Trial to Assess the Effects of Vorapaxar (SCH 530348; MK-5348) in Preventing Heart Attack and Stroke in Patients With Atherosclerosis (TRA 2°P - TIMI 50) (P04737)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Collaborator:
The Thrombolysis in Myocardial Infarction Study (TIMI) Group

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00526474

First received: September 6, 2007
Last updated: April 24, 2015
Last verified: April 2015
History of Changes

Purpose

The study is designed to determine whether vorapaxar, when added to the existing standard of care (SOC) for preventing heart attack and stroke (eg, aspirin, clopidogrel) in participants with a known history of atherosclerosis, will yield additional benefit over the existing standard of care without vorapaxar in preventing heart attack and stroke.

The study is also designed to assess risk of bleeding with vorapaxar added to the standard of care versus the standard of care alone.

Condition	Intervention	Phase
Atherosclerosis Ischemia Myocardial Infarction Cerebrovascular Accident Peripheral Arterial Disease	Drug: Vorapaxar Drug: Placebo	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator, Outcomes Assessor)
Primary Purpose: Prevention

Official Title: A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of SCH 530348 in Addition to Standard of Care in Subjects With a History of Atherosclerotic Disease: Thrombin Receptor Antagonist in Secondary Prevention of Atherothrombotic Ischemic Events (TRA 2°P - TIMI 50)

Resource links provided by NLM:

MedlinePlus related topics: Atherosclerosis Heart Attack

Drug Information available for: Vorapaxar Vorapaxar sulfate

U.S. FDA Resources

Further study details as provided by Merck Sharp & Dohme Corp.:

Primary Outcome Measures:

- Kaplan-Meier Estimate of the Percentage of Participants Who Experienced Cardiovascular (CV) Death, Myocardial Infarction (MI), Stroke, or Urgent Coronary Revascularization (UCR) Within 3 Years From Randomization [Time Frame: up to 3 years] [Designated as safety issue: No]

  The time (in days) from study start to the first occurrence of any of the following clinical outcomes was recorded: CV death, MI, stroke, or UCR. A Clinical Endpoints Committee (CEC) reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). If a participant had a fatal event that was not part of a specific endpoint for analysis, they were censored at the time of death. The Kaplan-Meier estimate reports the percentage of participants who experienced CV death, MI, stroke, or UCR within 3 years from randomization.

Secondary Outcome Measures:

- Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death, MI, or Stroke Within 3 Years From Randomization [Time Frame: up to 3 years] [Designated as safety issue: No]

  The time (in days) from study start to the first occurrence of any of the following clinical outcomes was recorded: CV death, MI, or stroke. A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). If a participant had a fatal event that was not part of a specific endpoint for analysis, they were censored at the time of death. The Kaplan-Meier estimate reports the percentage of participants who experienced CV death, MI, or stroke within 3 years from randomization.

- Kaplan-Meier Estimate of the Percentage of Participants Who Met Global Utilization of Streptokinase and Tissue Plasminogen Activator for Occluded Arteries (GUSTO) Moderate or Severe Bleeding Criteria Within 3 Years From Randomization [Time Frame: up to 3 years] [Designated as safety issue: Yes]

  Adverse events were categorized as "bleeding events" if the intensity, frequency, or type of the event was other or more than would be normally expected in the given situation (eg, mild nosebleed in a person who does not normally have nosebleeds, greater bruising than expected for a given injury, greater volume of blood loss than expected for a given procedure). The investigator graded the intensity of bleeding events according to the GUSTO cooperative group criteria as follows: Mild , Moderate or Severe and the grading was adjudicated by the CEC. The Kaplan-Meier estimate reports the percentage of participants who experienced GUSTO moderate or severe bleeding within 3 years from randomization.

- Kaplan-Meier Estimate of the Percentage of Participants Who Experienced Clinically Significant Bleeding Within 3 Years From Randomization [Time Frame: up to 3 years] [Designated as safety issue: Yes]

  Adverse events were categorized as "bleeding events" if the intensity, frequency, or type of the event was other or more than would be normally expected in the given situation (eg, mild nosebleed in a person who does not normally have nosebleeds, greater bruising than expected for a given injury, greater volume of blood loss than expected for a given procedure). The investigator graded the intensity of bleeding events according to the Thrombolysis in Myocardial Infarction (TIMI) Study Group criteria as major, minor or other. "Clinically Significant Bleeding" was defined as the composite of TIMI Major bleeding, TIMI Minor bleeding, or bleeding that required unplanned medical or surgical treatment or unplanned laboratory evaluation even if it did not meet the criteria for TIMI major or minor bleeding. The Kaplan-Meier estimate reports the percentage of participants who experienced clinically significant bleeding within 3 years from randomization.

- Kaplan-Meier Estimate of the Percentage of Participants Who Experienced Death From Any Cause, MI, Stroke, or UCR Within 3 Years From Randomization [Time Frame: up to 3 years] [Designated as safety issue: No]

  The time (in days) from study start to the occurrence of any of the following clinical outcomes was recorded: death from any cause, MI, stroke, or UCR. A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). The Kaplan-Meier estimate reports the percentage of participants who experienced death from any cause, MI, stroke, or UCR within 3 years from randomization.

- Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death or an MI Within 3 Years From Randomization [Time Frame: up to 3 years] [Designated as safety issue: No]

  The time (in days) from study start to the occurrence of CV death or MI. A CEC reviewed and adjudicated each suspected efficacy endpoint

event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). If a participant had a fatal event that was not part of a specific endpoint for analysis, they were censored at the time of death. The Kaplan-Meier estimate reports the percentage of participants who experienced CV death or MI within 3 years from randomization.

- Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death, MI, Stroke, UCR, or Urgent Hospitalization for Vascular Cause of Ischemic Nature (UH-VCIN) Within 3 Years From Randomization [Time Frame: up to 3 years] [Designated as safety issue: No]

  The time (in days) from study start to the first occurrence of any of the following clinical outcomes was recorded: CV death, MI, stroke, UCR or UH-VCIN. A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). If a participant had a fatal event that was not part of a specific endpoint for analysis, they were censored at the time of death. The Kaplan-Meier estimate reports the percentage of participants who experienced CV death, MI, stroke, UCR, or UH-VCIN within 3 years from randomization.

- Kaplan-Meier Estimate of the Percentage of Participants Who Died From Any Cause, or Experienced an MI, Stroke, or Any Revascularization Within 3 Years From Randomization [Time Frame: up to 3 years] [Designated as safety issue: No]

  The time (in days) from study start to death from any cause or the first occurrence of any of the following clinical outcomes was recorded: MI, stroke, or any revascularization procedure . A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). The Kaplan-Meier estimate reports the percentage of participants who died from any cause, or experienced an MI, stroke, or any revascularization within 3 years from randomization.

- Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death, MI, Stroke, Any Revascularization, or UH-VCIN Within 3 Years From Randomization [Time Frame: up to 3 years] [Designated as safety issue: No]

  The time (in days) from study start to the first occurrence of any of the following clinical outcomes was recorded: CV death, MI, stroke, any revascularization, or UH-VCIN. A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). If a participant had a fatal event that was not part of a specific endpoint for analysis, they were censored at the time of death. The Kaplan-Meier estimate reports the percentage of participants who experienced CV death, MI, stroke, any revascularization procedure, or UH-VCIN within 3 years from randomization.

- Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death Within 3 Years From Randomization [Time Frame: up to 3 years] [Designated as safety issue: No]

  The time (in days) from study start to CV death (if reported) was recorded. A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). If a participant had a fatal event that was not part of a specific endpoint for analysis, they were censored at the time of death. The Kaplan-Meier estimate reports the percentage of participants who experienced CV death within 3 years from randomization.

- Kaplan-Meier Estimate of the Percentage of Participants Who Experienced an MI Within 3 Years From Randomization [Time Frame: up to 3 years] [Designated as safety issue: No]

  The time (in days) from study start to the first occurrence of an MI was recorded. A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). If a participant had a fatal event that was not part of a specific endpoint for analysis, they were censored at the time of death. The Kaplan-Meier estimate reports the percentage of participants who experienced an MI within 3 years from randomization.

- Kaplan-Meier Estimate of the Percentage of Participants Who Experienced UCR Within 3 Years From Randomization [Time Frame: up to 3 years] [Designated as safety issue: No]

  The time (in days) from study start to the first occurrence of UCR was recorded. A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). If a participant had a fatal event that was not part of a specific endpoint for analysis, they were censored at the time of death. The Kaplan-Meier estimate reports the percentage of participants who experienced UCR within 3 years from randomization.

- Kaplan-Meier Estimate of the Percentage of Participants Who Experienced a Stroke Within 3 Years From Randomization [Time Frame: up to 3 years] [Designated as safety issue: No]

  The time (in days) from study start to first experience of a stroke was recorded. A CEC reviewed and adjudicated each suspected efficacy

endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). If a participant had a fatal event that was not part of a specific endpoint for analysis, they were censored at the time of death. The Kaplan-Meier estimate reports the percentage of participants who experienced a stroke within 3 years from randomization.

- Kaplan-Meier Estimate of the Percentage of Participants Who Died From Any Cause Within 3 Years From Randomization [Time Frame: up to 3 years] [Designated as safety issue: No]

  The time (in days) from study start to death from any cause was recorded. A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). The Kaplan-Meier estimate reports the percentage of participants who died from any cause within 3 years from randomization.

- Kaplan-Meier Estimate of the Percentage of Participants Who Had a UH-VCIN Within 3 Years From Randomization [Time Frame: up to 3 years] [Designated as safety issue: No]

  The time (in days) from study start to the first occurrence of an UH-VCIN was recorded. A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). If a participant had a fatal event that was not part of a specific endpoint for analysis, they were censored at the time of death. The Kaplan-Meier estimate reports the percentage of participants who had a UH-VCIN within 3 years from randomization.

- Kaplan-Meier Estimate of the Percentage of Participants Who Had Any Revascularization Performed Within 3 Years From Randomization [Time Frame: up to 3 years] [Designated as safety issue: No]

  The time (in days) from study start to the first occurrence of a revascularization was recorded. A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). If a participant had a fatal event that was not part of a specific endpoint for analysis, they were censored at the time of death. The Kaplan-Meier estimate reports the percentage of participants who had any revascularization performed within 3 years from randomization.

Enrollment:	26449
Study Start Date:	September 2007
Study Completion Date:	December 2011
Primary Completion Date:	December 2011 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Placebo Comparator: Placebo 1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.	Drug: Placebo matching tablet daily for at least 1 year
Experimental: Vorapaxar one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.	Drug: Vorapaxar 2.5-mg tablet daily for at least 1 year

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

Men and women at least 18 years old with evidence or a history of atherosclerosis involving the coronary, cerebral, or peripheral vascular systems by one or more of the following:

- history of myocardial infarction (heart attack)
- history of ischemic stroke (stroke due to a blocked artery)
- history of peripheral arterial disease

Exclusion Criteria:

- history of intracranial hemorrhage or of central nervous system (CNS) surgery, tumor, or aneurysm
- any bleeding disorder or abnormality
- sustained severe hypertension or valvular heart disease
- current or recent platelet count <100,000 mm^3
- planned or ongoing treatment with a blood thinning medication
- pregnancy
- any significant medical or physiological condition or abnormality that could put the subject at increased risk or limit the subject's ability to participate for the duration of the study

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00526474

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

The Thrombolysis in Myocardial Infarction Study (TIMI) Group

Investigators

Study Director: Medical Director Merck Sharp & Dohme Corp.

More Information

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Bohula EA, Aylward PE, Bonaca MP, Corbalan RL, Kiss RG, Murphy SA, Scirica BM, White H, Braunwald E, Morrow DA. Efficacy and Safety of Vorapaxar With and Without a Thienopyridine for Secondary Prevention in Patients With Previous Myocardial Infarction and No History of Stroke or Transient Ischemic Attack: Results from TRA 2°P-TIMI 50. Circulation. 2015 Nov 17;132(20):1871-9. doi: 10.1161/CIRCULATIONAHA.114.015042. Epub 2015 Sep 3.

Magnani G, Bonaca MP, Braunwald E, Dalby AJ, Fox KA, Murphy SA, Nicolau JC, Oude Ophuis T, Scirica BM, Spinar J, Theroux P, Morrow DA. Efficacy and safety of vorapaxar as approved for clinical use in the United States. J Am Heart Assoc. 2015 Mar 19;4(3):e001505. doi: 10.1161/JAHA.114.001505. Erratum in: J Am Heart Assoc. 2015 Apr;4(4). pii: e000633. doi: 10.1161/JAHA.115.000633.

Cavender MA, Scirica BM, Bonaca MP, Angiolillo DJ, Dalby AJ, Dellborg M, Morais J, Murphy SA, Ophuis TO, Tendera M, Braunwald E, Morrow DA. Vorapaxar in patients with diabetes mellitus and previous myocardial infarction: findings from the thrombin receptor antagonist in secondary prevention of atherothrombotic ischemic events-TIMI 50 trial. Circulation. 2015 Mar 24;131(12):1047-53. doi: 10.1161/CIRCULATIONAHA.114.013774. Epub 2015 Feb 13.

Bonaca MP, Scirica BM, Braunwald E, Wiviott SD, Goto S, Nilsen DW, Bonarjee V, Murphy SA, Morrow DA. New ischemic stroke and outcomes with vorapaxar versus placebo: results from the TRA 2 °P-TIMI 50 trial. J Am Coll Cardiol. 2014 Dec 9;64(22):2318-26. doi: 10.1016/j.jacc.2014.07.997. Epub 2014 Dec 1.

Bonaca MP, Scirica BM, Braunwald E, Wiviott SD, O'Donoghue ML, Murphy SA, Morrow DA. Coronary stent thrombosis with vorapaxar versus placebo: results from the TRA 2° P-TIMI 50 trial. J Am Coll Cardiol. 2014 Dec 9;64(22):2309-17. doi: 10.1016/j.jacc.2014.09.037. Epub 2014 Dec 1.

Bonaca MP, Scirica BM, Creager MA, Olin J, Bounameaux H, Dellborg M, Lamp JM, Murphy SA, Braunwald E, Morrow DA. Vorapaxar in patients with peripheral artery disease: results from TRA2{degrees}P-TIMI 50. Circulation. 2013 Apr 9;127(14):1522-9, 1529e1-6. doi: 10.1161/CIRCULATIONAHA.112.000679. Epub 2013 Mar 15.

Morrow DA, Alberts MJ, Mohr JP, Ameriso SF, Bonaca MP, Goto S, Hankey GJ, Murphy SA, Scirica BM, Braunwald E; Thrombin Receptor Antagonist in Secondary Prevention of Atherothrombotic Ischemic Events–TIMI 50 Steering Committee and Investigators. Efficacy and safety of vorapaxar in patients with prior ischemic stroke. Stroke. 2013 Mar;44(3):691-8. doi: 10.1161/STROKEAHA.111.000433. Epub 2013 Feb 8.

Scirica BM, Bonaca MP, Braunwald E, De Ferrari GM, Isaza D, Lewis BS, Mehrhof F, Merlini PA, Murphy SA, Sabatine MS, Tendera M, Van de Werf F, Wilcox R, Morrow DA; TRA 2°P-TIMI 50 Steering Committee Investigators. Vorapaxar for secondary prevention of thrombotic events for patients with previous myocardial infarction: a prespecified subgroup analysis of the TRA 2°P-TIMI 50 trial. Lancet. 2012 Oct 13;380(9850):1317-24. doi: 10.1016/S0140-6736(12)61269-0. Epub 2012 Aug 26.

Morrow DA, Braunwald E, Bonaca MP, Ameriso SF, Dalby AJ, Fish MP, Fox KA, Lipka LJ, Liu X, Nicolau JC, Ophuis AJ, Paolasso E, Scirica BM, Spinar J, Theroux P, Wiviott SD, Strony J, Murphy SA; TRA 2P–TIMI 50 Steering Committee and Investigators. Vorapaxar in the secondary prevention of atherothrombotic events. N Engl J Med. 2012 Apr 12;366(15):1404-13. doi: 10.1056/NEJMoa1200933. Epub 2012 Mar 24.

Morrow DA, Scirica BM, Fox KA, Berman G, Strony J, Veltri E, Bonaca MP, Fish P, McCabe CH, Braunwald E; TRA 2(o)P-TIMI 50 Investigators. Evaluation of a novel antiplatelet agent for secondary prevention in patients with a history of atherosclerotic disease: design and rationale for the Thrombin-Receptor Antagonist in Secondary Prevention of Atherothrombotic Ischemic Events (TRA 2 degrees P)-TIMI 50 trial. Am Heart J. 2009 Sep;158(3):335-341.e3. doi: 10.1016/j.ahj.2009.06.027.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00526474 History of Changes
Other Study ID Numbers:	P04737 TRA 2°P - TIMI 50 2006-002942-12 MK-5348-015
Study First Received:	September 6, 2007
Results First Received:	May 16, 2014
Last Updated:	April 24, 2015
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

Atherosclerosis	Cardiovascular Diseases
Myocardial Infarction	Central Nervous System Diseases
Peripheral Arterial Disease	Cerebrovascular Disorders
Peripheral Vascular Diseases	Heart Diseases
Stroke	Myocardial Ischemia
Arterial Occlusive Diseases	Nervous System Diseases
Arteriosclerosis	Vascular Diseases
Brain Diseases	

ClinicalTrials.gov processed this record on May 08, 2016

TO TOP

For Patients and Families | For Researchers | For Study Record Managers

HOME RSS FEEDS SITE MAP TERMS AND CONDITIONS DISCLAIMER CONTACT NLM HELP DESK

Trial to Assess the Effects of Vorapaxar (SCH 530348; MK-5348) in Preventing Heart Attack and Stroke in Patients With Atherosclerosis (TRA 2°P - TIMI 50) (P04737)

This study has been completed.

Sponsor:
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ClinicalTrials.gov Identifier:
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First received: September 6, 2007
Last updated: April 24, 2015
Last verified: April 2015
History of Changes

Results First Received: May 16, 2014

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator, Outcomes Assessor); Primary Purpose: Prevention
Conditions:	Atherosclerosis Ischemia Myocardial Infarction Cerebrovascular Accident Peripheral Arterial Disease
Interventions:	Drug: Vorapaxar Drug: Placebo

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations

Prior to planned study completion, the Data Safety Monitoring Board (DSMB) recommended discontinuation of study drug in all participants with a pre- or post-randomization history of stroke. A total of 4510 participants had study medication stopped, however these participants were

included in the overall population for efficacy and safety analyses.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
The Intent to Treat (ITT) Population, defined as all enrolled participants who were randomly assigned to a treatment group.

Reporting Groups

	Description
Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.

Participant Flow: Overall Study

	Placebo	**Vorapaxar**
STARTED	**13224**	**13225**
Received Study Drug	**13166**	**13186**
COMPLETED	**12932**	**12953**
NOT COMPLETED	**292**	**272**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Intent to Treat (ITT) Population, defined as all enrolled participants who were randomly assigned to a treatment group.

Reporting Groups

	Description
Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Total	Total of all reporting groups

Baseline Measures

	Placebo	**Vorapaxar**	**Total**
Number of Participants [units: participants]	**13224**	**13225**	**26449**
Age, Customized [units: Participants]			

<65 years	**8273**	**8188**	**16461**
65-<75 years	**3445**	**3523**	**6968**
>=75 years	**1506**	**1514**	**3020**
Gender [units: Participants]			
Female	**3172**	**3154**	**6326**
Male	**10052**	**10071**	**20123**

Outcome Measures

Hide All Outcome Measures

1. Primary: Kaplan-Meier Estimate of the Percentage of Participants Who Experienced Cardiovascular (CV) Death, Myocardial Infarction (MI), Stroke, or Urgent Coronary Revascularization (UCR) Within 3 Years From Randomization [Time Frame: up to 3 years]

Measure Type	Primary
Measure Title	Kaplan-Meier Estimate of the Percentage of Participants Who Experienced Cardiovascular (CV) Death, Myocardial Infarction (MI), Stroke, or Urgent Coronary Revascularization (UCR) Within 3 Years From Randomization
Measure Description	The time (in days) from study start to the first occurrence of any of the following clinical outcomes was recorded: CV death, MI, stroke, or UCR. A Clinical Endpoints Committee (CEC) reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). If a participant had a fatal event that was not part of a specific endpoint for analysis, they were censored at the time of death. The Kaplan-Meier estimate reports the percentage of participants who experienced CV death, MI, stroke, or UCR within 3 years from randomization.
Time Frame	up to 3 years
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent to Treat (ITT) Population, defined as all participants who were randomly assigned to a treatment arm.

Reporting Groups

	Description
Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.

Measured Values

	Placebo	**Vorapaxar**
Number of Participants Analyzed [units: participants]	**13224**	**13225**

Kaplan-Meier Estimate of the Percentage of Participants Who Experienced Cardiovascular (CV) Death, Myocardial Infarction (MI), Stroke, or Urgent Coronary Revascularization (UCR) Within 3 Years From Randomization [units: Percentage of Participants]	**12.4**	**11.2**

Statistical Analysis 1 for Kaplan-Meier Estimate of the Percentage of Participants Who Experienced Cardiovascular (CV) Death, Myocardial Infarction (MI), Stroke, or Urgent Coronary Revascularization (UCR) Within 3 Years From Randomization

Groups [1]	All groups
Method [2]	Cox Proportional Hazards Regression
P Value [3]	0.001
Cox Proportional Hazard [4]	0.88
95% Confidence Interval	0.82 to 0.95

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Hazard Ratio calculated with covariates for treatment and stratification factors
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	Hazard ratio calculated by dividing the Kaplan-Meier (KM) Estimate for vorapaxar by the KM Estimate for Placebo and correcting for covariates. A hazard ratio <1 would indicate a lower hazard associated with vorapaxar relative to placebo.

2. Secondary: Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death, MI, or Stroke Within 3 Years From Randomization [Time Frame: up to 3 years]

Measure Type	Secondary
Measure Title	Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death, MI, or Stroke Within 3 Years From Randomization
Measure Description	The time (in days) from study start to the first occurrence of any of the following clinical outcomes was recorded: CV death, MI, or stroke. A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). If a participant had a fatal event that was not part of a specific endpoint for analysis, they were censored at the time of death. The Kaplan-Meier estimate reports the percentage of participants who experienced CV death, MI, or stroke within 3 years from randomization.
Time Frame	up to 3 years
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
ITT Population, defined as all participants who were randomly assigned to a treatment arm.

Reporting Groups

	Description
Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.

Measured Values

	Placebo	Vorapaxar
Number of Participants Analyzed [units: participants]	**13224**	**13225**
Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death, MI, or Stroke Within 3 Years From Randomization [units: Percentage of Participants]	**10.5**	**9.3**

Statistical Analysis 1 for Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death, MI, or Stroke Within 3 Years From Randomization

Groups [1]	All groups
Method [2]	Cox Proportional Hazards Regression
P Value [3]	<0.001
Cox Proportional Hazard [4]	0.87
95% Confidence Interval	0.80 to 0.94

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Hazard Ratio calculated with covariates for treatment and stratification factors
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	Hazard ratio calculated by dividing the Kaplan-Meier (KM) Estimate for vorapaxar by the KM Estimate for Placebo and correcting for covariates. A hazard ratio <1 would indicate a lower hazard associated with vorapaxar relative to placebo.

3. Secondary: Kaplan-Meier Estimate of the Percentage of Participants Who Met Global Utilization of Streptokinase and Tissue Plasminogen Activator for Occluded Arteries (GUSTO) Moderate or Severe Bleeding Criteria Within 3 Years From Randomization [Time Frame: up to 3 years]

Measure Type	Secondary
Measure Title	Kaplan-Meier Estimate of the Percentage of Participants Who Met Global Utilization of Streptokinase and Tissue Plasminogen Activator for Occluded Arteries (GUSTO) Moderate or Severe Bleeding Criteria Within 3 Years From

	Randomization
Measure Description	Adverse events were categorized as “bleeding events” if the intensity, frequency, or type of the event was other or more than would be normally expected in the given situation (eg, mild nosebleed in a person who does not normally have nosebleeds, greater bruising than expected for a given injury, greater volume of blood loss than expected for a given procedure). The investigator graded the intensity of bleeding events according to the GUSTO cooperative group criteria as follows: Mild , Moderate or Severe and the grading was adjudicated by the CEC. The Kaplan-Meier estimate reports the percentage of participants who experienced GUSTO moderate or severe bleeding within 3 years from randomization.
Time Frame	up to 3 years
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
As Treated Population, which included all participants who received at least 1 dose of study medication.

Reporting Groups

	Description
Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.

Measured Values

	Placebo	**Vorapaxar**
Number of Participants Analyzed [units: participants]	**13166**	**13186**
Kaplan-Meier Estimate of the Percentage of Participants Who Met Global Utilization of Streptokinase and Tissue Plasminogen Activator for Occluded Arteries (GUSTO) Moderate or Severe Bleeding Criteria Within 3 Years From Randomization [units: Percentage of Participants]	**2.9**	**4.2**

Statistical Analysis 1 for Kaplan-Meier Estimate of the Percentage of Participants Who Met Global Utilization of Streptokinase and Tissue Plasminogen Activator for Occluded Arteries (GUSTO) Moderate or Severe Bleeding Criteria Within 3 Years From Randomization

Groups [1]	All groups
Method [2]	Cox Proportional Hazards Regression
P Value [3]	<0.001
Cox Proportional Hazard [4]	1.51
95% Confidence Interval	1.31 to 1.74

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:

	Hazard Ratio calculated with covariates for treatment and stratification factors
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	Hazard ratio calculated by dividing the Kaplan-Meier (KM) Estimate for vorapaxar by the KM Estimate for Placebo and correcting for covariates. A hazard ratio <1 would indicate a lower hazard associated with vorapaxar relative to placebo.

4. Secondary: Kaplan-Meier Estimate of the Percentage of Participants Who Experienced Clinically Significant Bleeding Within 3 Years From Randomization [Time Frame: up to 3 years]

Measure Type	Secondary
Measure Title	Kaplan-Meier Estimate of the Percentage of Participants Who Experienced Clinically Significant Bleeding Within 3 Years From Randomization
Measure Description	Adverse events were categorized as “bleeding events” if the intensity, frequency, or type of the event was other or more than would be normally expected in the given situation (eg, mild nosebleed in a person who does not normally have nosebleeds, greater bruising than expected for a given injury, greater volume of blood loss than expected for a given procedure). The investigator graded the intensity of bleeding events according to the Thrombolysis in Myocardial Infarction (TIMI) Study Group criteria as major, minor or other. “Clinically Significant Bleeding” was defined as the composite of TIMI Major bleeding, TIMI Minor bleeding, or bleeding that required unplanned medical or surgical treatment or unplanned laboratory evaluation even if it did not meet the criteria for TIMI major or minor bleeding. The Kaplan-Meier estimate reports the percentage of participants who experienced clinically significant bleeding within 3 years from randomization.
Time Frame	up to 3 years
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
As Treated Population, which included all participants who received at least 1 dose of study medication.

Reporting Groups

	Description
Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.

Measured Values

	Placebo	**Vorapaxar**
Number of Participants Analyzed [units: participants]	**13166**	**13186**
Kaplan-Meier Estimate of the Percentage of Participants Who Experienced Clinically Significant Bleeding Within 3 Years From Randomization [units: Percentage of Participants]	**11.3**	**15.4**

Statistical Analysis 1 for Kaplan-Meier Estimate of the Percentage of Participants Who Experienced Clinically Significant Bleeding Within 3 Years From Randomization

Groups [1]	All groups
Method [2]	Cox Proportional Hazards Regression
P Value [3]	<0.001
Cox Proportional Hazard [4]	1.41
95% Confidence Interval	1.31 to 1.51

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Hazard Ratio calculated with covariates for treatment and stratification factors
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	Hazard ratio calculated by dividing the Kaplan-Meier (KM) Estimate for vorapaxar by the KM Estimate for Placebo and correcting for covariates. A hazard ratio <1 would indicate a lower hazard associated with vorapaxar relative to placebo.

5. Secondary: Kaplan-Meier Estimate of the Percentage of Participants Who Experienced Death From Any Cause, MI, Stroke, or UCR Within 3 Years From Randomization [Time Frame: up to 3 years]

Measure Type	Secondary
Measure Title	Kaplan-Meier Estimate of the Percentage of Participants Who Experienced Death From Any Cause, MI, Stroke, or UCR Within 3 Years From Randomization
Measure Description	The time (in days) from study start to the occurrence of any of the following clinical outcomes was recorded: death from any cause, MI, stroke, or UCR. A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). The Kaplan-Meier estimate reports the percentage of participants who experienced death from any cause, MI, stroke, or UCR within 3 years from randomization.
Time Frame	up to 3 years
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
ITT Population, defined as all participants who were randomly assigned to a treatment arm.

Reporting Groups

	Description
Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued

	to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.

Measured Values

	Placebo	Vorapaxar
Number of Participants Analyzed [units: participants]	**13224**	**13225**
Kaplan-Meier Estimate of the Percentage of Participants Who Experienced Death From Any Cause, MI, Stroke, or UCR Within 3 Years From Randomization [units: Perentage of Participants]	**14.2**	**13.2**

Statistical Analysis 1 for Kaplan-Meier Estimate of the Percentage of Participants Who Experienced Death From Any Cause, MI, Stroke, or UCR Within 3 Years From Randomization

Groups [1]	All groups
Method [2]	Cox Proportional Hazards Regression
P Value [3]	0.009
Cox Proportional Hazard [4]	0.91
95% Confidence Interval	0.85 to 0.98

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Hazard Ratio calculated with covariates for treatment and stratification factors
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	Hazard ratio calculated by dividing the Kaplan-Meier (KM) Estimate for vorapaxar by the KM Estimate for Placebo and correcting for covariates. A hazard ratio <1 would indicate a lower hazard associated with vorapaxar relative to placebo.

6. Secondary: Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death or an MI Within 3 Years From Randomization [Time Frame: up to 3 years]

Measure Type	Secondary
Measure Title	Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death or an MI Within 3 Years From Randomization
Measure Description	The time (in days) from study start to the occurrence of CV death or MI. A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). If a participant had a fatal event that was not part of a specific endpoint for analysis, they were censored at the time of death. The Kaplan-Meier estimate reports the percentage of participants who experienced CV

	death or MI within 3 years from randomization.
Time Frame	up to 3 years
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
ITT Population, defined as all participants who were randomly assigned to a treatment arm.

Reporting Groups

	Description
Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.

Measured Values

	Placebo	**Vorapaxar**
Number of Participants Analyzed [units: participants]	**13224**	**13225**
Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death or an MI Within 3 Years From Randomization [units: Percentage of Participants]	**8.2**	**7.3**

Statistical Analysis 1 for Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death or an MI Within 3 Years From Randomization

Groups [1]	All groups
Method [2]	Cox Proportional Hazards Regression
P Value [3]	0.002
Cox Proportional Hazard [4]	0.86
95% Confidence Interval	0.78 to 0.94

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Hazard Ratio calculated with covariates for treatment and stratification factors
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	Hazard ratio calculated by dividing the Kaplan-Meier (KM) Estimate for vorapaxar by the KM Estimate for Placebo and correcting for

covariates. A hazard ratio <1 would indicate a lower hazard associated with vorapaxar relative to placebo.

7. Secondary: Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death, MI, Stroke, UCR, or Urgent Hospitalization for Vascular Cause of Ischemic Nature (UH-VCIN) Within 3 Years From Randomization [Time Frame: up to 3 years]

Measure Type	Secondary
Measure Title	Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death, MI, Stroke, UCR, or Urgent Hospitalization for Vascular Cause of Ischemic Nature (UH-VCIN) Within 3 Years From Randomization
Measure Description	The time (in days) from study start to the first occurrence of any of the following clinical outcomes was recorded: CV death, MI, stroke, UCR or UH-VCIN. A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). If a participant had a fatal event that was not part of a specific endpoint for analysis, they were censored at the time of death. The Kaplan-Meier estimate reports the percentage of participants who experienced CV death, MI, stroke, UCR, or UH-VCIN within 3 years from randomization.
Time Frame	up to 3 years
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
ITT Population, defined as all participants who were randomly assigned to a treatment arm.

Reporting Groups

	Description
Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.

Measured Values

	Placebo	**Vorapaxar**
Number of Participants Analyzed [units: participants]	**13224**	**13225**
Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death, MI, Stroke, UCR, or Urgent Hospitalization for Vascular Cause of Ischemic Nature (UH-VCIN) Within 3 Years From Randomization [units: Percentage of Participants]	**14.7**	**13.1**

Statistical Analysis 1 for Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death, MI, Stroke, UCR, or Urgent Hospitalization for Vascular Cause of Ischemic Nature (UH-VCIN) Within 3 Years From Randomization

Groups [1]	All groups
Method [2]	Cox Proportional Hazards Regression
P Value [3]	<0.001

Cox Proportional Hazard [4]	0.87
95% Confidence Interval	0.81 to 0.93

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Hazard Ratio calculated with covariates for treatment and stratification factors
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	Hazard ratio calculated by dividing the Kaplan-Meier (KM) Estimate for vorapaxar by the KM Estimate for Placebo and correcting for covariates. A hazard ratio <1 would indicate a lower hazard associated with vorapaxar relative to placebo.

8. Secondary: Kaplan-Meier Estimate of the Percentage of Participants Who Died From Any Cause, or Experienced an MI, Stroke, or Any Revascularization Within 3 Years From Randomization [Time Frame: up to 3 years]

Measure Type	Secondary
Measure Title	Kaplan-Meier Estimate of the Percentage of Participants Who Died From Any Cause, or Experienced an MI, Stroke, or Any Revascularization Within 3 Years From Randomization
Measure Description	The time (in days) from study start to death from any cause or the first occurrence of any of the following clinical outcomes was recorded: MI, stroke, or any revascularization procedure . A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). The Kaplan-Meier estimate reports the percentage of participants who died from any cause, or experienced an MI, stroke, or any revascularization within 3 years from randomization.
Time Frame	up to 3 years
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
ITT Population, defined as all participants who were randomly assigned to a treatment arm.

Reporting Groups

	Description
Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.

Measured Values

	Placebo	**Vorapaxar**

Number of Participants Analyzed [units: participants]	**13224**	**13225**
Kaplan-Meier Estimate of the Percentage of Participants Who Died From Any Cause, or Experienced an MI, Stroke, or Any Revascularization Within 3 Years From Randomization [units: Percentage of Participants]	**22.6**	**20.7**

Statistical Analysis 1 for Kaplan-Meier Estimate of the Percentage of Participants Who Died From Any Cause, or Experienced an MI, Stroke, or Any Revascularization Within 3 Years From Randomization

Groups [1]	All groups
Method [2]	Cox Proportional Hazards Regression
P Value [3]	0.001
Cox Proportional Hazard [4]	0.91
95% Confidence Interval	0.86 to 0.96

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Hazard Ratio calculated with covariates for treatment and stratification factors
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	Hazard ratio calculated by dividing the Kaplan-Meier (KM) Estimate for vorapaxar by the KM Estimate for Placebo and correcting for covariates. A hazard ratio <1 would indicate a lower hazard associated with vorapaxar relative to placebo.

9. Secondary: Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death, MI, Stroke, Any Revascularization, or UH-VCIN Within 3 Years From Randomization [Time Frame: up to 3 years]

Measure Type	Secondary
Measure Title	Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death, MI, Stroke, Any Revascularization, or UH-VCIN Within 3 Years From Randomization
Measure Description	The time (in days) from study start to the first occurrence of any of the following clinical outcomes was recorded: CV death, MI, stroke, any revascularization, or UH-VCIN. A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). If a participant had a fatal event that was not part of a specific endpoint for analysis, they were censored at the time of death. The Kaplan-Meier estimate reports the percentage of participants who experienced CV death, MI, stroke, any revascularization procedure, or UH-VCIN within 3 years from randomization.
Time Frame	up to 3 years
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

ITT Population, defined as all participants who were randomly assigned to a treatment arm.

Reporting Groups

	Description
Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.

Measured Values

	Placebo	Vorapaxar
Number of Participants Analyzed [units: participants]	**13224**	**13225**
Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death, MI, Stroke, Any Revascularization, or UH-VCIN Within 3 Years From Randomization [units: Percentage of Participants]	**22.1**	**19.9**

Statistical Analysis 1 for Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death, MI, Stroke, Any Revascularization, or UH-VCIN Within 3 Years From Randomization

Groups [1]	All groups
Method [2]	Cox Proportional Hazards Regression
P Value [3]	<0.001
Cox Proportional Hazard [4]	0.90
95% Confidence Interval	0.85 to 0.95

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Hazard Ratio calculated with covariates for treatment and stratification factors
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	Hazard ratio calculated by dividing the Kaplan-Meier (KM) Estimate for vorapaxar by the KM Estimate for Placebo and correcting for covariates. A hazard ratio <1 would indicate a lower hazard associated with vorapaxar relative to placebo.

10. Secondary: Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death Within 3 Years From Randomization [Time Frame: up to 3 years]

Measure Type	Secondary

Measure Title	Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death Within 3 Years From Randomization
Measure Description	The time (in days) from study start to CV death (if reported) was recorded. A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). If a participant had a fatal event that was not part of a specific endpoint for analysis, they were censored at the time of death. The Kaplan-Meier estimate reports the percentage of participants who experienced CV death within 3 years from randomization.
Time Frame	up to 3 years
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
ITT Population, defined as all participants who were randomly assigned to a treatment arm.

Reporting Groups

	Description
Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.

Measured Values

	Placebo	**Vorapaxar**
Number of Participants Analyzed [units: participants]	**13224**	**13225**
Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death Within 3 Years From Randomization [units: Percentage of Participants]	**3.0**	**2.7**

Statistical Analysis 1 for Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death Within 3 Years From Randomization

Groups [1]	All groups
Method [2]	Cox Proportional Hazards Regression
P Value [3]	0.151
Cox Proportional Hazard [4]	0.89
95% Confidence Interval	0.76 to 1.04

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Hazard Ratio calculated with covariates for treatment and stratification factors
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

	No text entered.
[4]	Other relevant estimation information:
	Hazard ratio calculated by dividing the Kaplan-Meier (KM) Estimate for vorapaxar by the KM Estimate for Placebo and correcting for covariates. A hazard ratio <1 would indicate a lower hazard associated with vorapaxar relative to placebo.

11. Secondary: Kaplan-Meier Estimate of the Percentage of Participants Who Experienced an MI Within 3 Years From Randomization [Time Frame: up to 3 years]

Measure Type	Secondary
Measure Title	Kaplan-Meier Estimate of the Percentage of Participants Who Experienced an MI Within 3 Years From Randomization
Measure Description	The time (in days) from study start to the first occurrence of an MI was recorded. A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). If a participant had a fatal event that was not part of a specific endpoint for analysis, they were censored at the time of death. The Kaplan-Meier estimate reports the percentage of participants who experienced an MI within 3 years from randomization.
Time Frame	up to 3 years
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
ITT Population, defined as all participants who were randomly assigned to a treatment arm.

Reporting Groups

	Description
Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.

Measured Values

	Placebo	**Vorapaxar**
Number of Participants Analyzed [units: participants]	**13224**	**13225**
Kaplan-Meier Estimate of the Percentage of Participants Who Experienced an MI Within 3 Years From Randomization [units: Percentage of Participants]	**6.1**	**5.2**

Statistical Analysis 1 for Kaplan-Meier Estimate of the Percentage of Participants Who Experienced an MI Within 3 Years From Randomization

Groups [1]	All groups
Method [2]	Cox Proportional Hazards Regression
P Value [3]	0.001

Cox Proportional Hazard [4]	0.83
95% Confidence Interval	0.74 to 0.93

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Hazard Ratio calculated with covariates for treatment and stratification factors
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	Hazard ratio calculated by dividing the Kaplan-Meier (KM) Estimate for vorapaxar by the KM Estimate for Placebo and correcting for covariates. A hazard ratio <1 would indicate a lower hazard associated with vorapaxar relative to placebo.

12. Secondary: Kaplan-Meier Estimate of the Percentage of Participants Who Experienced UCR Within 3 Years From Randomization [Time Frame: up to 3 years]

Measure Type	Secondary
Measure Title	Kaplan-Meier Estimate of the Percentage of Participants Who Experienced UCR Within 3 Years From Randomization
Measure Description	The time (in days) from study start to the first occurrence of UCR was recorded. A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). If a participant had a fatal event that was not part of a specific endpoint for analysis, they were censored at the time of death. The Kaplan-Meier estimate reports the percentage of participants who experienced UCR within 3 years from randomization.
Time Frame	up to 3 years
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
ITT Population, defined as all participants who were randomly assigned to a treatment arm.

Reporting Groups

	Description
Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.

Measured Values

	Placebo	**Vorapaxar**
Number of Participants Analyzed	**13224**	**13225**

[units: participants]		
Kaplan-Meier Estimate of the Percentage of Participants Who Experienced UCR Within 3 Years From Randomization [units: Percentage of Participants]	**2.6**	**2.5**

Statistical Analysis 1 for Kaplan-Meier Estimate of the Percentage of Participants Who Experienced UCR Within 3 Years From Randomization

Groups [1]	All groups
Method [2]	Cox Proportional Hazards Regression
P Value [3]	0.108
Cox Proportional Hazard [4]	0.88
95% Confidence Interval	0.75 to 1.03

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Hazard Ratio calculated with covariates for treatment and stratification factors
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	Hazard ratio calculated by dividing the Kaplan-Meier (KM) Estimate for vorapaxar by the KM Estimate for Placebo and correcting for covariates. A hazard ratio <1 would indicate a lower hazard associated with vorapaxar relative to placebo.

13. Secondary: Kaplan-Meier Estimate of the Percentage of Participants Who Experienced a Stroke Within 3 Years From Randomization [Time Frame: up to 3 years]

Measure Type	Secondary
Measure Title	Kaplan-Meier Estimate of the Percentage of Participants Who Experienced a Stroke Within 3 Years From Randomization
Measure Description	The time (in days) from study start to first experience of a stroke was recorded. A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). If a participant had a fatal event that was not part of a specific endpoint for analysis, they were censored at the time of death. The Kaplan-Meier estimate reports the percentage of participants who experienced a stroke within 3 years from randomization.
Time Frame	up to 3 years
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
ITT Population, defined as all participants who were randomly assigned to a treatment arm.

Reporting Groups

	Description
Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.

Measured Values

	Placebo	Vorapaxar
Number of Participants Analyzed [units: participants]	**13224**	**13225**
Kaplan-Meier Estimate of the Percentage of Participants Who Experienced a Stroke Within 3 Years From Randomization [units: Percentage of Participants]	**2.8**	**2.8**

Statistical Analysis 1 for Kaplan-Meier Estimate of the Percentage of Participants Who Experienced a Stroke Within 3 Years From Randomization

Groups [1]	All groups
Method [2]	Cox Proportional Hazards Regression
P Value [3]	0.733
Cox Proportional Hazard [4]	0.97
95% Confidence Interval	0.83 to 1.14

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Hazard Ratio calculated with covariates for treatment and stratification factors
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	Hazard ratio calculated by dividing the Kaplan-Meier (KM) Estimate for vorapaxar by the KM Estimate for Placebo and correcting for covariates. A hazard ratio <1 would indicate a lower hazard associated with vorapaxar relative to placebo.

14. Secondary: Kaplan-Meier Estimate of the Percentage of Participants Who Died From Any Cause Within 3 Years From Randomization [Time Frame: up to 3 years]

Measure Type	Secondary
Measure Title	Kaplan-Meier Estimate of the Percentage of Participants Who Died From Any Cause Within 3 Years From Randomization
Measure Description	The time (in days) from study start to death from any cause was recorded. A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information

	(last study visit). The Kaplan-Meier estimate reports the percentage of participants who died from any cause within 3 years from randomization.
Time Frame	up to 3 years
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
ITT Population, defined as all participants who were randomly assigned to a treatment arm.

Reporting Groups

	Description
Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.

Measured Values

	Placebo	**Vorapaxar**
Number of Participants Analyzed [units: participants]	**13224**	**13225**
Kaplan-Meier Estimate of the Percentage of Participants Who Died From Any Cause Within 3 Years From Randomization [units: Percentage of Participants]	**5.3**	**5.0**

Statistical Analysis 1 for Kaplan-Meier Estimate of the Percentage of Participants Who Died From Any Cause Within 3 Years From Randomization

Groups [1]	All groups
Method [2]	Cox Proportional Hazards Regression
P Value [3]	0.411
Cox Proportional Hazard [4]	0.95
95% Confidence Interval	0.85 to 1.07

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	Hazard ratio calculated by dividing the Kaplan-Meier (KM) Estimate for vorapaxar by the KM Estimate for Placebo and correcting for covariates. A hazard ratio <1 would indicate a lower hazard associated with vorapaxar relative to placebo.

15. Secondary: Kaplan-Meier Estimate of the Percentage of Participants Who Had a UH-VCIN Within 3 Years From Randomization [Time Frame: up to 3 years]

Measure Type	Secondary
Measure Title	Kaplan-Meier Estimate of the Percentage of Participants Who Had a UH-VCIN Within 3 Years From Randomization
Measure Description	The time (in days) from study start to the first occurrence of an UH-VCIN was recorded. A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). If a participant had a fatal event that was not part of a specific endpoint for analysis, they were censored at the time of death. The Kaplan-Meier estimate reports the percentage of participants who had a UH-VCIN within 3 years from randomization.
Time Frame	up to 3 years
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
ITT Population, defined as all participants who were randomly assigned to a treatment arm.

Reporting Groups

	Description
Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.

Measured Values

	Placebo	**Vorapaxar**
Number of Participants Analyzed [units: participants]	**13224**	**13225**
Kaplan-Meier Estimate of the Percentage of Participants Who Had a UH-VCIN Within 3 Years From Randomization [units: Percentage of Participants]	**5.5**	**4.7**

Statistical Analysis 1 for Kaplan-Meier Estimate of the Percentage of Participants Who Had a UH-VCIN Within 3 Years From Randomization

Groups [1]	All groups
Method [2]	Cox Proportional Hazards Regression
P Value [3]	0.001
Cox Proportional Hazard [4]	0.83
95% Confidence Interval	0.74 to 0.93

[1]	Additional details about the analysis, such as null hypothesis and power calculation:

	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Hazard Ratio calculated with covariates for treatment and stratification factors
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	Hazard ratio calculated by dividing the Kaplan-Meier (KM) Estimate for vorapaxar by the KM Estimate for Placebo and correcting for covariates. A hazard ratio <1 would indicate a lower hazard associated with vorapaxar relative to placebo.

16. Secondary: Kaplan-Meier Estimate of the Percentage of Participants Who Had Any Revascularization Performed Within 3 Years From Randomization [Time Frame: up to 3 years]

Measure Type	Secondary
Measure Title	Kaplan-Meier Estimate of the Percentage of Participants Who Had Any Revascularization Performed Within 3 Years From Randomization
Measure Description	The time (in days) from study start to the first occurrence of a revascularization was recorded. A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). If a participant had a fatal event that was not part of a specific endpoint for analysis, they were censored at the time of death. The Kaplan-Meier estimate reports the percentage of participants who had any revascularization performed within 3 years from randomization.
Time Frame	up to 3 years
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
ITT Population, defined as all participants who were randomly assigned to a treatment arm.

Reporting Groups

	Description
Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.

Measured Values

	Placebo	**Vorapaxar**
Number of Participants Analyzed [units: participants]	**13224**	**13225**
Kaplan-Meier Estimate of the Percentage of Participants Who Had Any Revascularization Performed Within 3 Years From Randomization [units: Percentage of Participants]	**15.5**	**13.6**

Statistical Analysis 1 for Kaplan-Meier Estimate of the Percentage of Participants Who Had Any Revascularization Performed Within 3 Years From Randomization

Groups [1]	All groups
Method [2]	Cox Proportional Hazards Regression
P Value [3]	<0.001
Cox Proportional Hazard [4]	0.89
95% Confidence Interval	0.83 to 0.95

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Hazard Ratio calculated with covariates for treatment and stratification factors
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	Hazard ratio calculated by dividing the Kaplan-Meier (KM) Estimate for vorapaxar by the KM Estimate for Placebo and correcting for covariates. A hazard ratio <1 would indicate a lower hazard associated with vorapaxar relative to placebo.

17. Post-Hoc: Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death, MI, Stroke, or UCR Within 3 Years From Randomization [Time Frame: up to 3 years]

Measure Type	Post-Hoc
Measure Title	Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death, MI, Stroke, or UCR Within 3 Years From Randomization
Measure Description	The time (in days) from study start to the first occurrence of any of the following clinical outcomes was recorded: CV death, MI, stroke, or UCR. A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). If a participant had a fatal event that was not part of a specific endpoint for analysis, they were censored at the time of death. The Kaplan-Meier estimate reports the percentage of participants who experienced CV death, MI, stroke, or UCR within 3 years from randomization.
Time Frame	up to 3 years
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intended Label Population: all enrolled participants with coronary arterial disease (CAD) or peripheral arterial disease (PAD) and no history of a stroke or transient ischemic attack (TIA)

Reporting Groups

	Description
Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.

Measured Values

	Placebo	Vorapaxar
Number of Participants Analyzed [units: participants]	**10090**	**10080**
Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death, MI, Stroke, or UCR Within 3 Years From Randomization [units: Percentage of Participants]	**11.8**	**10.1**

Statistical Analysis 1 for Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death, MI, Stroke, or UCR Within 3 Years From Randomization

Groups [1]	All groups
Method [2]	Cox Proportional Hazards Regression
P Value [3]	<0.001
Cox Proportional Hazard [4]	0.83
95% Confidence Interval	0.76 to 0.90

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Hazard Ratio calculated with covariates for treatment and stratification factors
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	Hazard ratio calculated by dividing the Kaplan-Meier (KM) Estimate for vorapaxar by the KM Estimate for Placebo and correcting for covariates. A hazard ratio <1 would indicate a lower hazard associated with vorapaxar relative to placebo.

18. Post-Hoc: Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death, MI, or Stroke Within 3 Years From Randomization [Time Frame: up to 3 years]

Measure Type	Post-Hoc
Measure Title	Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death, MI, or Stroke Within 3 Years From Randomization
Measure Description	The time (in days) from study start to the first occurrence of any of the following clinical outcomes was recorded: CV death, MI, or stroke. A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to

	treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). If a participant had a fatal event that was not part of a specific endpoint for analysis, they were censored at the time of death. The Kaplan-Meier estimate reports the percentage of participants who experienced CV death, MI, or stroke within 3 years from randomization.
Time Frame	up to 3 years
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intended Label Population: all enrolled participants with CAD or PAD and no history of a stroke or TIA

Reporting Groups

	Description
Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.

Measured Values

	Placebo	**Vorapaxar**
Number of Participants Analyzed [units: participants]	**10090**	**10080**
Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death, MI, or Stroke Within 3 Years From Randomization [units: Percentage of Participants]	**9.5**	**7.9**

Statistical Analysis 1 for Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death, MI, or Stroke Within 3 Years From Randomization

Groups [1]	All groups
Method [2]	Cox Proportional Hazards Regression
P Value [3]	<0.001
Cox Proportional Hazard [4]	0.80
95% Confidence Interval	0.73 to 0.89

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Hazard Ratio calculated with covariates for treatment and stratification factors
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

[4]	Other relevant estimation information:
	Hazard ratio calculated by dividing the Kaplan-Meier (KM) Estimate for vorapaxar by the KM Estimate for Placebo and correcting for covariates. A hazard ratio <1 would indicate a lower hazard associated with vorapaxar relative to placebo.

19. Post-Hoc: Kaplan-Meier Estimate of the Percentage of Participants Who Met GUSTO Moderate or Severe Bleeding Criteria Within 3 Years From Randomization [Time Frame: up to 3 years]

Measure Type	Post-Hoc
Measure Title	Kaplan-Meier Estimate of the Percentage of Participants Who Met GUSTO Moderate or Severe Bleeding Criteria Within 3 Years From Randomization
Measure Description	Adverse events were categorized as “bleeding events” if the intensity, frequency, or type of the event was other or more than would be normally expected in the given situation (eg, mild nosebleed in a person who does not normally have nosebleeds, greater bruising than expected for a given injury, greater volume of blood loss than expected for a given procedure). The investigator graded the intensity of bleeding events according to the GUSTO cooperative group criteria as follows: Mild , Moderate or Severe and the grading was adjudicated by the CEC. The Kaplan-Meier estimate reports the percentage of participants who experienced GUSTO moderate or severe bleeding within 3 years from randomization.
Time Frame	up to 3 years
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intended Label Safety Population: all enrolled participants with CAD or PAD and no history of a stroke or TIA who received at least 1 dose of study drug

Reporting Groups

	Description
Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.

Measured Values

	Placebo	**Vorapaxar**
Number of Participants Analyzed [units: participants]	**10049**	**10059**
Kaplan-Meier Estimate of the Percentage of Participants Who Met GUSTO Moderate or Severe Bleeding Criteria Within 3 Years From Randomization [units: Percentage of Participants]	**2.7**	**3.8**

Statistical Analysis 1 for Kaplan-Meier Estimate of the Percentage of Participants Who Met GUSTO Moderate or Severe Bleeding Criteria Within 3 Years From Randomization

Groups [1]	All groups

Method [2]	Cox Proportional Hazards Regression
P Value [3]	<0.001
Cox Proportional Hazard [4]	1.45
95% Confidence Interval	1.23 to 1.71

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Hazard Ratio calculated with covariates for treatment and stratification factors
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	Hazard ratio calculated by dividing the Kaplan-Meier (KM) Estimate for vorapaxar by the KM Estimate for Placebo and correcting for covariates. A hazard ratio <1 would indicate a lower hazard associated with vorapaxar relative to placebo.

20. Post-Hoc: Kaplan-Meier Estimate of the Percentage of Participants Who Experienced Clinically Significant Bleeding Within 3 Years From Randomization [Time Frame: up to 3 years]

Measure Type	Post-Hoc
Measure Title	Kaplan-Meier Estimate of the Percentage of Participants Who Experienced Clinically Significant Bleeding Within 3 Years From Randomization
Measure Description	Adverse events were categorized as “bleeding events” if the intensity, frequency, or type of the event was other or more than would be normally expected in the given situation (eg, mild nosebleed in a person who does not normally have nosebleeds, greater bruising than expected for a given injury, greater volume of blood loss than expected for a given procedure). The investigator graded the intensity of bleeding events according to the TIMI Study Group criteria as major, minor or other. “Clinically Significant Bleeding” was defined as the composite of TIMI Major bleeding, TIMI Minor bleeding, or bleeding that required unplanned medical or surgical treatment or unplanned laboratory evaluation even if it did not meet the criteria for TIMI major or minor bleeding. The Kaplan-Meier estimate reports the percentage of participants who experienced clinically significant bleeding within 3 years from randomization.
Time Frame	up to 3 years
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intended Label Safety Population: all enrolled participants with CAD or PAD and no history of a stroke or TIA who received at least 1 dose of study drug

Reporting Groups

	Description
Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.

Measured Values

	Placebo	Vorapaxar
Number of Participants Analyzed [units: participants]	**10049**	**10059**
Kaplan-Meier Estimate of the Percentage of Participants Who Experienced Clinically Significant Bleeding Within 3 Years From Randomization [units: Percentage of Participants]	**11.1**	**15.2**

Statistical Analysis 1 for Kaplan-Meier Estimate of the Percentage of Participants Who Experienced Clinically Significant Bleeding Within 3 Years From Randomization

Groups [1]	All groups
Method [2]	Cox Proportional Hazards Regression
P Value [3]	<0.001
Cox Proportional Hazard [4]	1.42
95% Confidence Interval	1.31 to 1.54

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Hazard Ratio calculated with covariates for treatment and stratification factors
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	Hazard ratio calculated by dividing the Kaplan-Meier (KM) Estimate for vorapaxar by the KM Estimate for Placebo and correcting for covariates. A hazard ratio <1 would indicate a lower hazard associated with vorapaxar relative to placebo.

21. Post-Hoc: Kaplan-Meier Estimate of the Percentage of Participants Who Experienced Death From Any Cause, MI, Stroke, or UCR Within 3 Years From Randomization [Time Frame: up to 3 years]

Measure Type	Post-Hoc
Measure Title	Kaplan-Meier Estimate of the Percentage of Participants Who Experienced Death From Any Cause, MI, Stroke, or UCR Within 3 Years From Randomization
Measure Description	The time (in days) from study start to the occurrence of any of the following clinical outcomes was recorded: death from any cause, MI, stroke, or UCR. A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). The Kaplan-Meier estimate reports the percentage of participants who experienced death from any cause, MI, stroke, or UCR within 3 years from randomization.
Time Frame	up to 3 years

Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intended Label Population: all enrolled participants with CAD or PAD and no history of a stroke or TIA

Reporting Groups

	Description
Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.

Measured Values

	Placebo	**Vorapaxar**
Number of Participants Analyzed [units: participants]	**10090**	**10080**
Kaplan-Meier Estimate of the Percentage of Participants Who Experienced Death From Any Cause, MI, Stroke, or UCR Within 3 Years From Randomization [units: Percentage of Participants]	**13.5**	**11.9**

Statistical Analysis 1 for Kaplan-Meier Estimate of the Percentage of Participants Who Experienced Death From Any Cause, MI, Stroke, or UCR Within 3 Years From Randomization

Groups [1]	All groups
Method [2]	Cox Proportional Hazards Regression
P Value [3]	<0.001
Cox Proportional Hazard [4]	0.86
95% Confidence Interval	0.79 to 0.93

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Hazard Ratio calculated with covariates for treatment and stratification factors
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	Hazard ratio calculated by dividing the Kaplan-Meier (KM) Estimate for vorapaxar by the KM Estimate for Placebo and correcting for covariates. A hazard ratio <1 would indicate a lower hazard associated with vorapaxar relative to placebo.

22. Post-Hoc: Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death or an MI Within 3 Years From Randomization [Time Frame: up to 3 years]

Measure Type	Post-Hoc
Measure Title	Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death or an MI Within 3 Years From Randomization
Measure Description	The time (in days) from study start to the occurrence of CV death or first occurrence of an MI. A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). If a participant had a fatal event that was not part of a specific endpoint for analysis, they were censored at the time of death. The Kaplan-Meier estimate reports the percentage of participants who experienced CV death or MI within 3 years from randomization.
Time Frame	up to 3 years
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intended Label Population: all enrolled participants with CAD or PAD and no history of a stroke or TIA

Reporting Groups

	Description
Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.

Measured Values

	Placebo	**Vorapaxar**
Number of Participants Analyzed [units: participants]	**10090**	**10080**
Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death or an MI Within 3 Years From Randomization [units: Percentage of Partcipants]	**8.3**	**7.2**

Statistical Analysis 1 for Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death or an MI Within 3 Years From Randomization

Groups [1]	All groups
Method [2]	Cox Proportional Hazards Regression
P Value [3]	<0.001
Cox Proportional Hazard [4]	0.83
95% Confidence Interval	0.75 to 0.93

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Hazard Ratio calculated with covariates for treatment and stratification factors
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	Hazard ratio calculated by dividing the Kaplan-Meier (KM) Estimate for vorapaxar by the KM Estimate for Placebo and correcting for covariates. A hazard ratio <1 would indicate a lower hazard associated with vorapaxar relative to placebo.

23. Post-Hoc: Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death, MI, Stroke, UCR, or UH-VCIN Within 3 Years From Randomization [Time Frame: up to 3 years]

Measure Type	Post-Hoc
Measure Title	Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death, MI, Stroke, UCR, or UH-VCIN Within 3 Years From Randomization
Measure Description	The time (in days) from study start to the first occurrence of any of the following clinical outcomes was recorded: CV death, MI, stroke, UCR, or UH-VCIN . A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). If a participant had a fatal event that was not part of a specific endpoint for analysis, they were censored at the time of death. The Kaplan-Meier estimate reports the percentage of participants who experienced CV death, MI, stroke, UCR, or UH-VCIN within 3 years from randomization.
Time Frame	up to 3 years
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intended Label Population: all enrolled participants with CAD or PAD and no history of a stroke or TIA

Reporting Groups

	Description
Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.

Measured Values

	Placebo	**Vorapaxar**
Number of Participants Analyzed [units: participants]	**10090**	**10080**

Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death, MI, Stroke, UCR, or UH-VCIN Within 3 Years From Randomization [units: Percentage of Participants]	**13.9**	**11.9**

Statistical Analysis 1 for Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death, MI, Stroke, UCR, or UH-VCIN Within 3 Years From Randomization

Groups [1]	All groups
Method [2]	Cox Proportional Hazards Regression
P Value [3]	<0.001
Cox Proportional Hazard [4]	0.83
95% Confidence Interval	0.77 to 0.90

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Hazard Ratio calculated with covariates for treatment and stratification factors
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	Hazard ratio calculated by dividing the Kaplan-Meier (KM) Estimate for vorapaxar by the KM Estimate for Placebo and correcting for covariates. A hazard ratio <1 would indicate a lower hazard associated with vorapaxar relative to placebo.

24. Post-Hoc: Kaplan-Meier Estimate of the Percentage of Participants Who Died From Any Cause, or Experienced an MI, Stroke, or Any Revascularization Within 3 Years From Randomization [Time Frame: up to 3 years]

Measure Type	Post-Hoc
Measure Title	Kaplan-Meier Estimate of the Percentage of Participants Who Died From Any Cause, or Experienced an MI, Stroke, or Any Revascularization Within 3 Years From Randomization
Measure Description	The time (in days) from study start to death from any cause or the first occurrence of any of the following clinical outcomes was recorded: MI, stroke, or any revascularization procedure . A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). The Kaplan-Meier estimate reports the percentage of participants who died from any cause, or experienced an MI, stroke, or any revascularization within 3 years from randomization.
Time Frame	up to 3 years
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intended Label Population: all enrolled participants with CAD or PAD and no history of a stroke or TIA

Reporting Groups

	Description
Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.

Measured Values

	Placebo	Vorapaxar
Number of Participants Analyzed [units: participants]	**10090**	**10080**
Kaplan-Meier Estimate of the Percentage of Participants Who Died From Any Cause, or Experienced an MI, Stroke, or Any Revascularization Within 3 Years From Randomization [units: Percentage of Participants]	**22.5**	**20.1**

Statistical Analysis 1 for Kaplan-Meier Estimate of the Percentage of Participants Who Died From Any Cause, or Experienced an MI, Stroke, or Any Revascularization Within 3 Years From Randomization

Groups [1]	All groups
Method [2]	Cox Proportional Hazards Regression
P Value [3]	<0.001
Cox Proportional Hazard [4]	0.89
95% Confidence Interval	0.83 to 0.95

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Hazard Ratio calculated with covariates for treatment and stratification factors
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	Hazard ratio calculated by dividing the Kaplan-Meier (KM) Estimate for vorapaxar by the KM Estimate for Placebo and correcting for covariates. A hazard ratio <1 would indicate a lower hazard associated with vorapaxar relative to placebo.

25. Post-Hoc: Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death, MI, Stroke, Any Revascularization, or UH-VCIN Within 3 Years From Randomization [Time Frame: up to 3 years]

Measure Type	Post-Hoc
Measure Title	Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death, MI, Stroke, Any Revascularization, or UH-VCIN Within 3 Years From Randomization

Measure Description	The time (in days) from study start to the first occurrence of any of the following clinical outcomes was recorded: CV death, MI, stroke, any revascularization, or UH-VCIN. A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). If a participant had a fatal event that was not part of a specific endpoint for analysis, they were censored at the time of death. The Kaplan-Meier estimate reports the percentage of participants who experienced CV death, MI, stroke, any revascularization procedure, or UH-VCIN within 3 years from randomization.
Time Frame	up to 3 years
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intended Label Population: all enrolled participants with CAD or PAD and no history of a stroke or TIA

Reporting Groups

	Description
Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.

Measured Values

	Placebo	**Vorapaxar**
Number of Participants Analyzed [units: participants]	**10090**	**10080**
Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death, MI, Stroke, Any Revascularization, or UH-VCIN Within 3 Years From Randomization [units: Percentage of Participants]	**21.8**	**19.3**

Statistical Analysis 1 for Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death, MI, Stroke, Any Revascularization, or UH-VCIN Within 3 Years From Randomization

Groups [1]	All groups
Method [2]	Cox Proportional Hazards Regression
P Value [3]	<0.001
Cox Proportional Hazard [4]	0.88
95% Confidence Interval	0.83 to 0.94

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Hazard Ratio calculated with covariates for treatment and stratification factors
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical

	significance:
	No text entered.
[4]	Other relevant estimation information:
	Hazard ratio calculated by dividing the Kaplan-Meier (KM) Estimate for vorapaxar by the KM Estimate for Placebo and correcting for covariates. A hazard ratio <1 would indicate a lower hazard associated with vorapaxar relative to placebo.

26. Post-Hoc: Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death Within 3 Years From Randomization [Time Frame: up to 3 years]

Measure Type	Post-Hoc
Measure Title	Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death Within 3 Years From Randomization
Measure Description	The time (in days) from study start to the CV death (if reported) was recorded. A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). If a participant had a fatal event that was not part of a specific endpoint for analysis, they were censored at the time of death. The Kaplan-Meier estimate reports the percentage of participants who experienced CV death within 3 years from randomization.
Time Frame	up to 3 years
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intended Label Population: all enrolled participants with CAD or PAD and no history of a stroke or TIA

Reporting Groups

	Description
Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.

Measured Values

	Placebo	**Vorapaxar**
Number of Participants Analyzed [units: participants]	**10090**	**10080**
Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death Within 3 Years From Randomization [units: Percentage of Participants]	**2.8**	**2.4**

Statistical Analysis 1 for Kaplan-Meier Estimate of the Percentage of Participants Who Experienced CV Death Within 3 Years From Randomization

Groups [1]	All groups
[2]	Cox Proportional Hazards Regression

Method	
P Value [3]	0.108
Cox Proportional Hazard [4]	0.86
95% Confidence Interval	0.71 to 1.03

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Hazard Ratio calculated with covariates for treatment and stratification factors
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	Hazard ratio calculated by dividing the Kaplan-Meier (KM) Estimate for vorapaxar by the KM Estimate for Placebo and correcting for covariates. A hazard ratio <1 would indicate a lower hazard associated with vorapaxar relative to placebo.

27. Post-Hoc: Kaplan-Meier Estimate of the Percentage of Participants Who Experienced an MI Within 3 Years From Randomization [Time Frame: up to 3 years]

Measure Type	Post-Hoc
Measure Title	Kaplan-Meier Estimate of the Percentage of Participants Who Experienced an MI Within 3 Years From Randomization
Measure Description	The time (in days) from study start to the first occurrence of an MI was recorded. A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). If a participant had a fatal event that was not part of a specific endpoint for analysis, they were censored at the time of death. The Kaplan-Meier estimate reports the percentage of participants who experienced an MI within 3 years from randomization.
Time Frame	up to 3 years
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intended Label Population: all enrolled participants with CAD or PAD and no history of a stroke or TIA

Reporting Groups

	Description
Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.

Measured Values

	Placebo	**Vorapaxar**

Number of Participants Analyzed [units: participants]	**10090**	**10080**
Kaplan-Meier Estimate of the Percentage of Participants Who Experienced an MI Within 3 Years From Randomization [units: Percentage of Participants]	**6.4**	**5.4**

Statistical Analysis 1 for Kaplan-Meier Estimate of the Percentage of Participants Who Experienced an MI Within 3 Years From Randomization

Groups [1]	All groups
Method [2]	Cox Proportional Hazards Regression
P Value [3]	0.002
Cox Proportional Hazard [4]	0.82
95% Confidence Interval	0.73 to 0.93

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Hazard Ratio calculated with covariates for treatment and stratification factors
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	Hazard ratio calculated by dividing the Kaplan-Meier (KM) Estimate for vorapaxar by the KM Estimate for Placebo and correcting for covariates. A hazard ratio <1 would indicate a lower hazard associated with vorapaxar relative to placebo.

28. Post-Hoc: Kaplan-Meier Estimate of the Percentage of Participants Who Experienced UCR Within 3 Years From Randomization [Time Frame: up to 3 years]

Measure Type	Post-Hoc
Measure Title	Kaplan-Meier Estimate of the Percentage of Participants Who Experienced UCR Within 3 Years From Randomization
Measure Description	The time (in days) from study start to the first occurrence of UCR was recorded. A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). If a participant had a fatal event that was not part of a specific endpoint for analysis, they were censored at the time of death. The Kaplan-Meier estimate reports the percentage of participants who experienced UCR within 3 years from randomization.
Time Frame	up to 3 years
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

Intended Label Population: all enrolled participants with CAD or PAD and no history of a stroke or TIA

Reporting Groups

	Description
Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.

Measured Values

	Placebo	Vorapaxar
Number of Participants Analyzed [units: participants]	**10090**	**10080**
Kaplan-Meier Estimate of the Percentage of Participants Who Experienced UCR Within 3 Years From Randomization [units: Percentage of Participants]	**3.0**	**2.8**

Statistical Analysis 1 for Kaplan-Meier Estimate of the Percentage of Participants Who Experienced UCR Within 3 Years From Randomization

Groups [1]	All groups
Method [2]	Cox Proportional Hazards Regression
P Value [3]	0.127
Cox Proportional Hazard [4]	0.88
95% Confidence Interval	0.74 to 1.04

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Hazard Ratio calculated with covariates for treatment and stratification factors
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	Hazard ratio calculated by dividing the Kaplan-Meier (KM) Estimate for vorapaxar by the KM Estimate for Placebo and correcting for covariates. A hazard ratio <1 would indicate a lower hazard associated with vorapaxar relative to placebo.

29. Post-Hoc: Kaplan-Meier Estimate of the Percentage of Participants Who Experienced a Stroke Within 3 Years From Randomization [Time Frame: up to 3 years]

Measure Type	Post-Hoc
Measure Title	Kaplan-Meier Estimate of the Percentage of Participants Who Experienced a Stroke Within 3 Years From Randomization
Measure Description	The time (in days) from study start to first experience of a stroke was recorded. A CEC reviewed and adjudicated each

	suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). If a participant had a fatal event that was not part of a specific endpoint for analysis, they were censored at the time of death. The Kaplan-Meier estimate reports the percentage of participants who experienced a stroke within 3 years from randomization.
Time Frame	up to 3 years
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intended Label Population: all enrolled participants with CAD or PAD and no history of a stroke or TIA

Reporting Groups

	Description
Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.

Measured Values

	Placebo	**Vorapaxar**
Number of Participants Analyzed [units: participants]	**10090**	**10080**
Kaplan-Meier Estimate of the Percentage of Participants Who Experienced a Stroke Within 3 Years From Randomization [units: Percentage of Participants]	**1.6**	**1.2**

Statistical Analysis 1 for Kaplan-Meier Estimate of the Percentage of Participants Who Experienced a Stroke Within 3 Years From Randomization

Groups [1]	All groups
Method [2]	Cox Proportional Hazards Regression
P Value [3]	0.002
Cox Proportional Hazard [4]	0.67
95% Confidence Interval	0.52 to 0.87

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Hazard Ratio calculated with covariates for treatment and stratification factors
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:

Hazard ratio calculated by dividing the Kaplan-Meier (KM) Estimate for vorapaxar by the KM Estimate for Placebo and correcting for covariates. A hazard ratio <1 would indicate a lower hazard associated with vorapaxar relative to placebo.

30. Post-Hoc: Kaplan-Meier Estimate of the Percentage of Participants Who Died From Any Cause Within 3 Years From Randomization [Time Frame: up to 3 years]

Measure Type	Post-Hoc
Measure Title	Kaplan-Meier Estimate of the Percentage of Participants Who Died From Any Cause Within 3 Years From Randomization
Measure Description	The time (in days) from study start to death from any cause was recorded. A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). The Kaplan-Meier estimate reports the percentage of participants who died from any cause within 3 years from randomization.
Time Frame	up to 3 years
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intended Label Population: all enrolled participants with CAD or PAD and no history of a stroke or TIA

Reporting Groups

	Description
Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.

Measured Values

	Placebo	**Vorapaxar**
Number of Participants Analyzed [units: participants]	**10090**	**10080**
Kaplan-Meier Estimate of the Percentage of Participants Who Died From Any Cause Within 3 Years From Randomization [units: Percentage of Participants]	**4.8**	**4.5**

Statistical Analysis 1 for Kaplan-Meier Estimate of the Percentage of Participants Who Died From Any Cause Within 3 Years From Randomization

Groups [1]	All groups
Method [2]	Cox Proportional Hazards Regression
P Value [3]	0.249
Cox Proportional Hazard [4]	0.92
95% Confidence Interval	0.80 to 1.06

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Hazard Ratio calculated with covariates for treatment and stratification factors
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	Hazard ratio calculated by dividing the Kaplan-Meier (KM) Estimate for vorapaxar by the KM Estimate for Placebo and correcting for covariates. A hazard ratio <1 would indicate a lower hazard associated with vorapaxar relative to placebo.

31. Post-Hoc: Kaplan-Meier Estimate of the Percentage of Participants Who Had a UH-VCIN Within 3 Years From Randomization [Time Frame: up to 3 years]

Measure Type	Post-Hoc
Measure Title	Kaplan-Meier Estimate of the Percentage of Participants Who Had a UH-VCIN Within 3 Years From Randomization
Measure Description	The time (in days) from study start to the first occurrence of a UH-VCIN was recorded. A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). If a participant had a fatal event that was not part of a specific endpoint for analysis, they were censored at the time of death. The Kaplan-Meier estimate reports the percentage of participants who had a UH-VCIN within 3 years from randomization.
Time Frame	up to 3 years
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intended Label Population: all enrolled participants with CAD or PAD and no history of a stroke or TIA

Reporting Groups

	Description
Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.

Measured Values

	Placebo	**Vorapaxar**
Number of Participants Analyzed [units: participants]	**10090**	**10080**
Kaplan-Meier Estimate of the Percentage of Participants Who Had a UH-VCIN Within 3 Years From Randomization	**5.6**	**4.9**

[units: Percentage of Participants]		

Statistical Analysis 1 for Kaplan-Meier Estimate of the Percentage of Participants Who Had a UH-VCIN Within 3 Years From Randomization

Groups [1]	All groups
Method [2]	Cox Proportional Hazards Regression
P Value [3]	0.019
Cox Proportional Hazard [4]	0.86
95% Confidence Interval	0.76 to 0.98

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Hazard Ratio calculated with covariates for treatment and stratification factors
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	Hazard ratio calculated by dividing the Kaplan-Meier (KM) Estimate for vorapaxar by the KM Estimate for Placebo and correcting for covariates. A hazard ratio <1 would indicate a lower hazard associated with vorapaxar relative to placebo.

32. Post-Hoc: Kaplan-Meier Estimate of the Percentage of Participants Who Had Any Revascularization Performed Within 3 Years From Randomization [Time Frame: up to 3 years]

Measure Type	Post-Hoc
Measure Title	Kaplan-Meier Estimate of the Percentage of Participants Who Had Any Revascularization Performed Within 3 Years From Randomization
Measure Description	The time (in days) from study start to the first occurrence of any revascularization was recorded. A CEC reviewed and adjudicated each suspected efficacy endpoint event while blinded to treatment. Participants who did not have any endpoint event until last visit or participants who were lost to follow-up and had no event were censored at the time of last available information (last study visit). If a participant had a fatal event that was not part of a specific endpoint for analysis, they were censored at the time of death. The Kaplan-Meier estimate reports the percentage of participants who had any revascularization performed within 3 years from randomization.
Time Frame	up to 3 years
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intended Label Population: all enrolled participants with CAD or PAD and no history of a stroke or TIA

Reporting Groups

	Description

Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.

Measured Values

	Placebo	Vorapaxar
Number of Participants Analyzed [units: participants]	**10090**	**10080**
Kaplan-Meier Estimate of the Percentage of Participants Who Had Any Revascularization Performed Within 3 Years From Randomization [units: Percentage of Participants]	**16.6**	**14.7**

Statistical Analysis 1 for Kaplan-Meier Estimate of the Percentage of Participants Who Had Any Revascularization Performed Within 3 Years From Randomization

Groups [1]	All groups
Method [2]	Cox Proportional Hazards Regression
P Value [3]	0.003
Cox Proportional Hazard [4]	0.89
95% Confidence Interval	0.83 to 0.96

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Hazard Ratio calculated with covariates for treatment and stratification factors
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	Hazard ratio calculated by dividing the Kaplan-Meier (KM) Estimate for vorapaxar by the KM Estimate for Placebo and correcting for covariates. A hazard ratio <1 would indicate a lower hazard associated with vorapaxar relative to placebo.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	up to 3 years
Additional Description	Adverse events are reported using the As Treated Population, which included all participants who received at least 1 dose of study medication and are reported according to treatment received

Reporting Groups

	Description
Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.

Serious Adverse Events

	Placebo	Vorapaxar
Total, serious adverse events		
# participants affected / at risk	**3419/13166 (25.97%)**	**3514/13186 (26.65%)**
Blood and lymphatic system disorders		
ANAEMIA † 1		
# participants affected / at risk	**12/13166 (0.09%)**	**45/13186 (0.34%)**
# events	**13**	**47**
ANAEMIA HAEMOLYTIC AUTOIMMUNE † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
ANAEMIA OF CHRONIC DISEASE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
APLASIA PURE RED CELL † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
AUTOIMMUNE THROMBOCYTOPENIA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
COAGULOPATHY † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
FEBRILE NEUTROPENIA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
HAEMORRHAGIC ANAEMIA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
HAEMORRHAGIC DIATHESIS † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**7/13186 (0.05%)**
# events	**4**	**7**
HEPARIN-INDUCED THROMBOCYTOPENIA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
IDIOPATHIC THROMBOCYTOPENIC PURPURA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**3/13186 (0.02%)**
# events	**0**	**3**

IRON DEFICIENCY ANAEMIA † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**16/13186 (0.12%)**
# events	**4**	**16**
LEUKOCYTOSIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**2**
LEUKOPENIA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**2**
LYMPHADENOPATHY † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**2**
MICROCYTIC ANAEMIA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**3/13186 (0.02%)**
# events	**0**	**3**
NEPHROGENIC ANAEMIA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
NEUTROPENIA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**2**
NORMOCHROMIC NORMOCYTIC ANAEMIA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
PANCYTOPENIA † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**3/13186 (0.02%)**
# events	**2**	**3**
PERNICIOUS ANAEMIA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
RETROPERITONEAL LYMPHADENOPATHY † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
SPLENIC HAEMORRHAGE † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**2**	**0**
THROMBOCYTOPENIA † 1		
# participants affected / at risk	**23/13166 (0.17%)**	**19/13186 (0.14%)**
# events	**23**	**20**
THROMBOCYTOSIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
THROMBOTIC THROMBOCYTOPENIC PURPURA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
Cardiac disorders		

ACUTE CORONARY SYNDROME † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
ADAMS-STOKES SYNDROME † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
ANGINA PECTORIS † 1		
# participants affected / at risk	**7/13166 (0.05%)**	**2/13186 (0.02%)**
# events	**8**	**2**
AORTIC VALVE INCOMPETENCE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
AORTIC VALVE STENOSIS † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**5/13186 (0.04%)**
# events	**4**	**5**
ARRHYTHMIA † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**3/13186 (0.02%)**
# events	**2**	**3**
ARRHYTHMIA SUPRAVENTRICULAR † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
ATRIAL FIBRILLATION † 1		
# participants affected / at risk	**106/13166 (0.81%)**	**137/13186 (1.04%)**
# events	**118**	**156**
ATRIAL FLUTTER † 1		
# participants affected / at risk	**18/13166 (0.14%)**	**28/13186 (0.21%)**
# events	**19**	**28**
ATRIAL TACHYCARDIA † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**3**	**0**
ATRIAL THROMBOSIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**2**
ATRIOVENTRICULAR BLOCK † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**3/13186 (0.02%)**
# events	**3**	**3**
ATRIOVENTRICULAR BLOCK COMPLETE † 1		
# participants affected / at risk	**13/13166 (0.10%)**	**19/13186 (0.14%)**
# events	**13**	**19**
ATRIOVENTRICULAR BLOCK FIRST DEGREE † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
ATRIOVENTRICULAR BLOCK SECOND DEGREE † 1		
# participants affected / at risk	**8/13166 (0.06%)**	**4/13186 (0.03%)**
# events	**9**	**4**

BIFASCICULAR BLOCK † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
BRADYCARDIA † 1		
# participants affected / at risk	**27/13166 (0.21%)**	**20/13186 (0.15%)**
# events	**27**	**20**
BUNDLE BRANCH BLOCK LEFT † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**3**	**0**
BUNDLE BRANCH BLOCK RIGHT † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**2**	**0**
CARDIAC ANEURYSM † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
CARDIAC ARREST † 1		
# participants affected / at risk	**13/13166 (0.10%)**	**2/13186 (0.02%)**
# events	**13**	**2**
CARDIAC ASTHMA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
CARDIAC FAILURE † 1		
# participants affected / at risk	**174/13166 (1.32%)**	**183/13186 (1.39%)**
# events	**222**	**245**
CARDIAC FAILURE ACUTE † 1		
# participants affected / at risk	**5/13166 (0.04%)**	**4/13186 (0.03%)**
# events	**5**	**5**
CARDIAC FAILURE CHRONIC † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
CARDIAC FAILURE CONGESTIVE † 1		
# participants affected / at risk	**82/13166 (0.62%)**	**95/13186 (0.72%)**
# events	**99**	**121**
CARDIAC TAMPONADE † 1		
# participants affected / at risk	**5/13166 (0.04%)**	**4/13186 (0.03%)**
# events	**5**	**5**
CARDIO-RESPIRATORY ARREST † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**3/13186 (0.02%)**
# events	**4**	**3**
CARDIOGENIC SHOCK † 1		
# participants affected / at risk	**10/13166 (0.08%)**	**8/13186 (0.06%)**
# events	**10**	**8**
CARDIOMYOPATHY † 1		
# participants affected / at risk	**5/13166 (0.04%)**	**3/13186 (0.02%)**
# events	**5**	**3**
† 1		

CARDIOPULMONARY FAILURE		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
CHRONOTROPIC INCOMPETENCE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
CONDUCTION DISORDER † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**2**	**0**
CONGESTIVE CARDIOMYOPATHY † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
CORONARY ARTERY DISEASE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
DRESSLER'S SYNDROME † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**3**
EXTRASYSTOLES † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**2**	**0**
HEART VALVE INCOMPETENCE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
HYPERTENSIVE HEART DISEASE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
INTRACARDIAC THROMBUS † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**1/13186 (0.01%)**
# events	**3**	**1**
ISCHAEMIC CARDIOMYOPATHY † 1		
# participants affected / at risk	**8/13166 (0.06%)**	**11/13186 (0.08%)**
# events	**8**	**11**
LEFT VENTRICULAR DYSFUNCTION † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**10/13186 (0.08%)**
# events	**2**	**10**
LEFT VENTRICULAR FAILURE † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
MITRAL VALVE INCOMPETENCE † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**4/13186 (0.03%)**
# events	**4**	**4**
MITRAL VALVE PROLAPSE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
† 1		

MITRAL VALVE STENOSIS		
# participants affected / at risk	**1/13166 (0.01%)**	**3/13186 (0.02%)**
# events	**1**	**3**
MYOCARDIAL RUPTURE † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**2**	**0**
MYOPERICARDITIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
NODAL ARRHYTHMIA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**2**
PALPITATIONS † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**7/13186 (0.05%)**
# events	**3**	**7**
PERICARDIAL EFFUSION † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**3/13186 (0.02%)**
# events	**4**	**3**
PERICARDIAL HAEMORRHAGE † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**8/13186 (0.06%)**
# events	**2**	**8**
PERICARDITIS † 1		
# participants affected / at risk	**9/13166 (0.07%)**	**3/13186 (0.02%)**
# events	**9**	**3**
PULSELESS ELECTRICAL ACTIVITY † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**3/13186 (0.02%)**
# events	**1**	**3**
SICK SINUS SYNDROME † 1		
# participants affected / at risk	**20/13166 (0.15%)**	**20/13186 (0.15%)**
# events	**20**	**22**
SINUS ARREST † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
SINUS ARRHYTHMIA † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**4/13186 (0.03%)**
# events	**4**	**4**
SINUS BRADYCARDIA † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**3/13186 (0.02%)**
# events	**4**	**3**
SINUS TACHYCARDIA † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**4/13186 (0.03%)**
# events	**4**	**4**
STRESS CARDIOMYOPATHY † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**2**
† 1		

SUPRAVENTRICULAR EXTRASYSTOLES		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
SUPRAVENTRICULAR TACHYCARDIA † 1		
# participants affected / at risk	**16/13166 (0.12%)**	**13/13186 (0.10%)**
# events	**20**	**14**
TACHYARRHYTHMIA † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**1/13186 (0.01%)**
# events	**2**	**1**
TACHYCARDIA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**2**
TORSADE DE POINTES † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
VENTRICULAR ARRHYTHMIA † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**3/13186 (0.02%)**
# events	**2**	**3**
VENTRICULAR ASYSTOLE † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
VENTRICULAR DYSFUNCTION † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
VENTRICULAR DYSSYNCHRONY † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
VENTRICULAR EXTRASYSTOLES † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**4/13186 (0.03%)**
# events	**5**	**4**
VENTRICULAR FIBRILLATION † 1		
# participants affected / at risk	**15/13166 (0.11%)**	**16/13186 (0.12%)**
# events	**16**	**16**
VENTRICULAR TACHYCARDIA † 1		
# participants affected / at risk	**37/13166 (0.28%)**	**37/13186 (0.28%)**
# events	**49**	**42**
Congenital, familial and genetic disorders		
ARTERIOVENOUS MALFORMATION † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
ATRIAL SEPTAL DEFECT † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
EPIDERMOLYSIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**

# events	1	0
GASTROINTESTINAL ANGIODYSPLASIA † 1		
# participants affected / at risk	0/13166 (0.00%)	2/13186 (0.02%)
# events	0	2
GASTROINTESTINAL ANGIODYSPLASIA HAEMORRHAGIC † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
GASTROINTESTINAL ARTERIOVENOUS MALFORMATION † 1		
# participants affected / at risk	1/13166 (0.01%)	1/13186 (0.01%)
# events	1	1
HAEMORRHAGIC ARTERIOVENOUS MALFORMATION † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
HIP DYSPLASIA † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
HYDROCELE † 1		
# participants affected / at risk	2/13166 (0.02%)	0/13186 (0.00%)
# events	2	0
PHIMOSIS † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
PORPHYRIA † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
PYLORIC STENOSIS † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
VENTRICULAR SEPTAL DEFECT † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
Ear and labyrinth disorders		
ACUTE VESTIBULAR SYNDROME † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
DEAFNESS † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
HYPOACUSIS † 1		
# participants affected / at risk	0/13166 (0.00%)	2/13186 (0.02%)
# events	0	2
MENIERE'S DISEASE † 1		
# participants affected / at risk	3/13166 (0.02%)	0/13186 (0.00%)
# events	3	0
SUDDEN HEARING LOSS † 1		

# participants affected / at risk	2/13166 (0.02%)	1/13186 (0.01%)
# events	2	1
VERTIGO † 1		
# participants affected / at risk	16/13166 (0.12%)	23/13186 (0.17%)
# events	17	24
VERTIGO POSITIONAL † 1		
# participants affected / at risk	5/13166 (0.04%)	3/13186 (0.02%)
# events	5	3
VESTIBULAR DISORDER † 1		
# participants affected / at risk	0/13166 (0.00%)	2/13186 (0.02%)
# events	0	2
Endocrine disorders		
ADDISON'S DISEASE † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
ADRENAL MASS † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
AUTOIMMUNE THYROIDITIS † 1		
# participants affected / at risk	1/13166 (0.01%)	1/13186 (0.01%)
# events	1	1
BASEDOW'S DISEASE † 1		
# participants affected / at risk	1/13166 (0.01%)	1/13186 (0.01%)
# events	1	1
GOITRE † 1		
# participants affected / at risk	5/13166 (0.04%)	1/13186 (0.01%)
# events	5	1
HYPERCALCAEMIA OF MALIGNANCY † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
HYPERPARATHYROIDISM † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
HYPERTHYROIDISM † 1		
# participants affected / at risk	3/13166 (0.02%)	4/13186 (0.03%)
# events	3	4
HYPOTHYROIDISM † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION † 1		
# participants affected / at risk	2/13166 (0.02%)	0/13186 (0.00%)
# events	2	0
Eye disorders		
AMAUROSIS † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)

# events	0	1
BLINDNESS UNILATERAL † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
CATARACT † 1		
# participants affected / at risk	15/13166 (0.11%)	10/13186 (0.08%)
# events	15	12
CONJUNCTIVAL HAEMORRHAGE † 1		
# participants affected / at risk	0/13166 (0.00%)	2/13186 (0.02%)
# events	0	2
CORNEAL OEDEMA † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
DIABETIC RETINOPATHY † 1		
# participants affected / at risk	2/13166 (0.02%)	2/13186 (0.02%)
# events	2	3
ENDOCRINE OPHTHALMOPATHY † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
EYE HAEMORRHAGE † 1		
# participants affected / at risk	5/13166 (0.04%)	3/13186 (0.02%)
# events	6	3
GLAUCOMA † 1		
# participants affected / at risk	3/13166 (0.02%)	1/13186 (0.01%)
# events	3	1
HYPHAEMA † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
LACRIMATION INCREASED † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
MACULAR DEGENERATION † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
MACULAR FIBROSIS † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
MACULAR HOLE † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
OCULAR HYPERTENSION † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
OPTIC ISCHAEMIC NEUROPATHY † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0

OPTIC NEUROPATHY † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
POSTERIOR CAPSULE OPACIFICATION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
RETINAL ARTERY THROMBOSIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
RETINAL DETACHMENT † 1		
# participants affected / at risk	**6/13166 (0.05%)**	**4/13186 (0.03%)**
# events	**6**	**4**
RETINAL VEIN OCCLUSION † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
RETINAL VEIN THROMBOSIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
ULCERATIVE KERATITIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
VISION BLURRED † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
VISUAL IMPAIRMENT † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
VITREOUS HAEMORRHAGE † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**2**	**0**
Gastrointestinal disorders		
ABDOMINAL ADHESIONS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**2**
ABDOMINAL COMPARTMENT SYNDROME † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
ABDOMINAL DISCOMFORT † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
ABDOMINAL HERNIA † 1		
# participants affected / at risk	**6/13166 (0.05%)**	**4/13186 (0.03%)**
# events	**6**	**4**
ABDOMINAL HERNIA OBSTRUCTIVE † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**

# events	0	1
ABDOMINAL MASS † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
ABDOMINAL PAIN † 1		
# participants affected / at risk	17/13166 (0.13%)	9/13186 (0.07%)
# events	18	9
ABDOMINAL PAIN LOWER † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
ABDOMINAL PAIN UPPER † 1		
# participants affected / at risk	9/13166 (0.07%)	10/13186 (0.08%)
# events	9	10
ABDOMINAL WALL HAEMORRHAGE † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
ACUTE ABDOMEN † 1		
# participants affected / at risk	2/13166 (0.02%)	0/13186 (0.00%)
# events	2	0
ANAL FISTULA † 1		
# participants affected / at risk	2/13166 (0.02%)	2/13186 (0.02%)
# events	2	2
ANAL HAEMORRHAGE † 1		
# participants affected / at risk	1/13166 (0.01%)	2/13186 (0.02%)
# events	2	2
ASCITES † 1		
# participants affected / at risk	2/13166 (0.02%)	1/13186 (0.01%)
# events	2	1
BARRETT'S OESOPHAGUS † 1		
# participants affected / at risk	2/13166 (0.02%)	1/13186 (0.01%)
# events	2	1
BUCCAL POLYP † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
COLITIS † 1		
# participants affected / at risk	7/13166 (0.05%)	9/13186 (0.07%)
# events	7	9
COLITIS EROSIVE † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
COLITIS ISCHAEMIC † 1		
# participants affected / at risk	8/13166 (0.06%)	8/13186 (0.06%)
# events	8	9
COLITIS ULCERATIVE † 1		
# participants affected / at risk	1/13166 (0.01%)	2/13186 (0.02%)

# events	1	2
COLONIC POLYP † 1		
# participants affected / at risk	6/13166 (0.05%)	14/13186 (0.11%)
# events	6	14
COLONIC PSEUDO-OBSTRUCTION † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
CONSTIPATION † 1		
# participants affected / at risk	10/13166 (0.08%)	11/13186 (0.08%)
# events	10	11
CROHN'S DISEASE † 1		
# participants affected / at risk	3/13166 (0.02%)	3/13186 (0.02%)
# events	3	3
DENTAL CARIES † 1		
# participants affected / at risk	1/13166 (0.01%)	1/13186 (0.01%)
# events	1	1
DENTAL NECROSIS † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
DIABETIC GASTROPARESIS † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
DIARRHOEA † 1		
# participants affected / at risk	4/13166 (0.03%)	7/13186 (0.05%)
# events	4	8
DIARRHOEA HAEMORRHAGIC † 1		
# participants affected / at risk	2/13166 (0.02%)	2/13186 (0.02%)
# events	2	2
DIVERTICULAR PERFORATION † 1		
# participants affected / at risk	2/13166 (0.02%)	0/13186 (0.00%)
# events	2	0
DIVERTICULITIS INTESTINAL HAEMORRHAGIC † 1		
# participants affected / at risk	1/13166 (0.01%)	1/13186 (0.01%)
# events	1	1
DIVERTICULUM † 1		
# participants affected / at risk	3/13166 (0.02%)	4/13186 (0.03%)
# events	3	4
DIVERTICULUM INTESTINAL † 1		
# participants affected / at risk	0/13166 (0.00%)	2/13186 (0.02%)
# events	0	2
DIVERTICULUM INTESTINAL HAEMORRHAGIC † 1		
# participants affected / at risk	0/13166 (0.00%)	3/13186 (0.02%)
# events	0	5
DIVERTICULUM OESOPHAGEAL † 1		
# participants affected / at risk	1/13166 (0.01%)	1/13186 (0.01%)
# events	1	1

DUODENAL PERFORATION † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**2**	**0**
DUODENAL ULCER † 1		
# participants affected / at risk	**5/13166 (0.04%)**	**8/13186 (0.06%)**
# events	**5**	**9**
DUODENAL ULCER HAEMORRHAGE † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**3/13186 (0.02%)**
# events	**3**	**3**
DUODENITIS † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**1/13186 (0.01%)**
# events	**2**	**1**
DYSPEPSIA † 1		
# participants affected / at risk	**5/13166 (0.04%)**	**10/13186 (0.08%)**
# events	**5**	**10**
DYSPHAGIA † 1		
# participants affected / at risk	**5/13166 (0.04%)**	**4/13186 (0.03%)**
# events	**5**	**4**
ENTERITIS † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**2/13186 (0.02%)**
# events	**4**	**2**
ENTEROCELE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
ENTEROCOLITIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
ENTEROCOLITIS HAEMORRHAGIC † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
ENTEROVESICAL FISTULA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
EPIGASTRIC DISCOMFORT † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
EPIPLOIC APPENDAGITIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
EROSIVE DUODENITIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
EROSIVE OESOPHAGITIS † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**4/13186 (0.03%)**
# events	**3**	**4**

FAECALOMA † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**2/13186 (0.02%)**
# events	**4**	**2**
FAECES DISCOLOURED † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
FEMORAL HERNIA, OBSTRUCTIVE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
FOOD POISONING † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
FUNCTIONAL GASTROINTESTINAL DISORDER † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
GASTRIC DISORDER † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
GASTRIC HAEMORRHAGE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**3/13186 (0.02%)**
# events	**2**	**3**
GASTRIC PERFORATION † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
GASTRIC ULCER † 1		
# participants affected / at risk	**6/13166 (0.05%)**	**11/13186 (0.08%)**
# events	**6**	**11**
GASTRIC ULCER HAEMORRHAGE † 1		
# participants affected / at risk	**5/13166 (0.04%)**	**6/13186 (0.05%)**
# events	**5**	**6**
GASTRIC ULCER PERFORATION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
GASTRIC VOLVULUS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
GASTRITIS † 1		
# participants affected / at risk	**29/13166 (0.22%)**	**26/13186 (0.20%)**
# events	**29**	**26**
GASTRITIS ALCOHOLIC † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
GASTRITIS ATROPHIC † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
† 1		

GASTRITIS EROSIVE		
# participants affected / at risk	**3/13166 (0.02%)**	**6/13186 (0.05%)**
# events	**3**	**7**
GASTRODUODENAL ULCER † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
GASTROINTESTINAL DISORDER † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
GASTROINTESTINAL HAEMORRHAGE † 1		
# participants affected / at risk	**38/13166 (0.29%)**	**62/13186 (0.47%)**
# events	**42**	**70**
GASTROINTESTINAL INFLAMMATION † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**2**	**0**
GASTROINTESTINAL NECROSIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**3/13186 (0.02%)**
# events	**0**	**3**
GASTROINTESTINAL OBSTRUCTION † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**1/13186 (0.01%)**
# events	**2**	**1**
GASTROINTESTINAL TELANGIECTASIA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
GASTROINTESTINAL ULCER HAEMORRHAGE † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**2**	**0**
GASTROOESOPHAGEAL REFLUX DISEASE † 1		
# participants affected / at risk	**31/13166 (0.24%)**	**23/13186 (0.17%)**
# events	**33**	**24**
GINGIVAL BLEEDING † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
HAEMATEMESIS † 1		
# participants affected / at risk	**19/13166 (0.14%)**	**28/13186 (0.21%)**
# events	**19**	**28**
HAEMATOCHEZIA † 1		
# participants affected / at risk	**21/13166 (0.16%)**	**16/13186 (0.12%)**
# events	**24**	**18**
HAEMORRHOIDAL HAEMORRHAGE † 1		
# participants affected / at risk	**5/13166 (0.04%)**	**7/13186 (0.05%)**
# events	**6**	**7**
HAEMORRHOIDS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**4/13186 (0.03%)**
# events	**1**	**4**
† 1		

HERNIAL EVENTRATION		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**2**	**0**
HIATUS HERNIA † 1		
# participants affected / at risk	**5/13166 (0.04%)**	**4/13186 (0.03%)**
# events	**5**	**4**
ILEAL STENOSIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
ILEUS † 1		
# participants affected / at risk	**5/13166 (0.04%)**	**8/13186 (0.06%)**
# events	**5**	**10**
IMPAIRED GASTRIC EMPTYING † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**2/13186 (0.02%)**
# events	**2**	**2**
INFLAMMATORY BOWEL DISEASE † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
INGUINAL HERNIA † 1		
# participants affected / at risk	**35/13166 (0.27%)**	**42/13186 (0.32%)**
# events	**35**	**44**
INGUINAL HERNIA STRANGULATED † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
INGUINAL HERNIA, OBSTRUCTIVE † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**4/13186 (0.03%)**
# events	**2**	**4**
INTESTINAL ISCHAEMIA † 1		
# participants affected / at risk	**8/13166 (0.06%)**	**3/13186 (0.02%)**
# events	**8**	**3**
INTESTINAL MASS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
INTESTINAL OBSTRUCTION † 1		
# participants affected / at risk	**9/13166 (0.07%)**	**13/13186 (0.10%)**
# events	**9**	**14**
INTESTINAL PERFORATION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**7/13186 (0.05%)**
# events	**1**	**7**
INTESTINAL POLYP † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**2**
INTESTINAL STRANGULATION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
† 1		

JEJUNAL PERFORATION		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
LARGE INTESTINAL HAEMORRHAGE † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
LARGE INTESTINAL OBSTRUCTION † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
LARGE INTESTINAL ULCER † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
LARGE INTESTINAL ULCER HAEMORRHAGE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
LARGE INTESTINE PERFORATION † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**4/13186 (0.03%)**
# events	**2**	**4**
LOWER GASTROINTESTINAL HAEMORRHAGE † 1		
# participants affected / at risk	**8/13166 (0.06%)**	**5/13186 (0.04%)**
# events	**8**	**5**
LUMBAR HERNIA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
MALABSORPTION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
MALLORY-WEISS SYNDROME † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**2/13186 (0.02%)**
# events	**2**	**2**
MECHANICAL ILEUS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
MELAENA † 1		
# participants affected / at risk	**44/13166 (0.33%)**	**69/13186 (0.52%)**
# events	**49**	**76**
MESENTERIC ARTERY STENOSIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
MESENTERIC ARTERY THROMBOSIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
MESENTERIC VASCULAR INSUFFICIENCY † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
† 1		

MOUTH CYST		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
NAUSEA † 1		
# participants affected / at risk	**5/13166 (0.04%)**	**8/13186 (0.06%)**
# events	**5**	**8**
OESOPHAGEAL ACHALASIA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
OESOPHAGEAL HAEMORRHAGE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
OESOPHAGEAL OBSTRUCTION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
OESOPHAGEAL RUPTURE † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
OESOPHAGEAL SPASM † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
OESOPHAGEAL STENOSIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
OESOPHAGEAL ULCER † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
OESOPHAGEAL ULCER HAEMORRHAGE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
OESOPHAGITIS † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**10/13186 (0.08%)**
# events	**4**	**11**
PANCREATIC CYST † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
PANCREATIC DISORDER † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
PANCREATITIS † 1		
# participants affected / at risk	**17/13166 (0.13%)**	**17/13186 (0.13%)**
# events	**21**	**18**
PANCREATITIS ACUTE † 1		
# participants affected / at risk	**11/13166 (0.08%)**	**9/13186 (0.07%)**
# events	**13**	**11**
† 1		

PANCREATITIS RELAPSING		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
PAPILLA OF VATER STENOSIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
PAROTID GLAND ENLARGEMENT † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
PEPTIC ULCER † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**5/13186 (0.04%)**
# events	**2**	**5**
PEPTIC ULCER HAEMORRHAGE † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
PERITONEAL HAEMORRHAGE † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
PHARYNGOESOPHAGEAL DIVERTICULUM † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
POLYP COLORECTAL † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
PROCTITIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
PROCTITIS HAEMORRHAGIC † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
PROCTITIS ULCERATIVE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
RECTAL HAEMORRHAGE † 1		
# participants affected / at risk	**37/13166 (0.28%)**	**53/13186 (0.40%)**
# events	**41**	**59**
RECTAL PROLAPSE † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
RECTAL ULCER † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
RETROPERITONEAL HAEMATOMA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
† 1		

RETROPERITONEAL HAEMORRHAGE		
# participants affected / at risk	**3/13166 (0.02%)**	**8/13186 (0.06%)**
# events	**3**	**8**
SALIVARY GLAND CALCULUS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
SMALL INTESTINAL HAEMORRHAGE † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**2/13186 (0.02%)**
# events	**2**	**2**
SMALL INTESTINAL OBSTRUCTION † 1		
# participants affected / at risk	**14/13166 (0.11%)**	**12/13186 (0.09%)**
# events	**18**	**12**
SMALL INTESTINAL PERFORATION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
SPIGELIAN HERNIA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
SPLENIC ARTERY ANEURYSM † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
SUBILEUS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
THROMBOSIS MESENTERIC VESSEL † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
TONGUE HAEMATOMA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
TONGUE OEDEMA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
UMBILICAL HERNIA † 1		
# participants affected / at risk	**10/13166 (0.08%)**	**6/13186 (0.05%)**
# events	**10**	**6**
UMBILICAL HERNIA, OBSTRUCTIVE † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**2/13186 (0.02%)**
# events	**2**	**2**
UPPER GASTROINTESTINAL HAEMORRHAGE † 1		
# participants affected / at risk	**17/13166 (0.13%)**	**15/13186 (0.11%)**
# events	**20**	**16**
VARICES OESOPHAGEAL † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
† 1		

VOMITING		
# participants affected / at risk	**4/13166 (0.03%)**	**1/13186 (0.01%)**
# events	**4**	**1**
General disorders		
ADVERSE DRUG REACTION † 1		
# participants affected / at risk	**12/13166 (0.09%)**	**16/13186 (0.12%)**
# events	**12**	**16**
APPLICATION SITE BLEEDING † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
ASTHENIA † 1		
# participants affected / at risk	**5/13166 (0.04%)**	**1/13186 (0.01%)**
# events	**5**	**1**
CATHETER SITE HAEMATOMA † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**8/13186 (0.06%)**
# events	**4**	**8**
CATHETER SITE HAEMORRHAGE † 1		
# participants affected / at risk	**5/13166 (0.04%)**	**5/13186 (0.04%)**
# events	**5**	**5**
CHEST DISCOMFORT † 1		
# participants affected / at risk	**10/13166 (0.08%)**	**6/13186 (0.05%)**
# events	**11**	**6**
CHEST PAIN † 1		
# participants affected / at risk	**14/13166 (0.11%)**	**15/13186 (0.11%)**
# events	**16**	**15**
CYST † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
CYST RUPTURE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
DEVICE BREAKAGE † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
DEVICE DISLOCATION † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**3/13186 (0.02%)**
# events	**3**	**4**
DEVICE FAILURE † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
DEVICE LEAD DAMAGE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**2**
DEVICE MALFUNCTION † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**7/13186 (0.05%)**

# events	3	7
DEVICE OCCLUSION † 1		
# participants affected / at risk	1/13166 (0.01%)	1/13186 (0.01%)
# events	1	1
DISCOMFORT † 1		
# participants affected / at risk	2/13166 (0.02%)	0/13186 (0.00%)
# events	2	0
DRUG INTERACTION † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
EXERCISE TOLERANCE DECREASED † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
FATIGUE † 1		
# participants affected / at risk	1/13166 (0.01%)	2/13186 (0.02%)
# events	1	2
GAIT DISTURBANCE † 1		
# participants affected / at risk	2/13166 (0.02%)	2/13186 (0.02%)
# events	2	2
GENERAL PHYSICAL HEALTH DETERIORATION † 1		
# participants affected / at risk	1/13166 (0.01%)	1/13186 (0.01%)
# events	1	1
GRAVITATIONAL OEDEMA † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
HERNIA † 1		
# participants affected / at risk	2/13166 (0.02%)	2/13186 (0.02%)
# events	2	3
HERNIA OBSTRUCTIVE † 1		
# participants affected / at risk	0/13166 (0.00%)	2/13186 (0.02%)
# events	0	2
HYPERPLASIA † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
HYPERTROPHY † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
HYPOTHERMIA † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
ILL-DEFINED DISORDER † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
IMPAIRED HEALING † 1		
# participants affected / at risk	5/13166 (0.04%)	6/13186 (0.05%)
# events	5	6

IMPLANT SITE EROSION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
IMPLANT SITE PAIN † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
INFLAMMATION † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**2**	**0**
MALAISE † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**0/13186 (0.00%)**
# events	**4**	**0**
MEDICAL DEVICE COMPLICATION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
MUCOSAL INFLAMMATION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
MULTI-ORGAN DISORDER † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
MULTI-ORGAN FAILURE † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**6/13186 (0.05%)**
# events	**4**	**6**
NECROSIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
NODULE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
NON-CARDIAC CHEST PAIN † 1		
# participants affected / at risk	**458/13166 (3.48%)**	**443/13186 (3.36%)**
# events	**548**	**519**
OEDEMA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
OEDEMA PERIPHERAL † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**4/13186 (0.03%)**
# events	**4**	**4**
PAIN † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
PERFORATED ULCER † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**2**	**0**

POLYP † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**3/13186 (0.02%)**
# events	**1**	**3**
POLYSEROSITIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
PYREXIA † 1		
# participants affected / at risk	**11/13166 (0.08%)**	**9/13186 (0.07%)**
# events	**12**	**9**
SYSTEMIC INFLAMMATORY RESPONSE SYNDROME † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**2**	**0**
THROMBOSIS IN DEVICE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
ULCER † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
ULCER HAEMORRHAGE † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**1/13186 (0.01%)**
# events	**2**	**1**
Hepatobiliary disorders		
BILE DUCT OBSTRUCTION † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
BILE DUCT STONE † 1		
# participants affected / at risk	**6/13166 (0.05%)**	**4/13186 (0.03%)**
# events	**6**	**4**
BILIARY COLIC † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**3/13186 (0.02%)**
# events	**2**	**3**
BILIARY DILATATION † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
BILIARY DYSKINESIA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
CHOLANGITIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**3/13186 (0.02%)**
# events	**1**	**3**
CHOLANGITIS ACUTE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
CHOLECYSTITIS † 1		
# participants affected / at risk	**26/13166 (0.20%)**	**31/13186 (0.24%)**

# events	26	32
CHOLECYSTITIS ACUTE † 1		
# participants affected / at risk	18/13166 (0.14%)	18/13186 (0.14%)
# events	19	18
CHOLECYSTITIS CHRONIC † 1		
# participants affected / at risk	1/13166 (0.01%)	3/13186 (0.02%)
# events	1	3
CHOLELITHIASIS † 1		
# participants affected / at risk	42/13166 (0.32%)	42/13186 (0.32%)
# events	42	43
CHOLESTASIS † 1		
# participants affected / at risk	2/13166 (0.02%)	0/13186 (0.00%)
# events	2	0
GALLBLADDER DISORDER † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
GALLBLADDER POLYP † 1		
# participants affected / at risk	1/13166 (0.01%)	1/13186 (0.01%)
# events	1	1
HEPATIC CIRRHOSIS † 1		
# participants affected / at risk	5/13166 (0.04%)	1/13186 (0.01%)
# events	5	1
HEPATIC FAILURE † 1		
# participants affected / at risk	1/13166 (0.01%)	3/13186 (0.02%)
# events	1	3
HEPATIC MASS † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
HEPATIC STEATOSIS † 1		
# participants affected / at risk	1/13166 (0.01%)	1/13186 (0.01%)
# events	1	1
HEPATITIS † 1		
# participants affected / at risk	1/13166 (0.01%)	1/13186 (0.01%)
# events	1	1
HEPATITIS ACUTE † 1		
# participants affected / at risk	1/13166 (0.01%)	1/13186 (0.01%)
# events	1	1
HEPATITIS TOXIC † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
HEPATORENAL SYNDROME † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
HEPATOTOXICITY † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0

ISCHAEMIC HEPATITIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
LIVER DISORDER † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
Immune system disorders		
ALLERGY TO ARTHROPOD STING † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
ANAPHYLACTIC REACTION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**2**
ANAPHYLACTIC SHOCK † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**1/13186 (0.01%)**
# events	**2**	**1**
DRUG HYPERSENSITIVITY † 1		
# participants affected / at risk	**10/13166 (0.08%)**	**4/13186 (0.03%)**
# events	**10**	**4**
FOOD ALLERGY † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
HYPERSENSITIVITY † 1		
# participants affected / at risk	**6/13166 (0.05%)**	**1/13186 (0.01%)**
# events	**6**	**1**
HYPOGAMMAGLOBULINAEMIA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
Infections and infestations		
ABDOMINAL ABSCESS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**2**
ABDOMINAL WALL ABSCESS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
ABSCESS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
ABSCESS INTESTINAL † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
ABSCESS LIMB † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**7/13186 (0.05%)**
# events	**4**	**7**
† 1		

ABSCESS ORAL		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
ANAL ABSCESS † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**6/13186 (0.05%)**
# events	**4**	**7**
APPENDICEAL ABSCESS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
APPENDICITIS † 1		
# participants affected / at risk	**23/13166 (0.17%)**	**20/13186 (0.15%)**
# events	**23**	**20**
ARTERIOVENOUS FISTULA SITE INFECTION † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
ARTERIOVENOUS GRAFT SITE ABSCESS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
ARTERIOVENOUS GRAFT SITE INFECTION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
ARTHRITIS BACTERIAL † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**2/13186 (0.02%)**
# events	**2**	**2**
ARTHRITIS INFECTIVE † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**2**	**0**
ASPERGILLOMA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
BACTERAEMIA † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**3/13186 (0.02%)**
# events	**2**	**3**
BACTERIAL INFECTION † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**3/13186 (0.02%)**
# events	**0**	**3**
BACTERIAL PROSTATITIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
BILIARY SEPSIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
BLASTOCYSTIS INFECTION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
† 1		

BORRELIA INFECTION		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
BRONCHIOLITIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
BRONCHITIS † 1		
# participants affected / at risk	**29/13166 (0.22%)**	**27/13186 (0.20%)**
# events	**29**	**27**
BRONCHITIS BACTERIAL † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**1/13186 (0.01%)**
# events	**2**	**1**
BRONCHOPNEUMONIA † 1		
# participants affected / at risk	**10/13166 (0.08%)**	**12/13186 (0.09%)**
# events	**10**	**12**
BURSITIS INFECTIVE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**2**
CAMPYLOBACTER GASTROENTERITIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**2**
CAMPYLOBACTER INTESTINAL INFECTION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
CARDIAC INFECTION † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
CELLULITIS † 1		
# participants affected / at risk	**38/13166 (0.29%)**	**42/13186 (0.32%)**
# events	**41**	**45**
CELLULITIS OF MALE EXTERNAL GENITAL ORGAN † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
CENTRAL NERVOUS SYSTEM INFECTION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
CHOLECYSTITIS INFECTIVE † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**2/13186 (0.02%)**
# events	**2**	**2**
CHRONIC SINUSITIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**2**
CLOSTRIDIAL INFECTION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
† 1		

CLOSTRIDIUM COLITIS		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
CLOSTRIDIUM DIFFICILE COLITIS † 1		
# participants affected / at risk	**16/13166 (0.12%)**	**4/13186 (0.03%)**
# events	**18**	**4**
COCCIDIOIDOMYCOSIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
CYSTITIS † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**7/13186 (0.05%)**
# events	**2**	**7**
CYTOMEGALOVIRUS INFECTION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
DENGUE FEVER † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
DEVICE RELATED INFECTION † 1		
# participants affected / at risk	**7/13166 (0.05%)**	**5/13186 (0.04%)**
# events	**9**	**5**
DEVICE RELATED SEPSIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**2**	**0**
DIABETIC FOOT INFECTION † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**3/13186 (0.02%)**
# events	**5**	**3**
DIABETIC GANGRENE † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
DISSEMINATED TUBERCULOSIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
DIVERTICULITIS † 1		
# participants affected / at risk	**20/13166 (0.15%)**	**16/13186 (0.12%)**
# events	**21**	**17**
DYSENTERY † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
EAR INFECTION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
ECZEMA INFECTED † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
† 1		

EMPYEMA		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
ENCEPHALITIS HERPES † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
ENDOCARDITIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**2**
ENDOPHTHALMITIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
ENTERITIS INFECTIOUS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
ENTEROBACTER INFECTION † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
ENTEROCOLITIS INFECTIOUS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
EPIDEMIC NEPHROPATHY † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
EPIGLOTTITIS † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**2**	**0**
ERYSIPELAS † 1		
# participants affected / at risk	**18/13166 (0.14%)**	**14/13186 (0.11%)**
# events	**19**	**15**
ESCHERICHIA BACTERAEMIA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
ESCHERICHIA INFECTION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
ESCHERICHIA SEPSIS † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**2/13186 (0.02%)**
# events	**3**	**2**
ESCHERICHIA URINARY TRACT INFECTION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
EYE ABSCESS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
† 1		

FUNGAEMIA		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
GANGRENE † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**1/13186 (0.01%)**
# events	**3**	**1**
GASTRIC INFECTION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
GASTROENTERITIS † 1		
# participants affected / at risk	**37/13166 (0.28%)**	**36/13186 (0.27%)**
# events	**39**	**37**
GASTROENTERITIS ESCHERICHIA COLI † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
GASTROENTERITIS NOROVIRUS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
GASTROENTERITIS VIRAL † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**2/13186 (0.02%)**
# events	**4**	**2**
GASTROINTESTINAL BACTERIAL INFECTION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
GASTROINTESTINAL VIRAL INFECTION † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
GINGIVAL ABSCESS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
GRAFT INFECTION † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**5/13186 (0.04%)**
# events	**3**	**5**
GROIN ABSCESS † 1		
# participants affected / at risk	**7/13166 (0.05%)**	**4/13186 (0.03%)**
# events	**7**	**4**
GROIN INFECTION † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**2**	**0**
H1N1 INFLUENZA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**3/13186 (0.02%)**
# events	**1**	**3**
HAEMATOMA INFECTION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
† 1		

HELICOBACTER INFECTION		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
HEPATITIS B † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**3**	**0**
HEPATITIS C † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**1/13186 (0.01%)**
# events	**2**	**1**
HERPES SIMPLEX † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**2**	**0**
HERPES ZOSTER † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**3/13186 (0.02%)**
# events	**4**	**3**
HISTOPLASMOSIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
HIV INFECTION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
IMPLANT SITE INFECTION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
INCISION SITE INFECTION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
INFECTED BITES † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
INFECTED DERMAL CYST † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
INFECTED SKIN ULCER † 1		
# participants affected / at risk	**9/13166 (0.07%)**	**9/13186 (0.07%)**
# events	**9**	**9**
INFECTION † 1		
# participants affected / at risk	**5/13166 (0.04%)**	**7/13186 (0.05%)**
# events	**5**	**7**
INFECTIOUS PERITONITIS † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**1/13186 (0.01%)**
# events	**4**	**1**
INFECTIOUS PLEURAL EFFUSION † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
† 1		

INFECTIVE EXACERBATION OF CHRONIC OBSTRUCTIVE AIRWAYS DISEASE		
# participants affected / at risk	**5/13166 (0.04%)**	**0/13186 (0.00%)**
# events	**5**	**0**
INFLUENZA † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**1/13186 (0.01%)**
# events	**4**	**1**
INFUSION SITE INFECTION † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
LABYRINTHITIS † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**4/13186 (0.03%)**
# events	**2**	**4**
LIVER ABSCESS † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**1/13186 (0.01%)**
# events	**3**	**1**
LOBAR PNEUMONIA † 1		
# participants affected / at risk	**20/13166 (0.15%)**	**23/13186 (0.17%)**
# events	**20**	**23**
LOCALISED INFECTION † 1		
# participants affected / at risk	**9/13166 (0.07%)**	**6/13186 (0.05%)**
# events	**9**	**8**
LOWER RESPIRATORY TRACT INFECTION † 1		
# participants affected / at risk	**8/13166 (0.06%)**	**6/13186 (0.05%)**
# events	**9**	**6**
LOWER RESPIRATORY TRACT INFECTION VIRAL † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
LUNG ABSCESS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
LUNG INFECTION † 1		
# participants affected / at risk	**6/13166 (0.05%)**	**3/13186 (0.02%)**
# events	**6**	**3**
LYME DISEASE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
LYMPHANGITIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
MASTOIDITIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
MEDIASTINITIS † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**1/13186 (0.01%)**
# events	**2**	**1**
† 1		

MENINGITIS		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
MENINGITIS ASEPTIC † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
MENINGITIS BACTERIAL † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
MENINGITIS VIRAL † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
MYCOBACTERIUM AVIUM COMPLEX INFECTION † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
NECROTISING FASCIITIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
OESOPHAGEAL CANDIDIASIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
ONYCHOMYCOSIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
ORAL CANDIDIASIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
ORAL INFECTION † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
ORCHITIS † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**4/13186 (0.03%)**
# events	**3**	**4**
OSTEOMYELITIS † 1		
# participants affected / at risk	**17/13166 (0.13%)**	**14/13186 (0.11%)**
# events	**19**	**16**
OSTEOMYELITIS CHRONIC † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
OTITIS EXTERNA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
OTITIS MEDIA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
† 1		

OTITIS MEDIA CHRONIC		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
PAROTITIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
PERICARDITIS INFECTIVE † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**2**
PERIDIVERTICULAR ABSCESS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
PERINEAL ABSCESS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
PERINEPHRIC ABSCESS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
PERIORBITAL CELLULITIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
PERIRECTAL ABSCESS † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**1/13186 (0.01%)**
# events	**2**	**1**
PERITONSILLAR ABSCESS † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**2**	**0**
PHARYNGITIS BACTERIAL † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
PILONIDAL CYST † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
PNEUMOCYSTIS JIROVECI PNEUMONIA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
PNEUMONIA † 1		
# participants affected / at risk	**186/13166 (1.41%)**	**167/13186 (1.27%)**
# events	**205**	**185**
PNEUMONIA BACTERIAL † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**2/13186 (0.02%)**
# events	**3**	**2**
PNEUMONIA ESCHERICHIA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
† 1		

PNEUMONIA FUNGAL		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
PNEUMONIA MYCOPLASMAL † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
PNEUMONIA PNEUMOCOCCAL † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**2**
PNEUMONIA STAPHYLOCOCCAL † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**3/13186 (0.02%)**
# events	**2**	**3**
PNEUMONIA VIRAL † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
POST PROCEDURAL CELLULITIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
POST PROCEDURAL INFECTION † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**4/13186 (0.03%)**
# events	**4**	**4**
POST PROCEDURAL SEPSIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
POSTOPERATIVE ABSCESS † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**2**	**0**
POSTOPERATIVE WOUND INFECTION † 1		
# participants affected / at risk	**21/13166 (0.16%)**	**10/13186 (0.08%)**
# events	**24**	**10**
PSEUDOMEMBRANOUS COLITIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
PSOAS ABSCESS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
PULMONARY SEPSIS † 1		
# participants affected / at risk	**12/13166 (0.09%)**	**18/13186 (0.14%)**
# events	**13**	**18**
PULMONARY TUBERCULOSIS † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**2**	**0**
PYELONEPHRITIS † 1		
# participants affected / at risk	**11/13166 (0.08%)**	**10/13186 (0.08%)**
# events	**11**	**10**
† 1		

PYELONEPHRITIS ACUTE		
# participants affected / at risk	**1/13166 (0.01%)**	**3/13186 (0.02%)**
# events	**1**	**3**
RECTAL ABSCESS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
RESPIRATORY TRACT INFECTION † 1		
# participants affected / at risk	**8/13166 (0.06%)**	**6/13186 (0.05%)**
# events	**9**	**6**
RESPIRATORY TRACT INFECTION VIRAL † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
SALMONELLA SEPSIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
SALMONELLOSIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
SCROTAL ABSCESS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
SEPSIS † 1		
# participants affected / at risk	**34/13166 (0.26%)**	**28/13186 (0.21%)**
# events	**34**	**29**
SEPTIC NECROSIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
SEPTIC SHOCK † 1		
# participants affected / at risk	**22/13166 (0.17%)**	**13/13186 (0.10%)**
# events	**22**	**13**
SERRATIA INFECTION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
SIALOADENITIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
SINUSITIS † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**3/13186 (0.02%)**
# events	**3**	**3**
SINUSITIS BACTERIAL † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
SKIN INFECTION † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**1/13186 (0.01%)**
# events	**2**	**1**
† 1		

SOFT TISSUE INFECTION		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
STAPHYLOCOCCAL ABSCESS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
STAPHYLOCOCCAL BACTERAEMIA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
STAPHYLOCOCCAL INFECTION † 1		
# participants affected / at risk	**9/13166 (0.07%)**	**4/13186 (0.03%)**
# events	**9**	**4**
STAPHYLOCOCCAL SEPSIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**2**	**0**
SUBCUTANEOUS ABSCESS † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**2/13186 (0.02%)**
# events	**4**	**2**
SUPERINFECTION † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
SYPHILIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
SYSTEMIC CANDIDA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
TONSILLITIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
TOOTH ABSCESS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**2**
TUBERCULOSIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
TYPHUS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
UPPER RESPIRATORY TRACT INFECTION † 1		
# participants affected / at risk	**9/13166 (0.07%)**	**4/13186 (0.03%)**
# events	**9**	**4**
URINARY TRACT INFECTION † 1		
# participants affected / at risk	**50/13166 (0.38%)**	**62/13186 (0.47%)**
# events	**53**	**67**
† 1		

URINARY TRACT INFECTION BACTERIAL		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
URINARY TRACT INFECTION PSEUDOMONAL † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
URINARY TRACT INFECTION STAPHYLOCOCCAL † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
UROSEPSIS † 1		
# participants affected / at risk	**10/13166 (0.08%)**	**27/13186 (0.20%)**
# events	**10**	**27**
VAGINAL INFECTION † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**2**	**0**
VARICELLA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
VESTIBULAR NEURONITIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**2**
VIRAL INFECTION † 1		
# participants affected / at risk	**8/13166 (0.06%)**	**11/13186 (0.08%)**
# events	**8**	**11**
VIRAL LABYRINTHITIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
VIRAL MYOCARDITIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
VIRAL UPPER RESPIRATORY TRACT INFECTION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
WOUND ABSCESS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
WOUND INFECTION † 1		
# participants affected / at risk	**6/13166 (0.05%)**	**11/13186 (0.08%)**
# events	**6**	**11**
WOUND INFECTION PSEUDOMONAS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
WOUND INFECTION STAPHYLOCOCCAL † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
† 1		

WOUND SEPSIS		
# participants affected / at risk	**2/13166 (0.02%)**	**1/13186 (0.01%)**
# events	**2**	**1**
Injury, poisoning and procedural complications		
ABDOMINAL WOUND DEHISCENCE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
ACCIDENT † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**2**	**0**
ACCIDENTAL OVERDOSE † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**2**	**0**
ACETABULUM FRACTURE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
ALCOHOL POISONING † 1		
# participants affected / at risk	**8/13166 (0.06%)**	**8/13186 (0.06%)**
# events	**8**	**8**
ANAEMIA POSTOPERATIVE † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**3/13186 (0.02%)**
# events	**2**	**3**
ANASTOMOTIC COMPLICATION † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
ANASTOMOTIC STENOSIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**2**
ANKLE FRACTURE † 1		
# participants affected / at risk	**15/13166 (0.11%)**	**17/13186 (0.13%)**
# events	**16**	**18**
ARTERIAL INJURY † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
ARTHROPOD BITE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
ARTHROPOD STING † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
BRAIN CONTUSION † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
BURNS THIRD DEGREE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**

# events	1	0
CARBON MONOXIDE POISONING † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	2
CARDIAC FUNCTION DISTURBANCE POSTOPERATIVE † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
CARTILAGE INJURY † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
CERVICAL VERTEBRAL FRACTURE † 1		
# participants affected / at risk	3/13166 (0.02%)	3/13186 (0.02%)
# events	3	3
CHEMICAL EYE INJURY † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
CHEST INJURY † 1		
# participants affected / at risk	0/13166 (0.00%)	2/13186 (0.02%)
# events	0	2
CLAVICLE FRACTURE † 1		
# participants affected / at risk	2/13166 (0.02%)	4/13186 (0.03%)
# events	2	4
CONCUSSION † 1		
# participants affected / at risk	7/13166 (0.05%)	4/13186 (0.03%)
# events	8	4
CONFUSION POSTOPERATIVE † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
CONTUSION † 1		
# participants affected / at risk	11/13166 (0.08%)	7/13186 (0.05%)
# events	14	7
CRANIOCEREBRAL INJURY † 1		
# participants affected / at risk	2/13166 (0.02%)	1/13186 (0.01%)
# events	2	1
CYSTITIS RADIATION † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
EAR INJURY † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
ELECTRIC SHOCK † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
EXCORIATION † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0

EXTRADURAL HAEMATOMA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
FACE INJURY † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
FACIAL BONES FRACTURE † 1		
# participants affected / at risk	**10/13166 (0.08%)**	**1/13186 (0.01%)**
# events	**10**	**1**
FALL † 1		
# participants affected / at risk	**10/13166 (0.08%)**	**11/13186 (0.08%)**
# events	**10**	**11**
FEBRILE NONHAEMOLYTIC TRANSFUSION REACTION † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
FEMORAL NECK FRACTURE † 1		
# participants affected / at risk	**6/13166 (0.05%)**	**4/13186 (0.03%)**
# events	**6**	**4**
FEMUR FRACTURE † 1		
# participants affected / at risk	**22/13166 (0.17%)**	**16/13186 (0.12%)**
# events	**23**	**16**
FIBULA FRACTURE † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**1/13186 (0.01%)**
# events	**3**	**1**
FLAIL CHEST † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
FOOT FRACTURE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**2**
FOREARM FRACTURE † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**3**	**0**
FOREIGN BODY † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**1/13186 (0.01%)**
# events	**2**	**1**
FRACTURE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
GASTROINTESTINAL STOMA COMPLICATION † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
GUN SHOT WOUND † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**4/13186 (0.03%)**
# events	**0**	**4**

HAND FRACTURE † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**2/13186 (0.02%)**
# events	**3**	**2**
HEAD INJURY † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**8/13186 (0.06%)**
# events	**3**	**8**
HEAT EXHAUSTION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
HEAT STROKE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
HIP FRACTURE † 1		
# participants affected / at risk	**19/13166 (0.14%)**	**16/13186 (0.12%)**
# events	**19**	**16**
HUMERUS FRACTURE † 1		
# participants affected / at risk	**9/13166 (0.07%)**	**9/13186 (0.07%)**
# events	**9**	**10**
INCISION SITE HAEMORRHAGE † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
INCISION SITE PAIN † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
INCISIONAL HERNIA † 1		
# participants affected / at risk	**9/13166 (0.07%)**	**7/13186 (0.05%)**
# events	**9**	**7**
INJURY † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
INTERVERTEBRAL DISC INJURY † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
JAW FRACTURE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
JOINT DISLOCATION † 1		
# participants affected / at risk	**9/13166 (0.07%)**	**9/13186 (0.07%)**
# events	**10**	**9**
JOINT INJURY † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**3/13186 (0.02%)**
# events	**1**	**3**
LACERATION † 1		
# participants affected / at risk	**10/13166 (0.08%)**	**6/13186 (0.05%)**
# events	**11**	**6**
† 1		

LIGAMENT RUPTURE		
# participants affected / at risk	**3/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**3**	**0**
LIMB INJURY † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**5/13186 (0.04%)**
# events	**1**	**5**
LIMB TRAUMATIC AMPUTATION † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**1/13186 (0.01%)**
# events	**2**	**1**
LOWER LIMB FRACTURE † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**6/13186 (0.05%)**
# events	**2**	**6**
LUMBAR VERTEBRAL FRACTURE † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
MENISCUS LESION † 1		
# participants affected / at risk	**8/13166 (0.06%)**	**4/13186 (0.03%)**
# events	**8**	**4**
MULTIPLE DRUG OVERDOSE † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**2**	**0**
MULTIPLE FRACTURES † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**2/13186 (0.02%)**
# events	**2**	**2**
MULTIPLE INJURIES † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**6/13186 (0.05%)**
# events	**3**	**7**
MUSCLE RUPTURE † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**3/13186 (0.02%)**
# events	**4**	**3**
MUSCLE STRAIN † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
NERVE INJURY † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
OPEN FRACTURE † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
OPEN WOUND † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
OPERATIVE HAEMORRHAGE † 1		
# participants affected / at risk	**19/13166 (0.14%)**	**23/13186 (0.17%)**
# events	**20**	**23**
† 1		

OVERDOSE		
# participants affected / at risk	**4/13166 (0.03%)**	**7/13186 (0.05%)**
# events	**4**	**7**
PATELLA FRACTURE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
PELVIC FRACTURE † 1		
# participants affected / at risk	**5/13166 (0.04%)**	**3/13186 (0.02%)**
# events	**5**	**3**
PERIPROSTHETIC FRACTURE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
POISONING † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
POST PROCEDURAL COMPLICATION † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**4/13186 (0.03%)**
# events	**2**	**4**
POST PROCEDURAL DISCHARGE † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
POST PROCEDURAL HAEMATOMA † 1		
# participants affected / at risk	**5/13166 (0.04%)**	**2/13186 (0.02%)**
# events	**5**	**2**
POST PROCEDURAL HAEMORRHAGE † 1		
# participants affected / at risk	**23/13166 (0.17%)**	**39/13186 (0.30%)**
# events	**24**	**40**
POSTOPERATIVE ADHESION † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
POSTOPERATIVE FEVER † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**3**	**0**
POSTOPERATIVE ILEUS † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**5/13186 (0.04%)**
# events	**2**	**6**
POSTOPERATIVE RESPIRATORY DISTRESS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
POSTOPERATIVE THORACIC PROCEDURE COMPLICATION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**2**
POSTPERICARDIOTOMY SYNDROME † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
† 1		

PROCEDURAL HYPOTENSION		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
PROCEDURAL PAIN † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**3/13186 (0.02%)**
# events	**2**	**3**
PUBIS FRACTURE † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**1/13186 (0.01%)**
# events	**3**	**1**
RADIATION ASSOCIATED PAIN † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
RADIATION INJURY † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
RADIATION OESOPHAGITIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
RADIUS FRACTURE † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**3/13186 (0.02%)**
# events	**2**	**3**
RIB FRACTURE † 1		
# participants affected / at risk	**7/13166 (0.05%)**	**12/13186 (0.09%)**
# events	**7**	**12**
ROAD TRAFFIC ACCIDENT † 1		
# participants affected / at risk	**16/13166 (0.12%)**	**13/13186 (0.10%)**
# events	**16**	**13**
SCAPULA FRACTURE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
SEROMA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
SKIN FLAP NECROSIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
SKULL FRACTURE † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
SNAKE BITE † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
SOFT TISSUE INJURY † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
† 1		

SPINAL COLUMN INJURY		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
SPINAL COMPRESSION FRACTURE † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**5/13186 (0.04%)**
# events	**3**	**6**
SPINAL FRACTURE † 1		
# participants affected / at risk	**6/13166 (0.05%)**	**2/13186 (0.02%)**
# events	**6**	**2**
SPLENIC RUPTURE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
STAB WOUND † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
STERNAL FRACTURE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**2**
STRUCK BY LIGHTNING † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
SUBDURAL HAEMATOMA † 1		
# participants affected / at risk	**11/13166 (0.08%)**	**14/13186 (0.11%)**
# events	**12**	**14**
SUBDURAL HAEMORRHAGE † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
TENDON RUPTURE † 1		
# participants affected / at risk	**5/13166 (0.04%)**	**11/13186 (0.08%)**
# events	**5**	**11**
THERMAL BURN † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
THORACIC VERTEBRAL FRACTURE † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**2/13186 (0.02%)**
# events	**2**	**2**
TIBIA FRACTURE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**6/13186 (0.05%)**
# events	**1**	**6**
TOXICITY TO VARIOUS AGENTS † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**4/13186 (0.03%)**
# events	**2**	**4**
TRANSFUSION-RELATED ACUTE LUNG INJURY † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
† 1		

TRAUMATIC ARTHRITIS		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
TRAUMATIC HAEMATOMA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
TRAUMATIC HAEMORRHAGE † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
TRAUMATIC INTRACRANIAL HAEMORRHAGE † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
TRAUMATIC LIVER INJURY † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
ULNA FRACTURE † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**2**	**0**
UPPER LIMB FRACTURE † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**5/13186 (0.04%)**
# events	**2**	**5**
VACCINATION COMPLICATION † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
VASCULAR INJURY † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
VASCULAR PSEUDOANEURYSM † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**5/13186 (0.04%)**
# events	**3**	**5**
WOUND † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**4/13186 (0.03%)**
# events	**0**	**4**
WOUND DEHISCENCE † 1		
# participants affected / at risk	**6/13166 (0.05%)**	**0/13186 (0.00%)**
# events	**6**	**0**
WOUND EVISCERATION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
WOUND HAEMORRHAGE † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
WOUND NECROSIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
† 1		

WRIST FRACTURE		
# participants affected / at risk	**1/13166 (0.01%)**	**4/13186 (0.03%)**
# events	**1**	**4**
Investigations		
ALANINE AMINOTRANSFERASE INCREASED † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**1/13186 (0.01%)**
# events	**2**	**1**
ASPARTATE AMINOTRANSFERASE INCREASED † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**2/13186 (0.02%)**
# events	**2**	**2**
BLOOD CREATINE PHOSPHOKINASE INCREASED † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**3/13186 (0.02%)**
# events	**1**	**3**
BLOOD GLUCOSE DECREASED † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
BLOOD TRIGLYCERIDES INCREASED † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
CARDIAC STRESS TEST ABNORMAL † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
CLOSTRIDIUM TEST POSITIVE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
EJECTION FRACTION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
EJECTION FRACTION ABNORMAL † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
EJECTION FRACTION DECREASED † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
EXERCISE ELECTROCARDIOGRAM ABNORMAL † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
EXERCISE TEST ABNORMAL † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
HAEMATOCRIT DECREASED † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
HAEMOGLOBIN DECREASED † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**

# events	1	2
HEPATIC ENZYME ABNORMAL † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
HEPATIC ENZYME INCREASED † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
HIV TEST POSITIVE † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
INTERNATIONAL NORMALISED RATIO INCREASED † 1		
# participants affected / at risk	2/13166 (0.02%)	1/13186 (0.01%)
# events	2	1
OCCULT BLOOD † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
OCCULT BLOOD POSITIVE † 1		
# participants affected / at risk	3/13166 (0.02%)	1/13186 (0.01%)
# events	3	1
PLATELET COUNT ABNORMAL † 1		
# participants affected / at risk	2/13166 (0.02%)	0/13186 (0.00%)
# events	2	0
PLATELET COUNT DECREASED † 1		
# participants affected / at risk	7/13166 (0.05%)	4/13186 (0.03%)
# events	7	4
PRECANCEROUS CELLS PRESENT † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
PROTEIN URINE PRESENT † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
PULMONARY FUNCTION TEST DECREASED † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
RED BLOOD CELL COUNT DECREASED † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
RED BLOOD CELLS URINE POSITIVE † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
TRANSAMINASES INCREASED † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
WEIGHT DECREASED † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1

WHITE BLOOD CELL COUNT DECREASED † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
WHITE BLOOD CELL COUNT INCREASED † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
Metabolism and nutrition disorders		
DEHYDRATION † 1		
# participants affected / at risk	**33/13166 (0.25%)**	**28/13186 (0.21%)**
# events	**34**	**28**
DIABETES MELLITUS † 1		
# participants affected / at risk	**12/13166 (0.09%)**	**22/13186 (0.17%)**
# events	**12**	**23**
DIABETES MELLITUS INADEQUATE CONTROL † 1		
# participants affected / at risk	**12/13166 (0.09%)**	**16/13186 (0.12%)**
# events	**13**	**17**
DIABETIC COMPLICATION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**2**
DIABETIC FOOT † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**3/13186 (0.02%)**
# events	**3**	**4**
DIABETIC KETOACIDOSIS † 1		
# participants affected / at risk	**5/13166 (0.04%)**	**9/13186 (0.07%)**
# events	**6**	**10**
ELECTROLYTE IMBALANCE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
FAILURE TO THRIVE † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**4/13186 (0.03%)**
# events	**3**	**4**
FLUID OVERLOAD † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**3/13186 (0.02%)**
# events	**1**	**4**
GOUT † 1		
# participants affected / at risk	**5/13166 (0.04%)**	**10/13186 (0.08%)**
# events	**5**	**11**
HAEMOSIDEROSIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
HYPERGLYCAEMIA † 1		
# participants affected / at risk	**19/13166 (0.14%)**	**18/13186 (0.14%)**
# events	**19**	**19**
HYPERKALAEMIA † 1		
# participants affected / at risk	**10/13166 (0.08%)**	**7/13186 (0.05%)**

# events	10	7
HYPERVOLAEMIA † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
HYPOGLYCAEMIA † 1		
# participants affected / at risk	17/13166 (0.13%)	23/13186 (0.17%)
# events	18	26
HYPOKALAEMIA † 1		
# participants affected / at risk	4/13166 (0.03%)	2/13186 (0.02%)
# events	4	2
HYPONATRAEMIA † 1		
# participants affected / at risk	9/13166 (0.07%)	6/13186 (0.05%)
# events	9	6
HYPOPHAGIA † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
HYPOVOLAEMIA † 1		
# participants affected / at risk	3/13166 (0.02%)	2/13186 (0.02%)
# events	3	2
IRON METABOLISM DISORDER † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
MALNUTRITION † 1		
# participants affected / at risk	0/13166 (0.00%)	2/13186 (0.02%)
# events	0	2
METABOLIC ACIDOSIS † 1		
# participants affected / at risk	2/13166 (0.02%)	1/13186 (0.01%)
# events	2	1
OBESITY † 1		
# participants affected / at risk	3/13166 (0.02%)	3/13186 (0.02%)
# events	3	3
TYPE 1 DIABETES MELLITUS † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
TYPE 2 DIABETES MELLITUS † 1		
# participants affected / at risk	5/13166 (0.04%)	7/13186 (0.05%)
# events	5	7
VITAMIN B12 DEFICIENCY † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
Musculoskeletal and connective tissue disorders		
ARTHRALGIA † 1		
# participants affected / at risk	2/13166 (0.02%)	7/13186 (0.05%)
# events	2	7
ARTHRITIS † 1		

# participants affected / at risk	20/13166 (0.15%)	16/13186 (0.12%)
# events	23	16
ARTHROFIBROSIS † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
ARTHROPATHY † 1		
# participants affected / at risk	4/13166 (0.03%)	2/13186 (0.02%)
# events	4	2
BACK PAIN † 1		
# participants affected / at risk	16/13166 (0.12%)	11/13186 (0.08%)
# events	18	11
BONE CYST † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
BONE FISTULA † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
BONE PAIN † 1		
# participants affected / at risk	1/13166 (0.01%)	2/13186 (0.02%)
# events	1	2
BURSITIS † 1		
# participants affected / at risk	7/13166 (0.05%)	2/13186 (0.02%)
# events	7	2
CERVICAL SPINAL STENOSIS † 1		
# participants affected / at risk	6/13166 (0.05%)	4/13186 (0.03%)
# events	6	4
CHONDROMALACIA † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
COMPARTMENT SYNDROME † 1		
# participants affected / at risk	6/13166 (0.05%)	4/13186 (0.03%)
# events	6	4
COSTOCHONDRITIS † 1		
# participants affected / at risk	6/13166 (0.05%)	2/13186 (0.02%)
# events	6	2
DUPUYTREN'S CONTRACTURE † 1		
# participants affected / at risk	1/13166 (0.01%)	3/13186 (0.02%)
# events	1	3
EXOSTOSIS † 1		
# participants affected / at risk	0/13166 (0.00%)	2/13186 (0.02%)
# events	0	2
FIBROMYALGIA † 1		
# participants affected / at risk	2/13166 (0.02%)	0/13186 (0.00%)
# events	2	0
FLANK PAIN † 1		
# participants affected / at risk	3/13166 (0.02%)	1/13186 (0.01%)

# events	4	1
FOOT DEFORMITY † 1		
# participants affected / at risk	1/13166 (0.01%)	2/13186 (0.02%)
# events	1	2
FRACTURE NONUNION † 1		
# participants affected / at risk	3/13166 (0.02%)	0/13186 (0.00%)
# events	3	0
GOUTY ARTHRITIS † 1		
# participants affected / at risk	4/13166 (0.03%)	2/13186 (0.02%)
# events	4	2
GROIN PAIN † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
HAEMARTHROSIS † 1		
# participants affected / at risk	1/13166 (0.01%)	1/13186 (0.01%)
# events	1	1
INTERVERTEBRAL DISC DEGENERATION † 1		
# participants affected / at risk	7/13166 (0.05%)	8/13186 (0.06%)
# events	8	8
INTERVERTEBRAL DISC DISORDER † 1		
# participants affected / at risk	2/13166 (0.02%)	0/13186 (0.00%)
# events	2	0
INTERVERTEBRAL DISC PROTRUSION † 1		
# participants affected / at risk	31/13166 (0.24%)	19/13186 (0.14%)
# events	31	19
LIGAMENT LAXITY † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
LUMBAR SPINAL STENOSIS † 1		
# participants affected / at risk	14/13166 (0.11%)	7/13186 (0.05%)
# events	14	7
MENISCAL DEGENERATION † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
MONARTHRITIS † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
MUSCLE ATROPHY † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
MUSCLE HAEMORRHAGE † 1		
# participants affected / at risk	0/13166 (0.00%)	3/13186 (0.02%)
# events	0	3
MUSCLE SPASMS † 1		
# participants affected / at risk	3/13166 (0.02%)	1/13186 (0.01%)

# events	3	1
MUSCULAR WEAKNESS † 1		
# participants affected / at risk	3/13166 (0.02%)	3/13186 (0.02%)
# events	3	3
MUSCULOSKELETAL CHEST PAIN † 1		
# participants affected / at risk	27/13166 (0.21%)	41/13186 (0.31%)
# events	29	44
MUSCULOSKELETAL DISCOMFORT † 1		
# participants affected / at risk	2/13166 (0.02%)	0/13186 (0.00%)
# events	3	0
MUSCULOSKELETAL PAIN † 1		
# participants affected / at risk	17/13166 (0.13%)	15/13186 (0.11%)
# events	17	15
MUSCULOSKELETAL STIFFNESS † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
MYALGIA † 1		
# participants affected / at risk	5/13166 (0.04%)	2/13186 (0.02%)
# events	6	2
MYOFASCIAL PAIN SYNDROME † 1		
# participants affected / at risk	1/13166 (0.01%)	1/13186 (0.01%)
# events	1	1
MYOSITIS † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
NEUROPATHIC ARTHROPATHY † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
OSTEITIS † 1		
# participants affected / at risk	2/13166 (0.02%)	0/13186 (0.00%)
# events	2	0
OSTEOARTHRITIS † 1		
# participants affected / at risk	84/13166 (0.64%)	71/13186 (0.54%)
# events	89	76
OSTEOCHONDROSIS † 1		
# participants affected / at risk	1/13166 (0.01%)	1/13186 (0.01%)
# events	1	1
OSTEOLYSIS † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
OSTEONECROSIS † 1		
# participants affected / at risk	2/13166 (0.02%)	2/13186 (0.02%)
# events	2	2
OSTEOPOROSIS † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1

PAIN IN EXTREMITY † 1		
# participants affected / at risk	**6/13166 (0.05%)**	**5/13186 (0.04%)**
# events	**6**	**5**
PAIN IN JAW † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
PERIARTHRITIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
POLYARTHRITIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**2**
POLYMYALGIA RHEUMATICA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
PSEUDARTHROSIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
RHABDOMYOLYSIS † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**3/13186 (0.02%)**
# events	**4**	**3**
RHEUMATOID ARTHRITIS † 1		
# participants affected / at risk	**6/13166 (0.05%)**	**2/13186 (0.02%)**
# events	**6**	**2**
ROTATOR CUFF SYNDROME † 1		
# participants affected / at risk	**9/13166 (0.07%)**	**14/13186 (0.11%)**
# events	**9**	**14**
SCOLIOSIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
SPINAL COLUMN STENOSIS † 1		
# participants affected / at risk	**21/13166 (0.16%)**	**14/13186 (0.11%)**
# events	**21**	**14**
SPINAL DISORDER † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
SPINAL OSTEOARTHRITIS † 1		
# participants affected / at risk	**12/13166 (0.09%)**	**8/13186 (0.06%)**
# events	**12**	**8**
SPONDYLITIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
SPONDYLOLISTHESIS † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**1/13186 (0.01%)**
# events	**2**	**1**

SYMPATHETIC POSTERIOR CERVICAL SYNDROME † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
SYNOVIAL CYST † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**4/13186 (0.03%)**
# events	**2**	**4**
SYSTEMIC LUPUS ERYTHEMATOSUS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
TENDON DISORDER † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**2**	**0**
TENDON NECROSIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
TENDONITIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
TENOSYNOVITIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
TRIGGER FINGER † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
VERTEBRAL WEDGING † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
ACUTE LEUKAEMIA † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**2**	**0**
ACUTE LYMPHOCYTIC LEUKAEMIA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
ACUTE MYELOID LEUKAEMIA † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**3/13186 (0.02%)**
# events	**2**	**3**
ADENOCARCINOMA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
ADENOMA BENIGN † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
ADRENAL ADENOMA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**

# events	0	1
ADRENAL NEOPLASM † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
ANAL CANCER † 1		
# participants affected / at risk	1/13166 (0.01%)	2/13186 (0.02%)
# events	1	2
ANAL NEOPLASM † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
ANOGENITAL WARTS † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
ASTROCYTOMA MALIGNANT † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
ATYPICAL FIBROXANTHOMA † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
B-CELL LYMPHOMA † 1		
# participants affected / at risk	3/13166 (0.02%)	0/13186 (0.00%)
# events	3	0
BASAL CELL CARCINOMA † 1		
# participants affected / at risk	14/13166 (0.11%)	14/13186 (0.11%)
# events	20	15
BENIGN CARDIAC NEOPLASM † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
BENIGN LUNG NEOPLASM † 1		
# participants affected / at risk	0/13166 (0.00%)	2/13186 (0.02%)
# events	0	2
BENIGN NEOPLASM † 1		
# participants affected / at risk	1/13166 (0.01%)	1/13186 (0.01%)
# events	1	1
BENIGN NEOPLASM OF BLADDER † 1		
# participants affected / at risk	2/13166 (0.02%)	0/13186 (0.00%)
# events	2	0
BENIGN NEOPLASM OF SKIN † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
BENIGN NEOPLASM OF TESTIS † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
BENIGN NEOPLASM OF THYROID GLAND † 1		
# participants affected / at risk	1/13166 (0.01%)	1/13186 (0.01%)
# events	1	1

BENIGN RENAL NEOPLASM † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
BENIGN SALIVARY GLAND NEOPLASM † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**1/13186 (0.01%)**
# events	**2**	**1**
BILE DUCT CANCER † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**5/13186 (0.04%)**
# events	**1**	**5**
BILIARY CANCER METASTATIC † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
BILIARY NEOPLASM † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
BLADDER CANCER † 1		
# participants affected / at risk	**21/13166 (0.16%)**	**25/13186 (0.19%)**
# events	**21**	**25**
BLADDER CANCER RECURRENT † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**5/13186 (0.04%)**
# events	**3**	**6**
BLADDER NEOPLASM † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**3/13186 (0.02%)**
# events	**2**	**3**
BLADDER PAPILLOMA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
BLADDER TRANSITIONAL CELL CARCINOMA † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**3/13186 (0.02%)**
# events	**3**	**3**
BONE NEOPLASM MALIGNANT † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
BRAIN NEOPLASM † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**3/13186 (0.02%)**
# events	**4**	**3**
BREAST CANCER † 1		
# participants affected / at risk	**19/13166 (0.14%)**	**17/13186 (0.13%)**
# events	**19**	**17**
BREAST CANCER IN SITU † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
BREAST CANCER METASTATIC † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**2/13186 (0.02%)**
# events	**3**	**2**

BREAST CANCER RECURRENT † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
BREAST NEOPLASM † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
BRONCHIAL CARCINOMA † 1		
# participants affected / at risk	**5/13166 (0.04%)**	**4/13186 (0.03%)**
# events	**5**	**4**
BRONCHIOLOALVEOLAR CARCINOMA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
CARCINOID TUMOUR OF THE DUODENUM † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
CARCINOMA IN SITU † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
CERVIX CANCER METASTATIC † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
CERVIX CARCINOMA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
CHLOROMA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
CHOLESTEATOMA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
CHONDROMA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
CHONDROSARCOMA METASTATIC † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
CHOROID MELANOMA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
CHRONIC LYMPHOCYTIC LEUKAEMIA † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**7/13186 (0.05%)**
# events	**2**	**7**
CHRONIC MYELOID LEUKAEMIA † 1		
# participants affected / at risk	**6/13166 (0.05%)**	**1/13186 (0.01%)**
# events	**6**	**1**
† 1		

COLON ADENOMA		
# participants affected / at risk	**5/13166 (0.04%)**	**3/13186 (0.02%)**
# events	**5**	**3**
COLON CANCER † 1		
# participants affected / at risk	**25/13166 (0.19%)**	**27/13186 (0.20%)**
# events	**25**	**27**
COLON CANCER METASTATIC † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**9/13186 (0.07%)**
# events	**4**	**9**
COLON CANCER STAGE 0 † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
COLON NEOPLASM † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**2**
COLORECTAL CANCER METASTATIC † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
CONNECTIVE TISSUE NEOPLASM † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
ENDOMETRIAL CANCER † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**2**	**0**
ESSENTIAL THROMBOCYTHAEMIA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
FIBROUS HISTIOCYTOMA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
GASTRIC ADENOMA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
GASTRIC CANCER † 1		
# participants affected / at risk	**9/13166 (0.07%)**	**6/13186 (0.05%)**
# events	**9**	**6**
GASTRIC CANCER STAGE III † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
GASTRIC NEOPLASM † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
GASTROINTESTINAL CANCER METASTATIC † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
† 1		

GASTROINTESTINAL CARCINOMA		
# participants affected / at risk	**2/13166 (0.02%)**	**2/13186 (0.02%)**
# events	**2**	**2**
GASTROINTESTINAL TRACT ADENOMA † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**3/13186 (0.02%)**
# events	**2**	**3**
GLIOBLASTOMA † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**2/13186 (0.02%)**
# events	**3**	**2**
GLIOBLASTOMA MULTIFORME † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
HAEMANGIOMA OF SPLEEN † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
HEPATIC ANGIOSARCOMA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
HEPATIC CANCER METASTATIC † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
HEPATIC NEOPLASM † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
HEPATIC NEOPLASM MALIGNANT † 1		
# participants affected / at risk	**5/13166 (0.04%)**	**6/13186 (0.05%)**
# events	**5**	**6**
HEPATIC NEOPLASM MALIGNANT RECURRENT † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
HODGKIN'S DISEASE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
HYPOPHARYNGEAL CANCER † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
HYPOPHARYNGEAL CANCER STAGE III † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
INFECTED NEOPLASM † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
INTESTINAL ADENOCARCINOMA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**2**
† 1		

INTRADUCTAL PAPILLOMA OF BREAST		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
KERATOACANTHOMA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
LARGE CELL CARCINOMA OF THE RESPIRATORY TRACT STAGE UNSPECIFIED † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
LARGE CELL LUNG CANCER METASTATIC † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
LARGE GRANULAR LYMPHOCYTOSIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
LARYNGEAL CANCER † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**4/13186 (0.03%)**
# events	**1**	**4**
LARYNGEAL CANCER METASTATIC † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
LARYNGEAL CANCER STAGE 0 † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
LARYNGEAL NEOPLASM † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
LEIOMYOMA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
LEIOMYOSARCOMA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
LEIOMYOSARCOMA METASTATIC † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
LEUKAEMIA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
LIP AND/OR ORAL CAVITY CANCER † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
LIP NEOPLASM MALIGNANT STAGE UNSPECIFIED † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**

LIPOMA † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**3/13186 (0.02%)**
# events	**4**	**3**
LIPOSARCOMA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
LUNG ADENOCARCINOMA † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**12/13186 (0.09%)**
# events	**4**	**12**
LUNG ADENOCARCINOMA METASTATIC † 1		
# participants affected / at risk	**5/13166 (0.04%)**	**4/13186 (0.03%)**
# events	**5**	**4**
LUNG ADENOCARCINOMA RECURRENT † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
LUNG CANCER METASTATIC † 1		
# participants affected / at risk	**27/13166 (0.21%)**	**18/13186 (0.14%)**
# events	**27**	**18**
LUNG CARCINOMA CELL TYPE UNSPECIFIED STAGE IV † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
LUNG NEOPLASM † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**3/13186 (0.02%)**
# events	**4**	**3**
LUNG NEOPLASM MALIGNANT † 1		
# participants affected / at risk	**29/13166 (0.22%)**	**29/13186 (0.22%)**
# events	**29**	**29**
LUNG SQUAMOUS CELL CARCINOMA METASTATIC † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
LUNG SQUAMOUS CELL CARCINOMA STAGE I † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
LUNG SQUAMOUS CELL CARCINOMA STAGE IV † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
LUNG SQUAMOUS CELL CARCINOMA STAGE UNSPECIFIED † 1		
# participants affected / at risk	**7/13166 (0.05%)**	**4/13186 (0.03%)**
# events	**7**	**4**
LYMPHANGIOMA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
LYMPHOCYTIC LEUKAEMIA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**

LYMPHOCYTIC LYMPHOMA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
LYMPHOMA † 1		
# participants affected / at risk	**5/13166 (0.04%)**	**3/13186 (0.02%)**
# events	**5**	**3**
MALIGNANT FIBROUS HISTIOCYTOMA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
MALIGNANT GLIOMA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
MALIGNANT MELANOMA † 1		
# participants affected / at risk	**6/13166 (0.05%)**	**3/13186 (0.02%)**
# events	**6**	**3**
MALIGNANT NEOPLASM OF EYE † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
MALIGNANT PLEURAL EFFUSION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
MANTLE CELL LYMPHOMA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
MELANOMA RECURRENT † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
MENINGIOMA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
MENINGIOMA BENIGN † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
MESOTHELIOMA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
MESOTHELIOMA MALIGNANT † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
METASTASES TO BONE † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**3/13186 (0.02%)**
# events	**2**	**3**
METASTASES TO CENTRAL NERVOUS SYSTEM † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**2**
† 1		

METASTASES TO LIVER		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
METASTASES TO LUNG † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
METASTASES TO PERITONEUM † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**3/13186 (0.02%)**
# events	**0**	**3**
METASTASIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
METASTATIC BRONCHIAL CARCINOMA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
METASTATIC CARCINOMA OF THE BLADDER † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**3/13186 (0.02%)**
# events	**4**	**3**
METASTATIC GASTRIC CANCER † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**6/13186 (0.05%)**
# events	**4**	**6**
METASTATIC LYMPHOMA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
METASTATIC MALIGNANT MELANOMA † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**2/13186 (0.02%)**
# events	**4**	**2**
METASTATIC NEOPLASM † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**6/13186 (0.05%)**
# events	**4**	**6**
METASTATIC SALIVARY GLAND CANCER † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
METASTATIC SQUAMOUS CELL CARCINOMA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**3/13186 (0.02%)**
# events	**1**	**3**
MONOCLONAL GAMMOPATHY † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
MULTIPLE MYELOMA † 1		
# participants affected / at risk	**5/13166 (0.04%)**	**3/13186 (0.02%)**
# events	**5**	**3**
MYELODYSPLASTIC SYNDROME † 1		
# participants affected / at risk	**5/13166 (0.04%)**	**1/13186 (0.01%)**
# events	**5**	**1**
† 1		

MYELOID LEUKAEMIA		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
NASOPHARYNGEAL CANCER † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
NASOPHARYNGEAL CANCER RECURRENT † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
NEOPLASM † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
NEOPLASM MALIGNANT † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**2**
NEOPLASM PROSTATE † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**2**	**0**
NEUROENDOCRINE CARCINOMA METASTATIC † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
NEUROMA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
NON-HODGKIN'S LYMPHOMA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**3/13186 (0.02%)**
# events	**1**	**3**
NON-HODGKIN'S LYMPHOMA METASTATIC † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
NON-HODGKIN'S LYMPHOMA RECURRENT † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
NON-HODGKIN'S LYMPHOMA STAGE II † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
NON-SMALL CELL LUNG CANCER † 1		
# participants affected / at risk	**7/13166 (0.05%)**	**5/13186 (0.04%)**
# events	**7**	**5**
NON-SMALL CELL LUNG CANCER METASTATIC † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**3/13186 (0.02%)**
# events	**0**	**3**
NON-SMALL CELL LUNG CANCER STAGE IIIB † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
† 1		

NON-SMALL CELL LUNG CANCER STAGE IV		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
OESOPHAGEAL ADENOCARCINOMA † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**2/13186 (0.02%)**
# events	**2**	**2**
OESOPHAGEAL CANCER METASTATIC † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**3/13186 (0.02%)**
# events	**1**	**3**
OESOPHAGEAL CARCINOMA † 1		
# participants affected / at risk	**7/13166 (0.05%)**	**3/13186 (0.02%)**
# events	**7**	**3**
OESOPHAGEAL SQUAMOUS CELL CARCINOMA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
ORAL CAVITY CANCER METASTATIC † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**2**
ORAL PAPILLOMA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
OROPHARYNGEAL CANCER STAGE UNSPECIFIED † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
OSTEOCHONDROMA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
OVARIAN ADENOMA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
OVARIAN CANCER † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
OVARIAN CANCER METASTATIC † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**2/13186 (0.02%)**
# events	**2**	**2**
OVARIAN EPITHELIAL CANCER METASTATIC † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
OVARIAN NEOPLASM † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
PANCREATIC CARCINOMA † 1		
# participants affected / at risk	**7/13166 (0.05%)**	**7/13186 (0.05%)**
# events	**7**	**7**
† 1		

PANCREATIC CARCINOMA METASTATIC		
# participants affected / at risk	**9/13166 (0.07%)**	**10/13186 (0.08%)**
# events	**9**	**10**
PAPILLOMA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
PARAPROTEINAEMIA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
PARATHYROID TUMOUR BENIGN † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
PENIS CARCINOMA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
PENIS CARCINOMA STAGE II † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
PHARYNGEAL CANCER METASTATIC † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
PITUITARY TUMOUR † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
PITUITARY TUMOUR BENIGN † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**3/13186 (0.02%)**
# events	**1**	**3**
PLEURAL MESOTHELIOMA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**2**	**0**
POLYCYTHAEMIA VERA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
PROSTATE CANCER † 1		
# participants affected / at risk	**54/13166 (0.41%)**	**38/13186 (0.29%)**
# events	**54**	**39**
PROSTATE CANCER METASTATIC † 1		
# participants affected / at risk	**7/13166 (0.05%)**	**9/13186 (0.07%)**
# events	**7**	**9**
PROSTATE CANCER RECURRENT † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**1/13186 (0.01%)**
# events	**2**	**1**
PROSTATE CANCER STAGE I † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
† 1		

PROSTATE CANCER STAGE II		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
PROSTATE CANCER STAGE IV † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
PROSTATIC ADENOMA † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**1/13186 (0.01%)**
# events	**3**	**1**
RECTAL ADENOMA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
RECTAL CANCER † 1		
# participants affected / at risk	**13/13166 (0.10%)**	**4/13186 (0.03%)**
# events	**13**	**4**
RECTOSIGMOID CANCER † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
RENAL CANCER † 1		
# participants affected / at risk	**5/13166 (0.04%)**	**3/13186 (0.02%)**
# events	**5**	**3**
RENAL CANCER METASTATIC † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
RENAL CANCER STAGE III † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
RENAL CELL CARCINOMA † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**7/13186 (0.05%)**
# events	**4**	**7**
RENAL CELL CARCINOMA RECURRENT † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
RENAL NEOPLASM † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
RENAL ONCOCYTOMA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
RHABDOMYOSARCOMA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
SALIVARY GLAND CANCER † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
† 1		

SALIVARY GLAND NEOPLASM		
# participants affected / at risk	**2/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**2**	**0**
SEBORRHOEIC KERATOSIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
SKIN CANCER † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**2/13186 (0.02%)**
# events	**3**	**2**
SKIN NEOPLASM BLEEDING † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
SMALL CELL CARCINOMA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
SMALL CELL LUNG CANCER METASTATIC † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**1/13186 (0.01%)**
# events	**2**	**1**
SMALL CELL LUNG CANCER STAGE UNSPECIFIED † 1		
# participants affected / at risk	**6/13166 (0.05%)**	**7/13186 (0.05%)**
# events	**6**	**7**
SMALL INTESTINE CARCINOMA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
SMALL INTESTINE CARCINOMA METASTATIC † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
SQUAMOUS CELL CARCINOMA † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**8/13186 (0.06%)**
# events	**4**	**8**
SQUAMOUS CELL CARCINOMA OF SKIN † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**3/13186 (0.02%)**
# events	**0**	**3**
SQUAMOUS CELL CARCINOMA OF THE CERVIX † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
T-CELL LYMPHOMA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
THYMOMA MALIGNANT † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
THYROID ADENOMA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
† 1		

THYROID CANCER		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
THYROID CANCER METASTATIC † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
TONGUE NEOPLASM MALIGNANT STAGE UNSPECIFIED † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**2**
TONSIL CANCER † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**1/13186 (0.01%)**
# events	**2**	**1**
TRANSITIONAL CELL CARCINOMA † 1		
# participants affected / at risk	**6/13166 (0.05%)**	**9/13186 (0.07%)**
# events	**6**	**10**
TRANSITIONAL CELL CARCINOMA METASTATIC † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
TUMOUR HAEMORRHAGE † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**3/13186 (0.02%)**
# events	**3**	**3**
URETERAL NEOPLASM † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
URETERIC CANCER † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
UTERINE CANCER † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**1/13186 (0.01%)**
# events	**2**	**1**
UTERINE LEIOMYOMA † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**4/13186 (0.03%)**
# events	**4**	**4**
UTERINE NEOPLASM † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
VULVAL CANCER † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
Nervous system disorders		
ALTERED STATE OF CONSCIOUSNESS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
AMYOTROPHIC LATERAL SCLEROSIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**3/13186 (0.02%)**

# events	1	3
ATAXIA † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
AUTONOMIC NERVOUS SYSTEM IMBALANCE † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
BASAL GANGLIA HAEMORRHAGE † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
BRAIN OEDEMA † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
BRAIN STEM HAEMORRHAGE † 1		
# participants affected / at risk	0/13166 (0.00%)	2/13186 (0.02%)
# events	0	2
CAROTID ARTERY ANEURYSM † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
CAROTID ARTERY STENOSIS † 1		
# participants affected / at risk	1/13166 (0.01%)	2/13186 (0.02%)
# events	1	2
CARPAL TUNNEL SYNDROME † 1		
# participants affected / at risk	1/13166 (0.01%)	1/13186 (0.01%)
# events	1	1
CAUDA EQUINA SYNDROME † 1		
# participants affected / at risk	1/13166 (0.01%)	1/13186 (0.01%)
# events	1	1
CEREBRAL AMYLOID ANGIOPATHY † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
CEREBRAL CYST † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
CEREBRAL HAEMORRHAGE † 1		
# participants affected / at risk	2/13166 (0.02%)	6/13186 (0.05%)
# events	2	6
CEREBRAL INFARCTION † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
CEREBROVASCULAR ACCIDENT † 1		
# participants affected / at risk	0/13166 (0.00%)	2/13186 (0.02%)
# events	0	2
CEREBROVASCULAR INSUFFICIENCY † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0

CERVICAL MYELOPATHY † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**3/13186 (0.02%)**
# events	**2**	**3**
CERVICOBRACHIAL SYNDROME † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**6/13186 (0.05%)**
# events	**1**	**6**
CNS VENTRICULITIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
COGNITIVE DISORDER † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
COMA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
COMPLEX PARTIAL SEIZURES † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
COMPLEX REGIONAL PAIN SYNDROME † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
COMPLICATED MIGRAINE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**2**
CONVULSION † 1		
# participants affected / at risk	**24/13166 (0.18%)**	**18/13186 (0.14%)**
# events	**27**	**19**
CRANIAL NERVE PARALYSIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
CUBITAL TUNNEL SYNDROME † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
DEMENTIA † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**4/13186 (0.03%)**
# events	**4**	**4**
DEMENTIA ALZHEIMER'S TYPE † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**1/13186 (0.01%)**
# events	**2**	**1**
DEMYELINATING POLYNEUROPATHY † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**2**	**0**
DIABETIC COMA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**

DIABETIC NEUROPATHY † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**3/13186 (0.02%)**
# events	**2**	**3**
DIZZINESS † 1		
# participants affected / at risk	**6/13166 (0.05%)**	**16/13186 (0.12%)**
# events	**6**	**16**
DIZZINESS EXERTIONAL † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
DIZZINESS POSTURAL † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
DYSAESTHESIA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
DYSARTHRIA † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**1/13186 (0.01%)**
# events	**3**	**1**
ENCEPHALITIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
ENCEPHALOMYELITIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
ENCEPHALOPATHY † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
EPILEPSY † 1		
# participants affected / at risk	**15/13166 (0.11%)**	**20/13186 (0.15%)**
# events	**15**	**22**
FACIAL PARESIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
GRAND MAL CONVULSION † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**3/13186 (0.02%)**
# events	**2**	**3**
GUILLAIN-BARRE SYNDROME † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**2**
HAEMORRHAGE INTRACRANIAL † 1		
# participants affected / at risk	**42/13166 (0.32%)**	**75/13186 (0.57%)**
# events	**43**	**75**
HAEMORRHAGIC CEREBRAL INFARCTION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
† 1		

HAEMORRHAGIC STROKE		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
HAEMORRHAGIC TRANSFORMATION STROKE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**6/13186 (0.05%)**
# events	**1**	**6**
HEADACHE † 1		
# participants affected / at risk	**7/13166 (0.05%)**	**9/13186 (0.07%)**
# events	**7**	**10**
HEMIANOPIA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
HEMIPARESIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**4/13186 (0.03%)**
# events	**1**	**4**
HYDROCEPHALUS † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**1/13186 (0.01%)**
# events	**2**	**1**
HYPERTENSIVE ENCEPHALOPATHY † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
HYPOAESTHESIA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
HYPOGLYCAEMIC COMA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**2**
HYPOXIC-ISCHAEMIC ENCEPHALOPATHY † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**0/13186 (0.00%)**
# events	**4**	**0**
IIIRD NERVE PARALYSIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
INTERCOSTAL NEURALGIA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
INTRACRANIAL ANEURYSM † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**3/13186 (0.02%)**
# events	**0**	**3**
INTRACRANIAL HAEMATOMA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
INTRACRANIAL HYPOTENSION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
† 1		

INTRAVENTRICULAR HAEMORRHAGE		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
LETHARGY [† 1]		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
LEUKOENCEPHALOPATHY [† 1]		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
LEWIS-SUMNER SYNDROME [† 1]		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
LOSS OF CONSCIOUSNESS [† 1]		
# participants affected / at risk	**1/13166 (0.01%)**	**3/13186 (0.02%)**
# events	**1**	**3**
LUMBAR RADICULOPATHY [† 1]		
# participants affected / at risk	**4/13166 (0.03%)**	**2/13186 (0.02%)**
# events	**4**	**2**
MENTAL IMPAIRMENT [† 1]		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
METABOLIC ENCEPHALOPATHY [† 1]		
# participants affected / at risk	**3/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**3**	**0**
MIGRAINE [† 1]		
# participants affected / at risk	**8/13166 (0.06%)**	**6/13186 (0.05%)**
# events	**8**	**7**
MONOPLEGIA [† 1]		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
MYELOPATHY [† 1]		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
MYOCLONUS [† 1]		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
NERVE COMPRESSION [† 1]		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**2**
NERVE ROOT COMPRESSION [† 1]		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
NERVOUS SYSTEM DISORDER [† 1]		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
[† 1]		

NEURALGIA		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
NEURITIS † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**2**	**0**
NEUROLOGICAL SYMPTOM † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
NEUROPATHY PERIPHERAL † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
NORMAL PRESSURE HYDROCEPHALUS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**3/13186 (0.02%)**
# events	**0**	**3**
PARAESTHESIA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**5/13186 (0.04%)**
# events	**1**	**5**
PARAPARESIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
PARAPLEGIA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
PARKINSON'S DISEASE † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**5/13186 (0.04%)**
# events	**5**	**6**
PARKINSONISM † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
PARTIAL SEIZURES † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**1/13186 (0.01%)**
# events	**2**	**1**
PARTIAL SEIZURES WITH SECONDARY GENERALISATION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
PERIPHERAL NERVE LESION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
POLYNEUROPATHY † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**4/13186 (0.03%)**
# events	**1**	**5**
PRESYNCOPE † 1		
# participants affected / at risk	**20/13166 (0.15%)**	**21/13186 (0.16%)**
# events	**20**	**22**
† 1		

PUTAMEN HAEMORRHAGE		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
QUADRIPARESIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
RADICULITIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
RADICULOPATHY † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**1/13186 (0.01%)**
# events	**2**	**1**
SCIATICA † 1		
# participants affected / at risk	**7/13166 (0.05%)**	**2/13186 (0.02%)**
# events	**8**	**2**
SEDATION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
SOMNOLENCE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
SPINAL CLAUDICATION † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
SPINAL CORD COMPRESSION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
STATUS EPILEPTICUS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**2**
SUBARACHNOID HAEMORRHAGE † 1		
# participants affected / at risk	**3/13166 (0.02%)**	**5/13186 (0.04%)**
# events	**3**	**5**
SYNCOPE † 1		
# participants affected / at risk	**60/13166 (0.46%)**	**81/13186 (0.61%)**
# events	**65**	**87**
SYRINGOMYELIA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
TENSION HEADACHE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
THORACIC OUTLET SYNDROME † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
† 1		

TRANSIENT GLOBAL AMNESIA		
# participants affected / at risk	**2/13166 (0.02%)**	**2/13186 (0.02%)**
# events	**2**	**2**
TREMOR † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
TRIGEMINAL NEURALGIA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
ULNAR NEURITIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
UPPER MOTOR NEURONE LESION † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**2**
VASCULAR DEMENTIA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**3**
VASCULAR PARKINSONISM † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
VERTEBRAL ARTERY STENOSIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
VIITH NERVE PARALYSIS † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**2/13186 (0.02%)**
# events	**4**	**2**
VITH NERVE PARALYSIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
VOCAL CORD PARALYSIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
WERNICKE'S ENCEPHALOPATHY † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
Pregnancy, puerperium and perinatal conditions		
ABORTION MISSED † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
Psychiatric disorders		
ADJUSTMENT DISORDER † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
ALCOHOL ABUSE † 1		

# participants affected / at risk	2/13166 (0.02%)	1/13186 (0.01%)
# events	2	1
ALCOHOLISM † 1		
# participants affected / at risk	2/13166 (0.02%)	2/13186 (0.02%)
# events	4	2
ANXIETY † 1		
# participants affected / at risk	9/13166 (0.07%)	10/13186 (0.08%)
# events	9	10
ANXIETY DISORDER † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
BIPOLAR DISORDER † 1		
# participants affected / at risk	2/13166 (0.02%)	2/13186 (0.02%)
# events	2	2
BIPOLAR I DISORDER † 1		
# participants affected / at risk	0/13166 (0.00%)	2/13186 (0.02%)
# events	0	2
COMPLETED SUICIDE † 1		
# participants affected / at risk	3/13166 (0.02%)	6/13186 (0.05%)
# events	3	6
CONFUSIONAL STATE † 1		
# participants affected / at risk	5/13166 (0.04%)	7/13186 (0.05%)
# events	5	7
CONVERSION DISORDER † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
DELIRIUM † 1		
# participants affected / at risk	4/13166 (0.03%)	2/13186 (0.02%)
# events	4	2
DEPRESSED MOOD † 1		
# participants affected / at risk	0/13166 (0.00%)	2/13186 (0.02%)
# events	0	2
DEPRESSION † 1		
# participants affected / at risk	19/13166 (0.14%)	18/13186 (0.14%)
# events	20	19
HALLUCINATION † 1		
# participants affected / at risk	0/13166 (0.00%)	2/13186 (0.02%)
# events	0	2
MAJOR DEPRESSION † 1		
# participants affected / at risk	4/13166 (0.03%)	8/13186 (0.06%)
# events	4	8
MANIA † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
MENTAL DISORDER † 1		
# participants affected / at risk	1/13166 (0.01%)	1/13186 (0.01%)

# events	1	1
MENTAL STATUS CHANGES † 1		
# participants affected / at risk	2/13166 (0.02%)	4/13186 (0.03%)
# events	2	4
PANIC ATTACK † 1		
# participants affected / at risk	2/13166 (0.02%)	1/13186 (0.01%)
# events	2	1
POLYDIPSIA PSYCHOGENIC † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
POST STROKE DEPRESSION † 1		
# participants affected / at risk	0/13166 (0.00%)	3/13186 (0.02%)
# events	0	3
PSYCHOTIC DISORDER † 1		
# participants affected / at risk	3/13166 (0.02%)	1/13186 (0.01%)
# events	3	1
RESTLESSNESS † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
SCHIZOPHRENIA † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
SOMATOFORM DISORDER † 1		
# participants affected / at risk	1/13166 (0.01%)	1/13186 (0.01%)
# events	2	1
STRESS † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
SUBSTANCE ABUSE † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
SUICIDAL IDEATION † 1		
# participants affected / at risk	6/13166 (0.05%)	5/13186 (0.04%)
# events	7	5
SUICIDE ATTEMPT † 1		
# participants affected / at risk	11/13166 (0.08%)	7/13186 (0.05%)
# events	11	7
TRANSIENT PSYCHOSIS † 1		
# participants affected / at risk	1/13166 (0.01%)	1/13186 (0.01%)
# events	1	1
Renal and urinary disorders		
ACUTE PRERENAL FAILURE † 1		
# participants affected / at risk	2/13166 (0.02%)	1/13186 (0.01%)
# events	2	1
AZOTAEMIA † 1		

# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
BLADDER DISORDER † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
BLADDER NECK OBSTRUCTION † 1		
# participants affected / at risk	0/13166 (0.00%)	2/13186 (0.02%)
# events	0	2
BLADDER NECK SCLEROSIS † 1		
# participants affected / at risk	1/13166 (0.01%)	1/13186 (0.01%)
# events	1	1
BLADDER OUTLET OBSTRUCTION † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
BLADDER PERFORATION † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
BLADDER PROLAPSE † 1		
# participants affected / at risk	1/13166 (0.01%)	1/13186 (0.01%)
# events	1	1
BLADDER SPASM † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
BLADDER STENOSIS † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	3	0
CALCULUS BLADDER † 1		
# participants affected / at risk	2/13166 (0.02%)	3/13186 (0.02%)
# events	2	3
CALCULUS URETERIC † 1		
# participants affected / at risk	6/13166 (0.05%)	6/13186 (0.05%)
# events	6	6
CALCULUS URETHRAL † 1		
# participants affected / at risk	2/13166 (0.02%)	0/13186 (0.00%)
# events	2	0
CALCULUS URINARY † 1		
# participants affected / at risk	2/13166 (0.02%)	3/13186 (0.02%)
# events	2	3
CYSTITIS HAEMORRHAGIC † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
CYSTITIS NONINFECTIVE † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
DIABETIC NEPHROPATHY † 1		

# participants affected / at risk	3/13166 (0.02%)	1/13186 (0.01%)
# events	3	1
DYSURIA † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
GLOMERULONEPHRITIS † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
GLOMERULONEPHRITIS MEMBRANOUS † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
HAEMATURIA † 1		
# participants affected / at risk	38/13166 (0.29%)	66/13186 (0.50%)
# events	42	72
HAEMORRHAGE URINARY TRACT † 1		
# participants affected / at risk	1/13166 (0.01%)	5/13186 (0.04%)
# events	1	6
HYDRONEPHROSIS † 1		
# participants affected / at risk	0/13166 (0.00%)	3/13186 (0.02%)
# events	0	3
HYDROURETER † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
KIDNEY FIBROSIS † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
MICTURITION URGENCY † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
NEPHROLITHIASIS † 1		
# participants affected / at risk	28/13166 (0.21%)	22/13186 (0.17%)
# events	33	22
NEPHROPATHY † 1		
# participants affected / at risk	0/13166 (0.00%)	3/13186 (0.02%)
# events	0	3
NEPHROTIC SYNDROME † 1		
# participants affected / at risk	2/13166 (0.02%)	1/13186 (0.01%)
# events	2	1
OBSTRUCTIVE UROPATHY † 1		
# participants affected / at risk	1/13166 (0.01%)	1/13186 (0.01%)
# events	1	1
PELVI-URETERIC OBSTRUCTION † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
POLYURIA † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)

# events	0	1
RENAL ARTERY OCCLUSION † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
RENAL ARTERY STENOSIS † 1		
# participants affected / at risk	1/13166 (0.01%)	2/13186 (0.02%)
# events	1	2
RENAL COLIC † 1		
# participants affected / at risk	3/13166 (0.02%)	3/13186 (0.02%)
# events	3	3
RENAL CYST † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
RENAL FAILURE † 1		
# participants affected / at risk	40/13166 (0.30%)	33/13186 (0.25%)
# events	42	34
RENAL FAILURE ACUTE † 1		
# participants affected / at risk	54/13166 (0.41%)	43/13186 (0.33%)
# events	61	44
RENAL FAILURE CHRONIC † 1		
# participants affected / at risk	18/13166 (0.14%)	9/13186 (0.07%)
# events	18	13
RENAL IMPAIRMENT † 1		
# participants affected / at risk	4/13166 (0.03%)	3/13186 (0.02%)
# events	4	3
RENAL INFARCT † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
RENAL MASS † 1		
# participants affected / at risk	1/13166 (0.01%)	2/13186 (0.02%)
# events	1	2
RENAL TUBULAR NECROSIS † 1		
# participants affected / at risk	1/13166 (0.01%)	1/13186 (0.01%)
# events	1	1
STAG HORN CALCULUS † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
STRESS URINARY INCONTINENCE † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
TUBULOINTERSTITIAL NEPHRITIS † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
URETERIC RUPTURE † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)

# events	1	0
URETERIC STENOSIS † 1		
# participants affected / at risk	2/13166 (0.02%)	0/13186 (0.00%)
# events	3	0
URETHRAL OBSTRUCTION † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
URETHRAL STENOSIS † 1		
# participants affected / at risk	2/13166 (0.02%)	5/13186 (0.04%)
# events	2	6
URINARY BLADDER POLYP † 1		
# participants affected / at risk	1/13166 (0.01%)	1/13186 (0.01%)
# events	1	1
URINARY INCONTINENCE † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
URINARY RETENTION † 1		
# participants affected / at risk	14/13166 (0.11%)	4/13186 (0.03%)
# events	14	4
URINARY TRACT DISORDER † 1		
# participants affected / at risk	1/13166 (0.01%)	1/13186 (0.01%)
# events	1	1
VESICOURETERIC REFLUX † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
Reproductive system and breast disorders		
BALANITIS † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
BENIGN PROSTATIC HYPERPLASIA † 1		
# participants affected / at risk	27/13166 (0.21%)	35/13186 (0.27%)
# events	28	36
BREAST ENLARGEMENT † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
CYSTOCELE † 1		
# participants affected / at risk	5/13166 (0.04%)	0/13186 (0.00%)
# events	5	0
ENDOMETRIAL HYPERPLASIA † 1		
# participants affected / at risk	1/13166 (0.01%)	2/13186 (0.02%)
# events	1	2
EPIDIDYMITIS † 1		
# participants affected / at risk	2/13166 (0.02%)	0/13186 (0.00%)
# events	2	0
ERECTILE DYSFUNCTION † 1		

# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
FIBROCYSTIC BREAST DISEASE † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
GENITAL HAEMORRHAGE † 1		
# participants affected / at risk	2/13166 (0.02%)	2/13186 (0.02%)
# events	2	2
GENITAL TRACT INFLAMMATION † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
MENOMETRORRHAGIA † 1		
# participants affected / at risk	0/13166 (0.00%)	2/13186 (0.02%)
# events	0	2
MENORRHAGIA † 1		
# participants affected / at risk	2/13166 (0.02%)	5/13186 (0.04%)
# events	2	6
MENSTRUAL DISORDER † 1		
# participants affected / at risk	0/13166 (0.00%)	2/13186 (0.02%)
# events	0	2
METRORRHAGIA † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
ORCHITIS NONINFECTIVE † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
OVARIAN CYST † 1		
# participants affected / at risk	4/13166 (0.03%)	3/13186 (0.02%)
# events	4	3
PELVIC HAEMATOMA † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
PELVIC PROLAPSE † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
POSTMENOPAUSAL HAEMORRHAGE † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
PROSTATIC HAEMORRHAGE † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
PROSTATISM † 1		
# participants affected / at risk	1/13166 (0.01%)	1/13186 (0.01%)
# events	1	1
PROSTATITIS † 1		
# participants affected / at risk	4/13166 (0.03%)	3/13186 (0.02%)

# events	4	3
PROSTATOMEGALY † 1		
# participants affected / at risk	1/13166 (0.01%)	2/13186 (0.02%)
# events	1	2
RECTOCELE † 1		
# participants affected / at risk	1/13166 (0.01%)	2/13186 (0.02%)
# events	1	2
SPERMATOCELE † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
TESTICULAR OEDEMA † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
UTERINE CYST † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
UTERINE HAEMORRHAGE † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
UTERINE PROLAPSE † 1		
# participants affected / at risk	2/13166 (0.02%)	3/13186 (0.02%)
# events	2	3
UTEROVAGINAL PROLAPSE † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
VAGINAL HAEMORRHAGE † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
VAGINAL LACERATION † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
VAGINAL PROLAPSE † 1		
# participants affected / at risk	3/13166 (0.02%)	0/13186 (0.00%)
# events	3	0
VAGINAL ULCERATION † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
Respiratory, thoracic and mediastinal disorders		
ACUTE PULMONARY OEDEMA † 1		
# participants affected / at risk	3/13166 (0.02%)	5/13186 (0.04%)
# events	3	5
ACUTE RESPIRATORY DISTRESS SYNDROME † 1		
# participants affected / at risk	1/13166 (0.01%)	2/13186 (0.02%)
# events	1	2
ACUTE RESPIRATORY FAILURE † 1		

# participants affected / at risk	18/13166 (0.14%)	7/13186 (0.05%)
# events	19	9
ADENOIDAL DISORDER † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
APNOEA † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
ASPHYXIA † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
ASTHMA † 1		
# participants affected / at risk	8/13166 (0.06%)	12/13186 (0.09%)
# events	13	15
ATELECTASIS † 1		
# participants affected / at risk	3/13166 (0.02%)	1/13186 (0.01%)
# events	3	1
BRAIN HYPOXIA † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
BRONCHIAL HYPERREACTIVITY † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
BRONCHOSPASM † 1		
# participants affected / at risk	1/13166 (0.01%)	3/13186 (0.02%)
# events	1	3
CHRONIC OBSTRUCTIVE PULMONARY DISEASE † 1		
# participants affected / at risk	75/13166 (0.57%)	79/13186 (0.60%)
# events	100	112
COUGH † 1		
# participants affected / at risk	2/13166 (0.02%)	0/13186 (0.00%)
# events	2	0
DIAPHRAGMATIC PARALYSIS † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
DYSPNOEA † 1		
# participants affected / at risk	18/13166 (0.14%)	13/13186 (0.10%)
# events	18	13
DYSPNOEA EXERTIONAL † 1		
# participants affected / at risk	1/13166 (0.01%)	2/13186 (0.02%)
# events	1	2
DYSPNOEA PAROXYSMAL NOCTURNAL † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
EMPHYSEMA † 1		

# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
EOSINOPHILIC PNEUMONIA ACUTE † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
EPISTAXIS † 1		
# participants affected / at risk	16/13166 (0.12%)	29/13186 (0.22%)
# events	16	30
HAEMOPTYSIS † 1		
# participants affected / at risk	11/13166 (0.08%)	13/13186 (0.10%)
# events	12	13
HAEMOTHORAX † 1		
# participants affected / at risk	6/13166 (0.05%)	7/13186 (0.05%)
# events	6	7
HYDROTHORAX † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
HYPERVENTILATION † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
HYPOVENTILATION † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
HYPOXIA † 1		
# participants affected / at risk	1/13166 (0.01%)	2/13186 (0.02%)
# events	1	2
IDIOPATHIC PULMONARY FIBROSIS † 1		
# participants affected / at risk	1/13166 (0.01%)	1/13186 (0.01%)
# events	1	1
INTERSTITIAL LUNG DISEASE † 1		
# participants affected / at risk	5/13166 (0.04%)	2/13186 (0.02%)
# events	5	2
LARYNGEAL MASS † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
LARYNGEAL STENOSIS † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
LUNG CONSOLIDATION † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
LUNG DISORDER † 1		
# participants affected / at risk	2/13166 (0.02%)	3/13186 (0.02%)
# events	2	3
NASAL POLYPS † 1		
# participants affected / at risk	2/13166 (0.02%)	3/13186 (0.02%)

# events	2	3
NASAL SEPTUM DEVIATION † 1		
# participants affected / at risk	5/13166 (0.04%)	1/13186 (0.01%)
# events	5	1
NASAL SEPTUM DISORDER † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
NASAL TURBINATE HYPERTROPHY † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
OBSTRUCTIVE AIRWAYS DISORDER † 1		
# participants affected / at risk	3/13166 (0.02%)	0/13186 (0.00%)
# events	3	0
PHARYNGEAL HAEMORRHAGE † 1		
# participants affected / at risk	1/13166 (0.01%)	1/13186 (0.01%)
# events	1	1
PLEURAL EFFUSION † 1		
# participants affected / at risk	11/13166 (0.08%)	13/13186 (0.10%)
# events	12	14
PLEURISY † 1		
# participants affected / at risk	3/13166 (0.02%)	0/13186 (0.00%)
# events	4	0
PLEURITIC PAIN † 1		
# participants affected / at risk	1/13166 (0.01%)	1/13186 (0.01%)
# events	1	1
PNEUMONIA ASPIRATION † 1		
# participants affected / at risk	12/13166 (0.09%)	4/13186 (0.03%)
# events	15	4
PNEUMONITIS † 1		
# participants affected / at risk	1/13166 (0.01%)	2/13186 (0.02%)
# events	1	2
PNEUMOTHORAX † 1		
# participants affected / at risk	10/13166 (0.08%)	9/13186 (0.07%)
# events	10	13
PULMONARY CALCIFICATION † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
PULMONARY CONGESTION † 1		
# participants affected / at risk	0/13166 (0.00%)	2/13186 (0.02%)
# events	0	2
PULMONARY EMBOLISM † 1		
# participants affected / at risk	45/13166 (0.34%)	23/13186 (0.17%)
# events	45	24
PULMONARY FIBROSIS † 1		
# participants affected / at risk	6/13166 (0.05%)	3/13186 (0.02%)

# events	6	3
PULMONARY HAEMORRHAGE † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
PULMONARY HYPERTENSION † 1		
# participants affected / at risk	2/13166 (0.02%)	1/13186 (0.01%)
# events	2	1
PULMONARY INFARCTION † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
PULMONARY MASS † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
PULMONARY NECROSIS † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
PULMONARY OEDEMA † 1		
# participants affected / at risk	8/13166 (0.06%)	8/13186 (0.06%)
# events	8	8
RESPIRATORY ACIDOSIS † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
RESPIRATORY ARREST † 1		
# participants affected / at risk	2/13166 (0.02%)	0/13186 (0.00%)
# events	2	0
RESPIRATORY DISTRESS † 1		
# participants affected / at risk	1/13166 (0.01%)	4/13186 (0.03%)
# events	1	4
RESPIRATORY FAILURE † 1		
# participants affected / at risk	12/13166 (0.09%)	21/13186 (0.16%)
# events	12	22
RHINITIS ALLERGIC † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
SINUS POLYP † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
SLEEP APNOEA SYNDROME † 1		
# participants affected / at risk	4/13166 (0.03%)	6/13186 (0.05%)
# events	4	6
TONSILLAR HAEMORRHAGE † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
VOCAL CORD ATROPHY † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1

VOCAL CORD POLYP † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
WHEEZING † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
Skin and subcutaneous tissue disorders		
ANGIODERMATITIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
ANGIOEDEMA † 1		
# participants affected / at risk	**6/13166 (0.05%)**	**7/13186 (0.05%)**
# events	**6**	**7**
DECUBITUS ULCER † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**1/13186 (0.01%)**
# events	**2**	**1**
DERMATITIS † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**0/13186 (0.00%)**
# events	**2**	**0**
DERMATITIS ALLERGIC † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
DERMATITIS EXFOLIATIVE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
DERMATOMYOSITIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
DIABETIC DERMOPATHY † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
DIABETIC ULCER † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
DRY GANGRENE † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
ECCHYMOSIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**3/13186 (0.02%)**
# events	**0**	**3**
ECZEMA † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**2/13186 (0.02%)**
# events	**0**	**2**
HYPERHIDROSIS † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**

# events	0	1
LEUKOCYTOCLASTIC VASCULITIS † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
PEMPHIGOID † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
PEMPHIGUS † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
PETECHIAE † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
PSORIASIS † 1		
# participants affected / at risk	0/13166 (0.00%)	2/13186 (0.02%)
# events	0	2
PURPURA † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
RASH † 1		
# participants affected / at risk	1/13166 (0.01%)	1/13186 (0.01%)
# events	1	1
SCAR † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
SEGMENTED HYALINISING VASCULITIS † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
SKIN HAEMORRHAGE † 1		
# participants affected / at risk	2/13166 (0.02%)	2/13186 (0.02%)
# events	2	2
SKIN NECROSIS † 1		
# participants affected / at risk	3/13166 (0.02%)	0/13186 (0.00%)
# events	3	0
SKIN ULCER † 1		
# participants affected / at risk	4/13166 (0.03%)	7/13186 (0.05%)
# events	4	7
STASIS DERMATITIS † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
URTICARIA † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
Social circumstances		
SOCIAL PROBLEM † 1		

# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
Surgical and medical procedures		
ABDOMINAL OPERATION † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
FINGER AMPUTATION † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
GASTRIC BANDING † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
HIP ARTHROPLASTY † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
INGUINAL HERNIA REPAIR † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
POLYPECTOMY † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
SPINAL DECOMPRESSION † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
SURGERY † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
Vascular disorders		
ACCELERATED HYPERTENSION † 1		
# participants affected / at risk	2/13166 (0.02%)	1/13186 (0.01%)
# events	2	1
ANEURYSM † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
ANEURYSM RUPTURED † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
ANGIODYSPLASIA † 1		
# participants affected / at risk	1/13166 (0.01%)	1/13186 (0.01%)
# events	1	1
AORTIC ANEURYSM † 1		
# participants affected / at risk	18/13166 (0.14%)	18/13186 (0.14%)
# events	18	18
AORTIC ANEURYSM RUPTURE † 1		
# participants affected / at risk	8/13166 (0.06%)	3/13186 (0.02%)

# events	8	5
AORTIC DILATATION † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
AORTIC DISSECTION † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	2
AORTIC STENOSIS † 1		
# participants affected / at risk	3/13166 (0.02%)	7/13186 (0.05%)
# events	3	7
ARTERIAL DISORDER † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
ARTERIAL HAEMORRHAGE † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
ARTERIAL RUPTURE † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	2
ARTERIOSCLEROSIS † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
ARTERIOVENOUS FISTULA † 1		
# participants affected / at risk	1/13166 (0.01%)	2/13186 (0.02%)
# events	1	2
BLEEDING VARICOSE VEIN † 1		
# participants affected / at risk	1/13166 (0.01%)	2/13186 (0.02%)
# events	1	3
CIRCULATORY COLLAPSE † 1		
# participants affected / at risk	1/13166 (0.01%)	0/13186 (0.00%)
# events	1	0
DEEP VEIN THROMBOSIS † 1		
# participants affected / at risk	22/13166 (0.17%)	19/13186 (0.14%)
# events	23	20
ESSENTIAL HYPERTENSION † 1		
# participants affected / at risk	0/13166 (0.00%)	2/13186 (0.02%)
# events	0	2
EXTREMITY NECROSIS † 1		
# participants affected / at risk	1/13166 (0.01%)	1/13186 (0.01%)
# events	1	1
FEMORAL ARTERY ANEURYSM † 1		
# participants affected / at risk	0/13166 (0.00%)	1/13186 (0.01%)
# events	0	1
HAEMATOMA † 1		
# participants affected / at risk	16/13166 (0.12%)	25/13186 (0.19%)
# events	17	26

HAEMODYNAMIC INSTABILITY † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
HAEMORRHAGE † 1		
# participants affected / at risk	**23/13166 (0.17%)**	**36/13186 (0.27%)**
# events	**24**	**40**
HYPERTENSION † 1		
# participants affected / at risk	**26/13166 (0.20%)**	**27/13186 (0.20%)**
# events	**26**	**32**
HYPERTENSIVE CRISIS † 1		
# participants affected / at risk	**31/13166 (0.24%)**	**20/13186 (0.15%)**
# events	**35**	**25**
HYPERTENSIVE EMERGENCY † 1		
# participants affected / at risk	**4/13166 (0.03%)**	**4/13186 (0.03%)**
# events	**4**	**5**
HYPOPERFUSION † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
HYPOTENSION † 1		
# participants affected / at risk	**29/13166 (0.22%)**	**31/13186 (0.24%)**
# events	**29**	**31**
HYPOVOLAEMIC SHOCK † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**2/13186 (0.02%)**
# events	**1**	**2**
INTRA-ABDOMINAL HAEMORRHAGE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
LABILE BLOOD PRESSURE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
LYMPHATIC FISTULA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
LYMPHOCELE † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
LYMPHOEDEMA † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
MALIGNANT HYPERTENSION † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**1/13186 (0.01%)**
# events	**2**	**1**
ORTHOSTATIC HYPERTENSION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**

ORTHOSTATIC HYPOTENSION † 1		
# participants affected / at risk	**20/13166 (0.15%)**	**13/13186 (0.10%)**
# events	**20**	**15**
PERIPHERAL ARTERY ANEURYSM † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**
PERIPHERAL EMBOLISM † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
PHLEBITIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
POOR PERIPHERAL CIRCULATION † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
RAYNAUD'S PHENOMENON † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
SHOCK † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
SUBCLAVIAN VEIN THROMBOSIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**0/13186 (0.00%)**
# events	**1**	**0**
TEMPORAL ARTERITIS † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**1/13186 (0.01%)**
# events	**2**	**1**
VARICOSE VEIN † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**3/13186 (0.02%)**
# events	**2**	**3**
VENOUS INSUFFICIENCY † 1		
# participants affected / at risk	**0/13166 (0.00%)**	**1/13186 (0.01%)**
# events	**0**	**1**
VENOUS THROMBOSIS † 1		
# participants affected / at risk	**2/13166 (0.02%)**	**2/13186 (0.02%)**
# events	**2**	**2**
WEGENER'S GRANULOMATOSIS † 1		
# participants affected / at risk	**1/13166 (0.01%)**	**1/13186 (0.01%)**
# events	**1**	**1**

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 14.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	up to 3 years
Additional Description	Adverse events are reported using the As Treated Population, which included all participants who received at least 1 dose of study medication and are reported according to treatment received

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Placebo	1 placebo tablet, orally, daily for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.
Vorapaxar	one 2.5 mg tablet daily, orally, for at least 1 year in addition to current treatment of atherosclerotic disease, which will be continued to be administered as per current standard of care.

Other Adverse Events

	Placebo	Vorapaxar
Total, other (not including serious) adverse events		
# participants affected / at risk	**2280/13166 (17.32%)**	**2541/13186 (19.27%)**
General disorders		
CHEST PAIN † 1		
# participants affected / at risk	**687/13166 (5.22%)**	**672/13186 (5.10%)**
# events	**785**	**789**
Nervous system disorders		
DIZZINESS † 1		
# participants affected / at risk	**704/13166 (5.35%)**	**662/13186 (5.02%)**
# events	**781**	**746**
Respiratory, thoracic and mediastinal disorders		
EPISTAXIS † 1		
# participants affected / at risk	**401/13166 (3.05%)**	**807/13186 (6.12%)**
# events	**513**	**1044**
Vascular disorders		
HYPERTENSION † 1		
# participants affected / at risk	**736/13166 (5.59%)**	**712/13186 (5.40%)**
# events	**789**	**761**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 14.1

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data

Prior to the completion of the study, based on a communication from the Data and Safety Monitoring Board, all participants who had experienced a stroke either before or during the study had study drug discontinued.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Restriction Description: The investigators agreed not to publish or publicly present any interim results of the study without the prior written consent of the sponsor. The investigator further agreed to provide to the sponsor review copies of abstracts or manuscripts for publication 45 days prior to submission.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck Sharp & Dohme Corp.
phone: 1-800-672-6372
e-mail: ClinicalTrialsDisclosure@merck.com

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Bohula EA, Aylward PE, Bonaca MP, Corbalan RL, Kiss RG, Murphy SA, Scirica BM, White H, Braunwald E, Morrow DA. Efficacy and Safety of Vorapaxar With and Without a Thienopyridine for Secondary Prevention in Patients With Previous Myocardial Infarction and No History of Stroke or Transient Ischemic Attack: Results from TRA 2°P-TIMI 50. Circulation. 2015 Nov 17;132(20):1871-9. doi: 10.1161/CIRCULATIONAHA.114.015042. Epub 2015 Sep 3.

Magnani G, Bonaca MP, Braunwald E, Dalby AJ, Fox KA, Murphy SA, Nicolau JC, Oude Ophuis T, Scirica BM, Spinar J, Theroux P, Morrow DA. Efficacy and safety of vorapaxar as approved for clinical use in the United States. J Am Heart Assoc. 2015 Mar 19;4(3):e001505. doi: 10.1161/JAHA.114.001505. Erratum in: J Am Heart Assoc. 2015 Apr;4(4). pii: e000633. doi: 10.1161/JAHA.115.000633.

Cavender MA, Scirica BM, Bonaca MP, Angiolillo DJ, Dalby AJ, Dellborg M, Morais J, Murphy SA, Ophuis TO, Tendera M, Braunwald E, Morrow DA. Vorapaxar in patients with diabetes mellitus and previous myocardial infarction: findings from the thrombin receptor antagonist in secondary prevention of atherothrombotic ischemic events-TIMI 50 trial. Circulation. 2015 Mar 24;131(12):1047-53. doi: 10.1161/CIRCULATIONAHA.114.013774. Epub 2015 Feb 13.

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TO TOP

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