%)	0	0	0
Iron deficiency	鉄欠乏	3 (<0.1%)	0	0	0
Ketoacidosis	ケトアシドーシス	1 (<0.1%)	0	0	0

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Lactic acidosis	乳酸アシドーシス	1 (<0.1%)	0	0	0
Metabolic disorder	代謝障害	0	1 (<0.1%)	0	0
Polydipsia	多飲症	0	1 (<0.1%)	0	0
Type 1 diabetes mellitus	１型糖尿病	0	2 (<0.1%)	0	0
Type 2 diabetes mellitus	２型糖尿病	14 (0.5%)	12 (0.4%)	0	0
Type 3 diabetes mellitus	３型糖尿病	0	1 (<0.1%)	0	0
Vitamin B complex deficiency	ビタミンＢ群欠乏	1 (<0.1%)	0	0	0
Vitamin B12 deficiency	ビタミンＢ１２欠乏	0	3 (<0.1%)	0	0
Vitamin D deficiency	ビタミンＤ欠乏	5 (0.2%)	1 (<0.1%)	0	0
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	190 (6.3%)	211 (7.0%)	1 (<0.1%)	5 (0.2%)
Acquired claw toe	後天性鉤爪趾	0	1 (<0.1%)	0	0
Arthralgia	関節痛	17 (0.6%)	32 (1.1%)	0	0
Arthritis	関節炎	3 (<0.1%)	4 (0.1%)	0	0
Back pain	背部痛	24 (0.8%)	31 (1.0%)	0	0
Bone disorder	骨障害	1 (<0.1%)	1 (<0.1%)	0	0
Bone formation increased	骨形成亢進	0	1 (<0.1%)	0	0
Bone loss	骨喪失	1 (<0.1%)	0	0	0
Bone pain	骨痛	3 (<0.1%)	1 (<0.1%)	0	0
Bone swelling	骨腫脹	0	1 (<0.1%)	0	0
Bursitis	滑液包炎	5 (0.2%)	8 (0.3%)	0	0
Cervical spinal stenosis	頚部脊柱管狭窄症	0	1 (<0.1%)	0	0
Compartment syndrome	コンパートメント症候群	0	1 (<0.1%)	0	0
Diffuse idiopathic skeletal hyperostosis	びまん性特発性骨増殖症	0	1 (<0.1%)	0	0
Dupuytren's contracture	デュプイトラン拘縮	1 (<0.1%)	0	0	0
Enthesopathy	腱付着部症	0	1 (<0.1%)	0	0
Fistula	瘻孔	1 (<0.1%)	0	0	0
Flank pain	側腹部痛	1 (<0.1%)	1 (<0.1%)	0	0
Foot deformity	足変形	0	2 (<0.1%)	0	0
Fracture nonunion	骨折による偽関節	0	1 (<0.1%)	0	0
Gouty arthritis	痛風性関節炎	3 (<0.1%)	1 (<0.1%)	0	0
Gouty tophus	痛風結節	0	1 (<0.1%)	0	0
Groin pain	鼠径部痛	3 (<0.1%)	3 (<0.1%)	0	0
Intervertebral disc degeneration	椎間板変性症	3 (<0.1%)	0	0	0
Intervertebral disc disorder	椎間板障害	1 (<0.1%)	0	0	0
Intervertebral disc protrusion	椎間板突出	11 (0.4%)	11 (0.4%)	0	0
Joint ankylosis	関節強直	0	1 (<0.1%)	0	0
Joint effusion	関節滲出液	1 (<0.1%)	1 (<0.1%)	0	0
Joint stiffness	関節硬直	0	1 (<0.1%)	0	0
Joint swelling	関節腫脹	5 (0.2%)	2 (<0.1%)	0	0
Knee deformity	膝関節変形	0	1 (<0.1%)	0	0
Ligament disorder	靭帯障害	0	1 (<0.1%)	0	0
Limb discomfort	四肢不快感	2 (<0.1%)	2 (<0.1%)	0	0
Lumbar spinal stenosis	腰部脊柱管狭窄症	4 (0.1%)	3 (<0.1%)	0	0
Metatarsalgia	中足骨痛	0	1 (<0.1%)	0	0
Mobility decreased	運動性低下	1 (<0.1%)	0	0	0
Muscle discomfort	筋不快感	1 (<0.1%)	0	0	0
Muscle disorder	筋障害	0	1 (<0.1%)	0	0
Muscle spasms	筋痙縮	13 (0.4%)	13 (0.4%)	0	1 (<0.1%)
Muscle tightness	筋緊張	1 (<0.1%)	0	0	0
Muscle twitching	筋攣縮	1 (<0.1%)	0	0	0
Muscular weakness	筋力低下	5 (0.2%)	5 (0.2%)	0	1 (<0.1%)

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Musculoskeletal chest pain	筋骨格系胸痛	4 (0.1%)	1 (<0.1%)	0	0
Musculoskeletal discomfort	筋骨格不快感	0	1 (<0.1%)	0	0
Musculoskeletal disorder	筋骨格障害	0	1 (<0.1%)	0	0
Musculoskeletal pain	筋骨格痛	11 (0.4%)	12 (0.4%)	0	0
Myalgia	筋肉痛	5 (0.2%)	4 (0.1%)	0	0
Myopathy	ミオパチー	0	1 (<0.1%)	0	0
Myosclerosis	筋硬化症	1 (<0.1%)	0	0	0
Myositis	筋炎	1 (<0.1%)	0	0	0
Neck pain	頚部痛	2 (<0.1%)	1 (<0.1%)	0	0
Osteitis	骨炎	0	1 (<0.1%)	0	0
Osteoarthritis	変形性関節症	22 (0.7%)	25 (0.8%)	1 (<0.1%)	0
Osteochondrosis	骨端症	0	1 (<0.1%)	0	0
Osteonecrosis	骨壊死	1 (<0.1%)	1 (<0.1%)	0	0
Osteonecrosis of jaw	顎骨壊死	1 (<0.1%)	0	0	0
Osteopenia	骨減少症	1 (<0.1%)	0	0	0
Osteoporotic fracture	骨粗鬆症性骨折	1 (<0.1%)	1 (<0.1%)	0	0
Pain in extremity	四肢痛	52 (1.7%)	64 (2.1%)	0	3 (<0.1%)
Pathological fracture	病的骨折	1 (<0.1%)	0	0	0
Periarthritis	関節周囲炎	1 (<0.1%)	1 (<0.1%)	0	0
Plantar fascial fibromatosis	足底腱膜線維腫症	1 (<0.1%)	0	0	0
Plantar fasciitis	足底筋膜炎	0	3 (<0.1%)	0	0
Polymyalgia rheumatica	リウマチ性多発筋痛	3 (<0.1%)	2 (<0.1%)	0	0
Pseudarthrosis	偽関節	0	1 (<0.1%)	0	0
Psoriatic arthropathy	乾癬性関節症	1 (<0.1%)	0	0	0
Rhabdomyolysis	横紋筋融解症	0	1 (<0.1%)	0	0
Rheumatic disorder	リウマチ性障害	0	1 (<0.1%)	0	0
Rheumatoid arthritis	関節リウマチ	1 (<0.1%)	1 (<0.1%)	0	0
Rotator cuff syndrome	肩回旋筋腱板症候群	4 (0.1%)	3 (<0.1%)	0	0
Soft tissue disorder	軟部組織障害	1 (<0.1%)	0	0	0
Soft tissue necrosis	軟部組織壊死	1 (<0.1%)	1 (<0.1%)	0	0
Spinal osteoarthritis	変形性脊椎症	4 (0.1%)	4 (0.1%)	0	0
Spinal pain	脊椎痛	1 (<0.1%)	5 (0.2%)	0	0
Spinal stenosis	脊柱管狭窄症	10 (0.3%)	7 (0.2%)	0	0
Spondyloarthropathy	脊椎関節障害	1 (<0.1%)	0	0	0
Spondylolisthesis	脊椎すべり症	2 (<0.1%)	2 (<0.1%)	0	0
Synovial cyst	滑液嚢腫	0	1 (<0.1%)	0	0
Synovitis	滑膜炎	0	1 (<0.1%)	0	0
Systemic scleroderma	全身性強皮症	0	1 (<0.1%)	0	0
Tendon discomfort	腱不快感	1 (<0.1%)	0	0	0
Tendon disorder	腱障害	1 (<0.1%)	1 (<0.1%)	0	0
Tendon pain	腱痛	1 (<0.1%)	0	0	0
Tendonitis	腱炎	2 (<0.1%)	1 (<0.1%)	0	0
Tenosynovitis	腱鞘炎	0	1 (<0.1%)	0	0
Tenosynovitis stenosans	狭窄性腱鞘炎	0	1 (<0.1%)	0	0
Trigger finger	弾発指	1 (<0.1%)	1 (<0.1%)	0	0
Vertebral foraminal stenosis	椎間孔狭窄	0	1 (<0.1%)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	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）	120 (4.0%)	117 (3.9%)	1 (<0.1%)	0
Acute myeloid leukaemia	急性骨髄性白血病	1 (<0.1%)	0	0	0
Adenocarcinoma gastric	胃腺癌	0	1 (<0.1%)	0	0
Adenocarcinoma of colon	結腸腺癌	2 (<0.1%)	2 (<0.1%)	0	0
Adenolymphoma	腺リンパ腫	0	1 (<0.1%)	0	0

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Adrenal neoplasm	副腎新生物	1 (<0.1%)	0	0	0
Anogenital warts	肛門性器疣贅	0	1 (<0.1%)	0	0
B-cell lymphoma	Ｂ細胞性リンパ腫	1 (<0.1%)	1 (<0.1%)	0	0
Basal cell carcinoma	基底細胞癌	4 (0.1%)	7 (0.2%)	0	0
Benign laryngeal neoplasm	喉頭の良性新生物	1 (<0.1%)	0	0	0
Benign neoplasm	良性新生物	1 (<0.1%)	0	0	0
Benign neoplasm of skin	皮膚良性新生物	1 (<0.1%)	0	0	0
Benign ovarian tumour	卵巣良性腫瘍	1 (<0.1%)	0	0	0
Benign salivary gland neoplasm	唾液腺の良性新生物	1 (<0.1%)	0	0	0
Bile duct cancer	胆管癌	0	2 (<0.1%)	0	0
Bladder cancer	膀胱癌	4 (0.1%)	4 (0.1%)	0	0
Bladder cancer stage IV	膀胱癌第４期	0	1 (<0.1%)	0	0
Bladder neoplasm	膀胱新生物	2 (<0.1%)	1 (<0.1%)	0	0
Bladder transitional cell carcinoma	膀胱移行上皮癌	2 (<0.1%)	0	0	0
Bone cancer	骨癌	0	1 (<0.1%)	0	0
Brain neoplasm	脳新生物	0	1 (<0.1%)	0	0
Breast cancer	乳癌	2 (<0.1%)	1 (<0.1%)	0	0
Bronchial carcinoma	気管支癌	1 (<0.1%)	0	0	0
Central nervous system lymphoma	中枢神経系リンパ腫	1 (<0.1%)	0	0	0
Cervix carcinoma	子宮頚部癌	0	1 (<0.1%)	0	0
Cholangiocarcinoma	胆管細胞癌	1 (<0.1%)	0	0	0
Chronic lymphocytic leukaemia	慢性リンパ性白血病	1 (<0.1%)	1 (<0.1%)	0	0
Chronic lymphocytic leukaemia stage 0	慢性リンパ性白血病第０期	1 (<0.1%)	0	0	0
Chronic myelomonocytic leukaemia	慢性骨髄単球性白血病	0	1 (<0.1%)	0	0
Colon adenoma	大腸腺腫	2 (<0.1%)	1 (<0.1%)	0	0
Colon cancer	結腸癌	4 (0.1%)	4 (0.1%)	0	0
Colon cancer stage 0	結腸癌第０期	1 (<0.1%)	0	0	0
Colorectal adenocarcinoma	結腸直腸腺癌	0	1 (<0.1%)	0	0
Ductal adenocarcinoma of pancreas	膵腺管癌	0	1 (<0.1%)	0	0
Endometrial cancer	子宮内膜癌	1 (<0.1%)	0	0	0
Endometrial cancer metastatic	遠隔転移を伴う子宮内膜癌	0	1 (<0.1%)	0	0
Essential thrombocythaemia	本態性血小板血症	0	1 (<0.1%)	0	0
Follicular thyroid cancer	濾胞性甲状腺癌	1 (<0.1%)	0	0	0
Gastric adenoma	胃腺腫	1 (<0.1%)	0	0	0
Gastric cancer	胃癌	0	3 (<0.1%)	0	0
Gastric cancer stage II	胃癌第２期	0	1 (<0.1%)	0	0
Gastrointestinal adenocarcinoma	消化器腺癌	1 (<0.1%)	0	0	0
Gingival cancer	歯肉癌	1 (<0.1%)	0	0	0
Haemangioma	血管腫	1 (<0.1%)	0	0	0
Head and neck cancer	頭頚部癌	1 (<0.1%)	0	0	0
Hepatic cancer	肝癌	0	1 (<0.1%)	0	0
Hepatocellular carcinoma	肝細胞癌	1 (<0.1%)	0	0	0
Hodgkin's disease	ホジキン病	1 (<0.1%)	0	0	0
Hodgkin's disease stage IV	ホジキン病第４期	1 (<0.1%)	0	0	0
Keratoacanthoma	ケラトアカントーマ	0	1 (<0.1%)	0	0
Laryngeal cancer	喉頭癌	1 (<0.1%)	2 (<0.1%)	0	0
Laryngeal neoplasm	喉頭新生物	2 (<0.1%)	1 (<0.1%)	0	0

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Leiomyosarcoma	平滑筋肉腫	0	1 (<0.1%)	0	0
Lip and/or oral cavity cancer	口唇および口腔内癌	0	1 (<0.1%)	0	0
Lung adenocarcinoma	肺腺癌	4 (0.1%)	4 (0.1%)	0	0
Lung adenocarcinoma recurrent	再発肺腺癌	1 (<0.1%)	0	0	0
Lung adenocarcinoma stage IV	肺腺癌第４期	1 (<0.1%)	1 (<0.1%)	0	0
Lung cancer metastatic	遠隔転移を伴う肺癌	3 (<0.1%)	3 (<0.1%)	0	0
Lung carcinoma cell type unspecified recurrent	再発肺癌、細胞タイプ不明	1 (<0.1%)	0	0	0
Lung carcinoma cell type unspecified stage IV	肺癌第４期、細胞タイプ不明	1 (<0.1%)	0	0	0
Lung neoplasm	肺新生物	4 (0.1%)	4 (0.1%)	0	0
Lung neoplasm malignant	肺の悪性新生物	7 (0.2%)	13 (0.4%)	0	0
Lung squamous cell carcinoma metastatic	遠隔転移を伴う肺扁平上皮癌	0	1 (<0.1%)	0	0
Lung squamous cell carcinoma stage IV	肺扁平上皮癌第４期	1 (<0.1%)	0	0	0
Malignant genitourinary tract neoplasm	泌尿生殖器の悪性新生物	1 (<0.1%)	0	0	0
Malignant melanoma	悪性黒色腫	1 (<0.1%)	2 (<0.1%)	0	0
Malignant neoplasm papilla of Vater	ファーター乳頭部の悪性新生物	0	1 (<0.1%)	0	0
Metastases to central nervous system	中枢神経系転移	0	1 (<0.1%)	0	0
Metastases to liver	肝転移	4 (0.1%)	1 (<0.1%)	0	0
Metastases to lung	肺転移	1 (<0.1%)	0	0	0
Metastases to lymph nodes	リンパ節転移	2 (<0.1%)	1 (<0.1%)	0	0
Metastases to neck	頚部転移	0	1 (<0.1%)	0	0
Metastases to peritoneum	腹膜転移	0	1 (<0.1%)	0	0
Metastatic neoplasm	遠隔転移を伴う新生物	0	1 (<0.1%)	0	0
Metastatic squamous cell carcinoma	遠隔転移を伴う扁平上皮癌	0	1 (<0.1%)	0	0
Myelodysplastic syndrome	骨髄異形成症候群	1 (<0.1%)	1 (<0.1%)	1 (<0.1%)	0
Myeloproliferative neoplasm	骨髄増殖性新生物	1 (<0.1%)	0	0	0
Neoplasm malignant	悪性新生物	1 (<0.1%)	2 (<0.1%)	0	0
Neoplasm skin	皮膚の新生物	0	1 (<0.1%)	0	0
Neuroendocrine carcinoma	神経内分泌癌	1 (<0.1%)	0	0	0
Neuroendocrine carcinoma of the skin	皮膚神経内分泌癌	0	1 (<0.1%)	0	0
Non-small cell lung cancer	非小細胞肺癌	1 (<0.1%)	0	0	0
Non-small cell lung cancer metastatic	遠隔転移を伴う非小細胞肺癌	0	1 (<0.1%)	0	0
Oesophageal adenocarcinoma	食道腺癌	2 (<0.1%)	1 (<0.1%)	0	0
Oesophageal cancer metastatic	遠隔転移を伴う食道癌	1 (<0.1%)	1 (<0.1%)	0	0
Oesophageal carcinoma	食道癌	3 (<0.1%)	1 (<0.1%)	0	0
Oesophageal carcinoma recurrent	再発食道癌	1 (<0.1%)	1 (<0.1%)	0	0
Oesophageal neoplasm	食道新生物	1 (<0.1%)	1 (<0.1%)	0	0
Oropharyngeal cancer	中咽頭癌	1 (<0.1%)	2 (<0.1%)	0	0
Pancreatic carcinoma	膵癌	2 (<0.1%)	1 (<0.1%)	0	0
Pancreatic carcinoma stage IV	膵癌第４期	1 (<0.1%)	1 (<0.1%)	0	0

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Pancreatic neoplasm	膵新生物	0	1 (<0.1%)	0	0
Papillary serous endometrial carcinoma	乳頭状漿液性子宮内膜癌	0	1 (<0.1%)	0	0
Plasma cell myeloma	形質細胞性骨髄腫	1 (<0.1%)	0	0	0
Pleural mesothelioma	胸膜中皮腫	1 (<0.1%)	0	0	0
Polycythaemia vera	真性多血症	2 (<0.1%)	1 (<0.1%)	0	0
Prostate cancer	前立腺癌	9 (0.3%)	5 (0.2%)	0	0
Prostate cancer stage III	前立腺癌第３期	0	1 (<0.1%)	0	0
Prostatic adenoma	前立腺腺腫	0	1 (<0.1%)	0	0
Rectal adenocarcinoma	直腸腺癌	2 (<0.1%)	0	0	0
Rectal adenoma	直腸腺腫	1 (<0.1%)	0	0	0
Rectal cancer	直腸癌	1 (<0.1%)	1 (<0.1%)	0	0
Rectal cancer stage I	直腸癌第１期	0	1 (<0.1%)	0	0
Rectal cancer stage IV	直腸癌第４期	1 (<0.1%)	0	0	0
Rectal neoplasm	直腸新生物	1 (<0.1%)	1 (<0.1%)	0	0
Rectosigmoid cancer	直腸Ｓ状結腸癌	0	1 (<0.1%)	0	0
Renal cancer	腎癌	3 (<0.1%)	0	0	0
Renal cell carcinoma	腎細胞癌	0	1 (<0.1%)	0	0
Renal neoplasm	腎新生物	1 (<0.1%)	1 (<0.1%)	0	0
Respiratory tract neoplasm	気道新生物	0	1 (<0.1%)	0	0
Salivary gland adenoma	唾液腺腫	1 (<0.1%)	0	0	0
Skin cancer	皮膚癌	1 (<0.1%)	0	0	0
Skin papilloma	皮膚乳頭腫	0	1 (<0.1%)	0	0
Skin squamous cell carcinoma recurrent	再発皮膚有棘細胞癌	1 (<0.1%)	0	0	0
Small cell carcinoma	小細胞癌	0	1 (<0.1%)	0	0
Small cell lung cancer	小細胞肺癌	2 (<0.1%)	0	0	0
Spinal meningioma benign	良性脊髄髄膜腫	1 (<0.1%)	0	0	0
Squamous cell carcinoma	扁平上皮癌	0	1 (<0.1%)	0	0
Squamous cell carcinoma of lung	肺扁平上皮癌	1 (<0.1%)	2 (<0.1%)	0	0
Squamous cell carcinoma of skin	皮膚有棘細胞癌	2 (<0.1%)	1 (<0.1%)	0	0
Squamous cell carcinoma of the oral cavity	口腔内扁平上皮癌	1 (<0.1%)	2 (<0.1%)	0	0
Squamous cell carcinoma of the tongue	舌扁平上皮癌	0	2 (<0.1%)	0	0
T-cell lymphoma	Ｔ細胞性リンパ腫	1 (<0.1%)	0	0	0
Tongue neoplasm	舌新生物	1 (<0.1%)	0	0	0
Transitional cell carcinoma	移行上皮癌	2 (<0.1%)	3 (<0.1%)	0	0
Nervous system disorders	神経系障害	156 (5.2%)	190 (6.3%)	11 (0.4%)	5 (0.2%)
Alcoholic seizure	アルコール性痙攣	0	1 (<0.1%)	0	0
Altered state of consciousness	意識変容状態	1 (<0.1%)	0	0	0
Amputation stump pain	断端痛	1 (<0.1%)	0	0	0
Balance disorder	平衡障害	0	1 (<0.1%)	0	0
Brachial plexopathy	腕神経叢障害	1 (<0.1%)	0	0	0
Brain injury	脳損傷	1 (<0.1%)	0	0	0
Burning sensation	灼熱感	1 (<0.1%)	1 (<0.1%)	0	0
Carotid arteriosclerosis	頚動脈硬化症	0	2 (<0.1%)	0	0
Carotid artery disease	頚動脈疾患	1 (<0.1%)	1 (<0.1%)	0	0
Carotid artery occlusion	頚動脈閉塞	0	1 (<0.1%)	0	0
Carotid artery stenosis	頚動脈狭窄	20 (0.7%)	28 (0.9%)	0	0
Carpal tunnel syndrome	手根管症候群	3 (<0.1%)	8 (0.3%)	0	0
Cerebellar atrophy	小脳萎縮	1 (<0.1%)	0	0	0

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Cerebral atrophy	大脳萎縮	2 (<0.1%)	1 (<0.1%)	0	0
Cerebral calcification	大脳石灰化	1 (<0.1%)	0	0	0
Cerebral infarction	脳梗塞	0	2 (<0.1%)	0	0
Cerebral small vessel ischaemic disease	虚血性脳小血管疾患	2 (<0.1%)	0	0	0
Cerebrovascular disorder	脳血管障害	0	1 (<0.1%)	0	0
Cervical radiculopathy	頚髄神経根障害	1 (<0.1%)	2 (<0.1%)	0	0
Cervicobrachial syndrome	頚腕症候群	1 (<0.1%)	0	0	0
Cervicogenic vertigo	頚原性回転性めまい	0	1 (<0.1%)	0	0
Cognitive disorder	認知障害	1 (<0.1%)	2 (<0.1%)	0	0
Colloid brain cyst	脳コロイド嚢胞	0	1 (<0.1%)	0	0
Cranial nerve disorder	脳神経障害	0	1 (<0.1%)	0	0
Dementia	認知症	4 (0.1%)	2 (<0.1%)	0	0
Dementia Alzheimer's type	アルツハイマー型認知症	0	1 (<0.1%)	0	0
Diabetic neuropathy	糖尿病性ニューロパチー	5 (0.2%)	6 (0.2%)	0	0
Dizziness	浮動性めまい	25 (0.8%)	29 (1.0%)	5 (0.2%)	4 (0.1%)
Drop attacks	転倒発作	0	1 (<0.1%)	0	0
Dysaesthesia	異常感覚	0	1 (<0.1%)	0	0
Dysarthria	構語障害	1 (<0.1%)	0	0	0
Dysgeusia	味覚不全	1 (<0.1%)	0	0	0
Encephalopathy	脳症	0	1 (<0.1%)	0	0
Epilepsy	てんかん	2 (<0.1%)	1 (<0.1%)	0	0
Facial paralysis	顔面麻痺	1 (<0.1%)	1 (<0.1%)	0	0
Facial paresis	顔面不全麻痺	1 (<0.1%)	0	0	0
Facial spasm	顔面痙攣	1 (<0.1%)	0	0	0
Guillain-Barre syndrome	ギラン・バレー症候群	0	1 (<0.1%)	0	0
Headache	頭痛	18 (0.6%)	19 (0.6%)	5 (0.2%)	1 (<0.1%)
Hemiparaesthesia	片側錯感覚	1 (<0.1%)	0	0	0
Hemiparesis	不全片麻痺	0	1 (<0.1%)	0	0
Horner's syndrome	ホルネル症候群	0	1 (<0.1%)	0	0
Hyperaesthesia	知覚過敏	1 (<0.1%)	0	0	0
Hyperkinesia	運動過多	0	1 (<0.1%)	0	0
Hypertensive encephalopathy	高血圧性脳症	0	1 (<0.1%)	0	0
Hypoaesthesia	感覚鈍麻	6 (0.2%)	8 (0.3%)	0	0
Hypotonia	筋緊張低下	1 (<0.1%)	0	0	0
Intercostal neuralgia	肋間神経痛	2 (<0.1%)	0	0	0
Intracranial aneurysm	頭蓋内動脈瘤	0	1 (<0.1%)	0	0
Ischaemic neuropathy	虚血性ニューロパチー	0	2 (<0.1%)	0	0
Ischaemic stroke	虚血性脳卒中	0	1 (<0.1%)	0	0
Loss of consciousness	意識消失	1 (<0.1%)	1 (<0.1%)	0	0
Lumbar radiculopathy	腰髄神経根障害	4 (0.1%)	2 (<0.1%)	0	0
Lumbosacral radiculopathy	腰仙部神経根障害	0	1 (<0.1%)	0	0
Memory impairment	記憶障害	2 (<0.1%)	1 (<0.1%)	0	0
Mental impairment	精神的機能障害	1 (<0.1%)	0	0	0
Meralgia paraesthetica	感覚異常性大腿神経痛	1 (<0.1%)	1 (<0.1%)	0	0
Migraine	片頭痛	1 (<0.1%)	1 (<0.1%)	0	0
Monoparesis	不全単麻痺	0	1 (<0.1%)	0	0
Morton's neuralgia	モートン神経痛	0	1 (<0.1%)	0	0
Motor neurone disease	運動ニューロン疾患	0	1 (<0.1%)	0	0
Myelopathy	脊髄症	1 (<0.1%)	1 (<0.1%)	0	0
Myoclonus	ミオクローヌス	1 (<0.1%)	0	0	0
Nerve compression	神経圧迫	1 (<0.1%)	0	0	0
Nervous system disorder	神経系障害	1 (<0.1%)	0	0	0
Neuralgia	神経痛	2 (<0.1%)	4 (0.1%)	0	0
Neuropathy peripheral	末梢性ニューロパチー	5 (0.2%)	1 (<0.1%)	0	0

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Occipital neuralgia	後頭神経痛	1 (<0.1%)	0	0	0
Orthostatic intolerance	起立不耐性	0	1 (<0.1%)	0	0
Paraesthesia	錯感覚	4 (0.1%)	9 (0.3%)	0	0
Parkinson's disease	パーキンソン病	3 (<0.1%)	3 (<0.1%)	0	0
Parkinsonism	パーキンソニズム	1 (<0.1%)	1 (<0.1%)	0	0
Peripheral nerve lesion	末梢神経病変	0	1 (<0.1%)	0	0
Peripheral nerve paresis	末梢神経不全麻痺	0	1 (<0.1%)	0	0
Peripheral sensorimotor neuropathy	末梢性感覚運動ニューロパチー	1 (<0.1%)	0	0	0
Phantom limb syndrome	幻肢症候群	0	1 (<0.1%)	0	0
Polyneuropathy	多発ニューロパチー	1 (<0.1%)	4 (0.1%)	0	0
Poor quality sleep	睡眠の質低下	1 (<0.1%)	0	0	0
Presyncope	失神寸前の状態	3 (<0.1%)	3 (<0.1%)	0	0
Pseudoradicular syndrome	偽性根症候群	1 (<0.1%)	0	0	0
Radiculopathy	神経根障害	3 (<0.1%)	0	0	0
Restless legs syndrome	下肢静止不能症候群	2 (<0.1%)	1 (<0.1%)	0	0
Sacral radiculopathy	仙部神経根症	1 (<0.1%)	0	0	0
Sciatica	坐骨神経痛	7 (0.2%)	17 (0.6%)	0	0
Seizure	痙攣発作	0	1 (<0.1%)	0	0
Senile dementia	老年認知症	1 (<0.1%)	0	0	0
Somnolence	傾眠	1 (<0.1%)	1 (<0.1%)	0	0
Spinal claudication	脊髄性跛行症	4 (0.1%)	1 (<0.1%)	0	0
Spinal cord compression	脊髄圧迫	0	1 (<0.1%)	0	0
Status epilepticus	てんかん重積状態	1 (<0.1%)	0	0	0
Syncope	失神	12 (0.4%)	20 (0.7%)	1 (<0.1%)	0
Tension headache	緊張性頭痛	1 (<0.1%)	1 (<0.1%)	0	0
Thermohyperaesthesia	温度覚過敏	1 (<0.1%)	0	0	0
Tonic convulsion	強直性痙攣	1 (<0.1%)	0	0	0
Tremor	振戦	1 (<0.1%)	1 (<0.1%)	0	0
Trigeminal neuralgia	三叉神経痛	1 (<0.1%)	1 (<0.1%)	0	0
Vascular dementia	血管性認知症	1 (<0.1%)	0	0	0
Vascular encephalopathy	血管性脳症	1 (<0.1%)	3 (<0.1%)	0	0
Vertebral artery stenosis	椎骨動脈狭窄	0	1 (<0.1%)	0	0
Visual field defect	視野欠損	0	1 (<0.1%)	0	0
Product issues	製品の問題	8 (0.3%)	1 (<0.1%)	0	0
Device breakage	医療機器破損	2 (<0.1%)	0	0	0
Device connection issue	医療機器接続不具合	1 (<0.1%)	0	0	0
Device failure	医療機器不具合	1 (<0.1%)	0	0	0
Device loosening	医療機器のゆるみ	2 (<0.1%)	0	0	0
Device material opacification	医療機器材質の混濁	1 (<0.1%)	0	0	0
Device occlusion	医療機器閉塞	0	1 (<0.1%)	0	0
Patient-device incompatibility	患者と医療機器間の不適合	1 (<0.1%)	0	0	0
Psychiatric disorders	精神障害	30 (1.0%)	41 (1.4%)	2 (<0.1%)	4 (0.1%)
Acute psychosis	急性精神病	0	1 (<0.1%)	0	0
Adjustment disorder with depressed mood	抑うつ気分を伴う適応障害	0	1 (<0.1%)	0	0
Alcohol abuse	アルコール乱用	1 (<0.1%)	2 (<0.1%)	0	0
Alcohol withdrawal syndrome	アルコール離脱症候群	0	1 (<0.1%)	0	0
Alcoholism	アルコール症	1 (<0.1%)	0	0	0
Anxiety	不安	3 (<0.1%)	3 (<0.1%)	0	1 (<0.1%)
Completed suicide	自殺既遂	4 (0.1%)	0	0	0
Confusional state	錯乱状態	2 (<0.1%)	2 (<0.1%)	0	0
Delirium	譫妄	0	4 (0.1%)	0	0

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Depression	うつ病	12 (0.4%)	18 (0.6%)	0	1 (<0.1%)
Drug abuse	薬物乱用	0	1 (<0.1%)	0	0
Insomnia	不眠症	2 (<0.1%)	1 (<0.1%)	1 (<0.1%)	0
Intentional self-injury	故意の自傷行為	1 (<0.1%)	0	0	0
Loss of libido	リビドー消失	1 (<0.1%)	0	0	0
Mental status changes	精神状態変化	1 (<0.1%)	4 (0.1%)	0	0
Mood altered	気分変化	0	1 (<0.1%)	0	1 (<0.1%)
Nervousness	神経過敏	0	1 (<0.1%)	0	0
Organic brain syndrome	器質性脳症候群	1 (<0.1%)	1 (<0.1%)	0	0
Restlessness	落ち着きのなさ	1 (<0.1%)	1 (<0.1%)	0	1 (<0.1%)
Sleep disorder	睡眠障害	2 (<0.1%)	1 (<0.1%)	1 (<0.1%)	0
Stress	ストレス	0	1 (<0.1%)	0	0
Transient psychosis	一過性精神病	1 (<0.1%)	0	0	0
Renal and urinary disorders	腎および尿路障害	75 (2.5%)	62 (2.1%)	4 (0.1%)	4 (0.1%)
Acute kidney injury	急性腎障害	14 (0.5%)	21 (0.7%)	0	1 (<0.1%)
Bladder irritation	膀胱刺激症状	1 (<0.1%)	0	0	0
Bladder mass	膀胱腫瘤	1 (<0.1%)	0	0	0
Calculus bladder	膀胱結石	2 (<0.1%)	1 (<0.1%)	0	0
Calculus urinary	尿路結石	0	1 (<0.1%)	0	0
Chronic kidney disease	慢性腎臓病	11 (0.4%)	2 (<0.1%)	0	0
Diabetic nephropathy	糖尿病性腎症	1 (<0.1%)	0	0	0
Dysuria	排尿困難	3 (<0.1%)	4 (0.1%)	0	0
End stage renal disease	末期腎疾患	1 (<0.1%)	2 (<0.1%)	0	0
Haematuria	血尿	4 (0.1%)	2 (<0.1%)	3 (<0.1%)	2 (<0.1%)
Microalbuminuria	ミクロアルブミン尿	0	1 (<0.1%)	0	0
Nephrolithiasis	腎結石症	4 (0.1%)	3 (<0.1%)	0	0
Nephrosclerosis	腎硬化症	0	1 (<0.1%)	0	0
Nocturia	夜間頻尿	0	1 (<0.1%)	0	0
Pelvi-ureteric obstruction	骨盤部尿管閉塞	1 (<0.1%)	0	0	0
Pollakiuria	頻尿	1 (<0.1%)	1 (<0.1%)	0	0
Polyuria	多尿	1 (<0.1%)	1 (<0.1%)	0	0
Proteinuria	蛋白尿	1 (<0.1%)	0	0	0
Renal artery stenosis	腎動脈狭窄症	2 (<0.1%)	2 (<0.1%)	0	0
Renal colic	腎仙痛	4 (0.1%)	1 (<0.1%)	0	0
Renal cyst	腎嚢胞	2 (<0.1%)	2 (<0.1%)	0	0
Renal failure	腎不全	7 (0.2%)	7 (0.2%)	1 (<0.1%)	0
Renal impairment	腎機能障害	5 (0.2%)	5 (0.2%)	0	1 (<0.1%)
Renal injury	腎損傷	0	1 (<0.1%)	0	0
Stress urinary incontinence	腹圧性尿失禁	0	1 (<0.1%)	0	0
Ureteric fistula	尿管瘻	1 (<0.1%)	0	0	0
Ureterolithiasis	尿管結石症	1 (<0.1%)	1 (<0.1%)	0	0
Urethral stenosis	尿道狭窄	1 (<0.1%)	3 (<0.1%)	0	0
Urge incontinence	切迫性尿失禁	1 (<0.1%)	1 (<0.1%)	0	0
Urinary incontinence	尿失禁	3 (<0.1%)	2 (<0.1%)	0	0
Urinary retention	尿閉	4 (0.1%)	3 (<0.1%)	0	0
Urinary tract obstruction	尿路閉塞	2 (<0.1%)	0	0	0
Reproductive system and breast disorders	生殖系および乳房障害	20 (0.7%)	19 (0.6%)	0	0
Benign prostatic hyperplasia	良性前立腺肥大症	7 (0.2%)	11 (0.4%)	0	0
Cervical polyp	子宮頚管ポリープ	1 (<0.1%)	0	0	0
Erectile dysfunction	勃起不全	0	1 (<0.1%)	0	0
Gynaecomastia	女性化乳房	1 (<0.1%)	0	0	0
Ovarian cyst	卵巣嚢胞	1 (<0.1%)	0	0	0
Pelvic pain	骨盤痛	2 (<0.1%)	0	0	0
Pelvic prolapse	骨盤脱	0	1 (<0.1%)	0	0

Primary system organ class Preferred term MedDRA version 22.1	Primary system organ class Preferred term MedDRA version 22.1	Treatment-emergent Rivaroxaban 2.5 mg bid, Aspirin 100mg od N=3027 (100%)	Treatment-emergent Rivaroxaban Placebo, Aspirin 100 mg od N=3019 (100%)	Study drug-related Rivaroxaban 2.5 mg bid, Aspirin 100mg od N=3027 (100%)	Study drug-related Rivaroxaban Placebo, Aspirin 100 mg od N=3019 (100%)
Prostatic obstruction	前立腺閉塞	1 (<0.1%)	0	0	0
Prostatism	前立腺症	1 (<0.1%)	1 (<0.1%)	0	0
Prostatitis	前立腺炎	2 (<0.1%)	1 (<0.1%)	0	0
Scrotal swelling	陰嚢腫脹	0	1 (<0.1%)	0	0
Sexual dysfunction	性機能不全	0	1 (<0.1%)	0	0
Spermatocele	精液瘤	1 (<0.1%)	0	0	0
Testicular disorder	精巣障害	1 (<0.1%)	0	0	0
Uterine prolapse	子宮脱	2 (<0.1%)	0	0	0
Vulval eczema	外陰部湿疹	0	1 (<0.1%)	0	0
Vulvar dysplasia	外陰異形成	1 (<0.1%)	0	0	0
Vulvovaginal pain	外陰腟痛	0	1 (<0.1%)	0	0
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	94 (3.1%)	92 (3.0%)	7 (0.2%)	3 (<0.1%)
Acute pulmonary oedema	急性肺水腫	2 (<0.1%)	2 (<0.1%)	0	0
Acute respiratory distress syndrome	急性呼吸窮迫症候群	1 (<0.1%)	0	0	0
Acute respiratory failure	急性呼吸不全	2 (<0.1%)	7 (0.2%)	0	0
Allergic cough	アレルギー性咳嗽	0	1 (<0.1%)	0	0
Aspiration	誤嚥	1 (<0.1%)	0	0	0
Asthma	喘息	1 (<0.1%)	2 (<0.1%)	0	0
Bronchiectasis	気管支拡張症	2 (<0.1%)	0	0	0
Bronchitis chronic	慢性気管支炎	0	3 (<0.1%)	0	0
Bronchospasm	気管支痙攣	0	1 (<0.1%)	0	0
Catarrh	カタル	0	1 (<0.1%)	0	0
Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	20 (0.7%)	13 (0.4%)	0	0
Chronic respiratory disease	慢性呼吸疾患	1 (<0.1%)	0	0	0
Cough	咳嗽	9 (0.3%)	14 (0.5%)	0	0
Dyspnoea	呼吸困難	13 (0.4%)	21 (0.7%)	0	1 (<0.1%)
Dyspnoea at rest	安静時呼吸困難	1 (<0.1%)	0	0	0
Dyspnoea exertional	労作性呼吸困難	3 (<0.1%)	5 (0.2%)	0	0
Emphysema	肺気腫	1 (<0.1%)	0	0	0
Epistaxis	鼻出血	9 (0.3%)	3 (<0.1%)	6 (0.2%)	1 (<0.1%)
Haemoptysis	喀血	0	1 (<0.1%)	0	1 (<0.1%)
Hypoxia	低酸素症	2 (<0.1%)	0	0	0
Interstitial lung disease	間質性肺疾患	0	1 (<0.1%)	0	0
Lung infiltration	肺浸潤	0	1 (<0.1%)	0	0
Nasal discharge discolouration	鼻汁変色	1 (<0.1%)	0	1 (<0.1%)	0
Nasal dryness	鼻乾燥	0	1 (<0.1%)	0	0
Nasal obstruction	鼻閉塞	1 (<0.1%)	0	0	0
Nasal septum deviation	鼻中隔弯曲	1 (<0.1%)	1 (<0.1%)	0	0
Oropharyngeal pain	口腔咽頭痛	1 (<0.1%)	2 (<0.1%)	0	0
Pharyngeal lesion	咽頭病変	0	1 (<0.1%)	0	0
Pharyngeal swelling	咽頭腫脹	0	1 (<0.1%)	0	0
Pleural effusion	胸水	6 (0.2%)	4 (0.1%)	0	0
Pneumonia aspiration	誤嚥性肺炎	4 (0.1%)	2 (<0.1%)	0	0
Pneumonitis	肺臓炎	0	1 (<0.1%)	0	0
Pneumothorax	気胸	1 (<0.1%)	2 (<0.1%)	0	0
Pneumothorax spontaneous	自然気胸	1 (<0.1%)	0	0	0
Productive cough	湿性咳嗽	0	1 (<0.1%)	0	0
Pulmonary congestion	肺うっ血	1 (<0.1%)	0	0	0
Pulmonary embolism	肺塞栓症	0	1 (<0.1%)	0	0
Pulmonary fibrosis	肺線維症	0	1 (<0.1%)	0	0
Pulmonary hypertension	肺高血圧症	1 (<0.1%)	0	0	0
Pulmonary mass	肺腫瘤	3 (<0.1%)	1 (<0.1%)	0	0

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Pulmonary oedema	肺水腫	1 (<0.1%)	2 (<0.1%)	0	0
Respiratory distress	呼吸窮迫	1 (<0.1%)	1 (<0.1%)	0	0
Respiratory failure	呼吸不全	5 (0.2%)	4 (0.1%)	0	0
Rhinitis allergic	アレルギー性鼻炎	1 (<0.1%)	0	0	0
Rhinorrhoea	鼻漏	1 (<0.1%)	1 (<0.1%)	0	0
Sinus polyp	副鼻腔ポリープ	1 (<0.1%)	0	0	0
Sleep apnoea syndrome	睡眠時無呼吸症候群	1 (<0.1%)	1 (<0.1%)	0	0
Sneezing	くしゃみ	0	1 (<0.1%)	0	0
Status asthmaticus	喘息発作重積	0	1 (<0.1%)	0	0
Tonsillar cyst	扁桃嚢胞	0	1 (<0.1%)	0	0
Vocal cord inflammation	声帯の炎症	1 (<0.1%)	0	0	0
Vocal cord polyp	声帯ポリープ	0	1 (<0.1%)	0	0
Wheezing	喘鳴	1 (<0.1%)	0	0	0
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	111 (3.7%)	113 (3.7%)	21 (0.7%)	28 (0.9%)
Actinic keratosis	光線角化症	1 (<0.1%)	0	0	0
Alopecia	脱毛症	3 (<0.1%)	0	0	0
Angioedema	血管浮腫	0	2 (<0.1%)	0	0
Blister	水疱	0	1 (<0.1%)	0	0
Brow ptosis	眉毛下垂	1 (<0.1%)	0	0	0
Decubitus ulcer	褥瘡性潰瘍	2 (<0.1%)	4 (0.1%)	0	0
Dermal cyst	皮膚嚢腫	1 (<0.1%)	2 (<0.1%)	0	0
Dermatitis	皮膚炎	2 (<0.1%)	3 (<0.1%)	0	0
Dermatitis allergic	アレルギー性皮膚炎	2 (<0.1%)	4 (0.1%)	1 (<0.1%)	2 (<0.1%)
Dermatitis contact	接触皮膚炎	0	2 (<0.1%)	0	1 (<0.1%)
Diabetic foot	糖尿病性足病変	14 (0.5%)	9 (0.3%)	0	0
Diabetic ulcer	糖尿病性潰瘍	2 (<0.1%)	0	0	0
Drug eruption	薬疹	2 (<0.1%)	1 (<0.1%)	1 (<0.1%)	0
Dry skin	皮膚乾燥	0	2 (<0.1%)	0	1 (<0.1%)
Ecchymosis	斑状出血	5 (0.2%)	2 (<0.1%)	2 (<0.1%)	2 (<0.1%)
Eczema	湿疹	2 (<0.1%)	3 (<0.1%)	0	0
Erythema	紅斑	2 (<0.1%)	5 (0.2%)	0	1 (<0.1%)
Hair growth abnormal	毛髪成長異常	0	1 (<0.1%)	0	0
Henoch-Schonlein purpura	ヘノッホ・シェーンライン紫斑病	0	1 (<0.1%)	0	1 (<0.1%)
Hidradenitis	汗腺炎	0	1 (<0.1%)	0	0
Hyperhidrosis	多汗症	1 (<0.1%)	1 (<0.1%)	0	1 (<0.1%)
Intertrigo	間擦疹	0	1 (<0.1%)	0	0
Ischaemic skin ulcer	虚血性皮膚潰瘍	3 (<0.1%)	1 (<0.1%)	0	0
Melanocytic hyperplasia	メラニン細胞過形成	1 (<0.1%)	0	0	0
Myxoid cyst	粘液様嚢胞	1 (<0.1%)	0	0	0
Nail dystrophy	爪ジストロフィー	1 (<0.1%)	0	0	0
Neurodermatitis	神経皮膚炎	1 (<0.1%)	1 (<0.1%)	0	0
Neuropathic ulcer	神経障害性潰瘍	0	1 (<0.1%)	0	0
Pemphigoid	類天疱瘡	2 (<0.1%)	0	0	0
Pemphigus	天疱瘡	0	1 (<0.1%)	0	0
Petechiae	点状出血	1 (<0.1%)	1 (<0.1%)	0	1 (<0.1%)
Precancerous skin lesion	前癌性皮膚病変	0	1 (<0.1%)	0	0
Prurigo	痒疹	1 (<0.1%)	0	1 (<0.1%)	0
Pruritus	そう痒症	10 (0.3%)	7 (0.2%)	4 (0.1%)	3 (<0.1%)
Pruritus allergic	アレルギー性そう痒症	2 (<0.1%)	1 (<0.1%)	2 (<0.1%)	1 (<0.1%)
Psoriasis	乾癬	2 (<0.1%)	0	0	0
Rash	発疹	15 (0.5%)	17 (0.6%)	8 (0.3%)	11 (0.4%)
Rash erythematous	紅斑性皮疹	0	1 (<0.1%)	0	0
Rash macular	斑状皮疹	0	1 (<0.1%)	0	0
Rash papular	丘疹性皮疹	0	1 (<0.1%)	0	0
Rash pruritic	そう痒性皮疹	1 (<0.1%)	2 (<0.1%)	0	1 (<0.1%)
Scar pain	瘢痕痛	0	1 (<0.1%)	0	0

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Skin discolouration	皮膚変色	1 (<0.1%)	0	0	0
Skin disorder	皮膚障害	2 (<0.1%)	0	0	0
Skin exfoliation	皮膚剥脱	1 (<0.1%)	0	0	0
Skin lesion	皮膚病変	1 (<0.1%)	1 (<0.1%)	0	0
Skin necrosis	皮膚壊死	1 (<0.1%)	2 (<0.1%)	0	0
Skin reaction	皮膚反応	0	1 (<0.1%)	0	1 (<0.1%)
Skin ulcer	皮膚潰瘍	24 (0.8%)	26 (0.9%)	0	0
Solar lentigo	日光黒子	1 (<0.1%)	0	0	0
Stasis dermatitis	うっ滞性皮膚炎	1 (<0.1%)	0	0	0
Toxic skin eruption	中毒性皮疹	0	1 (<0.1%)	0	0
Urticaria	蕁麻疹	8 (0.3%)	5 (0.2%)	4 (0.1%)	3 (<0.1%)
Social circumstances	社会環境	0	2 (<0.1%)	0	0
Disease risk factor	疾患の危険因子	0	2 (<0.1%)	0	0
Surgical and medical procedures	外科および内科処置	44 (1.5%)	45 (1.5%)	1 (<0.1%)	0
Amputation	切断	1 (<0.1%)	0	0	0
Angioplasty	血管形成	3 (<0.1%)	3 (<0.1%)	0	0
Bladder calculus removal	膀胱結石除去	0	1 (<0.1%)	0	0
Bladder neoplasm surgery	膀胱新生物手術	1 (<0.1%)	1 (<0.1%)	0	0
Bladder polypectomy	膀胱ポリープ切除	0	1 (<0.1%)	0	0
Blepharoplasty	眼瞼形成	1 (<0.1%)	0	0	0
Brain tumour operation	脳腫瘍手術	1 (<0.1%)	0	0	0
Cardioversion	心臓除細動	1 (<0.1%)	0	0	0
Carotid endarterectomy	頚動脈内膜剥離術	2 (<0.1%)	1 (<0.1%)	0	0
Cataract operation	白内障手術	5 (0.2%)	8 (0.3%)	0	0
Cholecystectomy	胆嚢切除	0	1 (<0.1%)	0	0
Cystoprostatectomy	膀胱前立腺摘除	1 (<0.1%)	1 (<0.1%)	0	0
Debridement	デブリードマン	2 (<0.1%)	0	0	0
Dental care	デンタルケア	1 (<0.1%)	1 (<0.1%)	0	0
Elective surgery	待期的手術	1 (<0.1%)	0	0	0
Eventration repair	脱出臓器還納	0	1 (<0.1%)	0	0
Eyelid operation	眼瞼手術	0	1 (<0.1%)	0	0
Foot amputation	足切断	1 (<0.1%)	1 (<0.1%)	0	0
Glaucoma surgery	緑内障手術	1 (<0.1%)	0	0	0
Hip arthroplasty	股関節形成	1 (<0.1%)	0	0	0
Inguinal hernia repair	鼠径部ヘルニア修復	1 (<0.1%)	0	0	0
Knee arthroplasty	膝関節形成	0	2 (<0.1%)	0	0
Large intestinal polypectomy	大腸ポリープ切除	0	1 (<0.1%)	0	0
Limb reconstructive surgery	四肢再建手術	0	2 (<0.1%)	0	0
Mole excision	色素性母斑切除	1 (<0.1%)	0	0	0
Neuroprosthesis implantation	神経補綴装置埋込み	1 (<0.1%)	0	0	0
Oral surgery	口腔手術	1 (<0.1%)	0	0	0
Papilloma excision	乳頭腫切除	0	1 (<0.1%)	0	0
Peripheral artery angioplasty	末梢動脈形成	1 (<0.1%)	2 (<0.1%)	0	0
Peripheral artery bypass	末梢動脈バイパス	0	1 (<0.1%)	0	0
Peripheral artery stent insertion	末梢動脈ステント挿入	1 (<0.1%)	0	0	0
Peripheral endarterectomy	末梢動脈内膜剥離術	0	1 (<0.1%)	0	0
Peripheral revascularisation	末梢血行再建	0	1 (<0.1%)	0	0
Polypectomy	ポリープ切除	1 (<0.1%)	1 (<0.1%)	0	0
Radical prostatectomy	根治的前立腺摘除	0	1 (<0.1%)	0	0

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Rehabilitation therapy	リハビリテーション療法	1 (<0.1%)	0	0	0
Sebaceous cyst excision	皮脂腺嚢胞切除	1 (<0.1%)	0	0	0
Sequestrectomy	腐骨摘出	1 (<0.1%)	0	0	0
Skin graft	植皮	1 (<0.1%)	0	0	0
Skin implant	皮膚内植込み	1 (<0.1%)	0	0	0
Spinal nerve stimulator implantation	脊髄神経刺激装置埋込み	1 (<0.1%)	0	0	0
Strabismus correction	斜視矯正術	1 (<0.1%)	0	0	0
Sympathectomy	交感神経切除	0	2 (<0.1%)	0	0
Synovectomy	滑膜切除	0	1 (<0.1%)	0	0
Tenoplasty	腱形成	1 (<0.1%)	0	0	0
Thyroidectomy	甲状腺摘除	0	1 (<0.1%)	0	0
Toe amputation	足指切断	1 (<0.1%)	1 (<0.1%)	0	0
Tooth extraction	抜歯	6 (0.2%)	5 (0.2%)	1 (<0.1%)	0
Transurethral bladder resection	経尿道的膀胱切除	0	1 (<0.1%)	0	0
Umbilical hernia repair	臍ヘルニア修復	1 (<0.1%)	0	0	0
Ureteral stent insertion	尿管ステント挿入	1 (<0.1%)	0	0	0
Vitrectomy	硝子体切除	1 (<0.1%)	1 (<0.1%)	0	0
Vascular disorders	血管障害	351 (11.6%)	370 (12.3%)	7 (0.2%)	5 (0.2%)
Angiopathy	血管障害	1 (<0.1%)	1 (<0.1%)	0	0
Aortic aneurysm	大動脈瘤	2 (<0.1%)	5 (0.2%)	0	0
Aortic arteriosclerosis	大動脈硬化症	1 (<0.1%)	0	0	0
Aortic dissection	大動脈解離	1 (<0.1%)	0	0	0
Aortic stenosis	大動脈狭窄	6 (0.2%)	6 (0.2%)	0	0
Arterial occlusive disease	動脈閉塞性疾患	1 (<0.1%)	1 (<0.1%)	0	0
Arteriosclerosis	動脈硬化症	1 (<0.1%)	1 (<0.1%)	0	0
Arteriovenous fistula	動静脈瘻	0	2 (<0.1%)	0	0
Blood pressure fluctuation	血圧変動	1 (<0.1%)	2 (<0.1%)	1 (<0.1%)	0
Blood pressure inadequately controlled	コントロール不良の血圧	1 (<0.1%)	1 (<0.1%)	0	0
Circulatory collapse	循環虚脱	1 (<0.1%)	2 (<0.1%)	0	0
Diabetic macroangiopathy	糖尿病性大血管障害	0	2 (<0.1%)	0	0
Diabetic microangiopathy	糖尿病性微小血管症	0	1 (<0.1%)	0	0
Dry gangrene	乾性壊疽	3 (<0.1%)	6 (0.2%)	0	0
Essential hypertension	本態性高血圧症	0	1 (<0.1%)	0	0
Extremity necrosis	四肢壊死	15 (0.5%)	12 (0.4%)	0	0
Haematoma	血腫	1 (<0.1%)	2 (<0.1%)	1 (<0.1%)	0
Hot flush	ほてり	0	1 (<0.1%)	0	0
Hypertension	高血圧	49 (1.6%)	53 (1.8%)	0	1 (<0.1%)
Hypertensive crisis	高血圧クリーゼ	16 (0.5%)	18 (0.6%)	0	0
Hypertensive emergency	高血圧緊急症	1 (<0.1%)	0	0	0
Hypertensive urgency	高血圧切迫症	0	1 (<0.1%)	0	0
Hypotension	低血圧	10 (0.3%)	3 (<0.1%)	1 (<0.1%)	1 (<0.1%)
Hypovolaemic shock	血液量減少性ショック	1 (<0.1%)	0	0	0
Iliac artery occlusion	腸骨動脈閉塞	1 (<0.1%)	0	0	0
Iliac artery stenosis	腸骨動脈狭窄	3 (<0.1%)	4 (0.1%)	0	0
Intermittent claudication	間欠性跛行	76 (2.5%)	91 (3.0%)	1 (<0.1%)	2 (<0.1%)
Ischaemic limb pain	虚血性四肢痛	2 (<0.1%)	1 (<0.1%)	0	0
Lymphatic fistula	リンパ瘻	2 (<0.1%)	3 (<0.1%)	0	0
Lymphocele	リンパ嚢腫	1 (<0.1%)	4 (0.1%)	0	0
Lymphoedema	リンパ浮腫	1 (<0.1%)	3 (<0.1%)	0	0
Lymphorrhoea	リンパ漏	3 (<0.1%)	2 (<0.1%)	0	0
Lymphostasis	リンパうっ滞	1 (<0.1%)	1 (<0.1%)	0	0

Primary system organ class Preferred term MedDRA version 22.1	Primary system organ class Preferred term MedDRA version 22.1	Treatment-emergent Rivaroxaban 2.5 mg bid, Aspirin 100mg od N=3027 (100%)	Treatment-emergent Rivaroxaban Placebo, Aspirin 100 mg od N=3019 (100%)	Study drug-related Rivaroxaban 2.5 mg bid, Aspirin 100mg od N=3027 (100%)	Study drug-related Rivaroxaban Placebo, Aspirin 100 mg od N=3019 (100%)
Microangiopathy	微小血管症	0	1 (<0.1%)	0	0
Orthostatic hypotension	起立性低血圧	0	1 (<0.1%)	0	0
Pallor	蒼白	0	1 (<0.1%)	0	0
Penetrating atherosclerotic ulcer	穿通性アテローム動脈硬化性潰瘍	0	1 (<0.1%)	0	0
Peripheral arterial occlusive disease	末梢動脈閉塞性疾患	98 (3.2%)	94 (3.1%)	2 (<0.1%)	0
Peripheral artery aneurysm	末梢動脈瘤	1 (<0.1%)	2 (<0.1%)	0	0
Peripheral artery dissection	末梢動脈解離	0	1 (<0.1%)	0	0
Peripheral artery occlusion	末梢動脈閉塞	9 (0.3%)	20 (0.7%)	0	0
Peripheral artery stenosis	末梢動脈狭窄	25 (0.8%)	21 (0.7%)	0	0
Peripheral artery thrombosis	末梢動脈血栓症	2 (<0.1%)	5 (0.2%)	0	0
Peripheral coldness	末梢冷感	0	2 (<0.1%)	0	0
Peripheral embolism	末梢血管塞栓症	2 (<0.1%)	2 (<0.1%)	0	0
Peripheral ischaemia	末梢性虚血	31 (1.0%)	23 (0.8%)	0	1 (<0.1%)
Peripheral vascular disorder	末梢血管障害	8 (0.3%)	8 (0.3%)	0	0
Peripheral venous disease	末梢静脈疾患	2 (<0.1%)	2 (<0.1%)	0	0
Poor peripheral circulation	末梢循環不良	2 (<0.1%)	1 (<0.1%)	0	0
Raynaud's phenomenon	レイノー現象	1 (<0.1%)	1 (<0.1%)	0	0
Renovascular hypertension	腎血管性高血圧	1 (<0.1%)	0	0	0
Reperfusion injury	再潅流障害	1 (<0.1%)	1 (<0.1%)	0	0
Spider vein	くも状静脈	1 (<0.1%)	0	0	0
Subclavian artery stenosis	鎖骨下動脈狭窄	1 (<0.1%)	2 (<0.1%)	0	0
Subclavian steal syndrome	鎖骨下動脈スチール症候群	1 (<0.1%)	0	0	0
Systolic hypertension	収縮期高血圧	1 (<0.1%)	1 (<0.1%)	0	0
Temporal arteritis	側頭動脈炎	1 (<0.1%)	0	0	0
Thrombophlebitis	血栓性静脈炎	1 (<0.1%)	0	0	0
Thrombophlebitis superficial	表在性血栓性静脈炎	1 (<0.1%)	3 (<0.1%)	0	0
Varicose vein	静脈瘤	2 (<0.1%)	2 (<0.1%)	0	0
Vascular stenosis	血管狭窄	0	1 (<0.1%)	0	0
Vasodilatation	血管拡張	0	1 (<0.1%)	0	0
Venous occlusion	静脈閉塞	1 (<0.1%)	0	1 (<0.1%)	0

Source: 5.3.5.1.3 17454_add1/Table 1.1/2

付表 2.7.6.1.a.1-7 重篤な TEAE（外国人集団、SAF）

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3027 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3019 (100%)	Total N=6046 (100%)
Number (%) of subjects with at least one adverse event		809 (26.7%)	803 (26.6%)	1612 (26.7%)
Blood and lymphatic system disorders	血液およびリンパ系障害	18 (0.6%)	12 (0.4%)	30 (0.5%)
Anaemia	貧血	12 (0.4%)	9 (0.3%)	21 (0.3%)
Blood loss anaemia	失血性貧血	1 (<0.1%)	0	1 (<0.1%)
Iron deficiency anaemia	鉄欠乏性貧血	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Leukocytosis	白血球増加症	1 (<0.1%)	0	1 (<0.1%)
Microcytic anaemia	小球性貧血	0	1 (<0.1%)	1 (<0.1%)
Normochromic normocytic anaemia	正色素性正球性貧血	1 (<0.1%)	0	1 (<0.1%)
Normocytic anaemia	正球性貧血	1 (<0.1%)	0	1 (<0.1%)
Thrombocytopenia	血小板減少症	0	1 (<0.1%)	1 (<0.1%)
Thrombocytosis	血小板増加症	1 (<0.1%)	0	1 (<0.1%)
Cardiac disorders	心臓障害	86 (2.8%)	100 (3.3%)	186 (3.1%)
Acute left ventricular failure	急性左室不全	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Acute myocardial infarction	急性心筋梗塞	0	1 (<0.1%)	1 (<0.1%)
Angina pectoris	狭心症	8 (0.3%)	6 (0.2%)	14 (0.2%)
Angina unstable	不安定狭心症	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Aortic valve stenosis	大動脈弁狭窄	1 (<0.1%)	0	1 (<0.1%)
Arrhythmia	不整脈	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Arrhythmia supraventricular	上室性不整脈	0	1 (<0.1%)	1 (<0.1%)
Arteriosclerosis coronary artery	冠動脈硬化症	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Atrial fibrillation	心房細動	19 (0.6%)	19 (0.6%)	38 (0.6%)
Atrial flutter	心房粗動	0	1 (<0.1%)	1 (<0.1%)
Atrioventricular block complete	完全房室ブロック	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Atrioventricular block first degree	第一度房室ブロック	0	1 (<0.1%)	1 (<0.1%)
Atrioventricular block second degree	第二度房室ブロック	0	2 (<0.1%)	2 (<0.1%)
Bradycardia	徐脈	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cardiac arrest	心停止	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cardiac failure	心不全	12 (0.4%)	12 (0.4%)	24 (0.4%)
Cardiac failure acute	急性心不全	2 (<0.1%)	6 (0.2%)	8 (0.1%)
Cardiac failure chronic	慢性心不全	4 (0.1%)	3 (<0.1%)	7 (0.1%)
Cardiac failure congestive	うっ血性心不全	9 (0.3%)	7 (0.2%)	16 (0.3%)
Cardiac tamponade	心タンポナーデ	1 (<0.1%)	0	1 (<0.1%)
Cardio-respiratory arrest	心肺停止	2 (<0.1%)	0	2 (<0.1%)
Cardiogenic shock	心原性ショック	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cardiopulmonary failure	心肺不全	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Congestive cardiomyopathy	うっ血性心筋症	1 (<0.1%)	0	1 (<0.1%)
Coronary artery disease	冠動脈疾患	14 (0.5%)	21 (0.7%)	35 (0.6%)
Coronary artery occlusion	冠動脈閉塞	1 (<0.1%)	0	1 (<0.1%)
Coronary artery stenosis	冠動脈狭窄	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Cyanosis	チアノーゼ	1 (<0.1%)	0	1 (<0.1%)
Hypertensive heart disease	高血圧性心疾患	0	2 (<0.1%)	2 (<0.1%)
Ischaemic cardiomyopathy	虚血性心筋症	1 (<0.1%)	0	1 (<0.1%)
Myocardial infarction	心筋梗塞	1 (<0.1%)	0	1 (<0.1%)
Myocardial ischaemia	心筋虚血	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pericardial effusion	心嚢液貯留	0	1 (<0.1%)	1 (<0.1%)
Pericarditis	心膜炎	0	1 (<0.1%)	1 (<0.1%)
Right ventricular failure	右室不全	0	1 (<0.1%)	1 (<0.1%)
Sinus arrest	洞停止	1 (<0.1%)	0	1 (<0.1%)
Sinus bradycardia	洞性徐脈	0	1 (<0.1%)	1 (<0.1%)
Sinus node dysfunction	洞結節機能不全	0	2 (<0.1%)	2 (<0.1%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3027 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3019 (100%)	Total N=6046 (100%)
Supraventricular tachyarrhythmia	上室性頻脈性不整脈	0	1 (<0.1%)	1 (<0.1%)
Supraventricular tachycardia	上室性頻脈	2 (<0.1%)	0	2 (<0.1%)
Ventricular arrhythmia	心室性不整脈	0	1 (<0.1%)	1 (<0.1%)
Ventricular fibrillation	心室細動	0	1 (<0.1%)	1 (<0.1%)
Ventricular tachycardia	心室性頻脈	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Congenital, familial and genetic disorders	先天性、家族性および遺伝性障害	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Adenomatous polyposis coli	大腸腺腫性ポリポーシス	1 (<0.1%)	0	1 (<0.1%)
Congenital bladder neck obstruction	先天性膀胱頚部閉塞症	0	1 (<0.1%)	1 (<0.1%)
Hydrocele	陰嚢水瘤	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Phimosis	包茎	0	2 (<0.1%)	2 (<0.1%)
Ear and labyrinth disorders	耳および迷路障害	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Deafness	難聴	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Sudden hearing loss	突発性難聴	1 (<0.1%)	0	1 (<0.1%)
Vertigo	回転性めまい	0	1 (<0.1%)	1 (<0.1%)
Endocrine disorders	内分泌障害	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Goitre	甲状腺腫	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Thyroid mass	甲状腺腫瘤	1 (<0.1%)	0	1 (<0.1%)
Eye disorders	眼障害	10 (0.3%)	11 (0.4%)	21 (0.3%)
Cataract	白内障	5 (0.2%)	5 (0.2%)	10 (0.2%)
Detachment of macular retinal pigment epithelium	黄斑網膜色素上皮剥離	0	1 (<0.1%)	1 (<0.1%)
Diabetic retinopathy	糖尿病網膜症	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Glaucoma	緑内障	2 (<0.1%)	0	2 (<0.1%)
Iridocyclitis	虹彩毛様体炎	0	1 (<0.1%)	1 (<0.1%)
Macular degeneration	黄斑変性	1 (<0.1%)	0	1 (<0.1%)
Macular detachment	黄斑剥離	0	1 (<0.1%)	1 (<0.1%)
Macular oedema	黄斑浮腫	1 (<0.1%)	0	1 (<0.1%)
Myopia	近視	0	1 (<0.1%)	1 (<0.1%)
Retinal detachment	網膜剥離	0	1 (<0.1%)	1 (<0.1%)
Vitreoretinal traction syndrome	硝子体網膜牽引症候群	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal disorders	胃腸障害	52 (1.7%)	52 (1.7%)	104 (1.7%)
Abdominal adhesions	腹部癒着	0	1 (<0.1%)	1 (<0.1%)
Abdominal incarcerated hernia	嵌頓腹部ヘルニア	1 (<0.1%)	0	1 (<0.1%)
Abdominal mass	腹部腫瘤	0	1 (<0.1%)	1 (<0.1%)
Abdominal pain	腹痛	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Abdominal pain lower	下腹部痛	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Abdominal pain upper	上腹部痛	0	1 (<0.1%)	1 (<0.1%)
Alcoholic pancreatitis	アルコール性膵炎	1 (<0.1%)	0	1 (<0.1%)
Anal fissure	裂肛	0	1 (<0.1%)	1 (<0.1%)
Ascites	腹水	0	1 (<0.1%)	1 (<0.1%)
Chronic gastritis	慢性胃炎	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Colitis	大腸炎	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Colitis ischaemic	虚血性大腸炎	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Constipation	便秘	1 (<0.1%)	0	1 (<0.1%)
Crohn's disease	クローン病	2 (<0.1%)	0	2 (<0.1%)
Dental alveolar anomaly	歯槽異常	0	1 (<0.1%)	1 (<0.1%)
Diaphragmatic hernia	横隔膜ヘルニア	0	1 (<0.1%)	1 (<0.1%)
Diarrhoea	下痢	3 (<0.1%)	0	3 (<0.1%)
Dry mouth	口内乾燥	0	1 (<0.1%)	1 (<0.1%)
Duodenal ulcer	十二指腸潰瘍	0	1 (<0.1%)	1 (<0.1%)
Dysphagia	嚥下障害	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3027 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3019 (100%)	Total N=6046 (100%)
Enterovesical fistula	腸膀胱瘻	0	1 (<0.1%)	1 (<0.1%)
Gallstone ileus	胆石性イレウス	0	1 (<0.1%)	1 (<0.1%)
Gastric antral vascular ectasia	胃前庭部毛細血管拡張症	1 (<0.1%)	0	1 (<0.1%)
Gastric polyps	胃ポリープ	0	1 (<0.1%)	1 (<0.1%)
Gastric ulcer	胃潰瘍	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Gastritis	胃炎	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Gastritis erosive	びらん性胃炎	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Gastrointestinal necrosis	消化管壊死	1 (<0.1%)	0	1 (<0.1%)
Gastrooesophageal reflux disease	胃食道逆流性疾患	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hiatus hernia	裂孔ヘルニア	0	1 (<0.1%)	1 (<0.1%)
Ileus	イレウス	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Impaired gastric emptying	胃排出不全	2 (<0.1%)	0	2 (<0.1%)
Inguinal hernia	鼠径ヘルニア	3 (<0.1%)	4 (0.1%)	7 (0.1%)
Intestinal angina	腸管アンギナ	0	1 (<0.1%)	1 (<0.1%)
Intestinal ischaemia	腸管虚血	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Intestinal obstruction	腸閉塞	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Intestinal perforation	腸管穿孔	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Intestinal ulcer	腸潰瘍	0	1 (<0.1%)	1 (<0.1%)
Large intestinal obstruction	大腸閉塞	0	1 (<0.1%)	1 (<0.1%)
Large intestine perforation	大腸穿孔	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Large intestine polyp	大腸ポリープ	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Mechanical ileus	機械的イレウス	1 (<0.1%)	0	1 (<0.1%)
Nausea	悪心	1 (<0.1%)	0	1 (<0.1%)
Obstructive pancreatitis	閉塞性膵炎	0	1 (<0.1%)	1 (<0.1%)
Oedematous pancreatitis	浮腫性膵炎	1 (<0.1%)	0	1 (<0.1%)
Oesophagitis	食道炎	1 (<0.1%)	0	1 (<0.1%)
Pancreatic duct stenosis	膵管狭窄	0	1 (<0.1%)	1 (<0.1%)
Pancreatic mass	膵腫瘤	0	1 (<0.1%)	1 (<0.1%)
Pancreatitis	膵炎	3 (<0.1%)	0	3 (<0.1%)
Pancreatitis acute	急性膵炎	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Pancreatitis chronic	慢性膵炎	0	3 (<0.1%)	3 (<0.1%)
Pancreatitis necrotising	壊死性膵炎	1 (<0.1%)	0	1 (<0.1%)
Peptic ulcer perforation	穿孔性消化性潰瘍	0	1 (<0.1%)	1 (<0.1%)
Small intestinal obstruction	小腸閉塞	0	3 (<0.1%)	3 (<0.1%)
Small intestinal perforation	小腸穿孔	1 (<0.1%)	0	1 (<0.1%)
Subileus	亜イレウス	1 (<0.1%)	0	1 (<0.1%)
Umbilical hernia	臍ヘルニア	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Umbilical hernia, obstructive	閉塞性臍ヘルニア	0	1 (<0.1%)	1 (<0.1%)
Vomiting	嘔吐	0	2 (<0.1%)	2 (<0.1%)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	27 (0.9%)	30 (1.0%)	57 (0.9%)
Asthenia	無力症	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Chest discomfort	胸部不快感	0	1 (<0.1%)	1 (<0.1%)
Chest pain	胸痛	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Crepitations	捻髪音	0	1 (<0.1%)	1 (<0.1%)
Death	死亡	1 (<0.1%)	0	1 (<0.1%)
Drug intolerance	薬物不耐性	0	1 (<0.1%)	1 (<0.1%)
Gait disturbance	歩行障害	0	1 (<0.1%)	1 (<0.1%)
General physical health deterioration	全身健康状態悪化	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Granuloma	肉芽腫	1 (<0.1%)	0	1 (<0.1%)
Hernia	ヘルニア	0	1 (<0.1%)	1 (<0.1%)
Impaired healing	治癒不良	3 (<0.1%)	7 (0.2%)	10 (0.2%)
Inflammation	炎症	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Multiple organ dysfunction syndrome	多臓器機能不全症候群	0	2 (<0.1%)	2 (<0.1%)
Non-cardiac chest pain	非心臓性胸痛	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Oedema peripheral	末梢性浮腫	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)

2.7.6.1.a 付録 1

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3027 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3019 (100%)	Total N=6046 (100%)
Organ failure	臓器不全	1 (<0.1%)	0	1 (<0.1%)
Pain	疼痛	1 (<0.1%)	0	1 (<0.1%)
Peripheral swelling	末梢腫脹	0	2 (<0.1%)	2 (<0.1%)
Pyrexia	発熱	1 (<0.1%)	0	1 (<0.1%)
Stent-graft endoleak	ステントグラフトエンドリーク	1 (<0.1%)	0	1 (<0.1%)
Systemic inflammatory response syndrome	全身性炎症反応症候群	1 (<0.1%)	0	1 (<0.1%)
Vascular device occlusion	血管デバイス閉塞	0	1 (<0.1%)	1 (<0.1%)
Vascular stent occlusion	血管ステント閉塞	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Vascular stent stenosis	血管ステント狭窄	7 (0.2%)	3 (<0.1%)	10 (0.2%)
Hepatobiliary disorders	肝胆道系障害	19 (0.6%)	22 (0.7%)	41 (0.7%)
Bile duct obstruction	胆管閉塞	0	3 (<0.1%)	3 (<0.1%)
Bile duct stone	胆管結石	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Biliary dyskinesia	胆道ジスキネジア	1 (<0.1%)	0	1 (<0.1%)
Cholangitis acute	急性胆管炎	1 (<0.1%)	0	1 (<0.1%)
Cholecystitis	胆嚢炎	7 (0.2%)	3 (<0.1%)	10 (0.2%)
Cholecystitis acute	急性胆嚢炎	2 (<0.1%)	11 (0.4%)	13 (0.2%)
Cholelithiasis	胆石症	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cholestasis	胆汁うっ滞	0	1 (<0.1%)	1 (<0.1%)
Cirrhosis alcoholic	アルコール性肝硬変	1 (<0.1%)	0	1 (<0.1%)
Hepatic cirrhosis	肝硬変	3 (<0.1%)	0	3 (<0.1%)
Hepatic failure	肝不全	0	1 (<0.1%)	1 (<0.1%)
Hepatic function abnormal	肝機能異常	2 (<0.1%)	0	2 (<0.1%)
Hepatic steatosis	脂肪肝	0	1 (<0.1%)	1 (<0.1%)
Hepatorenal syndrome	肝腎症候群	0	1 (<0.1%)	1 (<0.1%)
Primary biliary cholangitis	原発性胆汁性胆管炎	1 (<0.1%)	0	1 (<0.1%)
Steatohepatitis	脂肪性肝炎	0	1 (<0.1%)	1 (<0.1%)
Immune system disorders	免疫系障害	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Anaphylactic reaction	アナフィラキシー反応	0	2 (<0.1%)	2 (<0.1%)
Hypersensitivity	過敏症	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Infections and infestations	感染症および寄生虫症	220 (7.3%)	217 (7.2%)	437 (7.2%)
Abdominal infection	腹部感染	1 (<0.1%)	0	1 (<0.1%)
Abscess	膿瘍	1 (<0.1%)	0	1 (<0.1%)
Abscess limb	四肢膿瘍	6 (0.2%)	5 (0.2%)	11 (0.2%)
Acute sinusitis	急性副鼻腔炎	0	1 (<0.1%)	1 (<0.1%)
Appendicitis	虫垂炎	4 (0.1%)	5 (0.2%)	9 (0.1%)
Arteriosclerotic gangrene	動脈硬化性壊疽	1 (<0.1%)	0	1 (<0.1%)
Arthritis bacterial	細菌性関節炎	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Arthritis infective	感染性関節炎	1 (<0.1%)	0	1 (<0.1%)
Bacteraemia	菌血症	0	1 (<0.1%)	1 (<0.1%)
Blister infected	感染性水疱	0	1 (<0.1%)	1 (<0.1%)
Bone abscess	骨膿瘍	1 (<0.1%)	0	1 (<0.1%)
Bronchiolitis	細気管支炎	0	1 (<0.1%)	1 (<0.1%)
Bronchitis	気管支炎	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Burn infection	熱傷部感染	1 (<0.1%)	0	1 (<0.1%)
Carbuncle	よう	0	1 (<0.1%)	1 (<0.1%)
Cellulitis	蜂巣炎	15 (0.5%)	17 (0.6%)	32 (0.5%)
Cellulitis gangrenous	壊疽性蜂巣炎	0	1 (<0.1%)	1 (<0.1%)
Cholecystitis infective	感染性胆嚢炎	0	1 (<0.1%)	1 (<0.1%)
Clostridium difficile colitis	クロストリジウム・ディフィシレ大腸炎	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Complicated appendicitis	合併症を伴う虫垂炎	0	1 (<0.1%)	1 (<0.1%)
Cystitis	膀胱炎	0	1 (<0.1%)	1 (<0.1%)
Cystitis bacterial	細菌性膀胱炎	1 (<0.1%)	0	1 (<0.1%)
Dermo-hypodermitis	皮膚皮下組織炎	1 (<0.1%)	0	1 (<0.1%)
Device related infection	医療機器関連感染	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Diabetic foot infection	糖尿病性足感染	1 (<0.1%)	6 (0.2%)	7 (0.1%)

2.7.6.1.a 付録 1

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3027 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3019 (100%)	Total N=6046 (100%)
Diabetic gangrene	糖尿病性壊疽	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Diarrhoea infectious	感染性下痢	1 (<0.1%)	0	1 (<0.1%)
Diverticulitis	憩室炎	4 (0.1%)	4 (0.1%)	8 (0.1%)
Ear infection	耳感染	0	1 (<0.1%)	1 (<0.1%)
Eczema infected	感染性湿疹	1 (<0.1%)	0	1 (<0.1%)
Endocarditis	心内膜炎	1 (<0.1%)	0	1 (<0.1%)
Epididymitis	精巣上体炎	0	1 (<0.1%)	1 (<0.1%)
Erysipelas	丹毒	1 (<0.1%)	10 (0.3%)	11 (0.2%)
Escherichia sepsis	大腸菌性敗血症	1 (<0.1%)	0	1 (<0.1%)
Extradural abscess	硬膜外膿瘍	1 (<0.1%)	0	1 (<0.1%)
Fournier's gangrene	フルニエー壊疽	0	1 (<0.1%)	1 (<0.1%)
Fungal cystitis	真菌性膀胱炎	0	1 (<0.1%)	1 (<0.1%)
Fungal skin infection	皮膚真菌感染	1 (<0.1%)	0	1 (<0.1%)
Gangrene	壊疽	16 (0.5%)	20 (0.7%)	36 (0.6%)
Gastric infection	胃感染	0	1 (<0.1%)	1 (<0.1%)
Gastroenteritis	胃腸炎	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Gastroenteritis viral	ウイルス性胃腸炎	2 (<0.1%)	0	2 (<0.1%)
Graft infection	移植片感染	1 (<0.1%)	0	1 (<0.1%)
Groin abscess	鼠径部膿瘍	3 (<0.1%)	0	3 (<0.1%)
Groin infection	鼠径部感染	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Haematoma infection	血腫感染	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Infected lymphocele	感染性リンパ嚢腫	2 (<0.1%)	0	2 (<0.1%)
Infected seroma	感染性漿液腫	1 (<0.1%)	0	1 (<0.1%)
Infected skin ulcer	感染性皮膚潰瘍	6 (0.2%)	4 (0.1%)	10 (0.2%)
Infectious pleural effusion	感染性胸水	0	1 (<0.1%)	1 (<0.1%)
Infective exacerbation of chronic obstructive airways disease	感染による慢性閉塞性気道疾患の増悪	3 (<0.1%)	2 (<0.1%)	5 (<0.1%)
Influenza	インフルエンザ	2 (<0.1%)	0	2 (<0.1%)
Intervertebral discitis	椎間板炎	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Large intestine infection	大腸感染	0	1 (<0.1%)	1 (<0.1%)
Localised infection	限局性感染	19 (0.6%)	11 (0.4%)	30 (0.5%)
Lower respiratory tract infection	下気道感染	0	2 (<0.1%)	2 (<0.1%)
Lymph gland infection	リンパ節感染	1 (<0.1%)	0	1 (<0.1%)
Lymphangitis	リンパ管炎	1 (<0.1%)	0	1 (<0.1%)
Mastoiditis	乳様突起炎	1 (<0.1%)	0	1 (<0.1%)
Medical device site infection	医療機器使用部位感染	1 (<0.1%)	0	1 (<0.1%)
Medical device site joint infection	医療機器使用部位関節感染	0	3 (<0.1%)	3 (<0.1%)
Oesophageal candidiasis	食道カンジダ症	1 (<0.1%)	0	1 (<0.1%)
Ophthalmic herpes zoster	眼帯状疱疹	1 (<0.1%)	0	1 (<0.1%)
Orchitis	精巣炎	1 (<0.1%)	0	1 (<0.1%)
Osteomyelitis	骨髄炎	11 (0.4%)	12 (0.4%)	23 (0.4%)
Osteomyelitis chronic	慢性骨髄炎	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Otitis media	中耳炎	0	1 (<0.1%)	1 (<0.1%)
Perineal abscess	会陰膿瘍	2 (<0.1%)	0	2 (<0.1%)
Perineal cellulitis	会陰蜂巣炎	0	1 (<0.1%)	1 (<0.1%)
Perinephric abscess	腎周囲膿瘍	1 (<0.1%)	0	1 (<0.1%)
Peritonitis	腹膜炎	0	1 (<0.1%)	1 (<0.1%)
Periumbilical abscess	臍帯周囲膿瘍	0	1 (<0.1%)	1 (<0.1%)
Pharyngitis	咽頭炎	0	1 (<0.1%)	1 (<0.1%)
Pneumocystis jirovecii pneumonia	ニューモシスチス・イロベチイ肺炎	1 (<0.1%)	0	1 (<0.1%)
Pneumonia	肺炎	33 (1.1%)	42 (1.4%)	75 (1.2%)
Pneumonia bacterial	細菌性肺炎	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Post procedural infection	処置後感染	1 (<0.1%)	0	1 (<0.1%)
Post procedural sepsis	処置後敗血症	0	1 (<0.1%)	1 (<0.1%)
Postoperative wound infection	術後創感染	26 (0.9%)	24 (0.8%)	50 (0.8%)
Pseudomembranous colitis	偽膜性大腸炎	1 (<0.1%)	0	1 (<0.1%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3027 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3019 (100%)	Total N=6046 (100%)
Pulmonary sepsis	肺敗血症	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Pulmonary tuberculosis	肺結核	2 (<0.1%)	0	2 (<0.1%)
Pyelonephritis	腎盂腎炎	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pyelonephritis acute	急性腎盂腎炎	1 (<0.1%)	0	1 (<0.1%)
Respiratory tract infection	気道感染	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Scrotal abscess	陰嚢膿瘍	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Sepsis	敗血症	12 (0.4%)	12 (0.4%)	24 (0.4%)
Septic shock	敗血症性ショック	1 (<0.1%)	5 (0.2%)	6 (<0.1%)
Sinusitis	副鼻腔炎	0	2 (<0.1%)	2 (<0.1%)
Skin infection	皮膚感染	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Soft tissue infection	軟部組織感染	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Subcutaneous abscess	皮下組織膿瘍	1 (<0.1%)	0	1 (<0.1%)
Superinfection bacterial	細菌重複感染	0	1 (<0.1%)	1 (<0.1%)
Tonsillitis	扁桃炎	1 (<0.1%)	0	1 (<0.1%)
Tuberculosis	結核	0	1 (<0.1%)	1 (<0.1%)
Urinary tract infection	尿路感染	11 (0.4%)	10 (0.3%)	21 (0.3%)
Urosepsis	尿路性敗血症	0	5 (0.2%)	5 (<0.1%)
Vascular device infection	血管デバイス感染	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Wound infection	創傷感染	15 (0.5%)	15 (0.5%)	30 (0.5%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	85 (2.8%)	97 (3.2%)	182 (3.0%)
Accidental overdose	偶発的過量投与	1 (<0.1%)	0	1 (<0.1%)
Alcohol poisoning	アルコール中毒	2 (<0.1%)	0	2 (<0.1%)
Ankle fracture	足関節部骨折	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Arterial bypass occlusion	動脈バイパス閉塞	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Arterial bypass stenosis	動脈バイパス狭窄	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Arterial bypass thrombosis	動脈バイパス血栓症	0	1 (<0.1%)	1 (<0.1%)
Bone contusion	骨挫傷	1 (<0.1%)	0	1 (<0.1%)
Carbon monoxide poisoning	一酸化炭素中毒	1 (<0.1%)	0	1 (<0.1%)
Chemical burn of skin	皮膚化学熱傷	0	1 (<0.1%)	1 (<0.1%)
Chest injury	胸部損傷	0	1 (<0.1%)	1 (<0.1%)
Compression fracture	圧迫骨折	0	1 (<0.1%)	1 (<0.1%)
Concussion	脳振盪	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Contusion	挫傷	1 (<0.1%)	0	1 (<0.1%)
Craniocerebral injury	頭蓋脳損傷	2 (<0.1%)	0	2 (<0.1%)
Facial bones fracture	顔面骨骨折	0	1 (<0.1%)	1 (<0.1%)
Failure to anastomose	吻合不全	0	1 (<0.1%)	1 (<0.1%)
Fall	転倒	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Femoral neck fracture	大腿骨頚部骨折	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
Femur fracture	大腿骨骨折	8 (0.3%)	11 (0.4%)	19 (0.3%)
Fibula fracture	腓骨骨折	3 (<0.1%)	0	3 (<0.1%)
Foot fracture	足骨折	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Forearm fracture	前腕骨折	0	1 (<0.1%)	1 (<0.1%)
Foreign body in gastrointestinal tract	消化管内異物	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal anastomotic leak	胃腸吻合部漏出	0	1 (<0.1%)	1 (<0.1%)
Graft thrombosis	移植片血栓症	1 (<0.1%)	0	1 (<0.1%)
Head injury	頭部損傷	2 (<0.1%)	0	2 (<0.1%)
Hip fracture	股関節部骨折	5 (0.2%)	5 (0.2%)	10 (0.2%)
Humerus fracture	上腕骨骨折	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Incisional hernia	瘢痕ヘルニア	1 (<0.1%)	0	1 (<0.1%)
Injury	損傷	2 (<0.1%)	0	2 (<0.1%)
Intentional overdose	企図的過量投与	1 (<0.1%)	0	1 (<0.1%)
Joint dislocation	関節脱臼	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Limb injury	四肢損傷	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Lower limb fracture	下肢骨折	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Lumbar vertebral fracture	腰椎骨折	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Meniscus injury	半月板損傷	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Open fracture	開放骨折	0	1 (<0.1%)	1 (<0.1%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3027 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3019 (100%)	Total N=6046 (100%)
Patella fracture	膝蓋骨骨折	1 (<0.1%)	0	1 (<0.1%)
Pelvic fracture	骨盤骨折	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Penetrating abdominal trauma	鋭的腹部外傷	0	1 (<0.1%)	1 (<0.1%)
Peripheral artery restenosis	末梢動脈再狭窄	4 (0.1%)	8 (0.3%)	12 (0.2%)
Periprosthetic fracture	人工関節周囲骨折	0	1 (<0.1%)	1 (<0.1%)
Post laminectomy syndrome	椎弓切除後症候群	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Post procedural bile leak	処置後胆汁漏出	0	1 (<0.1%)	1 (<0.1%)
Post procedural complication	処置後合併症	1 (<0.1%)	0	1 (<0.1%)
Post procedural discharge	処置後分泌物	0	1 (<0.1%)	1 (<0.1%)
Post procedural oedema	処置後浮腫	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Postoperative thoracic procedure complication	術後胸部処置合併症	0	1 (<0.1%)	1 (<0.1%)
Procedural complication	処置合併症	0	1 (<0.1%)	1 (<0.1%)
Procedural intestinal perforation	処置による腸管穿孔	0	1 (<0.1%)	1 (<0.1%)
Pubis fracture	恥骨骨折	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Radius fracture	橈骨骨折	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Rib fracture	肋骨骨折	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Road traffic accident	交通事故	1 (<0.1%)	0	1 (<0.1%)
Seroma	漿液腫	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Skin laceration	皮膚裂傷	0	1 (<0.1%)	1 (<0.1%)
Skin scar contracture	皮膚瘢痕拘縮	0	1 (<0.1%)	1 (<0.1%)
Skull fractured base	頭蓋底骨折	1 (<0.1%)	0	1 (<0.1%)
Spinal column injury	脊柱損傷	0	1 (<0.1%)	1 (<0.1%)
Spinal compression fracture	脊椎圧迫骨折	0	4 (0.1%)	4 (<0.1%)
Spinal fracture	脊椎骨折	0	1 (<0.1%)	1 (<0.1%)
Tendon rupture	腱断裂	1 (<0.1%)	0	1 (<0.1%)
Thoracic vertebral fracture	胸椎骨折	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Tibia fracture	脛骨骨折	3 (<0.1%)	0	3 (<0.1%)
Traumatic fracture	外傷性骨折	0	1 (<0.1%)	1 (<0.1%)
Traumatic ulcer	外傷性潰瘍	1 (<0.1%)	0	1 (<0.1%)
Underdose	過少量投与	0	1 (<0.1%)	1 (<0.1%)
Upper limb fracture	上肢骨折	1 (<0.1%)	0	1 (<0.1%)
Vascular graft complication	移植血管合併症	5 (0.2%)	1 (<0.1%)	6 (<0.1%)
Vascular graft occlusion	移植血管閉塞	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Vascular graft restenosis	移植血管再狭窄	0	1 (<0.1%)	1 (<0.1%)
Vascular graft stenosis	移植血管狭窄	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Vascular graft thrombosis	血管グラフト血栓症	1 (<0.1%)	0	1 (<0.1%)
Vascular procedure complication	血管処置合併症	1 (<0.1%)	0	1 (<0.1%)
Vascular pseudoaneurysm	血管偽動脈瘤	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Wound complication	創合併症	1 (<0.1%)	0	1 (<0.1%)
Wound dehiscence	創離開	4 (0.1%)	3 (<0.1%)	7 (0.1%)
Wound necrosis	創壊死	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Investigations	臨床検査	4 (0.1%)	6 (0.2%)	10 (0.2%)
Blood creatinine increased	血中クレアチニン増加	0	1 (<0.1%)	1 (<0.1%)
Blood glucose increased	血中ブドウ糖増加	0	1 (<0.1%)	1 (<0.1%)
Blood potassium increased	血中カリウム増加	0	1 (<0.1%)	1 (<0.1%)
Blood pressure increased	血圧上昇	0	1 (<0.1%)	1 (<0.1%)
Cardiac stress test abnormal	心臓負荷試験異常	0	1 (<0.1%)	1 (<0.1%)
Cardiovascular function test abnormal	心血管機能検査異常	0	1 (<0.1%)	1 (<0.1%)
Cystoscopy	膀胱鏡検査	1 (<0.1%)	0	1 (<0.1%)
Hepatic enzyme increased	肝酵素上昇	1 (<0.1%)	0	1 (<0.1%)
Immunoglobulins decreased	免疫グロブリン減少	1 (<0.1%)	0	1 (<0.1%)
Vascular test	血管検査	1 (<0.1%)	0	1 (<0.1%)
Metabolism and nutrition disorders	代謝および栄養障害	26 (0.9%)	30 (1.0%)	56 (0.9%)
Decreased appetite	食欲減退	0	1 (<0.1%)	1 (<0.1%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3027 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3019 (100%)	Total N=6046 (100%)
Dehydration	脱水	6 (0.2%)	1 (<0.1%)	7 (0.1%)
Diabetes mellitus	糖尿病	3 (<0.1%)	5 (0.2%)	8 (0.1%)
Diabetes mellitus inadequate control	コントロール不良の糖尿病	2 (<0.1%)	0	2 (<0.1%)
Diabetic ketoacidosis	糖尿病性ケトアシドーシス	2 (<0.1%)	0	2 (<0.1%)
Diabetic metabolic decompensation	糖尿病性代謝代償不全	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hyperglycaemia	高血糖	1 (<0.1%)	3 (<0.1%)	4 (<0.1%)
Hyperglycaemic hyperosmolar nonketotic syndrome	高血糖性高浸透圧性非ケトン性症候群	0	1 (<0.1%)	1 (<0.1%)
Hyperkalaemia	高カリウム血症	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Hypoglycaemia	低血糖	2 (<0.1%)	5 (0.2%)	7 (0.1%)
Hypokalaemia	低カリウム血症	0	1 (<0.1%)	1 (<0.1%)
Hyponatraemia	低ナトリウム血症	3 (<0.1%)	4 (0.1%)	7 (0.1%)
Ketoacidosis	ケトアシドーシス	1 (<0.1%)	0	1 (<0.1%)
Lactic acidosis	乳酸アシドーシス	1 (<0.1%)	0	1 (<0.1%)
Metabolic disorder	代謝障害	0	1 (<0.1%)	1 (<0.1%)
Type 1 diabetes mellitus	１型糖尿病	0	2 (<0.1%)	2 (<0.1%)
Type 2 diabetes mellitus	２型糖尿病	3 (<0.1%)	5 (0.2%)	8 (0.1%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	47 (1.6%)	59 (2.0%)	106 (1.8%)
Acquired claw toe	後天性鉤爪趾	0	1 (<0.1%)	1 (<0.1%)
Arthritis	関節炎	0	1 (<0.1%)	1 (<0.1%)
Back pain	背部痛	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Bone disorder	骨障害	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bone formation increased	骨形成亢進	0	1 (<0.1%)	1 (<0.1%)
Bone loss	骨喪失	1 (<0.1%)	0	1 (<0.1%)
Bursitis	滑液包炎	0	1 (<0.1%)	1 (<0.1%)
Cervical spinal stenosis	頚部脊柱管狭窄症	0	1 (<0.1%)	1 (<0.1%)
Compartment syndrome	コンパートメント症候群	0	1 (<0.1%)	1 (<0.1%)
Foot deformity	足変形	0	1 (<0.1%)	1 (<0.1%)
Fracture nonunion	骨折による偽関節	0	1 (<0.1%)	1 (<0.1%)
Gouty arthritis	痛風性関節炎	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Intervertebral disc disorder	椎間板障害	1 (<0.1%)	0	1 (<0.1%)
Intervertebral disc protrusion	椎間板突出	6 (0.2%)	6 (0.2%)	12 (0.2%)
Ligament disorder	靭帯障害	0	1 (<0.1%)	1 (<0.1%)
Lumbar spinal stenosis	腰部脊柱管狭窄症	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Metatarsalgia	中足骨痛	0	1 (<0.1%)	1 (<0.1%)
Muscle disorder	筋障害	0	1 (<0.1%)	1 (<0.1%)
Muscle spasms	筋痙縮	1 (<0.1%)	0	1 (<0.1%)
Muscular weakness	筋力低下	1 (<0.1%)	0	1 (<0.1%)
Musculoskeletal chest pain	筋骨格系胸痛	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Musculoskeletal pain	筋骨格痛	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Osteitis	骨炎	0	1 (<0.1%)	1 (<0.1%)
Osteoarthritis	変形性関節症	12 (0.4%)	11 (0.4%)	23 (0.4%)
Osteonecrosis	骨壊死	1 (<0.1%)	0	1 (<0.1%)
Osteoporotic fracture	骨粗鬆症性骨折	0	1 (<0.1%)	1 (<0.1%)
Pain in extremity	四肢痛	6 (0.2%)	14 (0.5%)	20 (0.3%)
Pathological fracture	病的骨折	1 (<0.1%)	0	1 (<0.1%)
Polymyalgia rheumatica	リウマチ性多発筋痛	1 (<0.1%)	0	1 (<0.1%)
Pseudarthrosis	偽関節	0	1 (<0.1%)	1 (<0.1%)
Rhabdomyolysis	横紋筋融解症	0	1 (<0.1%)	1 (<0.1%)
Rotator cuff syndrome	肩回旋筋腱板症候群	0	2 (<0.1%)	2 (<0.1%)
Soft tissue disorder	軟部組織障害	1 (<0.1%)	0	1 (<0.1%)
Soft tissue necrosis	軟部組織壊死	0	1 (<0.1%)	1 (<0.1%)
Spinal osteoarthritis	変形性脊椎症	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Spinal pain	脊椎痛	0	1 (<0.1%)	1 (<0.1%)
Spinal stenosis	脊柱管狭窄症	6 (0.2%)	2 (<0.1%)	8 (0.1%)
Spondyloarthropathy	脊椎関節障害	1 (<0.1%)	0	1 (<0.1%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3027 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3019 (100%)	Total N=6046 (100%)
Spondylolisthesis	脊椎すべり症	0	2 (<0.1%)	2 (<0.1%)
Synovial cyst	滑液嚢腫	0	1 (<0.1%)	1 (<0.1%)
Systemic scleroderma	全身性強皮症	0	1 (<0.1%)	1 (<0.1%)
Tendon disorder	腱障害	0	1 (<0.1%)	1 (<0.1%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	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）	101 (3.3%)	99 (3.3%)	200 (3.3%)
Acute myeloid leukaemia	急性骨髄性白血病	1 (<0.1%)	0	1 (<0.1%)
Adenocarcinoma gastric	胃腺癌	0	1 (<0.1%)	1 (<0.1%)
Adenocarcinoma of colon	結腸腺癌	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Adenolymphoma	腺リンパ腫	0	1 (<0.1%)	1 (<0.1%)
Adrenal neoplasm	副腎新生物	1 (<0.1%)	0	1 (<0.1%)
B-cell lymphoma	Ｂ細胞性リンパ腫	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Basal cell carcinoma	基底細胞癌	3 (<0.1%)	6 (0.2%)	9 (0.1%)
Benign laryngeal neoplasm	喉頭の良性新生物	1 (<0.1%)	0	1 (<0.1%)
Benign neoplasm of skin	皮膚良性新生物	1 (<0.1%)	0	1 (<0.1%)
Benign ovarian tumour	卵巣良性腫瘍	1 (<0.1%)	0	1 (<0.1%)
Bile duct cancer	胆管癌	0	2 (<0.1%)	2 (<0.1%)
Bladder cancer	膀胱癌	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Bladder cancer stage IV	膀胱癌第４期	0	1 (<0.1%)	1 (<0.1%)
Bladder neoplasm	膀胱新生物	0	1 (<0.1%)	1 (<0.1%)
Bladder transitional cell carcinoma	膀胱移行上皮癌	2 (<0.1%)	0	2 (<0.1%)
Bone cancer	骨癌	0	1 (<0.1%)	1 (<0.1%)
Brain neoplasm	脳新生物	0	1 (<0.1%)	1 (<0.1%)
Breast cancer	乳癌	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Bronchial carcinoma	気管支癌	1 (<0.1%)	0	1 (<0.1%)
Central nervous system lymphoma	中枢神経系リンパ腫	1 (<0.1%)	0	1 (<0.1%)
Cervix carcinoma	子宮頚部癌	0	1 (<0.1%)	1 (<0.1%)
Cholangiocarcinoma	胆管細胞癌	1 (<0.1%)	0	1 (<0.1%)
Chronic myelomonocytic leukaemia	慢性骨髄単球性白血病	0	1 (<0.1%)	1 (<0.1%)
Colon adenoma	大腸腺腫	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Colon cancer	結腸癌	4 (0.1%)	4 (0.1%)	8 (0.1%)
Colorectal adenocarcinoma	結腸直腸腺癌	0	1 (<0.1%)	1 (<0.1%)
Ductal adenocarcinoma of pancreas	膵腺管癌	0	1 (<0.1%)	1 (<0.1%)
Endometrial cancer	子宮内膜癌	1 (<0.1%)	0	1 (<0.1%)
Follicular thyroid cancer	濾胞性甲状腺癌	1 (<0.1%)	0	1 (<0.1%)
Gastric cancer	胃癌	0	2 (<0.1%)	2 (<0.1%)
Gastric cancer stage II	胃癌第２期	0	1 (<0.1%)	1 (<0.1%)
Gastrointestinal adenocarcinoma	消化器腺癌	1 (<0.1%)	0	1 (<0.1%)
Gingival cancer	歯肉癌	1 (<0.1%)	0	1 (<0.1%)
Head and neck cancer	頭頚部癌	1 (<0.1%)	0	1 (<0.1%)
Hepatic cancer	肝癌	0	1 (<0.1%)	1 (<0.1%)
Hepatocellular carcinoma	肝細胞癌	1 (<0.1%)	0	1 (<0.1%)
Hodgkin's disease	ホジキン病	1 (<0.1%)	0	1 (<0.1%)
Hodgkin's disease stage IV	ホジキン病第４期	1 (<0.1%)	0	1 (<0.1%)
Laryngeal cancer	喉頭癌	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Laryngeal neoplasm	喉頭新生物	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Lip and/or oral cavity cancer	口唇および口腔内癌	0	1 (<0.1%)	1 (<0.1%)
Lung adenocarcinoma	肺腺癌	4 (0.1%)	3 (<0.1%)	7 (0.1%)
Lung adenocarcinoma recurrent	再発肺腺癌	1 (<0.1%)	0	1 (<0.1%)
Lung adenocarcinoma stage IV	肺腺癌第４期	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Lung cancer metastatic	遠隔転移を伴う肺癌	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Lung carcinoma cell type unspecified recurrent	再発肺癌、細胞タイプ不明	1 (<0.1%)	0	1 (<0.1%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3027 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3019 (100%)	Total N=6046 (100%)
Lung carcinoma cell type unspecified stage IV	肺癌第４期、細胞タイプ不明	1 (<0.1%)	0	1 (<0.1%)
Lung neoplasm	肺新生物	4 (0.1%)	4 (0.1%)	8 (0.1%)
Lung neoplasm malignant	肺の悪性新生物	7 (0.2%)	12 (0.4%)	19 (0.3%)
Lung squamous cell carcinoma metastatic	遠隔転移を伴う肺扁平上皮癌	0	1 (<0.1%)	1 (<0.1%)
Lung squamous cell carcinoma stage IV	肺扁平上皮癌第４期	1 (<0.1%)	0	1 (<0.1%)
Malignant genitourinary tract neoplasm	泌尿生殖器の悪性新生物	1 (<0.1%)	0	1 (<0.1%)
Malignant melanoma	悪性黒色腫	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Malignant neoplasm papilla of Vater	ファーター乳頭部の悪性新生物	0	1 (<0.1%)	1 (<0.1%)
Metastases to central nervous system	中枢神経系転移	0	1 (<0.1%)	1 (<0.1%)
Metastases to liver	肝転移	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Metastases to lung	肺転移	1 (<0.1%)	0	1 (<0.1%)
Metastases to lymph nodes	リンパ節転移	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Metastases to neck	頚部転移	0	1 (<0.1%)	1 (<0.1%)
Metastases to peritoneum	腹膜転移	0	1 (<0.1%)	1 (<0.1%)
Metastatic neoplasm	遠隔転移を伴う新生物	0	1 (<0.1%)	1 (<0.1%)
Metastatic squamous cell carcinoma	遠隔転移を伴う扁平上皮癌	0	1 (<0.1%)	1 (<0.1%)
Myelodysplastic syndrome	骨髄異形成症候群	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Neoplasm malignant	悪性新生物	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Neoplasm skin	皮膚の新生物	0	1 (<0.1%)	1 (<0.1%)
Neuroendocrine carcinoma	神経内分泌癌	1 (<0.1%)	0	1 (<0.1%)
Non-small cell lung cancer	非小細胞肺癌	1 (<0.1%)	0	1 (<0.1%)
Non-small cell lung cancer metastatic	遠隔転移を伴う非小細胞肺癌	0	1 (<0.1%)	1 (<0.1%)
Oesophageal adenocarcinoma	食道腺癌	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Oesophageal cancer metastatic	遠隔転移を伴う食道癌	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Oesophageal carcinoma	食道癌	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Oesophageal carcinoma recurrent	再発食道癌	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Oesophageal neoplasm	食道新生物	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Oropharyngeal cancer	中咽頭癌	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pancreatic carcinoma	膵癌	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Pancreatic carcinoma stage IV	膵癌第４期	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Pancreatic neoplasm	膵新生物	0	1 (<0.1%)	1 (<0.1%)
Papillary serous endometrial carcinoma	乳頭状漿液性子宮内膜癌	0	1 (<0.1%)	1 (<0.1%)
Plasma cell myeloma	形質細胞性骨髄腫	1 (<0.1%)	0	1 (<0.1%)
Pleural mesothelioma	胸膜中皮腫	1 (<0.1%)	0	1 (<0.1%)
Prostate cancer	前立腺癌	8 (0.3%)	2 (<0.1%)	10 (0.2%)
Prostate cancer stage III	前立腺癌第３期	0	1 (<0.1%)	1 (<0.1%)
Rectal adenocarcinoma	直腸腺癌	2 (<0.1%)	0	2 (<0.1%)
Rectal adenoma	直腸腺腫	1 (<0.1%)	0	1 (<0.1%)
Rectal cancer	直腸癌	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Rectal cancer stage I	直腸癌第１期	0	1 (<0.1%)	1 (<0.1%)
Rectal cancer stage IV	直腸癌第４期	1 (<0.1%)	0	1 (<0.1%)
Rectal neoplasm	直腸新生物	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Rectosigmoid cancer	直腸Ｓ状結腸癌	0	1 (<0.1%)	1 (<0.1%)
Renal cancer	腎癌	3 (<0.1%)	0	3 (<0.1%)
Renal cell carcinoma	腎細胞癌	0	1 (<0.1%)	1 (<0.1%)
Renal neoplasm	腎新生物	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Respiratory tract neoplasm	気道新生物	0	1 (<0.1%)	1 (<0.1%)
Salivary gland adenoma	唾液腺腫	1 (<0.1%)	0	1 (<0.1%)
Skin squamous cell carcinoma recurrent	再発皮膚有棘細胞癌	1 (<0.1%)	0	1 (<0.1%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3027 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3019 (100%)	Total N=6046 (100%)
Small cell carcinoma	小細胞癌	0	1 (<0.1%)	1 (<0.1%)
Small cell lung cancer	小細胞肺癌	2 (<0.1%)	0	2 (<0.1%)
Squamous cell carcinoma	扁平上皮癌	0	1 (<0.1%)	1 (<0.1%)
Squamous cell carcinoma of lung	肺扁平上皮癌	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Squamous cell carcinoma of skin	皮膚有棘細胞癌	0	1 (<0.1%)	1 (<0.1%)
Squamous cell carcinoma of the oral cavity	口腔内扁平上皮癌	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Squamous cell carcinoma of the tongue	舌扁平上皮癌	0	2 (<0.1%)	2 (<0.1%)
T-cell lymphoma	Ｔ細胞性リンパ腫	1 (<0.1%)	0	1 (<0.1%)
Transitional cell carcinoma	移行上皮癌	2 (<0.1%)	3 (<0.1%)	5 (<0.1%)
Nervous system disorders	神経系障害	57 (1.9%)	67 (2.2%)	124 (2.1%)
Brain injury	脳損傷	1 (<0.1%)	0	1 (<0.1%)
Carotid artery disease	頚動脈疾患	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Carotid artery occlusion	頚動脈閉塞	0	1 (<0.1%)	1 (<0.1%)
Carotid artery stenosis	頚動脈狭窄	20 (0.7%)	23 (0.8%)	43 (0.7%)
Carpal tunnel syndrome	手根管症候群	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Cerebral atrophy	大脳萎縮	0	1 (<0.1%)	1 (<0.1%)
Cerebral infarction	脳梗塞	0	1 (<0.1%)	1 (<0.1%)
Cervical radiculopathy	頚髄神経根障害	0	1 (<0.1%)	1 (<0.1%)
Colloid brain cyst	脳コロイド嚢胞	0	1 (<0.1%)	1 (<0.1%)
Cranial nerve disorder	脳神経障害	0	1 (<0.1%)	1 (<0.1%)
Dementia	認知症	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Diabetic neuropathy	糖尿病性ニューロパチー	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Dizziness	浮動性めまい	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Drop attacks	転倒発作	0	1 (<0.1%)	1 (<0.1%)
Epilepsy	てんかん	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Facial paresis	顔面不全麻痺	1 (<0.1%)	0	1 (<0.1%)
Guillain-Barre syndrome	ギラン・バレー症候群	0	1 (<0.1%)	1 (<0.1%)
Hemiparesis	不全片麻痺	0	1 (<0.1%)	1 (<0.1%)
Ischaemic neuropathy	虚血性ニューロパチー	0	1 (<0.1%)	1 (<0.1%)
Ischaemic stroke	虚血性脳卒中	0	1 (<0.1%)	1 (<0.1%)
Lumbar radiculopathy	腰髄神経根障害	1 (<0.1%)	0	1 (<0.1%)
Mental impairment	精神的機能障害	1 (<0.1%)	0	1 (<0.1%)
Myelopathy	脊髄症	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Nerve compression	神経圧迫	1 (<0.1%)	0	1 (<0.1%)
Neuralgia	神経痛	0	2 (<0.1%)	2 (<0.1%)
Parkinson's disease	パーキンソン病	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Parkinsonism	パーキンソニズム	0	1 (<0.1%)	1 (<0.1%)
Polyneuropathy	多発ニューロパチー	0	1 (<0.1%)	1 (<0.1%)
Presyncope	失神寸前の状態	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Pseudoradicular syndrome	偽性根症候群	1 (<0.1%)	0	1 (<0.1%)
Restless legs syndrome	下肢静止不能症候群	1 (<0.1%)	0	1 (<0.1%)
Sacral radiculopathy	仙部神経根症	1 (<0.1%)	0	1 (<0.1%)
Sciatica	坐骨神経痛	2 (<0.1%)	4 (0.1%)	6 (<0.1%)
Somnolence	傾眠	0	1 (<0.1%)	1 (<0.1%)
Spinal claudication	脊髄性跛行症	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Status epilepticus	てんかん重積状態	1 (<0.1%)	0	1 (<0.1%)
Syncope	失神	9 (0.3%)	11 (0.4%)	20 (0.3%)
Tension headache	緊張性頭痛	1 (<0.1%)	0	1 (<0.1%)
Tonic convulsion	強直性痙攣	1 (<0.1%)	0	1 (<0.1%)
Vascular encephalopathy	血管性脳症	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Vertebral artery stenosis	椎骨動脈狭窄	0	1 (<0.1%)	1 (<0.1%)
Product issues	製品の問題	3 (<0.1%)	1 (<0.1%)	4 (<0.1%)
Device breakage	医療機器破損	2 (<0.1%)	0	2 (<0.1%)
Device occlusion	医療機器閉塞	0	1 (<0.1%)	1 (<0.1%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3027 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3019 (100%)	Total N=6046 (100%)
Patient-device incompatibility	患者と医療機器間の不適合	1 (<0.1%)	0	1 (<0.1%)
Psychiatric disorders	精神障害	12 (0.4%)	13 (0.4%)	25 (0.4%)
Acute psychosis	急性精神病	0	1 (<0.1%)	1 (<0.1%)
Alcohol abuse	アルコール乱用	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Alcohol withdrawal syndrome	アルコール離脱症候群	0	1 (<0.1%)	1 (<0.1%)
Alcoholism	アルコール症	1 (<0.1%)	0	1 (<0.1%)
Completed suicide	自殺既遂	4 (0.1%)	0	4 (<0.1%)
Depression	うつ病	3 (<0.1%)	5 (0.2%)	8 (0.1%)
Drug abuse	薬物乱用	0	1 (<0.1%)	1 (<0.1%)
Intentional self-injury	故意の自傷行為	1 (<0.1%)	0	1 (<0.1%)
Mental status changes	精神状態変化	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Organic brain syndrome	器質性脳症候群	0	1 (<0.1%)	1 (<0.1%)
Transient psychosis	一過性精神病	1 (<0.1%)	0	1 (<0.1%)
Renal and urinary disorders	腎および尿路障害	33 (1.1%)	29 (1.0%)	62 (1.0%)
Acute kidney injury	急性腎障害	8 (0.3%)	17 (0.6%)	25 (0.4%)
Calculus bladder	膀胱結石	2 (<0.1%)	0	2 (<0.1%)
Calculus urinary	尿路結石	0	1 (<0.1%)	1 (<0.1%)
Chronic kidney disease	慢性腎臓病	4 (0.1%)	1 (<0.1%)	5 (<0.1%)
End stage renal disease	末期腎疾患	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Nephrolithiasis	腎結石症	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Pelvi-ureteric obstruction	骨盤部尿管閉塞	1 (<0.1%)	0	1 (<0.1%)
Renal artery stenosis	腎動脈狭窄症	0	1 (<0.1%)	1 (<0.1%)
Renal colic	腎仙痛	4 (0.1%)	0	4 (<0.1%)
Renal failure	腎不全	5 (0.2%)	2 (<0.1%)	7 (0.1%)
Renal impairment	腎機能障害	2 (<0.1%)	1 (<0.1%)	3 (<0.1%)
Ureteric fistula	尿管瘻	1 (<0.1%)	0	1 (<0.1%)
Ureterolithiasis	尿管結石症	0	1 (<0.1%)	1 (<0.1%)
Urethral stenosis	尿道狭窄	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Urinary incontinence	尿失禁	1 (<0.1%)	0	1 (<0.1%)
Urinary retention	尿閉	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Urinary tract obstruction	尿路閉塞	1 (<0.1%)	0	1 (<0.1%)
Reproductive system and breast disorders	生殖系および乳房障害	8 (0.3%)	4 (0.1%)	12 (0.2%)
Benign prostatic hyperplasia	良性前立腺肥大症	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Cervical polyp	子宮頚管ポリープ	1 (<0.1%)	0	1 (<0.1%)
Pelvic prolapse	骨盤脱	0	1 (<0.1%)	1 (<0.1%)
Prostatic obstruction	前立腺閉塞	1 (<0.1%)	0	1 (<0.1%)
Spermatocele	精液瘤	1 (<0.1%)	0	1 (<0.1%)
Uterine prolapse	子宮脱	2 (<0.1%)	0	2 (<0.1%)
Vulval eczema	外陰部湿疹	0	1 (<0.1%)	1 (<0.1%)
Vulvar dysplasia	外陰異形成	1 (<0.1%)	0	1 (<0.1%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	45 (1.5%)	39 (1.3%)	84 (1.4%)
Acute pulmonary oedema	急性肺水腫	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Acute respiratory distress syndrome	急性呼吸窮迫症候群	1 (<0.1%)	0	1 (<0.1%)
Acute respiratory failure	急性呼吸不全	2 (<0.1%)	5 (0.2%)	7 (0.1%)
Aspiration	誤嚥	1 (<0.1%)	0	1 (<0.1%)
Asthma	喘息	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	16 (0.5%)	9 (0.3%)	25 (0.4%)
Chronic respiratory disease	慢性呼吸疾患	1 (<0.1%)	0	1 (<0.1%)
Cough	咳嗽	1 (<0.1%)	0	1 (<0.1%)
Dyspnoea	呼吸困難	2 (<0.1%)	6 (0.2%)	8 (0.1%)
Hypoxia	低酸素症	1 (<0.1%)	0	1 (<0.1%)
Nasal septum deviation	鼻中隔弯曲	1 (<0.1%)	0	1 (<0.1%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3027 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3019 (100%)	Total N=6046 (100%)
Pharyngeal lesion	咽頭病変	0	1 (<0.1%)	1 (<0.1%)
Pleural effusion	胸水	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Pneumonia aspiration	誤嚥性肺炎	4 (0.1%)	2 (<0.1%)	6 (<0.1%)
Pneumothorax	気胸	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Pneumothorax spontaneous	自然気胸	1 (<0.1%)	0	1 (<0.1%)
Pulmonary congestion	肺うっ血	1 (<0.1%)	0	1 (<0.1%)
Pulmonary embolism	肺塞栓症	0	1 (<0.1%)	1 (<0.1%)
Pulmonary fibrosis	肺線維症	0	1 (<0.1%)	1 (<0.1%)
Pulmonary mass	肺腫瘤	1 (<0.1%)	0	1 (<0.1%)
Pulmonary oedema	肺水腫	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Respiratory distress	呼吸窮迫	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Respiratory failure	呼吸不全	5 (0.2%)	4 (0.1%)	9 (0.1%)
Sinus polyp	副鼻腔ポリープ	1 (<0.1%)	0	1 (<0.1%)
Tonsillar cyst	扁桃嚢胞	0	1 (<0.1%)	1 (<0.1%)
Vocal cord polyp	声帯ポリープ	0	1 (<0.1%)	1 (<0.1%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	30 (1.0%)	31 (1.0%)	61 (1.0%)
Angioedema	血管浮腫	0	2 (<0.1%)	2 (<0.1%)
Decubitus ulcer	褥瘡性潰瘍	0	2 (<0.1%)	2 (<0.1%)
Dermatitis	皮膚炎	2 (<0.1%)	0	2 (<0.1%)
Dermatitis allergic	アレルギー性皮膚炎	1 (<0.1%)	0	1 (<0.1%)
Dermatitis contact	接触皮膚炎	0	1 (<0.1%)	1 (<0.1%)
Diabetic foot	糖尿病性足病変	9 (0.3%)	8 (0.3%)	17 (0.3%)
Diabetic ulcer	糖尿病性潰瘍	1 (<0.1%)	0	1 (<0.1%)
Hidradenitis	汗腺炎	0	1 (<0.1%)	1 (<0.1%)
Ischaemic skin ulcer	虚血性皮膚潰瘍	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Myxoid cyst	粘液様嚢胞	1 (<0.1%)	0	1 (<0.1%)
Pemphigoid	類天疱瘡	2 (<0.1%)	0	2 (<0.1%)
Pemphigus	天疱瘡	0	1 (<0.1%)	1 (<0.1%)
Skin exfoliation	皮膚剥脱	1 (<0.1%)	0	1 (<0.1%)
Skin lesion	皮膚病変	0	1 (<0.1%)	1 (<0.1%)
Skin necrosis	皮膚壊死	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Skin ulcer	皮膚潰瘍	10 (0.3%)	12 (0.4%)	22 (0.4%)
Toxic skin eruption	中毒性皮疹	0	1 (<0.1%)	1 (<0.1%)
Urticaria	蕁麻疹	1 (<0.1%)	0	1 (<0.1%)
Social circumstances	社会環境	0	1 (<0.1%)	1 (<0.1%)
Disease risk factor	疾患の危険因子	0	1 (<0.1%)	1 (<0.1%)
Surgical and medical procedures	外科および内科処置	9 (0.3%)	13 (0.4%)	22 (0.4%)
Amputation	切断	1 (<0.1%)	0	1 (<0.1%)
Bladder calculus removal	膀胱結石除去	0	1 (<0.1%)	1 (<0.1%)
Bladder neoplasm surgery	膀胱新生物手術	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Bladder polypectomy	膀胱ポリープ切除	0	1 (<0.1%)	1 (<0.1%)
Blepharoplasty	眼瞼形成	1 (<0.1%)	0	1 (<0.1%)
Brain tumour operation	脳腫瘍手術	1 (<0.1%)	0	1 (<0.1%)
Carotid endarterectomy	頚動脈内膜剥離術	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Cystoprostatectomy	膀胱前立腺摘除	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Eventration repair	脱出臓器還納	0	1 (<0.1%)	1 (<0.1%)
Foot amputation	足切断	1 (<0.1%)	0	1 (<0.1%)
Knee arthroplasty	膝関節形成	0	2 (<0.1%)	2 (<0.1%)
Limb reconstructive surgery	四肢再建手術	0	1 (<0.1%)	1 (<0.1%)
Peripheral artery angioplasty	末梢動脈形成	1 (<0.1%)	0	1 (<0.1%)
Peripheral artery bypass	末梢動脈バイパス	0	1 (<0.1%)	1 (<0.1%)
Peripheral artery stent insertion	末梢動脈ステント挿入	1 (<0.1%)	0	1 (<0.1%)
Peripheral revascularisation	末梢血行再建	0	1 (<0.1%)	1 (<0.1%)
Radical prostatectomy	根治的前立腺摘除	0	1 (<0.1%)	1 (<0.1%)
Transurethral bladder resection	経尿道的膀胱切除	0	1 (<0.1%)	1 (<0.1%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=3027 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=3019 (100%)	Total N=6046 (100%)
Umbilical hernia repair	臍ヘルニア修復	1 (<0.1%)	0	1 (<0.1%)
Vitrectomy	硝子体切除	0	1 (<0.1%)	1 (<0.1%)
Vascular disorders	血管障害	205 (6.8%)	208 (6.9%)	413 (6.8%)
Angiopathy	血管障害	1 (<0.1%)	0	1 (<0.1%)
Aortic aneurysm	大動脈瘤	1 (<0.1%)	4 (0.1%)	5 (<0.1%)
Aortic stenosis	大動脈狭窄	6 (0.2%)	3 (<0.1%)	9 (0.1%)
Arterial occlusive disease	動脈閉塞性疾患	0	1 (<0.1%)	1 (<0.1%)
Arteriovenous fistula	動静脈瘻	0	1 (<0.1%)	1 (<0.1%)
Circulatory collapse	循環虚脱	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Dry gangrene	乾性壊疽	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Extremity necrosis	四肢壊死	11 (0.4%)	7 (0.2%)	18 (0.3%)
Hypertension	高血圧	1 (<0.1%)	5 (0.2%)	6 (<0.1%)
Hypertensive crisis	高血圧クリーゼ	5 (0.2%)	6 (0.2%)	11 (0.2%)
Hypertensive emergency	高血圧緊急症	1 (<0.1%)	0	1 (<0.1%)
Hypertensive urgency	高血圧切迫症	0	1 (<0.1%)	1 (<0.1%)
Hypotension	低血圧	3 (<0.1%)	0	3 (<0.1%)
Hypovolaemic shock	血液量減少性ショック	1 (<0.1%)	0	1 (<0.1%)
Iliac artery stenosis	腸骨動脈狭窄	3 (<0.1%)	3 (<0.1%)	6 (<0.1%)
Intermittent claudication	間欠性跛行	41 (1.4%)	50 (1.7%)	91 (1.5%)
Ischaemic limb pain	虚血性四肢痛	0	1 (<0.1%)	1 (<0.1%)
Lymphatic fistula	リンパ瘻	0	3 (<0.1%)	3 (<0.1%)
Lymphocele	リンパ嚢腫	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Lymphoedema	リンパ浮腫	0	1 (<0.1%)	1 (<0.1%)
Lymphorrhoea	リンパ漏	2 (<0.1%)	0	2 (<0.1%)
Orthostatic hypotension	起立性低血圧	0	1 (<0.1%)	1 (<0.1%)
Peripheral arterial occlusive disease	末梢動脈閉塞性疾患	78 (2.6%)	75 (2.5%)	153 (2.5%)
Peripheral artery aneurysm	末梢動脈瘤	0	1 (<0.1%)	1 (<0.1%)
Peripheral artery occlusion	末梢動脈閉塞	5 (0.2%)	9 (0.3%)	14 (0.2%)
Peripheral artery stenosis	末梢動脈狭窄	14 (0.5%)	12 (0.4%)	26 (0.4%)
Peripheral artery thrombosis	末梢動脈血栓症	2 (<0.1%)	2 (<0.1%)	4 (<0.1%)
Peripheral coldness	末梢冷感	0	1 (<0.1%)	1 (<0.1%)
Peripheral embolism	末梢血管塞栓症	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Peripheral ischaemia	末梢性虚血	28 (0.9%)	17 (0.6%)	45 (0.7%)
Peripheral vascular disorder	末梢血管障害	3 (<0.1%)	5 (0.2%)	8 (0.1%)
Peripheral venous disease	末梢静脈疾患	1 (<0.1%)	0	1 (<0.1%)
Poor peripheral circulation	末梢循環不良	1 (<0.1%)	1 (<0.1%)	2 (<0.1%)
Renovascular hypertension	腎血管性高血圧	1 (<0.1%)	0	1 (<0.1%)
Subclavian artery stenosis	鎖骨下動脈狭窄	0	1 (<0.1%)	1 (<0.1%)
Temporal arteritis	側頭動脈炎	1 (<0.1%)	0	1 (<0.1%)
Thrombophlebitis superficial	表在性血栓性静脈炎	0	1 (<0.1%)	1 (<0.1%)
Varicose vein	静脈瘤	1 (<0.1%)	2 (<0.1%)	3 (<0.1%)
Vascular stenosis	血管狭窄	0	1 (<0.1%)	1 (<0.1%)
Venous occlusion	静脈閉塞	1 (<0.1%)	0	1 (<0.1%)

The safety analysis set includes all randomized subjects who received at least one dose of study drug (rivaroxaban or rivaroxaban placebo).
Adverse events are sorted in alphabetical order by primary SOC and preferred term.
A subject is counted only once within each preferred term or any primary SOC.
bid = twice daily, od = once daily, ASA = acetylsalicylic acid
Treatment emergent events are defined as all events with an onset date on or after the date of randomization until 2 days following permanent discontinuation of the study drug (rivaroxaban or rivaroxaban placebo).
Source: 5.3.5.1.1 PH-40164/Table 14.3.1.2/3

付表 2.7.6.1.a.1-8 すべての TEAE 及び治験薬と関連のある TEAE（日本人集団、SAF）

Primary system organ class Preferred term MedDRA version 22.1	Primary system organ class Preferred term MedDRA version 22.1	Treatment-emergent Rivaroxaban 2.5 mg bid, Aspirin 100mg od N=229 (100%)	Treatment-emergent Rivaroxaban Placebo, Aspirin 100 mg od N=229 (100%)	Study drug-related Rivaroxaban 2.5 mg bid, Aspirin 100mg od N=229 (100%)	Study drug-related Rivaroxaban Placebo, Aspirin 100 mg od N=229 (100%)
Number of subjects (%) with at least one adverse event	Number of subjects (%) with at least one adverse event	154 (67.2%)	139 (60.7%)	15 (6.6%)	15 (6.6%)
Blood and lymphatic system disorders	血液およびリンパ系障害	11 (4.8%)	3 (1.3%)	4 (1.7%)	2 (0.9%)
Anaemia	貧血	6 (2.6%)	3 (1.3%)	3 (1.3%)	2 (0.9%)
Iron deficiency anaemia	鉄欠乏性貧血	4 (1.7%)	0	1 (0.4%)	0
Nephrogenic anaemia	腎性貧血	1 (0.4%)	0	0	0
Cardiac disorders	心臓障害	25 (10.9%)	17 (7.4%)	0	1 (0.4%)
Angina pectoris	狭心症	2 (0.9%)	4 (1.7%)	0	0
Angina unstable	不安定狭心症	1 (0.4%)	0	0	0
Aortic valve stenosis	大動脈弁狭窄	1 (0.4%)	1 (0.4%)	0	0
Atrial fibrillation	心房細動	5 (2.2%)	6 (2.6%)	0	0
Atrial flutter	心房粗動	2 (0.9%)	0	0	0
Bradycardia	徐脈	1 (0.4%)	0	0	0
Cardiac failure	心不全	2 (0.9%)	2 (0.9%)	0	0
Cardiac failure acute	急性心不全	1 (0.4%)	0	0	0
Cardiac failure chronic	慢性心不全	2 (0.9%)	0	0	0
Cardiac failure congestive	うっ血性心不全	1 (0.4%)	1 (0.4%)	0	0
Cardiac valve disease	心臓弁膜疾患	1 (0.4%)	0	0	0
Coronary artery disease	冠動脈疾患	1 (0.4%)	0	0	0
Coronary artery stenosis	冠動脈狭窄	3 (1.3%)	0	0	0
Myocardial ischaemia	心筋虚血	2 (0.9%)	0	0	0
Pericardial effusion	心嚢液貯留	0	1 (0.4%)	0	0
Pericardial haemorrhage	心嚢内出血	0	1 (0.4%)	0	1 (0.4%)
Right ventricular failure	右室不全	0	1 (0.4%)	0	0
Stress cardiomyopathy	ストレス心筋症	0	1 (0.4%)	0	0
Supraventricular extrasystoles	上室性期外収縮	1 (0.4%)	0	0	0
Supraventricular tachycardia	上室性頻脈	2 (0.9%)	0	0	0
Ear and labyrinth disorders	耳および迷路障害	1 (0.4%)	1 (0.4%)	0	0
Sudden hearing loss	突発性難聴	1 (0.4%)	0	0	0
Vertigo	回転性めまい	0	1 (0.4%)	0	0
Eye disorders	眼障害	7 (3.1%)	8 (3.5%)	1 (0.4%)	0
Cataract	白内障	4 (1.7%)	5 (2.2%)	0	0
Cataract subcapsular	嚢下白内障	1 (0.4%)	0	0	0
Diabetic retinopathy	糖尿病網膜症	0	1 (0.4%)	0	0
Eyelid ptosis	眼瞼下垂	0	1 (0.4%)	0	0
Macular hole	黄斑円孔	1 (0.4%)	0	0	0
Retinal haemorrhage	網膜出血	0	1 (0.4%)	0	0
Vitreoretinal traction syndrome	硝子体網膜牽引症候群	1 (0.4%)	0	0	0
Vitreous haemorrhage	硝子体出血	1 (0.4%)	0	1 (0.4%)	0
Gastrointestinal disorders	胃腸障害	21 (9.2%)	14 (6.1%)	7 (3.1%)	2 (0.9%)
Abdominal pain	腹痛	0	1 (0.4%)	0	0
Abdominal pain upper	上腹部痛	2 (0.9%)	0	0	0
Anal stenosis	肛門狭窄	0	1 (0.4%)	0	0
Colitis ischaemic	虚血性大腸炎	0	1 (0.4%)	0	0
Diverticulum intestinal haemorrhagic	出血性腸憩室	1 (0.4%)	1 (0.4%)	1 (0.4%)	1 (0.4%)
Gastric haemorrhage	胃出血	1 (0.4%)	0	0	0
Gastric ulcer	胃潰瘍	2 (0.9%)	1 (0.4%)	1 (0.4%)	0

Primary system organ class Preferred term MedDRA version 22.1	Primary system organ class Preferred term MedDRA version 22.1	Treatment-emergent Rivaroxaban 2.5 mg bid, Aspirin 100mg od N=229 (100%)	Treatment-emergent Rivaroxaban Placebo, Aspirin 100 mg od N=229 (100%)	Study drug-related Rivaroxaban 2.5 mg bid, Aspirin 100mg od N=229 (100%)	Study drug-related Rivaroxaban Placebo, Aspirin 100 mg od N=229 (100%)
Gastric ulcer haemorrhage	出血性胃潰瘍	1 (0.4%)	0	1 (0.4%)	0
Gastritis	胃炎	1 (0.4%)	0	0	0
Gastrooesophageal reflux disease	胃食道逆流性疾患	0	1 (0.4%)	0	0
Glossitis	舌炎	1 (0.4%)	0	0	0
Haemorrhoids	痔核	0	1 (0.4%)	0	0
Ileus	イレウス	1 (0.4%)	0	0	0
Inguinal hernia	鼠径ヘルニア	1 (0.4%)	0	0	0
Intestinal ischaemia	腸管虚血	1 (0.4%)	0	0	0
Large intestine polyp	大腸ポリープ	7 (3.1%)	4 (1.7%)	0	0
Lower gastrointestinal haemorrhage	下部消化管出血	1 (0.4%)	0	1 (0.4%)	0
Melaena	メレナ	1 (0.4%)	0	1 (0.4%)	0
Pancreatitis	膵炎	1 (0.4%)	1 (0.4%)	0	1 (0.4%)
Pancreatitis acute	急性膵炎	0	1 (0.4%)	0	0
Pancreatitis chronic	慢性膵炎	0	1 (0.4%)	0	1 (0.4%)
Periodontal disease	歯周病	1 (0.4%)	0	0	0
Tooth loss	歯の脱落	0	1 (0.4%)	0	0
Upper gastrointestinal haemorrhage	上部消化管出血	2 (0.9%)	0	2 (0.9%)	0
Volvulus	腸の軸捻転	0	1 (0.4%)	0	0
General disorders and administration site conditions	一般・全身障害および投与部位の状態	9 (3.9%)	11 (4.8%)	1 (0.4%)	1 (0.4%)
Chest pain	胸痛	4 (1.7%)	2 (0.9%)	0	0
Oedema	浮腫	0	1 (0.4%)	0	0
Oedema peripheral	末梢性浮腫	0	2 (0.9%)	0	1 (0.4%)
Puncture site haemorrhage	穿刺部位出血	1 (0.4%)	0	1 (0.4%)	0
Vascular stent stenosis	血管ステント狭窄	4 (1.7%)	6 (2.6%)	0	0
Vascular stent thrombosis	血管ステント血栓症	0	1 (0.4%)	0	0
Hepatobiliary disorders	肝胆道系障害	3 (1.3%)	5 (2.2%)	0	0
Bile duct stone	胆管結石	1 (0.4%)	1 (0.4%)	0	0
Cholangitis	胆管炎	1 (0.4%)	3 (1.3%)	0	0
Cholecystitis acute	急性胆嚢炎	0	1 (0.4%)	0	0
Cholelithiasis	胆石症	1 (0.4%)	0	0	0
Immune system disorders	免疫系障害	1 (0.4%)	0	0	0
Hypersensitivity	過敏症	1 (0.4%)	0	0	0
Infections and infestations	感染症および寄生虫症	18 (7.9%)	17 (7.4%)	0	0
Arthritis bacterial	細菌性関節炎	1 (0.4%)	0	0	0
Cellulitis	蜂巣炎	4 (1.7%)	1 (0.4%)	0	0
Diverticulitis	憩室炎	0	1 (0.4%)	0	0
Gastroenteritis	胃腸炎	0	2 (0.9%)	0	0
Gastroenteritis salmonella	サルモネラ菌性胃腸炎	0	1 (0.4%)	0	0
Herpes zoster	帯状疱疹	1 (0.4%)	1 (0.4%)	0	0
Nasopharyngitis	上咽頭炎	0	2 (0.9%)	0	0
Oral herpes	口腔ヘルペス	0	1 (0.4%)	0	0
Osteomyelitis	骨髄炎	0	1 (0.4%)	0	0
Osteomyelitis bacterial	細菌性骨髄炎	0	1 (0.4%)	0	0
Periodontitis	歯周炎	0	1 (0.4%)	0	0
Peritonitis	腹膜炎	1 (0.4%)	0	0	0
Pharyngitis	咽頭炎	1 (0.4%)	0	0	0
Pneumonia	肺炎	8 (3.5%)	3 (1.3%)	0	0
Pneumonia bacterial	細菌性肺炎	0	2 (0.9%)	0	0

Primary system organ class Preferred term MedDRA version 22.1	Primary system organ class Preferred term MedDRA version 22.1	Treatment-emergent Rivaroxaban 2.5 mg bid, Aspirin 100mg od N=229 (100%)	Treatment-emergent Rivaroxaban Placebo, Aspirin 100 mg od N=229 (100%)	Study drug-related Rivaroxaban 2.5 mg bid, Aspirin 100mg od N=229 (100%)	Study drug-related Rivaroxaban Placebo, Aspirin 100 mg od N=229 (100%)
Postoperative wound infection	術後創感染	1 (0.4%)	1 (0.4%)	0	0
Pyelonephritis	腎盂腎炎	0	2 (0.9%)	0	0
Sepsis	敗血症	0	1 (0.4%)	0	0
Streptococcal sepsis	レンサ球菌性敗血症	0	1 (0.4%)	0	0
Urinary tract infection	尿路感染	2 (0.9%)	1 (0.4%)	0	0
Wound infection	創傷感染	2 (0.9%)	0	0	0
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	26 (11.4%)	17 (7.4%)	0	1 (0.4%)
Anastomotic stenosis	吻合部狭窄	0	1 (0.4%)	0	0
Brain herniation	脳ヘルニア	0	1 (0.4%)	0	0
Cerebral hyperperfusion syndrome	脳過潅流症候群	1 (0.4%)	0	0	0
Contusion	挫傷	0	1 (0.4%)	0	0
Coronary artery restenosis	冠動脈再狭窄	1 (0.4%)	0	0	0
Facial bones fracture	顔面骨骨折	0	1 (0.4%)	0	0
Femur fracture	大腿骨骨折	2 (0.9%)	1 (0.4%)	0	0
Foot fracture	足骨折	0	1 (0.4%)	0	0
Fractured sacrum	仙骨骨折	0	1 (0.4%)	0	0
Humerus fracture	上腕骨骨折	0	1 (0.4%)	0	0
Incisional hernia	癒痕ヘルニア	0	1 (0.4%)	0	0
Meniscus injury	半月板損傷	0	1 (0.4%)	0	0
Multiple injuries	多発性外傷	1 (0.4%)	0	0	0
Peripheral arterial reocclusion	末梢動脈再閉塞	4 (1.7%)	2 (0.9%)	0	0
Peripheral artery restenosis	末梢動脈再狭窄	12 (5.2%)	7 (3.1%)	0	0
Procedural pain	処置による疼痛	1 (0.4%)	0	0	0
Radius fracture	橈骨骨折	2 (0.9%)	0	0	0
Rib fracture	肋骨骨折	1 (0.4%)	0	0	0
Spinal compression fracture	脊椎圧迫骨折	1 (0.4%)	0	0	0
Thermal burn	熱傷	1 (0.4%)	0	0	0
Thoracic vertebral fracture	胸椎骨折	1 (0.4%)	0	0	0
Traumatic intracranial haemorrhage	外傷性頭蓋内出血	0	1 (0.4%)	0	1 (0.4%)
Vascular access site haematoma	血管確保部位血腫	1 (0.4%)	0	0	0
Vascular graft restenosis	移植血管再狭窄	0	1 (0.4%)	0	0
Investigations	臨床検査	2 (0.9%)	1 (0.4%)	0	0
Blood potassium increased	血中カリウム増加	1 (0.4%)	0	0	0
Carbohydrate antigen 19-9 increased	糖鎖抗原１９－９増加	1 (0.4%)	0	0	0
Cardiothoracic ratio increased	心胸郭比増加	0	1 (0.4%)	0	0
Metabolism and nutrition disorders	代謝および栄養障害	6 (2.6%)	8 (3.5%)	0	0
Decreased appetite	食欲減退	1 (0.4%)	0	0	0
Diabetes mellitus	糖尿病	3 (1.3%)	4 (1.7%)	0	0
Dyslipidaemia	脂質異常症	0	1 (0.4%)	0	0
Hypoglycaemia	低血糖	1 (0.4%)	1 (0.4%)	0	0
Hypokalaemia	低カリウム血症	1 (0.4%)	0	0	0
Hyponatraemia	低ナトリウム血症	0	1 (0.4%)	0	0
Hypophagia	過小食	0	1 (0.4%)	0	0

Primary system organ class Preferred term MedDRA version 22.1	Primary system organ class Preferred term MedDRA version 22.1	Treatment-emergent Rivaroxaban 2.5 mg bid, Aspirin 100mg od N=229 (100%)	Treatment-emergent Rivaroxaban Placebo, Aspirin 100 mg od N=229 (100%)	Study drug-related Rivaroxaban 2.5 mg bid, Aspirin 100mg od N=229 (100%)	Study drug-related Rivaroxaban Placebo, Aspirin 100 mg od N=229 (100%)
Type 2 diabetes mellitus	２型糖尿病	1 (0.4%)	0	0	0
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	12 (5.2%)	9 (3.9%)	1 (0.4%)	0
Arthralgia	関節痛	1 (0.4%)	0	0	0
Back pain	背部痛	2 (0.9%)	1 (0.4%)	0	0
Intervertebral disc protrusion	椎間板突出	1 (0.4%)	0	0	0
Jaw cyst	顎骨嚢胞	1 (0.4%)	0	0	0
Joint swelling	関節腫脹	1 (0.4%)	0	0	0
Lumbar spinal stenosis	腰部脊柱管狭窄症	3 (1.3%)	1 (0.4%)	0	0
Myalgia	筋肉痛	1 (0.4%)	0	1 (0.4%)	0
Osteoarthritis	変形性関節症	2 (0.9%)	2 (0.9%)	0	0
Osteoporosis	骨粗鬆症	0	1 (0.4%)	0	0
Rheumatic disorder	リウマチ性障害	0	1 (0.4%)	0	0
Rotator cuff syndrome	肩回旋筋腱板症候群	0	2 (0.9%)	0	0
Spinal osteoarthritis	変形性脊椎症	0	2 (0.9%)	0	0
Spondylolisthesis	脊椎すべり症	1 (0.4%)	0	0	0
Vertebral column mass	脊柱腫瘤	1 (0.4%)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	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）	18 (7.9%)	22 (9.6%)	0	0
Adenocarcinoma	腺癌	0	1 (0.4%)	0	0
Adenocarcinoma of colon	結腸腺癌	1 (0.4%)	0	0	0
Adenocarcinoma pancreas	膵腺癌	0	1 (0.4%)	0	0
B-cell lymphoma	Ｂ細胞性リンパ腫	0	1 (0.4%)	0	0
Basal cell carcinoma	基底細胞癌	0	1 (0.4%)	0	0
Bladder cancer	膀胱癌	1 (0.4%)	1 (0.4%)	0	0
Cholangiocarcinoma	胆管細胞癌	1 (0.4%)	0	0	0
Cholesteatoma	真珠腫	0	1 (0.4%)	0	0
Chronic myeloid leukaemia	慢性骨髄性白血病	0	1 (0.4%)	0	0
Colon adenoma	大腸腺腫	1 (0.4%)	0	0	0
Colon cancer	結腸癌	1 (0.4%)	0	0	0
Colorectal cancer	結腸直腸癌	0	1 (0.4%)	0	0
Gallbladder cancer	胆嚢癌	1 (0.4%)	0	0	0
Gallbladder neoplasm	胆嚢新生物	1 (0.4%)	0	0	0
Gastric cancer	胃癌	5 (2.2%)	3 (1.3%)	0	0
Gastric cancer stage I	胃癌第１期	1 (0.4%)	0	0	0
Inflammatory pseudotumour	炎症性偽腫瘍	1 (0.4%)	0	0	0
Laryngeal cancer	喉頭癌	0	1 (0.4%)	0	0
Lung carcinoma cell type unspecified stage IV	肺癌第４期、細胞タイプ不明	0	1 (0.4%)	0	0
Lung neoplasm	肺新生物	0	1 (0.4%)	0	0
Lung neoplasm malignant	肺の悪性新生物	1 (0.4%)	2 (0.9%)	0	0
Oesophageal carcinoma	食道癌	0	1 (0.4%)	0	0
Pancreatic carcinoma	膵癌	0	2 (0.9%)	0	0
Prostate cancer	前立腺癌	1 (0.4%)	0	0	0
Rectal cancer	直腸癌	1 (0.4%)	1 (0.4%)	0	0
Small cell lung cancer	小細胞肺癌	1 (0.4%)	2 (0.9%)	0	0
Thymoma malignant	悪性胸腺腫	1 (0.4%)	0	0	0
Nervous system disorders	神経系障害	8 (3.5%)	10 (4.4%)	0	3 (1.3%)
Carotid artery stenosis	頚動脈狭窄	2 (0.9%)	2 (0.9%)	0	0
Cerebral haemorrhage	脳出血	0	1 (0.4%)	0	1 (0.4%)

Primary system organ class Preferred term MedDRA version 22.1	Primary system organ class Preferred term MedDRA version 22.1	Treatment-emergent Rivaroxaban 2.5 mg bid, Aspirin 100mg od N=229 (100%)	Treatment-emergent Rivaroxaban Placebo, Aspirin 100 mg od N=229 (100%)	Study drug-related Rivaroxaban 2.5 mg bid, Aspirin 100mg od N=229 (100%)	Study drug-related Rivaroxaban Placebo, Aspirin 100 mg od N=229 (100%)
Dementia	認知症	1 (0.4%)	1 (0.4%)	0	0
Dementia Alzheimer's type	アルツハイマー型認知症	0	1 (0.4%)	0	0
Dizziness	浮動性めまい	2 (0.9%)	0	0	0
Dizziness postural	体位性めまい	1 (0.4%)	0	0	0
Hydrocephalus	水頭症	0	1 (0.4%)	0	0
Intracranial aneurysm	頭蓋内動脈瘤	0	1 (0.4%)	0	0
Myelopathy	脊髄症	0	1 (0.4%)	0	0
Parkinson's disease	パーキンソン病	1 (0.4%)	0	0	0
Putamen haemorrhage	被殻出血	0	1 (0.4%)	0	1 (0.4%)
Sciatica	坐骨神経痛	1 (0.4%)	0	0	0
Subarachnoid haemorrhage	くも膜下出血	0	1 (0.4%)	0	1 (0.4%)
Vascular dementia	血管性認知症	0	1 (0.4%)	0	0
Product issues	製品の問題	2 (0.9%)	0	0	0
Device battery issue	医療機器バッテリー問題	1 (0.4%)	0	0	0
Device dislocation	医療機器位置異常	1 (0.4%)	0	0	0
Renal and urinary disorders	腎および尿路障害	7 (3.1%)	5 (2.2%)	1 (0.4%)	1 (0.4%)
Acute kidney injury	急性腎障害	1 (0.4%)	0	0	0
Calculus bladder	膀胱結石	1 (0.4%)	0	0	0
Chronic kidney disease	慢性腎臓病	2 (0.9%)	1 (0.4%)	0	0
Diabetic nephropathy	糖尿病性腎症	1 (0.4%)	0	0	0
Renal failure	腎不全	1 (0.4%)	1 (0.4%)	0	0
Renal impairment	腎機能障害	1 (0.4%)	3 (1.3%)	1 (0.4%)	1 (0.4%)
Reproductive system and breast disorders	生殖系および乳房障害	2 (0.9%)	0	0	0
Benign prostatic hyperplasia	良性前立腺肥大症	1 (0.4%)	0	0	0
Prostatitis	前立腺炎	1 (0.4%)	0	0	0
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	9 (3.9%)	11 (4.8%)	1 (0.4%)	1 (0.4%)
Acute interstitial pneumonitis	急性間質性肺臓炎	0	1 (0.4%)	0	0
Aspirin-exacerbated respiratory disease	アスピリン増悪呼吸器疾患	0	1 (0.4%)	0	0
Asthma	喘息	0	1 (0.4%)	0	0
Chronic obstructive pulmonary disease	慢性閉塞性肺疾患	1 (0.4%)	0	0	0
Dyspnoea	呼吸困難	2 (0.9%)	0	0	0
Emphysema	肺気腫	0	1 (0.4%)	0	0
Haemoptysis	喀血	0	2 (0.9%)	0	1 (0.4%)
Interstitial lung disease	間質性肺疾患	1 (0.4%)	1 (0.4%)	0	0
Nasal polyps	鼻茸	1 (0.4%)	0	0	0
Pleural effusion	胸水	0	1 (0.4%)	0	0
Pneumonia aspiration	誤嚥性肺炎	1 (0.4%)	4 (1.7%)	0	0
Pneumothorax	気胸	2 (0.9%)	0	0	0
Pulmonary fibrosis	肺線維症	1 (0.4%)	0	1 (0.4%)	0
Pulmonary hypertension	肺高血圧症	0	1 (0.4%)	0	0
Sputum increased	喀痰増加	0	1 (0.4%)	0	0
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	4 (1.7%)	10 (4.4%)	1 (0.4%)	5 (2.2%)
Dermal cyst	皮膚嚢腫	1 (0.4%)	1 (0.4%)	0	0
Diabetic foot	糖尿病性足病変	0	1 (0.4%)	0	0

Primary system organ class Preferred term MedDRA version 22.1	Primary system organ class Preferred term MedDRA version 22.1	Treatment-emergent Rivaroxaban 2.5 mg bid, Aspirin 100mg od N=229 (100%)	Treatment-emergent Rivaroxaban Placebo, Aspirin 100 mg od N=229 (100%)	Study drug-related Rivaroxaban 2.5 mg bid, Aspirin 100mg od N=229 (100%)	Study drug-related Rivaroxaban Placebo, Aspirin 100 mg od N=229 (100%)
Drug eruption	薬疹	1 (0.4%)	0	1 (0.4%)	0
Drug reaction with eosinophilia and systemic symptoms	好酸球増加と全身症状を伴う薬物反応	0	1 (0.4%)	0	1 (0.4%)
Eczema	湿疹	0	1 (0.4%)	0	1 (0.4%)
Haemorrhage subcutaneous	皮下出血	0	1 (0.4%)	0	1 (0.4%)
Ischaemic skin ulcer	虚血性皮膚潰瘍	0	2 (0.9%)	0	0
Rash	発疹	1 (0.4%)	1 (0.4%)	0	1 (0.4%)
Rash erythematous	紅斑性皮疹	0	1 (0.4%)	0	1 (0.4%)
Urticaria	蕁麻疹	1 (0.4%)	0	0	0
Urticarial vasculitis	蕁麻疹様血管炎	0	1 (0.4%)	0	0
Surgical and medical procedures	外科および内科処置	0	1 (0.4%)	0	0
Diabetes mellitus management	糖尿病管理	0	1 (0.4%)	0	0
Vascular disorders	血管障害	67 (29.3%)	66 (28.8%)	1 (0.4%)	0
Aortic aneurysm	大動脈瘤	1 (0.4%)	0	0	0
Aortic dissection	大動脈解離	1 (0.4%)	0	0	0
Dry gangrene	乾性壊疽	0	1 (0.4%)	0	0
Extremity necrosis	四肢壊死	1 (0.4%)	1 (0.4%)	0	0
Haematoma	血腫	1 (0.4%)	0	1 (0.4%)	0
Hypertension	高血圧	1 (0.4%)	1 (0.4%)	0	0
Hypotension	低血圧	1 (0.4%)	0	0	0
Iliac artery stenosis	腸骨動脈狭窄	1 (0.4%)	0	0	0
Intermittent claudication	間欠性跛行	2 (0.9%)	2 (0.9%)	0	0
Peripheral arterial occlusive disease	末梢動脈閉塞性疾患	47 (20.5%)	55 (24.0%)	0	0
Peripheral artery occlusion	末梢動脈閉塞	2 (0.9%)	1 (0.4%)	0	0
Peripheral artery stenosis	末梢動脈狭窄	11 (4.8%)	2 (0.9%)	0	0
Peripheral artery thrombosis	末梢動脈血栓症	1 (0.4%)	0	0	0
Peripheral ischaemia	末梢性虚血	6 (2.6%)	12 (5.2%)	0	0

Source: 5.3.5.1.3 17454_add1/Table 1.1/2

付表 2.7.6.1.a.1-9 重篤な TEAE（日本人集団、SAF）

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=229 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=229 (100%)	Total N=458 (100%)
Number (%) of subjects with at least one adverse event		139 (60.7%)	124 (54.1%)	263 (57.4%)
Blood and lymphatic system disorders	血液およびリンパ系障害	5 (2.2%)	1 (0.4%)	6 (1.3%)
Anaemia	貧血	2 (0.9%)	1 (0.4%)	3 (0.7%)
Iron deficiency anaemia	鉄欠乏性貧血	2 (0.9%)	0	2 (0.4%)
Nephrogenic anaemia	腎性貧血	1 (0.4%)	0	1 (0.2%)
Cardiac disorders	心臓障害	15 (6.6%)	11 (4.8%)	26 (5.7%)
Angina pectoris	狭心症	2 (0.9%)	4 (1.7%)	6 (1.3%)
Angina unstable	不安定狭心症	1 (0.4%)	0	1 (0.2%)
Aortic valve stenosis	大動脈弁狭窄	1 (0.4%)	0	1 (0.2%)
Atrial fibrillation	心房細動	0	1 (0.4%)	1 (0.2%)
Bradycardia	徐脈	1 (0.4%)	0	1 (0.2%)
Cardiac failure	心不全	2 (0.9%)	2 (0.9%)	4 (0.9%)
Cardiac failure acute	急性心不全	1 (0.4%)	0	1 (0.2%)
Cardiac failure chronic	慢性心不全	2 (0.9%)	0	2 (0.4%)
Cardiac failure congestive	うっ血性心不全	1 (0.4%)	1 (0.4%)	2 (0.4%)
Coronary artery disease	冠動脈疾患	1 (0.4%)	0	1 (0.2%)
Coronary artery stenosis	冠動脈狭窄	3 (1.3%)	0	3 (0.7%)
Myocardial ischaemia	心筋虚血	1 (0.4%)	0	1 (0.2%)
Pericardial effusion	心嚢液貯留	0	1 (0.4%)	1 (0.2%)
Pericardial haemorrhage	心嚢内出血	0	1 (0.4%)	1 (0.2%)
Right ventricular failure	右室不全	0	1 (0.4%)	1 (0.2%)
Stress cardiomyopathy	ストレス心筋症	0	1 (0.4%)	1 (0.2%)
Supraventricular tachycardia	上室性頻脈	1 (0.4%)	0	1 (0.2%)
Ear and labyrinth disorders	耳および迷路障害	1 (0.4%)	1 (0.4%)	2 (0.4%)
Sudden hearing loss	突発性難聴	1 (0.4%)	0	1 (0.2%)
Vertigo	回転性めまい	0	1 (0.4%)	1 (0.2%)
Eye disorders	眼障害	6 (2.6%)	6 (2.6%)	12 (2.6%)
Cataract	白内障	3 (1.3%)	3 (1.3%)	6 (1.3%)
Cataract subcapsular	嚢下白内障	1 (0.4%)	0	1 (0.2%)
Diabetic retinopathy	糖尿病網膜症	0	1 (0.4%)	1 (0.2%)
Eyelid ptosis	眼瞼下垂	0	1 (0.4%)	1 (0.2%)
Macular hole	黄斑円孔	1 (0.4%)	0	1 (0.2%)
Retinal haemorrhage	網膜出血	0	1 (0.4%)	1 (0.2%)
Vitreoretinal traction syndrome	硝子体網膜牽引症候群	1 (0.4%)	0	1 (0.2%)
Vitreous haemorrhage	硝子体出血	1 (0.4%)	0	1 (0.2%)
Gastrointestinal disorders	胃腸障害	17 (7.4%)	11 (4.8%)	28 (6.1%)
Abdominal pain	腹痛	0	1 (0.4%)	1 (0.2%)
Anal stenosis	肛門狭窄	0	1 (0.4%)	1 (0.2%)
Colitis ischaemic	虚血性大腸炎	0	1 (0.4%)	1 (0.2%)
Diverticulum intestinal haemorrhagic	出血性腸憩室	1 (0.4%)	1 (0.4%)	2 (0.4%)
Gastric haemorrhage	胃出血	1 (0.4%)	0	1 (0.2%)
Gastric ulcer	胃潰瘍	1 (0.4%)	0	1 (0.2%)
Gastric ulcer haemorrhage	出血性胃潰瘍	1 (0.4%)	0	1 (0.2%)
Haemorrhoids	痔核	0	1 (0.4%)	1 (0.2%)
Ileus	イレウス	1 (0.4%)	0	1 (0.2%)
Inguinal hernia	鼠径ヘルニア	1 (0.4%)	0	1 (0.2%)
Intestinal ischaemia	腸管虚血	1 (0.4%)	0	1 (0.2%)
Large intestine polyp	大腸ポリープ	7 (3.1%)	3 (1.3%)	10 (2.2%)
Lower gastrointestinal haemorrhage	下部消化管出血	1 (0.4%)	0	1 (0.2%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=229 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=229 (100%)	Total N=458 (100%)
Pancreatitis	膵炎	1 (0.4%)	1 (0.4%)	2 (0.4%)
Pancreatitis acute	急性膵炎	0	1 (0.4%)	1 (0.2%)
Pancreatitis chronic	慢性膵炎	0	1 (0.4%)	1 (0.2%)
Periodontal disease	歯周病	1 (0.4%)	0	1 (0.2%)
Tooth loss	歯の脱落	0	1 (0.4%)	1 (0.2%)
Upper gastrointestinal haemorrhage	上部消化管出血	2 (0.9%)	0	2 (0.4%)
Volvulus	腸の軸捻転	0	1 (0.4%)	1 (0.2%)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	8 (3.5%)	8 (3.5%)	16 (3.5%)
Chest pain	胸痛	3 (1.3%)	1 (0.4%)	4 (0.9%)
Oedema	浮腫	0	1 (0.4%)	1 (0.2%)
Oedema peripheral	末梢性浮腫	0	1 (0.4%)	1 (0.2%)
Puncture site haemorrhage	穿刺部位出血	1 (0.4%)	0	1 (0.2%)
Vascular stent stenosis	血管ステント狭窄	4 (1.7%)	5 (2.2%)	9 (2.0%)
Vascular stent thrombosis	血管ステント血栓症	0	1 (0.4%)	1 (0.2%)
Hepatobiliary disorders	肝胆道系障害	3 (1.3%)	5 (2.2%)	8 (1.7%)
Bile duct stone	胆管結石	1 (0.4%)	1 (0.4%)	2 (0.4%)
Cholangitis	胆管炎	1 (0.4%)	3 (1.3%)	4 (0.9%)
Cholecystitis acute	急性胆嚢炎	0	1 (0.4%)	1 (0.2%)
Cholelithiasis	胆石症	1 (0.4%)	0	1 (0.2%)
Infections and infestations	感染症および寄生虫症	16 (7.0%)	14 (6.1%)	30 (6.6%)
Arthritis bacterial	細菌性関節炎	1 (0.4%)	0	1 (0.2%)
Cellulitis	蜂巣炎	4 (1.7%)	1 (0.4%)	5 (1.1%)
Diverticulitis	憩室炎	0	1 (0.4%)	1 (0.2%)
Gastroenteritis	胃腸炎	0	1 (0.4%)	1 (0.2%)
Gastroenteritis salmonella	サルモネラ菌性胃腸炎	0	1 (0.4%)	1 (0.2%)
Osteomyelitis bacterial	細菌性骨髄炎	0	1 (0.4%)	1 (0.2%)
Periodontitis	歯周炎	0	1 (0.4%)	1 (0.2%)
Peritonitis	腹膜炎	1 (0.4%)	0	1 (0.2%)
Pharyngitis	咽頭炎	1 (0.4%)	0	1 (0.2%)
Pneumonia	肺炎	7 (3.1%)	3 (1.3%)	10 (2.2%)
Pneumonia bacterial	細菌性肺炎	0	2 (0.9%)	2 (0.4%)
Postoperative wound infection	術後創感染	1 (0.4%)	1 (0.4%)	2 (0.4%)
Pyelonephritis	腎盂腎炎	0	2 (0.9%)	2 (0.4%)
Sepsis	敗血症	0	1 (0.4%)	1 (0.2%)
Streptococcal sepsis	レンサ球菌性敗血症	0	1 (0.4%)	1 (0.2%)
Urinary tract infection	尿路感染	2 (0.9%)	1 (0.4%)	3 (0.7%)
Wound infection	創傷感染	2 (0.9%)	0	2 (0.4%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	24 (10.5%)	17 (7.4%)	41 (9.0%)
Anastomotic stenosis	吻合部狭窄	0	1 (0.4%)	1 (0.2%)
Brain herniation	脳ヘルニア	0	1 (0.4%)	1 (0.2%)
Cerebral hyperperfusion syndrome	脳過潅流症候群	1 (0.4%)	0	1 (0.2%)
Contusion	挫傷	0	1 (0.4%)	1 (0.2%)
Coronary artery restenosis	冠動脈再狭窄	1 (0.4%)	0	1 (0.2%)
Facial bones fracture	顔面骨骨折	0	1 (0.4%)	1 (0.2%)
Femur fracture	大腿骨骨折	2 (0.9%)	1 (0.4%)	3 (0.7%)
Foot fracture	足骨折	0	1 (0.4%)	1 (0.2%)
Fractured sacrum	仙骨骨折	0	1 (0.4%)	1 (0.2%)
Humerus fracture	上腕骨骨折	0	1 (0.4%)	1 (0.2%)
Incisional hernia	瘢痕ヘルニア	0	1 (0.4%)	1 (0.2%)
Meniscus injury	半月板損傷	0	1 (0.4%)	1 (0.2%)
Multiple injuries	多発性外傷	1 (0.4%)	0	1 (0.2%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=229 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=229 (100%)	Total N=458 (100%)
Peripheral arterial reocclusion	末梢動脈再閉塞	4 (1.7%)	2 (0.9%)	6 (1.3%)
Peripheral artery restenosis	末梢動脈再狭窄	12 (5.2%)	7 (3.1%)	19 (4.1%)
Radius fracture	橈骨骨折	2 (0.9%)	0	2 (0.4%)
Spinal compression fracture	脊椎圧迫骨折	1 (0.4%)	0	1 (0.2%)
Thermal burn	熱傷	1 (0.4%)	0	1 (0.2%)
Thoracic vertebral fracture	胸椎骨折	1 (0.4%)	0	1 (0.2%)
Traumatic intracranial haemorrhage	外傷性頭蓋内出血	0	1 (0.4%)	1 (0.2%)
Vascular access site haematoma	血管確保部位血腫	1 (0.4%)	0	1 (0.2%)
Vascular graft restenosis	移植血管再狭窄	0	1 (0.4%)	1 (0.2%)
Investigations	臨床検査	2 (0.9%)	0	2 (0.4%)
Blood potassium increased	血中カリウム増加	1 (0.4%)	0	1 (0.2%)
Carbohydrate antigen 19-9 increased	糖鎖抗原１９－９増加	1 (0.4%)	0	1 (0.2%)
Metabolism and nutrition disorders	代謝および栄養障害	3 (1.3%)	6 (2.6%)	9 (2.0%)
Diabetes mellitus	糖尿病	3 (1.3%)	3 (1.3%)	6 (1.3%)
Hypoglycaemia	低血糖	1 (0.4%)	1 (0.4%)	2 (0.4%)
Hyponatraemia	低ナトリウム血症	0	1 (0.4%)	1 (0.2%)
Hypophagia	過小食	0	1 (0.4%)	1 (0.2%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	7 (3.1%)	7 (3.1%)	14 (3.1%)
Back pain	背部痛	0	1 (0.4%)	1 (0.2%)
Jaw cyst	顎骨嚢胞	1 (0.4%)	0	1 (0.2%)
Lumbar spinal stenosis	腰部脊柱管狭窄症	2 (0.9%)	1 (0.4%)	3 (0.7%)
Osteoarthritis	変形性関節症	2 (0.9%)	2 (0.9%)	4 (0.9%)
Rotator cuff syndrome	肩回旋筋腱板症候群	0	2 (0.9%)	2 (0.4%)
Spinal osteoarthritis	変形性脊椎症	0	2 (0.9%)	2 (0.4%)
Spondylolisthesis	脊椎すべり症	1 (0.4%)	0	1 (0.2%)
Vertebral column mass	脊柱腫瘤	1 (0.4%)	0	1 (0.2%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	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）	18 (7.9%)	20 (8.7%)	38 (8.3%)
Adenocarcinoma	腺癌	0	1 (0.4%)	1 (0.2%)
Adenocarcinoma of colon	結腸腺癌	1 (0.4%)	0	1 (0.2%)
Adenocarcinoma pancreas	膵腺癌	0	1 (0.4%)	1 (0.2%)
B-cell lymphoma	Ｂ細胞性リンパ腫	0	1 (0.4%)	1 (0.2%)
Basal cell carcinoma	基底細胞癌	0	1 (0.4%)	1 (0.2%)
Bladder cancer	膀胱癌	1 (0.4%)	1 (0.4%)	2 (0.4%)
Cholangiocarcinoma	胆管細胞癌	1 (0.4%)	0	1 (0.2%)
Cholesteatoma	真珠腫	0	1 (0.4%)	1 (0.2%)
Chronic myeloid leukaemia	慢性骨髄性白血病	0	1 (0.4%)	1 (0.2%)
Colon adenoma	大腸腺腫	1 (0.4%)	0	1 (0.2%)
Colon cancer	結腸癌	1 (0.4%)	0	1 (0.2%)
Colorectal cancer	結腸直腸癌	0	1 (0.4%)	1 (0.2%)
Gallbladder cancer	胆嚢癌	1 (0.4%)	0	1 (0.2%)
Gastric cancer	胃癌	5 (2.2%)	2 (0.9%)	7 (1.5%)
Gastric cancer stage I	胃癌第１期	1 (0.4%)	0	1 (0.2%)
Inflammatory pseudotumour	炎症性偽腫瘍	1 (0.4%)	0	1 (0.2%)
Laryngeal cancer	喉頭癌	0	1 (0.4%)	1 (0.2%)
Lung carcinoma cell type unspecified stage IV	肺癌第４期、細胞タイプ不明	0	1 (0.4%)	1 (0.2%)
Lung neoplasm malignant	肺の悪性新生物	1 (0.4%)	2 (0.9%)	3 (0.7%)
Oesophageal carcinoma	食道癌	0	1 (0.4%)	1 (0.2%)
Pancreatic carcinoma	膵癌	0	2 (0.9%)	2 (0.4%)
Prostate cancer	前立腺癌	1 (0.4%)	0	1 (0.2%)

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=229 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=229 (100%)	Total N=458 (100%)
Rectal cancer	直腸癌	1 (0.4%)	1 (0.4%)	2 (0.4%)
Small cell lung cancer	小細胞肺癌	1 (0.4%)	2 (0.9%)	3 (0.7%)
Thymoma malignant	悪性胸腺腫	1 (0.4%)	0	1 (0.2%)
Nervous system disorders	神経系障害	5 (2.2%)	7 (3.1%)	12 (2.6%)
Carotid artery stenosis	頚動脈狭窄	2 (0.9%)	1 (0.4%)	3 (0.7%)
Cerebral haemorrhage	脳出血	0	1 (0.4%)	1 (0.2%)
Dementia	認知症	0	1 (0.4%)	1 (0.2%)
Dizziness	浮動性めまい	2 (0.9%)	0	2 (0.4%)
Dizziness postural	体位性めまい	1 (0.4%)	0	1 (0.2%)
Hydrocephalus	水頭症	0	1 (0.4%)	1 (0.2%)
Intracranial aneurysm	頭蓋内動脈瘤	0	1 (0.4%)	1 (0.2%)
Myelopathy	脊髄症	0	1 (0.4%)	1 (0.2%)
Putamen haemorrhage	被殻出血	0	1 (0.4%)	1 (0.2%)
Subarachnoid haemorrhage	くも膜下出血	0	1 (0.4%)	1 (0.2%)
Product issues	製品の問題	2 (0.9%)	0	2 (0.4%)
Device battery issue	医療機器バッテリー問題	1 (0.4%)	0	1 (0.2%)
Device dislocation	医療機器位置異常	1 (0.4%)	0	1 (0.2%)
Renal and urinary disorders	腎および尿路障害	5 (2.2%)	4 (1.7%)	9 (2.0%)
Acute kidney injury	急性腎障害	1 (0.4%)	0	1 (0.2%)
Calculus bladder	膀胱結石	1 (0.4%)	0	1 (0.2%)
Chronic kidney disease	慢性腎臓病	1 (0.4%)	1 (0.4%)	2 (0.4%)
Renal failure	腎不全	1 (0.4%)	1 (0.4%)	2 (0.4%)
Renal impairment	腎機能障害	1 (0.4%)	2 (0.9%)	3 (0.7%)
Reproductive system and breast disorders	生殖系および乳房障害	1 (0.4%)	0	1 (0.2%)
Benign prostatic hyperplasia	良性前立腺肥大症	1 (0.4%)	0	1 (0.2%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	8 (3.5%)	7 (3.1%)	15 (3.3%)
Acute interstitial pneumonitis	急性間質性肺臓炎	0	1 (0.4%)	1 (0.2%)
Asthma	喘息	0	1 (0.4%)	1 (0.2%)
Dyspnoea	呼吸困難	2 (0.9%)	0	2 (0.4%)
Emphysema	肺気腫	0	1 (0.4%)	1 (0.2%)
Interstitial lung disease	間質性肺疾患	1 (0.4%)	1 (0.4%)	2 (0.4%)
Nasal polyps	鼻茸	1 (0.4%)	0	1 (0.2%)
Pneumonia aspiration	誤嚥性肺炎	1 (0.4%)	4 (1.7%)	5 (1.1%)
Pneumothorax	気胸	2 (0.9%)	0	2 (0.4%)
Pulmonary fibrosis	肺線維症	1 (0.4%)	0	1 (0.2%)
Pulmonary hypertension	肺高血圧症	0	1 (0.4%)	1 (0.2%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	2 (0.9%)	5 (2.2%)	7 (1.5%)
Dermal cyst	皮膚嚢腫	1 (0.4%)	0	1 (0.2%)
Diabetic foot	糖尿病性足病変	0	1 (0.4%)	1 (0.2%)
Drug reaction with eosinophilia and systemic symptoms	好酸球増加と全身症状を伴う薬物反応	0	1 (0.4%)	1 (0.2%)
Haemorrhage subcutaneous	皮下出血	0	1 (0.4%)	1 (0.2%)
Ischaemic skin ulcer	虚血性皮膚潰瘍	0	2 (0.9%)	2 (0.4%)
Urticaria	蕁麻疹	1 (0.4%)	0	1 (0.2%)
Surgical and medical procedures	外科および内科処置	0	1 (0.4%)	1 (0.2%)
Diabetes mellitus management	糖尿病管理	0	1 (0.4%)	1 (0.2%)
Vascular disorders	血管障害	65 (28.4%)	64 (27.9%)	129 (28.2%)
Aortic aneurysm	大動脈瘤	1 (0.4%)	0	1 (0.2%)

2.7.6.1.a 付録 1

Primary system organ class Preferred term MedDRA version 22.1		Rivaroxaban 2.5 mg bid + ASA 100 mg od N=229 (100%)	Rivaroxaban placebo bid + ASA 100 mg od N=229 (100%)	Total N=458 (100%)
Aortic dissection	大動脈解離	1 (0.4%)	0	1 (0.2%)
Dry gangrene	乾性壊疽	0	1 (0.4%)	1 (0.2%)
Extremity necrosis	四肢壊死	1 (0.4%)	1 (0.4%)	2 (0.4%)
Haematoma	血腫	1 (0.4%)	0	1 (0.2%)
Hypotension	低血圧	1 (0.4%)	0	1 (0.2%)
Iliac artery stenosis	腸骨動脈狭窄	1 (0.4%)	0	1 (0.2%)
Intermittent claudication	間欠性跛行	2 (0.9%)	2 (0.9%)	4 (0.9%)
Peripheral arterial occlusive disease	末梢動脈閉塞性疾患	47 (20.5%)	55 (24.0%)	102 (22.3%)
Peripheral artery occlusion	末梢動脈閉塞	2 (0.9%)	0	2 (0.4%)
Peripheral artery stenosis	末梢動脈狭窄	11 (4.8%)	2 (0.9%)	13 (2.8%)
Peripheral ischaemia	末梢性虚血	6 (2.6%)	12 (5.2%)	18 (3.9%)

The safety analysis set includes all randomized subjects who received at least one dose of study drug (rivaroxaban or rivaroxaban placebo).
Adverse events are sorted in alphabetical order by primary SOC and preferred term.
A subject is counted only once within each preferred term or any primary SOC.
bid = twice daily, od = once daily, ASA = acetylsalicylic acid
Treatment emergent events are defined as all events with an onset date on or after the date of randomization until 2 days following permanent discontinuation of the study drug (rivaroxaban or rivaroxaban placebo).
Source: 5.3.5.1.1 PH-40164/Table 14.3.1.2/3

2.7.6.1.a.2 死亡又は重大な出血事象を発現した日本人被験者の詳細

死亡又は重大な出血事象を発現した日本人被験者のうち、下線で表示した被験者の詳細は治験総括報告書に、その他の被験者の詳細を本 2.7.6.1.a.2 に、並びに以下の全被験者の要約に一覧表を 2.7.6.1.a.3 に示す。

CV death	Non-CV death	Other death	Major intracranial bleeding	Major eye related bleeding	Major gastrointestinal tract bleeding
[redacted]*	[redacted]	[redacted]	[redacted]		[redacted]

*：要約表のみ提示

2.7.6.1.a 付録2

2.7.6.1.a.3 死亡又は重大な出血事象を発現した日本人被験者の要約の一覧表 3
Listing 1 / 1: Subject identifier : [redacted] 3
Listing 1 / 2: Subject identifier : [redacted] 10
Listing 1 / 3: Subject identifier : [redacted] 19
Listing 1 / 4: Subject identifier : [redacted] 26
Listing 1 / 5: Subject identifier : [redacted] 34
Listing 1 / 6: Subject identifier : [redacted] 41
Listing 1 / 7: Subject identifier : [redacted] 48
Listing 1 / 8: Subject identifier : [redacted] 55
Listing 1 / 9: Subject identifier : [redacted] 62
Listing 1 / 10: Subject identifier : [redacted] 69
Listing 1 / 11: Subject identifier : [redacted] 76
Listing 1 / 12: Subject identifier : [redacted] 83
Listing 1 / 13: Subject identifier : [redacted] 90
Listing 1 / 14: Subject identifier : [redacted] 97
Listing 1 / 15: Subject identifier : [redacted] 104
Listing 1 / 16: Subject identifier : [redacted] 113
Listing 1 / 17: Subject identifier : [redacted] 121
Listing 1 / 18: Subject identifier : [redacted] 129
Listing 1 / 19: Subject identifier : [redacted] 136
Listing 1 / 20: Subject identifier : [redacted] 145
Listing 1 / 21: Subject identifier : [redacted] 152
Listing 1 / 22: Subject identifier : [redacted] 159
Listing 1 / 23: Subject identifier : [redacted] 166
Listing 1 / 24: Subject identifier : [redacted] 173
Listing 1 / 25: Subject identifier : [redacted] 180
Listing 1 / 26: Subject identifier : [redacted] 187
Listing 1 / 27: Subject identifier : [redacted] 194
Listing 1 / 28: Subject identifier : [redacted] 201
Listing 1 / 29: Subject identifier : [redacted] 208
Listing 1 / 30: Subject identifier : [redacted] 215
Listing 1 / 31: Subject identifier : [redacted] 222
Listing 1 / 32: Subject identifier : [redacted] 230