

ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt  
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## Study Identification

Unique Protocol ID: D5130C05262

Brief Title: A Comparison of Ticagrelor (AZD6140) and Clopidogrel in Patients With Acute Coronary Syndrome ( PLATO )

Official Title: A Randomised, Double-blind, Parallel Group, Phase 3, Efficacy and Safety Study of Ticagrelor Compared With Clopidogrel for Prevention of Vascular Events in Patients With Non-ST or ST Elevation Acute Coronary Syndromes (ACS) [PLATO- a Study of PLATelet Inhibition and Patient Outcomes]

Secondary IDs: PLATO

## Study Status

Record Verification: February 2012

Overall Status: Completed

Study Start: October 2006

Primary Completion: March 2009 [Actual]

Study Completion: March 2009 [Actual]

## Sponsor/Collaborators

Sponsor: AstraZeneca

Responsible Party: Sponsor

Collaborators:

## Oversight

FDA Regulated?: Yes

Applicable Trial?: Section 801 Clinical Trial? Yes  
Delayed Posting? No

IND/IDE Protocol?: Yes

IND/IDE Information: Grantor: CDER  
IND/IDE Number: 65,808  
Serial Number: 118  
Has Expanded Access? No

Review Board: Approval Status:  
Board Name:  
Board Affiliation:  
Phone:  
Email:

Data Monitoring?:

Plan to Share Data?:

Oversight Authorities: United States: Food and Drug Administration

## Study Description

Brief Summary: Ticagrelor is a new, reversible binding, anti-platelet medication. Anti-platelet medications work to prevent the formation of blood clots. Ticagrelor is being developed as a treatment for patients with acute coronary syndrome (ACS). ACS is a term that is used to describe both heart attacks in progress or the imminent threat of a heart attack. ACS is usually caused by the formation of a blood clot in an artery that partially or totally blocks the blood supply to a portion of the heart muscle. Ticagrelor will be compared with clopidogrel to determine which drug, when either is used in conjunction with aspirin, is better at reducing deaths from vascular causes, future heart attacks and/or strokes in patients with ACS.

Detailed Description:

## Conditions

Conditions: Acute Coronary Syndrome

Keywords: ACS  
Acute coronary syndrome  
Heart attack  
Unstable angina  
Coronary artery disease

## Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Intervention Model: Parallel Assignment

Number of Arms: 2

Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)

Allocation: Randomized

Endpoint Classification: Safety/Efficacy Study

Enrollment: 18624 [Actual]

## Arms and Interventions

Arms	Assigned Interventions
Active Comparator: Clopidogrel Oral treatment	Drug: Clopidogrel Clopidogrel 75 mg once daily dose (ODD)  Other Names: <ul style="list-style-type: none"><li>• Plavix®</li></ul>
Experimental: Ticagrelor Oral treatment	Drug: Ticagrelor Ticagrelor (AZD6140) 90 mg twice daily dose (BD)  Other Names: <ul style="list-style-type: none"><li>• AZD6140</li></ul>

## Outcome Measures

[See Results Section.]

## Eligibility

Minimum Age: 18 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Male or female 18 years or older who has been hospitalised for chest pain and potential ACS
- Females of child-bearing potential must have a negative pregnancy test at enrollment and be willing to use 2 methods of reliable contraception

Exclusion Criteria:

- Persons with moderate or severe liver disease
- Persons who have already been treated with an invasive (angioplasty) procedure for the current episode of ACS
- Persons who are being treated with blood clotting agents that cannot be stopped

## Contacts/Locations

Study Officials: Robert Harrington, MD  
Study Principal Investigator  
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Lars Wallentin, MD  
Study Principal Investigator  
Uppsala Clinical Research Centre

Jonathan C. Fox, MD  
Study Director  
AstraZeneca

Locations: Argentina  
Research Site  
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Buenos Aires, Buenos Aires, Argentina

Research Site  
Capital Federal, Buenos Aires, Argentina

Research Site  
Ciudad Autonoma de Bs. As., Buenos Aires, Argentina

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Cordoba, Cordoba, Argentina

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Corrientes, Corrientes, Argentina

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Moron, Pcia. de Buenos Aires, Argentina

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Quilmes, Buenos Aires, Argentina

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Rosario, Santa Fe, Argentina

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Salta, Salta, Argentina

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San Miguel de Tucuman, Argentina

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Santa Fe, Santa Fe, Argentina

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Tucuman, Tucuman - Argentina, Argentina

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Bedford Park, South Australia, Australia

Australia, Australian Capital Territory  
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Bruce, Australian Capital Territory, Australia

Australia, Queensland  
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Chermside, Queensland, Australia

Australia, Victoria  
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Dandenong, Victoria, Australia

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Research Site  
Kreuzlingen, Switzerland

Research Site  
Lugano, Switzerland

Research Site  
Mendrisio, Ticino, Switzerland

Taiwan  
Research Site  
Kweishan Shiang, Taoyuan Hsien, Taiwan

Research Site  
Niao-song-shiang, Kaohsiung, Taiwan

Research Site  
Taipei, Taiwan

Thailand  
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Bangkok, Bangkok, Thailand

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Chiang Mai, Thailand, Thailand

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Khon Kaen, Thailand, Thailand

Turkey  
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Ankara, Sihhiye, Turkey

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Antalya, Turkey

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Istanbul, Kartal, Turkey

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Mersin, Turkey

Ukraine  
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Dnepropetrovsk, Ukraine

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Donetsk, Ukraine

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Kharkov, Ukraine

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Kiev, Ukraine

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Makiyivka, Ukraine

United States, New Mexico  
Research Site  
Albuquerque, New Mexico, United States



United States, Texas  
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Amarillo, Texas, United States

United States, South Carolina  
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Anderson, South Carolina, United States

United States, Michigan  
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Ann Arbor, Michigan, United States

United States, Kentucky  
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Ashland, Kentucky, United States

United States, Florida  
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Atlantis, Florida, United States

United States, Maine  
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Auburn, Maine, United States

United States, Texas  
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Austin, Texas, United States

United States, California  
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Bakersfield, California, United States

United States, Maryland  
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Baltimore, Maryland, United States

United States, Maine  
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Bangor, Maine, United States

United States, Oregon  
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Bend, Oregon, United States

United States, Maryland  
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Bethesda, Maryland, United States

United States, California

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Beverly Hills, California, United States

United States, Alabama

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Birmingham, Alabama, United States

United States, Massachusetts

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Boston, Massachusetts, United States

United States, New York

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Brooklyn, New York, United States

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Buffalo, New York, United States

United States, California

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Burbank, California, United States

United States, Vermont

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Burlington, Vermont, United States

United States, Pennsylvania

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Camp Hill, Pennsylvania, United States

United States, North Carolina

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Chapel Hill, North Carolina, United States

United States, South Carolina

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Charleston, South Carolina, United States

United States, North Carolina

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Charlotte, North Carolina, United States

United States, Illinois

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Chicago, Illinois, United States

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Danbury, Connecticut, United States

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United States, Florida  
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Daytona Beach, Florida, United States

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Doylestown, Pennsylvania, United States

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Fort Collins, Colorado, United States

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Fredericksburg, Virginia, United States

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Ft. Lauderdale, Florida, United States

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Green Bay, Wisconsin, United States

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Greensboro, North Carolina, United States

United States, South Carolina  
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Greenville, South Carolina, United States

United States, Pennsylvania  
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Harrisburg, Pennsylvania, United States

United States, Connecticut  
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Hartford, Connecticut, United States

United States, California  
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Healdsburg, California, United States

United States, North Carolina  
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High Point, North Carolina, United States

United States, Florida  
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Hollywood, Florida, United States

United States, Texas

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Houston, Texas, United States

United States, Alabama

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Huntsville, Alabama, United States

United States, Indiana

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Indianapolis, Indiana, United States

United States, Iowa

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Iowa City, Iowa, United States

United States, Tennessee

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Jackson, Tennessee, United States

United States, Florida

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Jacksonville, Florida, United States

United States, New York

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Johnson City, New York, United States

United States, Missouri

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Joplin, Missouri, United States

United States, Florida

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Jupiter, Florida, United States

United States, Michigan

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Kalamazoo, Michigan, United States

United States, Kansas

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Kansas City, Kansas, United States

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Kettering, Ohio, United States

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Kingston, New York, United States

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Knoxville, Tennessee, United States

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Langhorne, Pennsylvania, United States

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Louisville, Kentucky, United States

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Melbourne, Florida, United States

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Memphis, Tennessee, United States

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Miami Beach, Florida, United States

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Mobile, Alabama, United States

United States, West Virginia  
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Morgantown, West Virginia, United States

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Muncie, Indiana, United States

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Rapid City, South Dakota, United States

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San Juan, Puerto Rico, United States

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United States, Indiana  
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Valparaiso, Indiana, United States

United States, Texas  
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Victoria, Texas, United States

United States, Rhode Island  
Research Site

Wakefield, Rhode Island, United States

United States, District of Columbia

Research Site

Washington, District of Columbia, United States

United States, Iowa

Research Site

West Des Moines, Iowa, United States

United States, New York

Research Site

Williamsville, New York, United States

United States, Virginia

Research Site

Winchester, Virginia, United States

United States, North Carolina

Research Site

Winston-salem, North Carolina, United States

United States, Pennsylvania

Research Site

Wormleysburg, Pennsylvania, United States

Research Site

York, Pennsylvania, United States

United States, Michigan

Research Site

Ypsilanti, Michigan, United States

United States, Ohio

Research Site

Zanesville, Ohio, United States

## References

Citations:

Links:

Study Data/Documents:

## Study Results

### Participant Flow

Recruitment Details	The first participant was enrolled on 11 October 2006 and the last participant completed the study on 27 February 2009. Study participants were randomized from 855 centers in 43 countries.
Pre-Assignment Details	Participants will already be hospitalized due to their acute condition, and must be enrolled and randomized within 24 hours of the onset of their most recent cardiac ischemic symptoms. Randomization should take place as soon as possible after presentation.

#### Reporting Groups

	Description
TICAGRELOR	Ticagrelor 90 mg twice daily dose (BD)
CLOPIDOGREL	Clopidogrel 75 mg once daily dose (ODD)

#### Overall Study

	TICAGRELOR	CLOPIDOGREL
Started	9333	9291
Completed	9026	9036
Not Completed	307	255
Protocol Violation	7	2
Withdrawal by Subject	296	249
Reason unknown	2	4
Lost to Follow-up	2	0

### Baseline Characteristics

#### Reporting Groups

	Description
TICAGRELOR	Ticagrelor 90 mg twice daily dose (BD)
CLOPIDOGREL	Clopidogrel 75 mg once daily dose (ODD)

## Baseline Measures

	TICAGRELOR	CLOPIDOGREL	Total
Number of Participants	9333	9291	18624
Age, Continuous [units: years] Mean (Standard Deviation)	62.1 (11.21)	62.3 (11.21)	62.2 (22.42)
Gender, Male/Female [units: Participants]			
Female	2655	2633	5288
Male	6678	6658	13336



## Outcome Measures

### 1. Primary Outcome Measure:

Measure Title	Participants With Any Event From the Composite of Death From Vascular Causes, Myocardial Infarction (MI), and Stroke
Measure Description	Participants with death from vascular causes, MI, or stroke. If no event, censoring occurs at the earliest of patient withdrawal consent or date of scheduled withdrawal from therapy. Intention To Treat (ITT) analysis of whole population. Events were adjudicated by an endpoint committee.
Time Frame	Randomization up to 12 months
Safety Issue?	No

### Analysis Population Description

The population was the full analysis set, which included all randomized patients

### Reporting Groups

	Description
TICAGRELOR	Ticagrelor 90 mg twice daily dose (BD)
CLOPIDOGREL	Clopidogrel 75 mg once daily dose (ODD)

### Measured Values

	TICAGRELOR	CLOPIDOGREL
Number of Participants Analyzed	9333	9291
Participants With Any Event From the Composite of Death From Vascular Causes, Myocardial Infarction (MI), and Stroke	864	1014

	TICAGRELOR	CLOPIDOGREL
[units: Participants]		

## 2. Primary Outcome Measure:

Measure Title	Participants With Any Major Bleeding Event
Measure Description	Participants with major (fatal/life-threatening or other) bleed by a study protocol scale based on need for treatment, number of transfusions, hemoglobin decrease, and other factors. Events were adjudicated by an endpoint committee.
Time Frame	First dosing up to 12 months
Safety Issue?	Yes

### Analysis Population Description

The population was the safety analysis set, which included all randomized patients who took at least one dose of study drug

### Reporting Groups

	Description
TICAGRELOR	Ticagrelor 90 mg twice daily dose (BD)
CLOPIDOGREL	Clopidogrel 75 mg once daily dose (ODD)

### Measured Values

	TICAGRELOR	CLOPIDOGREL
Number of Participants Analyzed	9235	9186
Participants With Any Major Bleeding Event [units: Participants]	961	929

## 3. Secondary Outcome Measure:

Measure Title	Participants With Any Event From the Composite of Death From Vascular Causes, MI, and Stroke for the Subgroup of Patients With Intent for Invasive Management at Randomization
Measure Description	Participants with death from vascular causes, MI, or stroke. If no event, censoring occurs at the earliest of patient withdrawal consent or date of scheduled withdrawal from therapy. ITT analysis of intent for invasive management population. Events were adjudicated by an endpoint committee.
Time Frame	Randomization up to 12 months

Safety Issue?	No
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#### Analysis Population Description

The subgroup of patients with intent for invasive management at randomization

#### Reporting Groups

	Description
TICAGRELOR	Ticagrelor 90 mg twice daily dose (BD)
CLOPIDOGREL	Clopidogrel 75 mg once daily dose (ODD)

#### Measured Values

	TICAGRELOR	CLOPIDOGREL
Number of Participants Analyzed	6732	6676
Participants With Any Event From the Composite of Death From Vascular Causes, MI, and Stroke for the Subgroup of Patients With Intent for Invasive Management at Randomization [units: Participants]	569	668

#### 4. Secondary Outcome Measure:

Measure Title	Participants With Any Event From the Composite of All-cause Mortality, MI, and Stroke
Measure Description	Participants with death from any cause, MI, or stroke. If no event, censoring occurs at the earliest of patient withdrawal of consent or date of scheduled withdrawal from therapy. ITT analysis of whole population. Events were adjudicated by an endpoint committee.
Time Frame	Randomization up to 12 months
Safety Issue?	No

#### Analysis Population Description

The population was the full analysis set, which included all randomized patients

#### Reporting Groups

	Description
TICAGRELOR	Ticagrelor 90 mg twice daily dose (BD)
CLOPIDOGREL	Clopidogrel 75 mg once daily dose (ODD)



#### Measured Values

	TICAGRELOR	CLOPIDOGREL
Number of Participants Analyzed	9333	9291
Participants With Any Event From the Composite of All-cause Mortality, MI, and Stroke [units: Participants]	901	1065

#### 5. Secondary Outcome Measure:

Measure Title	Participants With Any Event From the Composite of Death From Vascular Causes, MI (Including Silent), Stroke, Recurrent Ischemia, Transient Ischemic Attack (TIA) and Other Arterial Thrombotic Events.
Measure Description	Participants with death from vascular causes, MI, stroke, recurrent ischemia, or other thrombotic events. If no event, censoring occurs at the earliest of patient withdrawal consent or date of scheduled withdrawal from therapy. ITT analysis of whole population. Events were adjudicated.
Time Frame	Randomization up to 12 months
Safety Issue?	No

#### Analysis Population Description

The population was the full analysis set, which included all randomized patients

#### Reporting Groups

	Description
TICAGRELOR	Ticagrelor 90 mg twice daily dose (BD)
CLOPIDOGREL	Clopidogrel 75 mg once daily dose (ODD)

#### Measured Values

	TICAGRELOR	CLOPIDOGREL
Number of Participants Analyzed	9333	9291
Participants With Any Event From the Composite of Death From Vascular Causes, MI (Including Silent), Stroke, Recurrent Ischemia, Transient Ischemic Attack (TIA) and Other Arterial Thrombotic Events. [units: Participants]	1290	1456

#### 6. Secondary Outcome Measure:

Measure Title	Participants With MI Event
Measure Description	Participants with MI event. If no event, censoring occurs at the earliest of patient withdrawal consent or date of scheduled withdrawal from therapy. ITT (intention to treat) analysis of whole population. Events were adjudicated by an endpoint committee.
Time Frame	Randomization up to 12 months
Safety Issue?	No

#### Analysis Population Description

The population was the full analysis set, which included all randomized patients

#### Reporting Groups

	Description
TICAGRELOR	Ticagrelor 90 mg twice daily dose (BD)
CLOPIDOGREL	Clopidogrel 75 mg once daily dose (ODD)

#### Measured Values

	TICAGRELOR	CLOPIDOGREL
Number of Participants Analyzed	9333	9291
Participants With MI Event [units: Participants]	504	593

#### 7. Secondary Outcome Measure:

Measure Title	Participants With Death From Vascular Causes
Measure Description	Participants with death from vascular causes. If no event, censoring occurs at the earliest of patient withdrawal consent or date of scheduled withdrawal from therapy. ITT (intention to treat) analysis of whole population. Events were adjudicated by an endpoint committee.
Time Frame	Randomization up to 12 months
Safety Issue?	No

#### Analysis Population Description

The population was the full analysis set, which included all randomized patients

#### Reporting Groups

	Description
TICAGRELOR	Ticagrelor 90 mg twice daily dose (BD)
CLOPIDOGREL	Clopidogrel 75 mg once daily dose (ODD)

#### Measured Values

	TICAGRELOR	CLOPIDOGREL
Number of Participants Analyzed	9333	9291
Participants With Death From Vascular Causes [units: Participants]	353	442

#### 8. Secondary Outcome Measure:

Measure Title	Participants With Stroke
Measure Description	Participants with stroke. If no event, censoring occurs at the earliest of patient withdrawal consent or date of scheduled withdrawal from therapy. ITT (intention to treat) analysis of whole population. Events were adjudicated by an endpoint committee.
Time Frame	Randomization up to 12 months
Safety Issue?	No

#### Analysis Population Description

The population was the full analysis set, which included all randomized patients

#### Reporting Groups

	Description
TICAGRELOR	Ticagrelor 90 mg twice daily dose (BD)
CLOPIDOGREL	Clopidogrel 75 mg once daily dose (ODD)

#### Measured Values

	TICAGRELOR	CLOPIDOGREL
Number of Participants Analyzed	9333	9291
Participants With Stroke [units: Participants]	125	106

9. Secondary Outcome Measure:

Measure Title	Participants With Death From Any Cause
Measure Description	Participants with death from any cause. If no event, censoring occurs at the earliest of patient withdrawal consent or date of scheduled withdrawal from therapy. ITT (intention to treat) analysis of whole population. Events were adjudicated by an endpoint committee.
Time Frame	Randomization up to 12 months
Safety Issue?	No

Analysis Population Description

The population was the full analysis set, which included all randomized patients

Reporting Groups

	Description
TICAGRELOR	Ticagrelor 90 mg twice daily dose (BD)
CLOPIDOGREL	Clopidogrel 75 mg once daily dose (ODD)

Measured Values

	TICAGRELOR	CLOPIDOGREL
Number of Participants Analyzed	9333	9291
Participants With Death From Any Cause [units: Participants]	399	506

10. Secondary Outcome Measure:

Measure Title	Participants With Non-CABG (Coronary Artery Bypass Graft) Related Major Bleeding
Measure Description	Participants with non CABG related major (fatal/life-threatening or other) bleed by a study protocol scale based on need for treatment, number of transfusions, hemoglobin decrease, and other factors. Events were adjudicated by an endpoint committee.
Time Frame	First dosing up to 12 months
Safety Issue?	Yes

Analysis Population Description

The population was the safety analysis set, which included all randomized patients who took at least one dose of study drug

#### Reporting Groups

	Description
TICAGRELOR	Ticagrelor 90 mg twice daily dose (BD)
CLOPIDOGREL	Clopidogrel 75 mg once daily dose (ODD)

#### Measured Values

	TICAGRELOR	CLOPIDOGREL
Number of Participants Analyzed	9235	9186
Participants With Non-CABG (Coronary Artery Bypass Graft) Related Major Bleeding [units: Participants]	362	306

#### 11. Secondary Outcome Measure:

Measure Title	Participants With Major or Minor Bleeding
Measure Description	Participants with major (fatal/life-threatening or other) or minor bleed by a study protocol scale based on need for treatment, number of transfusions, hemoglobin decrease, and other factors. Events were adjudicated by an endpoint committee.
Time Frame	First dosing up to 12 months
Safety Issue?	Yes

#### Analysis Population Description

The population was the safety analysis set, which included all randomized patients who took at least one dose of study drug

#### Reporting Groups

	Description
TICAGRELOR	Ticagrelor 90 mg twice daily dose (BD)
CLOPIDOGREL	Clopidogrel 75 mg once daily dose (ODD)

#### Measured Values

	TICAGRELOR	CLOPIDOGREL
Number of Participants Analyzed	9235	9186
Participants With Major or Minor Bleeding [units: Participants]	1339	1215

12. Secondary Outcome Measure:

Measure Title	Participants With Non-procedural Major Bleeding
Measure Description	Participants with non-procedural major bleed by a study protocol scale based on need for treatment, number of transfusions, hemoglobin decrease, and other factors. Events were adjudicated by an endpoint committee.
Time Frame	First dosing up to 12 months
Safety Issue?	Yes

Analysis Population Description

The population was the safety analysis set, which included all randomized patients who took at least one dose of study drug

Reporting Groups

	Description
TICAGRELOR	Ticagrelor 90 mg twice daily dose (BD)
CLOPIDOGREL	Clopidogrel 75 mg once daily dose (ODD)

Measured Values

	TICAGRELOR	CLOPIDOGREL
Number of Participants Analyzed	9235	9186
Participants With Non-procedural Major Bleeding [units: Participants]	235	180

13. Secondary Outcome Measure:

Measure Title	Participants With Coronary Artery Bypass Graft (CABG) Major Bleeding
Measure Description	Participants with a major CABG-related bleed by a study protocol scale based on need for treatment, number of transfusions, hemoglobin decrease, and other factors. All CABG surgeries were submitted for adjudication by an endpoint committee as potential bleeds.
Time Frame	First dosing up to 12 months
Safety Issue?	Yes

Analysis Population Description

Population is all patients who underwent CABG surgery within 7 days of last dose of active study medication.

#### Reporting Groups

	Description
TICAGRELOR	Ticagrelor 90 mg twice daily dose (BD)
CLOPIDOGREL	Clopidogrel 75 mg once daily dose (ODD)

#### Measured Values

	TICAGRELOR	CLOPIDOGREL
Number of Participants Analyzed	770	814
Participants With Coronary Artery Bypass Graft (CABG) Major Bleeding [units: Participants]	619	654

#### 14. Secondary Outcome Measure:

Measure Title	Participants With Coronary Artery Bypass Graft (CABG) Major Fatal/Life-threatening Bleeding
Measure Description	Number of participants with a major fatal/life-threatening CABG-related bleed by a study protocol scale based on need for treatment, number of transfusions, hemoglobin decrease, and other factors. All CABG surgeries were submitted for adjudication by an endpoint committee as potential bleeds.
Time Frame	First dosing up to 12 months
Safety Issue?	Yes

#### Analysis Population Description

Population is all patients who underwent CABG surgery within 7 days of last dose of active study medication.

#### Reporting Groups

	Description
TICAGRELOR	Ticagrelor 90 mg twice daily dose (BD)
CLOPIDOGREL	Clopidogrel 75 mg once daily dose (ODD)

#### Measured Values

	TICAGRELOR	CLOPIDOGREL
Number of Participants Analyzed	770	814
Participants With Coronary Artery Bypass Graft (CABG) Major Fatal/Life-threatening Bleeding	329	341

	TICAGRELOR	CLOPIDOGREL
[units: Participants]		

15. Secondary Outcome Measure:

Measure Title	Participants With Ventricular Pauses of Greater Than or Equal to 3 Seconds in Patients Monitored by Holter 24-hour ECG Recorders for 1 Week Following Randomization
Measure Description	Number of participants who were observed to have at least 1 ventricular pause of at least 3 seconds. Population is all patients who were observed over 2 week-long periods. Pauses were flagged algorithmically and confirmed by Thrombolysis in Myocardial Infarction (TIMI) group cardiologists.
Time Frame	1-week period following randomization
Safety Issue?	Yes

Analysis Population Description

Participants with Holter data in the week after Randomization

Reporting Groups

	Description
TICAGRELOR	Ticagrelor 90 mg twice daily dose (BD)
CLOPIDOGREL	Clopidogrel 75 mg once daily dose (ODD)

Measured Values

	TICAGRELOR	CLOPIDOGREL
Number of Participants Analyzed	1451	1415
Participants With Ventricular Pauses of Greater Than or Equal to 3 Seconds in Patients Monitored by Holter 24-hour ECG Recorders for 1 Week Following Randomization [units: Participants]	84	51

16. Secondary Outcome Measure:

Measure Title	Participants With Ventricular Pauses of Greater Than or Equal to 3 Seconds in Patients Monitored by Holter 24 Hour ECG Recorders for 1 Week at 1 Month Following Randomization
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Measure Description	Number of participants who were observed to have at least 1 ventricular pause of at least 3 seconds. Population is all patients who were observed over 2 week-long periods. Pauses were flagged algorithmically and confirmed by TIMI cardiologists.
Time Frame	1-week period following randomization
Safety Issue?	Yes

#### Analysis Population Description

Patients who were monitored for one week following randomization (and for one week one month later).

#### Reporting Groups

	Description
TICAGRELOR	Ticagrelor 90 mg twice daily dose (BD)
CLOPIDOGREL	Clopidogrel 75 mg once daily dose (ODD)

#### Measured Values

	TICAGRELOR	CLOPIDOGREL
Number of Participants Analyzed	964	985
Participants With Ventricular Pauses of Greater Than or Equal to 3 Seconds in Patients Monitored by Holter 24 Hour ECG Recorders for 1 Week at 1 Month Following Randomization [units: Participants]	21	16



## Reported Adverse Events

Time Frame	[Not specified]
Additional Description	[Not specified]

#### Reporting Groups

	Description
TICAGRELOR	Ticagrelor 90 mg twice daily dose (BD)
CLOPIDOGREL	Clopidogrel 75 mg once daily dose (ODD)

# Serious Adverse Events

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Total	2108/	2117/
Blood and lymphatic system disorders		
Anaemia <sup>A</sup> †	35/9333 (0.38%)	25/9291 (0.27%)
Coagulopathy <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Disseminated Intravascular Coagulation <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Granulocytopenia <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Haemorrhagic Anaemia <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Hypochromic Anaemia <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Iron Deficiency Anaemia <sup>A</sup> †	2/9333 (0.02%)	6/9291 (0.06%)
Leukocytosis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Leukopenia <sup>A</sup> †	1/9333 (0.01%)	2/9291 (0.02%)
Lymphadenitis <sup>A</sup> †	2/9333 (0.02%)	0/9291 (0%)
Lymphadenopathy <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Microcytic Anaemia <sup>A</sup> †	1/9333 (0.01%)	2/9291 (0.02%)
Nephrogenic Anaemia <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Neutropenia <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Normochromic Normocytic Anaemia <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Pancytopenia <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Polycythaemia <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Splenic Lesion <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Spontaneous Haematoma <sup>A</sup> †	2/9333 (0.02%)	0/9291 (0%)
Thrombocythaemia <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Thrombocytopenia <sup>A</sup> †	7/9333 (0.08%)	8/9291 (0.09%)
Cardiac disorders		
Acute Coronary Syndrome <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Acute Left Ventricular Failure <sup>A</sup> †	3/9333 (0.03%)	2/9291 (0.02%)
Angina Pectoris <sup>A</sup> †	7/9333 (0.08%)	14/9291 (0.15%)
Aortic Valve Stenosis <sup>A</sup> †	2/9333 (0.02%)	3/9291 (0.03%)
Arrhythmia <sup>A</sup> †	8/9333 (0.09%)	4/9291 (0.04%)
Arrhythmia Supraventricular <sup>A</sup> †	1/9333 (0.01%)	2/9291 (0.02%)
Arteriosclerosis Coronary Artery <sup>A</sup> †	0/9333 (0%)	2/9291 (0.02%)
Arteriospasm Coronary <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Atrial Fibrillation <sup>A</sup> †	70/9333 (0.75%)	68/9291 (0.73%)
Atrial Flutter <sup>A</sup> †	11/9333 (0.12%)	7/9291 (0.08%)
Atrial Rupture <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Atrial Tachycardia <sup>A</sup> †	1/9333 (0.01%)	3/9291 (0.03%)
Atrioventricular Block <sup>A</sup> †	3/9333 (0.03%)	5/9291 (0.05%)
Atrioventricular Block Complete <sup>A</sup> †	19/9333 (0.2%)	19/9291 (0.2%)
Atrioventricular Block Second Degree <sup>A</sup> †	4/9333 (0.04%)	0/9291 (0%)
Bradyarrhythmia <sup>A</sup> †	3/9333 (0.03%)	3/9291 (0.03%)
Bradycardia <sup>A</sup> †	26/9333 (0.28%)	31/9291 (0.33%)
Bundle Branch Block <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Bundle Branch Block Left <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Cardiac Aneurysm <sup>A</sup> †	1/9333 (0.01%)	3/9291 (0.03%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Cardiac Arrest <sup>A</sup> †	38/9333 (0.41%)	44/9291 (0.47%)
Cardiac Asthma <sup>A</sup> †	3/9333 (0.03%)	6/9291 (0.06%)
Cardiac Disorder <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Cardiac Failure <sup>A</sup> †	122/9333 (1.31%)	129/9291 (1.39%)
Cardiac Failure Acute <sup>A</sup> †	18/9333 (0.19%)	18/9291 (0.19%)
Cardiac Failure Chronic <sup>A</sup> †	5/9333 (0.05%)	2/9291 (0.02%)
Cardiac Failure Congestive <sup>A</sup> †	51/9333 (0.55%)	46/9291 (0.5%)
Cardiac Tamponade <sup>A</sup> †	11/9333 (0.12%)	16/9291 (0.17%)
Cardiac Valve Disease <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Cardio-Respiratory Arrest <sup>A</sup> †	8/9333 (0.09%)	12/9291 (0.13%)
Cardiogenic Shock <sup>A</sup> †	60/9333 (0.64%)	66/9291 (0.71%)
Cardiomyopathy <sup>A</sup> †	1/9333 (0.01%)	3/9291 (0.03%)
Cardiopulmonary Failure <sup>A</sup> †	1/9333 (0.01%)	2/9291 (0.02%)
Cardiovascular Disorder <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Chordae Tendinae Rupture <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Coronary Artery Disease <sup>A</sup> †	5/9333 (0.05%)	3/9291 (0.03%)
Coronary Artery Dissection <sup>A</sup> †	5/9333 (0.05%)	3/9291 (0.03%)
Coronary Artery Insufficiency <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Coronary Artery Occlusion <sup>A</sup> †	0/9333 (0%)	2/9291 (0.02%)
Coronary Artery Perforation <sup>A</sup> †	3/9333 (0.03%)	0/9291 (0%)
Coronary Artery Stenosis <sup>A</sup> †	2/9333 (0.02%)	1/9291 (0.01%)
Coronary Artery Thrombosis <sup>A</sup> †	2/9333 (0.02%)	3/9291 (0.03%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Cyanosis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Dissecting Coronary Artery Aneurysm <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Dressler's Syndrome <sup>A</sup> †	3/9333 (0.03%)	3/9291 (0.03%)
Electromechanical Dissociation <sup>A</sup> †	3/9333 (0.03%)	4/9291 (0.04%)
Extrasystoles <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Hypertrophic Cardiomyopathy <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Interventricular Septum Rupture <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Intracardiac Thrombus <sup>A</sup> †	13/9333 (0.14%)	15/9291 (0.16%)
Ischaemic Cardiomyopathy <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Left Ventricular Dysfunction <sup>A</sup> †	3/9333 (0.03%)	3/9291 (0.03%)
Left Ventricular Failure <sup>A</sup> †	10/9333 (0.11%)	5/9291 (0.05%)
Long Qt Syndrome <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Low Cardiac Output Syndrome <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Mitral Valve Incompetence <sup>A</sup> †	4/9333 (0.04%)	6/9291 (0.06%)
Myocardial Infarction <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Myocardial Ischaemia <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Myocardial Rupture <sup>A</sup> †	2/9333 (0.02%)	4/9291 (0.04%)
Myocarditis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Nodal Rhythm <sup>A</sup> †	1/9333 (0.01%)	2/9291 (0.02%)
Palpitations <sup>A</sup> †	8/9333 (0.09%)	7/9291 (0.08%)
Papillary Muscle Disorder <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Papillary Muscle Rupture <sup>A</sup> †	2/9333 (0.02%)	1/9291 (0.01%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Pericardial Effusion <sup>A</sup> †	9/9333 (0.1%)	10/9291 (0.11%)
Pericardial Haemorrhage <sup>A</sup> †	3/9333 (0.03%)	2/9291 (0.02%)
Pericarditis <sup>A</sup> †	6/9333 (0.06%)	8/9291 (0.09%)
Right Ventricular Failure <sup>A</sup> †	2/9333 (0.02%)	1/9291 (0.01%)
Sick Sinus Syndrome <sup>A</sup> †	7/9333 (0.08%)	2/9291 (0.02%)
Sinus Arrest <sup>A</sup> †	1/9333 (0.01%)	3/9291 (0.03%)
Sinus Bradycardia <sup>A</sup> †	1/9333 (0.01%)	4/9291 (0.04%)
Stress Cardiomyopathy <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Supraventricular Tachycardia <sup>A</sup> †	8/9333 (0.09%)	8/9291 (0.09%)
Tachyarrhythmia <sup>A</sup> †	4/9333 (0.04%)	4/9291 (0.04%)
Tachycardia <sup>A</sup> †	1/9333 (0.01%)	4/9291 (0.04%)
Torsade De Pointes <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Ventricle Rupture <sup>A</sup> †	2/9333 (0.02%)	3/9291 (0.03%)
Ventricular Arrhythmia <sup>A</sup> †	3/9333 (0.03%)	6/9291 (0.06%)
Ventricular Dysfunction <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Ventricular Extrasystoles <sup>A</sup> †	6/9333 (0.06%)	1/9291 (0.01%)
Ventricular Fibrillation <sup>A</sup> †	48/9333 (0.51%)	64/9291 (0.69%)
Ventricular Tachyarrhythmia <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Ventricular Tachycardia <sup>A</sup> †	29/9333 (0.31%)	33/9291 (0.36%)
Congenital, familial and genetic disorders		
Carbohydrate Metabolism Disorder <sup>A</sup> †	0/9333 (0%)	2/9291 (0.02%)
Diverticulitis Meckel's <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Gastrointestinal Angiodysplasia Haemorrhagic <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Haemorrhagic Arteriovenous Malformation <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Ventricular Septal Defect <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Ear and labyrinth disorders		
Deafness <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Hypoacusis <sup>A</sup> †	2/9333 (0.02%)	0/9291 (0%)
Sudden Hearing Loss <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Tinnitus <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Vertigo <sup>A</sup> †	8/9333 (0.09%)	5/9291 (0.05%)
Vertigo Positional <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Vestibular Neuronitis <sup>A</sup> †	1/9333 (0.01%)	3/9291 (0.03%)
Endocrine disorders		
Goitre <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Hyperthyroidism <sup>A</sup> †	2/9333 (0.02%)	2/9291 (0.02%)
Pituitary-Dependent Cushing's Syndrome <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Thyrotoxic Crisis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Eye disorders		
Amaurosis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Amaurosis Fugax <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Blindness <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Cataract <sup>A</sup> †	3/9333 (0.03%)	2/9291 (0.02%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Cataract Nuclear <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Chorioretinitis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Conjunctival Haemorrhage <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Diabetic Retinopathy <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Diplopia <sup>A</sup> †	2/9333 (0.02%)	1/9291 (0.01%)
Eye Haemorrhage <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Glaucoma <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Macular Degeneration <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Posterior Capsule Opacification <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Retinal Artery Embolism <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Retinal Detachment <sup>A</sup> †	2/9333 (0.02%)	2/9291 (0.02%)
Visual Impairment <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Vitreous Haemorrhage <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Gastrointestinal disorders		
Abdominal Discomfort <sup>A</sup> †	0/9333 (0%)	2/9291 (0.02%)
Abdominal Hernia Obstructive <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Abdominal Pain <sup>A</sup> †	21/9333 (0.23%)	10/9291 (0.11%)
Abdominal Pain Upper <sup>A</sup> †	9/9333 (0.1%)	15/9291 (0.16%)
Anal Fistula <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Anal Haemorrhage <sup>A</sup> †	0/9333 (0%)	3/9291 (0.03%)
Appendicitis Perforated <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Ascites <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)



	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Colitis Ischaemic <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Colitis Ulcerative <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Colonic Polyp <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Constipation <sup>A</sup> †	1/9333 (0.01%)	2/9291 (0.02%)
Dental Caries <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Diarrhoea <sup>A</sup> †	12/9333 (0.13%)	9/9291 (0.1%)
Diarrhoea Haemorrhagic <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Diverticular Perforation <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Diverticulitis Intestinal Haemorrhagic <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Diverticulum <sup>A</sup> †	3/9333 (0.03%)	0/9291 (0%)
Diverticulum Intestinal <sup>A</sup> †	2/9333 (0.02%)	0/9291 (0%)
Diverticulum Intestinal Haemorrhagic <sup>A</sup> †	1/9333 (0.01%)	2/9291 (0.02%)
Duodenal Ulcer <sup>A</sup> †	3/9333 (0.03%)	2/9291 (0.02%)
Duodenal Ulcer Haemorrhage <sup>A</sup> †	10/9333 (0.11%)	2/9291 (0.02%)
Duodenitis <sup>A</sup> †	0/9333 (0%)	2/9291 (0.02%)
Dyspepsia <sup>A</sup> †	6/9333 (0.06%)	5/9291 (0.05%)
Dysphagia <sup>A</sup> †	2/9333 (0.02%)	2/9291 (0.02%)
Enteritis <sup>A</sup> †	0/9333 (0%)	3/9291 (0.03%)
Enterocolitis Haemorrhagic <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Epigastric Discomfort <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Erosive Oesophagitis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Faecal Incontinence <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Faeces Discoloured <sup>A</sup> †	2/9333 (0.02%)	0/9291 (0%)
Food Poisoning <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Gastric Disorder <sup>A</sup> †	0/9333 (0%)	2/9291 (0.02%)
Gastric Haemorrhage <sup>A</sup> †	3/9333 (0.03%)	4/9291 (0.04%)
Gastric Ulcer <sup>A</sup> †	4/9333 (0.04%)	2/9291 (0.02%)
Gastric Ulcer Haemorrhage <sup>A</sup> †	11/9333 (0.12%)	6/9291 (0.06%)
Gastritis <sup>A</sup> †	8/9333 (0.09%)	9/9291 (0.1%)
Gastritis Atrophic <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Gastritis Erosive <sup>A</sup> †	4/9333 (0.04%)	2/9291 (0.02%)
Gastritis Haemorrhagic <sup>A</sup> †	1/9333 (0.01%)	2/9291 (0.02%)
Gastroduodenal Haemorrhage <sup>A</sup> †	2/9333 (0.02%)	0/9291 (0%)
Gastrointestinal Disorder <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Gastrointestinal Haemorrhage <sup>A</sup> †	45/9333 (0.48%)	42/9291 (0.45%)
Gastrointestinal Necrosis <sup>A</sup> †	3/9333 (0.03%)	0/9291 (0%)
Gastrointestinal Pain <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Gastrointestinal Ulcer Haemorrhage <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Gastrooesophageal Reflux Disease <sup>A</sup> †	4/9333 (0.04%)	7/9291 (0.08%)
Gingival Bleeding <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Gingivitis Ulcerative <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Haematemesis <sup>A</sup> †	5/9333 (0.05%)	3/9291 (0.03%)
Haematochezia <sup>A</sup> †	4/9333 (0.04%)	2/9291 (0.02%)
Haemorrhagic Erosive Gastritis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Haemorrhoidal Haemorrhage <sup>A</sup> †	2/9333 (0.02%)	3/9291 (0.03%)
Haemorrhoids <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Hiatus Hernia <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Ileus Paralytic <sup>A</sup> †	2/9333 (0.02%)	0/9291 (0%)
Inguinal Hernia <sup>A</sup> †	4/9333 (0.04%)	4/9291 (0.04%)
Inguinal Hernia Strangulated <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Intestinal Haemorrhage <sup>A</sup> †	1/9333 (0.01%)	2/9291 (0.02%)
Intestinal Ischaemia <sup>A</sup> †	0/9333 (0%)	2/9291 (0.02%)
Intestinal Obstruction <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Intestinal Polyp <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Intra-Abdominal Haemorrhage <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Large Intestine Perforation <sup>A</sup> †	2/9333 (0.02%)	1/9291 (0.01%)
Lower Gastrointestinal Haemorrhage <sup>A</sup> †	1/9333 (0.01%)	4/9291 (0.04%)
Mallory-Weiss Syndrome <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Melaena <sup>A</sup> †	10/9333 (0.11%)	3/9291 (0.03%)
Mesenteric Artery Embolism <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Mouth Haemorrhage <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Nausea <sup>A</sup> †	3/9333 (0.03%)	4/9291 (0.04%)
Oesophageal Food Impaction <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Oesophageal Haemorrhage <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Oesophageal Pain <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Oesophageal Varices Haemorrhage <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Oesophagitis <sup>A</sup> †	1/9333 (0.01%)	2/9291 (0.02%)
Oesophagitis Haemorrhagic <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Pancreatic Disorder <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Pancreatic Haemorrhage <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Pancreatitis <sup>A</sup> †	4/9333 (0.04%)	5/9291 (0.05%)
Pancreatitis Acute <sup>A</sup> †	5/9333 (0.05%)	1/9291 (0.01%)
Pancreatitis Chronic <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Peptic Ulcer <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Peptic Ulcer Haemorrhage <sup>A</sup> †	3/9333 (0.03%)	1/9291 (0.01%)
Peritonitis <sup>A</sup> †	1/9333 (0.01%)	3/9291 (0.03%)
Pneumoperitoneum <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Polyp Colorectal <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Proctitis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Rectal Haemorrhage <sup>A</sup> †	7/9333 (0.08%)	6/9291 (0.06%)
Rectal Polyp <sup>A</sup> †	2/9333 (0.02%)	0/9291 (0%)
Reflux Oesophagitis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Retroperitoneal Fibrosis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Retroperitoneal Haematoma <sup>A</sup> †	3/9333 (0.03%)	3/9291 (0.03%)
Retroperitoneal Haemorrhage <sup>A</sup> †	5/9333 (0.05%)	3/9291 (0.03%)
Small Intestinal Haemorrhage <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Small Intestinal Obstruction <sup>A</sup> †	2/9333 (0.02%)	1/9291 (0.01%)
Small Intestinal Perforation <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Stomach Mass <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Subileus <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Thrombosis Mesenteric Vessel <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Tongue Oedema <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Toothache <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Upper Gastrointestinal Haemorrhage <sup>A</sup> †	9/9333 (0.1%)	7/9291 (0.08%)
Volvulus <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Vomiting <sup>A</sup> †	10/9333 (0.11%)	4/9291 (0.04%)
General disorders		
Accidental Death <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Alcohol Interaction <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Application Site Inflammation <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Asthenia <sup>A</sup> †	6/9333 (0.06%)	4/9291 (0.04%)
Cardiac Death <sup>A</sup> †	3/9333 (0.03%)	1/9291 (0.01%)
Catheter Site Haemorrhage <sup>A</sup> †	1/9333 (0.01%)	2/9291 (0.02%)
Chest Discomfort <sup>A</sup> †	4/9333 (0.04%)	2/9291 (0.02%)
Chest Pain <sup>A</sup> †	54/9333 (0.58%)	63/9291 (0.68%)
Death <sup>A</sup> †	21/9333 (0.23%)	31/9291 (0.33%)
Discomfort <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Fatigue <sup>A</sup> †	1/9333 (0.01%)	2/9291 (0.02%)
Foaming At Mouth <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Gait Disturbance <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
General Physical Health Deterioration <sup>A</sup> †	1/9333 (0.01%)	5/9291 (0.05%)
Generalised Oedema <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Hernia <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Hypothermia <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Impaired Healing <sup>A</sup> †	1/9333 (0.01%)	4/9291 (0.04%)
Inflammation <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Inflammation Of Wound <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Injection Site Haemorrhage <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Injection Site Swelling <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Malaise <sup>A</sup> †	6/9333 (0.06%)	3/9291 (0.03%)
Multi-Organ Failure <sup>A</sup> †	9/9333 (0.1%)	9/9291 (0.1%)
Non-Cardiac Chest Pain <sup>A</sup> †	101/9333 (1.08%)	103/9291 (1.11%)
Oedema Peripheral <sup>A</sup> †	4/9333 (0.04%)	1/9291 (0.01%)
Pain <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Pelvic Mass <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Puncture Site Haemorrhage <sup>A</sup> †	4/9333 (0.04%)	1/9291 (0.01%)
Pyrexia <sup>A</sup> †	10/9333 (0.11%)	5/9291 (0.05%)
Sudden Cardiac Death <sup>A</sup> †	14/9333 (0.15%)	25/9291 (0.27%)
Sudden Death <sup>A</sup> †	17/9333 (0.18%)	27/9291 (0.29%)
Systemic Inflammatory Response Syndrome <sup>A</sup> †	1/9333 (0.01%)	2/9291 (0.02%)
Ulcer Haemorrhage <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Unevaluable Event <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Vessel Puncture Site Haematoma <sup>A</sup> †	8/9333 (0.09%)	12/9291 (0.13%)
Vessel Puncture Site Haemorrhage <sup>A</sup> †	9/9333 (0.1%)	6/9291 (0.06%)
Hepatobiliary disorders		
Bile Duct Obstruction <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Bile Duct Stone <sup>A</sup> †	2/9333 (0.02%)	2/9291 (0.02%)
Biliary Colic <sup>A</sup> †	1/9333 (0.01%)	2/9291 (0.02%)
Cholangitis <sup>A</sup> †	1/9333 (0.01%)	2/9291 (0.02%)
Cholecystitis <sup>A</sup> †	7/9333 (0.08%)	10/9291 (0.11%)
Cholecystitis Acute <sup>A</sup> †	5/9333 (0.05%)	7/9291 (0.08%)
Cholecystitis Chronic <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Cholelithiasis <sup>A</sup> †	9/9333 (0.1%)	9/9291 (0.1%)
Cholestasis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Gallbladder Disorder <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Gallbladder Necrosis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Hepatic Cirrhosis <sup>A</sup> †	1/9333 (0.01%)	2/9291 (0.02%)
Hepatic Failure <sup>A</sup> †	2/9333 (0.02%)	4/9291 (0.04%)
Hepatic Function Abnormal <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Hepatitis Toxic <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Hepatocellular Injury <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Ischaemic Hepatitis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Jaundice <sup>A</sup> †	0/9333 (0%)	2/9291 (0.02%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Liver Disorder <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Immune system disorders		
Allergy To Arthropod Bite <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Anaphylactic Reaction <sup>A</sup> †	0/9333 (0%)	3/9291 (0.03%)
Anaphylactic Shock <sup>A</sup> †	3/9333 (0.03%)	1/9291 (0.01%)
Contrast Media Allergy <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Drug Hypersensitivity <sup>A</sup> †	1/9333 (0.01%)	3/9291 (0.03%)
Hypersensitivity <sup>A</sup> †	1/9333 (0.01%)	2/9291 (0.02%)
Infections and infestations		
Abdominal Abscess <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Abdominal Wall Infection <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Abscess <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Abscess Limb <sup>A</sup> †	2/9333 (0.02%)	0/9291 (0%)
Acquired Immunodeficiency Syndrome <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Acute Sinusitis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Acute Tonsillitis <sup>A</sup> †	2/9333 (0.02%)	0/9291 (0%)
Anal Abscess <sup>A</sup> †	2/9333 (0.02%)	2/9291 (0.02%)
Appendicitis <sup>A</sup> †	6/9333 (0.06%)	2/9291 (0.02%)
Arthritis Bacterial <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Arthritis Infective <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Bacteraemia <sup>A</sup> †	2/9333 (0.02%)	1/9291 (0.01%)
Bacterial Infection <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)



	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Breast Abscess <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Bronchiectasis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Bronchitis <sup>A</sup> †	13/9333 (0.14%)	15/9291 (0.16%)
Bronchitis Viral <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Bronchopneumonia <sup>A</sup> †	10/9333 (0.11%)	4/9291 (0.04%)
Catheter Related Infection <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Catheter Site Infection <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Cellulitis <sup>A</sup> †	9/9333 (0.1%)	9/9291 (0.1%)
Cholecystitis Infective <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Clostridium Difficile Colitis <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Cystitis <sup>A</sup> †	3/9333 (0.03%)	2/9291 (0.02%)
Dengue Fever <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Device Related Infection <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Diarrhoea Infectious <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Diverticulitis <sup>A</sup> †	7/9333 (0.08%)	8/9291 (0.09%)
Endocarditis <sup>A</sup> †	3/9333 (0.03%)	2/9291 (0.02%)
Endometritis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Enterococcal Infection <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Enterocolitis Infectious <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Erysipelas <sup>A</sup> †	4/9333 (0.04%)	4/9291 (0.04%)
Febrile Infection <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Gangrene <sup>A</sup> †	2/9333 (0.02%)	3/9291 (0.03%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Gastric Infection <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Gastroenteritis <sup>A</sup> †	17/9333 (0.18%)	11/9291 (0.12%)
Gastroenteritis Caliciviral <sup>A</sup> †	2/9333 (0.02%)	0/9291 (0%)
Gastroenteritis Rotavirus <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Gastroenteritis Salmonella <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Gastroenteritis Viral <sup>A</sup> †	2/9333 (0.02%)	0/9291 (0%)
Gastrointestinal Infection <sup>A</sup> †	3/9333 (0.03%)	1/9291 (0.01%)
Groin Abscess <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Groin Infection <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Haematoma Infection <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Helicobacter Gastritis <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Hepatitis Viral <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Herpes Zoster <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Histoplasmosis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Impetigo <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Incision Site Abscess <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Incision Site Infection <sup>A</sup> †	2/9333 (0.02%)	1/9291 (0.01%)
Infected Skin Ulcer <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Infection <sup>A</sup> †	1/9333 (0.01%)	5/9291 (0.05%)
Infective Exacerbation Of Chronic Obstructive Airways Disease <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Infective Tenosynovitis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Inguinal Hernia Gangrenous <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Injection Site Cellulitis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Intervertebral Discitis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Laryngitis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Liver Abscess <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Lobar Pneumonia <sup>A</sup> †	0/9333 (0%)	2/9291 (0.02%)
Localised Infection <sup>A</sup> †	0/9333 (0%)	2/9291 (0.02%)
Lower Respiratory Tract Infection <sup>A</sup> †	3/9333 (0.03%)	4/9291 (0.04%)
Lung Infection <sup>A</sup> †	5/9333 (0.05%)	4/9291 (0.04%)
Lyme Disease <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Mediastinitis <sup>A</sup> †	11/9333 (0.12%)	4/9291 (0.04%)
Meningitis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Necrotising Fasciitis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Orchitis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Osteomyelitis <sup>A</sup> †	3/9333 (0.03%)	3/9291 (0.03%)
Pancreatic Abscess <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Perineal Abscess <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Pharyngitis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Pneumococcal Sepsis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Pneumonia <sup>A</sup> †	69/9333 (0.74%)	95/9291 (1.02%)
Pneumonia Staphylococcal <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Post Procedural Cellulitis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Post Procedural Infection <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Post Procedural Sepsis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Postoperative Wound Infection <sup>A</sup> †	9/9333 (0.1%)	3/9291 (0.03%)
Pulmonary Sepsis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Pulmonary Tuberculosis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Puncture Site Abscess <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Puncture Site Infection <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Pyelonephritis <sup>A</sup> †	3/9333 (0.03%)	2/9291 (0.02%)
Pyelonephritis Acute <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Pyothorax <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Rectal Abscess <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Renal Abscess <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Respiratory Tract Infection <sup>A</sup> †	9/9333 (0.1%)	5/9291 (0.05%)
Retroperitoneal Abscess <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Sepsis <sup>A</sup> †	17/9333 (0.18%)	27/9291 (0.29%)
Septic Shock <sup>A</sup> †	5/9333 (0.05%)	10/9291 (0.11%)
Sinusitis <sup>A</sup> †	2/9333 (0.02%)	0/9291 (0%)
Skin Infection <sup>A</sup> †	2/9333 (0.02%)	2/9291 (0.02%)
Staphylococcal Infection <sup>A</sup> †	2/9333 (0.02%)	0/9291 (0%)
Staphylococcal Mediastinitis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Staphylococcal Sepsis <sup>A</sup> †	3/9333 (0.03%)	1/9291 (0.01%)
Sterinitis <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Subcutaneous Abscess <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Syphilis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Tooth Abscess <sup>A</sup> †	0/9333 (0%)	2/9291 (0.02%)
Tooth Infection <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Tracheitis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Tracheobronchitis <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Upper Respiratory Tract Infection <sup>A</sup> †	3/9333 (0.03%)	3/9291 (0.03%)
Urinary Tract Infection <sup>A</sup> †	25/9333 (0.27%)	19/9291 (0.2%)
Urosepsis <sup>A</sup> †	4/9333 (0.04%)	2/9291 (0.02%)
Viral Myocarditis <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Viral Pericarditis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Wound Infection <sup>A</sup> †	7/9333 (0.08%)	8/9291 (0.09%)
Injury, poisoning and procedural complications		
Alanine Aminotransferase Increased <sup>A</sup> †	1/9333 (0.01%)	3/9291 (0.03%)
Alcohol Poisoning <sup>A</sup> †	2/9333 (0.02%)	0/9291 (0%)
Anaemia Postoperative <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Angiogram <sup>A</sup> †	2/9333 (0.02%)	0/9291 (0%)
Ankle Fracture <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Antiphospholipid Antibodies <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Aspartate Aminotransferase Increased <sup>A</sup> †	1/9333 (0.01%)	4/9291 (0.04%)
Blood Creatine Phosphokinase Increased <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Blood Creatinine Increased <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Blood Glucose Increased <sup>A</sup> †	2/9333 (0.02%)	1/9291 (0.01%)
Blood Potassium Decreased <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Blood Potassium Increased <sup>A</sup> †	0/9333 (0%)	2/9291 (0.02%)
Blood Pressure Decreased <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Blood Pressure Increased <sup>A</sup> †	3/9333 (0.03%)	3/9291 (0.03%)
Blood Sodium Decreased <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Blood Urine Present <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Body Temperature Increased <sup>A</sup> †	2/9333 (0.02%)	0/9291 (0%)
Brain Contusion <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
C-Reactive Protein Increased <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Cardiac Enzymes Increased <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Cardiac Pacemaker Malfunction <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Cardiac Procedure Complication <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Cardiac Stress Test Abnormal <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Chest Injury <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Clavicle Fracture <sup>A</sup> †	0/9333 (0%)	2/9291 (0.02%)
Concussion <sup>A</sup> †	2/9333 (0.02%)	2/9291 (0.02%)
Contrast Media Reaction <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Contusion <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Coronary Artery Reocclusion <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Coronary Artery Restenosis <sup>A</sup> †	4/9333 (0.04%)	9/9291 (0.1%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Device Breakage <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Device Dislocation <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Device Malfunction <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Device Migration <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Electrocardiogram Qt Prolonged <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Electrocardiogram T Wave Inversion <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Facial Bones Fracture <sup>A</sup> †	2/9333 (0.02%)	1/9291 (0.01%)
Fall <sup>A</sup> †	1/9333 (0.01%)	5/9291 (0.05%)
Fat Embolism <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Femoral Neck Fracture <sup>A</sup> †	3/9333 (0.03%)	5/9291 (0.05%)
Femur Fracture <sup>A</sup> †	3/9333 (0.03%)	7/9291 (0.08%)
Fibrin D Dimer Increased <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Foot Fracture <sup>A</sup> †	0/9333 (0%)	2/9291 (0.02%)
Forearm Fracture <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Fracture <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Fractured Ischium <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Graft Thrombosis <sup>A</sup> †	0/9333 (0%)	2/9291 (0.02%)
Haemoglobin Decreased <sup>A</sup> †	6/9333 (0.06%)	8/9291 (0.09%)
Hand Fracture <sup>A</sup> †	3/9333 (0.03%)	0/9291 (0%)
Head Injury <sup>A</sup> †	1/9333 (0.01%)	3/9291 (0.03%)
Heart Rate Increased <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Hepatic Enzyme Increased <sup>A</sup> †	2/9333 (0.02%)	2/9291 (0.02%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Hip Fracture <sup>A</sup> †	4/9333 (0.04%)	2/9291 (0.02%)
Humerus Fracture <sup>A</sup> †	2/9333 (0.02%)	1/9291 (0.01%)
Implantable Defibrillator Malfunction <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
In-Stent Arterial Restenosis <sup>A</sup> †	10/9333 (0.11%)	12/9291 (0.13%)
In-Stent Coronary Artery Restenosis <sup>A</sup> †	35/9333 (0.38%)	25/9291 (0.27%)
Incision Site Haemorrhage <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Incisional Hernia <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Injury <sup>A</sup> †	1/9333 (0.01%)	3/9291 (0.03%)
International Normalised Ratio Increased <sup>A</sup> †	1/9333 (0.01%)	2/9291 (0.02%)
Intraocular Pressure Increased <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Joint Dislocation <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Joint Injury <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Joint Sprain <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Ligament Rupture <sup>A</sup> †	2/9333 (0.02%)	0/9291 (0%)
Limb Injury <sup>A</sup> †	2/9333 (0.02%)	0/9291 (0%)
Limb Traumatic Amputation <sup>A</sup> †	2/9333 (0.02%)	0/9291 (0%)
Liver Function Test Abnormal <sup>A</sup> †	2/9333 (0.02%)	3/9291 (0.03%)
Lower Limb Fracture <sup>A</sup> †	0/9333 (0%)	4/9291 (0.04%)
Lumbar Vertebral Fracture <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Meniscus Lesion <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Occult Blood <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Open Wound <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)



	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Operative Haemorrhage <sup>A</sup> †	2/9333 (0.02%)	3/9291 (0.03%)
Overdose <sup>A</sup> †	2/9333 (0.02%)	0/9291 (0%)
Pancreatic Enzymes Increased <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Pelvic Fracture <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Platelet Count Decreased <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Post Procedural Complication <sup>A</sup> †	4/9333 (0.04%)	4/9291 (0.04%)
Post Procedural Haematoma <sup>A</sup> †	7/9333 (0.08%)	1/9291 (0.01%)
Post Procedural Haematuria <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Post Procedural Haemorrhage <sup>A</sup> †	56/9333 (0.6%)	47/9291 (0.51%)
Postoperative Thoracic Procedure Complication <sup>A</sup> †	3/9333 (0.03%)	3/9291 (0.03%)
Postoperative Thrombosis <sup>A</sup> †	1/9333 (0.01%)	2/9291 (0.02%)
Postoperative Wound Complication <sup>A</sup> †	2/9333 (0.02%)	3/9291 (0.03%)
Postpericardiotomy Syndrome <sup>A</sup> †	5/9333 (0.05%)	2/9291 (0.02%)
Procedural Complication <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Procedural Hypotension <sup>A</sup> †	0/9333 (0%)	2/9291 (0.02%)
Procedural Pain <sup>A</sup> †	3/9333 (0.03%)	0/9291 (0%)
Prostatic Specific Antigen Abnormal <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Prostatic Specific Antigen Increased <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Radius Fracture <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Renal Injury <sup>A</sup> †	1/9333 (0.01%)	2/9291 (0.02%)
Rib Fracture <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Road Traffic Accident <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Scrotal Haematoma <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Spinal Compression Fracture <sup>A</sup> †	2/9333 (0.02%)	2/9291 (0.02%)
Stent Occlusion <sup>A</sup> †	1/9333 (0.01%)	2/9291 (0.02%)
Subcutaneous Haematoma <sup>A</sup> †	3/9333 (0.03%)	0/9291 (0%)
Subdural Haematoma <sup>A</sup> †	4/9333 (0.04%)	2/9291 (0.02%)
Suture Rupture <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Tendon Rupture <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Thermal Burn <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Thrombosis In Device <sup>A</sup> †	35/9333 (0.38%)	57/9291 (0.61%)
Tibia Fracture <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Tracheal Haemorrhage <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Tracheal Obstruction <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Transfusion Reaction <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Traumatic Haemorrhage <sup>A</sup> †	1/9333 (0.01%)	2/9291 (0.02%)
Traumatic Intracranial Haemorrhage <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Troponin Increased <sup>A</sup> †	1/9333 (0.01%)	2/9291 (0.02%)
Ulna Fracture <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Upper Limb Fracture <sup>A</sup> †	1/9333 (0.01%)	2/9291 (0.02%)
Urinary Bladder Rupture <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Urinary Retention Postoperative <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Vascular Graft Occlusion <sup>A</sup> †	2/9333 (0.02%)	0/9291 (0%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Vascular Procedure Complication <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Vascular Pseudoaneurysm <sup>A</sup> †	15/9333 (0.16%)	23/9291 (0.25%)
Vascular Pseudoaneurysm Ruptured <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Vertebral Injury <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Weaning Failure <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Weight Decreased <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Wound Complication <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Wound Dehiscence <sup>A</sup> †	3/9333 (0.03%)	2/9291 (0.02%)
Wrist Fracture <sup>A</sup> †	4/9333 (0.04%)	0/9291 (0%)
Metabolism and nutrition disorders		
Anorexia <sup>A</sup> †	3/9333 (0.03%)	0/9291 (0%)
Dehydration <sup>A</sup> †	11/9333 (0.12%)	5/9291 (0.05%)
Diabetes Mellitus <sup>A</sup> †	6/9333 (0.06%)	7/9291 (0.08%)
Diabetes Mellitus Inadequate Control <sup>A</sup> †	3/9333 (0.03%)	9/9291 (0.1%)
Diabetic Foot <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Diabetic Ketoacidosis <sup>A</sup> †	2/9333 (0.02%)	1/9291 (0.01%)
Electrolyte Depletion <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Failure To Thrive <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Fluid Overload <sup>A</sup> †	0/9333 (0%)	2/9291 (0.02%)
Gout <sup>A</sup> †	2/9333 (0.02%)	2/9291 (0.02%)
Hyperglycaemia <sup>A</sup> †	7/9333 (0.08%)	2/9291 (0.02%)
Hyperkalaemia <sup>A</sup> †	1/9333 (0.01%)	4/9291 (0.04%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Hyperosmolar State <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Hypoglycaemia <sup>A</sup> †	11/9333 (0.12%)	8/9291 (0.09%)
Hypokalaemia <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Hyponatraemia <sup>A</sup> †	3/9333 (0.03%)	1/9291 (0.01%)
Hypovolaemia <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Ketoacidosis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Metabolic Acidosis <sup>A</sup> †	0/9333 (0%)	2/9291 (0.02%)
Metabolic Disorder <sup>A</sup> †	0/9333 (0%)	2/9291 (0.02%)
Metabolic Syndrome <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Type 2 Diabetes Mellitus <sup>A</sup> †	2/9333 (0.02%)	2/9291 (0.02%)
Musculoskeletal and connective tissue disorders		
Arthralgia <sup>A</sup> †	3/9333 (0.03%)	4/9291 (0.04%)
Arthritis <sup>A</sup> †	2/9333 (0.02%)	2/9291 (0.02%)
Back Pain <sup>A</sup> †	3/9333 (0.03%)	6/9291 (0.06%)
Bone Pain <sup>A</sup> †	1/9333 (0.01%)	2/9291 (0.02%)
Bursitis <sup>A</sup> †	2/9333 (0.02%)	1/9291 (0.01%)
Chondropathy <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Costochondritis <sup>A</sup> †	2/9333 (0.02%)	1/9291 (0.01%)
Dupuytren's Contracture <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Gouty Arthritis <sup>A</sup> †	2/9333 (0.02%)	0/9291 (0%)
Groin Pain <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Intervertebral Disc Degeneration <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Intervertebral Disc Disorder <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Intervertebral Disc Protrusion <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Joint Swelling <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Lumbar Spinal Stenosis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Monarthritis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Muscle Tightness <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Muscular Weakness <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Musculoskeletal Chest Pain <sup>A</sup> †	15/9333 (0.16%)	16/9291 (0.17%)
Musculoskeletal Pain <sup>A</sup> †	5/9333 (0.05%)	4/9291 (0.04%)
Myalgia <sup>A</sup> †	3/9333 (0.03%)	3/9291 (0.03%)
Myalgia Intercostal <sup>A</sup> †	2/9333 (0.02%)	0/9291 (0%)
Myositis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Neck Pain <sup>A</sup> †	1/9333 (0.01%)	2/9291 (0.02%)
Osteoarthritis <sup>A</sup> †	7/9333 (0.08%)	5/9291 (0.05%)
Osteochondrosis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Osteolysis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Osteoporosis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Pain In Extremity <sup>A</sup> †	3/9333 (0.03%)	2/9291 (0.02%)
Pain In Jaw <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Pathological Fracture <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Polyarthritis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Polymyalgia Rheumatica <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Polymyositis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Rhabdomyolysis <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Rheumatoid Arthritis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Spinal Disorder <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Spinal Osteoarthritis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Wrist Deformity <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Abdominal Neoplasm <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Acute Myeloid Leukaemia <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Adenocarcinoma <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Adenocarcinoma Pancreas <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
B-Cell Lymphoma <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Benign Duodenal Neoplasm <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Benign Neoplasm Of Skin <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Benign Uterine Neoplasm <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Bladder Cancer <sup>A</sup> †	2/9333 (0.02%)	6/9291 (0.06%)
Bladder Cancer Recurrent <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Bladder Neoplasm <sup>A</sup> †	0/9333 (0%)	3/9291 (0.03%)
Bladder Transitional Cell Carcinoma <sup>A</sup> †	2/9333 (0.02%)	1/9291 (0.01%)
Bone Neoplasm Malignant <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Brain Cancer Metastatic <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Brain Neoplasm <sup>A</sup> †	1/9333 (0.01%)	3/9291 (0.03%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Breast Cancer <sup>A</sup> †	3/9333 (0.03%)	9/9291 (0.1%)
Breast Cancer Metastatic <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Bronchial Carcinoma <sup>A</sup> †	1/9333 (0.01%)	3/9291 (0.03%)
Bronchial Neoplasm <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Carcinoid Tumour Of The Caecum <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Carcinoid Tumour Of The Duodenum <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Chronic Leukaemia <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Chronic Lymphocytic Leukaemia <sup>A</sup> †	2/9333 (0.02%)	1/9291 (0.01%)
Colon Adenoma <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Colon Cancer <sup>A</sup> †	10/9333 (0.11%)	3/9291 (0.03%)
Colon Neoplasm <sup>A</sup> †	1/9333 (0.01%)	5/9291 (0.05%)
Colorectal Cancer <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Endometrial Cancer <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Extranodal Marginal Zone B-Cell Lymphoma (Malt Type) <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Gastric Cancer <sup>A</sup> †	3/9333 (0.03%)	3/9291 (0.03%)
Gastric Neoplasm <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Gastrointestinal Carcinoma <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Gastrointestinal Neoplasm <sup>A</sup> †	2/9333 (0.02%)	0/9291 (0%)
Glioblastoma <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Haemangioma Of Liver <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Hepatic Cancer Metastatic <sup>A</sup> †	2/9333 (0.02%)	1/9291 (0.01%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Hepatic Neoplasm <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Intestinal Adenocarcinoma <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Laryngeal Cancer <sup>A</sup> †	0/9333 (0%)	2/9291 (0.02%)
Lip And/Or Oral Cavity Cancer <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Lung Adenocarcinoma <sup>A</sup> †	2/9333 (0.02%)	0/9291 (0%)
Lung Cancer Metastatic <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Lung Neoplasm <sup>A</sup> †	7/9333 (0.08%)	5/9291 (0.05%)
Lung Neoplasm Malignant <sup>A</sup> †	6/9333 (0.06%)	10/9291 (0.11%)
Lymphangiosis Carcinomatosa <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Lymphocytic Lymphoma <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Lymphoma <sup>A</sup> †	2/9333 (0.02%)	1/9291 (0.01%)
Malignant Melanoma <sup>A</sup> †	1/9333 (0.01%)	2/9291 (0.02%)
Malignant Pleural Effusion <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Meningioma <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Metastases To Bone <sup>A</sup> †	1/9333 (0.01%)	2/9291 (0.02%)
Metastases To Central Nervous System <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Metastases To Liver <sup>A</sup> †	0/9333 (0%)	3/9291 (0.03%)
Metastases To Lung <sup>A</sup> †	0/9333 (0%)	2/9291 (0.02%)
Metastases To Lymph Nodes <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Metastatic Neoplasm <sup>A</sup> †	2/9333 (0.02%)	0/9291 (0%)
Myelodysplastic Syndrome <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Neoplasm Malignant <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)



	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Neoplasm Prostate <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Nipple Neoplasm <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Oesophageal Carcinoma <sup>A</sup> †	0/9333 (0%)	2/9291 (0.02%)
Ovarian Cancer <sup>A</sup> †	2/9333 (0.02%)	1/9291 (0.01%)
Pancreatic Carcinoma Recurrent <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Pleural Mesothelioma <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Polycythaemia Vera <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Prostate Cancer <sup>A</sup> †	6/9333 (0.06%)	8/9291 (0.09%)
Prostate Cancer Metastatic <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Prostate Cancer Recurrent <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Prostatic Adenoma <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Rectal Cancer <sup>A</sup> †	3/9333 (0.03%)	2/9291 (0.02%)
Rectal Cancer Metastatic <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Renal Cancer <sup>A</sup> †	2/9333 (0.02%)	1/9291 (0.01%)
Renal Cancer Metastatic <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Renal Neoplasm <sup>A</sup> †	5/9333 (0.05%)	3/9291 (0.03%)
Retroperitoneal Neoplasm <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Small Cell Lung Cancer Metastatic <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Small Cell Lung Cancer Stage Unspecified <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Spinal Cord Neoplasm <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Squamous Cell Carcinoma <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Testis Cancer <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Thyroid Adenoma <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Thyroid Cancer Metastatic <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Thyroid Neoplasm <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Tongue Neoplasm <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Transitional Cell Carcinoma <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Uterine Leiomyoma <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Nervous system disorders		
Altered State Of Consciousness <sup>A</sup> †	0/9333 (0%)	2/9291 (0.02%)
Balance Disorder <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Brain Oedema <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Brain Stem Infarction <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Brain Stem Ischaemia <sup>A</sup> †	0/9333 (0%)	2/9291 (0.02%)
Brain Stem Stroke <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Carotid Artery Disease <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Carotid Artery Occlusion <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Carotid Artery Stenosis <sup>A</sup> †	3/9333 (0.03%)	2/9291 (0.02%)
Carotid Artery Thrombosis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Carotid Sinus Syndrome <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Central Nervous System Lesion <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Cerebellar Infarction <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Cerebral Atrophy <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Cerebral Disorder <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Cerebral Haemorrhage <sup>A</sup> †	9/9333 (0.1%)	3/9291 (0.03%)
Cerebral Infarction <sup>A</sup> †	7/9333 (0.08%)	8/9291 (0.09%)
Cerebral Ischaemia <sup>A</sup> †	2/9333 (0.02%)	1/9291 (0.01%)
Cerebrovascular Accident <sup>A</sup> †	75/9333 (0.8%)	50/9291 (0.54%)
Cerebrovascular Disorder <sup>A</sup> †	0/9333 (0%)	2/9291 (0.02%)
Cerebrovascular Insufficiency <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Cervicobrachial Syndrome <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Cognitive Disorder <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Complex Partial Seizures <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Convulsion <sup>A</sup> †	3/9333 (0.03%)	3/9291 (0.03%)
Dementia <sup>A</sup> †	0/9333 (0%)	2/9291 (0.02%)
Depressed Level Of Consciousness <sup>A</sup> †	0/9333 (0%)	3/9291 (0.03%)
Diabetic Hyperosmolar Coma <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Diabetic Neuropathy <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Dizziness <sup>A</sup> †	13/9333 (0.14%)	7/9291 (0.08%)
Dysphasia <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Embolic Cerebral Infarction <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Encephalitis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Encephalopathy <sup>A</sup> †	2/9333 (0.02%)	1/9291 (0.01%)
Epilepsy <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Extrapyramidal Disorder <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Facial Paresis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Febrile Convulsion <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Haemorrhage Intracranial <sup>A</sup> †	5/9333 (0.05%)	2/9291 (0.02%)
Haemorrhagic Cerebral Infarction <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Haemorrhagic Stroke <sup>A</sup> †	6/9333 (0.06%)	7/9291 (0.08%)
Headache <sup>A</sup> †	6/9333 (0.06%)	3/9291 (0.03%)
Hemiparesis <sup>A</sup> †	4/9333 (0.04%)	2/9291 (0.02%)
Hepatic Encephalopathy <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Hypoaesthesia <sup>A</sup> †	2/9333 (0.02%)	3/9291 (0.03%)
Hypotonia <sup>A</sup> †	3/9333 (0.03%)	0/9291 (0%)
Hypoxic Encephalopathy <sup>A</sup> †	0/9333 (0%)	2/9291 (0.02%)
Intracranial Haematoma <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Ischaemic Cerebral Infarction <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Ischaemic Stroke <sup>A</sup> †	20/9333 (0.21%)	28/9291 (0.3%)
Lacunar Infarction <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Loss Of Consciousness <sup>A</sup> †	4/9333 (0.04%)	2/9291 (0.02%)
Lumbar Radiculopathy <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Mental Impairment <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Migraine <sup>A</sup> †	3/9333 (0.03%)	1/9291 (0.01%)
Myelitis Transverse <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Narcolepsy <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Neuralgia <sup>A</sup> †	2/9333 (0.02%)	0/9291 (0%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Paraesthesia <sup>A</sup> †	5/9333 (0.05%)	4/9291 (0.04%)
Parkinson's Disease <sup>A</sup> †	1/9333 (0.01%)	4/9291 (0.04%)
Parkinsonism <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Partial Seizures <sup>A</sup> †	2/9333 (0.02%)	0/9291 (0%)
Phrenic Nerve Paralysis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Post Herpetic Neuralgia <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Presyncope <sup>A</sup> †	8/9333 (0.09%)	2/9291 (0.02%)
Progressive Supranuclear Palsy <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Psychomotor Hyperactivity <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Sciatica <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Speech Disorder <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Spinal Cord Compression <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Spinal Cord Disorder <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Subarachnoid Haemorrhage <sup>A</sup> †	4/9333 (0.04%)	2/9291 (0.02%)
Syncope <sup>A</sup> †	32/9333 (0.34%)	30/9291 (0.32%)
Syncope Vasovagal <sup>A</sup> †	4/9333 (0.04%)	2/9291 (0.02%)
Thalamus Haemorrhage <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Thrombotic Stroke <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Transient Ischaemic Attack <sup>A</sup> †	19/9333 (0.2%)	23/9291 (0.25%)
Vascular Encephalopathy <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Vertebrobasilar Insufficiency <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Vith Nerve Paralysis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Vocal Cord Paresis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Psychiatric disorders		
Acute Stress Disorder <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Agitation <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Alcohol Abuse <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Alcoholism <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Anxiety <sup>A</sup> †	9/9333 (0.1%)	6/9291 (0.06%)
Anxiety Disorder <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Completed Suicide <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Confusional State <sup>A</sup> †	4/9333 (0.04%)	2/9291 (0.02%)
Delirium <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Depression <sup>A</sup> †	9/9333 (0.1%)	7/9291 (0.08%)
Drug Abuse <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Insomnia <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Mania <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Mental Disorder <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Nervousness <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Neurosis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Panic Attack <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Post-Traumatic Amnestic Disorder <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Psychotic Disorder <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Schizophrenia, Paranoid Type <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Sleep Disorder <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Suicidal Ideation <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Suicide Attempt <sup>A</sup> †	1/9333 (0.01%)	2/9291 (0.02%)
Tension <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Transient Psychosis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Renal and urinary disorders		
Anuria <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Azotaemia <sup>A</sup> †	2/9333 (0.02%)	1/9291 (0.01%)
Bladder Mass <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Bladder Prolapse <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Bladder Tamponade <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Calculus Bladder <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Calculus Ureteric <sup>A</sup> †	2/9333 (0.02%)	4/9291 (0.04%)
Calculus Urethral <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Calculus Urinary <sup>A</sup> †	0/9333 (0%)	3/9291 (0.03%)
Cystitis Haemorrhagic <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Cystitis Noninfective <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Dysuria <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Glomerulonephritis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Glomerulonephritis Membranous <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Glomerulonephritis Minimal Lesion <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Haematuria <sup>A</sup> †	15/9333 (0.16%)	10/9291 (0.11%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Haemorrhage Urinary Tract <sup>A</sup> †	3/9333 (0.03%)	1/9291 (0.01%)
Hydronephrosis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Nephritis Autoimmune <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Nephrolithiasis <sup>A</sup> †	3/9333 (0.03%)	3/9291 (0.03%)
Nephropathy Toxic <sup>A</sup> †	3/9333 (0.03%)	2/9291 (0.02%)
Nephrotic Syndrome <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Obstructive Uropathy <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Oliguria <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Renal Artery Stenosis <sup>A</sup> †	2/9333 (0.02%)	3/9291 (0.03%)
Renal Artery Thrombosis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Renal Colic <sup>A</sup> †	3/9333 (0.03%)	1/9291 (0.01%)
Renal Disorder <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Renal Failure <sup>A</sup> †	25/9333 (0.27%)	24/9291 (0.26%)
Renal Failure Acute <sup>A</sup> †	34/9333 (0.36%)	25/9291 (0.27%)
Renal Failure Chronic <sup>A</sup> †	7/9333 (0.08%)	7/9291 (0.08%)
Renal Haemorrhage <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Renal Impairment <sup>A</sup> †	5/9333 (0.05%)	4/9291 (0.04%)
Renal Mass <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Urethral Haemorrhage <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Urinary Bladder Haemorrhage <sup>A</sup> †	2/9333 (0.02%)	0/9291 (0%)
Urinary Bladder Polyp <sup>A</sup> †	0/9333 (0%)	2/9291 (0.02%)
Urinary Incontinence <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)



	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Urinary Retention <sup>A</sup> †	3/9333 (0.03%)	7/9291 (0.08%)
Urinary Tract Obstruction <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Reproductive system and breast disorders		
Balanitis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Benign Prostatic Hyperplasia <sup>A</sup> †	5/9333 (0.05%)	3/9291 (0.03%)
Cervical Dysplasia <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Epididymitis <sup>A</sup> †	3/9333 (0.03%)	1/9291 (0.01%)
Menometrorrhagia <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Ovarian Cyst <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Prostatic Haemorrhage <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Prostatism <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Prostatitis <sup>A</sup> †	1/9333 (0.01%)	2/9291 (0.02%)
Spermatocele <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Uterine Haemorrhage <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Vaginal Haemorrhage <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Respiratory, thoracic and mediastinal disorders		
Acute Pulmonary Oedema <sup>A</sup> †	20/9333 (0.21%)	32/9291 (0.34%)
Acute Respiratory Distress Syndrome <sup>A</sup> †	4/9333 (0.04%)	3/9291 (0.03%)
Acute Respiratory Failure <sup>A</sup> †	5/9333 (0.05%)	6/9291 (0.06%)
Alveolitis Fibrosing <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Apnoea <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Aspiration <sup>A</sup> †	0/9333 (0%)	3/9291 (0.03%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Asthma <sup>A</sup> †	5/9333 (0.05%)	3/9291 (0.03%)
Atelectasis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Brain Hypoxia <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Bronchial Haemorrhage <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Bronchial Obstruction <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Bronchitis Chronic <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Bronchospasm <sup>A</sup> †	2/9333 (0.02%)	1/9291 (0.01%)
Chronic Obstructive Pulmonary Disease <sup>A</sup> †	22/9333 (0.24%)	17/9291 (0.18%)
Cough <sup>A</sup> †	3/9333 (0.03%)	0/9291 (0%)
Dyspnoea <sup>A</sup> †	75/9333 (0.8%)	50/9291 (0.54%)
Dyspnoea Exertional <sup>A</sup> †	3/9333 (0.03%)	2/9291 (0.02%)
Dyspnoea Paroxysmal Nocturnal <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Emphysema <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Epistaxis <sup>A</sup> †	15/9333 (0.16%)	9/9291 (0.1%)
Haemoptysis <sup>A</sup> †	7/9333 (0.08%)	8/9291 (0.09%)
Haemothorax <sup>A</sup> †	0/9333 (0%)	3/9291 (0.03%)
Hydrothorax <sup>A</sup> †	2/9333 (0.02%)	5/9291 (0.05%)
Hyperventilation <sup>A</sup> †	2/9333 (0.02%)	1/9291 (0.01%)
Hypoxia <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Interstitial Lung Disease <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Laryngeal Leukoplakia <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Laryngeal Oedema <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Laryngeal Stenosis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Laryngospasm <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Lower Respiratory Tract Inflammation <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Lung Consolidation <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Lung Disorder <sup>A</sup> †	2/9333 (0.02%)	1/9291 (0.01%)
Mediastinal Haematoma <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Mediastinal Haemorrhage <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Nasal Polyps <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Nocturnal Dyspnoea <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Pleural Effusion <sup>A</sup> †	21/9333 (0.23%)	19/9291 (0.2%)
Pleurisy <sup>A</sup> †	2/9333 (0.02%)	2/9291 (0.02%)
Pleuritic Pain <sup>A</sup> †	0/9333 (0%)	3/9291 (0.03%)
Pneumonia Aspiration <sup>A</sup> †	3/9333 (0.03%)	6/9291 (0.06%)
Pneumonitis <sup>A</sup> †	3/9333 (0.03%)	0/9291 (0%)
Pneumothorax <sup>A</sup> †	3/9333 (0.03%)	9/9291 (0.1%)
Pulmonary Alveolar Haemorrhage <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Pulmonary Congestion <sup>A</sup> †	5/9333 (0.05%)	3/9291 (0.03%)
Pulmonary Embolism <sup>A</sup> †	31/9333 (0.33%)	20/9291 (0.22%)
Pulmonary Fibrosis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Pulmonary Haematoma <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Pulmonary Haemorrhage <sup>A</sup> †	1/9333 (0.01%)	2/9291 (0.02%)
Pulmonary Mass <sup>A</sup> †	3/9333 (0.03%)	0/9291 (0%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Pulmonary Oedema <sup>A</sup> †	33/9333 (0.35%)	53/9291 (0.57%)
Respiratory Arrest <sup>A</sup> †	2/9333 (0.02%)	3/9291 (0.03%)
Respiratory Distress <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Respiratory Failure <sup>A</sup> †	16/9333 (0.17%)	16/9291 (0.17%)
Respiratory Tract Haemorrhage <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Rhinorrhoea <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Systemic Sclerosis Pulmonary <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Tachypnoea <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Thoracic Haemorrhage <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Tonsillar Disorder <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Tracheal Stenosis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Vocal Cord Polyp <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Wegener's Granulomatosis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Wheezing <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Skin and subcutaneous tissue disorders		
Alopecia <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Angioedema <sup>A</sup> †	3/9333 (0.03%)	4/9291 (0.04%)
Blister <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Decubitus Ulcer <sup>A</sup> †	2/9333 (0.02%)	0/9291 (0%)
Dermatitis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Dermatitis Allergic <sup>A</sup> †	1/9333 (0.01%)	6/9291 (0.06%)
Dermatomyositis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Dry Gangrene <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Eczema Nummular <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Erythema <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Hyperhidrosis <sup>A</sup> †	2/9333 (0.02%)	0/9291 (0%)
Hypoaesthesia Facial <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Increased Tendency To Bruise <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Leukocytoclastic Vasculitis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Pruritus <sup>A</sup> †	1/9333 (0.01%)	3/9291 (0.03%)
Pruritus Generalised <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Rash <sup>A</sup> †	4/9333 (0.04%)	3/9291 (0.03%)
Rash Erythematous <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Rash Generalised <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Seborrhoeic Dermatitis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Skin Inflammation <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Skin Necrosis <sup>A</sup> †	2/9333 (0.02%)	1/9291 (0.01%)
Skin Ulcer <sup>A</sup> †	3/9333 (0.03%)	0/9291 (0%)
Urticaria <sup>A</sup> †	3/9333 (0.03%)	4/9291 (0.04%)
Wound Haemorrhage <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Surgical and medical procedures		
Cardiac Pacemaker Insertion <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Coronary Artery Bypass <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Implantable Defibrillator Insertion <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Leg Amputation <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Thoracic Cavity Drainage <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Vascular disorders		
Accelerated Hypertension <sup>A</sup> †	1/9333 (0.01%)	5/9291 (0.05%)
Aneurysm <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Aneurysm Ruptured <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Angiodysplasia <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Aortic Aneurysm <sup>A</sup> †	0/9333 (0%)	7/9291 (0.08%)
Aortic Aneurysm Rupture <sup>A</sup> †	2/9333 (0.02%)	1/9291 (0.01%)
Aortic Dilatation <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Aortic Dissection <sup>A</sup> †	2/9333 (0.02%)	4/9291 (0.04%)
Aortic Stenosis <sup>A</sup> †	0/9333 (0%)	3/9291 (0.03%)
Arterial Disorder <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Arterial Occlusive Disease <sup>A</sup> †	2/9333 (0.02%)	2/9291 (0.02%)
Arterial Rupture <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Arterial Thrombosis <sup>A</sup> †	1/9333 (0.01%)	4/9291 (0.04%)
Arterial Thrombosis Limb <sup>A</sup> †	5/9333 (0.05%)	4/9291 (0.04%)
Arteriosclerosis <sup>A</sup> †	3/9333 (0.03%)	3/9291 (0.03%)
Arteriosclerosis Obliterans <sup>A</sup> †	1/9333 (0.01%)	2/9291 (0.02%)
Arteriovenous Fistula <sup>A</sup> †	2/9333 (0.02%)	1/9291 (0.01%)
Arteritis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Artery Dissection <sup>A</sup> †	2/9333 (0.02%)	0/9291 (0%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Bleeding Varicose Vein <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Blood Pressure Inadequately Controlled <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Cardiovascular Insufficiency <sup>A</sup> †	2/9333 (0.02%)	1/9291 (0.01%)
Circulatory Collapse <sup>A</sup> †	4/9333 (0.04%)	0/9291 (0%)
Deep Vein Thrombosis <sup>A</sup> †	6/9333 (0.06%)	6/9291 (0.06%)
Embolism <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Embolism Venous <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Extremity Necrosis <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Femoral Arterial Stenosis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Femoral Artery Aneurysm <sup>A</sup> †	1/9333 (0.01%)	3/9291 (0.03%)
Femoral Artery Occlusion <sup>A</sup> †	2/9333 (0.02%)	2/9291 (0.02%)
Haematoma <sup>A</sup> †	3/9333 (0.03%)	8/9291 (0.09%)
Haemodynamic Instability <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Haemorrhage <sup>A</sup> †	2/9333 (0.02%)	3/9291 (0.03%)
Hypertension <sup>A</sup> †	17/9333 (0.18%)	24/9291 (0.26%)
Hypertensive Crisis <sup>A</sup> †	7/9333 (0.08%)	12/9291 (0.13%)
Hypertensive Emergency <sup>A</sup> †	3/9333 (0.03%)	3/9291 (0.03%)
Hypotension <sup>A</sup> †	18/9333 (0.19%)	21/9291 (0.23%)
Hypovolaemic Shock <sup>A</sup> †	3/9333 (0.03%)	2/9291 (0.02%)
Iliac Artery Occlusion <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Iliac Artery Stenosis <sup>A</sup> †	1/9333 (0.01%)	2/9291 (0.02%)
Iliac Artery Thrombosis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Intermittent Claudication <sup>A</sup> †	6/9333 (0.06%)	6/9291 (0.06%)
Leriche Syndrome <sup>A</sup> †	2/9333 (0.02%)	1/9291 (0.01%)
Orthostatic Hypotension <sup>A</sup> †	4/9333 (0.04%)	3/9291 (0.03%)
Peripheral Arterial Occlusive Disease <sup>A</sup> †	4/9333 (0.04%)	5/9291 (0.05%)
Peripheral Artery Aneurysm <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Peripheral Artery Dissection <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Peripheral Embolism <sup>A</sup> †	1/9333 (0.01%)	1/9291 (0.01%)
Peripheral Ischaemia <sup>A</sup> †	10/9333 (0.11%)	7/9291 (0.08%)
Peripheral Vascular Disorder <sup>A</sup> †	5/9333 (0.05%)	3/9291 (0.03%)
Phlebitis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Reperfusion Injury <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Shock <sup>A</sup> †	7/9333 (0.08%)	3/9291 (0.03%)
Shock Haemorrhagic <sup>A</sup> †	2/9333 (0.02%)	0/9291 (0%)
Subclavian Artery Stenosis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Subclavian Artery Thrombosis <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Subclavian Vein Thrombosis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Thrombophlebitis <sup>A</sup> †	2/9333 (0.02%)	3/9291 (0.03%)
Thrombophlebitis Superficial <sup>A</sup> †	2/9333 (0.02%)	1/9291 (0.01%)
Thrombosis <sup>A</sup> †	2/9333 (0.02%)	0/9291 (0%)
Vascular Occlusion <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Vasculitis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)
Vena Cava Thrombosis <sup>A</sup> †	1/9333 (0.01%)	0/9291 (0%)



	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Venous Insufficiency <sup>A</sup> †	0/9333 (0%)	1/9291 (0.01%)
Venous Thrombosis <sup>A</sup> †	2/9333 (0.02%)	3/9291 (0.03%)
Venous Thrombosis Limb <sup>A</sup> †	0/9333 (0%)	2/9291 (0.02%)

† Indicates events were collected by systematic assessment.

A Term from vocabulary, MedDRA 10.0

#### Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	TICAGRELOR	CLOPIDOGREL
	Affected/At Risk (%)	Affected/At Risk (%)
Total	2278/	1665/
Nervous system disorders		
Headache <sup>A</sup> †	621/9333 (6.65%)	565/9291 (6.08%)
Respiratory, thoracic and mediastinal disorders		
Cough <sup>A</sup> †	490/9333 (5.25%)	467/9291 (5.03%)
Dyspnoea <sup>A</sup> †	1106/9333 (11.85%)	623/9291 (6.71%)
Epistaxis <sup>A</sup> †	566/9333 (6.06%)	317/9291 (3.41%)

† Indicates events were collected by systematic assessment.

A Term from vocabulary, MedDRA 10.0

## Limitations and Caveats

[Not specified]

## More Information

Certain Agreements:

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

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

An Investigator agrees to provide a copy of the publication to AstraZeneca (AZ) for review at least 60 days in advance of submission for publication.

Investigators in multicenter (MC) studies agree to postpone MC publications until the earlier of the date of the first AZ-authorized MC publication or a period up to 18 months from study completion at all sites.

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